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**Article**

**\*37 THE FIRST INVENTOR DEFENSE: A LIMITED PRIOR USER RIGHT FINDS ITS WAY  
INTO US PATENT LAW**

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**\*39 I. INTRODUCTION**

Many of the world's most important patent systems allow a prior user of an invention that is subsequently patented by another to continue to use that invention, subject to certain qualifications and limitations, notwithstanding the patent. [FN1] Though a part of early US patent law, prior user rights have been absent in the United States since 1952 [FN2] and are viewed by some as an unwarranted assault on the sanctity of a patent owner's right to exclude all others from practicing a claimed invention. [FN3] As a result of the American Inventors Protection Act of 1999, however, a prior user right is now available to a limited category of prior users in the United States. [FN4]

**\*40** The new right, formally titled the "First Inventor Defense," [FN5] is available only to those accused of infringing a patented "method of doing or conducting business." [FN6] To qualify for the defense, the accused infringer must satisfy some rather stringent prerequisites, including proving, by clear and convincing evidence, [FN7] (1) an actual reduction to practice of the claimed method at least one year prior to the patentee's effective filing date, [FN8] and (2) commercial use of the claimed method prior to the patentee's effective filing date. [FN9] The defense is personal to the prior user and almost entirely non-transferable. [FN10] Successful assertion of the defense does not result in invalidation of the patent at issue, which remains enforceable against all others who are unable to qualify for the defense. [FN11]

The restrictive nature of the First Inventor Defense, and particularly its unavailability outside the narrow area of business method patents, means that its impact on the United States patent community will be slight. Nevertheless, the defense is worthy of serious analysis, as it represents the only legislative response to date to *State Street Bank & Trust Co. v. Signature \*41 Financial Group, Inc.*, the controversial 1998 Federal Circuit decision that struck down the so-called "business method exception." [FN12] Moreover, the defense may be used as a model for future efforts to enact a broader prior user right. Before delving into the specifics of the First Inventor Defense, however, this article will first discuss the longstanding debate over prior user rights in the United States. [FN13]

In recent years, a number of commentators have argued for the reinstatement of prior user rights into US patent law, contending that such rights encourage investment in new technology, [FN14] protect the value of trade **\*42** secrets, [FN15] provide a just solution to the problem of secret prior art, [FN16] and balance the playing field between US

and foreign businesses. [FN17] Opponents have argued that prior user rights weaken the value of the patent grant and undercut the public disclosure goal of the patent system by reducing the incentive to seek a patent. [FN18] Prior user rights have often been opposed by smaller entities, universities, and independent inventors [FN19] because of the perception that the adverse consequences "fall far more heavily on individual inventors, small businesses and non-corporate users of the patent system, such as universities, research groups, and risk-capital investors, than on large, well-financed corporations [which are] likely to be the recipients of most of the prior user rights." [FN20] A majority of published \*43 articles favor some form of prior user right, but no overwhelming consensus has emerged among patent scholars. [FN21]

Proposals that would have made prior user rights a part of the US patent law have been advanced regularly in Congress in recent years, either as stand-alone bills, [FN22] or as part of broader patent reform efforts. [FN23] Some elements of the patent community have supported these efforts, [FN24] but \*44 considerable opposition has emerged as well. [FN25] The lack of a clear consensus in the patent community helped to ensure that no prior user rights bill was enacted into law until the First Inventor Defense in 1999. The First Inventor Defense succeeded where earlier efforts failed because it applies solely to business method patents, a compromise designed to appease opponents of a more widely applicable prior user right. The First Inventor Defense had its genesis in a House bill, reported on favorably by the House Judiciary Committee, that would have applied to all process and method patents. [FN26] New language limiting the defense to business methods was hastily added by the bill's managers without much in the way of public \*45 deliberation or debate, immediately prior to the House vote on the bill. [FN27] The longstanding debate over prior user rights is likely to continue unabated because the First Inventor Defense is too restricted to satisfy proponents of such rights.

Though one commentator has already warned that the First Inventor Defense may constitute a "disaster" for the patent law, [FN28] this article concludes that the First Inventor Defense is a minor but positive addition to US patent law. The defense is a highly restricted example of a prior user right and, in most respects, it will be a relatively straightforward task to determine whether the defense applies. Unfortunately, because the so-called "business method exception" to patentability was never very well defined, it may be uncertain in some cases whether a specific claimed invention constitutes a "method of doing business" subject to the defense, at least until further clarification is provided by court decisions. Frivolous assertion of the defense is unlikely because if the defense is pled absent a reasonable basis, the party asserting the defense may become liable for the opponents' attorney fees. [FN29]

\*46 To a small extent, the defense strengthens trade secret protection at the expense of patents, but the harm to the patent system is likely to be de minimus rather than a "disaster" and is outweighed by the equitable and economic benefits of protecting secret users of business methods that were subsequently patented by others. The defense is thus a reasonable response to State Street, albeit one that fails to fully answer the serious concerns over the wisdom

of permitting patents on business methods in the first place.

## **II. THE DEBATE OVER PRIOR USER RIGHTS**

### **A. What Are Prior User Rights?**

As used herein and consistent with its use throughout most of the literature, a "prior user right" is a non-patent-defeating, defensive right to the continued use of an invention patented by another. [FN30] Because prior public use ordinarily invalidates a patent, [FN31] prior user rights generally focus on processes and methods that are practiced in secret, rather than on \*47 tangible products. [FN32] Prior user rights are generally viewed as personal to the prior user and not transferable. [FN33]

Supporters of prior user rights differ over the details of how the right should be crafted. [FN34] Some believe that prior user rights should be limited to bona fide first inventors, [FN35] meaning those who would prevail over the patentee in a contest for priority but whose own activity renders them ineligible to obtain a patent. [FN36] Others would extend protection beyond first \*48 inventors, as long as the prior user did not derive the invention from the patentee, [FN37] in part because determining first inventor status is too complicated and costly. [FN38]

Most formulations of a prior user right require commercial use of the patented invention, or at least substantial preparations for such use, prior to some deadline relating to the patent at issue. [FN39] Frequently, \*49 commercialization prior to the patentee's filing date is thought to be the appropriate prerequisite for qualifying as a prior user, but some argue for a more lenient deadline, such as the publication or issuance date, citing the arbitrariness of using a secret filing date as a cutoff. [FN40] In addition, in order to preserve the full sanctity of the one year grace period, some believe that prior user rights should only be granted if the prior user possessed the invention more than one year before the patentee's filing date. [FN41] Others contend that such a requirement is too restrictive. [FN42]

### **\*50 B. Why Are Prior User Rights Controversial?**

Fundamentally, prior user rights are an exception to the statutory right of a patent owner to exclude all others from practicing the claimed subject matter during the life of the patent. [FN43] In light of the perceived importance of the patent system in encouraging innovation and advancing technological competitiveness, it is no surprise that any weakening of the patent right, regardless of the alleged countervailing advantages, is a source of controversy. [FN44] Adding to the controversy is the perception that large corporations are likely to be the principal beneficiaries of prior user rights at the expense of smaller businesses, universities, and independent inventors. [FN45] This perception is not entirely inaccurate since the latter groups, as compared with larger companies, are not only potentially more vulnerable to the weakening of the patent's exclusivity but also less likely to commercialize new

technologies and thus less likely to be able to take advantage of the protection offered by a prior user right.

**\*51** The exclusive nature of the patent grant ultimately derives from the United States Constitution, which authorizes Congress to secure "for limited Times to ... Inventors the exclusive Right to their ... Discoveries." [FN46] Some have argued that prior user rights are unconstitutional, [FN47] but the position is difficult to maintain in light of the fact that such rights were part of the US Patent Code between 1836 and 1952. [FN48] Moreover, notwithstanding the constitutional language, exceptions to a patent owner's exclusivity recognized by the courts or the Patent Code include: (1) exercise of the US Government's eminent domain power, [FN49] (2) continued use of patented inventions by state or local governments, [FN50] (3) redress of antitrust violations caused by patent misuse, [FN51] and (4) equitable limitations on the scope of reissued patents. [FN52] Nevertheless, prior user rights are arguably distinct from these exceptions, because they do not involve monetary compensation to the patentee, as is the case with exceptions (1) and (2), and because they **\*52** arise without any misconduct or error on behalf of the patentee, as with exceptions (3) and (4). [FN53]

### **C. The Arguments for Prior User Rights**

Advocates of prior user rights generally start with the proposition that, as a practical matter, not all inventions can be patented. [FN54] They argue that inventors sometimes rationally choose to forego a patent in favor of protecting their invention as a trade secret. [FN55] Obtaining a patent, particularly if worldwide protection is sought, is a costly and uncertain **\*53** process [FN56] and the commercial return, whether through licensing income or the competitive advantage of precluding others from using the patented technology, does not always justify the expense. [FN57] In particular, processes that are practiced outside of public view are frequently not patented because infringement of patented processes can be difficult to detect, and thus the protection offered by those patents is somewhat illusory. [FN58]

Supporters of a prior user right argue, as a matter of both fairness and economic efficiency, that a bona fide first inventor should have the option of commercializing an invention without seeking a patent. [FN59] Though such an inventor is obviously not entitled to the exclusive right that comes with patent protection, a prior user right permits the inventor to continue to use the invention notwithstanding its subsequent patenting by another. Absent the protection afforded by a prior user right--the argument goes--commercialization of useful technology can be delayed because of the fear that another party will subsequently obtain a patent on that **\*54** technology. [FN60] Moreover, considerable resources are devoted to obtaining defensive patents because of the absence of a prior use right. [FN61]

Although some supporters of prior user rights focus on the need to protect first inventors who for valid economic reasons do not seek a patent, others argue that the right to continued use should arise based on commercialization rather than on first inventor status. [FN62] For one thing, requiring an interference-like procedure to determine whether the patentee or the purported prior user was the true first inventor would greatly complicate prior user right

disputes. [FN63] More important, perhaps, is the alleged public benefit resulting from a "race to commercialize" that is \*55 encouraged by a prior user right that derives from commercialization of an invention. [FN64]

Prior user rights are also frequently advanced as a just solution to the difficult problem of secret prior art. [FN65] At present, determining whether a secret prior use invalidates a patent requires a somewhat arcane analysis. In *W.L. Gore & Assoc. v. Garlock, Inc.*, the Federal Circuit found for a patentee over a secret prior user, holding that a secret prior use does not constitute an invalidating "public" use under Section 102(b), or, presumably, Section 102(a). [FN66] Under Section 102(g), however, a patent is invalid if the invention \*56 had previously been made by another unless the prior invention was "abandoned, suppressed or concealed." [FN67]

Though the Federal Circuit has not directly addressed the issue, other case law indicates that secret commercialization does not constitute abandonment, suppression, or concealment. In *Dunlop Holdings Ltd. v. Ram Golf Corp.*, the Seventh Circuit held that a prior sale by an earlier inventor, though non-informing, invalidated a patent subsequently obtained by a later inventor. [FN68] Though some have sought to harmonize *W.L. Gore* and *Dunlop* by noting that the former involved a process practiced in secret, while the latter involved a public (though non-informing) sale, [FN69] the more fundamental problem is that absent a prior user right, the patent system must choose between two extremes: (1) treat the secret prior use as prior art and invalidate the patent, or (2) uphold the patent and render illegal any further use by the prior user after the patent's date of issuance. [FN70]

Advocates of a prior user right argue that at least in some circumstances, both "winner-take-all" alternatives are too harsh, either \*57 "invalidating an otherwise good patent over secret prior art [or] enjoining a bona fide inventor from continued use of her own invention." [FN71] They contend that when two parties independently achieve an invention, and one practices it in secret while the other seeks a patent, it is unjust to deny a patent reward to the party who disclosed the invention to the public, but equally unjust to enjoin the continued use of the invention by the party who commercially used the invention without seeking patent protection. [FN72] A non-invalidating prior user right, they suggest, is the appropriate middle ground. [FN73]

A final argument in favor of prior user rights is that a US prior user right is needed to "level the playing field" with the world's other major industrial powers, whose patent systems almost universally provide for such a right. [FN74] Proponents of a US prior user right argue that when a US company obtains a patent in a foreign country, it may find itself unable to preclude the use of the invention by prior users in that country, while a foreign company that obtains a US patent faces no such obstacles here. [FN75] The disparity between the United States and the rest of the world is largely \*58 explained by the fact that most foreign patent systems grant patents to the "first to file" rather than to the "first to invent." [FN76] Irrespective of the relative merits of the "first to file" and "first to invent" systems, the absence of a US prior user right creates a competitive disadvantage for US businesses. [FN77]

#### **\*59 D. The Arguments Against Prior User Rights**

Opponents argue that prior user rights weaken the patent system by eroding the patent grant's value, which derives from the right to exclude all others from practicing the claimed invention during the life of the patent. [FN78] Turning the fairness argument around, critics of prior user rights contend that it is inequitable to penalize the patent owner, who went to the expense and effort of seeking a patent and in the process informed the public of the invention, in favor of a secret user who conferred no such public benefit. [FN79]

Perhaps more significantly, a prior user right, by making trade secret protection more attractive, in effect provides an economic incentive for inventors to bypass the patent system. [FN80] Opponents of a prior user right \*60 tend to place a high value on the public benefits of disclosure of inventions through the publication of patents, and are dismissive of the alleged public benefits of trade secret protection. [FN81] While not necessarily disputing the contention that as a practical matter not every invention can be patented, opponents argue that "the law should discourage trade secret protection when patent protection is available because trade secret protection tends to discourage innovation by eliminating disclosure." [FN82]

Opponents also contend that a prior user right diminishes the usefulness of the one year grace period provided under the United States' first to invent system. [FN83] The grace period allows an inventor a full year to test and refine an invention without affecting the patentability of the invention. [FN84] If prior user rights are part of the patent system, however, such rights might accrue during the grace period, depending upon how the right is crafted. [FN85] Those who might otherwise benefit from the grace period are thus effectively encouraged to file hastily to reduce the chances that the patent's value will be diminished by the establishment of prior user rights. [FN86]

#### **\*61 E. Resolving the Debate?**

The debate over prior user rights is not easy to resolve because it involves economic questions about the impact of altering the patent reward that legal scholars are ill-equipped to answer. [FN87] Legal analysis cannot really tell us (1) to what degree the incentive to innovate is reduced by making an occasional exception to the exclusive right of a patentee; (2) how often the availability of a prior user right would influence inventors to choose trade secret protection over patent protection; (3) to what extent, if any, an increased reliance on trade secret protection would harm society by reducing the public disclosure of technology through patent applications; (4) to what extent the public would benefit from the commercialization of unpatented inventions that is encouraged by prior user rights; or (5) to what extent the existing disparity between the United States and its principal industrial competitors with regard to prior user rights adversely impacts research and investment in the United States. Moreover, even if a consensus were reached about these questions, prior user rights would still be controversial because larger corporations would likely be the primary beneficiaries of such rights, arguably at the expense of smaller entities, universities, and independent inventors.

Having acknowledged the limitations of legal analysis, however, it must be concluded that while both sides in the

debate have valid concerns, the arguments in favor of a prior user right seem more compelling. While \*62 prior user rights do favor trade secrets at the expense of patents, there is little reason to suspect that many inventors will desert the patent system because of the availability of a purely defensive prior user right. It seems reasonable to expect a slight shift to reliance on trade secret protection, a slight increase in the commercialization of unpatented technology, but little overall impact on innovation.

Additionally, the argument that prior user rights harm patent owners is based in part on the assumption that absent such a right, a patent holder has the ability to enjoin secret prior users from practicing a claimed invention. [FN88] As discussed above, however, the state of the law regarding secret prior use is confused, and it remains uncertain whether a first inventor who secretly commercializes an invention can in fact be enjoined by a subsequent patentee. Indeed, one advocate of prior user rights, Karl Jorda, has frequently pointed out that in no reported case has a bona fide first inventor been enjoined from practicing his invention by a later inventor's patent. [FN89] Because of this uncertainty, prior user rights are less of an imposition on the rights of patentees than is commonly assumed. \*63 Moreover, almost everyone agrees that prior user rights would rarely be asserted. [FN90] The direct impact of prior user rights on patent holders is thus likely to be minimal. [FN91]

Finally, opponents of a prior user right have no effective rebuttal to the "level playing field" argument. Though they argue that we should not weaken our patent system by enacting a prior user right just because other countries have done so, [FN92] the reality is that foreign businesses, which obtain a significant proportion of US patents, [FN93] are unhindered by a prior user right when enforcing their patents against US entities in this country, while US \*64 businesses seeking to enforce foreign patents abroad generally must contend with such rights.

### **III. THE FIRST INVENTOR DEFENSE**

Part III will address the specific provisions of the First Inventor Defense.

#### **A. When Is the First Inventor Defense Available?**

A party asserting the First Inventor Defense must establish two key facts: (1) an actual reduction to practice of the claimed invention at least one year prior to the patentee's effective filing date, and (2) commercial use of the claimed invention prior to the patentee's effective filing date. [FN94] The defense is unavailable if the party asserting it derived the invention from the patentee [FN95] or otherwise failed to act in good faith. [FN96] Successful assertion of the defense requires clear and convincing evidence, with the burden of proof on the party asserting the defense. [FN97] Finally, and most important, the defense is available only if the claimed invention is for a method of doing or conducting business. [FN98] The implications of these requirements are discussed in the following subsections.

**\*65 1. The First Inventor Defense Requires an Actual Reduction to Practice Before the Patentee's Critical Date**

## and Commercial Use in the United States Before the Patentee's Effective Filing Date

As suggested by its name, Congress enacted the First Inventor Defense to provide protection to persons who invented a patented business method prior to the patentee. [FN99] Rather than require a full-blown Section 102(g)-style priority contest to determine "first inventor" status, however, Congress opted to establish a two-prong, bright line test. To qualify for the defense, an accused infringer must have (1) actually reduced the claimed subject matter to practice at least one year before the patentee's effective filing date, and (2) used the claimed subject matter commercially, in the United States, before the patentee's effective filing date. [FN100] Both prongs must be satisfied by the same "person." [FN101] Coupled with the non-derivation requirement discussed in the following subsection, this two-pronged test effectively ensures that only first inventors will qualify for the defense.

**\*66** "Reduction to practice" is a familiar concept in patent law, so the first prong of the defense presents little difficulty. The commercial use prong, however, requires further elaboration. "Commercial use" is defined as any use in the United States in connection with an internal commercial use or an actual arm's-length sale of a useful end product. [FN102] Precisely what is meant by an "internal commercial use" is not entirely clear, though the defense specifies that "commercial use" need not make the subject matter of the invention accessible to the public. [FN103] Presumably, use in the course of research and development or testing for marketing does not constitute a "commercial use," or else virtually any use by a commercial entity would qualify. [FN104] "Commercial use" is deemed to include use by nonprofit research entities for the benefit of the public, [FN105] but subsequent commercialization or use outside of the nonprofit entity would not be entitled to the defense. [FN106] Even the slightest "commercial use" is sufficient to qualify for the defense, but abandonment of "commercial use" renders the defense unavailable, unless resumed prior to the patentee's effective filing date. [FN107]

**\*67** A virtue of the First Inventor Defense is that it will not significantly complicate patent litigation. The only facts needed to establish entitlement to the defense are the patentee's effective filing date and the accused infringer's dates of actual reduction to practice and commercialization. Since the patentee's effective filing date is readily ascertainable, and the other relevant dates are within the knowledge to the accused infringer, there will ordinarily be no need for any guesswork or discovery before deciding whether to assert the defense. The patentee is of course free to investigate and challenge the dates asserted for the accused infringer's actual reduction to practice and commercialization of the claimed invention, but factual disputes about these elements of the defense should be easily resolvable.

In contrast, a Section 102(g) priority contest can require determination of both parties' respective dates of conception and reduction to practice and, in some cases, an inquiry into reasonable diligence. [FN108] If this type of factual inquiry were required in order to establish the defense, litigation costs would increase. Accused infringers, lacking knowledge of the patentee's dates of conception and reduction to practice, would be forced to assert the defense speculatively and conduct discovery to resolve these difficult factual issues. The bright line tests established by the

defense thus avoid the complexities associated with determining first inventor status under Section 102(g).

\*68 Bright line standards have their drawbacks, however. The defense's requirement of a reduction to practice one year before the patentee's effective filing date helps ensure that only first inventors will qualify for the defense, but it is arguably too stringent because not all first inventors can satisfy it. Consider a case where Party A, the accused infringer, conceives of an invention on January 1 and reduces it to practice on May 1. Party B, the patentee, independently conceives of the same invention on June 1, reduces it to practice on September 1, and files a patent application on December 1. After the patent issues, B sues A for infringement. Even though A is clearly the earlier inventor under Section 102(g) principles, having reduced the invention to practice before B even conceived it, A cannot rely on the First Inventor Defense because A's reduction to practice is less than one year prior to B's filing date. [FN109]

The second prong of the defense--the requirement of commercial use prior to the patentee's effective filing date--is also open to criticism. Because patent filings are secret, the First Inventor Defense essentially sets up a "race to commercialize" against an unknown deadline. Moreover, some inventions may require a considerable investment of time and money before commercialization can be achieved. Recognizing this, an earlier version of the First Inventor Defense, considered by Congress in 1997, contained a provision deeming "effective and serious preparation" for commercial use prior to the patentee's filing date the equivalent of actual \*69 commercial use. [FN110] This provision is absent from the defense as enacted, [FN111] making for a stronger bright line test but at the expense of businesses that make significant investments in new business methods but are unable to achieve actual commercialization quickly enough to qualify for the defense. [FN112]

An additional criticism can be directed at the requirement that both prongs of the defense must be satisfied by the same "person." Consider a hypothetical case in which an individual inventor reduces a new business method to practice one year and a day before another inventor files for patent protection on the same subject matter. One week after reducing it to practice, the first inventor licenses the invention to several businesses who use the licensed method commercially prior to the subsequent inventor's filing date. Somewhat unfairly, neither the individual inventor (who did not personally use the method commercially), or the licensees (who did not personally reduce the invention to practice more than one year prior to the patentee's filing date) are entitled to the defense. Moreover, even if the first inventor had used the method commercially as well as licensed it to others, \*70 and thus qualifies for the defense personally, the licensees would still be out of luck because the defense would not be transferable under these circumstances. [FN113] It seems contrary to the policies behind the defense to preclude its assertion by a party who acquired a business method through a bona fide license from a true first inventor and used it commercially prior to the subsequent inventor's filing date.

In sum, the First Inventor Defense's two prongs have the virtue of being simpler than a full-blown priority contest. No one is likely to complain that the defense is too easy to qualify for; if anything, it is entirely too restrictive, to the

point of excluding from the defense parties deserving of its protection.

## **2. The First Inventor Defense Cannot Be Asserted by One Who Derived the Subject Matter at Issue from the Patentee**

The First Inventor Defense is unavailable to persons who derived the subject matter at issue from the patentee or from persons in privity with the patentee. [FN114] This uncontroversial provision ensures that the defense applies only to bona fide independent inventors and is somewhat redundant in light of the requirement of a reduction to practice more than one year prior to the patentee's effective filing date. A party asserting the defense is also required to have acted in good faith, [FN115] but it is unclear whether this adds anything of substance over and above the non-derivation requirement.

### **\*71 3. A Party Asserting the First Inventor Defense Must Establish Entitlement to the Defense by Clear and Convincing Evidence, and Failure to Do So May Render the Party Liable for the Opponent's Attorney Fees**

Congress included two provisions aimed at discouraging frivolous assertion of the First Inventor Defense. First, the burden of proof is placed on the party asserting the defense, under the clear and convincing standard. [FN116] Second, if the defense is pled by a defendant who is unable to demonstrate a reasonable basis for asserting the defense, the defendant may become liable for the plaintiff's attorney fees. [FN117] Because the facts necessary to establish the defense are relatively straightforward and easily ascertainable by the party raising the defense, these provisions seem reasonable to help ensure that the defense is raised only when appropriate.

## **4. The First Inventor Defense Is Limited to Methods of Doing or Conducting Business**

The most significant limitation on the First Inventor Defense is that it applies only to "subject matter that would otherwise infringe one or more claims for a method," [FN118] defined as a "method of doing or conducting \*72 business." [FN119] This limitation raises an obvious question: How does one determine whether a claimed invention constitutes a method of doing or conducting business? On its face, the term could be interpreted in a number of ways. [FN120] Nevertheless, the legislative history shows that this limitation, which came relatively late in the legislative process, was understood as restricting the defense to the types of inventions that were thought to be unpatentable prior to the State Street decision. Before delving into that legislative history, a brief discussion of the State Street controversy will provide some needed context. [FN121]

### **\*73 a. State Street Bank & Trust Co. v. Signature Financial Group, Inc.**

The 1998 State Street decision is surely the most-discussed patent case to issue from the Federal Circuit in recent years. [FN122] The patent at issue in the case, directed to a data processing system for managing a certain type of investment portfolio involving pooled mutual funds organized as a partnership, was granted to Signature Financial

Group ("Signature") in 1993. [FN123] As a practical matter, it appears that compliance with Internal Revenue Service regulations for this type of portfolio could not be achieved without use of a system like that claimed in the Signature patent. [FN124] State Street Bank & Trust Co. ("State Street"), after unsuccessfully negotiating to obtain a license from Signature, filed a declaratory judgment action \*74 challenging, inter alia, the validity of the Signature patent. [FN125] The Massachusetts District Court found the patent invalid due to failure to claim statutory subject matter under Section 101. [FN126]

On Signature's appeal, the Federal Circuit addressed two theories under which the Signature patent was arguably invalid under Section 101. [FN127] First, it considered whether the claimed subject matter was unpatentable as a "mathematical algorithm." [FN128] The court held that this exception to patentability applied only where the mathematical subject matter expressed "merely abstract ideas." [FN129] According to the court, however, Signature's claimed method produced "a useful, concrete and tangible result," even though expressed in numbers, and thus constituted patentable subject matter. [FN130]

Turning next to the "business method exception," the court surprised many in the patent community by concluding that no such \*75 exception existed. [FN131] In the court's view, the alleged exception, at least since the 1952 Patent Act, "merely represented the application of some general, but no longer applicable legal principle." [FN132] Moreover, the court claimed that none of its prior decisions, nor any decision of its predecessor the Court of Customs and Patent Appeals, had invoked the business method exception to render a patent invalid. [FN133] The court concluded that business method claims should be treated not as a distinct category of patentable subject matter but like any other process claims. [FN134]

There is at least some room for debate over the extent to which State Street represented a departure from existing law and practice with regard to business methods. One commentator, writing before State Street and cited in the decision itself, argued that the "so-called 'business method' cases, without exception, [had] been decided on grounds other than subject matter eligibility." [FN135] Moreover, even prior to State Street, the Patent and Trademark Office's Examination Guidelines recommended treating claims directed to methods of doing business like any other process claims, [FN136] and the PTO's Manual of Patent Examining Procedure had not contained a reference to the possibility of a subject matter rejection for methods of doing \*76 business for a number of years. [FN137] Thus, one critic of State Street conceded that "[i]n some sense, State Street merely presents the latest in a series of cases confirming Patent Office practice regarding the subject matter appropriate for patenting." [FN138] Nevertheless, prior to State Street it appears to have been widely believed that patents on business methods would not stand up to validity challenges in court.

Reaction to State Street in the academic press has been largely negative. The decision's analysis has been persuasively criticized on several grounds, [FN139] and the patent-worthiness of the "invention" at issue has been called into question. [FN140] One commentator has noted, and a subsequent Federal Circuit decision arguably

confirmed, that the subject matter inquiry \*77 has now effectively been reduced to the question of utility, heretofore a separate requirement for patentability. [FN141] Nevertheless, the patent community quickly accommodated itself to the new reality by aggressively filing patent applications "ranging from financial software to Internet-based business models." [FN142] The resulting "boom" [FN143] in business method patents has caused commentators to question both the quality of the patents being issued by the PTO, and, more fundamentally, the wisdom of bringing business methods within the patent system. [FN144]

The concerns over the quality of patents being issued for methods of doing business stem largely from the relative difficulty in identifying sources of prior art for business method inventions. [FN145] There is at the very least considerable anecdotal evidence of patents being issued and, in some instances upheld by courts, on "shockingly mundane business \*78 inventions." [FN146] As expressed by one commentator, "[a] significant part of the perceived problem with business-method patents is a sense that the subject matter is typically obvious but the patent system is now set up in a way that business-method patents will not be adjudicated as obvious." [FN147] Over time, this problem can probably be expected to gradually lessen as the PTO and the courts become more adept at dealing with business method inventions. [FN148]

The more difficult and weightier question is whether extending the patent regime to methods of doing business is a good idea. A number of commentators have questioned the appropriateness of granting patents for business methods, arguing that the traditional rationales for rewarding innovation through the patent system are unpersuasive with regard to business methods. [FN149] Others have concluded that we lack the necessary data \*79 to determine whether granting patents for methods of doing business is economically justified. [FN150] One commentator has argued, on philosophical rather than economic grounds, that patenting of business methods defies "our perception of what technology is" and that the patent system should be confined to inventions that are susceptible to "industrial application." [FN151]

The State Street court made no attempt to justify business method patents on economic or philosophical grounds, nor did it claim to find any express Congressional authorization of such patents. [FN152] Instead, the Federal Circuit relied upon the broad language of Section 101, coupled with the supposed lack of clear statutory or case law authority excluding business methods from patentability. [FN153] To the extent that State Street represents a change in course for the patent law, and most believe it does, the troublesome aspect is that neither Congress nor the Federal Circuit has \*80 given any real consideration to the wisdom of permitting business method patents. Congress could, of course, overrule State Street and "re-establish" a business method exception [FN154] but there appears to be little possibility of that. [FN155] Somewhat more conceivable is legislation aimed at improving the quality of business method patents issued by the PTO. [FN156]

## **b. The Legislative History Behind the First Inventor Defense**

Though one might assume that the 1998 State Street decision was the primary impetus behind the 1999 enactment of the First Inventor Defense, the defense was actually the culmination of legislative efforts that predate State Street. [FN157] As far back as 1967, Congress considered a bill that would have reversed the 1952 Patent Act's repeal of prior user rights. [FN158] The genesis of the First Inventor Defense can more fairly be traced, however, to the patent harmonization efforts of the early 1990s, during which Congress considered and ultimately rejected switching to a first-to-file patent system \*81 with a prior user right. [FN159] Even after Congress chose to retain the first-to-invent system, prior user defense bills were regularly proposed throughout the 1990s either as stand-alone bills or as part of larger patent reform efforts. [FN160] Perhaps the most prominent such effort was House Bill 400, introduced in 1997, which contained a First Inventor Defense with no subject matter restrictions but otherwise almost identical to the defense subsequently enacted in 1999. [FN161]

After the failure of House Bill 400 in 1997, the House returned to its patent reform efforts in 1999 with a new bill designated House Bill 1907. [FN162] House Bill 1907, as reported out of the House Judiciary Committee, contained a number of compromises on issues that had proven controversial in House Bill 400. [FN163] Among other changes, House Bill 1907's First Inventor Defense was now limited to claims "asserting a process or \*82 method in the patent" [FN164] including inventions meeting the statutory definition of "process" [FN165] as well as "any invention that produces a useful end product or service which has been or could have been claimed in a patent in the form of a process." [FN166] Thus the bill was not limited solely to business methods newly patentable in the wake of State Street, though the House Committee Report cites State Street as "add[ing] to the urgency" of the need for a prior user defense. [FN167]

In an unusual legislative maneuver, the supporters of House Bill 1907, after consultation with key opponents, modified the bill subsequent to its approval by the House Judiciary Committee but prior to its consideration by the full House so as to increase its chances for passage. [FN168] Along with changes to other aspects of the bill, the First Inventor Defense was restricted solely to "business methods" [FN169] rather than applying to all \*83 processes and methods as approved by the Committee. [FN170] Representative Howard Coble, the bill's primary sponsor, explained during a brief floor debate prior to the House vote on the bill that the First Inventor Defense was now "limited ... to the State Street Bank case." [FN171] He elaborated: "Perhaps the first inventive defense should apply to processes as well as methods. But we finally concluded that we would restrict it to methods only, and that, by having done that, we were able to satisfy some folks who were opposed to the bill otherwise." [FN172]

Confirming Representative Coble's account, Representative Rohrabacher, an opponent of the original bill in part because of its broader First Inventor Defense, voiced his approval of the bill as amended, stating: "Instead of a prior user defense [i.e., a First Inventor Defense] that applies to all inventions ..., H.R. 1907 contains a very limited prior use defense that applies only to those business methods which have only been considered patentable in the last few years[.]" [FN173] Representative Manzullo made the link between the statutory definition of "method" and the State

Street decision even more explicit:

Before the State Street Bank [&] Trust case, ... it was universally thought that methods of doing or conducting business were not among the statutory items that could be patented. Before that case, everybody would keep their methods of doing or conducting business as secret as they could and never tried to patent them. In recognition of this pioneer clarification in the law, we felt that those who kept their business practices secret had an equitable cause not to be stopped by someone who subsequently reinvented the \*84 method of doing or conducting the business or conducting business and obtain[ing] a patent. We, therefore, limited the first inventor defense solely to that class of rights dealing with "methods of doing or conducting business." It is distinctly to be understood that we do not intend to create first inventor defense or prior use rights for any other process, method, or product, or other statutorily recognized class of patentable rights [.] [FN174]

House Bill 1907, as amended, passed the House overwhelmingly on August 4, 1999. [FN175] The next day, Representative Coble published extended remarks intended by him as a supplement to the House Committee Report. [FN176] Interestingly, these remarks, in contrast to various statements made during the August 3, 1999 floor debate by his fellow Representatives and even by Representative Coble himself, suggest that the First Inventor Defense is not strictly limited to the State Street case, but open to a broader interpretation:

The method that is the subject matter of the defense may be an internal method for doing business, such as an internal \*85 human resources management process, or a method for conducting business such as a preliminary or intermediate manufacturing procedure, which contributes to the effectiveness of the business by producing a useful end result for the internal operation of the business or for external sale. [FN177]

Support for a broad interpretation of "method" can also be found in the remarks of several Senators, including Senator Schumer:

[T]he term "method" is intended to be construed broadly .... It includes a practice, process, activity, or system that is used in the design, formulation, testing, or manufacture of any product or service. The defense will be applicable against method claims, as well as the claims involving machines or articles the manufacturer used to practice such methods (i.e., apparatus claims). [FN178]

It is perhaps tempting to suggest that "courts would be wise to ignore the legislative history altogether" in interpreting the business method limitation because one can find support for almost any \*86 interpretation therein. [FN179] Nevertheless, despite its limitations and contradictions, the legislative history gives rise to only one reasonable reading of Congressional intent--that the defense applies only to business method inventions believed to be not patentable prior to State Street. Language to the contrary in the House Committee Report must surely be disregarded, because the bill's language was significantly amended subsequent to the Report's publication.

Moreover, the best evidence of the specific intent behind that amendment is provided by the contemporaneous commentary during the brief House floor debate on the revised bill. [FN180] That commentary unquestionably demonstrates that the bill's language was changed to convince opponents of a broader First Inventor Defense to support the bill by limiting the defense to State Street. [FN181] As discussed in the next section, however, precisely what in practice is meant by "limiting the Defense to State Street" remains problematic.

### **c. The Practical Effect of Limiting the First Inventor Defense to Business Methods**

The legislative history provides a clear if not entirely consistent explanation of Congress' decision to restrict the First Inventor Defense to business methods. Nevertheless, determining whether the defense is applicable to a specific claimed invention will not always be a simple task. The difficulty arises because even if the defense is understood to apply only \*87 to inventions that were thought to be unpatentable prior to State Street, the pre-State Street "business method exception" was never very well-defined in the first place.

Prior to State Street, a business method exception to patentability was widely thought to exist, [FN182] but cases applying it were rare, and according to the Federal Circuit, no case actually relied on the exception to invalidate a patent. [FN183] One commentator has noted the "logical surrealism" involved in asking whether a claimed invention would have fallen within the business method exception prior to State Street in light of that decision's language suggesting that the exception never existed at all. [FN184] Moreover, one of the reasons cited by the Federal Circuit in "lay [ing] [the] ill-conceived [business method] exception to rest" was that "[a]ny historical distinctions between a method of 'doing' business and the means of carrying it out blur in the complexity of modern business." [FN185] Ironically, then, when the Federal Circuit is called upon to interpret the First Inventor Defense, it may have to \*88 delineate the bounds of an exception that it previously found to be "error prone, ... and obsolete." [FN186]

### **d. Is the First Inventor Defense a Sufficient Legislative Response to State Street?**

The First Inventor Defense is clearly not a complete solution to the problems that many have seen as arising from the State Street decision. First, the availability of the defense will not improve the quality of patents issued for business methods; if anything, the existence of the defense makes it less likely that questionable business method patents will be invalidated through litigation because prior users of patented business methods will find it more advantageous to take refuge in the safe harbor of the First Inventor Defense than to seek invalidation. [FN187] The defense also does nothing to address concerns over the wisdom of granting patents for business methods; indeed, the enactment of the defense suggests Congressional acquiescence in, if not approval of, State Street's decision to uphold such patents.

The defense does, however, provide a solution to a more narrow but still significant concern raised by State Street--the possibility that newly patented business methods would make infringers out of earlier inventors who

understandably did not seek patent protection. [FN188] The strongest \*89 equitable case for a prior user right arises when the prior user is a bona fide first inventor who did not seek a patent because the invention was believed to be unpatentable and whose own activities have made it impossible for him, though not another independent inventor, to obtain a patent. Users of business methods invented prior to State Street may find themselves in precisely this situation. It is difficult to know how often this scenario will arise, but most would agree that a finding of infringement under such circumstances would be unjust. Thus, whatever its flaws and limitations, the First Inventor Defense has the virtue of reducing the potential for injustice stemming from the State Street decision.

## **B. What Rights Are Granted by the First Inventor Defense?**

The preceding section discussed the requirements for successful assertion of the First Inventor Defense. The remaining subsections of this article will address the rights that are bestowed on a party who successfully asserts the defense, along with some accompanying restrictions.

### **1. The First Inventor Defense Is a Non-Invalidating Defense to an Infringement Action**

The First Inventor Defense provides a complete defense to patent infringement actions for parties who meet the defense's requirements. Consistent with the theory behind prior user rights, however, successful assertion of the defense does not render the patent at issue invalid. The statute specifically provides that the patent at issue is not deemed invalid solely by establishment of the defense, [FN189] but despite statements to the \*90 contrary in the legislative history, [FN190] the Act says nothing about whether the facts entitling a prior user to assert the defense might independently render the patent invalid. Given the uncertainties over the invalidating effects of secret prior use, it is conceivable that a defendant might be able to avail itself of the defense while also proving facts that result in invalidation. As a practical matter, however, defendants who are able to establish the defense will have little incentive to seek to invalidate the patent at issue because, in all probability, they will prefer for it to remain in force against all others.

### **2. The First Inventor Defense Is Not a General License**

Successful assertion of the defense does not create a general license in the entire patent at issue, instead it extends only to the specific claims for which the defense is established. [FN191] The defense does extend, however, to variations in quantity or volume of use and to improvements to the invention unless such improvements infringe other claims in the patent for which the defense cannot be established. [FN192] The absence of quantity restriction is important because even an economically insignificant "commercial use" prior to the patentee's effective filing date can give rise \*91 to what is essentially an unfettered right to compete with the patentee. This concern is tempered, however, by the personal nature of the defense. [FN193]

The defense also specifies that if the patented method at issue produces a useful end product, a party who

successfully asserts the defense is entitled to sell or otherwise dispose of such end product and, by so doing, the patent owner's rights are exhausted just as if the sale had been by the patent owner. [FN194] This "exhaustion" provision ensures that the prior user's ability to exploit the invention is unrestricted by any concern that a downstream purchaser might infringe the patent by using the end product produced by the patented method.

### **3. The First Inventor Defense Is Personal to the Prior User, with Significant Restrictions on Transferability**

The First Inventor Defense is personal to "the person who performed the acts necessary to establish the defense," and cannot be licensed, assigned or transferred to anyone else. [FN195] This limitation is aimed at preserving as much of the patent's value as possible by allowing the patent owner to retain the right to exclude all other parties from using the invention and to remain the only source of a license for those who are \*92 unable to qualify for the defense. [FN196] Without this limitation, a party entitled to the defense could compete with the patent owner in licensing the invention, greatly diluting the value of the patent. [FN197]

There is one exception to the non-transferability rule -- the defense can be assigned or transferred in conjunction with the good faith assignment or transfer of the entire enterprise or line of business to which the defense relates. [FN198] To qualify, the transfer of the defense must be ancillary and subordinate to the transfer of the entire business and such transfer must be for reasons other than merely the transfer of the defense itself. [FN199] As a further limitation, after such a transfer, the defense can only be asserted for uses of the patented method at sites where the method was in use prior to the transfer. [FN200] These limitations should ensure that the transferability provisions of the defense are not abused to the detriment of patentees.

### **\*93 IV. CONCLUSION**

In the aftermath of State Street's elimination of a widely-understood prohibition on the patentability of business methods, Congress enacted the First Inventor Defense. The defense is an equitable solution for pre-State Street inventors of business methods who might have sought a patent but for that perceived prohibition. By limiting the First Inventor Defense to business method patents, Congress avoided the much larger controversy that would have been attendant to the enactment of an unrestricted prior user right. Though the precise reach of the First Inventor Defense awaits clarification by court decisions, it is clear that the defense applies to only a small minority of issued patents. Because of this, and because the defense is in other respects a quite stringent version of a prior user right, the overall impact of the defense on the patent law will likely be minimal.

Prior user rights have long been a controversial subject in the US patent community. The enactment of the First Inventor Defense is a partial victory for prior user right proponents, but certainly does not signify an end to the debate. The First Inventor Defense was enacted not so much because Congress was convinced that the arguments in favor of prior user rights overrode those in opposition, but rather due to the fact that the defense focuses solely on business methods. The limitation of the First Inventor Defense to business methods makes it relatively

uncontroversial but leaves unanswered the question of whether a broader prior user right covering the whole expanse of patent law is warranted.

\*94 Advocates of prior user rights will likely point to the relatively benign impact of the defense as grounds for expanding prior user rights beyond business methods, while opponents will argue that the infrequency with which the defense is raised suggests that there is little need for a broader prior user right. [FN201] In short, the debate will continue, and it remains to be seen whether the First Inventor is the end or just the beginning for prior user rights in the United States.

[FNa1]. J.D., University of Maryland, 1991; LL.M., George Washington University, 2001. Mr. Hollander is an Investigative Attorney with the Office of Unfair Import Investigations of the United States International Trade Commission. The views expressed herein are solely those of the author. This article does not express the views of the United States International Trade Commission.

[FN1]. See, e.g., Gary L. Griswold et al., Prior User Rights: Neither a Rose nor a Thorn, 2 U. BALT. INTELL. PROP. L.J. 233, 236 (1994)(noting that countries recognizing prior user rights account for approximately 85% of the world's gross domestic product outside the United States).

[FN2]. Prior user rights were explicitly recognized in Section 7 of the Patent Act of 1839, and remained part of U.S. patent law until 1952. See, e.g., Kyla Harriel, Prior User Rights in a First-to-Invent Patent System: Why Not?, 36 IDEA 543, 547-50 (1996)(discussing the history of prior user rights prior to the Patent Act of 1952).

[FN3]. See, e.g., Robert L. Rohrback, Prior User Rights: Roses or Thorns?, 2 U. BALT. INTELL. PROP. L.J. 1, 13 (1993)("The adverse consequences of prior user rights which may be visited upon a patentee or applicant far outweigh any possible benefit derived from protecting prior users.").

[FN4]. The American Inventors Protection Act is Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999, which was enacted into law on November 29, 1999 as part of the Consolidated Appropriations Act for fiscal year 2000. See Consolidated Appropriations Act, 2000, Pub. L. No. 106-113, § 4001-4808, 113 Stat. 1501, 1501A-552 to 1501A-591 (1999); see generally Pat Costello, New Law Creates a Patent Infringement Defense and Restructures the Patent and Trademark Office, 6 B.U.J. SCI. & TECH. L. 16 (2000)(for a brief survey of the American Inventors Protection Act).

[FN5]. The First Inventor Defense Act is Subtitle C of the American Inventors Protection Act. See Consolidated Appropriations Act, 2000, § 4302, 113 Stat. at 1501A-555 to 1501A-557 (codified at 35 U.S.C. § 273). The First Inventor Defense is effective from the date of enactment, November 29, 1999, though not to infringement actions pending or adjudicated as of that date. See Consolidated Appropriations Act, 2000, § 4303, 113 Stat. at 1501A-557.

[FN6]. 35 U.S.C. § 273(a)(3) (Supp. V 1999).

[FN7]. 35 U.S.C. § 273(b)(4) (Supp. V 1999).

[FN8]. 35 U.S.C. § 273(b)(1) (Supp. V 1999).

[FN9]. *Id.*

[FN10]. 35 U.S.C. § 273(b)(6) (Supp. V 1999).

[FN11]. 35 U.S.C. § 273(b)(9) (Supp. V 1999).

[FN12]. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375, 47 U.S.P.Q.2d (BNA) 1596, 1602 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999)("Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.").

[FN13]. See generally *Prior User Rights (Relative to Patents): Hearings on S. 2272 Before the Subcomm. on Intellectual Prop. and Judicial Admin. of the House Comm. on the Judiciary, 103rd Cong. 2 (1994)*[hereinafter *Hearings on S. 2272*](statement of Rep. Hughes, Chairman, House Subcomm. on Intellectual Prop. and Judicial Admin.)("Prior user rights, as evidenced by past debates, is not a simple issue nor one that lacks controversy."); see also Symposium, *Franklin Pierce Law Center's Fifth Biennial Patent System Major Problems Conference-- IV. Prior User Rights*, 36 *IDEA* 406 (1996)[hereinafter *Franklin Pierce Law Center's*](for a sample of the viewpoints and opinions held by various members of the patent community on the subject of prior user rights).

[FN14]. See, e.g., Sylvie Strobel, *Prior User Rights: Introductory Comments*, 35 *IDEA* 207, 209 (1994)(a prior user right may encourage "R&D projects which would otherwise have been deemed too risky, secure in the knowledge that they will not be precluded from further using any successful research results" due to the subsequent patenting of the same invention by another).

[FN15]. See, e.g., Keith M. Kupferschmid, *Prior User Rights: The Inventor's Lottery Ticket*, 21 *AIPLA Q.J.* 213, 219-21 (1993).

[FN16]. See, e.g., F. Andrew Ubel, *Who's on First?--The Trade Secret Prior User or a Subsequent Patentee*, 76 *J. PAT. & TRADEMARK OFF. SOC'Y* 401, 407 (1994).

[FN17]. See, e.g., Pierre Jean Hubert, *The Prior User Right of H.R. 400: A Careful Balancing of Competing Interests*, 14 *SANTA CLARA COMPUTER & HIGH TECH. L.J.* 189, 212-13 (1998)("U.S. businesses that hold

patents in [countries that provide for prior user rights] cannot enforce these patent against prior users. However, the converse is not true.").

[FN18]. See, e.g., Rohrback, *supra* note 3, at 12-13.

[FN19]. See, e.g., Symposium, Prior User Rights, 34 IDEA 117, 136-37 (1994)[hereinafter Prior User Rights](remarks of Mr. Griswold noting that debate over prior user rights "tends to resolve itself frequently into a small company or university versus a large company discussion").

[FN20]. Rohrback, *supra* note 3, at 20; see also Robert Rines & Skip Kaltenheuser, Proposed patent laws would harm inventors, NAT'L L.J., Nov. 28, 1994, at A23-24 (noting that Prior User Rights Act then pending in Congress would benefit large companies but cripple the ability of inventors and start-up businesses to secure venture capital).

[FN21]. For articles supportive of prior user rights, see generally Griswold et al., *supra* note 1; Harriel, *supra* note 2; Kupferschmid, *supra* note 15; Ubel, *supra* note 16. The most prominent article opposing such rights is Rohrback, *supra* note 3. The first article commenting directly on the First Inventor Defense is also written from the anti-prior user defense perspective. See James R. Barney, The Prior User Defense: A Reprieve for Trade Secret Owners or a Disaster for the Patent Law?, 82 J. PAT. & TRADEMARK OFF. SOC'Y 261 (2000).

[FN22]. See generally S. Rep. No. 103-405 (1994)(reporting favorably on Senate Bill 2272, the "Patent Prior User Rights Act of 1994"); see also Paul R. Morico, Are Prior User Rights Consistent with Federal Patent Policy?: The U.S. Considers Legislation to Adopt Prior User Rights, 78 J. Pat. & Trademark Off. Soc'y 572, 573 (1996)(discussing House Bill 2235, the "Prior Domestic Commercial Use Act of 1995").

[FN23]. See generally S. Rep. No. 105-42 (1997)(reporting favorably on Senate Bill 507, the "Omnibus Patent Act of 1997," including Title IV, the "Prior Domestic Commercial Use Act of 1997"); H.R. Rep. No. 105-39 (1997)(reporting favorably on House Bill 400, the "21st Century Patent System Improvement Act," including Title III, the "Protection for Prior Users of Patented Technologies Act"); H.R. Rep. No. 104-784 (1996)(reporting favorably on House Bill 3460, the "Moorhead-Schroeder Patent Reform Act," including Title III, the "Prior Domestic Commercial Use Act of 1996").

[FN24]. Prominent supporters of prior user rights bills have included the Intellectual Property Owners Association ("IPO"). See 21st Century Patent System Improvement Act; Patent and Trademark Office Surcharge Extension Act of 1997; and Patent Term Restoration Act of 1997: Hearings on H.R. 400, H.R. 673, and H.R. 811 Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary, 105th Cong. 202 (1997)[hereinafter Hearings on H.R. 400](statement of Erwin F. Berrier, Jr., President, Intellectual Property Owners)(Intellectual Property Owners "strongly support[s]" House Bill 400's prior user rights provisions). Another supporter of the prior user rights bills is the American Intellectual Property Law Association ("AIPLA"). See Prior

Domestic Commercial Use Act of 1995: Hearings on H.R. 2235 Before the Subcomm. on Courts and Intellectual Prop. of the House Comm. on the Judiciary, 104th Cong. 65 (1995)[hereinafter Hearings on H.R. 2235](statement of Robert A. Armitage, President, AIPLA)("AIPLA has been before three Congresses now urging that a prior user right statute be enacted into U.S. law.").

[FN25]. Testimony opposing prior user rights has been offered by those purporting to speak for university researchers, see, e.g., Hearings on S. 2272, supra note 13, at 94 (statement of Teri F. Willey, Associate Director, Purdue Research Foundation)(noting that prior user rights discourage commercial collaboration between universities and for-profit companies), and individual inventors, see id. at 114 (statement of Arnold L. Newman, President, Synexus Corp.)(current system works well at rewarding inventors in exchange for disclosure of innovations, and "should not be diluted or unbalanced by prior user rights").

[FN26]. H.R. Rep. No. 106-287, pt. 1 (1999)(reporting favorably on House Bill 1907).

[FN27]. 145 Cong. Rec. H6929 (Aug. 3, 1999)(amended version of House Bill 1907 introduced, followed by 40 minutes of debate). House Bill 1907 passed the House on August 4, 1999. See 145 Cong. Rec. H6973 (Aug. 4, 1999)(yeas 376, nays 43, not voting 14).

[FN28]. Barney, supra note 21, at 261. Barney argues that the defense is in conflict with the public disclosure goal of patent law, may "eviscerate" the non-informing public use doctrine, and will discourage validity challenges against overly broad patents. Id. at 269-73.

[FN29]. 35 U.S.C. § 273(b)(8) (Supp. V 1999).

[FN30]. See Kupferschmid, supra note 15, at 216.

[FN31]. Public use by others before the patentee's invention date, or by any party more than one year before the patentee's application date, renders the patent invalid. See 35 U.S.C. §§ 102(a), 102(b)(Supp. V 1999).

[FN32]. See Harriel, supra note 2, at 558-59 (prior user rights protect users of process inventions "which generally are practiced away from public view"); see also Rohrback, supra note 3, at 4 ("If the commercialization [by the prior user] is enabling ..., no need exists for prior user rights.").

[FN33]. See Kupferschmid, supra note 15, at 247 ("Preventing the transfer of the prior user right preserves the equitable nature of the right and prevents the right from becoming a type of compulsory license.").

[FN34]. See, e.g., Hearings on S. 2272, supra note 13, at 84 (statement of R. Carl Moy, Assoc. Professor, William Mitchell College of Law)("The formulation of a prior-user right is, in theory, highly variable."); ADVISORY

COMMISSION ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE, at 49 (1992)("[T]he basic difficulty in providing a prior user right is crafting the right so that it does not undercut the value of the exclusive rights obtained through a patent grant, or the desirable goal of early disclosure of inventions.").

[FN35]. See, e.g., Morico, *supra* note 22, at 572 ("The rights of the first inventor [who did not seek a patent] to continue making, using, and/or selling the invention after the patent issues to the subsequent inventor are known as prior user rights.").

[FN36]. A secret commercial use by an inventor more than one year prior to the application date creates a statutory bar under Section 102(b). *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts, Co.*, 153 F.2d 516, 520, 68 U.S.P.Q. (BNA) 54, 58 (2d Cir. 1946), cert. denied, 328 U.S. 840 (1946). Secret commercial use may not necessarily prevent a subsequent inventor from obtaining a patent on the same invention, however. *D.L. Auld v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147, 219 U.S.P.Q. (BNA) 13, 16 (Fed. Cir. 1983).

[FN37]. See, e.g., Harriel, *supra* note 2, at 557 (noting that under 35 U.S.C. § 102(g), the first to reduce an invention to practice can lose "first inventor" status to another party who can show an earlier conception date coupled with reasonable diligence, and suggesting that protection in the form of a prior user right is warranted under these circumstances); Kupferschmid, *supra* note 15, at 216 ("prior user right operates independent of any claim to invention"); see also Ubel, *supra* note 16, at 437 n.133 (prior user right as recognized in Japan, Korea, and Malaysia requires only commercialization before the patentee's application date, assuming no derivation of the invention from the patentee).

[FN38]. See Franklin Pierce Law Center's, *supra* note 13, at 413-14 (remarks of Mr. Gholz)(priority contests are "very expensive" and "enormously socially dysfunctional"); see also Patent Reform and Patent and Trademark Office Reauthorization: Hearings on H.R. 1907 Before the Subcomm. on Courts and Intellectual Property of House Comm. on the Judiciary, 106th Cong. 88 (1999) [hereinafter Hearings on H.R. 1907] (statement of Ronald J. Stern, President, Patent Office Professional Association)("There is no utility in expanding the protracted procedures of interference proceedings to any other forum.").

[FN39]. See Kupferschmid, *supra* note 15, at 216 n.6 ("Generally, a party must prove that it commercialized the invention (or made serious preparations to do so) before the patentee's filing date or priority date."). But see Ubel, *supra* note 16, at 438 (France requires merely possession of the invention, with no need for commercialization, to qualify for the right).

[FN40]. See Franklin Pierce Law Center's, *supra* note 13, at 415 (remarks of Mr. Gholz)("cutoff date for prior user rights should be the issue or publication date"; commercializing prior user is "blind sided" by the patent regardless of whether commercialization occurs before or after the application date). But see *id.* at 417 (remarks of Mr.

Budinger) (using publication date as the deadline opens the door to abuse and fraud); cf. *id.* at 440 (remarks of Mr. Gholz)(fraud is usually detected).

[FN41]. See *id.* at 417-18 (remarks of Mr. Budinger)(requiring possession of the invention one year prior to application date allows inventors to use the full one year grace period without fear that invention will be copied and commercialized in order to establish a prior user right); see also Hearings on H.R. 2235, *supra* note 24, at 54 (statement of Gary L. Griswold, President, IPO) (purpose of one year limitation "is to allow patent owners to experiment with or market their inventions without risk during the patent law's one year grace period").

[FN42]. See Franklin Pierce Law Center's, *supra* note 13, at 432 (remarks of Mr. Jorda)(requiring possession of the invention one year prior to application date "guts [the] prior user defense" by excluding many bona fide first inventors); see also The Omnibus Patent Act of 1997: Hearings on S. 507 and H.R. 400 Before the Senate Comm. on the Judiciary, 105th Cong. 50 (1997) [hereinafter Hearings on S. 507 and H.R. 400](statement of William P. Parker, President, Vermont Inventors Association)("The one year prior requirement may be problematic, however. It is difficult to stay a year ahead in rapidly developing advanced technologies.").

[FN43]. 35 U.S.C. § 154 (Supp. V 1999)(patent grants "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States").

[FN44]. See Kupferschmid, *supra* note 15, at 248 ("Any exception [to the right of the patent holder to prevent others from infringing the invention claimed by that patent], regardless of its basis, diminishes the value of the patent to the patent holder and undermines the objectives of the patent system.").

[FN45]. See Hearings on H.R. 400, *supra* note 24, at 232 (statement of Dr. David L. Hill, Chairman, Advisory Committee, Alliance for American Innovation) (alleging that patent reform efforts, including prior user rights, are supported by elements of corporate America that seek to "skew[] the Patent System against the independent inventor"); see also Hearings on S. 2272, *supra* note 13, at 110 (statement of Arnold L. Newman, President, Synexus Corp.) (stating that prior user rights would put American universities at a disadvantage).

[FN46]. U.S. Const. art. I, § 8, cl. 8.

[FN47]. See, e.g., Hearings on S. 507 and H.R. 400, *supra* note 42, at 20 (statement of Rep. Rohrabacher)(proposed prior user defense "may also be unconstitutional in not granting 'Exclusive' rights to a patent holder").

[FN48]. See Hubert, *supra* note 17, at 202.

[FN49]. See *Fauber v. United States*, 81 F. Supp. 218, 222, 79 U.S.P.Q. (BNA) 410, 420 (Ct. Cl. 1948).

[FN50]. See *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593, 21 U.S.P.Q. (BNA) 69, 85-86 (7th Cir. 1934).

[FN51]. See *Hodosh v. Block Drug Co.*, 833 F.2d 1575, 1578, 4 U.S.P.Q.2d (BNA) 1935, 1937 (Fed. Cir. 1987).

[FN52]. 35 U.S.C. § 252 (Supp. V 1999).

[FN53]. See *Rohrback*, supra note 3, at 7-8 (arguing that none of the established exceptions to a patentee's exclusivity are comparable in scope or effect to prior user rights).

[FN54]. See, e.g., Hearings on H.R. 2235, supra note 24, at 21 (testimony of Karl F. Jorda)("It is not possible and practicable to obtain patents on all patentable albeit marginal inventions and it would be much too costly."); Hearings on S. 2272, supra note 13, at 10 (testimony of Bruce A. Lehman)("it is simply not feasible for a company to patent every invention it may develop").

[FN55]. Generally speaking, trade secret law, which is a matter of state rather than federal law, protects against wrongful misappropriation of an invention, but does not permit the trade secret holder to exclude use of the invention by an independent inventor. See Restatement (Third) of Unfair Competition § 40 (1995). In *Kewanee Oil Co. v. Bicron Corp.*, the Supreme Court held that state trade secret law "does not conflict with the patent policy of disclosure" and was not preempted by federal patent law. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489-91, 181 U.S.P.Q. (BNA) 673, 681-82 (1974). The Supreme Court concluded (1) that few holders of patentable inventions would decline to seek a patent in favor of reliance on trade secret protection, and (2) that choosing trade secret over patent protection is unlikely to impede scientific or technological progress. *Id.*

[FN56]. See *Ubel*, supra note 16, at 441 (noting the high monetary cost of obtaining a patent, particularly where invention is only a small advance over the prior art).

[FN57]. See, e.g., *Griswold et al.*, supra note 1, at 234 (inventors sometimes have "valid reasons for not filing a patent application" based on "compelling economic realities").

[FN58]. See, e.g., Hearings on H.R. 2235, supra note 24, at 68 (statement of Robert A. Armitage, President, AIPLA)(because of high costs and difficulties with enforcement, particularly as to process patents, "it is not feasible or even possible to patent every invention"); *Ubel*, supra note 16, at 441 (right to exclude others granted by patent law "may be hollow in situations where infringement is impossible to detect").

[FN59]. See, e.g., *Harriel*, supra note 2, at 554-55 ("Preventing prior users from continuing their commercial efforts ... stifle[s] individual motivation and disrupt[s] commercial viability"; those who make "substantial industrious

efforts" should be rewarded.).

[FN60]. See Hearings on S. 2272, supra note 13, at 11-12 (statement of Bruce A. Lehman)("[S]ocietal goal of realizing the benefits of innovation is best served by policies that provide American companies with maximum flexibility [...] Prior user rights ... will permit companies to choose with confidence ... the most commercially sound approach to commercially exploiting the innovation.").

[FN61]. See Hearings on H.R. 400, supra note 24, at 201-202 (statement of Erwin F. Berrier, Jr., President, IPO)("Manufacturers should not be required to file patent applications on all aspects of their manufacturing processes to assure future quiet enjoyment of their investment."); Morico, supra note 22, at 578 (money spent obtaining defensive patents "could be better spent on developing new technologies"). But see Kupferschmid, supra note 15, at 228 ("[D]iscouraging defensive patenting ... undercut[s] the [public disclosure] objectives of the patent system.").

[FN62]. See Franklin Pierce Law Center's, supra note 13, at 415 (remarks of Mr. Gholz)("[C]ompanies that have commercialized inventions, that have put real money into either actually commercializing or getting close to that point ... have contributed [whether or not they are the first inventor[.] [I]t seems reasonable to me that economic value should be protected.").

[FN63]. See id. at 414-15 (remarks of Mr. Gholz)(priority contests are "very expensive" and "enormously socially dysfunctional").

[FN64]. See Kupferschmid, supra note 15, at 229 ("[P]rior user rights ... benefit the public by making the invention available to the public earlier in the inventive process."); Franklin Pierce Law Center's, supra note 13, at 421- 22 (remarks of Mr. Balmer)(patent law's goal of promoting the progress of the useful arts is furthered by prior user rights which encourage prompt commercialization, to the benefit of society). But see Rohrback, supra note 3, at 22 (small companies are at a distinct disadvantage in the race to commercialize, and individual inventors are "unable to enter" the race at all).

[FN65]. See, e.g., Hearings on H.R. 2235, supra note 24, at 23 (testimony of Karl F. Jorda)(prior user rights are "the best and ideal solution and compromise between the clashing public policy considerations and the illogical extremes now faced by first inventors/trade secret owners and second inventors/patentees").

[FN66]. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 U.S.P.Q. (BNA) 303, 310 (Fed. Cir. 1983)(public sale of tape manufactured using secret process did not constitute "public use" because the sale did not inform the public of the process); see also *Gillman v. Stern*, 114 F.2d 28, 31-32, 46 U.S.P.Q. (BNA) 430, 431-32 (2d Cir. 1940)(secret use is not prior art under  $\beta$  102(a)).

[FN67]. 35 U.S.C. § 102(g) (Supp. V 1999). Section 102(g) governs priority contests between rival patent applicants, but also serves as a category of patent-invalidating prior art. *Id.*

[FN68]. *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 37, 188 U.S.P.Q. (BNA) 481, 484-85 (7th Cir. 1975)(first inventor's non-informing sale of golf balls with a new type of cover material did not constitute "concealment"); see also *Friction Div. Prods., Inc. v. E.I. du Pont de Nemours & Co.*, 658 F. Supp. 998, 1014, 3 U.S.P.Q.2d (BNA) 1775, 1787 (D. Del. 1987)("[T]he [patented] process itself does not have to be disclosed to the public in order to avoid a finding of abandonment, suppression or concealment of the invention.").

[FN69]. See *Ubel*, supra note 16, at 423-24 (noting, and criticizing, the distinction between "secret use" and "non-informing public use").

[FN70]. See *Hubert*, supra note 17, at 191 (referring to these alternatives as the "Invalidity" and "Infringement" Rules).

[FN71]. *Ubel*, supra note 16, at 407. "[A] prior user right is an alternative to the winner-take-all approach [and] is the best solution where [both parties] exercised inventive skill and thus, each deserves rights in the invention." *Id.*

[FN72]. See *id.*

[FN73]. See *id.*

[FN74]. See *Griswold et al.*, supra note 1, at 235 ("The United States needs to codify prior user rights to level the playing field of the patent rights granted by the United States with the patent systems of our trading partners.").

[FN75]. See *Morico*, supra note 22, at 578-79 ("Because of this inequity, multinational businesses are hesitant investing in plants and equipment in the United States for inventions that are not appropriate for patenting.").

[FN76]. It is generally agreed that a statutory prior user right is essential in a first-to-file system. See *Strobel*, supra note 14, at 208 ("[P]rior user rights are unanimously recognized in principle as just and desirable in a first-to-file system."); *Ubel*, supra note 16, at 433-35 (primary advantage of "first-to-file" system is efficiency and administrative convenience; prior user rights address the equitable shortcomings of this system). But see *Rohrback*, supra note 3, at 26 (arguing against prior user rights even if United States adopts a first-to-file approach); see also *Hearings on S. 2272*, supra note 13, at 16 (statement of Bruce A. Lehman, Commissioner of Patents and Trademarks)(noting that the 1991-1992 Advisory Commission on Patent Law Reform spent a significant amount of time discussing prior user rights as part of moving to a first-to-file system, and that the vote in favor of doing so was very close, with one member withdrawing from the Commission as a result of the outcome).

[FN77]. See Kupferschmid, *supra* note 15, at 221 (arguing that the lack of a U.S. prior user right "gives foreign industry a definite advantage over U.S. industry"); Morico, *supra* note 22, at 578-79 (noting that where prior user rights are available in foreign countries, that disparity "hurts U.S. businesses and puts them at a clear competitive disadvantage with countries that recognize prior user rights").

[FN78]. See Hearings on H.R. 400, *supra* note 24, at 238 (statement of David L. Hill, Ph.D)(stating that prior user rights deprive an "inventor who has diligently pursued [a patent] of the right of exclusion which is fundamental to the intent of the Constitutional empowerment to the Congress on intellectual property"); see also Franklin Pierce Law Center's, *supra* note 13, at 412 (remarks of Mr. Witte)("I am opposed to prior user rights on the classic grounds that it unreasonably erodes the basic exclusionary right of the patent.").

[FN79]. See Rohrback, *supra* note 3, at 6 (asserting that a prior user who failed to seek patent protection either failed to investigate the patentability of the invention, received incorrect legal advice regarding patentability, or deliberately disdained use of the patent system and that, in any of these cases, consequences should fall on the prior user rather than the patentee).

[FN80]. See Barney, *supra* note 21, at 267 (noting that the availability of prior user defense makes trade secret protection "relatively more attractive than patent protection in marginal cases"); Rohrback, *supra* note 3, at 10 (stating that "encouraging secret uses ... prevent[s] dissemination of technological information"). But see Morico, *supra* note 22, at 580 (asserting that "any suppression of inventions ... will be minor and will in no way undermine the patent system").

[FN81]. See Rohrback, *supra* note 3, at 12 (noting that federal patent law should be aimed at achieving the constitutional purpose of promoting the progress of the useful arts, and trade secrets do not serve this purpose). But see Kupferschmid, *supra* note 15, at 221 ("strengthening of trade secret protection is a legitimate consequence of implementing a prior user rights system").

[FN82]. Barney, *supra* note 21, at 266.

[FN83]. Rohrback, *supra* note 3, at 23.

[FN84]. *Id.* at 22.

[FN85]. See Rohrback, *supra* note 3, at 9 (noting that a delay in filing increases risk of adverse prior user rights).

[FN86]. See *id.* at 21 ("Small businesses, universities, research groups and individual inventors are the principal beneficiaries of the one-year grace period" and thus are more likely to be harmed by prior user rights than large businesses.). "Diminishing the value of the grace period [is likely to result in] [i]ncreased filing of poorly drafted

patent applications." *Id.* at 22.

[FN87]. See *Prior User Rights*, *supra* note 19, at 130 (remarks of Mr. Balmer)("The real issue is what is the desired societal benefit and that's one for the economists."); see also *id.* at 132 (remarks of Mr. Goldstein) ("[T]here's enough policy all the way around that you can basically justify either side of the prior user rights issue. To me, the bottom line ought to be U.S. economic policy and the effect a prior user system would have on it.").

[FN88]. See *Hearings on H.R. 2235*, *supra* note 24, at 21 (statement of Karl F. Jorda)("It is not true, though often assumed, that a patentee can enjoin a prior inventor of the same invention who kept it a trade secret.").

[FN89]. See Karl F. Jorda, *The Rights of the First Inventor--Trade Secret User as Against Those of the Second Inventor-Patentee (Part II)*, 61 *J. PAT. & TRADEMARK OFF. SOC'Y* 593, 600 (1979); Franklin Pierce Law Center's, *supra* note 13, at 430 (remarks of Mr. Jorda)("Now, the point has been made time and again that if you don't seek patent protection, a competitor happening on the same development may obtain a patent and exclude you from using your own innovation. Now, if you believe that, I have a certain bridge to sell you. You would delude yourself in believing this because there is no case on the law books where it has ever happened that a first inventor/prior user was enjoined by a later patentee of the same invention."); see also *Hearings on H.R. 2235*, *supra* note 24, at 21 (statement of Karl F. Jorda)("It doesn't happen and it's unlikely to happen because no patentee when he/she is not a bona fide first inventor is going to put his/her patent on the block.").

[FN90]. See *Hubert*, *supra* note 17, at 213 ("[T]he limited data available relating to operation of the prior user right in foreign countries suggests the incidence of prior user right problems which would arise in practice in the United States would be very small."); *Kupferschmid*, *supra* note 15, at 223-26 ("[P]rior user right litigation is minimal in countries presently having the right[.] [I]t is safe to conclude that there should be an extremely small number of prior user rights cases in the United States."). But see *Rohrback*, *supra* note 3, at 27 (noting that experience in other countries is of minimal value in predicting incidence of prior user rights cases in more litigious United States).

[FN91]. See *Kupferschmid*, *supra* note 15, at 236 ("[T]hough there may be certain merits to the arguments made by prior user rights opponents, most of the potential adverse effects ... will have little or no effect because of the extreme infrequency in which prior user cases will arise."). But see *Rohrback*, *supra* note 3, at 27 (contending that even absent significant numbers of prior user rights cases, risk that such rights might be asserted would "erode the potential value of many patents").

[FN92]. See *Rohrback*, *supra* note 3, at 3 (noting lack of information concerning negative impacts on patent owners and inventors from the existence of prior user rights in other countries' patent systems).

[FN93]. See *Hearings on S. 2272*, *supra* note 13, at 14 (testimony of Bruce A. Lehman)("Over 44% of all patents

issued in the United States are issued to foreign entities.").

[FN94]. 35 U.S.C. § 273(b)(1) (Supp. V 1999).

[FN95]. 35 U.S.C. § 273(b)(3)(B) (Supp. V 1999).

[FN96]. 35 U.S.C. § 273(b)(1) (Supp. V 1999).

[FN97]. 35 U.S.C. § 273(b)(4) (Supp. V 1999).

[FN98]. 35 U.S.C. §§ 273(a)(3), 273(b)(1), 273(b)(3)(A) (Supp. V 1999).

[FN99]. See H.R. Rep. No. 106-287, pt. 1, at 44-45 (1999) (noting that the defense "strikes an equitable balance between ... inventors who have invented and commercialized business methods ... and later ... inventors who have patented the processes").

[FN100]. 35 U.S.C. § 273 (b)(1) (Supp. V 1999). "Effective filing date" is defined as the actual filing date, or the date for which the patent holder claims priority under Sections 119, 120, or 365. 35 U.S.C. § 273 (a)(4) (Supp. V 1999).

[FN101]. 35 U.S.C. § 273(b)(6) (Supp. V 1999)(Defense may be asserted "only by the person who performed the acts necessary to establish the defense.").

[FN102]. 35 U.S.C. § 273(a)(1) (Supp. V 1999).

[FN103]. *Id.*

[FN104]. But cf. *id.* (noting that for inventions requiring a pre-marketing regulatory review period prior to commercial marketing or use, such a period is deemed a "commercial use").

[FN105]. 35 U.S.C. § 273(a)(2) (Supp. V 1999).

[FN106]. 35 U.S.C. § 273(a)(2)(B) (Supp. V 1999).

[FN107]. 35 U.S.C. §§ 273(b)(1), (5) (Supp. V 1999).

[FN108]. 35 U.S.C. § 102(g) (Supp. V 1999).

[FN109]. This hypothetical case illustrates how the defense weakens the usefulness of the one year grace period by

creating an incentive to file one's application as quickly as possible in order to make it more difficult for any potential independent inventors to qualify for the defense.

[FN110]. See Hubert, *supra* note 17, at 219 (House Bill 400, as passed by the House in 1997, provided that effective and serious preparation for commercialization was sufficient to establish the defense "with respect to subject matter that cannot be commercialized without a significant investment of time, money, and effort.").

[FN111]. See Hearings on H.R. 1907, *supra* note 38, at 57 (statement of Michael K. Kirk, Executive Director, AIPLA)(noting that the "preparation to achieve commercialization" language was dropped "to accommodate the concerns of opponents").

[FN112]. See *id.* (stating that "effective and serious preparation" provision "would have avoided the possibility that a domestic manufacturing firm would spend large sums of money in preparation for commercialization only to be blocked [by the patentee] before actual commercialization could be achieved"). It should be noted that this comment was made at a time when the proposed defense would have covered manufacturing processes as well as business methods. *Id.*

[FN113]. 35 U.S.C. § 273(b)(6) (Supp. V 1999)(stating that the defense is transferable only as part of a transfer of the entire enterprise or line of business to which the defense relates).

[FN114]. 35 U.S.C. § 273(b)(3)(B) (Supp. V 1999).

[FN115]. 35 U.S.C. § 273(b)(1) (Supp. V 1999).

[FN116]. 35 U.S.C. § 273(b)(4) (Supp. V 1999).

[FN117]. 35 U.S.C. § 273(b)(8) (Supp. V 1999)(stating that if the defendant pleads the First Inventor Defense without a reasonable basis and is subsequently found to have infringed the patent, the case is to be deemed exceptional for the purposes of awarding attorney fees under 35 U.S.C. § 285).

[FN118]. 35 U.S.C. § 273(b)(1) (Supp. V 1999)(emphasis added). Elsewhere, the defense reiterates that "[a] person may not assert the defense under this section unless the invention for which the defense is asserted is a method." 35 U.S.C. § 273(b)(3)(A) (Supp. V 1999).

[FN119]. 35 U.S.C. § 273(a)(3) (Supp. V 1999).

[FN120]. See, e.g., James R. Barney, *supra* note 21, at 262-64 (listing three possible interpretations--(1) "narrow," i.e., pure business methods "without a physical or software embodiment," (2) "moderate," i.e., business methods

thought unpatentable prior to State Street, and (3) "broad," i.e., all claims relating in any way to a method of doing business).

[FN121]. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

[FN122]. For a sampling of the many articles written in the wake of State Street, see, e.g., Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); Chad King, *Abort, Retry, Fail: Protection for Software-Related Inventions in the Wake of State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 85 CORNELL L. REV. 1118 (2000); Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights For Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999); Leo J. Raskind, *The State Street Bank Decision: The Bad Business of Unlimited Patent Protection for Methods of Doing Business*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 61 (1999); Jacob Razem, *Patent Protection for New Ways to Do Business and the Effect on Financial Institutions*, 4 N.C. BANKING INST. 521 (2000); Richard H. Stern, *Scope-of-Protection Problems with Patents and Copyrights on Methods of Doing Business*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 105 (1999); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999).

[FN123]. *State Street*, 149 F.3d at 1370, 47 U.S.P.Q.2d (BNA) at 1598.

[FN124]. See Stern, *supra* note 122, at 132 ("claim 1 thoroughly foreclosed compliance with tax law requirements for avoiding multiple taxation of pooled fund partnerships").

[FN125]. *State Street*, 149 F.3d at 1370, 47 U.S.P.Q.2d (BNA) at 1598.

[FN126]. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 927 F. Supp. 502, 517, 38 U.S.P.Q.2d (BNA) 1530, 1543 (D. Mass. 1996). Section 101 allows patents to be issued for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101 (Supp. V 1999).

[FN127]. *State Street*, 149 F.3d at 1373, 1375-77, 47 U.S.P.Q.2d (BNA) at 1600, 1602-04.

[FN128]. *Id.* at 1373, 47 U.S.P.Q.2d (BNA) at 1600.

[FN129]. *Id.*

[FN130]. *Id.* at 1373-75, 47 U.S.P.Q.2d (BNA) at 1601-02.

[FN131]. *Id.* at 1375-77, 47 U.S.P.Q.2d (BNA) at 1602-04.

[FN132]. *Id.* at 1375, 47 U.S.P.Q.2d (BNA) at 1602.

[FN133]. *Id.* at 1375, 47 U.S.P.Q.2d (BNA) at 1603.

[FN134]. *Id.* at 1377, 47 U.S.P.Q.2d (BNA) at 1604.

[FN135]. Rinaldo Del Gallo, III, Are "Methods of Doing Business" Finally Out as a Statutory Rejection? 38 IDEA 403, 435 (1998), cited in *State Street*, 149 F.3d at 1375 n.11, 47 U.S.P.Q.2d (BNA) at 1603 n.11.

[FN136]. See *id.* at 437 (citing PTO's Examination Guidelines, 61 Fed. Reg. 7478, 7479 (1996)).

[FN137]. Section 706.03(a) of the MANUAL OF PATENT EXAMINING PROCEDURE included such a reference as of August 1993, but has not since, at least as of September 1995. See Roberta J. Morris, Business Method Patents: Good or Bad, Old or New (And Other Miscellaneous Thoughts), 589 PLI/PAT 77, 80 (2000). The patent at issue in *State Street* was granted in 1993 on an application filed in 1991. *State Street*, 149 F.3d at 1370-71, 47 U.S.P.Q.2d (BNA) at 1598-99.

[FN138]. Thomas, *supra* note 122, at 1162.

[FN139]. See *id.* at 1158-59 (noting that the court's characterization of the claimed invention as generating a tangible result in the form of a "final share price" appears inaccurate based on a reading of the actual claims); *id.* at 1159-60 (noting that the decision misstates the chronology of the early "mathematical algorithm" decisions and fails to acknowledge the reasoning of several more recent Federal Circuit decisions); *id.* at 1160 (arguing that the court said more than was necessary regarding business method patents, as the patent at issue was not directed to a method, but to programmed computer hardware); see also Stern, *supra* note 122, at 123 (noting *State Street*'s "remarkable treatment of precedent").

[FN140]. See Raskind, *supra* note 122, at 86-91 (discussing difficulty of perceiving any innovation in the claimed invention).

[FN141]. See Thomas, *supra* note 122, at 1160 n.170 (citing *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 50 U.S.P.Q.2d 1447 (Fed. Cir. 1999)).

[FN142]. *Id.* at 1140.

[FN143]. See generally Carol B. Oberdorfer, Patents: 'Boom' in Business Method Patent Filings Has Followed 'State

Street' Ruling, PTO Says, Pat., Trademark & Copyright L. Daily (BNA) No. 57, at 115 (Dec. 10, 1998).

[FN144]. See Dreyfuss, supra note 122, at 268-72.

[FN145]. See id. at 269 ("[B]ecause business methods have not been patented in the past, there is very little patent-related prior art .... More important, because knowledge about business methods resides mainly in the practices and policies of the firms that use them, even common methods may not be documented in the sorts of materials that examiners can efficiently consult.").

[FN146]. Id. at 268 (citing [Priceline.com](#)'s patent on Dutch auctions, along with other examples); see also [Amazon.com](#), Inc. v. [Barnesandnoble.com](#), Inc., 73 F. Supp. 2d 1228, 1249, 53 U.S.P.Q.2d (BNA) 1115, 1131-32 (W.D. Wash. 1999)(granting preliminary injunction in favor of [Amazon.com](#)'s patent on "one-click" purchasing over the Internet), vacated by 239 F.3d 1343, 1366, 57 U.S.P.Q.2d (BNA) 1747, 1763 (Fed. Cir. 2001)(finding substantial questions regarding the validity of [Amazon.com](#)'s patent).

[FN147]. Stern, supra note 122, at 142.

[FN148]. Cf. Merges, supra note 122, at 590 (noting that "there were numerous complaints in the early years of biotechnology and software patents that the PTO was allowing too many overly broad patents"); see also U.S. PATENT & TRADEMARK OFFICE, FORMULATING & COMMUNICATING REJECTIONS UNDER 35 U.S.C. 103 FOR APPLICATIONS DIRECTED TO COMPUTER-IMPLEMENTED BUSINESS METHOD INVENTIONS (2001), available at [http:// www.uspto.gov/web/menu/busmethp/busmeth103rej.htm](http://www.uspto.gov/web/menu/busmethp/busmeth103rej.htm) (last modified Feb. 7, 2001).

[FN149]. See Dreyfuss, supra note 122, at 275 ("[N]either the free-rider nor the disclosure rationale justifies business method patents."); Raskind, supra note 122, at 78 ("In the absence of data showing a need to spur innovation in business methods, it is ... plausible that the spur of competition and the long tradition of competition by emulation have been sufficient to provide an adequate level of innovation in methods of doing business.").

[FN150]. See Merges, supra note 122, at 588 ("It is virtually impossible to determine--at least at this time--if truly valid business concept patents are a net drag on the economy, a net plus, or neutral."); Raskind, supra note 122, at 78 ("empirical data on the function of business method patents is insubstantial"); Thomas, supra note 122, at 1166 ("economic evaluation of this issue can often be reduced to thought experiments" divorced from any empirical evidence).

[FN151]. Thomas, supra note 122, at 1185.

[FN152]. But see Stern, supra note 122, at 129 ("Seeking congressional intent as to what should be potentially

patentable subject matter, and in particular whether business methods should, is ... useless.").

[FN153]. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1372-73, 1375-77, 47 U.S.P.Q.2d (BNA) 1596, 1602-04. (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

[FN154]. See *Thomas*, supra note 122, at 1178-84 (suggesting that Congress limit the scope of patent eligibility to inventions with industrial applicability). But see *Dreyfuss*, supra note 122, at 277 (questioning whether this "particular divide would distinguish between fields where patents make sense and fields where they do not"); accord *Stern*, supra note 122, at 129 n.102 ("[U]sing industrial arts as a defining category may turn out to be as inconclusive as using the concept of technological arts.").

[FN155]. See *Stern*, supra note 122, at 126 (suggesting that congressional action "would seem most improbable").

[FN156]. See H.R. 1332, 107th Cong. (1st Sess. 2001)(the "Business Method Patent Improvement Act of 2001").

[FN157]. Of course, *State Street* did increase the urgency of those efforts, at least with regard to business method patents.

[FN158]. See S. 1042, 90th Cong. § 274 (1967).

[FN159]. See ADVISORY COMMISSION ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE 43-55 (1992)(recommending switch to first-to-file system with a prior user right); see also Patent System Harmonization Act of 1992: Joint Hearings on S. 2605 and H.R. 4978 Before the Subcomm. on Patents, Copyrights, and Trademarks of the Senate Comm. on the Judiciary and the Subcomm. on Intellectual Prop. and Judicial Admin. of the House Comm. on the Judiciary, 102nd Cong. (1992).

[FN160]. See supra notes 22, 23.

[FN161]. H.R. 400, 105th Cong. § 1961 (1997); see also Pierre Jean Hubert, *The Prior User Right of H.R. 400: A Careful Balancing of Competing Interests*, 14 SANTA CLARA COMPUTER & HIGH TECH. L.J. 189, 217-20 (1998).

[FN162]. See H.R. Rep. No. 106-287, pt. 1 (1999)(reporting favorably on House Bill 1907).

[FN163]. *Id.* at 31-32 (noting that House Bill 1907 included amendments offered during debate over House Bill 400 on the floor of the House during the previous Congress in response to concerns raised by independent inventors).

[FN164]. *Id.* at 7.

[FN165]. Id. "Process" is defined as "process, art or method, [including] a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (1994 & Supp. V 1999).

[FN166]. See H.R. Rep. No. 106-287, pt. 1, at 7 (1999).

[FN167]. Id. at 45.

[FN168]. See 145 Cong. Rec. H6941-42 (Aug. 3, 1999)(statement of Rep. Coble)(amended bill was the "product of compromise and negotiation" with opponents of the earlier House Bill 400); 145 Cong. Rec. H6943-44 (Aug. 3, 1999)(statement of Rep. Rohrabacher)(after initially limiting the defense to processes and methods, opponents were able to further limit it to business methods only).

[FN169]. 145 Cong. Rec. H6931 (Aug. 3, 1999).

[FN170]. H.R. Rep. No. 106-287, pt. 1, at 7 (1999).

[FN171]. 145 Cong. Rec. H6942 (Aug. 3, 1999).

[FN172]. Id.

[FN173]. 145 Cong. Rec. H6943 (Aug. 3, 1999).

[FN174]. 145 Cong. Rec. H6947 (Aug. 3, 1999)(emphasis added).

[FN175]. 145 Cong. Rec. H6973 (Aug. 4, 1999)(yeas 376, nays 43, not voting 14). Those who voted against the bill seemed more concerned with the manner which the bill as amended was rushed to a vote than with any specific provision of the bill. See, e.g., 145 Cong. Rec. H6970 (Aug. 4, 1999) (statement of Rep. Kaptur)("Those who had concerns about the bill and did not even have a chance to read it were limited to 10 minutes on a bill with constitutional consequences."); accord 145 Cong. Rec. E1757 (Aug. 5, 1999) (speech of Rep. Mink made on Tuesday, Aug. 3, 1999)("I find the manner with which this bill was brought to the House floor unacceptable.").

[FN176]. 145 Cong. Rec. E1788 (Aug. 5, 1999)("[C]hanges have been made to the bill which are not reflected in the committee report that was filed. I therefore intend that this document supplement the report for purposes of detailing a more accurate legislative history of H.R. 1907.").

[FN177]. 145 Cong. Rec. E1789 (Aug. 5, 1999)(emphasis added). Adding to the confusion, Representative Coble further stated: "The issue of whether an invention is a method is to be determined based on its underlying nature and not on the technicality of the form of the claims in the patent." Id.

[FN178]. 145 Cong. Rec. S14837 (Nov. 18, 1999); accord 145 Cong. Rec. S14521 (Nov. 10, 1999)(remarks of Sen. Lieberman)("It is my understanding that any kind of method, regardless of its technological character, would be included within the scope of this definition, provided it is used in some manner by a company or other entity in the conduct of its business.").

[FN179]. Barney, *supra* note 21, at 264.

[FN180]. See *supra* notes 168-74 and accompanying text. In contrast, statements inserted into the record by individual legislators after the House vote are less probative of Congressional intent.

[FN181]. See *id.*; see also 145 Cong. Rec. H6944 (Aug. 3, 1999) (statement of Rep. Rohrabacher)(Defense "is strictly limited to business methods" and "will not affect the vast majority of independent inventors and small businesses."); 145 Cong. Rec. H6947 (Aug. 3, 1999)(statement of Rep. Manzullo)(explicitly linking limitation of defense to methods of doing or conducting business to the State Street case).

[FN182]. See, e.g., Claus D. Melarti, *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.: Ought the Mathematical Algorithm and Business Method Exceptions Return to Business As Usual?*, 6 J. INTELL. PROP. L. 359, 365 (1999)("business methods exception had become 'hornbook' law cast in stone"). But see Del Gallo, *supra* note 135, at 435 (business method exception, like the "Emperor's clothes, ... is a robe without substance").

[FN183]. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375-77, 47 U.S.P.Q.2d (BNA) 1596, 1603 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

[FN184]. See Barney, *supra* note 21, at 263.

[FN185]. *State Street*, 149 F.3d at 1375, 1376 n.13, 47 U.S.P.Q.2d (BNA) at 1602, 1604 n.13; see also Del Gallo, *supra* note 135, at 435 (arguing, prior to *State Street*, that the business method exception "serves no useful analytical purpose").

[FN186]. *State Street*, 149 F.3d at 1375 n.10, 47 U.S.P.Q.2d (BNA) at 1604 n.10 (quoting *In re Schrader*, 22 F.3d 290, 298, 30 U.S.P.Q.2d (BNA) 1455, 1462 (Fed. Cir. 1994)(Newman, J., dissenting)).

[FN187]. See Barney, *supra* note 21, at 272-73 (asserting that availability of the defense creates a disincentive to challenge overly broad patents).

[FN188]. See Thomas, *supra* note 122, at 1162 n.178 ("*State Street* holds particularly unsettling possibilities for inventors who maintained their business methods as trade secrets .... Because business method innovators may have opted for trade secret protection based upon the traditional rule that such methods were unpatentable, a practical

effect of State Street may be to convert the first inventors of business methods into infringers.").

[FN189]. 35 U.S.C. § 273(b)(9) (Supp. V 1999)(emphasis added).

[FN190]. See H.R. Rep. No. 106-287, pt. 1, at 49 (1999)(stating misleadingly that "[t]he bill provides that a party who uses a ... business method commercially in secrecy before the patent filing date and establishes a § 273 defense is not an earlier inventor for purposes of invalidating the patent").

[FN191]. 35 U.S.C. § 273(b)(3)(C) (Supp. V 1999).

[FN192]. *Id.*

[FN193]. 35 U.S.C. § 273(b)(6) (Supp. V 1999)(discussed in the next subsection).

[FN194]. 35 U.S.C. § 273(b)(2) (Supp. V 1999). As explained in the House Committee Report, "if a purchaser would have had the right to resell a product if bought from the patent owner, the purchaser has the same right if the product is purchased from a person entitled to a § 273 defense." H.R. Rep. No. 106-287, pt. 1, at 48 (1999).

[FN195]. 35 U.S.C. § 273(b)(6) (Supp. V 1999). Transfer to the patent owner, which would effectively relinquish the defense, is permitted, see *id.*, though the anti-competitive aspects of such a transfer could conceivably raise antitrust concerns.

[FN196]. See Hearings on S. 2272, *supra* note 13, at 44 (statement of Robert P. Merges, Law Professor, Boston University School of Law) ("[T]ransferability [of prior user rights] to third parties would seriously undermine a patentee's incentives."). But see Rohrbach, *supra* note 3, at 15 (despite limitation on transferability, if holder of prior user right is the patentee's only competitor or a market-dominating company, the patent is rendered nearly worthless).

[FN197]. See Ubel, *supra* note 16, at 439 (asserting that the personal nature of a prior user right "avoids the unfairness to the patent owner which would occur if the prior user were able to freely license its prior user rights in competition with the patent rights").

[FN198]. See *id.*

[FN199]. See *id.*

[FN200]. 35 U.S.C. § 273(b)(7) (Supp. V 1999). If the transfer of the business predated the patentee's filing date, then the defense extends to any sites where the method was put into use prior to the filing date. *Id.*

[FN201]. But cf. Hearings on H.R. 400, supra note 24, at 171 (testimony of Michael K. Kirk, Executive Director, AIPLA)("[T]he value of a prior user right defense should not be discounted simply because it will rarely be used. The availability of a prior user right defense will take the pressure off of U.S. companies to patent marginally valuable inventions and those which are difficult to enforce.").

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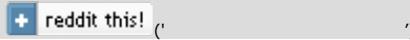
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## OTHERS

### The “Soleau” envelope system in France

#### 1. What is the “Soleau” envelope ?

It consists in an envelope having two compartments. “Soleau” is the name of the inventor of such an envelope.

#### 2. Filing and keeping of the envelope

“Soleau” envelopes are purchased from the French Patent Office (INPI=Institut National de la Propriété Industrielle) at a cost of currently 10€ each.

A copy of a same document is sealed in each compartment of the envelope and the envelope is filed with the INPI with the indication of the name and address of the applicant or representative (if any).

Both compartments are dry-stamped (laser stamp) by the INPI. One compartment is returned to the applicant. The other one is kept by the INPI for a time period of 5 years which can be renewed once only upon payment of an official fee (currently 10€).

The applicant should keep the returned and stamped compartment sealed.

The envelope should not have a thickness larger than 5mm or contain hard material for allowing dry stamping (perforation).

#### 3. Function of the envelope

The envelope is used as a means for keeping evidence that its content was known or had been created by the applicant at the date of stamping, without any disclosure of that content.

When provision of such evidence is needed, the compartment kept by the INPI is sent back to the applicant upon request and at his own costs.

If the time period of 5 years or 10 years (if renewed) has then lapsed, the compartment originally returned to the applicant may be used provided it has been kept unopened.

#### 4. Reasons for using the envelope

##### 4.1 Copyright protection

“Soleau” envelopes are mainly used by authors or creators to keep evidence of a date of creation. Indeed, copyright protection in France is acquired as from the date of creation without any filing being required.

It should be noted that copyright protection is also available in France for designs, including industrial designs but only with respect to any non-technical aspect.

Thus, in case of copyright infringement, the envelope can be used to prove that its content has been created by the applicant at a given date without the content or the date being questionable, thus showing the object and date of copyright protection.

##### 4.2 Inventions

“Soleau” envelopes enable inventors or companies to provide evidence that they had invented or knew what is described in the content of envelopes, at a particular date. This can be useful in the following circumstances :

- a) To assist in claiming rights in case of misappropriation of the invention by a third party,
- b) To benefit from the so-called prior possession rights under Article L.613-7 of the French Intellectual Property Code (IPC). Indeed, Article L. 613-7 IPC states:

“ Any person who, within the territory in which this Book applies, at the filing date or priority date of a patent was, in good faith, in possession of the invention which is the subject matter of the patent shall enjoy a personal right to work that invention despite the existence of the patent.

The right afforded by this Article may only be transferred together with business, the enterprise or the part of the enterprise to which it belongs.”

By contrast with many other countries, mere possession or knowledge of an invention is sufficient in France to be able to work that invention despite a patent covering the same invention has been later filed by a third party. There are similar provisions in Belgium, but in other countries in Europe, prior user’s rights only are granted, which means that the inventions should have been not only known, but also used or that actual and serious preparations for its use should have started.

#### 5. Limits of the use of “Soleau” envelopes for inventions

- a) “Soleau” envelopes do not grant legal protection. This is something frequently

misunderstood by inventors or by small companies in France. A “Soleau” envelope may assist in claiming prior possession rights which do not grant legal protection but can only make it possible to escape from patent rights owned by a third party;

b) The scope of “Soleau” envelopes is strictly interpreted. Since prior possession constitutes an exception to patent rights, the scope of prior possession is strictly limited to what is actually contained in the envelope. This is also something which is sometimes misunderstood by applicants who would only include in a “Soleau” envelope a general and not detailed description of the invention. French Courts have ruled that one cannot benefit from prior possession for features which were not actually described in the document contained in the envelope, regardless of the fact that such features might have been obvious from the content of the envelope.

c) The effect of “Soleau” envelopes is limited to the French territory. This means that products which may be put lawfully onto the market in France under the exception of prior possession rights vis-à-vis a French patent will constitute infringements in countries where they may be exported and where patents parallel to the French patent are in force and cover the products or their method of manufacture.

In practice, limitation c) is the most significant one for companies whose market is not limited to France. The “Soleau” envelope system is nevertheless used by some of our French clients, having international activity, but mainly as an interim measure, until a patent application is filed, in particular when development of the invention includes cooperation with third parties, to be then in a better position to claim back ownership of a patent application filed by a third party in case of misappropriation.

Jean-Jacques JOLY©Cabinet Beau de Loménie / January 2005

## PART I GENERAL AND INSTITUTIONAL PROVISIONS

### 1 General

The four principles of the European Patent Convention are: a common law for granting patents (Art.1) - called European patents (Art.2(1)) - designating one or more states (Art.3) - having the effect of a national patent in each state (Art.2(2)).

The EPC is self-executing and is independent of national laws for its implementation (J15/80).

### Chapter I *General Provisions*

#### Art. 1 European law for the grant of patents

A system of law, common to the Contracting States, for the grant of patents for invention is established by this Convention.

#### Art. 2 European patent

Art. 2(1) Patents granted under this Convention shall be called European patents.

Art. 2(2) The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless this Convention provides otherwise.

### 1 Effect of European patent

A European patent does not completely fall apart in a bundle of national patents. It retains its special character after the grant: the EPC overrules national law if EPC provisions relating to European patents are at variance with national law. The desire for the harmonization of rules governing patents has been expressed in the Preamble. The main EPC provisions relating to European patents are:

- The protection of a process patent extends to the direct products of the process (Art.64(2)).
- The term of the patent is 20 years (Art.63(1)), possibly extended on the grounds of Art.63(2).
- The text of the European patent in the language of the proceedings is the authentic text (Art.70(1)).
- A European patent may only be revoked in a national procedure on the grounds given in Art.138.

- The scope of protection is determined by the claims; the description and the drawings may be used for interpreting the claims (Art.69 and protocol).
  - The bundle of national patents is subject to the centralised opposition procedure of the EPC (Art.99) and the centralised limitation and revocation procedure of Art.105a-c.
  - Revocation in an opposition procedure has retroactive effect (Art.68).
  - A review of a board of appeal decision under Art.112a may affect a European patent.
  - The minimum period for first payment of the renewal fees for a granted patent to a national patent office is set by Art.141.
- The EPC allows a wide interpretation of patentability, including, for instance, pharmaceuticals and chemical products.

### Art. 3 Territorial effect

**The grant of a European patent may be requested for one or more of the Contracting States.**

- 1 **Patent for one or more contracting states**  
It was the intention of the drafters of the EPC 1973 to introduce a community patent. As this turned out to be impossible, the scope was reduced to a system for grant of patents for one or more states (see [7/90 I.6.1]. A list of contracting states is given in the notes to Art.169.

### Art. 4 European Patent Organisation

**Art. 4(1) A European Patent Organisation, hereinafter referred to as the Organisation, is established by this Convention. It shall have administrative and financial autonomy.**

**Art. 4(2) The organs of the Organisation shall be:**

- (a) the European Patent Office;
- (b) the Administrative Council.

- 1 **Organisation versus Office**

The 'European Patent Office' is abbreviated as 'EPO' in the notes of this book, whereas the 'European Patent Organisation' is written in full. The EPO is the executive body of the European Patent Organisation.

- 2 **Academy of the European Patent Organisation**

By a decision of 17.06.2004 the Administrative Council has set up a European Patent Academy for education and training in the field of European and international patent law, including the preparation of candidates for the European qualifying examination. The Academy is an institution of the European Patent Organisation and is managed by the European Patent Office. The Regulations of the Academy have been published in OJ 2004, 362.

**Art. 4(3) The task of the Organisation shall be to grant European patents. This shall be carried out by the European Patent Office supervised by the Administrative Council.**

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# 714 F.2d 1144: The D.L. Auld Company, Appellant, v. Chroma Graphics Corp., Appellee

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**United States Court of Appeals, Federal Circuit. - 714 F.2d 1144**

**Aug. 15, 1983**

Richard A. Killworth, Dayton, Ohio, argued for appellant. With him on the brief was A. Michael Knapp, Columbus, Ohio.

Andrew S. Neely, Knoxville, Tenn., argued for appellee. With him on the brief was Edwin M. Luedeka, Knoxville, Tenn.

Before MARKEY, Chief Judge, DAVIS and BALDWIN, Circuit Judges.

MARKEY, Chief Judge.

1

BACKGROUND

2

On October 15, 1981, the D.L. Auld Company (Auld) sued Chroma Graphics Corp. (Chroma) in the Eastern District of Tennessee for infringement of Patent No. 4,100,010 (the Waugh patent) issued on a continuing application filed July 2, 1976 of an original application filed June 12, 1974. The patent claims are drawn to a method of forming foil-backed inserts in the form of cast decorative emblems.<sup>1</sup>

3

The parties agreed on trial and entry of judgment before and by a magistrate and on direct appeal from that judgment.

4

Chroma took a discovery deposition of the inventor, Robert E. Waugh, who was also Vice President for Research and Development of Auld, the assignee of the patent. Submitting portions of that deposition and documents from Auld's files, Chroma moved for summary judgment on

the ground that the invention had been "on sale" for more than one year before June 12, 1974. 35 U.S.C. § 102(b).

5

Auld opposed the motion and asked for oral hearing, submitting other portions of Waugh's discovery deposition, an affidavit amending answers to interrogatories, affidavits of Robert A. Wanner and David L. Auld, both with attachments, and pages from a Waugh deposition taken in another case.

6

Chroma replied, submitting further parts of the Waugh discovery deposition.

7

On October 22, 1982, the magistrate entered an order granting the motion, accompanied by a memorandum opinion.

8

Auld moved to vacate the order because no hearing had been held. The magistrate treated the motion as one to alter or amend under Fed.R.Civ.P. 59(e) and held a hearing. The magistrate then entered an order denying Auld's motion, accompanied by a memorandum opinion.

9

## ISSUES

10

(1) Whether issues of material fact were present, rendering issuance of summary judgment improper.

11

(2) Whether absence of an oral hearing before issuance of the original order rendered that order invalid in this case.

12

## OPINION

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(1) Propriety of Summary Judgment

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The primary principles governing summary judgment are so well settled as not to require citation of authority. A summary judgment may not issue when material issues of fact requiring trial to resolve are present. Evidence and inferences must be viewed and drawn in a light most favorable to the nonmoving party. The moving party bears the burden of showing absence of a material fact issue and doubt will be resolved against that party. Summary judgment is an important means of conserving judicial and other resources. It must, however, be carefully employed in appropriate cases for an improvident grant may deny a party a chance to prove a worthy case and an improvident denial may force on a party and the court an unnecessary trial.

15

Concurring as they must in applicability of the foregoing principles,<sup>2</sup> the parties assert respectively the presence and absence in the record of an issue of fact material to a determination of whether the claimed invention was on sale before the critical date, June 12, 1973.

16

Though Auld asserts the contrary on appeal, the magistrate fully applied the principles listed above, saying in his memorandum opinion:

17

The only issue before the Court was whether the defendant was entitled to Summary Judgment as a matter of law or whether disputed issues of material fact remained requiring that the case proceed to trial.

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Various indicia of intent to sell preclude any serious possibility [sic] that these efforts were merely experimental. First of all, sales representatives, not the Research and Development people, carried these samples around in their briefcases and showed them to customers. Prices and delivery times were discussed. Mr. Waugh's deposition makes it abundantly clear that, over a period of about four years, the D.L. Auld Company attempted to obtain orders for emblems made according to the patented process. This is precisely the activity that Section 102(b) attempts to limit to one year.

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23

Even the most indulgent reading of The D.L. Auld Company's business records and the deposition testimony of its Vice-President for Research and Development Robert E. Waugh precludes any other finding but that at least some sample products were made in the laboratory according to the Waugh patent and were offered for sale well outside of the statutorily protected year.

24

Waugh's invention is a method. The parties cite numerous cases involving "on sale" considerations in respect of product inventions under 35 U.S.C. § 102(b). The focus of inquiry here, however, is on the method. If Auld produced an emblem by the method of the invention and offered that emblem for sale before the critical date, the right to a patent on the method must be declared forfeited. *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 68 USPQ 54 (2nd Cir.1946). The "forfeiture" theory expressed in *Metallizing* parallels the statutory scheme of 35 U.S.C. § 102(b), the intent of which is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed. The record includes testimonial and documentary evidence establishing that the claimed method was employed in preparing a number of sample emblems and that Auld attempted to profit from use of that method by offering some of those samples for sale to a number of potential buyers well before the critical date. Those facts operate to create a forfeiture of any right to the grant of a valid patent on the method to Auld.

25

Where a method is kept secret, and remains secret after a sale of the product of the method, that sale will not, of course, bar another inventor from the grant of a patent on that method. The situation is different where, as here, that sale is made by the applicant for patent or his assignee. Though the magistrate referred to § 102(b), he did so in recognizing that the "activity" of Auld here was that which the statute "attempts to limit to one year." In so doing, the magistrate correctly applied the concept explicated in *Metallizing*, i.e. that a party's placing of the product of a method invention on sale more than a year before that party's application filing date must act as a forfeiture of any right to the grant of a valid patent on the method to that party if circumvention of the policy animating § 102(b) is to be avoided in respect of patents on method inventions.

26

The involved emblems include a layer of clear plastic having a curved outer surface formed on a decoration-bearing base. Since 1965, Auld sold that type of emblem to the auto industry. The early emblems were made by the "Vitrolux" method, in which the base is a shallow cavity designed to receive a measured amount of liquid plastic, while the base was held horizontal. The quantity of plastic was greater than that required to fill the cavity, producing a curved upper surface. The plastic did not overflow the cavity walls because of its surface tension.

27

In about 1968, Waugh began work on a variation of the Vitrolux process. That work resulted in the Vitrofoil method, the subject of patent 4,100,010. The Vitrofoil method employs a flat sheet of metal as the base on which a metered amount of liquid plastic is deposited while the base is held horizontal. The plastic flows to the edge of the sheet without overflowing; its surface tension causing it to stop at the sheet's edge to form a curved upper surface.

28

Waugh testified in his deposition that as early as 1969, Auld was producing samples in accordance with the claimed method by hand, and that between 1969 and June 1973, Auld "showed these samples to people and said we [Auld] could do this, and we [Auld] could not generate any interest for the product".<sup>3</sup> Attempts to market those emblems were conducted by an outside manufacturer's representative and Auld's sales staff. The emblem produced by the Vitrofoil method initially would not sell and Auld for a period "shelved" the emblem produced by the Vitrofoil method.

29

Sample emblems were submitted to prospective customers, such as Cadillac, General Motors, Buick, Ford, Chrysler, and the National Hockey League and the National Football League, through a company called International Crest. Waugh said that the established sales practice in the automotive industry was to present samples to prospective customers, that Auld would not "tool up" without a purchase order, and that the submission of sample emblems produced by the Vitrofoil method followed Auld's established sales procedure.

30

Waugh testified that sample emblems submitted to prospective customers before the critical date were made in the laboratory following each of the steps set forth in Claim 1 of the patent in suit. He further said that the claimed method was not followed on some samples and a "postforming" operation was required on those particular emblems because they curled.

31

Waugh testified that of the samples submitted before June 1973 by the Auld sales department to International Crest, to interest them in the product for the National Football and Hockey

Leagues, some were not made by the claimed method, but that others were. Auld quoted pricing and delivery dates in writing, for an order of more than 150,000 emblems, to International Crest.

32

Thus the record evidence includes corporate documents and testimony establishing that some sample emblems were produced by hand, following the steps of the method, and that those hand-produced emblems were offered for sale before June 12, 1973. Against that evidence, Auld makes numerous arguments and assertions respecting other samples and other parts of the record, insisting that there are conflicts in testimony improperly resolved on a motion for summary judgment. On careful review of each such argument and assertion and after viewing all evidence and inferences in a light most favorable to Auld, we are convinced that no material conflicts or credibility questions were or needed to be resolved by the magistrate and that no issue of material fact requiring a trial to resolve is present on this record.

33

Auld admits that emblems were made between 1969 and 1972 and that at least one was supplied, with prices quoted, to International Crest in "late 1972--early 1973." It says, however, that those emblems were made by a "laboratory" method; that a material issue exists on whether the offers fell within the "experimental" exception to the "on sale" bar of 35 U.S.C. § 102(b); that whether the offers were for experimental purposes is a matter of Auld's intent and thus ill-suited to resolution by summary judgment; that the magistrate improperly shifted the burden of proof by requiring Auld to show that the offer for sale was for experimental purposes; that no sale was made to International Crest; that some samples were not made by the claimed method; that it was error to grant summary judgment without receiving the proffered testimony of Auld salesmen; that the claimed method was for a manufacturing process involving a series of emblems, while in the "laboratory" method emblems were made one by one and that method was not demonstrated to be practical or readily reproducible; that affidavits of Waugh, Tanner, and David Auld, filed to correct and clarify "ambiguities and inconsistencies" in Waugh's deposition, raise a material issue on whether the claimed method had been reduced to practice before June, 1973; and that those affidavits show that emblems provided Chrysler were not made by the patented method because they were not made in a manufacturing process involving a series of emblems, were not held flat, and had to be postformed.

34

Labeling the method employed in making the sample for International Crest as a "laboratory" method raises no material fact issue. The method was that of Claim 1 and was successfully performed to produce an emblem offered for sale, or resale, by International Crest. That is all the law requires. *Corona Cord Tire Co. v. Dovon Chemical Corp.*, [276 U.S. 358](#), 48 S.Ct. 380, 72 L.Ed. 610 (1928); *Breen v. Miller*, [347 F.2d 623](#), 52 CCPA 1539, 146 USPQ 127 (1965). Waugh's testimony establishes unequivocally that the "laboratory" method involved each step of the claimed method, and that each such step was performed in producing some early samples for International Crest. When carefully read, the "clarifying" affidavits do not contradict those facts. Portions of those affidavits quoted by Auld relate to different samples, to portions of the patent

specification (not the claims), to commercial production, and to other customers. Even then, the only asserted differences between the patented method and the "laboratory" method are the use of adhesive and holding the foil shapes flat. Waugh's testimony was unequivocal that those very steps were employed in making some samples by the "laboratory" method, and nothing in the affidavits contradicts that testimony.

35

Auld's attempt to establish a material issue of fact respecting the "experimental" exception to 35 U.S.C. § 102(b) is misdirected. First, each of Auld's citations to evidence in the record relates to later experimentation on mass production by machine for commercialization in quantity, not to any experimentation on the earlier performed method itself. *Land v. Regan*, [342 F.2d 92](#), 52 CCPA 1048, 144 USPQ 661 (1965). Second, Auld's reliance on the labeling of the sample emblems as "lab samples" submitted to customers for "evaluation" is irrelevant. The claim is for a method, not a product. That the method would produce the product was known. Submission of the emblems for sale if the customer liked them is not experimentation on the method. See *Kalvar Corp. v. Xidex Corp.*, 384 F.Supp. 1126, 182 USPQ 532 (N.D.Cal.1973), *Aff'd.*, [556 F.2d 966](#), 195 USPQ 146 (9th Cir.1977). *In re Theis*, [610 F.2d 786](#), 204 USPQ 188 (Cust. & Pat.App.1978).

36

Similarly, Auld's reliance on intent of the patent holder must fail. Mr. David Auld said International Crest was told that the samples were experimental. As above indicated, however, the question is whether the method had been successfully performed in making the samples, not whether the samples were themselves "experimental." The record establishes that the claimed method was successfully performed, albeit by hand, that it produced an emblem, and that the emblem was offered for sale. The corporate documents of Auld make plain its intent to sell the emblems produced by the "laboratory" method, which is the same as the claimed method. That Auld might have to tool up for mass production if a customer gave a large order bears no relation to whether experimentation was required on the claimed method itself. Moreover, if a mere allegation of experimental intent were sufficient, there would rarely if ever be room for summary judgment based on a true "on sale" defense under 35 U.S.C. § 102(b).

37

Nor did the magistrate effectively shift the burden to Auld on the experimentation issue. Once evidence that an invention was on sale or, as here, that the product of a method invention was on sale, is presented, countervailing evidence establishing an experimental purpose must necessarily come from the patentee. To defeat a motion for summary judgment, a patentee need not prove an experimental purpose, but must submit facts indicating an ability to come forward with evidence that such proof is possible. See *De Long Corp. v. Raymond International, Inc.*, [622 F.2d 1135](#), 206 USPQ 97 (3rd Cir.1980). The court in *De Long* pointed out that "the duty to come forward with possible contradiction of proof is the essence of Federal Rule of Procedure 56," citing *First National Bank in Billings v. First Bank Stock Corp.*, [306 F.2d 937](#) (9th Cir.1962).<sup>4</sup> Chroma having established a prima facie case, it fell to Auld to submit evidence, by affidavit or

otherwise, setting forth specific facts raising a genuine issue for trial. *First National Bank of Arizona v. Cities Service Co.*, [391 U.S. 253](#), 88 S.Ct. 1575, 20 L.Ed.2d 569 (1968).

38

Nothing in the submissions of Auld to the magistrate indicated any possibility that the performance by hand of the method in producing some of the International Crest samples was itself in any manner experimental. As above indicated, that Auld may have experimented, after the critical date, with means to achieve tooling for mass production bears no relation to whether the method of the claim had earlier been used and the product of that earlier use offered for sale.<sup>5</sup>

39

That no sale was actually made to International Crest is irrelevant. An offer to sell is sufficient under the policy animating the statute, which proscribes not a sale, but a placing "on sale." 35 U.S.C. § 102(b). *General Electric Co. v. U.S.*, [654 F.2d 55](#), 211 USPQ 867 (Ct.Cl.1981).

40

Similarly, submission of evidence that some samples offered for sale were not made by the claimed method cannot raise a material issue of fact, and thus preclude summary judgment, in the face of uncontradicted evidence that other samples had been made by the claimed method and offered for sale before the critical date.

41

The magistrate committed no error in refusing the testimony proffered by Auld. The proffer is couched in broad terms describing the subject matter and issues about which the unnamed witnesses would testify. It is devoid of specific facts sufficient to raise a material issue for trial.

42

In a further effort to distinguish what it calls its "laboratory" method from the claimed method, Auld says the Waugh patent is limited to "a manufacturing process, involving a series of foil shapes." [Emphasis Auld's ]. Its difficulty here is twofold. First, the claim is for "[a] method of forming foil backed inserts," supra note 1. It is not for a method of manufacturing or mass producing inserts, and the word "series" does not make it such. Second, Waugh testified unequivocally that a series of foil shapes were produced by hand (the "laboratory" method), following each step of the claimed method. If the "laboratory" method did involve the making of emblems one-by-one, that fact would merely mean a greater time interval between individual emblems in a series. There is nothing of record to indicate that the "laboratory" method was itself impractical or not readily reproducible as a method.

43

The affidavits filed in an effort to "clarify" Waugh's deposition fail to contradict his crucial testimony that every step of the claimed method was followed in producing emblems offered to International Crest. The Wanner and David Auld affidavits assert that the claimed method was "not reduced to practice" until August, 1973. Not only is that assertion a legal conclusion, it relates to the manufacturing of an order for Chrysler, and does not contradict Waugh's testimony establishing reduction to practice of the claimed method to produce the samples offered earlier to International Crest. Waugh's affidavit, being similarly directed to other samples and to a method "as performed in May 1973," does not contradict his unequivocal testimony that every step of the claimed method was successfully performed earlier in producing emblems offered to International Crest.

44

The effort here to staunch the fatal wound inflicted upon Auld's suit by Waugh's deposition testimony is not new to the law. In *International Harvester Co. v. Deere & Co.*, 478 F.Supp. 411 (D.Ill.1979), vacated on jurisdictional grounds, [623 F.2d 1207](#) (7th Cir.1980), the court held that no genuine issue of material fact was created by affidavits contradicting admissions of the patent owner and inventors. In the present case, Auld's affidavits do not contradict the crucial testimony of the inventor and are thus even less capable of creating a genuine issue of material fact.

45

Though the parties devote a good deal of their briefs to a dispute over whether a material issue exists respecting the emblems offered to Chrysler and whether they were made by the claimed method, we need not decide that question. No material issue of fact exists with respect to the emblems offered earlier to and through International Crest and their production by the claimed method.

46

In sum, the magistrate did not err in determining: (1) that no genuine material issue of fact was present; (2) that the uncontradicted facts of record establish that the claimed method invention had been commercially exploited more than a year before the crucial date; (3) that no possibility of proving an experimental purpose was present; and (4) that Patent No. 4,100,010 was, therefore, invalid within the intent of 35 U.S.C. § 102(b).

47

(2) Necessity For Oral Hearing

48

The magistrate apparently failed to note the last sentence in Auld's brief in opposition to the motion for summary judgment, in which sentence Auld requested an oral hearing, for the motion was granted without a hearing. That action, though doubtless inadvertent, was not in accord with

the letter of Local Rule 12(c) of the District Court which provides for oral hearing on request on motions determinative of the case on the merits.

49

Auld, on receipt of the magistrate's decision, filed a motion to vacate the judgment and grant a hearing. The magistrate, saying he did so to preserve Auld's right to appeal, treated the motion as one filed under Rule 59(e), held a hearing, and denied the motion to vacate his judgment, issuing with his order a Memorandum.

50

Auld's present argument is that (1) failure of the magistrate to follow Local Rule 12(c) requires reversal of the judgment and remand for trial of the case on the merits, and (2) the hearing granted on Auld's motion unfairly required Auld to bear a burden of trying to get the magistrate to change his mind; whereas, the burden of persuasion in a hearing on the motion for summary judgment would have rested on Chroma.

51

With respect to argument (1), no basis can be seen for reversal and remand for trial. Whether a hearing was or was not held before judgment in accord with the letter of Local 12(c) has no bearing on the merits of the grant of summary judgment on the record. That a pre-judgment hearing was not held on the motion cannot possibly justify a remand for an unnecessary trial. The cure for a failure to hold a hearing would normally be a remand with instructions to conduct that hearing. In the present case, however, it appears that Auld has already obtained a hearing, albeit in connection with its motion to vacate, and there is no way that a remand could provide the hearing before judgment on the motion for summary judgment envisaged by the letter of Local Rule 12(c).

52

Auld makes too much of argument (2), in our view. That argument is premised on the assumption that the magistrate, having issued judgment on the summary motion, would be reluctant to change that judgment no matter what was said to him by Auld's counsel at the hearing on Auld's motion. The magistrate's judgment on the summary motion, however, was based on the parties' briefs, the deposition testimony, and documentary exhibits of record. Auld's opportunity to point to specific errors in the magistrate's original opinion is not inconsequential. There is no basis in the record for assuming that the magistrate was incapable of or resistant to vacating his judgment after hearing both sides on Auld's motion, and that Auld was therefore prejudiced. On the contrary, the magistrate's full memorandum issued after the hearing on the motion makes clear that any such assumption would be unsupportable. In that memorandum, the magistrate recognized each of Auld's arguments and spelled out wherein the record impelled adherence to his judgment notwithstanding those arguments.

53

Strict compliance with local procedural rules is, of course, always desirable. When, as here, noncompliance is inadvertent and all steps open to the decisionmaker in rectification have been taken, there being no denial of a constitutional right to due process, it would not serve the ends of justice to assign controlling weight to the grant of a hearing after rather than before initial judgment. In all events, noncompliance with the letter of Local Rule 12(c) cannot in this case serve to cause a trial on the merits of the underlying lawsuit, the dismissal of which under Rule 56 of the Federal Rules of Civil Procedure was eminently proper.

54

CONCLUSION

55

The judgment of the District Court, acting through the magistrate, is affirmed in all respects.

56

AFFIRMED.

1

Independent claim 1 reads:

"A method of forming foil-backed inserts in the form of cast decorative emblems, comprising:

a. providing a series of flat decorative foil shapes onto which a clear, hard plastic composition suitable as a substitute for vitreous enamel is to be cast,

said foil shapes each having a top and bottom surface,

said foil shapes also having sharply defined peripheral sides which intersect with said top surface, and

having an adhesive coated on said bottom surface,

b. holding said series of foil shapes flat and horizontal on a supported surface free from surrounding side walls,

c. casting a measured amount of said plastic composition in liquid form, which liquid is poorly wetting with respect to the top surface of said foil shapes, directly onto the top surface of each of said foil shapes so that it flows to said sharply defined peripheral sides and forms a positive meniscus without flowing over said sharply defined peripheral sides,

d. allowing said cast plastic composition to cure while maintaining said foil shapes flat and horizontal, whereby said cured plastic composition gives a lens effect to the top surface of said foil shapes onto which it has been cast, and

e. utilizing said adhesive coated bottom surface of said foil shapes to adhere said inserts onto their intended base."

Dependent claims 2-10 define specific foil shapes and plastic compositions.

## 2

They diverge respecting application of the presumption of validity, 35 U.S.C. 282. Auld mistakenly says it increases the difficulty of showing an absence of factual issues. Chroma mistakenly says the presumption "has little or no effect" when the challenger presents "on sale" evidence that was not before the Patent and Trademark Office. The presumption is a procedural device, not a substantive rule. It assigns the burden, as set forth in the third sentence of § 282: "The burden of establishing invalidity ... shall rest on the party asserting it." Submission of evidence by a patent challenger may raise a need for a patentee to go forward with countering evidence, but the burden-assigning effect of the presumption is never lost. The statute requires that the burden of persuasion remain with the patent's challenger throughout the case, *Solder Removal Co. v. ITC*, [582 F.2d 628](#), 632, 65 CCPA 120, 199 USPQ 129, 132 (1978), and normally must be carried by clear and convincing evidence, *Astra-Sjuco, A.B. v. ITC*, [629 F.2d 682](#), 67 CCPA 128, 207 USPQ 1 (1980)

## 3

Waugh carefully reviewed and corrected his deposition, noting 116 corrections. Auld's assertion of material ambiguities and inconsistencies, in the deposition itself or in comparison with later filed affidavits, is unsupported in the record

## 4

In its initial brief, Auld cited part of the De Long opinion. Chroma cited a continuing part in which the requirement of coming forward was set forth. In its reply brief Auld points out that the patentee in De Long failed to oppose the motion for summary judgment. Though Auld submitted affidavits here, the result must be the same as in De Long, for those affidavits fail to present specific facts indicating that proof was possible of an experimental purpose relating to the method performed in producing some of the International Crest samples

## 5

Auld's brief quoted a segment of Waugh's testimony indicating that work had been exploratory and developmental. Chroma's brief supplied the full context, in which it is clear that Waugh was speaking of the work of developing machinery for mass production

# 7 New Framework for Protection and Management of Knowledge

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*Amid the rapid progress in industry and technology in Asian countries such as China, South Korea and Taiwan, it is time for Japan to drastically reform its conventional industrial structure, which is based on cost competitiveness through mass production. In order to survive fierce global competition, Japanese companies need to create technologies of an extremely high level that are unrivaled in foreign countries and make arrangements to prevent foreign companies from easily imitating their technologies.*

*Under such circumstances, various policy measures have been implemented in the intellectual property area. For further development of the Japanese industry, companies should make a choice, from a strategic perspective, between obtaining exclusive rights for their technologies by filing patent applications that are bound to be published, and applying tight control for their technologies as trade secrets and keeping them confidential. There is also a need to create an environment that enables a flexible response to companies' intellectual property strategies. This study is conducted by a committee consisting of experts from academic and industrial circles in order to discuss a new framework for protection and management of knowledge, focusing on the prior use system.*

## I Introduction

Under Section 79 of the Japanese Patent Law, a person who has commercially exploited an invention claimed in another person's application or carried out preparations therefor prior to the filing of the application (*prior user*) shall have a non-exclusive license based on prior use (*prior user right*). In response to warning notices or infringement actions, the party targeted by the allegation often defends itself by arguing that it has commercially exploited the invention or made preparations therefor prior to the filing of the application and therefore holds the prior user right.

Some companies choose to keep their inventions secret as know-how, rather than actively filing patent applications, and they frequently take security measures to prepare evidence to prove prior use.

The prior use system is criticized as not being very accessible to users because it is not easy to prove the existence of prior use and the contents of the prior user right are unclear. In particular, many such parties that intend to take security measures to obtain the prior user right point out the difficulty and heavy burden in preparing evidence to prove prior use.

Additionally, in accordance with the first-to-file principle under which the person who has filed the first patent application shall be entitled to have an exclusive right, it is necessary to consider how to design a system to create a balance between the person who has created an

invention first of all but not yet filed a patent application and the person who has filed a patent application and obtained a patent right with respect to that invention.

From this basic viewpoint, we discussed a new framework for the protection and management of *knowledge*.

## II Prior Use System in Japan

The prior user right guaranteed under Section 79 of the Patent Law is a non-exclusive license given as an exceptional relief under certain conditions to the person who has commercially exploited another person's patented invention or made preparations therefor prior to the filing of the patent application ("prior user"), so as to enable the prior user to continue the commercial exploitation. The prior user right is effective only as a defense against a patent right that subsequently comes into existence, and it does not give any title or status to the prior user beforehand.

The prior use system was first adopted under the 1909 Patent Law. The 1921 Patent Law adopted this system from the former law and provided for it in Section 37. This provision is construed to clearly state that the prior user right is a statutory license that is granted to correct the defect in the patent system under the first-to-file principle whereby a patent right shall be granted to the first applicant. Under the 1959 Patent Law, the provision on the prior user right was moved to Section 79 and revised to make the

following changes: “bona fide” changed to “without knowledge of the contents of an invention claimed in a patent application, has made the invention by himself or has learnt the invention from another person who has made the invention”; “business to exploit the invention” changed to “business in which the invention is exploited”; “equipment” changed to “preparation.” Subsequent revisions have not changed the meaning of the prior user’s right at all.

The commonly accepted meaning of the prior user right is based on the “equity theory” adopted by the Supreme Court in the *Walking Beam-Type Heating Furnace Case* (judgment of the Supreme Court of October 3, 1986).

Unlike a non-exclusive license granted under an agreement, the prior user right is effective against a third party even if it is not registered, but it may also be secured by registration. It may be transferred together with the business in which the invention is exploited or in the case of inheritance or other general succession.

### **III Actual Status and Problems of Protection and Management of Knowledge at Companies**

The following opinions were presented in regard to the actual status of protection and management of *knowledge* such as know-how.

#### **(1) From the viewpoint of electric machinery manufacturers**

Measures that they implement to protect their technologies can be divided into “legal protection” and “self-reliant protection” measures. Legal protection includes protection based on patent applications or copyrights, as well as protection based on the prior user right or under the Unfair Competition Prevention Law or protection as trade secrets. On the other hand, self-reliant protection means protection by measures other than legal ones, such as protection steps for corporate secrets.

#### **(2) From the viewpoint of electronic parts manufacturers**

The outflow of confidential know-how through the publication of patent applications has become an urgent issue. An effective measure to cope with this issue is to separate the inventions for which patent applications should be filed to obtain rights from the know-how that should be used as secret technology, thereby protecting and managing inventions as intellectual property

appropriately. However, under the existing system, there is no option but to “file applications or disclose technology” in order to protect inventions that have yet to reach the stage of commercial exploitation from the “risk of being claimed in competitors’ later applications.”

#### **(3) From the viewpoint of pharmaceutical manufacturers**

According to the actual status of protection and management of knowledge based on the prior user right in the pharmaceutical industry, pharmaceutical manufacturers do not select the option to keep candidate drugs themselves secret for the purpose of claiming prior use against a patent obtained by a third party. They also hardly choose this option as a means to protect the technology for manufacturing drugs. However, they claim prior use in rare cases where they receive warning notices from competitors that exercise patent rights for raw materials and preparations of drugs.

The following opinions were presented in regard to problems with the existing prior use system.

#### **(1) From the viewpoint of electric machinery manufacturers**

A problem with the existing prior use system is uncertainty of the scope of permissible changes in modes of operation of inventions. Another problem relates to who may claim prior use as a means to strengthen business groups and proceed with corporate transformation through M&A. The Supreme Court allows a party other than the prior user to claim prior use if it exploits the invention “as an organ of the prior user.” However, whether this can be applied to the prior user’s subsidiaries or affiliated companies is an important issue.

#### **(2) From the viewpoint of electronic parts manufacturers**

There are three major problems with the existing prior use system: (i) the prior user right cannot be exercised where the invention has not yet been exploited or preparations therefor have not yet been made; (ii) even where the person has exploited the invention before a third party files a patent application with respect to the invention, the person is required to prove that the invention is being exploited at the time of the filing of the third party’s application; (iii) international harmonization of rules has not yet been achieved with respect to prior use.

### **(3) From the viewpoint of pharmaceutical manufacturers**

Pharmaceutical manufactures are unlikely to claim prior use, and therefore there is no particular problem with the existing prior use system and the use of public notaries in this industry.

The following opinions were presented in regard to the clarification of details of the existing prior use system and the relaxation of requirements for claiming prior use.

#### **(1) From the viewpoint of electric machinery manufacturers**

For the purpose of making the prior use system more accessible so as to facilitate business activities, it is necessary to clarify and raise awareness of the current status regarding the modes of operation and the parties who may claim prior use. If the need to review the system arises from the perspective of strengthening industrial competitiveness, appropriate measures should be immediately considered and implemented. The requirements for claiming prior use should not be relaxed to the level where mere ideas can also be protected, which would lead to the first-to-invent principle.

#### **(2) From the viewpoint of electronic parts manufacturers**

The requirements for claiming prior use should be relaxed so that the exploitation of an invention at the stage of development or experimentation will also be regarded as exploitation based on the prior user right (on the condition that the invention is completely created). It is impossible to defend know-how, which has been obtained as a result of R&D, until it is actually employed in the mass-production process. To avoid such risk, there is currently no option but to disclose the technology or file defensive applications.

#### **(3) From the viewpoint of pharmaceutical manufacturers**

The details of the prior use system should be clarified in order to increase accessibility to public notaries for the purpose of proving prior use. The requirements for claiming prior use should not be relaxed, or in other words, a new system to grant a license to a prior inventor should not be introduced, because such a system would lead to the tendency to register any inventions only for the strategic purpose of

securing prior inventor's licenses. In that case, patent applicants who have made large investments at high risk would be easily surpassed by competitors with prior inventor's licenses, and unable to enjoy a monopoly under their patents.

## **IV Results of the Questionnaire Survey**

(1) More than 80% of the respondent companies have received warning notices or sales pitches relating to intellectual property, and one-third of such companies claimed prior use upon receiving warning notices or sales pitches. Thus, the prior use system is used relatively often. The number of companies that have claimed prior use in litigation is smaller, suggesting that in most cases, disputes are settled through compromises or licensing before they are brought to court.

(2) A relatively large number of companies faced difficulty only when claiming prior use, and about 20 companies did not find any difficulty with the prior use system because they had secured enough evidence and due to the existence of industry rules. On the other hand, those that faced difficulty pointed out the burden imposed by the need to collect evidence of exploitation or preparations therefor when claiming prior use, and the uncertain scope of the invention or of the objective of commercial exploitation when responding to the claim of prior use.

(3) Various measures are being taken to prove prior use. They differ significantly, and it is difficult to find the most appropriate measures among them. Many companies have found difficulty in proving prior use, mainly because of the difficulty in establishing the date of evidence, the non-existence of evidence, and the unclear scope of evidence that should be retained. On the other hand, a relatively large number of companies retained evidence to prove prior use in advance, by taking a variety of measures.

(4) About two-thirds have used a third party agency for preparing evidence to prove prior use, mostly for the purpose of providing proof for the exploitation of the invention at the time the patent application is filed as well as the technical contents of the invention. A popular third party agency employed is public notaries, which are frequently used to obtain a date of notary effect and less frequently used to obtain notarial deeds of fact observation.

(5) Only a very limited number of companies or about 2% filed patent applications with respect to

know-how, which they had actually sought to keep secret, for the purpose of preventing a third party from obtaining patent rights.

(6) Although a large number of companies agreed to the view that a new prior use system should be implemented by a public agency or the JPO should take charge of implementing such a new system, subsequent interviews with such companies suggest that most of them have not considered this issue in detail but simply believe that such a new system would be helpful.

(7) Based on their requests regarding the prior use system as a whole, they hope that the parties who may claim prior use will be clarified; however, most of them consider that a balance between the prior user and the patent holder should be maintained.

## **V Court Precedents on Prior User Rights in Japan**

### **1 Supreme Court Judgments on Prior User Rights**

Important rulings by the Supreme Court on prior user rights are the Walking Beam-Type Heating Furnace Case (judgment of October 3, 1986) and the Globe-Shaped Transistor Ratio Design Case. In the former case, the Supreme Court pointed out the requirements for claiming prior use, namely, “completion of the invention,” “preparations for commercial exploitation,” and “change or scope of the modes of exploitation.” In the latter case, the court determined the scope of parties who may claim prior use.

### **2 Study of Court Precedents on Prior User Rights: Focusing on the Scope of Effects of Prior User Rights**

#### **(1) Time of the filing of a patent application**

If the patent application has priority under the Paris Convention, the date when the first application is filed in another country of the Union, or in other words, the date when priority is claimed, should be the reference date. In the case of division of an application, the date of filing of the original application should be the reference date.

#### **(2) Preparations for exploitation**

The prior user right shall necessarily be denied if the products relating to the prior use claim that are manufactured or sold before the date of filing of the patent application cannot be

recognized as products in which the patented invention is exploited.

Regarding exploitation, a problem arises as to the extent of preparations that would be regarded as “preparations for commercial exploitation” under Section 79. Based on the general trend in court precedents, preparations for commercial exploitation are likely to be recognized where at least trial models have been created or specific investment has been made for the invention.

### **(3) Scope of the invention and commercial exploitation thereof**

Where the prior user continues to employ the mode of operation that has been employed at the time of the filing of the patent application, such an act should never constitute patent infringement. The question is whether an allegation of patent infringement can be avoided by claiming prior use even where the prior user has changed the mode of operation. The Supreme Court indicated a specific criterion for this issue: where the invention utilized in a product for which commercial exploitation (or preparations therefor) has been underway at the time of the filing of the patent application (Invention A) is identical to the patented invention (Invention P), the effect of the prior user right shall extend to the whole scope of the patented invention, whereas in the case where Invention A is identical to only a portion of Invention P, the effect of the prior user’s right shall extend only to that portion.

### **(4) Scope of parties who may claim prior use**

Since the prior user right under Section 79 is provided for as a non-exclusive license, in light of the language of the provision, it may be transferred only together with the business in which the invention is exploited or with the consent of the patent holder, or in the case of inheritance or other general succession (Section 94(1)).

It should be noted that parties other than the prior user may claim prior use without obtaining the prior user right. More specifically, (i) parties engaged in manufacturing as subcontractors of the prior user engaged in the manufacture and sale of the invention, or (ii) parties engaged in operating the invention by purchasing products in which the invention is exploited from the prior user engaged in the manufacture and sale of the invention, may claim prior use.

### **3 Study of Court Precedents on Prior User Rights: Focusing on Means to Provide Proof of Prior Use**

(1) Since there are only two cases in which the substantially probative value of the principal evidence of the existence of prior use has been directly challenged, it is difficult to study the necessary means to provide proof of prior use in detail based only on the available court precedents.

(2) In the case of a product invention, documents exchanged with or disclosed to a third party, such as design drawings, written contracts, receipts and research reports, are admitted as evidential materials relatively broadly and recognized as having substantial probative value. Tangible materials other than such documents are also regarded as having probative value as to the date of manufacture if they are handled under a certain kind of management system.

On the other hand, whether internal documents have substantially probative value is uncertain because there is no past precedent where they were admitted or denied as direct evidence.

In addition to evidential materials mentioned above, individuals inside or outside the company may be often admitted as personal witnesses but the content of their testimony has not been disclosed in court precedents available so far.

(3) In the case of an invention of the manufacturing process for a product, sample products manufactured using the process and drawings used for the manufacture were recognized as having substantial probative value.

(4) In the case of a simple process invention, there is no court precedent addressing the prior user right.

### **4 Analysis of Cases Involving Prior User Rights**

With the objective to understand to what extent prior use has been claimed in litigation and what judgments have been made regarding prior user rights, we extracted cases involving prior user rights and conducted a statistical analysis on such cases.

Based on the statistical analysis, both the number of infringement cases and the number of cases in which prior use is claimed as a defense have been increasing. Comparing the number of cases where the prior user right was recognized with the number of cases where prior use was

disputed, the prior user right was recognized in 48 of the 92 cases in the period following the *Globe-Shaped Transistor Ratio Design Case*, whereas it was recognized in 41 of the 68 cases in the period following the *Walking Beam-Type Heating Furnace Case*, indicating that the rate of cases where the prior user right is recognized has been increasing. This upward trend may be because in accordance with the reasoning given by the Supreme Court in the *Walking Beam-Type Heating Furnace Case*, prior use can be claimed as an appropriate defense and reasonable judgments are also made by the courts.

## **VI Prior Use System in Foreign Countries**

We conducted research on prior use systems in foreign countries. The major research results are as follows.

### **1 United Kingdom**

The prior user right is stipulated in Section 64 of the Patents Act. In order for a prior user right to exist, the person who claims prior use is required to exploit the invention or make preparations therefor prior to the priority date of the invention. The prior user may expand the business based on the prior user right and may change the mode of operation if such a change does not affect the essence of the invention. The prior user may assign or transmit his right on death (or in the case of a body corporate, on its dissolution) to any person who acquires that part of the business. Prior use may also be claimed by "any partner of the prior user for the time being in that business."

### **2 Germany**

The prior user right is stipulated in Section 12 of the Patent Law. In order for a prior user right to exist, the person who claims prior use is required to be in the course of exploiting the invention or making preparations therefor upon the filing of a patent application. The prior user may expand the business based on the prior user right. Regarding whether the mode of operation may be changed, the dominant opinion considers such change permissible. The prior user right "can only be inherited or transferred together with the business". The prior user may "authorize another party's plant or workshop to use the invention."

### **3 China**

The prior user right is stipulated in Article 63 of the Patent Law. In order for a prior user right to exist, the person who claims prior use is required to make the identical product or use the identical process or make preparations therefor prior to the filing date of a patent application. The prior user is not allowed to expand the business or change the mode of operation based on the prior user right. The prior user right can only be transferred together with the part of the company that owns the prior user right. What party other than the prior user may claim prior use is not clear due to a lack of court precedents.

### **4 South Korea**

The prior user right is stipulated in Article 103 of the Patent Law. In order for a prior user right to exist, the person who claims prior use is required to be in the course of exploiting the invention or making preparations therefor upon the filing of a patent application. The prior user may expand the business based on the prior user right, and may change the mode of operation to the extent that those skilled in the art are expected to employ the changed mode. The prior user right can be transferred together with the business, in the case of inheritance or other general succession, or with consent of the patent holder. Prior use may be claimed by a party that serves as an organ of the prior user.

### **5 Taiwan**

The prior user right is stipulated in Article 57 of the Patent Law. In order for a prior user right to exist, the person who claims prior use is required to exploit the invention or make preparations therefor prior to the filing date of a patent application. The prior user is not allowed to expand the business based on the prior user right, but is allowed to change the mode of operation to the extent that the invention has been exploited. The prior user right can be transferred together with the business. What party other than the prior user may claim prior use is not clear due to a lack of court precedents.

### **6 France**

The prior user right is stipulated in Article 613-7 of the Intellectual Property Law. In order for a prior user right to exist, the person who

claims prior use is not required to exploit the invention or make preparations but required to possess the invention upon the filing date or priority date of a patent application. The prior user right can be transferred “together with the business, the enterprise or the part of the enterprise to which it belongs.” Prior use may be claimed by companies of a business group that owns the prior user right.

### **7 Belgium**

The prior user right is stipulated in Article 30 of the Patent Act. In order for a prior user right to exist, the person who claims prior use is not required to exploit the invention or make preparations but required to use or possess the invention prior to the filing date or priority date of a patent application. The prior user right can be transferred “only together with the business.” Prior use may be claimed by companies of a business group that owns the prior user right.

### **8 United States**

The prior user right is stipulated in Section 273 of the Patent Act. . In order for a prior user right to exist, the person who claims prior use is required to exploit the invention before the effective filing date of a patent application. The prior user may expand the business based on the prior user right, and may also change the mode of operation within the scope of the subject matter of the invention. Transfer of the prior user right is allowed in cases where it is transferred to the patent holder, it is transferred to the prior user’s subsidiaries bona fide, or it is transferred together with the business as a whole. What party other than the prior user may claim prior use is not clear due to a lack of court precedents.

## **VII Use of Notarial Methods as a Means to Prove Prior Use**

Major notarial methods available as a means to prove prior use include obtaining a date of notary effect, authentication for private or sworn documents and notarial deeds of fact observation. A date of notary effect can be obtained by applying a seal to photos, operation manuals and products, as well as to CD-ROMs that record software applications. It should be noted that a date of notary effect only proves that the subject existed on that date, irrespective of the contents of the subject. Regarding authentication of

documents, companies should have relevant documents authenticated before storing them, including operation reports, research reports, and technical experiment reports prepared at the stage of technology development, and establish a system for securing objective and reliable evidence for future needs. Notarial deeds of fact observation can be prepared by: (i) stating the fact that the product was purchased on the market; (ii) observing the invention exploitation and recording the production process and technical details; (iii) recording (on video) the presentation of the invention.

Regarding the actual use of notarial methods as means to prove prior use and problems with such systems that should be resolved in the future, notary services have been recognized as an effective means to deal with the challenges posed by intellectual property and are used more frequently than before. However, they have not yet become very popular because many public notaries are not so familiar with the intellectual property field. Although the Japan Notary Association has been making efforts to raise awareness among companies and promote their use of notarial methods for dealing with intellectual property matters, companies have not yet fully grasped the significance or importance of such methods. It is hoped that various measures will be taken in the future to improve their understanding and promote the active use of notarial methods, including development of guidelines (collections of examples). At present, public notaries are authorized to observe facts at the notary public's office or the Legal Affairs Bureau or District Legal Affairs Bureau to which they belong. Considering that public notaries who are well versed in intellectual property matters are not available in some prefectures, such jurisdiction-related limitations create a disincentive for companies to actively use notarial methods.

## **VIII Future Framework of the Prior Use System**

### **1 Clarification of the System**

#### **(1) Statement of the issue**

Most users positively evaluate the existing prior use system to a certain extent with respect to the balance between the patent holder and the prior user and the scope of effect of prior user rights. However, at the same time the system is criticized for its uncertainties arising from interpretation of the provisions of Section 79 on

the following points:

- (a) To what extent the prior user is allowed to change the mode of operation, e.g. introducing a new model;
- (b) Who may claim prior use in cases where the prior user authorizes its subsidiaries or affiliated companies to operate the business in line with business expansion plans;
- (c) How to interpret the requirement of "at the time of the filing" when preparing evidence of the operation of the business (if this requirement is strictly interpreted, it would be extremely difficult to prove prior use);
- (d) To what extent preparations for the operation of the business are required to be made in order to prove prior use.

#### **(2) Past court rulings and interpretations**

While uncertainty of the prior use system is pointed out in terms of how to interpret the provisions of Section 79 as mentioned above, court rulings and the prevailing mindset in related fields have clarified the details of the system.

#### **(3) Major discussion on how to clarify the system**

Negative views were dominant regarding the idea of changing the balance between the patent holder and the prior user by revising the requirements for prior use. The majority of participants were positive about the idea of clarifying the prior use system so as to make the existing system more accessible and more reliable for companies.

#### **(4) Future discussion**

It would be most appropriate to analyze court decisions and academic theories on the points for which the provisions of Section 79 are criticized as being uncertain, and develop guidelines (collections of examples) with cooperation from the legal and industrial circles, with the aim to clarify the prior use system. It is also important to thoroughly publicize such guidelines (collections of examples) while paying attention to issues and court decisions that may arise in the future, so as to promote effective use of the prior use system.

### **2 Reduction of difficulty in proving prior use**

#### **(1) Statement of the issue**

The difficulty and burden imposed by the

requirement to prove prior use are pointed out because of the fact that what kind of evidence should be retained to provide proof of the “operation of the business” or “preparations for the business” and to what extent and how such evidence should be retained are uncertain. Although notarial methods are used in some cases as active measures to prepare evidence to prove prior use beforehand, public notaries are required to be able to grasp the technical matters in such cases.

## **(2) Major discussion on how to reduce the difficulty in providing proof of prior use**

The majority argued that guidelines (collections of examples) should be developed to provide examples of the use of notarial methods. While there were calls for a new notification system, concerns were also presented about this idea, such as a possible increase in administrative costs and workload and abuse of the system through registration without restriction.

## **(3) Future discussion**

In order to make the prior use system more accessible, it would be appropriate to develop guidelines (collections of examples) that provide examples of means to provide proof of prior use, including the use of notarial methods, while referring to the means of proof that are recognized in court decisions or academic theories or those actually employed by companies, and clarify what kind of proof should be retained as evidence to prove prior use and to what extent and how such evidence should be retained.

# **3 Harmonization of prior use systems**

## **(1) Statement of the issue**

Along with the globalization of economic activity, Japanese companies are establishing plants and facilities overseas. However, they face difficulty in launching stable business operations overseas because each country has a different prior use system.

## **(2) Future discussion**

From the perspective of encouraging Japanese companies to use prior use systems in foreign countries, it is important to harmonize these systems in terms of the scope of permissible changes to the mode of operation and the scope of parties who may claim prior use. Therefore, it is necessary to approach foreign countries through various channels in order to

bring about rule harmonization.

# **4 Others**

From the perspective of reducing difficulty in keeping know-how secret, opinions have been aired that a new system should be established to grant a statutory non-exclusive license to the person who “possesses the invention”. However, strong opposition has been raised to this idea among users because such a system would change the balance between the patent holder and the prior user, and it would be an unusual system based on worldwide comparisons and run contrary to the international harmonization of systems.

There are also concerns that publication of patent applications causes unintentional outflow of technologies. This is not an issue of system design but relates to each company’s strategy for filing applications.

# **IX Conclusion**

The prior user right guaranteed under Section 79 of the Patent Law is a non-exclusive license given as an exceptional measure of relief under certain conditions to the person who has commercially exploited another person’s patented invention or made preparations therefor prior to the filing of the patent application (“prior user”), so as to enable the prior user to continue the exploitation of the patented invention. If the prior user right were regarded as giving any title or status to the prior user beforehand, this would change the existing balance between the patent holder and the prior user significantly. The idea of granting a license to a prior inventor would cause a greater change to such a balance.

The existing patent system is based on the principle that a person who discloses an invention shall be entitled to have an exclusive right to the invention. Making changes to the prior use system as mentioned above would mean changing the core of the patent system. It is difficult to say that a consensus has been established for making such fundamental changes that would weaken the patent holder’s right or for officially starting discussion in that direction. It has been reported that the United States has introduced the publication system and is likely to shift from the first-to-invent principle to the first-to-file principle. A system to grant a license to a prior inventor would be an extremely peculiar system based on worldwide comparisons.

Rather, what we should do now is to identify problems with the existing prior use system from a practical perspective and clarify to the greatest possible extent the details and features of the system that should be noted when using it. In this context, we have concluded that it would be desirable to develop guidelines and improve understanding on prior use. Academic societies are expected to deepen discussion on a future framework for the prior use system. Attention should also be paid to court decisions on this issue.

Japanese companies need to give sufficient consideration to whether they select to file patent applications with respect to technologies that they have developed while disclosing such technologies to the public, or keep these technologies as secret know-how, and manage filing procedures appropriately.

(Researcher: Hiroo MAEDA)



## Case Text

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### **TUE FIRE-EXTINGUISHER CASE.**

GRAHAM, Adm'r, etc., and another v. JOHN:ITON and another.  
(Circuit Court, D. Maryland.

July 26, 1884.)

PATENTS FOR INVENTIONS-GRAHAM FIRE-EXTINGUISHER-SPECIAL, ACT OF  
CONGRESS OF JULIE 14, 1878, GRANTING PATENT TO HEIRS-CONSTITUTIONALITY -  
EFFECT OF-PATENT SUSTAINED.

The act of congress approved June 14, 1878, relieving the heirs of William A. Graham from all disabilities preventing them from renewing or reviving an application filed by Graham in 1837 for a patent for a novel method of extinguishing fires, held to be a constitutional exercise of the power of congress; and held, that the patent No. 205,942, granted July 9, 1878, to Graham's administrator, was properly issued in pursuance of the authority given by that act of congress. Held, that the intention of congress was to allow the original application of Graham to be revived, and that this intention is sufficiently expressed in the act, and that the novelty of the invention for which the patent was granted is to be tested as of the date of original application filed in 1837. Held that, at the date of his application, Graham was the first discoverer that carbonic acid gas and water, when condensed in a sufficiently strong vessel, would propel itself by its own elasticity in a sufficient stream to a sufficient distance to be a useful agent for extinguishing fires, and that he described both a portable and a fixed apparatus by which his method could be applied with beneficial results. Held, that the claim in the patent granted to his administrator for this method or process of extinguishing fires is valid. Held, that the defenses set up against the patent-that it was granted for several distinct inventions, that the specifications are deceptive and misleading, and that it covers a different claim from that set forth in the application-are not valid objections.

In Equity. Rufus W. Applegarth and L. L. Bond, for complainant. I. F. Williams, Abraham Sharp, and R. K. Evens, for respondents. MORRIS, J. This is a suit in equity for alleged infringement of patent No. 205,942, granted July 9, 1878, to Archibald Graham, administrator of William A. Graham, deceased, for a new method and an improved apparatus for extinguishing fires. The claims are as follows:

"I do not claim to have discovered a new element in nature, nor do I claim to have discovered the abstract principle that carbonic acid gas will not keep up combustion. What I claim as new, and desire to secure by letters patent, is (1) the method or process of extinguishing fires by means of

a properly directed stream of mingled carbonic acid gas and water projected by the pressure or expansive force of the mingled mass from which the stream is derived; (2) the combination of a strong vessel for containing the mixture of carbonic acid gas and water under pressure, with a stop-cock, flexible hoesetube, and a nozzle, substantially as and for the purpose specified; (3) the combination of fixed pipes or tubes, arranged by or through a building, with a stationary or fixed fountain or tank, for forcing mingled carbonic acid gas and water, by its own elasticity, through such pipes, substantially as specified; (4) an improved method of extinguishing fires, consisting—First, in condensing carbonic acid gas by artificial pressure or in generation; second, controlling it by a suitable vessel; and, finally, in directing its flow to the desired place, substantially as specified."

The original application of William A. Graham, of Lexington, Virginia, was filed in the patent-office, November 23, 1837, over 40 years

THE FIRE-EXTINGUISHER CASE. prior to the grant of the patent. In his applications, Graham claimed that he had discovered that carbonic acid gas compressed in water in the proportion of ten or more volumes of gas to one of water, in portable fountains or fixed reservoirs; could be usefully applied to extinguishing fires, and that he had devised suitable apparatus by which a stream of gaseous water, by the elastic force of the gas, would be projected a distance of 40 feet, so as to quickly, cheaply, and effectually subdue the fire. He fully described what he claimed as his invention, and accompanied his specifications with diagrams and descriptions of his apparatus. The commissioner of patents refused to grant him a patent, upon the ground that the specifications were not found to contain any practicable device for carrying the alleged discovery into operation, and because it did not appear that it admitted of being carried into operation. Graham made many unsuccessful efforts to convince the commissioner that his plan was useful and practicable, but want of means and ill-health prevented his exhibiting in Washington the apparatus with which he expected to demonstrate its efficiency, and he died in 1857 without obtaining a patent. In 1869 a patent was granted by the United States to Carlier & Vignon, of Paris, France, (No. 88,844, April 13, 1869; reissued, No. 4,994, July 16, 1872,) for "an improvement in the art of extinguishing fires, by throwing upon the fire or conflagration a properly directed stream of mingled carbonic acid gas and water by means of the pressure or expansive force exerted by the mass of mingled gas and water from which the stream is derived." Carlier & Vignon had previously obtained patents in France and England, but the date of their invention was not shown to have been earlier than 1861. The portable apparatus described by them was substantially identical in principle and operation with the apparatus described by Graham. Suit having been brought on their reissued patent in the circuit court for the Eastern district of Pennsylvania, it was tried in April, 1874, before Circuit Judge McKENNA. To show want of novelty in the patent, the respondent in that suit put in evidence the identical apparatus constructed and used by Graham, and Judge McKENNA, in a carefully considered decision, held that it was clearly proved that Graham, as early as 1852 or 1853, had made a public trial of this very apparatus in Lexington, Virginia. He held that it was proved that Graham was, as he claimed to be, the first inventor "of an original method of extinguishing fires by the combined agency of carbonic acid gas and water, and that he perfected and adopted his invention by embodying it in the form of mechanical appliances, capable of operative and successful use." · Northwestern Fire-extinguisher 00. v. Phila. Fire-extinguisher 00. 1 Ban. & A. 177. After the decision of this case the administrator of Graham, in 1876, filed in the patent-

office application for a patent for Graham's invention, but was refused upon the ground that in consequence of the long delay the invention had gone into public use.

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These facts being brought to the attention of congress, an act was passed, approved June 14, 1878, for the relief of Graham's heirs. By that act the heirs of Graham were relieved from all disabilities preventing them from renewing or reviving an application by his administrator for a patent for a novel method of extinguishing fires. The administrator was authorized to renew the application, conforming it to present rules, and the commissioner of patents was authorized to issue letters patent for the invention or inventions set forth in the application, to have the same force and effect from its date as though no delay had occurred; provided, that all persons having machines, containing the inventions, in use should have the right to continue to use them without being liable for any infringement. Under the authority given by this act the patent on which this suit is based was issued, founded upon the original application of Graham, filed November 23, 1837. It is contended by the respondents that this patent is void because congress had no constitutional power to pass the act; that as, by the general acts of congress on the subject of patents in force during the time between the filing of the original application and the passing of the special act, the applications of Graham and his administrator were declared abandoned, and 'all right to prosecute them was denied, it resulted that the public had acquired the right to use the inventions, and that right could not be taken away without the law being repugnant to the declaration of the constitution that no person shall be deprived of his property without due process of law. The theory of the encouragement given to inventors is that by disclosing under the regulations of law their discoveries they benefit the public, and the constitutional power of congress for securing to them the exclusive right to their inventions has only one restriction, viz., that it shall be for limited times. With regard to the terms upon which the exclusive right shall be granted, the time when the application for the original grant or for any renewal or extension of it shall be made, it has been frequently held that the regulations in these matters are merely self-imposed restrictions on the constitutional power of congress, which it can at its pleasure disregard in particular case. Walker, Pat. § 255. Special acts for the relief of particular inventors have often been passed by congress. Evans v. Eaton, 3 Wheat. 454. In the case of Co. v. Jordan, 7 Wall. 583, the supreme court sustained an act of congress which had been extended in pursuance of an act of congress, passed more than 20 years after the original patent had expired, and the invention had been free to the public. 'The act of congress in that case was quite similar to the one under in that it authorized the commissioner to entertain the application for extension as though it had been made within the time prescribed by the general law. In Blanchard v. Sprague, 2 Story, 170, Mr. Justice STORY, speaking of the right of congress to grant a patent to an

### **THE FIRE-EXTINGUISHER CASE.**

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inventor whose invention had, at the time of the passage of the 'act, gone into 'public use, says that the question is set at rest by Evans v. Eaton, and that he had never doubted the constitutional

authority of congress to make such a grant. The right which 'the public has acquired .t? use the thing , by reason of the applicant for a patent falling to do something prescribed by congress, and the necessity for which congress might, by previous legislation, have dispensed with, has never been held to be a vested right. The cases of *Evans v. Eaton*, supra; *Evans v. Jordan*, 9 Cranch, 199; *Bloomer v. Stolley*, 5 McLean, 161; *Jordan v. Dobson*, 2 Abb. (D. S.) 408, hal'dly leave this question debatable. It is further contended by the respondents, in opposition to the validity of the complainant's patent, that as by its terms the act of congress relieved the heirs of the inventor from all disabilities, preventing them from renewing or reviving an application by the administrator for a patent, provided the alleged invention should be found to have been new and useful at the time of filing such application, that "the time of filing such application" means the filing of the application by the administrator, and, consequently, if the invention was not new at that date, the commissioner was not authorized to grant the patent. It would be a singular miscarriage of the obvious intention of congress if this was the necessary interpretation of the language used in the act. It was always conceded that at the date of the application made by the administrator, viz., February 19, 1876, the invention was not new. The strongest argument in favor of the relief given by congress was the fact that the patent granted to Carlier & Vignon in 1869 had been in 1876 declared void for want of novelty, because Graham's invention, which he had described in 1837, had been proved to have been successfully used 8S early as 1853. The purpose of the act is remedial and beneficial, and is to be so construed, if possible. I think the fair construction of it is that the heirs of the inventor are relieved from all disabilities which would prevent the administrator from renewing or reviving an application for a patent for a novel method of extinguishing fires. The administrator is authorized to renew said application, and the commissioner is authorized to grant letters patent for the invention or inventions contained in such application, if the alleged inventions should be found to have been new and useful at the time of filing sllch application. It is, I think, clearly intended and sufficiently expressed that the application which was to be revived or renewed was the application of the original inventor. Taking, then, the date of the filing of the original applioation and specifications, November 23, 1837, as the point of time to which is to be referred the question of novelty, there has been no testimony at all adduced tending to disprove novelty at that time, except the description of the Manby machine in the *Mechanic's Magazine*, London, 1824, pp. 28-81, and the English patent to Bakewell, issued Ma.rch 8, 1832.

#### FEDERAL REPORTER

The contrivance described by Capt. Manby was intended for extinguishing fires. , It was a small, portable air-tight vessel for holding water, (or water to which might be added some substance, such as peadash, to increase its efficiency as an extinguishing fluid,) and into which atmospheric air had been pumped under sufficient pressure to cause the water to spurt out in a stream to the fire when the stop-cock was opened. The portable cylindrical vessel is quite similar in design to the portable strong vessel of Graham, but had no flexible hose tube and nozzle, and was apparently intended to be taken quite close to the fire. But we look in vain for any suggestion of the use of carbonic acid gas in connection with Capt. Manby's plan or apparatus. The English patent of March 8, 1832, to Bakewell is for an apparatus for making soda-water and other aerated waters. The substance of the invention was a device by which the gas could be conveniently generated in the fountain itself, and to assist in that operation the fountain was suspended between two right standards, vibrating freely on two pivots, so as to pour the acid,

contained in a vessel inclosed in the fountain, gradually upon the chalk or other substance from which the gas was to be generated. It is not only nowhere suggested that it could be used for extinguishing a fire, but the machine was so constructed as to prevent such a use. These are the only anticipating devices suggested which antedate the original application of Graham, and they do not seem to me to require further consideration. The patent is further assailed by the respondents upon the ground (1) that the patent as granted is for several separate and distinct inventions, and therefore void; (2) that the specifications are deceptive and misleading, and therefore the patent is void; (3) that the patent covers an invention different from that set forth in the application. As to the first point, the claims for which the patent was granted are four. The first and fourth are for the method of extinguishing fires by a properly directed stream of mingled carbonic acid gas and water escaping from pressure, and projected by its own expansive force; the second claim is for a portable apparatus by which the method or process could be usefully applied; and the third is for a stationary apparatus for the same purpose. If these are all proper subjects of claim, and are all inventions found in the application of Graham, then the language of the act of congress which authorizes the commissioner to issue a patent for whatever invention or inventions, "Where found in the application, is sufficient to justify his action." This was held sufficient in *Ellan v. Eaton*, 3 Wheat. 506. It is cited by the Supreme court in *Hogg v. Emerston*, 6 How. 483, that two or more patents may be united if they relate to a single subject, or are in their nature or operations connected together; *Walk. § 180*. The effect of the several claims of this patent is such that the granting in one patent, it seems to me, might be justified by this rule. But I incline to think that the substance of Graham's invention is

#### THE FIRE-EXTINGUISHING MACHINE.

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contained in the first claim, or in the first and fourth claims together, if there is any difference between them. He claims in his application that he is the first discoverer that carbonic acid gas condensed in water can be made, by the use of a suitable apparatus, a useful self-propelling agent for putting out fires. He then describes the construction and operation of a machine by which the gas may be generated, and also describes "one among the various modes by which it may be applied." After describing the apparatus used by him, he says: "Besides the portable apparatus, there are other ways or methods by which my invention or discovery may be carried into useful operation." The inventor was entitled to the exclusive use of the method or process discovered by him, and was bound only to describe some particular mode or apparatus by which the process could be applied with some beneficial result. *Tilghman v. Proctor*, 102 U. S. 729. I am inclined to doubt the validity of the second and third claims, if they are to be construed as patents for any particular form of apparatus or combinations of mechanical elements. There was nothing new in the portable apparatus intended to be covered by the second claim, (unless, perhaps, the flexible hose-tube;) except as applied to the use of carbonic acid gas and water; and the same may be said of the third claim. But if the first claim is valid, the fate of the second and third claims is not material, - certainly not in this case. The second point of the objection used by respondents, that the specification and claims are deceptive and misleading, is sought to be supported by testimony that in actual use of the apparatus so little of the carbonic acid gas reaches the fire that its effect as an extinguisher is not appreciable; that the only use of the gas is the elastic force which it exerts in the fountain, to eject the water with sufficient force to make it reach the fire; that it is

the water alone which acts as the extinguisher. So that it is urged that the pretension in the specification that the gas was an important agent in smothering the fire is false and misleading. The witnesses who testified on this point made experiments by catching the gas in open beakers at some distance from the fountain, and they differed very greatly as to the quantity of gas which was then found to remain commingled with the water. Some claimed that a quantity of gas remained, and others none at all. These tests were not very satisfactory. The weight of the evidence is, however, very conclusive that a stream from a fountain charged with carbonic acid gas and water in the manner described by Graham is an efficient agent for the purpose of extinguishing small fires; that the apparatus can be kept at hand for use in a sudden emergency, and can be operated without delay and before the fire has acquired headway. It is true, as claimed by him, that carbonic acid gas combines in a remarkable degree with water, so that by moderate pressure the water can be made to receive six to twelve times its volume of the gas; that the fountains can be kept charged or made to generate the gas when

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netd(led; that the gas has great elasticity; that it is heavier than air, and when combined with water has a specific gravity well adapted to pass in a stream through the air; that if any of the gas does by any means reach the flame or fire it will not support combustion, but has direct operation in extinguishing the flame and checking the combustion. All these merits claimed by him have been tested in actual use for many years, and the utility of the invention has created a large demand for the apparatus. With the utility thus established, I can see nothing fatal to the patent in the fact, if fact it be, that the inventor may perhaps have overrated the importance of some of the elements of his method and underrated others. With regard to the third point, that the patent is for a different invention from that described in the original application, after careful consideration I fail to see the force of the objection. My conclusion is that Graham was, as is claimed for him, the pioneer in the art of using mingled carbonic acid gas and water to extinguish fires, and was the first to discover that when condensed in a sufficiently strong vessel it would propel itself by its own elasticity to a sufficient distance and in a sufficient stream to be a useful agent for that purpose, and that he described both a portable and fixed apparatus by which the result could be accomplished. I hold the first and fourth claims of the patent to be valid, and in my judgment, it is immaterial in this case whether my doubts as to the validity of the other claims are well founded or not. There is no difficulty as to the infringement. The defendants can hardly be said to directly deny it in their answers. The defendant Johnston practically admits the making of six portable and six stationary machines, and says he desisted after being warned that they were infringements. The circulars and advertisements of the other defendant, in connection with the oral testimony, sufficiently show the infringement by it, and that the machines complained of contained the exact method of Graham, applied in substantially the same apparatus described by him. The complainants are entitled to a decree in their favor, and to a reference for an accounting. See, also, *Fire-extinguisher Manufg Co. v. Graham*, 16 FED. REP. 543.

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IIALTIMORIII OAR-WHEEL 00.

v. NORTH v.

**BALTIMORE PASSENGER RY.OO.**

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**BALTIMORE CAR-WHEEL CO.**

**NORTH BALTIMORE PASSENGER**

By. Co.

(Circuit Court, D. Maryland,

July 14, 1884.)

1.

No. 9,881. . The third claim of reissued patent No. 9,881, September 27, 1881, to Joseph Harris, held void, because the reissue was after 14 years' delay, and after adverse rights had accrued. 2. SAME-REISSUE No. 3,243. 'The first claim of reissued patent No. 3,243, granted December 22, 1868, to T. B. Stewart, if construed to cover the combination of two tubes fitting one within the other without flanges, and neither made oblong in shape, is void for want of novelty, if for no other reason.

**PATENTS FOR INVENTIONS-REISSUE**

**SAME-INFRINGEMENT-LICENSE.**

3.

In a case in which the complainant, suing for infringement of his patent, does not proceed to enforce remedies under a license granted by him, but treats the license as no longer in force; a purchaser from the supposed licensee is not estopped from denying the validity of the patent; and in no case is a mere purchaser from a licensee estopped from denying the validity of the patent in a suit against him for infringement.

In Equity. R. D. Williams and Benjamin Price, for complainant. Bernard Carte and B. F. Thurston, for defendant. MORRIS, J. This is a suit for the alleged infringement of two reissued patents for improvements in car axle-boxes, of which the complainant is owner by assignment, and which it is alleged that the respondent has infringed by using in its business -certain car-wheels and axle-boxes which it purchased from the Bemis Car-box Company of Springfield, Massachusetts. 'The two patents as to which infringement is alleged are the reissue to T. B. Stewart, No. 3,243, dated December 22, 1868, the original being No. 71,241, dated November 19, 1867; and the reissue to Joseph Harris, No. 9,881, dated September 27, 1881, the original being No. 71,873, dated December 10, 1867. The Harris patent was reissued 14 years after the original had been granted, and the third claim, which is the only one drawn in question, first

appeared in the reissue. This claim is for the combination with the neck or annular recess in the journal, and with the journal-box, of the key or shoulder made to slip on in the recess and straddle the journal, thereby keying the journal and the box together. The evidence is convincing that in the interval of 14 years between the original patent in which this device was not claimed and the reissue in which it was; the use of the key, shoulder, and recess in car axle-boxes had become general throughout the country; and it must be conceded, aB was practically admitted in the argument of the case, that this claim comes within the rulings which hold that what is not claimed in an original patent is dedicated to the public, unless the patent is time and surrendered and reissued within a rights have accrued. Miller v. Brass Co. 104 U. S. 350; James v.

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John Marshall Law Review  
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The Harmonization of International Patent Law

**\*567 PRIOR USER RIGHTS— A NECESSARY PART OF A FIRST-TO-FILE SYSTEM**

[Gary L. Griswold](#) HYPERLINK \l "Document1zzFa103146874" [FN<sub>a</sub>]

F. Andrew Ubel <sup>a</sup>

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INTRODUCTION

Harmonization of the world's patent laws is now being considered by various governments, including that of the United States. One of the most drastic changes urged upon the United States is a change from our current first-to-invent system to a first-to-file system. Under present law, virtually every other country awards patents to the first person to file a patent application, whereas the United States awards patents to the inventor who can prove the earliest invention date. [FN1]

Last year, Congress considered the Patent System Harmonization Act of 1992, which would have replaced current sections 102, 103, and 104 of Title 35 with section 106, thereby implementing a first-to-file system. [FN2] When patent applicants are competing, section 106 would give priority to the first applicant reaching the patent office. In conjunction with this proposal, Congress also considered adding section 273 to secure limited rights, known as prior user rights, for persons who independent of the patentee create or use the invention but lose the first-to-file race to the Patent Office. [FN3]

The reasons most often cited in support of a change to first-to-file priority are efficiency and ease of administration. [FN4] Proponents of this system do not contend that a first-to-file priority system is **\*568** necessarily more equitable on a case-by-case basis than the first-to-invent priority system. Instead, the first-to-file system is said to be simpler and less expensive on the whole. This system is also more closely aligned with the patent laws of the rest of the world with which the United States participates in numerous patent treaties. [FN5]

Most intellectual property law organizations debating the relative merits of a first-to-file system versus a first-to-invent system eventually conclude that the United States should change to "first-to-file" as the basis for priority decisions between patent applicants. [FN6] They qualify this support, though, with the requirement that this change be accompanied by changes in the laws in other countries to provide improvements in patent protection in those countries and uniformity in the patent laws in at least the major industrial countries.

But does the American public want global uniformity? Considering that 45% of the United States patents are foreign-owned, [FN7] if the present first-to-invent system provides occasional advantage [FN8] to domestic applicants versus foreign applicants why not stay with it? An important reason to align with the rest of the world is that the process of obtaining global patent protection is so expensive, complex and fraught with pitfalls that many inventions originated in the United States are not being protected outside of the United States.

In other words, United States inventors are making their inventions available to two-thirds of the world markets free of charge and are thus receiving absolutely no return for their use outside of the United States.

While some say that individual inventors, small businesses, and universities are not interested in patent rights in the rest of the world, the authors have never found this to be the case. It has been our experience that these parties do not pursue foreign patent protection for one of two reasons: either they have relied on the United States grace period [\[FN9\]](#) which has precluded them from obtaining\*569 valid foreign patent rights [\[FN10\]](#) or they have decided to forego foreign filing because of the cost of pursuing foreign patents. The result is that the invention becomes dedicated to the public in much of the world, a particularly troublesome situation with university inventions which are often supported with taxpayer money. Thus, our vision of harmonization is to provide a cost effective, uniform, predictable and forgiving global patent procurement system which accommodates the full spectrum of inventors and patent owners and promotes innovation on a global basis.

This Article describes the concept of a first-to-file system and explores the necessity of implementing prior user rights in conjunction with such a system. Arguments are presented both in favor of and against the adoption of prior user rights and the recommendations of the Advisory Commission on Patent Law Reform in this area are examined. This Article concludes that prior user rights must be adopted with a first-to-file system. Finally, the historical development of prior user rights in the United States are traced, demonstrating that prior user rights are not unprecedented.

#### I. THE FIRST NECESSARY CHANGE: FROM FIRST-TO-INVENT TO FIRST-TO-FILE

Because every country except the United States and the Philippines [\[FN11\]](#) operates under a first-to-file system, harmonization of world patent laws essentially requires the United States to adopt a first-to-file method of establishing priority. Such a system would likely be implemented as proposed in section 106 of the Patent System Harmonization Act of 1992. [\[FN12\]](#) Section 106 would establish the so-called “first-to-file rule” giving priority between competing patent \*570 applicants to the first applicant reaching the patent office. In contrast, under the current first-to-invent system, these rival applicants are entitled to prove their dates of invention to establish their respective priority. [\[FN13\]](#) If the determination of invention dates is not clear-cut, the rival applicants often engage in a battle for priority under section 102(g). [\[FN14\]](#) The first-to-file rule renders these costly interference procedures unnecessary. Priority under section 106 would be a faster, more efficient process based simply on the filing date of the application.

In practice, the majority of priority battles would have the same outcome under either system. Nevertheless, there is a justified concern that a first or “rightful” inventor who is slow to file his application might be shortchanged under the first-to-file system. [\[FN15\]](#) To ameliorate this potentially harsh rule, several statutory provisions have been proposed that would either work to facilitate the early filing of a low cost application or vest certain limited rights to the first-in-time inventor who either delays filing or fails to file at all. [\[FN16\]](#) One provision, section 273, provides limited but important \*571 rights to the prior user of an invention. [\[FN17\]](#) A prior user under proposed section 273 receives the personal right to continue his practice of the invention without liability as an infringer under a subsequently granted patent. To qualify for these rights, a user must demonstrate his own commercial use of the invention, or preparation therefor, in the United States prior to the filing date of the patent. Section 273 restricts the scope of these rights to the subject matter of the prior use. In addition, because these rights are personal to the prior user they may not be transferred or sold separately from the underlying business to which the rights pertain.

In addition to offering greater administrative efficiency during the patent application process, sections 106 and 273 would provide important advantages to the patent owner. A patent granted under these provisions would be valid despite the existence of a secret prior use. [FN18] Thus, certain prior uses by others that would be sufficient to invalidate a patent under our current first-to-invent system, such as a secret use by another, would not affect a patent issued under sections 106 and 273. [FN19] The inherent uncertainty that secret prior uses cast over patents issued through our current system may be eliminated by a first-to-file system. Eliminating this uncertainty \*572 as to the validity of issued patents may in some instances increase the market value of United States patents.

## II. THE SECOND NECESSARY CHANGE: ADOPTION OF PRIOR USER RIGHTS

So what are prior user rights and how do they fit into the first-to-file system? Under current United States law, we have the ability to invalidate patents or patent applications under sections 102(g) [FN20] and 103 [FN21] of the Patent Act. Under these statutes, a patent may be rendered invalid if the invention has been made in this country, or rendered obvious, by another who has not abandoned, suppressed or concealed the invention. For example, if inventor A made the invention first and does not apply for a patent, inventor A's act can invalidate the patent of inventor B who invents later and files for a patent. [FN22] In a first-to-file system this opportunity would not exist because the inventor who is first to file gets the patent. As a means of balancing this effect, the concept of prior user rights was developed to protect the investment of inventor A who has put into commercial use or made substantial preparations for commercial use of the invention which is the subject of B's later patent application.

### \*573 A. Prior User Rights Are an Alternative to "Winner Take All"

In general, when faced with a conflict between an issued patent and a prior use by another, we have three basic alternative legal rules from which to choose. These rules are as follows:

- (1) invalidate the patent and open the whole field to the public;
- (2) uphold the patent's validity and enjoin use by all others, including the prior user; or
- (3) uphold the patent's validity but exempt the prior user from some degree of liability for infringement.

The historical changes in the United States patent laws demonstrate indecision about which legal rule to follow. Currently, one of the first two options is chosen, depending on the relative equities of the parties. These two "winner-take-all" solutions obviously work best in situations where one party is clearly more deserving of the right to use the invention.

For example, application of the second option, i.e., upholding the patent's validity, is equitable where an ordinary infringer attempts to rely on a third party's secret prior use to invalidate a patent and escape liability for infringement. The patentee, who honestly sought a patent without knowledge of the third party's secret prior use, has the equitable high ground. The infringer, having no personal rights to the invention, can be justifiably enjoined. Under the current system, however, the courts' use of the winner-take-all options can have one of the following unfortunate outcomes: invalidating an otherwise good patent in response to secret prior art; or enjoining a bona fide first-in-time inventor from continued use of his own invention.

The third option, granting a prior user right, is an alternative to the winner-take-all approaches. This option is the best solution in cases where both the patentee and the prior user independently acquire the invention and thus, both deserve rights in the invention. Somewhat surprisingly, there is historical

precedent in American patent law for the explicit recognition of such rights. This precedent will be explored later in Section III of this Article.

Notably, prior user rights exist in most countries which have a first-to-file system. [\[FN23\]](#) For example, in Europe prior user rights are available in Austria, Denmark, France, Germany, Greece, Italy, The Netherlands, Norway, Sweden, Switzerland and the United Kingdom. [\[FN24\]](#) \*574 In Asia, prior user rights are available in China, Hong Kong, Japan, South Korea, Malaysia, Singapore and Taiwan. [\[FN25\]](#) Prior user rights are also available in Mexico and to a limited extent in Canada. A few countries (i.e. India, New Zealand, and Ireland) recognize only the prior user rights of their respective governments. Australia does not explicitly recognize prior user rights. Instead, Australia handles these situations through revocation of the patent. [\[FN26\]](#)

\*575 While the scope of the prior user right varies, in most countries it provides a legal defense against patent infringement and allows the prior user to continue that technical activity which the prior user had commercialized, or made substantial preparations to commercialize. Most countries also provide provisions for the prior user to expand the volume of their activity to meet market demand.

#### B. Current Proposals for Implementing Prior User Rights in the United States

The Patent Harmonization Act introduced in the United States Congress in 1992 provided:

A person shall not be liable as an infringer under a patent granted to another with respect to any subject matter claimed in the patent that such person has, acting in good faith, commercially used or commercially sold in the United States, or has made effective and serious preparation therefor in the United States, before the filing date or priority date of the application for patent. [\[FN27\]](#)

This Act was qualified as follows:

(1) “The rights based on prior use under this section are personal and shall not be subject to assignment or transfer to any other person or persons except in connection with the assignment or transfer of the entire business or enterprise to which the rights relate,” and

(2) “A person shall be deemed to have acted in good faith in establishing rights under this section if the subject matter has not been derived from the inventor.” [\[FN28\]](#)

These two qualifications deal with major concerns raised by those opposed to prior user rights. If the prior user right was readily separable from a business, the prior user right would go beyond its basic purpose of protecting the investment of the non-deriving inventor and would allow an accused infringer to search for and license a prior user right thereby avoiding infringement. This would inequitably diminish the value of the patent. However, there is a need to allow a business to transfer the right as part of the sale of a business; otherwise, small businesses that rely on trade secrets may become significantly less alienable. As an additional qualification, prior user rights were not to be based on subject matter derived from the patentee. It is believed to be unfair to allow one to claim a prior user right if the information is derived from the patentee,\*576 even if the information is gleaned from a publication of the patentee during the grace period. [\[FN29\]](#) Prior user rights are thus reserved for persons who independently acquire the invention.

Harmonization legislation may be reintroduced in Congress in 1993. The content of that legislation will likely not be dictated by the World Intellectual Property Organization (WIPO) Patent Law Treaty

because the latest proposals concerning that treaty, dated January 29, 1993, provide two alternatives for prior user rights. [\[FN30\]](#) One alternative in Article 20 provides that prior user rights are optional and the other provides that they are mandatory. Article 20 was included in the treaty only because of the existence of Article 19 relating to rights conferred by the patent. Since Article 19 is recommended to be deleted, the last observation by WIPO on Article 20 is:

In conclusion, it is suggested not to include any Article on prior users' rights in the Treaty. In any case, it should be noted, firstly, that leaving the matter entirely to national laws appears to be reasonable since the beneficiaries of a prior user right are, in the vast majority of cases, only residents of the territory of the Contracting Party in question, and, secondly, that it will always be possible, if the position of the United States of America on prior users' rights moves at a later stage towards the solutions preferred by most other prospective Contracting Parties, to conclude a Protocol on the matter under Article 32. [\[FN31\]](#)

Thus, a decision whether to implement a prior user rights provision will apparently be left to the United States. Prior user rights provide protection for business and jobs in the countries which adopt prior user rights. If a country desires to forego protection of its industry and distinguish itself from other countries who have provided a prior user right, the treaty will allow it to do so.

#### C. Report of the Advisory Commission on Patent Law Reform

The United States Secretary of Commerce in 1990 established the Advisory Commission on Patent Law Reform. In August, 1992, that commission issued a report including recommendations that the United States should change to a first-to-file system and that **\*577** limited prior user rights should be adopted. [\[FN32\]](#) The report included comments made by the public in response to requests by the Advisory Commission. Comments regarding prior user rights from that report, as well as the authors' observations, are noted below.

##### 1. Arguments in Support of Prior User Rights

Persons who advocate prior user rights support their position for the reasons that follow:

##### Global Competitiveness

The United States needs prior user rights to equalize the scope of patent rights granted by the United States patent system with the patent systems of our trading partners. Currently, prior users in most first-to-file countries can assert prior user rights against United States companies that hold patents in those countries. However, without a prior user rights provision, foreign owners of United States patents could prevent prior users in the United States from continuing to use their inventions, or require those users to pay royalties under a license. Thus, without prior user rights, the United States would expose domestic users to suit by foreigners who hold United States patents while the opposite situation would not occur. [\[FN33\]](#) Further, without the certainty provided by a prior user right, multinational businesses will hesitate to invest in plants and equipment in the United States for inventions that are not appropriate for patenting. [\[FN34\]](#)

##### Protection of trade secrets

Without prior user right, users of a trade secret run the risk of later independent invention and preclusive patenting by others. The public in turn may be deprived of the benefits provided by the invention. Notably, trade secret use of certain inventions, such as processes, is sometimes the best and only way to realize the benefit of the invention. [\[FN35\]](#) For example, in many cases a process patent affords inadequate protection in exchange for the inventor's disclosure, since process claims are often difficult if not impossible to police.\*578 Prior user rights, therefore, protect the valuable role trade secret law plays in the commercial arena.

No reduction in patent incentive

The incentive to patent major inventions would remain in the advent of a prior user right, so long as significant enforceable patent rights could be obtained to preclude others from using the invention. In addition, inventors would not feel compelled to file as many patent applications on minor inventions, such as improvements made during routine product development, as they would if a prior user right did not exist. [\[FN36\]](#) Furthermore, it is not in the United States' best interest to force inventors to disclose the best mode of an entire process to secure their rights in a small improvement. The base process would then be available for use by foreign manufacturers to the detriment of United States businesses.

No significant increase in litigation

Because litigation involving enforcement of prior user rights is rare in other countries, it is believed that such lawsuits should not significantly interfere with United States patent holders' activities. [\[FN37\]](#)

More equitable

Prior user rights as they exist in the United States today in section 102(g) are harsh, patent-defeating rights. In contrast, prior user rights, as proposed under the first-to-file system, are based on the equity of granting an inventor a right of limited scope to continue using an invention he conceived or independently created.

Stronger Patent Grant

In addition to offering greater administrative efficiency during the patent application process, a first-to-file priority system and a prior user right provision provide important advantages to the successful patent owner. A patent granted under these provisions would be valid despite the existence of a secret prior use. [\[FN38\]](#) Thus, certain prior uses by others that may be sufficient to invalidate under our current first-to-invent system (e.g., a secret use by another) would not affect a patent issued under this proposed \*579 system. [\[FN39\]](#)

Universities are certain to benefit from this change. Although universities infrequently possess trade secrets of the type that would vest them with prior user rights, they frequently patent their inventions. Under our current system, these inventions are exposed to invalidation by secret prior users. The change to a first-to-file system will enable a university to validly patent an invention which was secretly possessed by another. The university is then free to license the patent to whomever it wants. The prior user may themselves seek a license to maintain their exclusive position.

## 2. Arguments Against Prior User Rights

On the other hand, those who speak against the inclusion of prior user rights in a United States first-to-file system give as reasons the following:

### Encouragement of secrecy

The current United States patent system is based on a policy of encouraging the public disclosure of inventions. [\[FN40\]](#) By allowing someone to continue using an invention after it is patented by another, a system having prior user rights encourages secrecy and discourages disclosure of inventions. [\[FN41\]](#)

### Source of litigation

Prior user rights could increase the need for recordkeeping, and are a fertile ground for litigation and other burdens which characterize interference practice. [\[FN42\]](#) Even though suits to enforce prior user rights are not common outside of the United States, the United States is a litigious society. [\[FN43\]](#) Therefore, prior user rights would be claimed as a defense to infringement more frequently in the United States. In addition, it is likely that defendants here **\*580** would seek transfers of rights from bona fide prior users to avoid infringement.

### Destruction of patent exclusivity

Prior user rights threaten the exclusivity of the patent grant and jeopardize lucrative licensing deals and other opportunities of those who receive most of their income from licensing inventions. [\[FN44\]](#)

### No benefit to universities

Universities would rarely fall within the scope of a prior user right since they typically do not perform manufacturing activities. In addition, a university would not benefit from a prior user right since it does not have the means to transfer a prior user right with a business. [\[FN45\]](#)

## 3. Advisory Commission Recommendation

The Advisory Commission on Patent Law Reform considered the concerns of those opposed to prior user rights and developed a set of recommendations for limited prior user rights. The commission's recommendations and the authors' observations are noted below:

### Time

The Advisory Commission recommended that "The rights should be based only upon activit[ies] ... prior to the earliest filing date to which the relevant claim or claims of the patent is or are entitled." [\[FN46\]](#)

A survey of other countries' laws shows that in general, the use of the invention must precede the priority date of the patent application. [\[FN47\]](#) The use also must be continuing and ongoing. Abandoned experiments, for example, would not later establish a prior user right to resume use of the invention. [\[FN48\]](#)

#### \*581 Place Restrictions

The Advisory Commission recommends that only activities taking place “in the United States” are entitled to prior user rights. This is consistent with most prior user rights statutes which similarly recognize a narrow geographical scope. In general, the protected right extends only to the specific activity that was occurring within the given territory prior to the filing of the patent. Consider a trade secret process that has been practiced in the United Kingdom with the resulting product having been sold in the United Kingdom prior to the filing of a patent. In such a case, the acts of practicing the process and selling the product in the United Kingdom would entitle the user to prior user right protection. However, if this same process had been practiced outside of the United Kingdom and the resulting product had been imported to the United Kingdom, the prior user right would not extend to any practice of the process in the United Kingdom. Only the continued importation and sale of products produced outside of the United Kingdom by that process would be allowed.

This limitation raises an interesting problem were the United States to adopt proposed section 106 (establishing a first-to-file system) without adopting proposed section 273 (providing for prior user rights). Under such a scenario, a global asymmetry in the patent laws would develop, putting domestic industry at a competitive disadvantage to foreign industry. The United States would be giving up existing first-to-invent protections, which are similar to a prior user right, while exposing United States corporations to the threat that a foreign inventor who seeks a United States patent could preclude United States corporations from continuing to use their own inventions. The opposite situation would not occur, since a United States corporation's foreign patent would not preclude a foreign prior user from his own market.

The narrow geographical limits of prior user rights obviously favor those parties that have an active presence in the jurisdiction. These rights favor domestic inventors, corporations and universities over foreign parties because the acts necessary to qualify for these rights must occur domestically. Therefore, adoption of prior user rights is necessary to ensure that United States entities are not placed at a competitive disadvantage.

#### Independent Creation

The Advisory Commission's report requires that to qualify as a prior use, “the activity must have been done in good faith and without derivation from the patentee.” [\[FN49\]](#) Further, the use must be **\*582** based on independent development by the person claiming prior use, or by persons “who had an obligation at the time of such development to assign or license patent rights to or otherwise share such rights with such person.” [\[FN50\]](#) The Advisory Commission's recommendation is consistent with other countries' laws. Most countries' prior user rights statutes require good faith on the part of the prior user at the time that the patent application is filed. This requirement is not met if, for example, the prior user had misappropriated the invention from the patent owner or had acquired knowledge of the invention through illegitimate means.

#### Prior Activity

The Advisory Commission's report provides that “the prior user right must be based upon either actual use in commerce of the patented invention, or upon substantial material preparations for such commercial use.” [\[FN51\]](#) In addition, the prior user must have completed an actual reduction to practice. [\[FN52\]](#) The following factors were provided as examples to consider as to whether or not substantial preparation for use

has been proven by a potential prior user: (a) the costs incurred by the prior user; (b) the amount of time to complete the preparation for the commercial use; (c) the complexity of preparation; and (d) the diligence of the prior user in preparations for the prior use.

The Advisory Commission recommends that the burden of documenting the prior use be placed on the claimant. [FN53] In general, any commercial use of the invention prior to the application for patent by the second inventor will establish prior user rights in most countries having prior user rights statutes. For example, in Germany the rights are “due to anybody who, at the time of filing of the application, was already using the invention within ... Germany, or had made the necessary arrangements for using the same.” [FN54] Likewise, Japanese law explicitly requires that the invention either have been commercially worked in Japan or that commercialization has been prepared for in Japan. [FN55] France, on the other hand, will award prior user rights with less than full commercialization. [FN56] French law focuses instead merely on whether the prior user “possessed” the invention within France. Lodging a description of the invention in a closed envelope (“sous pli cachete”) with a Notary \*583 Public or with a scientific society is sufficient evidence of possession to warrant prior user rights. [FN57]

#### Scope of the Right

The Advisory Commission made the following recommendations concerning the scope of the prior user right:

The right created by the prior use or preparation should be limited to continuation of the particular activity which gives rise to the right. In the case of processes, this would limit the use to a continuation of use of an identified process but would not limit the products produced or affected by the process. In the case of products, the right would extend to future additions of the product only if they are not materially different from the version of the product which gave rise to the right. For example, improvements to the prior use should be permitted to the extent they do not fall within the scope of other claims in the patent. [FN58]

Further, the Commission recommended that “the prior user should be able to reasonably expand the prior use to meet reasonable market demands within the United States, rather than being restricted only to the pre-filing volume of use.” [FN59] Finally, the Commission's report rejects any restriction on the prior user based on the prior use having been separately developed and commercialized in different regions within the United States. [FN60]

In other countries, a prior user who has established a bona fide prior use receives certain limited rights to continue operating his invention in spite of the subsequent issuance of an otherwise valid patent. In general, these rights cover only those uses that occurred prior to the patent application. An issue that frequently arises is whether a prior user should be allowed to modify and improve his practice after receiving the benefit of the patent disclosure. This question has not been uniformly resolved. [FN61] In Japan, prior user rights are limited to the invention which is being worked at the time of the patent application. This limits the ability of the prior user to adapt his invention to take advantage of subsequent technological advances, whether or not these advantages were gleaned from the patent application or were independently developed. In contrast, recent United Kingdom case law appears to allow some \*584 future modifications by the prior user. [FN62]

However, the prior user must be content with his present practices or seek a license to cover

improvements disclosed and claimed in the patent which he wishes to incorporate. The authors submit that allowing the prior user to incorporate improvements which he has independently developed, or which are not disclosed in the patent application is fair. However, the prior user must be content with his present practices or seek a license to cover improvements disclosed in the patent which he wishes to incorporate.

In a majority of countries, there is no numerical limitation on the prior user to remain at their original level of activity. If the prior user expands his business he may commensurately increase his practice of the invention to meet the new demand.

#### Personal Nature of the Right

The Advisory Commission recommended that, in accordance with several countries' laws, "prior user rights should be personal in nature and should not be transferable except with that part of the business which exploits the right." [\[FN63\]](#) Specifically, this provision prevents accused infringers from taking a license from a prior user to establish a defense against an infringement suit brought by the patent owner and is designed to protect the value of the patent.

This recommendation mirrors most existing prior user rights statutes which provide only a personal defense against patent infringement. The "personal" nature of this defense means that the owner, in general, cannot transfer his rights to another party. However, most of the statutes allow the prior user to transfer his rights upon the sale of an entire business unit with which those rights are associated. [\[FN64\]](#) This limitation avoids any unfairness to the patent owner which would occur if the prior user were able to freely license his prior user rights in competition with the patent rights.

#### Legal or Equitable Nature of the Right

Another topic of debate is whether a prior user right should be legal, thus constituting a per se defense to infringement, or equitable, thus allowing courts discretion to evaluate the circumstances of the use before allowing the defense. The Advisory Commission recommends the latter, as follows:

**\*585** Prior user rights should be an equitable defense to a charge of patent infringement, and at a minimum should permit continuation of the use on the scale of commercial use undertaken, or for which sufficient preparations were made, before the patentee's earliest filing date. Where the totality of the circumstances make it appropriate, the Court should have the authority to access appropriate and reasonable royalties in favor of the patentee, or expand the right to ensure that justice is done. [\[FN65\]](#)

However, these authors favor a legal nature for prior user rights. Notably, the Patent Harmonization Act of 1992 provided that prior user rights were to be legal in nature. If the prior user rights are equitable in nature as proposed by the Advisory Commission, rather than legal as provided in the Harmonization Act of 1992 and in most other countries, the following problems will arise.

First, an "equitable" prior user right will be difficult, if not impossible, to value given the uncertainty of its being granted. As a rule, business managers need to quantify the financial obligations their companies will face. Therefore, the prior user may feel compelled to disclose his trade secrets to the patent holder in order to assess what, if any, liability there is to the patent holder and to prevent the accumulation of large royalty obligations. Thus, the inherent uncertainty of an "equitable" prior user right has the effect of forcing the prior user to disclose his trade secret to the patentee—just to avoid the risk of

a later unfavorable or costly decision.

In addition, the granting of an equitable prior user right will not automatically exempt the holder of that right from having to pay royalties or make other compensation to the patent holder. This will impact the alienability of businesses that hold and rely on prior user rights because the issue of potential future royalty obligations will have to be resolved before the business will be saleable.

Faced with the above lack of certainty and hindrance of alienability, inventors will be forced to the patent system to protect their inventions. This will result in the negative results discussed above regarding forced disclosure of trade secrets where significant and enforceable patents are not available.

Finally, since an equitable right necessarily has less value to a prior user than a legal right, the adoption of an equitable right will tend to discourage domestic manufacturing. That is to say, the decision of where to place a manufacturing plant will be made in favor of the jurisdiction which has an absolute defense rather than a country which has only an equitable right.

In summary, the adoption of an equitable prior user right fails to adequately protect the prior user. Furthermore, due to its uncertain nature, such a right would be perceived by most businesses as \*586 having little, if any, value. Thus, businesses could be expected to act as if the right did not exist at all.

#### Additional Characteristics of the Prior User Right

The Advisory Commission considered and rejected other provisions for inclusion in a prior user rights proposal. These rejected provisions included: (1) providing special treatment for non-manufacturing entities; and (2) barring the availability of prior user rights where the use was intentionally concealed. [\[FN66\]](#) As to the first provision, there is a legitimate concern about the transferability of prior user rights by non-manufacturing entities such as universities who cannot transfer a business. This may need to be addressed in future legislation.

The prior user right is sometimes characterized as a substantial advantage only for large companies and of no use to individual inventors, small businesses or universities. [\[FN67\]](#) Individual inventors and universities, however, will benefit when they license their technology to medium- and large-sized companies. First, the licensee may rely on trade secrets when commercializing the invention. Those trade secrets will in some cases involve prior user rights and the income received by the individual inventor or university for licensing that invention will be due in part to those trade secrets. Second, the certainty offered by the first-to-file system will undoubtedly increase the value of the patent and increase its expected return through licensing. Finally, small businesses that do not use the patent system because of its high cost in procurement and enforcement or because of its inadequate protection of their inventions will want to have the ability to carry on their trade secret processes. These small businesses will have the comfort of a prior user right to continue against a patent holder, be it foreign or United States. If the small business later decides to transfer its business to another party, it will be able to do so if the prior user right is legal in nature without being impeded by a necessity to liquidate the amount of compensation owed to any patent holder.

The rejection of the second provision was sound. To not allow prior user rights for trade secrets, that is, intentionally concealed prior uses which are commercialized, would gut the prior user right. The resulting system would have the same deficiencies as a system adopting first-to-file without prior user rights. As has been shown, prior user rights are highly desirable in a first-to-file system.

### \*587 III. HISTORICAL DEVELOPMENT (AND LOSS) OF STATUTORY PRIOR USER RIGHTS

The adoption of prior user rights in the United States is not without precedent. This section traces the treatment of prior user rights throughout the history of United States patent law.

Although the United States patent laws have historically attempted to limit the grant of a patent to the first inventor, the United States once had an explicit prior user rights statute which countered that limitation. [\[FN68\]](#) This section traces the historical treatment of prior user rights and seeks the present whereabouts of these rights.

#### A. Requirement That Inventions Not Be Known or Used by Others

Section 1 of the Patent Act of 1793 required that an invention for which a patent was sought not be “known or used before the application.” [\[FN69\]](#) This section was later interpreted by Justice Story, in the case of *Pennock v. Dialogue*, to mean that the invention could not be “known or used by others before the application.” [\[FN70\]](#) Section 6 of the Patent Act of 1836 codified this interpretation. [\[FN71\]](#)

Another portion of the *Pennock* decision that was incorporated in the 1836 Act was its policy against commercial exploitation by the inventor before the filing of a patent application. [\[FN72\]](#) Thus, the 1836 Act required that the machine, manufacture, or composition of matter not be “in public use or on sale, with his consent or allowance”<sup>\*588</sup> prior to the date of the patent application. [\[FN73\]](#) Under the 1836 Act, a prior public use or sale of the invention with the inventor's consent would bar a patent, while a prior public use or sale without the inventor's consent would not be a bar. [\[FN74\]](#)

#### B. The Prior User Rights Clause—Section 7 of the Act of 1839

The above requirements were drastically changed just three years later when Congress replaced section 6 with a complicated provision that created both a vested prior user right and a two-year grace period during which time the inventor could publicly use his invention. [\[FN75\]](#) Section 7 of the 1839 Act provided:

[1] That every person ... who has ... purchased or constructed any newly invented machine ... or composition of matter, prior to the application by the inventor ... shall be held to possess the right to use, and vend to others to be used, the specific machine ... or composition of matter so made or purchased, without liability therefor to the inventor ... and [2] no patent shall be held to be invalid, by reason of such ... use prior to the application for a patent ... except on proof of [i] abandonment of such invention to the public; or [ii] that such purchase, sale, or prior use has been for more than two years prior to such application for a patent. [\[FN76\]](#)

Under the first clause, a prior user was not liable for patent infringement; under the second clause, the validity of the patent was preserved, despite the prior use. [\[FN77\]](#)

The Supreme Court first addressed this prior user defense against infringement in the case of *McClurg v. Kingsland*. [\[FN78\]](#) This case involved an employee/patentee trying to enforce a patent against his former employer. Apparently, the experiments leading to the invention were made in the employer's shop while

the patentee was receiving wages. Later, the patentee left the employer's shop and assigned his rights in his invention to a competitive foundry. The assignee quickly sued the former employer for infringement of the patent. [FN79] In McClurg, the Court interpreted section 7 to have two objects: (1) "to protect the person who has used the thing patented, by having purchased, constructed, or made the machine ... from any liability to the patentee or his assignee;" and (2) "to protect the rights, granted to the patentee, against any infringement by any other person." The latter relieves the inventor from the effects of the Pennock decision, which would have invalidated \*589 the patent because the inventor permitted prior use of the patented article. [FN80] Section 7 spared the inventor's patent from invalidation as long as he filed his application within two years of such prior use. Thus, section 7 gave a "grace period" for prior uses.

In construing section 7, the Court also dealt with the scope of the protection created by the prior user right clause. The assignee argued that the privilege only encompassed the specific machines manufactured prior to the application date. The Court rejected this argument and applied an expansive view of the "right to use and vend to others." Under this interpretation, the prior user was allowed to continue to make and use the machines even after the date of application. [FN81] However, the Court limited the prior user right to what had been practiced; the right could not be claimed to allow use of the patentee's later improvements. [FN82]

### C. Restriction of Section 7

One year later, Justice Story (then sitting on the Massachusetts circuit court) refused to apply this expansive interpretation of the prior user rights clause. In Pierson v. Eagle Screw Co., [FN83] the court enforced the patent rights of the first inventor (Crum) against a second independent inventor (Read). Prior to Crum's application, Read had independently developed the same machine and sold a number of them to the defendant. Justice Story rejected the defendant's argument that he should be allowed to continue to use the machines. Justice Story limited the prior user right to cases where the pre-patent-application purchases were from the first inventor \*590 himself and effectively unstrung the first clause of section 7. [FN84]

Justice Story apparently adopted this restrictive view to circumvent the pirating of inventions by wrong-doers, even though the case before him presented an independent inventor rather than a "pirate." [FN85] The Supreme Court apparently adopted the Story "piracy" interpretation in 1858. In Kendall v. Winsor, the Court held that the jury was properly instructed that a defendant could not rely on section 7 prior user rights where the defendant surreptitiously derived the invention from the first inventor. [FN86]

Congress also adopted Story's interpretation in the Patent Act of 1870. By this Act, Section 7 was split into two independent sections. Section 24 of the Act of 1870 allowed a patent to be granted only for an invention which was not in public use or on sale for more than two years prior to the application for the patent, subject to the defense of abandonment within such two years. [FN87] Section 37 of the Act of 1870 allowed a prior user defense only in cases where the user shall have purchased the article from the inventor or constructed\*591 it with his knowledge and consent. [FN88]

Vestiges of prior user rights still remain in United States law. [FN89] They are found in one of the "winner-take-all" options discussed above, where the patentee may be divested of his patent rights because of a prior use. Upon the invalidation of the patent, all persons are entitled to make, use and sell the invention. A prior user may invoke any of the conditions of sections 102 and 103 to invalidate a patent which covers the subject matter that he had in fact invented and used, but had not patented. [FN90]

Significantly, however, this ability to invalidate a patent is not limited to prior inventors under the current system. Any defendant, even a blatant copier, may raise another's prior use and thereby invalidate the plaintiff's patent. Proposed section 106 eliminates this defense to infringement by rejecting the "winner-take-all" approaches. Under proposed sections 106 and 273, a defendant can rely only on his own prior use as a defense to infringement and cannot invalidate the patent based on another's secret prior use. Likewise, the patentee can enforce his patent rights against everyone but bona fide prior users. For these reasons, prior user rights are an important equitable component in a first-to-file system.

#### \*592 CONCLUSION

Those speaking against prior user rights tend to frame the discussion in terms of a struggle between United States inventors. The issue, however, is not between large and small businesses, between businesses and universities, or between individual inventors and groups of inventors. Rather, the issue is allowing all United States inventors to be competitive on a worldwide basis. To help accomplish this goal, the United States must harmonize its patent system with the rest of the world and adopt a cost effective first-to-file priority system—a system that includes prior user rights. Failure to harmonize will unnecessarily jeopardize the global protection of many United States originated inventions. As a result, two-thirds of the world markets will receive these inventions free of charge.

The change to the first-to-file priority system will be a fundamental, sweeping change. The first-to-file system, although more cost effective on the whole, can produce inequities for the first-in-time inventor who chooses not to seek a patent yet wants to commercialize his invention in the United States. Prior user rights are needed to protect and encourage domestic investment and commercialization in these inventions. Without this protection the inventor may instead choose to locate his investment in a jurisdiction which has a prior user right.

The Patent Harmonization Act of 1992 provides a well developed and fair prior user rights provision. Proposed section 273 provides adequate legal protection to bona fide prior users yet properly restricts these rights to those who independently acquire the invention. If the United States chooses to adopt a first-to-file priority system it should also adopt this prior user rights provision.

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[FN1]. See [http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP\\_16f4000091d86](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP_16f4000091d86) [35 U.S.C. § 102\(g\)](#) (1988). HYPERLINK

[FN2]. S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992).

[FN3]. See Joint Hearings on S. 2605 and H.R. 4978 Before the Senate Subcomm. on Patents, Copyrights and Trademarks and the House Subcomm. on Intellectual Property and Judicial Administration of the House and Senate Comm. on the Judiciary, 102d Cong., 2d Sess. (Apr. 9, 1992) [hereinafter Joint Hearings] (statement of Hon. William J. Hughes). See generally 138 CONG.REC. S5226-01, S5288 (1992) (introducing S. 2605); 43 PAT.TRADEMARK &

COPYRIGHT J. 519, 533 (1992); 44 PAT. TRADEMARK & COPYRIGHT J. 3, 4 (1992) (summarizing testimony from joint hearing on S. 2605 and H.R. 4978).

[FN4]. See, e.g., Blake R. Wiggs, Canada's First-To-File Experience—Should the U.S. Make the Move?, 73 J.PAT. & TRADEMARK OFF.SOC'Y 493, 502-03 (1991); Gregory J. Wrenn, What Should be Our Priority—Protection for the First to File or the First to Invent?, 72 J.PAT. & TRADEMARK OFF.SOC'Y 872, 878-80 (1990); Donald R. Dunner, First to File: Should Our Interference System be Abolished?, 68 J.PAT. & TRADEMARK OFF.SOC'Y 561, 562-63 (1986).

[FN5]. Joint Hearings, supra note 3 (statement of Hon. William J. Hughes).

[FN6]. These organizations include the National Association of Manufacturers; The Advisory Commission on Patent Law Reform; Intellectual Property Owners, Inc.; the American Intellectual Property Law Association (AIPLA); and the American Bar Association—Patent, Trademark and Copyright Section.

[FN7]. David Silverstein, [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=100388&FindType=Y&ReferencePositionType=S&SerialNum=0101103487&ReferencePosition=262"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=100388&FindType=Y&ReferencePositionType=S&SerialNum=0101103487&ReferencePosition=262) [Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness, 17 RUTGERS COMPUTER & TECH.L.J. 261, 262 \(1991\)](#). In 1983, the United States granted over 20% of its patents to the Japanese. Id.

[FN8]. Even this occasional advantage will be lost with Mexico and Canada when the North American Free Trade Agreement is implemented.

[FN9]. [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP\\_a83b000018c76"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP_a83b000018c76) [35 U.S.C. § 102\(b\)](#). The statute provides that “a person shall be entitled to a patent unless the invention was ... in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.” Id.

[FN10]. There is no grace period under foreign patent systems. See Pat K. Chew, [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1290&FindType=Y&ReferencePositionType=S&SerialNum=0101999364&ReferencePosition=310"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1290&FindType=Y&ReferencePositionType=S&SerialNum=0101999364&ReferencePosition=310) [Faculty-Generated Inventions: Who Owns the Golden Egg?, 1992 WIS.L.REV. 259, 310 n. 213 \(1992\)](#). Foreign patent systems require “absolute novelty,” which requires that the inventor file the patent application before any public disclosure of the invention. Id.

[FN11]. See Wrenn, supra note 4, at 872.

[FN12]. Proposed section 106 provides as follows:

(a) IN GENERAL.—An applicant shall be entitled to a patent unless—

[Anticipation] (1) the subject matter was disclosed in the prior art, which for the purposes of this section means that such subject matter was publicly known or publicly used in the United States, or patented or described in a publication in the United States or in a foreign country, before the filing date or priority date of the application for patent,

[Obviousness] (2) though the subject matter is not identically disclosed or described in the prior art, the differences between the subject matter of the claim and the prior art are such that the subject matter as a whole would have been obvious at the time the application for patent for the invention was filed to a

person having ordinary skill in the art to which said subject matter pertains, except that patentability shall not be negated by the manner in which the invention was made,

[Senior Priority] (3) the subject matter is described in an application for patent of another applicant that has been previously filed in the United States and has been opened to public inspection under section 122, or

[Loss of Right to Patent] (994) the subject matter—

[Derivation] (A) was derived from an inventor not named in the application for patent, except that subject matter representing an obvious variant developed by an inventor not named in the application shall not preclude patentability under this subparagraph if such subject matter and the claimed subject matter were, at the time the application for patent is filed, owned by the same person or subject to the same person, or

[Placement On Sale] (B) was on sale in the United States more than one year before the filing date of the application for patent.

(b) GRACE PERIOD.—Notwithstanding the provisions of subsection (a), subject matter disclosed in the prior art not more than one year preceding the filing date or priority date of the application for patent shall not affect novelty or nonobviousness under this section whenever it results from a disclosure of information obtained directly or indirectly from an inventor named in the application.

S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992).

[FN13].

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[FN14]. For a perspective on the pitfalls of interference practice, see generally Paul E. Morgan, So You Think You Want to Get Into an Interference? Some Things You Should be Aware of First, 74 J.PAT. & TRADEMARK OFF.SOC'Y 303 (1992).

[FN15]. S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992); Joint Hearings, supra note 3 (statement of Hon. William J. Hughes).

[FN16]. The Patent System Harmonization Act of 1992 provides an inexpensive procedure for filing a provisional application. Under amended section 41(a)(1), the fees due on filing an application may be paid in two parts. The first part, in the amount of \$150, is to be paid at the time of filing. The balance of the fees is deferred for up to 18 months, at which time the applicant may choose to either enter the examination phase and pay additional fees, or abandon the application, thereby preventing public disclosure of it, and incur no further costs. S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992)

[FN17]. Proposed section 273 provides as follows:

(a) IN GENERAL.—

[Prior User Rights] A person shall not be liable as an infringer under a patent granted to another with respect to any subject matter claimed in the patent that such person has, acting in good faith, commercially used or commercially sold in the United States, or has made effective and serious preparation therefor in the United States, before the filling date or priority date of the application for patent.

(b) QUALIFICATIONS.—

[Limits on Assignment] (1) The rights based on prior use under this section are personal and shall not be subject to assignment or transfer to any other person or persons except in connection with the assignment or transfer of the entire business or enterprise to which the rights relate.

[Derivation] (2) A person shall be deemed to have acted in good faith in establishing rights under this section if the subject matter has not been derived from the inventor.

S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992).

[FN18]. Secret prior uses which would not jeopardize a patent issued under section 106 include any non-informing public uses or secret uses, by others, prior to the applicant's filing date. However, under proposed section 106(a)(3), pending patent applications are held "secret" for 18 months and may operate to anticipate a later-filed application. See supra note 12 for the full text of section 106.

[FN19]. This is in contrast to our current law where the prior use of an invention would possibly invalidate a subsequent patent and cause the entire subject matter to revert to the public domain. However, invalidation is merely a possibility under current United States law because a court might alternatively find that the prior user had abandoned, suppressed or concealed the invention. See HYPERLINK "[http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP\\_16f4000091d86](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP_16f4000091d86)" [35 U.S.C. § 102\(g\)](#). In that case, the patentee would retain a valid patent—perhaps even as against the prior user.

[FN20]. HYPERLINK "[http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP\\_16f4000091d86](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L&ReferencePositionType=T&ReferencePosition=SP_16f4000091d86)" [35 U.S.C. § 102\(g\)](#). Regarding this law, Judge Newman of the Court of Appeals for the Federal Circuit has stated,

I have not seen anyone who was a prior user who has been stopped upon raising the 102(g) defense and from that viewpoint[,] it seems that the prior user right is alive and well. Because someone has kept it as a trade secret has not succeeded, as far as I can tell, in avoiding the defense, because if it has been in commercial use, even if the process has been kept secret, it is considered a bar. If we go to a first-to-file system[,] we must face the important points that have been raised about forcing people into the patent system, even for marginal inventions technologically, in order to protect their prior user right. But if we stay with the current first-to-invent system, we would be changing direction if we felt that there should not be prior user right.

32 IDEA J.L. & TECH. 7, 60 (1991-92) (reprinting transcript of conference held Apr. 27, 1991, hosted by the Franklin Pierce Law Center, in cooperation with the Kenneth J. Germeshausen Center for the Law of Innovation and Entrepreneurship, and the PTC Research Foundation). See also [Friction Division Prods. v. E.I. duPont de Nemours & Co.](#), 658 F.Supp. 998 (D.Del.1987), aff'd 883 F.2d 1027 (Fed.Cir.1989) (unpublished). Some argue that the patent-defeating ability of [35 U.S.C. § 102\(g\)](#) is limited, citing, for example, [W.L. Gore & Assoc. v. Garlock, Inc.](#), 721 F.2d 1540 (Fed.Cir.1983). However, that case involved [35 U.S.C. §§ 102\(a\)](#) and [\(b\)](#), not [§ 102\(g\)](#), and the prior secret use was not by the alleged infringer but by a third party.

[FN21]. HYPERLINK "<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS103&FindType=L>" [35 U.S.C. § 103 \(1988\)](#).

[FN22]. HYPERLINK

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[FN23]. For a description of many countries' patent laws, see the four-volume loose-leaf compilation, *MANUAL FOR THE HANDLING OF APPLICATIONS FOR PATENTS, DESIGNS, AND TRADE MARKS THROUGHOUT THE WORLD*, originally compiled in 1936 and updated regularly.

[FN24]. For example, section 3 of the French Patent Act provides as follows:

Anyone who, on the filing [or priority] date of the patent application, was already in possession of the invention, in good faith and within France, will have a personal right to use the invention notwithstanding the existence of the patent being granted for the said invention. (Such right cannot arise during the priority interval.) A right emanating from prior use can only be assigned together with the enterprise with which the right is connected.

See 1 *OCTROOIBUREAU LOS EN STIGTER, MANUAL FOR THE HANDLING OF APPLICATIONS FOR PATENTS, DESIGNS, AND TRADE MARKS THROUGHOUT THE WORLD* at France 4-5 (Supp. 59, Mar. 198 & Supp. 61, Mar. 1990) [hereinafter *MANUAL*]. Also, section 12 of the German Patent Law provides as follows:

Personal rights of third parties (rights of prior use) are due to anybody who, at the time of filing of the application, was already using the invention within the Federal Republic of Germany, or had made the necessary arrangements for using the same ... Third party rights of prior use are only transferable together with the business. No rights of prior use can arise during the priority interval if the patentee is a national of a country granting reciprocity in this respect.

See *Id.* at Germany 8-9 (Supp. 65, Apr. 1992). Section 6 of the United Kingdom Patents Act of 1977 provides:

(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention—

(a) does in good faith an act which would constitute infringement of the patent if it were in force, or

(b) makes in good faith effective and serious preparation to do such an act, has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a license to another person to do the act.

See 3 *Id.* at United Kingdom 5 (Supp. 63, Mar. 1991).

[FN25]. For example, section 79 of the Japanese Patent Code provides:

When at the time of filing of a patent application ... a person who has made an invention by himself without knowledge of the contents of an invention claimed in the patent application or has learned how to make the invention from a person just referred to, has been commercially working the invention in Japan or has been making preparations therefor, such person shall have a non-exclusive license on the patent right under the patent application. Such license shall be limited to the invention which is being worked or for which preparations for working are being made and to the purpose of such working or the preparation therefor.

See 2 *Id.* at Japan 3 (Supp. 66, Sept. 1992).

[FN26]. In Australia, the prior user problem is handled through negation of the patentee's rights. Group Reports, Congress of AIPPI, 40-44, Doc. Q89D (June 4-10, 1989) [hereinafter *Group Reports*]. Section 100 of the Australian Patents Act of 1952 provides that a standard patent may be revoked if the invention "was secretly used in Australia before the priority date of the claim." *Id.* at 42-43. Revocation is justified where any secret uses other than trial or

experimental uses are established. Therefore, secret commercial uses can be used to invalidate the patent. *Id.* The Australian contingent supports the rule laid down in WIPO Article 308. *Id.* at 41-42.

[FN27]. See S. 2605, 102d Cong., 2d Sess. (1992); H.R. 4978, 102d Cong., 2d Sess. (1992). The Patent System Harmonization Act of 1992 was introduced April 9, 1992 by Representative William J. Hughes and Senator Dennis DeConcini, in preparation for joint hearings on April 30, 1992.

[FN28]. *Id.*

[FN29]. Some Europeans argue that one should be able to invest in a published invention because the public does not know whether a patent application has been filed or not. In a first-to-file system with a personal grace period, a published article is prior art to everyone except the author of the publication during the grace period. Europeans argue a first-to-file system with a grace period can become a first-to-publish system. They say that allowing derivation would drive inventors to file before publication, thus depriving the scientific community of early disclosure through publication. However, in our opinion, derivation will not be acceptable in the United States.

[FN30]. Observations of the International Bureau Following the First Part (1991) of the Diplomatic Conference, WIPO, ¶ 20, Doc. PLT/DC/69 (Jan. 29, 1993). [hereinafter Observations]

[FN31]. Observations, *supra* note 30, ¶ 20.C.

[FN32]. THE ADVISORY COMMISSION ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE (1992) [hereinafter ADVISORY COMMISSION REPORT].

[FN33]. *Id.* at 49.

[FN34]. Lisa M. Brownlee, Trade Secret Use of Patentable Inventions, Prior User Rights and Patent Law Harmonization: An Analysis and Proposal, 72 J.PAT. & TRADEMARK OFF.SOC'Y 523, 535 (1990).

[FN35]. In *Kewanee Oil v. Bicron Corp.*, the United States Supreme Court stated that patents and trade secrets "have co-existed in this country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other." HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1974127179&ReferencePosition=493" 416 U.S. 470, 493 (1974).

[FN36]. *Id.*

[FN37]. *Id.*

[FN38]. Secret prior users which would not jeopardize a patent issued under section 106 include any non-informing public use or secret uses, by others, prior to the applicant's filing date. However, under § 106(a)(3) pending patent applications are held "secret" for 18 months and may operate to anticipate a later filed application.

[FN39]. This is in contrast to our current law where the prior use of an invention would possibly invalidate a subsequent patent and revert the entire subject matter to the public domain. However, invalidation is merely a possibility under current United States law because a court might alternatively find that the prior user had abandoned, suppressed or concealed the invention. In that case, the patentee would retain a valid

patent—perhaps even as against the prior user.

[FN40]. Id.; see also [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1974127179&ReferencePosition=486"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1974127179&ReferencePosition=486) [Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 486 \(1974\)](#) (describing the policy behind the patent system as a reward-for-disclosure policy).

[FN41]. ADVISORY COMMISSION REPORT, supra note 32, at 49.

[FN42]. Id.

[FN43]. Id.; see also James A. Forstner, The U.S. and Patent Harmonization: Potential Problems and Benefits, 7 World Intell.Prop.Rep. (BNA) 20 (Jan.1993).

[FN44]. ADVISORY COMMISSION REPORT, supra note 32, at 49.

[FN45]. Id.; see also Chew, supra note 10.

[FN46]. ADVISORY COMMISSION REPORT, supra note 32, at 49.

[FN47]. Japan, Korea and Malaysia require only that the commercialization be before the application date (not the priority date). However, derivation from the applicant will void the prior user right. See generally MANUAL, supra note 24 (describing each country's patent laws).

[FN48]. See, e.g., Norbert Marterer, The Prior User's Right, 21 IIC, INT'L REV.INDUS.PROP. & COPYRIGHT L. 521, 522 (1990) (discussing Austrian patent law).

[FN49]. ADVISORY COMMISSION REPORT, supra note 32.

[FN50]. Id.

[FN51]. Id. at 50.

[FN52]. Id.

[FN53]. Id.

[FN54]. See 1 MANUAL, supra note 24, at Germany 8-9 (Supp. 65, Apr. 1992).

[FN55]. See 2 Id. at Japan 3 (Supp. 66, Sept. 1992).

[FN56]. See 1 Id. at France 4-5 (Supp. 59, Mar. 1989 & Supp. 61, Mar. 1990).

[FN57]. Id.

[FN58]. ADVISORY COMMISSION REPORT, supra note 32, at 50.

[FN59]. *Id.*

[FN60]. *Id.*

[FN61]. Memorandum of the International Bureau, Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, WIPO, 4th Sess., Doc. HL/CE/IV/INF/2, Annex II (November 2, 1987) [hereinafter Memorandum]. For example, jurisdictions are split as to whether the prior user rights should encompass a limited right to only the scope of the original use or preparation or a broader right to expand the use to satisfy the needs of the prior user's own business.

[FN62]. *Helitune Ltd. v. Stewart Huges Ltd.*, 1991 Fleet Street Reports 171, 206 (1991) (“provided a person carried out an infringing act before the priority [date of the patent in question], he can continue to carry out that act although the product or process might be different to some degree”).

[FN63]. ADVISORY COMMISSION REPORT, *supra* note 32.

[FN64]. Group Reports, Congress of AIPPI, Doc. Q89D (June 4-10, 1989).

[FN65]. *Id.* at 51.

[FN66]. *Id.* at 51-52.

[FN67]. See Charles R.B. Macedo, [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1430&FindType=Y&ReferencePositionType=S&SerialNum=0100961474&ReferencePosition=228"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1430&FindType=Y&ReferencePositionType=S&SerialNum=0100961474&ReferencePosition=228) First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?, 18 AIPLA Q.J. 193, 228 (1990).

[FN68]. See Patent Act, ch. 357, § 6, 5 Stat. 117 (1836).

[FN69]. Patent Act, ch. 11, § 1, 1 Stat. 318 (1793).

[FN70]. [HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1800105795&ReferencePosition=18"](http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1800105795&ReferencePosition=18) Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 18 (1829). In *Pennock*, Justice Story pondered, “[W]hat then is the true meaning of the words ‘not known or used before the application?’ ” They cannot mean that the thing invented was not known or used before the application by the inventor himself, for that would be to prohibit him from the only means of obtaining a patent.... The words, then, to have any rational interpretation, must mean, not known or used by others before the application. *Id.* at 18-19.

[FN71]. Patent Act, ch. 357, § 6, 5 Stat. 117 (1836).

[FN72]. The *Pennock* Court interpreted the policy behind section 1 of the Act of 1793 to be the prevention of commercial exploitation by inventors prior to their application for a patent. The Court reasoned as follows:

[T]hus construed, there is much reason for the limitation thus imposed by the Act.... If an

inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, ... and then, and then only, when the danger of competition should force him to secure the exclusive right, ... it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

[Pennock, 27 U.S. \(2 Pet.\) at 19.](#)

[FN73]. Patent Act, ch. 357, § 6, 5 Stat. 117 (1836).

[FN74]. See DONALD CHISUM, PATENTS § 6.02[1] n. 9 (1992).

[FN75]. Patent Act, ch. 88, § 7, 5 Stat. 353 (1839).

[FN76]. *Id.*

[FN77]. This clause thus recognizes simultaneously both the right that an inventor has to his own invention and the rights and duties for obtaining a patent.

[FN78].

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"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1800104873&ReferencePosition=205>" [McClurg v. Kingsland, 42 U.S. \(1 How.\) 202, 205-06 \(1843\).](#)

[FN79].

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"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&FindType=Y&SerialNum=1800104873>  
" [Id. at 204.](#)

[FN80].

See

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"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1800105795&ReferencePosition=14>" [Pennock v. Dialogue, 27 U.S. \(2 Pet.\) 1, 14 \(1829\).](#) In *Pennock*, the Court stated:

That if an inventor makes his discovery public, looks on, and permits others freely to use it, without objection or assertion of claim to the invention, of which the public might take notice; he abandons the inchoate right to the exclusive use of the invention, to which a patent would have entitled him, had it been applied for before such use, and that it makes no difference in the principle that the article so publicly used, and afterwards patented, was made by a particular individual who did so by the private permission of the inventor.

*Id.* at 14.

[FN81].

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"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1800104873&ReferencePosition=210>" [McClurg, 42 U.S. \(1 How.\) at 210.](#) The Court found no error in the jury instructions that provided "the authority to use [the invention] before the patent carried the right to continue to make and use it after the patent had issued." HYPERLINK  
"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&FindType=Y&SerialNum=1800104873>

" [Id. at 204, 210.](#)

[FN82]. The Court stated, "The use of the invention before an application for a patent must be the specific improvement then invented and used by the person who had purchased, constructed, or used the machine to which the invention is applied." HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&FindType=Y&SerialNum=1800104873" [" Id. at 210.](#)

[FN83]. HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=349&FindType=Y&SerialNum=1800127977" [Pierson v. The Eagle Screw Co., 3 Story 402, 19 F.Cas. 672 \(C.C.R.I.1844\)](#) (No. 11,156).

[FN84]. Twenty-nine years later the Supreme Court reversed Story's interpretation of section 7 and held that the prior user rights apply to all pre-application makings, whether or not with the first inventor's consent or allowance. HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&ReferencePositionType=S&SerialNum=1887180266&ReferencePosition=273" [Driven-Well Cases, 123 U.S. 267, 273 \(1887\).](#) In *Driven-Well*, the Court stated:

The first clause [of section 7] provides for the protection of a person who, prior to the application for the patent, purchases or constructs a specific machine or article, and declares that he may use and sell such specific machine or article after the patent is issued, without liability to the patentee. The section does not require, in order to this protection, that the purchase or construction shall have been with the consent or allowance of the person who afterwards obtains the patent and seeks to enforce it against such purchaser or constructor. The words "consent or allowance" are not found in the provision. The only requirement is that the specific machine or article shall have been purchased or constructed at some time prior to the application for a patent.

*Id.* Justice Story's interpretation, however, had already been adopted in the Patent Act of 1870 and was therefore still the law. See Patent Act, ch. 230, § 24, 16 Stat. 198 (1870).

[FN85]. HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=744&FindType=Y&ReferencePositionType=S&SerialNum=1800127977&ReferencePosition=406" [Pierson, 3 Story at 406-07](#) (noting that "it could never have been the intention of this clause to confer on a fraudulent purchaser, or a purchaser with full notice [of the prior invention], a right to use an invention pirated from the original inventor, by wrong.").

[FN86]. HYPERLINK "http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=780&FindType=Y&SerialNum=1858104481" [Kendall v. Winsor, 62 U.S. \(21 How.\) 322 \(1858\).](#)

[FN87]. Section 24 provided in relevant part:

That any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof, not known or used by others in this country, and not patented, or described in any printed publication in this or any foreign country, before his invention or discovery thereof, and not in public use or on sale for more than two years prior to his application, unless the same is proved to have been abandoned,

may ... obtain a patent thereof.

Patent Act, ch. 230, § 24, 16 Stat. 198 (1870) (later section 4886 of the Revised Statutes).

[FN88]. Section 37 provided in relevant part:

That every person who may have purchased of the inventor, or with his knowledge and consent may have constructed any newly invented or discovered machine, or other patentable article, prior to the application by the inventor or discoverer for a patent, or sold or used one so constructed, shall have the right to use, and vend to others to be used, the specific thing so made or purchased, without liability therefor.

Patent Act, ch. 230, § 37, 16 Stat. 198 (1870) (later section 4899 of the Revised Statutes) (repealed 1952). Section 37 was replaced by section 4899 of the Revised Statutes and later repealed in 1952 with a note in the Committee Report that it was “redundant and unnecessary” and that similar results would follow for “some other reason.” The other reasons were not explained in the committee notes. It is possible that these reasons included modern developments in shop rights, laches and estoppel. Because section 4899 was restricted to instances where the user had the knowledge and consent of the inventor, it is unlikely that the “some other reason” included interference law under [section 102\(g\)](#) of the 1952 Act.

[FN89]. Although section 7 prior user rights may no longer be available as a defense to infringement, a prior user is not without a remedy. In fact, the opposite is true. Without section 7, the patentee is left holding a potentially invalid patent. In short, we have replaced the statutory defense for infringement by prior users with a “winner-take-all” patent infringement/validity battle.

[FN90].

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"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L>" [Section 102](#) is entitled, “Conditions for patentability; novelty and loss of right to patent” (emphasis added). HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L>" [35 U.S.C. § 102](#). The applicant must satisfy the requirements of this section to receive a patent. Once the patent is granted, a presumption of validity attaches. HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS282&FindType=L>" [35 U.S.C. § 282](#) (1988). HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS282&FindType=L>" [Section 282](#) provides, however, that one defense to an infringement suit is the “invalidity of the patent or any claim in suit on any ground specified ... as a condition for patentability.” HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS282&FindType=L>" [35 U.S.C. § 282](#). Therefore, any of the conditions in HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS102&FindType=L>" [sections 102](#) and HYPERLINK

"<http://www.westlaw.com/Find/Default.wl?rs=CAMP1.0&vr=2.0&DB=1000546&DocName=35USCAS103&FindType=L>" [103](#) may be raised by the accused infringer.

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## **PRIOR USE AT THE EUROPEAN PATENT OFFICE AND IN THE MEMBER STATES OF THE EUROPEAN PATENT CONVENTION**

In Europe one needs to distinguish between a public prior use that can be used as prior art against another patent or patent application and prior user rights which stem from a secret prior use and cannot be used to invalidate a patent but which are suitable as a defence in infringement proceedings. The latter is not regulated in the European Patent Convention (EPC) and cannot play a part in proceedings before the European Patent Office (EPO). This is because the EPC explicitly states that the infringement of a European patent shall be dealt with by national law. Accordingly, the defence of prior use is regulated in the patent laws of the individual member states.

### Prior use at the EPC

Article 54(2) EPC provides that the state of the art shall comprise, *inter alia*, subject-matter which was made available to the public by prior use. The important point here is that the prior use must have been public which means that the use must (or could<sup>1</sup>) have become known to at least one person who was not under an obligation of confidentiality. For example, it would be sufficient as prior use to sell an article to a single person, provided that person is not under any obligation to maintain confidentiality.

Proving a disclosure by means of public use before the EPO imposes higher demands on the evidence of availability and the contents of the disclosure than for a written disclosure. In particular, it needs to be proven when and where the disclosure happened, what was disclosed, who disclosed it and how the disclosure took place (see, for example, the decisions by the Board of Appeal T93/89 and T194/86). In cases where practically all evidence in support of the public prior use lies with an opponent in opposition proceedings, all these points need to be proven beyond reasonable doubt (“up to the hilt”). In other words, the EPO generally imposes a very high standard to prove a public prior use.

While a public prior use is not a defence to an infringement *per se*, it does of course provide a defence in the sense that a defendant can assert that the claim which is alleged to be infringed is not valid.

### Prior user rights under national law in the EPC member states

Unlike the EPC, the national law of the EPC member states explicitly provides for a defence of secret prior use. For instance, in the UK, the statute says that a person who performed an act or made “serious and effective preparations<sup>2</sup>” to do an act before the filing date of an application that

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<sup>1</sup> The fact that something could have become known is also sufficient as a disclosure. For example, the availability of a product in a shop constitutes a public disclosure even if nobody bought the product.

<sup>2</sup> The meaning of this expression has caused some difficulties in the courts. However, it is generally accepted that it means acts which were about to be commenced by the priority date of the other party’s application but which had not actually commenced.

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would be considered an infringement of a patent deriving from the application (had it been in force at the time) has the right to continue.

There are a number of restrictions which make these prior user rights very narrow. For instance, the act must have been performed within the member state. Thus, for example, if someone used a process secretly in the US before the priority date of the application and starts using it in the UK only after the application has been filed then that person could not rely on prior user rights and would be liable for infringement.

The statute also requires the act to be carried out in “good faith”. Thus, any acts are excluded from prior user rights which occurred as a result of breach of confidence or knowledge of the invention which has been illicitly obtained.

Prior user rights also only give the party the right to “continue the act”. This means that a party is not allowed to go beyond the act which was performed before the application was filed. This was confirmed, for example, by the German Supreme Court which held that prior user rights do not confer the right to use further developments going beyond the prior use. In other words, where the act was the sale of a product, a party is allowed continue selling that product but is not allowed to make significant modifications to the product.

A further limitation of the rights is that only the person who performed the act is allowed to continue it and that person is not allowed to license anyone else to do it. A party may, however, authorise business partners to use the invention and prior user rights may also be assigned or bequeathed as part of the business or a part thereof.

In court proceedings, the national courts generally apply a lower standard of proof for establishing prior user rights than the EPO’s “up to the hilt” principle. Thus, courts will often accept a statement by a party in infringement proceedings that an act giving rise to prior user rights was performed before the priority date of an application.

**PATENT AND COPYRIGHT TERM EXTENSION AND THE  
CONSTITUTION: A HISTORICAL PERSPECTIVE\***

by TYLER T. OCHOA\*\*

*The U.S. Constitution provides that patents and copyrights may only be granted “for limited Times.” This article analyzes the constitutionality of the Sonny Bono Copyright Term Extension Act of 1998 (CTEA) in light of the long history of congressional extensions of patents and copyrights. Congress has retroactively extended copyrights each time it has changed the basic term, a practice that has gone unchallenged until now; but only two copyrights have been extended by private legislation, and one of those extensions was invalidated as a violation of the Establishment Clause. By contrast, patents have been extended fewer times by general legislation, but many more times by private legislation. Between 1809 and 1874 (and again in 1962), many of those private patent term extensions were challenged in court as unconstitutional on various grounds, and all were upheld. Except for a single summary affirmance, however, none of these decisions were rendered by the U.S. Supreme Court; and the meaning of the phrase “for limited Times” was never expressly addressed or settled. (Congress has also extended many design patents on the insignia of various patriotic organizations, but the author concludes that these extensions are more properly treated as trademark legislation.)*

*The U.S. Supreme Court recently granted certiorari to review the two opinions of the D.C. Circuit in *Eldred v. Reno* and *Eldred v. Ashcroft*, upholding the constitutionality of the CTEA. The view of the Patent and Copyright Clause expressed in those opinions, that Congress may extend a patent or copyright for any finite term it chooses, does violence to the language and purpose of the*

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Clause, as it has been interpreted by the U.S. Supreme Court in recent decades. The alternative position that retroactive term extension is absolutely forbidden by the Clause has an appealing simplicity, but it is difficult to maintain in light of the long history of patent term extensions which were upheld in the mid-nineteenth century. A closer examination of those extensions, however, suggests an intermediate position: that Congress may extend patent and copyright terms in limited circumstances, in order to vindicate the expectation interest of authors and inventors who, for reasons beyond their control (such as war, judicial corruption, administrative error or delay in FDA approval), did not receive the term of years promised to them at the time the patent or copyright was granted. That position, however, does not support the indiscriminate twenty-year term extension provided by the CTEA.

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I. INTRODUCTION

On February 12, 1924, George Gershwin’s *Rhapsody in Blue* was played for the first time, to instant acclaim, at a concert of jazz music conducted by Paul Whiteman at Aeolian Hall in New York.<sup>1</sup> Following a concert tour by the Whiteman band, the work was recorded<sup>2</sup> and published,<sup>3</sup>

<sup>1</sup> DAVID SCHIFF, GERSHWIN: RHAPSODY IN BLUE 55, 61-62 (1997); EDWARD JABLONSKI, GERSHWIN 61, 72-75 (1988).

<sup>2</sup> The concert was repeated at Aeolian Hall on Mar. 7, at Carnegie Hall on Apr. 21, and in May in Rochester, Pittsburgh, Cleveland, Indianapolis and St. Louis. The work was recorded in New York in June. JABLONSKI, *supra*

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and it quickly became one of the most popular and successful works of American music ever written.

One may question whether Gershwin needed any financial incentive to compose the *Rhapsody in Blue* other than the substantial fees he received to perform the work.<sup>4</sup> It is clear, however, that Gershwin had an additional financial incentive: copyright. Under the terms of the 1909 Copyright Act which was then in effect, upon publication of the work and registration of the copyright with the U.S. Copyright Office, Gershwin was entitled to receive royalties for all copies, recordings and public performances of *Rhapsody in Blue* for an initial term of twenty-eight years.<sup>5</sup> If the work was successful (as it proved to be),<sup>6</sup> the copyright could be renewed once for an additional twenty-eight years.<sup>7</sup> Thus, at the time he composed the *Rhapsody in Blue*, Gershwin was assured by law that he or his heirs could continue to receive any royalties earned from the commercial exploitation of the work for a maximum duration of fifty-six years. After that, *Rhapsody in Blue* would enter the public domain, where it could be freely copied, recorded and performed by anyone wishing to do so.

Upon publication of the *Rhapsody in Blue*, the financial incentive provided to Gershwin by copyright law had served its constitutionally-mandated purpose. The Copyright and Patent Clause of the Constitution gives Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>8</sup> By granting the authors of new works the exclusive right to publish and perform them for up to fifty-six years, the 1909 Act encouraged the creation of new works of

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note 1, at 75. The recording sold a million copies. SCHIFF, *supra* note 1, at 62.

<sup>3</sup> The work is published in several different editions: for two pianos (Gershwin’s original), for piano and jazz band (arranged for the Whiteman band by Ferde Grofe), for piano and orchestra (orchestrated by Grofe), and for solo piano. SCHIFF, *supra* note 1, at 4-6.

<sup>4</sup> Gershwin performed the *Rhapsody* eleven times in 1924. JABLONSKI, *supra* note 1, at 77-78.

<sup>5</sup> Former 17 U.S.C. § 1(a) (exclusive right to publish and sell the copyrighted work); § 1(e) (exclusive right to publicly perform for profit and to make mechanical reproductions of musical compositions); § 23 (twenty-eight-year initial term) (1909; repealed eff. Jan. 1, 1978).

<sup>6</sup> It is estimated that “the royalties from sale of sheet music, records, and other subsidiary rights gathered more than a quarter of a million dollars in a decade.” DAVID EWEN, *A JOURNEY TO GREATNESS: THE LIFE AND MUSIC OF GEORGE GERSHWIN* 115 (1956). Gershwin was paid \$50,000 alone for the right to use the music in the motion picture *The King of Jazz* (1930). JABLONSKI, *supra* note 1, at 183.

<sup>7</sup> Former 17 U.S.C. § 23 (1909; repealed eff. Jan. 1, 1978).

<sup>8</sup> U.S. CONST. art. I, § 8, cl. 8.

authorship like the *Rhapsody in Blue*. At the same time, the law of copyright assured that the work would enter the public domain by the year 1980, and thereby continue to promote the creation of new works by providing raw material for other authors and composers to draw upon in fashioning new works of their own.<sup>9</sup> Composers wishing to pay homage to Gershwin could quote from the *Rhapsody* or make new arrangements of it without fear of liability for copyright infringement.<sup>10</sup> Placing the work in the public domain would also allow the free market to provide multiple editions of the *Rhapsody in Blue*, which would have the effect of lowering the price of the work to the public,<sup>11</sup> allowing many smaller orchestras who could not otherwise afford to perform the *Rhapsody* to bring this popular work to their communities.

George Gershwin died in 1937, but his estate continued to benefit from the copyrights he had obtained on works published during (and after) his lifetime. The heirs of the Gershwin estate, however, were unhappy with the copyright bargain that their illustrious and productive relative had accepted. In the 1960s, they joined many other publishing and authors' rights organizations in lobbying Congress to rewrite the rules of the copyright game and to give the new rules retroactive effect. Their efforts bore fruit in the Copyright Act of 1976, which granted a nineteen-year extension of the renewal term of all copyrights registered before January 1, 1978.<sup>12</sup> New works created on or after that date would receive a single copyright term, instead of an initial and a renewal term, and would enter

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<sup>9</sup> See Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965, 966-67 (1990) ("the very act of authorship in any medium is more akin to translation and recombination than it is to creating Aphrodite from the foam of the sea. Composers recombine sounds they have heard before . . . [and] all [authors] engage in the process of adapting, transforming, and recombining what is already 'out there' in some other form. This is not parasitism; it is the essence of authorship.").

<sup>10</sup> For musical examples, listen to JOHANNES BRAHMS, VARIATIONS ON A THEME BY HAYDN (1873); SERGEI RACHMANINOFF, RHAPSODY ON A THEME OF PAGANINI (1934); OTTORINO RESPIGHI, LA BOUTIQUE FANTASTIQUE (1919) (based on music of Rossini); JOAQUIN RODRIGO, FANTASIA PARA UN GENTILHOMBRE (1954) (based on music of Gaspar Sanz); IGOR STRAVINSKY, PULCINELLA (1920) (based on music of Pergolesi); and RALPH VAUGHAN WILLIAMS, FANTASIA ON A THEME OF THOMAS TALLIS (1910).

<sup>11</sup> A study of published works of classical music by Luck's Music Library demonstrates the benefit to the public of placing works in the public domain. For example, during the copyright term the publisher of Gustav Holst's *THE PLANETS* (1916) charged a community orchestra \$815 for two performances; after the work entered the public domain, it could be purchased for \$300 and performed an unlimited number of times without any additional charge. See <http://www.law.asu.edu/HomePages/Karjala/OpposingCopyrightExtension/letters/Luck'sMusic01.html> (last visited Oct. 31, 2001).

<sup>12</sup> Former 17 U.S.C. § 304 (1976; amended 1998).

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the public domain fifty years after the author's death.<sup>13</sup> Although the nineteen-year extension afforded to existing works was difficult to justify in terms of the incentive rationale for copyright, it was generally accepted as part of a comprehensive revision of U.S. copyright law that codified many important principles that had been judicially recognized under the 1909 Act<sup>14</sup> and harmonized the terms of future copyrights with the life-plus-fifty year term required by the Berne Convention.<sup>15</sup> Under the 1976 Act, Gershwin's heirs would continue to receive royalties from the *Rhapsody in Blue* until December 31, 1999.<sup>16</sup> The dawning of Y2K would place this musical landmark of the twentieth century in the public domain.

In the 1990s, however, having become accustomed to the affluent lifestyle afforded them by royalties they themselves did nothing to earn, the heirs of Gershwin and other popular songwriters were back in Congress,<sup>17</sup> together with music publishers and motion picture companies,<sup>18</sup> lobbying for yet another extension of copyright terms. Once again, they were successful: on October 27, 1998, President Clinton signed into law the Sonny Bono Copyright Term Extension Act of 1998,<sup>19</sup> which added an additional twenty years to the terms of all existing and future copyrights. Under this legislation, the copyright on *Rhapsody in Blue* will not expire until December 31, 2019; and it is not difficult to predict that if this latest round of copyright term extension is upheld by the courts, the heirs of the Gershwin estate will be back in Congress in another twenty years, seeking

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<sup>13</sup> Former 17 U.S.C. § 302 (1976; amended 1998).

<sup>14</sup> See, e.g., 17 U.S.C. § 102(a) (2000) (limiting copyright to "original works of authorship"); *Id.* § 107 (2000) (fair use).

<sup>15</sup> See Berne Convention for the Protection of Literary and Artistic Works, July 24, 1971 (Paris Revision), art. 7(1). The U.S. eventually adhered to the Berne Convention, effective Mar. 1, 1989. See Berne Convention Implementation Act of 1988, Pub. L. No. 100-568, 102 Stat. 2853.

<sup>16</sup> 17 U.S.C. § 305 (2000) extends all copyright terms to the end of the year in which they would otherwise expire.

<sup>17</sup> See William F. Patry, *The Failure of the American Copyright System: Protecting the Idle Rich*, 72 NOTRE DAME L. REV. 907, 932 (1997) ("The real impetus for term extension comes from a very small group: children and grandchildren of famous composers whose works are beginning to fall into the public domain, thereby threatening trust funds. These estates have considerable political and financial impact with ASCAP, the music performing rights collecting society. It is ASCAP and . . . [BMI] who are pushing term extension.").

<sup>18</sup> See Jonathan P. Decker, *Of Mice and (Congress)Men*, FORTUNE, Nov. 23, 1998, at 44 (discussing lobbying by Disney and the Motion Picture Association of America, including campaign contributions paid to the sponsors of copyright term extension); *Disney Lobbying for Copyright Extension No Mickey Mouse Effort*, CHI. TRIB., Oct. 17, 1998, at 22 (same).

<sup>19</sup> Pub. L. No. 105-298, 112 Stat. 2827 (1998).

yet another extension of copyright terms, at the expense of the public domain.

This latest round of copyright term extension has not gone unchallenged, however. On January 11, 1999, Eric Eldred, an individual who publishes public domain works on the Internet, filed suit against U.S. Attorney General Janet Reno in the U.S. District Court for the District of Columbia, seeking a judicial declaration that the Sonny Bono Copyright Term Extension Act is unconstitutional.<sup>20</sup> Eldred was later joined by nine other plaintiffs seeking to overturn the Act, on the ground that it violates the “limited Times” provision of the Copyright Clause and the First Amendment.<sup>21</sup> Both the District Court and the Court of Appeals have now rejected Eldred’s challenge, and the U.S. Supreme Court has granted certiorari to review those decisions.<sup>22</sup>

It is not the purpose of this article to evaluate the wisdom (or lack thereof) of Congress’ decision to extend copyright terms by twenty years.<sup>23</sup> That issue has already been discussed thoroughly in the legal literature.<sup>24</sup> Nor will this article discuss whether the Constitution places

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<sup>20</sup> Complaint, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), available at [http://cyber.law.harvard.edu/eldredvreno/complaint\\_orig.html](http://cyber.law.harvard.edu/eldredvreno/complaint_orig.html) (last visited Oct. 31, 2001).

<sup>21</sup> Second Amended Complaint, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), available at [http://cyber.law.harvard.edu/eldredvreno/complaint\\_amd2.html](http://cyber.law.harvard.edu/eldredvreno/complaint_amd2.html) (last visited Oct. 31, 2001).

<sup>22</sup> See *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), *aff’d*, 239 F.3d 372 (D.C. Cir. 2001), *petition for reh’g and reh’g en banc denied sub nom. Eldred v. Ashcroft*, 255 F.3d 849 (D.C. Cir. 2001), *petition for cert. granted*, 70 U.S.L.W. 3324 (U.S. Feb. 19, 2002) (No. 01-618).

<sup>23</sup> In the interest of full disclosure, the author notes that he was one of sixty professors who signed a statement written by Prof. Dennis J. Karjala of Arizona State University, opposing the enactment of the Copyright Term Extension Act. See Statement of Copyright and Intellectual Property Law Professors in Opposition to H.R. 604, H.R. 2589, and S. 505 (1998), available at <http://www.law.asu.edu/HomePages/Karjala/OpposingCopyrightExtension/legmats/1998Statement.html> (last visited Oct. 31, 2001).

<sup>24</sup> See, e.g., ROBERT L. BARD & LEWIS KURLANTZICK, *COPYRIGHT DURATION: DURATION, TERM EXTENSION, THE EUROPEAN UNION, AND THE MAKING OF COPYRIGHT POLICY* (1998); Hank Brown & David Miller, *Copyright Term Extension: Sapping American Creativity*, 44 J. COPYR. SOC’Y 94 (1996); Lisa M. Brownlee, *Recent Changes in the Duration of Copyright in the United States and European Union: Procedure and Policy*, 6 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 579 (1996); Shauna C. Bryce, *Life Plus Seventy: The Extension of Copyright Terms in the European Union and Proposed Legislation in the United States*, 37 HARV. INT’L L.J. 525 (1996); Jenny L. Dixon, Note, *The Copyright Term Extension Act: Is Life Plus Seventy Too Much?*, 18 HASTINGS COMM/ENT L.J. 945 (1996); Jerome N. Epping, Jr., Comment, *Harmonizing the United States and European Community Copyright Terms: Needed Adjustment or Money for Nothing?*, 65 U. CIN. L. REV.

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any outer limit on the duration of copyright protection for new works. Instead, this article will focus on one of the principal questions raised in *Eldred v. Reno*: whether the Sonny Bono Copyright Term Extension Act is unconstitutional as applied retroactively to existing copyrights.<sup>25</sup>

Should the Supreme Court decide to consider this question, it will not be writing on a clean slate. Although prior to *Eldred v. Reno* the issue of copyright term extension was never addressed in a published decision, there are a number of nineteenth-century decisions upholding various patent term extensions granted to inventors by Congress by means of special legislation.<sup>26</sup> In evaluating the arguments presented in *Eldred v. Reno*, therefore, the first question must be: has the constitutional validity of term extension under the Patent and Copyright Clause already been established? Or is there some way to distinguish *Eldred v. Reno* from the line of cases that apparently settled this question more than a century ago?

Part II of this article will review the history of copyright term extension legislation. This history shows that Congress has retroactively extended existing copyrights each time it has changed the basic term, a practice that has gone unchallenged until now. In contrast, only two copy-

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183 (1996); Marci A. Hamilton, *Copyright Duration Extension and the Dark Heart of Copyright*, 14 CARDOZO ARTS & ENT. L.J. 655 (1996); Joseph A. Lavigne, Comment, *For Limited Times? Making Rich Kids Richer Via the Copyright Term Extension Act of 1996*, 73 U. DETROIT-MERCY L. REV. 311 (1996); Arthur R. Miller, *Copyright Term Extension: Boon for American Creators and the American Economy*, 45 J. COPYR. SOC'Y 319 (1998); Patry, *Protecting the Idle Rich*, *supra* note 17, at 923-33; William F. Patry, *The Copyright Term Extension Act of 1995: Or How Publishers Managed to Steal the Bread from Authors*, 14 CARDOZO ARTS & ENT. L.J. 661 (1996); J.H. Reichman, *The Duration of Copyright and the Limits of Cultural Policy*, 14 CARDOZO ARTS & ENT. L.J. 625 (1996).

<sup>25</sup> With a few notable exceptions, most commentators agree that retroactive copyright term extension violates the Patent and Copyright Clause. See Michael H. Davis, *Extending Copyright and the Constitution: "Have I Stayed Too Long?"*, 52 FLA. L. REV. 989 (2000); Christina M. Gifford, Note, *The Sonny Bono Copyright Term Extension Act*, 30 U. MEM. L. REV. 363 (2000); Richard B. Graves III, *Private Rights, Public Uses and the Future of the Copyright Clause*, 80 NEB. L. REV. 64 (2001); Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119; Lavigne, *supra* note 24, at 352-58; Robert Patrick Merges & Glenn Harlan Reynolds, *The Proper Scope of the Copyright and Patent Power*, 37 HARV. J. ON LEGIS. 45 (2000); Edward C. Walterscheid, *Defining the Patent and Copyright Term: Term Limits and the Intellectual Property Clause*, 7 J. INTELL. PROP. L. 315 (2000); see also Symposium: Jane C. Ginsburg, Wendy J. Gordon, Arthur R. Miller & William F. Patry, *The Constitutionality of Copyright Term Extension: How Long is Too Long?*, 18 CARDOZO ARTS & ENT. L.J. 651 (2000) (panel debate).

<sup>26</sup> See notes 235-321 and accompanying text.

rights have been extended by private legislation, and one of those extensions was invalidated as a violation of the Establishment Clause. Part III will review the history of patent term extension legislation. This history shows that patents have been extended fewer times by general legislation, but many more times by private legislation. Many of these private patent term extensions were challenged in court as unconstitutional, and all were upheld. Part III-B will discuss several private design patent extensions passed by Congress, and will conclude that these extensions are more properly treated as private trademark legislation. Part III-C will examine the Patent and Copyright Clause in light of this history, and will analyze three possible interpretations of the Clause. This section demonstrates that most of the private patent term extensions can be justified as restoring to the inventor the period of years which he or she had expected to receive under the general patent law, but which had been lost due to circumstances beyond the inventor's control. Finally, Part IV will evaluate the arguments made in *Eldred v. Reno* in light of this legislative and judicial history.

## II. COPYRIGHT TERM EXTENSION

### A. General Laws

The first copyright statute, commonly known as the Statute of Anne, was adopted in England in 1710.<sup>27</sup> It provided for an initial term of fourteen years from the date of first publication of a new book;<sup>28</sup> and if the author was living at the expiration of the first term, the copyright could be renewed for another fourteen years.<sup>29</sup> Books that had previously been published were given a single term of twenty-one years.<sup>30</sup> After that time,

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<sup>27</sup> An Act for the Encouragement of Learning, by Vesting the Copies of Printed Books in the Authors or Purchasers of such Copies, during the Times therein mentioned, 8 Anne ch. 19 (1710) (Eng.). For a history of the origins of the Statute of Anne, see PAUL GOLDSTEIN, *COPYRIGHT'S HIGHWAY: FROM GUTENBERG TO THE CELESTIAL JUKEBOX* 39-43 (1994); 1 WILLIAM F. PATRY, *COPYRIGHT LAW AND PRACTICE* 3-11 (1994); or BENJAMIN KAPLAN, *AN UNHURRIED VIEW OF COPYRIGHT* 2-7 (1967).

<sup>28</sup> “[T]he author of any book or books already composed, and not printed or published, or that shall hereafter be composed, and his assignee or assigns, shall have the sole liberty of printing and reprinting such book and books for the term of fourteen years, to commence from the day of the first publishing the same, and no longer.” 8 Anne ch. 19 (1710) (Eng.).

<sup>29</sup> “Provided always, that after the expiration of the said term of fourteen years, the sole right of printing or disposing of copies shall return to the authors thereof, if they are then living, for another term of fourteen years.” *Id.*

<sup>30</sup> “[T]he author of any book or books already printed, who hath not transferred to any other the copy or copies of such book or books, share or shares thereof, or the bookseller or booksellers, printer or printers, or other person or persons, who hath or have purchased or acquired the copy or copies

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the work passed into the public domain, and could be freely copied by anyone.<sup>31</sup>

After the American colonies gained their independence from Great Britain, the new Continental Congress passed a resolution encouraging the States “to secure to the authors or publishers of any new books not hitherto printed . . . the copy right of such books for a certain time not less than fourteen years from the first publication; and to secure to the said authors, if they shall survive the term first mentioned, . . . the copy right” of such books for another term of time not less than fourteen years.<sup>32</sup> Three states had already enacted copyright statutes,<sup>33</sup> and within three years, nine other states followed suit.<sup>34</sup> Seven of the States followed the Statute of Anne and the Continental Congress’ resolution in providing two fourteen-year terms.<sup>35</sup> The five remaining States granted copyrights

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of any book or books, in order to print or reprint the same, shall have the sole right and liberty of printing such book or books for the term of one and twenty years, to commence from said tenth day of April, and no longer.”  
*Id.*

<sup>31</sup> It was not immediately obvious that this was the effect of the expiration of the statutory copyright. Printers and booksellers who had enjoyed exclusive rights under the statute attempted to argue that a perpetual copyright existed at common law, and that the Statute of Anne did not divest this common-law copyright but merely provided additional remedies. In the famous case of *Donaldson v. Beckett*, 4 Burr. 2408, 98 Eng. Rep. 257 (H.L. 1774), however, the House of Lords rejected this argument, holding that although the author of an unpublished manuscript had a common-law right of first publication, no common-law copyright existed after the work was published; and therefore that upon the expiration of the period provided by the Statute of Anne, any publisher could publish a competing copy of a previously copyrighted book. See Howard F. Abrams, *The Historic Foundation of American Copyright Law: Exploding the Myth of Common-Law Copyright*, 29 WAYNE L. REV. 1119, 1156-71, 1188-91 (1983).

<sup>32</sup> Resolution of May 2, 1783, reprinted in COPYRIGHT OFFICE BULLETIN No. 3, COPYRIGHT ENACTMENTS OF THE UNITED STATES, 1783-1906 (2d ed. 1906), at 11 [hereinafter COPYRIGHT ENACTMENTS].

<sup>33</sup> *Id.* at 11-16 (Connecticut, Massachusetts and Maryland).

<sup>34</sup> *Id.* at 16-31. In compiling these state statutes in 1906, the Register of Copyrights noted that “No copyright law seems to have been enacted by the State of Delaware.” *Id.* at 31.

It has been noted that Noah Webster played a significant role in the development of American copyright law by traveling from state to state to encourage the state legislatures to pass copyright legislation. See Irah Donner, *The Copyright Clause of the U.S. Constitution: Why Did the Framers Include It With Unanimous Approval?*, 36 J. AM. LEGAL HIST. 361, 370-71 (1992).

<sup>35</sup> Connecticut, Georgia, Maryland, New Jersey, New York, Pennsylvania, and South Carolina. See Francine Crawford, *Pre-Constitutional Copyright Statutes*, 23 BULL. COPYRIGHT SOC’Y 11, 21-22 (1975). Crawford erroneously asserts that “South Carolina did not legislate any renewal rights for anyone

for single terms of fourteen,<sup>36</sup> twenty,<sup>37</sup> and twenty-one<sup>38</sup> years' duration, with no right of renewal.

At the Constitutional Convention of 1787, both Charles C. Pinckney of South Carolina and James Madison of Virginia submitted proposals to give Congress the power to grant patents and copyrights.<sup>39</sup> The proposals were referred to the Committee of Eleven, which drafted the Patent and Copyright Clause as it exists today, and recommended its adoption.<sup>40</sup> The clause was approved by the delegates with no debate.<sup>41</sup> The only significant mention of the Clause in the subsequent ratification debates came in the *Federalist No. 43*, authored by James Madison:

The utility of this power will scarcely be questioned. The copy right of authors has been solemnly adjudged in Great Britain to be a right at Common Law. The right to useful inventions seems with equal reason to belong to the inventors. The public good coincides in both cases with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point by laws passed at the instance of Congress.<sup>42</sup>

From this scarce record, it is difficult to determine the meaning that the Framers attached to the phrase "for limited Times."<sup>43</sup> Several scholars,

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under any circumstances," *id.* at 22; but the legislation as passed clearly authorizes a fourteen-year renewal term. See Act of Mar. 26, 1784 (South Carolina), reprinted in COPYRIGHT ENACTMENTS, *supra* note 32, at 24.

<sup>36</sup> Crawford, *supra* note 35, at 22 (North Carolina).

<sup>37</sup> *Id.* at 23 (New Hampshire).

<sup>38</sup> *Id.* (Massachusetts, Rhode Island, and Virginia).

<sup>39</sup> Karl Fenning, *The Origin of the Patent and Copyright Clause of the Constitution*, 17 GEO. L. J. 109, 109-13 (1925). It is noteworthy that each of these proposals specified that patents and copyrights should be granted only for "a limited time" or "a certain time." *Id.* at 112-13.

<sup>40</sup> WALTERSCHEID, *infra* note 190, at 49.

<sup>41</sup> Fenning, *supra* note 39, at 114. For one historian's explanation for the unusual unanimity of the delegates on this subject, see Donner, *supra* note 34, at 361-78.

<sup>42</sup> JAMES MADISON, THE FEDERALIST NO. 43, at 279 (Modern Library ed. 1941). See also Donner, *supra* note 34, at 376-77 (quoting statements of Thomas McKean of Pennsylvania and James Iredell of North Carolina in support of the Clause).

<sup>43</sup> It is interesting to note that in recording Pinckney's proposal, Madison initially wrote "for a limited time," then crossed out the word "limited" and wrote in the word "certain." One commentator states that "[n]othing is known about the reason for this change." 1 PATRY, *supra* note 27, at 23 n.68. Two others argue that from the use of the word "certain" here and in the 1783 Continental Congress Resolution, "it seems clear that 'limited' also implies 'certain' — a term of copyright determined by a set numerical span of years, as was already the accepted practice in the states." Oscar Cargill & Patrick

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however, have pointed out that the Framers were strongly opposed to the granting of monopolies.<sup>44</sup> Patents and copyrights were exceptions to this opposition, but they were exceptions which needed to be carefully limited in order to prevent Congress from enacting more pernicious monopolies.<sup>45</sup> This accounts for the unusual fact that the Patent and Copyright Clause is the only clause which includes both a grant of power and the specific means by which that power was to be exercised.<sup>46</sup>

That insight, however, does not by itself supply a precise meaning for the phrase “for limited Times.” Perhaps the best evidence of the meaning of the phrase, therefore, is the first legislation passed under its authority.<sup>47</sup> The Patent Act of 1790 granted patents for a maximum term of fourteen years;<sup>48</sup> and the Copyright Act of 1790 granted copyrights for a term of “fourteen years from the time of recording the title thereof”;<sup>49</sup> with a right of renewal “for the further term of fourteen years” if the author survived

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A. Moran, *Copyright Duration v. The Constitution*, 17 WAYNE L. REV. 917, 927 (1971). Cargill and Moran therefore conclude that a copyright term of variable duration, based upon the life of the author, is unconstitutional. *Id.* at 927-28. Even accepting their premise that “limited” and “certain” were considered interchangeable, however, the argument is far from compelling. Compare 1 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 1.05[A][1], at 1-66.15 (2001 rev.) (life-plus-fifty term “in itself raises no constitutional problem under the ‘limited times’ limitation.”).

<sup>44</sup> See Heald & Sherry, *supra* note 25, at 1143-46, 1150; Walterscheid, *supra* note 25, at 318-46; Malla Pollack, *Purveyance and Power, or Over-Priced Free Lunch: The Intellectual Property Clause as an Ally of the Takings Clause in the Public’s Control of Government*, 30 SW. L. REV. 1, 106-12 (2000).

<sup>45</sup> See Heald & Sherry, *supra* note 25, at 1160-61; Walterscheid, *supra* note 25, at 318-19. The Framers may have been aware that Parliament had in 1775 granted ten colleges and universities perpetual copyrights to the King James Bible and several other works. 1 PATRY, *supra* note 27, at 175-76.

<sup>46</sup> See Heald & Sherry, *supra* note 25, at 1153; Walterscheid, *supra* note 25, at 316.

<sup>47</sup> See *Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 53, 57 (1884) (“The construction placed upon the constitution by the first act of 1790 . . . , by the men who were contemporary with its formation, many of whom were members of the convention which framed it, is of itself entitled to very great weight”). In the First Congress, ten of twenty-six Senators and nine of sixty-six Representatives were delegates at the Constitutional Convention of 1787. See 1 1787: DRAFTING THE CONSTITUTION 21-25 (Wilbourne E. Benton ed., 1986) (listing delegates); BIOGRAPHICAL DIRECTORY OF THE UNITED STATES CONGRESS, 1774-1989, 51-52 (1989) (listing members of First Congress).

<sup>48</sup> An Act to promote the progress of useful Arts, §1, 1 Stat. 109, 110 (Apr. 10, 1790).

<sup>49</sup> An Act for the encouragement of learning, §1, 1 Stat. 124 (May 31, 1790). The Act required that the copyright be registered “in the clerk’s office of the district court where the author or proprietor shall reside.” *Id.*, §3, 1 Stat. 125.

to the end of the first term.<sup>50</sup> Significantly, the first copyright act granted copyrights to the domestic authors of “any map, chart, book or books *already printed* within these United States” as well as to the domestic authors of “any map, chart, book or books already made and composed, but not printed or published, or that shall hereafter be made and composed.”<sup>51</sup> Thus, it appears that the First Congress was concerned not only with encouraging the creation and publication of new works, but also with rewarding the authors of works that had previously been published. Given that these works could have qualified for similar copyright protection under the English Statute of Anne<sup>52</sup> or under the laws of twelve of the thirteen original states,<sup>53</sup> however, this provision can be justified as a transitional measure, designed to ensure that no author was deprived of the term that he or she had been promised under previous legislation.<sup>54</sup>

In 1831, Congress undertook to revise the copyright laws. The 1831 Act granted a copyright to the authors of “any book or books, map, chart, or musical composition, which may be now made or composed, and not printed and published, or shall hereafter be made and composed . . . for the term of twenty-eight years from the time of recording the title thereof”;<sup>55</sup> with a right of renewal “for the further term of fourteen years.”<sup>56</sup> In addition, Section 16 of the 1831 Act extended the term of all existing copyrights:

for such additional period of time as will, together with the time which shall have elapsed from the first entry of such copyright, make up the term of twenty-eight years, with the same right to

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<sup>50</sup> *Id.*, § 1, 1 Stat. 124.

<sup>51</sup> *Id.*

<sup>52</sup> *But see* Heald & Sherry, *supra* note 25, at 1146 (noting uncertainty as to “whether the Statute of Anne was applicable at all to the colonies.”).

<sup>53</sup> Although “[f]ew authors . . . took advantage of the colonial statutes,” 1 PATRY, *supra* note 27, at 21, it is clear that some copyrights were in fact granted by the states, contrary to the suggestion of one recent scholar. Compare G. Thomas Tanselle, *Copyright Records and the Bibliographer*, 22 STUDIES IN BIBLIOGRAPHY 77, 81-85 (1969) (identifying state copyright records listing approximately forty books) with Walterscheid, *supra* note 25, at 349 n.136 (“I have been unable to find a reference to any copyright issued under these state statutes.”).

<sup>54</sup> *See* Heald & Sherry, *supra* note 25, at 1151 (arguing that “retroactive protection in the *first* copyright act was uniquely justified by several considerations.”) (emphasis in original).

<sup>55</sup> An Act to amend the several acts respecting copy rights, § 1, 4 Stat. 436 (Feb. 3, 1831). The same term was also granted to the authors of new prints and engravings. *Id.*

<sup>56</sup> Copyright Act of 1831, § 2, 4 Stat. 436. The right of renewal was extended for the first time to the author’s heirs, if the author died before the end of the first term. *Id.*

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his widow, child, or children, to renew the copyright, at the expiration thereof, as is above provided in relation to copyrights originally secured under this act. . . . *Provided*, That this act shall not extend to any copyright heretofore secured, the term of which has already expired.<sup>57</sup>

With this first general revision, therefore, Congress established a precedent of extending the terms of all copyrights that had not yet expired, but declining to revive the copyrights in works that had already fallen into the public domain.<sup>58</sup>

The legislative history of the 1831 Act reveals that one of its principal purposes was “to enlarge the period for the enjoyment of copy-right, and thereby to place authors in this country more nearly upon an equality with authors in other countries.”<sup>59</sup> Congress also expressed skepticism concerning the benefits of the public domain.<sup>60</sup> Although the utilitarian rationale for copyright was alluded to,<sup>61</sup> it is clear that many members of Congress believed that copyright was a natural right of the author.<sup>62</sup> This

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<sup>57</sup> *Id.*, § 16, 4 Stat. 439.

<sup>58</sup> In debating the extension of existing copyrights, Rep. Jabez W. Huntington of Connecticut asked “why . . . should the author who had sold his copyright a week ago, be placed in a worse situation than the author who should sell his work the day after the passing of that act?” 7 GALE & SEATON’S REGISTER OF DEBATES IN CONGRESS 424 (1831). This rhetorical question does not explain why the author whose copyright would have expired the day after the passing of the act should be placed in a better situation than the author whose copyright had expired a week earlier. The principle of preserving settled expectations provides an answer to the former question, but not to the latter.

<sup>59</sup> *Id.* at app. cxix. At the time, England had adopted a twenty-eight-year term, with a renewal term for the life of the author; and France had adopted a term of fifty years after the death of the author. *Id.*

<sup>60</sup> *Id.* at cxx (“There is no serious danger of a monopoly. The question is, whether the author or the bookseller shall reap the reward.”); *but see id.* at 423 (Rep. Michael Hoffman, N.Y.) (arguing the bill “went to establish a monopoly of which authors alone would reap the advantage, to the public detriment.”).

<sup>61</sup> *Id.* at cxx (“We ought to present every reasonable inducement to influence men to consecrate their talents to the advancement of science.”); *see also id.* at 423 (Rep. William W. Ellsworth, Conn.) (contending the bill would “enhance the literary character of the country, by holding forth to men of learning and genius additional inducements to devote their time and talents to literature and the fine arts.”).

<sup>62</sup> *Id.* at cxx (“Upon the first principles of proprietorship in property, an author has an exclusive and perpetual right, in preference to any other, to the fruits of his labor.”); *see also id.* at 424 (Rep. Gulian C. Verplanck, N.Y.) (“the work of an author was the result of his own labor. It was a right of property existing before the law of copyrights had been made. That statute . . . [was] merely a legal provision for the protection of a natural right.”).

rationale for copyright was rejected three years later, however, when the U.S. Supreme Court held in *Wheaton v. Peters*<sup>63</sup> that there was no common-law copyright that survived first publication of a work.<sup>64</sup> This decision therefore undercuts one of the principal justifications for the term extension of 1831. Moreover, unlike the enactments of the First Congress,<sup>65</sup> the Act of 1831 is not entitled to any special weight in construing the Constitution.<sup>66</sup>

The next general revision occurred in 1870, but the initial and renewal terms of copyright remained the same, providing a maximum duration for all copyrights of forty-two years.<sup>67</sup>

In 1890, during consideration of a bill that would extend U.S. copyright law to foreign authors, Representative Benjamin Butterworth of Ohio, speaking in favor of the bill, remarked that he “would willingly vote to reduce the term [of copyright] to eighteen years or even seventeen years.”<sup>68</sup> Representative Samuel Ritter Peters of Kansas, an opponent of the legislation, seized upon that suggestion and proposed that the bill be sent back to the Committee on Patents, “with instructions to make the limit of the copyright fourteen years.”<sup>69</sup> He rejected a suggestion by Representative Francis Spinola of New York to “[m]ake the term seventeen

<sup>63</sup> 33 U.S. 591 (1834).

<sup>64</sup> *Id.* at 657-63.

<sup>65</sup> *See* note 47 *supra*.

<sup>66</sup> By 1831, none of the delegates to the Constitutional Convention of 1787 remained in Congress. *See* BENTON, *supra* note 47, at 21-25 (listing delegates); BIOGRAPHICAL DIRECTORY, *supra* note 47, at 108-10 (listing members of 21st Congress). *See also* Heald & Sherry, *supra* note 25, at 1151-52 (“This isolated incident, coming more than forty years after the first copyright act and not repeated for another seventy-seven years, is more indicative of congressional reticence than of congressional assertion of authority.”).

<sup>67</sup> An Act to revise, consolidate, and amend the Statutes relating to Patents and Copyrights, §§ 87-88, 16 Stat. 198, 212-13 (July 8, 1870).

<sup>68</sup> 22 CONG. REC. 58 (Dec. 3, 1890). He reasoned that “when the copyright law was first enacted, it was not an easy matter to inform the public of the nature and content of a publication or to get books across the continent,” but that since that time, improvements in advertising and distribution had effectively eliminated such delays. *Id.*

<sup>69</sup> *Id.* at 59. It is somewhat unclear whether Rep. Peters’ motion referred to the duration of all copyrights, or only the copyrights of foreign authors. He initially stated “I move to recommit the bill to the Committee on Patents with instructions to limit the duration of *this* copyright privilege to five years.” *Id.* (emphasis added). When asked to reduce his motion to writing, he said “At the suggestion of a gentleman near me, I will modify my proposition so as to make the limit fourteen years instead of five years.” *Id.* The written motion that resulted is quoted in the text. Although this exchange could be interpreted to refer only to the term for foreign authors, in the context of Rep. Butterworth’s remark, the reasoning of which applied to

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years, the same as the term of a patent.”<sup>70</sup> The motion was apparently viewed as a strategic ploy only,<sup>71</sup> and it was rejected upon a vote of the full House.<sup>72</sup>

In 1905, the Librarian of Congress convened a conference of authors, publishers and other interested parties for the purpose of discussing a general revision of the copyright laws.<sup>73</sup> At the conference, both the American Copyright League (an association of authors) and the Music Publishers’ Association expressed the view “[t]hat the copyright term should be as long a period as possible”<sup>74</sup> and suggested a single term of life of the author plus fifty years.<sup>75</sup> The principal reasons advanced were that copyright was a natural right<sup>76</sup> (a position rejected by the U.S. Supreme Court<sup>77</sup>), that authors ought not to outlive their copyrights,<sup>78</sup> that the term would provide income to an author’s children and grandchildren,<sup>79</sup> and that it ought not to be shorter than the term in several European countries.<sup>80</sup> The Register of Copyrights prepared a draft embodying the proposal,<sup>81</sup> adding a provision extending the terms of existing copy-

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all copyrighted works, it seems that Rep. Peters was proposing a reduced term of general application.

<sup>70</sup> *Id.*

<sup>71</sup> Rep. William Simonds of Connecticut, the bill’s principal sponsor, complained “That is meant to kill the bill, nothing else.” *Id.*

<sup>72</sup> *Id.* The vote on the motion was 96 in favor, 138 against, and 96 not voting. *Id.*

<sup>73</sup> 1 E. FULTON BRYLAWSKI & ABE A. GOLDMAN, LEGISLATIVE HISTORY OF THE 1909 COPYRIGHT ACT C3 (1976) [hereinafter BRYLAWSKI & GOLDMAN].

<sup>74</sup> *Id.* at C7 (American Copyright League); *see also id.* at C11 (Music Publishers’ Association) (“We shall ask for the longest term of copyright”). Indeed, some of the conferees expressed the opinion that copyright should be perpetual. *See, e.g.,* 2 BRYLAWSKI & GOLDMAN, *supra* note 73, at D28, D218.

<sup>75</sup> 1 BRYLAWSKI & GOLDMAN, *supra* note 73, at C7, C11.

<sup>76</sup> *Id.* at C78 (“What the American Copyright League desires to emphasize is the fact that what we think is a natural right should be made a statutory right.”).

<sup>77</sup> *See* note 63 and accompanying text.

<sup>78</sup> 1 BRYLAWSKI & GOLDMAN, *supra* note 73, at C75.

<sup>79</sup> *Id.* at C75, C78.

<sup>80</sup> *Id.* The American Copyright League initially resolved to ask for life of the author plus thirty years, to protect works for one generation after the author’s death, but instead adopted the term provided for in France. *Id.* At the time, France and nine other European countries had adopted a life-plus-fifty-year term, while Germany had a term of life-plus-thirty years. 2 BRYLAWSKI & GOLDMAN, *supra* note 73, at 49; 3 BRYLAWSKI & GOLDMAN, *supra* note 73, at LIV (listing countries). England had a term of the longer of life plus seven years or forty-two years, but was considering a life-plus-thirty-year term. 4 BRYLAWSKI & GOLDMAN, *supra* note 73, at 12 (statement of Herbert Putnam, Librarian of Congress).

<sup>81</sup> Memorandum Draft of a Bill to Amend and Consolidate the Acts Respecting Copyright §§ 51-52 (Oct. 23, 1905) at 23-24, *reprinted in* 2 BRYLAWSKI & GOLDMAN, *supra* note 73, at D-XXXVI-VIII. The draft provided for a ba-

rights.<sup>82</sup> None of the conferees opposed making the extension retroactive, but they disagreed vehemently over whether the benefit of the extension should run to the author or to the author's assignees (i.e., to the publisher).<sup>83</sup>

During congressional hearings on the proposed revision in May 1906,<sup>84</sup> several witnesses questioned whether a life-plus-fifty term was a "limited time" within the meaning of the Constitution,<sup>85</sup> and one argued that extension of existing copyrights would impair the obligation of contracts.<sup>86</sup> Representing the Melville Clark Piano Company, Charles S. Burton submitted a written statement that was particularly eloquent on the question of duration:

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sic term of life of the author plus fifty years, with a flat fifty-year term from registration for collective works, derivative works, and photographs.

Concerned that Congress might oppose such a lengthy term, the American Copyright League later proposed an alternative term of the longer of forty-two years or life of the author plus twenty-one years, 2 BRYLAWSKI & GOLDMAN, *supra* note 73, at D37-49, but after discussion the conferees agreed to support the original proposal. *Id.* at D218-19.

<sup>82</sup> Memorandum Draft § 53 at 24-25, *reprinted in* 2 BRYLAWSKI & GOLDMAN, *supra* note 73, at D-XXXVIII-XIX.

<sup>83</sup> *Id.* at D24-25, D219-21; *see also* 3 BRYLAWSKI & GOLDMAN, *supra* note 73, at E297-304. The conferees eventually agreed on a proposal under which the copyright would be extended only if both the author or his heirs and the assignee agreed. *Id.* at E301-04.

<sup>84</sup> In the 1906 draft, the life-plus-fifty year term was in Section 18(c), and the extension of existing copyrights was in Section 19. 4 BRYLAWSKI & GOLDMAN, *supra* note 73, at Hvii-ix.

<sup>85</sup> *See* 4 BRYLAWSKI & GOLDMAN, *supra* note 73, at H53 (statement of George W. Ogilve, publisher) ("it seems to me that under the law as it is suggested, a term of fifty years from the date of the death of the youngest of authors is going beyond what the framers of the Constitution decided was a limited time."); *id.* at H136 (statement of H.N. Low, manufacturer of music rolls) ("The word 'limited' in the Constitution shows that the framers of that instrument had in mind to secure for the public certain benefits after the time had expired. To provide such a long copyright term as the authors seek to obtain in this bill would practically defeat the object of the said clause of the Constitution and the intention of its framers."); *id.* at H197 (statement of Charles S. Burton, Melville Clark Piano Company) ("The bill before your committee proposes a remarkable extension of the period of copyright beyond anything heretofore granted. This is believed to be contrary to sound public policy and of doubtful constitutionality.").

<sup>86</sup> *Id.* at H137 (statement of H.N. Low) ("Section 19 should, in my opinion, be canceled. It is retroactive in its character. Definite contracts have been entered into between authors and the public with respect to matters already copyrighted, and it would impair the obligations of those contracts to provide any renewal or extension of such copyrights. It has already been agreed between such authors and the public at what time their copyrighted works should pass into the public domain.").

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The Constitution expressly limits the power of Congress in respect to their copyright protection to granting such protection “for limited periods.” The term “limited” can have only a relative meaning, and the obvious meaning is limited with respect to or in comparison with the period during which the public will have desire or use for the copyrighted work. It is contemplated, evidently, that in compensation for the protection which the statute gives the composer for a limited period the public shall derive the unqualified use and benefit of the work for a remaining period. If there is no remaining period, the consideration for the protection has failed.

It needs no statistics to establish to the common knowledge of the committee that not one book in ten thousand has any commercial value fifty years after its publication. . . . If, therefore, the author is given the monopoly for fifty years, the public has nothing left to compensate it for that monopoly and protection.

Not one work in a million endures so as to have any value after one hundred years. But the bill proposes, as to the great bulk of copyrightable matter, that the period of copyright shall be substantially one hundred years—fifty years after the death of the author.

It is respectfully submitted that this transcends the intention of the constitutional limitation, and that the public would, by such an enactment, be deprived of substantially all the compensation which the Constitution intended should be reserved to it in return for the copyright protection granted the author.<sup>87</sup>

Another witness, Albert H. Walker of New York,<sup>88</sup> contended that Congress had the discretion to fix any term of copyright short of perpetuity,<sup>89</sup> but nonetheless stated:

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<sup>87</sup> *Id.* at H197-98 (statement of Charles S. Burton).

<sup>88</sup> Walker was a distinguished lawyer and the author of an influential treatise on patent law. See ALBERT HENRY WALKER, TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA (1st ed. 1883). Although greatly revised, his treatise is still updated today. See ERNEST BAINBRIDGE LIPSCOMB III, WALKER ON PATENTS (3d ed. 1984).

<sup>89</sup> See 4 BRYLAWSKI & GOLDMAN, *supra* note 73, at H163 (“the constitutional convention was influenced by this consideration: We will not grant a permanent property right in any intellectual production, because in our judgment that would be inconsistent with the progress of civilization as a whole.”); *id.* at H176 (“Mr. Currier: Do you think a hundred years is a limited time within the meaning of the Constitution? Mr. Walker: Oh, yes; certainly. A thousand would be. [Laughter.]”). As a matter of policy, Walker stated that “the longest period that could possibly be vindicated by argument for a

I am totally opposed to any law providing for the extension of any copyright or any patent. The public ought to know, when the copyright comes out and when the patent comes out, exactly when it is going to expire; and it ought not to made contingent upon anything so uncertain as human life.<sup>90</sup>

Perhaps in response to the objections raised in May, at the December 1906 hearings proponents of the life-plus-fifty-years proposal marshaled an impressive array of witnesses to testify in favor of the longer term. Dr. Edward Everett Hale<sup>91</sup> argued that copyright was a natural right of the author that should last as long as possible.<sup>92</sup> Mark Twain agreed, and he devoted the bulk of his statement to the proposition that copyright ought to last in perpetuity.<sup>93</sup> Recognizing, however, that perpetuity was both an unrealistic goal and forbidden by the Constitution, he pronounced himself satisfied with the life-plus-fifty term:

I like the fifty years' extension, because that benefits my two daughters, who are not as competent to earn a living as I am, because I have carefully raised them as young ladies, who don't know anything and can't do anything. So I hope Congress will extend to them that charity which they have failed to get from me.<sup>94</sup>

John Philip Sousa also made a plea on behalf of his children,<sup>95</sup> and the American Copyright League argued that copyright should provide for an author's children and minor grandchildren.<sup>96</sup> Finally, several witnesses ex-

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patent would be twenty years," but for copyright he advocated a fixed term of 100 years for original works, and fifty years for derivative works. *Id.*

<sup>90</sup> *Id.* at H175 (statement of Albert H. Walker).

<sup>91</sup> Hale, author of "The Man Without a Country," was at the time the Chaplain of the Senate. *Id.* at J80.

<sup>92</sup> *Id.* at J114-15 (statement of Rev. Edward Everett Hale). This view, of course, had been rejected by the Supreme Court in *Wheaton v. Peters*, 33 U.S. 591 (1834). *See* note 63 *supra*.

<sup>93</sup> *Id.* at J116 (statement of Samuel L. Clemens) ("I do not know why there should be a limit at all. I am quite unable to guess why there should be a limit to the possession of the product of a man's labor."); *id.* at J118-20.

<sup>94</sup> *Id.* at J117; *see also id.* at J116 ("I think that will satisfy any reasonable author, because it will take care of his children. Let the grandchildren take care of themselves.").

<sup>95</sup> *Id.* at J201 ("I have children who are in their teens, and I think that the limit of the copyright might very justly be extended. That may possibly yet be of some benefit to my children.").

<sup>96</sup> *Id.* at J87 (statement of Richard R. Bowker, Vice-President, American Copyright League) ("The term proposed in the bill provides for the author and his children's children during the probable minority of the grandchildren, a period to which the entail of realty is limited by our laws."). Bowker also noted that thirty-seven counties had adopted terms of life-plus-fifty-years or

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pressed the view that Congress had the discretion under the Constitution to enact a life-plus-fifty-year term.<sup>97</sup>

In January 1907, the Copyright Office prepared a memorandum expressing its views on the question of duration.<sup>98</sup> It indicated that copyright should be long enough to enable an author “to provide for his children until they reach the age where they are likely to be self-supporting, or, if daughters, married”; but that it “ought *not* to tie up automatically *all* copyrights whether or not they require a term so long. Experience shows that a large percentage of them do not.”<sup>99</sup> Believing that Congress was opposed to the life-plus-fifty-year term, it proposed an initial term of either twenty-eight or forty-two years, which could be extended to life-plus-thirty-years at the end of the initial term.<sup>100</sup> The report also included a rebuttal of several arguments against a longer term.<sup>101</sup> The House and Senate Committees incorporated the revised proposal (using a twenty-eight-year initial term) into their 1907 drafts.<sup>102</sup> Other issues, however, prevented the enactment of the copyright revision bills.

Ironically, it was the authors who ultimately turned the tide against the revised proposal. At congressional hearings in 1908, they objected

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longer; and he listed several prominent authors who had outlived their copyrights, including Emerson and Longfellow. *Id.*

<sup>97</sup> *Id.* at 136 (statement of Charles Porterfield) (stating that “the period of copyright . . . is a question for Congress in its wise discretion”; but expressing the opinion that life-plus-fifty years “is much too long.”); *id.* at J155-56 (statement of Arthur Steuart, former President of the American Bar Association) (“If the Courts thought that what Congress did was unreasonable, was practically unlimited, they would, of course, declare it to be unconstitutional. But within certain limits almost any time is within the jurisdiction of the committee.”); *id.* at J407-08 (Memorandum of the Committee on Copyright and Trademark of the Association of the Bar of the City of New York).

<sup>98</sup> The Copyright Term: Memorandum Accompanying Substitute Suggested by Copyright Office for Section 18 of the Bill (Jan. 22, 1907), *reprinted in* 5 BRYLAWSKI & GOLDMAN, *supra* note 73, at M31-38.

<sup>99</sup> *Id.* at M31 (emphasis in original). The report noted that approximately four-fifths of copyrights were not renewed under the 1831 Act. *Id.* at M33.

<sup>100</sup> *Id.* at M32.

<sup>101</sup> *Id.* at M34-37. It remarked that while an invention or discovery “may concern the essential welfare, even the lives, of the community, and should be freely available at the earliest possible moment not unjust to the creator of it,” no book “can be said to be essential to the welfare or protection of the community.” *Id.* at M34. It also dismissed the contention that competition would lower the price of works in the public domain, arguing that it would merely enrich publishers at the expense of authors, with little or no benefit to the public. *Id.* at M34-36.

<sup>102</sup> H.R. REP. NO. 59-7083 (1907), *reprinted in* 6 BRYLAWSKI & GOLDMAN, *supra* note 73, at N13-14 (report), N31-33 (bill); S. REP. NO. 59-6187 (1907), *reprinted in* 6 BRYLAWSKI & GOLDMAN, *supra* note 73, at Q6-8 (report), Q18-19 (bill).

that a life-plus-thirty-years term could result in a *shorter* term of copyright than the existing law if the author lived less than twelve years after completing the work.<sup>103</sup> The Librarian of Congress submitted a report concluding that while 50% of authors would gain additional protection under a life-plus-thirty term, 32% would end up with a shorter term.<sup>104</sup> Finally, Representative Frank Currier of New Hampshire recounted a discussion he had with Mark Twain:

Mr. Clemens told me that he sold the copyright for *Innocents Abroad* for a very small sum, and he got very little out of the *Innocents Abroad* until the twenty-eight year period expired, and then his contract did not cover the renewal period, and in the fourteen years of the renewal period he was able to get out of it all the profits.<sup>105</sup>

These considerations were apparently sufficient to convince Congress to retain a fixed term of years with a renewal term. In the final report accompanying the 1909 Act, the House Committee on Patents said:

Your committee, after full consideration, decided that it was distinctly to the advantage of the author to preserve the renewal period. It not infrequently happens that the author sells his copyright outright to a publisher for a comparatively small sum. If the work proves to be a great success and lives beyond the term of twenty-eight years, your committee felt that it should be the exclusive right of the author to take the renewal term, and the law should be framed as is the existing law, so that he could not be deprived of that right.

The present term of twenty-eight years, with the right of renewal for fourteen years, in many cases is insufficient. The terms, taken together, ought to be long enough to give the author the exclusive right to his work for such a period that there would be no probability of its being taken away from him in his old age, when, perhaps, he needs it the most.<sup>106</sup>

<sup>103</sup> 5 BRYLAWSKI & GOLDMAN, *supra* note 73, at K61-66 (statement of Robert Underwood Johnson, American Copyright League) (characterizing the life-plus-thirty-year term as a “backward step”); *id.* at K88 (written analysis by American Copyright League).

<sup>104</sup> *Id.* at K163 (statement of Herbert Putnam, Librarian of Congress).

<sup>105</sup> *Id.* at K20; *see also id.* at K62 (repeating the story).

<sup>106</sup> H.R. REP. NO. 60-2222 (1909), *reprinted in* 6 BRYLAWSKI & GOLDMAN, *supra* note 73, at S14. Taking a different view of “the existing law,” the Supreme Court held in *Fred Fisher Music Co. v. M. Witmark & Sons*, 318 U.S. 643 (1943), that a publisher could enforce an agreement made during the initial term requiring an author to assign both the initial and renewal terms. For a criticism of this decision, see Patry, *supra* note 24, at 670-71.

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Consequently, the Copyright Act of 1909 retained an initial term of twenty-eight years,<sup>107</sup> but it increased the duration of the renewal term to twenty-eight years,<sup>108</sup> for a maximum duration of fifty-six years. Like the 1831 Act, the 1909 Act extended the term of all existing copyrights,<sup>109</sup> but it did not revive any expired copyrights.<sup>110</sup>

In 1955, Congress authorized the Copyright Office to undertake a series of studies with an eye toward another comprehensive revision of the copyright laws.<sup>111</sup> This process culminated in a report to Congress by the Register of Copyrights in July 1961.<sup>112</sup> The Report recommended that the two-term structure be retained, with the renewal term extended to forty-eight years.<sup>113</sup> A vocal opposition insisted, however, that the U.S. should adopt a single term of life of the author plus fifty years, in order to permit eventual U.S. adherence to the Berne Convention.<sup>114</sup> Under the life-plus-fifty proposal, federal copyright protection would attach upon creation of the work, rather than on the date of first publication.<sup>115</sup> As the contro-

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<sup>107</sup> An Act To amend and consolidate the Acts respecting copyright, § 23, 35 Stat. 1075, 1080 (1909) (“the copyright secured by this Act shall endure for twenty-eight years from the date of first publication.”).

<sup>108</sup> *Id.* (author or specified successors “shall be entitled to a renewal and extension of the copyright in such work for a further term of twenty-eight years” upon proper registration). The consequences of failing to register a renewal were expressly stated for the first time: “provided further, That in default of the registration of such application for renewal and extension, the copyright in any work shall determine at the expiration of twenty-eight years from first publication.” *Id.*

<sup>109</sup> *Id.*, § 24, 35 Stat. 1080-81 (“the copyright subsisting in any work at the time when this Act goes into effect may, at the expiration of the term provided for under existing law, be renewed and extended . . . for a further period such that the entire term shall be equal to that secured by this Act, including the renewal period.”).

<sup>110</sup> *Id.*, § 7, 35 Stat. 1077 (“no copyright shall subsist in the original text of any work which is in the public domain, or in any work which was published in this country or any foreign country prior to the going into effect of this Act and has not been already copyrighted in the United States.”).

<sup>111</sup> 1 PATRY, *supra* note 27, at 74.

<sup>112</sup> REPORT OF THE REGISTER OF COPYRIGHTS ON THE GENERAL REVISION OF THE U.S. COPYRIGHT LAW, 87th Cong. (1961).

<sup>113</sup> 1 PATRY, *supra* note 27, at 76.

<sup>114</sup> *Id.* See Berne Convention for the Protection of Literary and Artistic Works, July 24, 1971 (Paris Revision), art. 7(1). Although the U.S. did adopt a life-plus-fifty term in 1976, its continued insistence on formalities such as notice and registration prevented its joining the Berne Convention until Mar. 1, 1989, when Congress removed these barriers to entry.

<sup>115</sup> Prior to the 1976 Act, most works were protected by state common-law copyright prior to first publication, and were eligible for federal statutory copyright only after publication with notice. See 1 NIMMER ON COPYRIGHT, *supra* note 43, at § 4.01[B]. The 1976 Act eliminated this dual state/federal

versy dragged on throughout 1962, it became clear that the general revision would not be enacted soon. Anticipating that any general revision would retroactively extend the terms of existing copyrights (but not revive expired copyrights), on September 19, 1962, Congress passed a law extending the renewal terms of all subsisting copyrights until December 31, 1965,<sup>116</sup> in order to keep older works under copyright until the general revision could be enacted.<sup>117</sup> The Department of Justice opposed the extension on the grounds that it would impede the public interest “in the early passing of copyrighted material into the public domain”;<sup>118</sup> but Congress brushed this objection aside, asserting that “the benefit arising from the expiration of copyright does not necessarily pass to the public.”<sup>119</sup>

Congress surely expected that three years would be enough time to finish the general revision; but in May 1965, the Senate Judiciary Committee reported “it is doubtful that a new law can be enacted before the expiration of the temporary extension.”<sup>120</sup> It recommended another extension until December 31, 1967, “so that the copyright holders may enjoy the benefit of any increase in term that may be enacted by the Congress.”<sup>121</sup> Congress passed the recommended two-year extension on August 28, 1965.<sup>122</sup> As work on the general revision continued, Congress enacted a

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system, replacing it with a unified federal term, and preempting all state laws providing protection “equivalent” to copyright. *See* 17 U.S.C. § 301(a) (2000). Because the Copyright Clause only allows Congress to protect “Writings,” however, federal copyright protection attaches only when the work is “fixed in a tangible medium of expression.” 17 U.S.C. § 102(a) (2000). Works of authorship that are not fixed can still be protected by state copyright law. *See, e.g.*, Cal. Civ. Code § 980(a)(1) (Deering 1990).

<sup>116</sup> Pub. L. No. 87-668, 76 Stat. 555 (1962).

<sup>117</sup> *See* Report of House Judiciary Committee on H.J. Res. 627, at 3 (1962), *reprinted in* 8 NIMMER ON COPYRIGHT, *supra* note 43, at app. 8-5 (“Although it is not possible to revive expired terms of copyright, it seems to the committee to be desirable to suspend further expiration of copyright for a period long enough to enable the working out of remaining obstacles to the overall revision of the copyright law.”).

<sup>118</sup> *Id.* at 6, *reprinted in* 8 NIMMER ON COPYRIGHT, *supra* note 43, at app. 8-10.

<sup>119</sup> *Id.* at 4, *reprinted in* 8 NIMMER ON COPYRIGHT, *supra* note 43, at app. 8-6.

<sup>120</sup> S. REP. NO. 89-548 (1965), *reprinted in* 1965 U.S.C.C.A.N. 2872, 2873.

<sup>121</sup> *Id.*

<sup>122</sup> Pub. L. No. 89-142, 79 Stat. 581 (1965).

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series of one-year extensions in 1967,<sup>123</sup> 1968,<sup>124</sup> 1969,<sup>125</sup> 1970,<sup>126</sup> and 1971.<sup>127</sup>

In dissenting from the House Report recommending passage of the 1971 extension, Congressman Robert W. Kastenmeier stated bluntly: “I regret I can no longer concur in the action of my colleagues in the matter of these annually recurring, ostensibly ‘interim,’ extensions of expiring

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<sup>123</sup> Act of November 16, 1967, Pub. L. No. 90-141, 81 Stat. 464 (1967). The stated purpose of the extension was identical to that for the 1965 extension: to benefit the holders of existing copyrights. H.R. REP. NO. 90-870, *reprinted in* 1967 U.S.C.C.A.N. 1921, 1922. The report was accompanied by a statement from the Register of Copyrights, estimating that 58,000 renewal copyrights would be affected, and adding: “The poignant irony of copyrights that have already been extended in anticipation of revision being allowed to fall into the public domain only a few months short of their goal is too obvious to require elaboration.” *Id.* at 1924. Thus, the mere fact of previous extensions having been granted was used as a justification for subsequent ones.

<sup>124</sup> Act of July 23, 1968, Pub. L. No. 90-416, 82 Stat. 397 (1968). Once again, the stated purpose was to benefit existing copyright holders. H.R. REP. NO. 90-1613 (1968), *reprinted in* 1968 U.S.C.C.A.N. 2701, 2702. In recommending passage of this extension, the Acting Librarian of Congress stated: “The series of extensions have been intended to keep works already in their second copyright term from falling into the public domain for the time being, so that they would have the advantage of the seventy-five-year term when the new copyright law comes into effect.” *Id.* at 2703.

<sup>125</sup> Act of Dec. 16, 1969, Pub. L. No. 91-147, 83 Stat. 360 (1969). The stated purpose was once again identical to that stated in 1965; and the recommendation of the Librarian of Congress was virtually identical to that of 1968. H.R. REP. NO. 91-651 (1969), *reprinted in* 1969 U.S.C.C.A.N. 1464, 1465, 1466.

<sup>126</sup> Act of Dec. 17, 1970, Pub. L. No. 91-555, 84 Stat. 1441 (1970). The boilerplate statement of purpose was repeated; and Congress estimated that some 86,800 copyrights would be affected by the extension. H.R. REP. NO. 91-1621, *reprinted in* 1970 U.S.C.C.A.N. 4969, 4970.

<sup>127</sup> Act of Nov. 24, 1971, Pub. L. No. 92-170, 85 Stat. 490 (1971). Congress’ explanation of its purpose was somewhat more elaborate than usual:

[T]he series of interim extension measures . . . stand revealed as legislation directed to the end that presently subsisting copyrights should, as far as possible, remain eligible for the advantage of longer term that will be derived by holders of copyrights that have not expired by the effective date. In short, the intent and purpose of the Congress has been to avoid lapses of copyright protection on the eve of the revision . . .

As a result, copyright holders have a real and reasonable expectancy that their copyright interests will survive long enough to benefit from the revision, . . . This expectancy should not be thwarted.

H.R. REP. NO. 92-605 (1971), *reprinted in* 1971 U.S.C.C.A.N. 1780, 1781. The Librarian of Congress estimated that an additional 12,700 works would be affected by the 1971 extension, bringing the total number of works affected to 99,500. *Id.* at 1782.

copyrights.”<sup>128</sup> He went on to question both the purpose and constitutionality of the interim extensions:

I now believe that [the resolution] affords a windfall to the holders of copyrights in their renewal term, where such term would otherwise expire this year. I find it impossible to identify any public interest that would be served by the enactment of this measure. . . .

The legislation makes what amounts to a retrospective reward for authorship at the expense of the public domain, in a situation in which the constitutional prescription “to promote the progress of useful Arts . . .” cannot directly be served.<sup>129</sup>

Despite Kastenmeier’s continued opposition,<sup>130</sup> Congress passed two more interim extensions of two years’ each, in 1972<sup>131</sup> and 1974.<sup>132</sup> This extraordinary series of extensions amply demonstrates that Congress believed that it had the constitutional power to extend the terms of copyrights that had not yet expired; but that the revival of expired copyrights would probably violate the “limited Times” provision of the Constitution.<sup>133</sup>

As finally enacted, the 1976 Act provided for a term of life-plus-fifty years for most works created on or after January 1, 1978.<sup>134</sup> Works made

<sup>128</sup> *Id.* at 1783 (dissenting views of Hon. Robert W. Kastenmeier).

<sup>129</sup> *Id.*

<sup>130</sup> See H.R. REP. NO. 92-1449 (1972) (dissenting views of Hon. Robert W. Kastenmeier, Hon. Don Edwards, Hon. John Conyers, Jr., and Hon. Robert F. Drinan), reprinted in 8 NIMMER ON COPYRIGHT, *supra* note 43, at app. 8-71 (interim extension “affords a windfall to the holders of copyrights in their renewal terms, . . . and it is impossible to identify any public interest that would be served by the enactment of this measure.”); H.R. REP. NO. 93-1581 (1974), reprinted in 1974 U.S.C.C.A.N. 6849, 6859 (views of Hon. Robert W. Kastenmeier, Dissenting in Part) (“It continues to be my belief that in too many instances the measure will operate to provide an unjustifiable windfall at the expense of the public domain.”).

<sup>131</sup> Act of Oct. 25, 1972, Pub. L. No. 95-566, 86 Stat. 1181 (1972).

<sup>132</sup> Act of Dec. 31, 1974, Pub. L. No. 93-573, § 104, 88 Stat. 1873 (1974). The Librarian of Congress estimated that 153,500 copyrighted works would be affected by the legislation. H.R. REP. NO. 93-1581 (1974), reprinted in 1974 U.S.C.C.A.N. 6849, 6858.

<sup>133</sup> See note 8 *supra*.

<sup>134</sup> “Copyright in a work created on or after January 1, 1978, subsists from its creation and, except as provided in the following subsections, endures for a term consisting of the life of the author and fifty years after the author’s death.” Former 17 U.S.C. § 302(a), as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2541, 2572 (1976). For joint works, the term was the life of the last surviving author plus fifty years. Former 17 U.S.C. § 302(b), as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2572 (1976).

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for hire were given a single term of seventy-five years from first publication, or 100 years from creation, whichever was shorter.<sup>135</sup> In order to unify federal and state law, works created before January 1, 1978, which were neither in the public domain nor copyrighted (and were therefore still subject to state common-law copyright) were given the basic term afforded to new works, subject to a statutory minimum of either twenty-five or fifty years.<sup>136</sup> Existing works still under copyright as of December 31, 1976 had their renewal terms extended by nineteen years, resulting in a maximum term of seventy-five years.<sup>137</sup> Finally, for administrative convenience, all existing and future copyrights were extended to “the end of the calendar year in which they would otherwise expire.”<sup>138</sup> Like its predecessors, the 1976 Act did not revive the copyrights of any works that had fallen into the public domain.<sup>139</sup>

Beginning on January 1, 1982, and each January 1 thereafter, works which had been copyrighted seventy-five years earlier and properly re-

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<sup>135</sup> Former 17 U.S.C. § 302(c), as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2572 (1976). The same term applies to anonymous works and pseudonymous works, unless the authors are identified in the records of the Copyright Office before the end of such term. *Id.*

<sup>136</sup> “Copyright in a work created before January 1, 1978, but not theretofore in the public domain or copyrighted, subsists from January 1, 1978, and endures for the term provided by section 302. In no case, however, shall the term of copyright in such a work expire before December 31, 2002; and, if the work is published on or before December 31, 2002, the term of copyright shall not expire before December 31, 2027.” Former 17 U.S.C. § 303, as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2573 (1976).

<sup>137</sup> For works still in their first term on Jan. 1, 1978, the Act provided a twenty-eight-year initial term, and a forty-seven-year renewal term. Former 17 U.S.C. § 304(a), as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2573 (1976). Subsection (b) provided:

The duration of any copyright, the renewal term of which is subsisting at any time between December 31, 1976, and December 31, 1977, inclusive, or for which a renewal registration is made between December 31, 1976, and December 31, 1977, inclusive, is extended to endure for a term of seventy-five years from the date copyright was originally secured.

Former 17 U.S.C. § 304(b), as enacted in Pub. L. No. 94-553, § 101, 90 Stat. 2574 (1976). Although the effective date of most of the 1976 Act was January 1, 1978, the Act expressly provided that this section would “take effect upon enactment.” Pub. L. No. 94-553, § 102, 90 Stat. 2599 (1976).

<sup>138</sup> 17 U.S.C. § 305 (2000).

<sup>139</sup> “This Act does not provide copyright protection for any work that goes into the public domain before January 1, 1978.” Pub. L. No. 94-553, § 103, 90 Stat. 2599 (1976). As a result of the interim extensions, however, the only works which were in the public domain by reason of age alone (as opposed to failure to comply with the required formalities or failure to renew) were those which had been copyrighted prior to Sept. 19, 1906. *See* notes 116-133 and accompanying text.

newed entered the public domain upon the expiration of their extended terms. This orderly progression continued until the mid-1990s, when two events converged to upset the status quo. First, members of the European Union extended the basic term of copyright for European authors to life-plus-seventy-years<sup>140</sup>; but under the rule of the shorter term, they refused to extend the terms for U.S. authors until the U.S. adopted a similar extension.<sup>141</sup> Second, as 1995 approached, the seventy-five-year term for older works threatened to begin to engulf works created in the 1920s and 1930s, an important period of artistic creativity in the U.S.<sup>142</sup> “Talking pictures” were introduced in 1927,<sup>143</sup> and film historians consider the 1930s to be the Golden Age of Hollywood. Commercial radio broadcasts began in the 1920s. The development of movies and radio in turn spurred the development of American popular song, and many of the creative giants of the age — Irving Berlin, George and Ira Gershwin, and Cole Porter, to name a few — published their most popular works in the 1920s and 1930s. Thus, movie studios, music publishers and the heirs of these popular songwriters were faced with the prospect of losing lucrative sources of revenue as these copyrighted works entered the public domain.<sup>144</sup> The extension of copyright terms in Europe gave these powerful economic interests the excuse they needed to seek an additional twenty years of copyright protection at the expense of the public domain.

<sup>140</sup> Council Directive 93/98, art. 1, para. 1, 1993 O.J. (L 290) [hereinafter EC Directive]. Works for which no natural author was identified were required to be given a term of seventy years “after the work is lawfully made available to the public.” EC Directive, art. 3 (anonymous and pseudonymous works), art. 4 (collective works and works made for hire).

<sup>141</sup> EC Directive, art. 7, para. 1 (“Where the country of origin of a work . . . is a third country, and the author of the work is not a Community national, the term of protection granted by Member States shall expire on the date of expiry of the protection granted in the country of origin of the work, but may not exceed the term laid down in Article 1.”).

<sup>142</sup> Cf. Lavigne, *supra* note 24, at 339 (“[D]uring the 1920s . . . the United States enjoyed a period of unprecedented growth and creativity. Hollywood emerged as the world headquarters of the motion picture industry, and the big band era, led by the likes of George Gershwin and Irving Berlin, was in full swing.”).

<sup>143</sup> See *THE JAZZ SINGER* (Warner Bros. 1927). The first animated talking picture was Walt Disney’s *Steamboat Willie* (1928), which introduced the original Mickey Mouse to the world.

<sup>144</sup> It is estimated that the Gershwin family trust alone will receive more than \$4 million dollars *per song* in additional royalties during the twenty-year extension. See John J. Fialka, *Songwriters’ Heirs Mourn Copyright Loss*, *WALL ST. J.*, Oct. 30, 1997, at B1 (reporting that a nationwide license for a single Gershwin song cost \$200,000 to \$250,000 annually). *Rhapsody in Blue* alone makes \$300,000 per year in royalties just for its use in United Airlines’ television commercials. SCHIFF, *supra* note 1, at 1.

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Legislation adding twenty years to all existing and future copyright terms was introduced in 1995,<sup>145</sup> but it failed to garner enough support in Congress. Although objections were raised to the constitutionality of term extension,<sup>146</sup> the main sticking point was ASCAP's and BMI's opposition to the Fairness in Music Licensing Act, a companion measure exempting many businesses and restaurants from having to pay licensing fees to play background music.<sup>147</sup> In 1998, however, Congress enacted both measures,<sup>148</sup> and the Sonny Bono Copyright Term Extension Act (named after the late singer-songwriter and Congressman) became law.<sup>149</sup> During the congressional debate on the CTEA, Mary Bono, Sonny's widow and congressional successor, proclaimed that perpetual copyright remained her ultimate goal, saying:

Actually, Sonny wanted the term of copyright protection to last forever. I am informed by staff that such a change would violate the Constitution. . . . As you know, there is also Jack Valenti's proposal for term to last forever less one day. Perhaps the Committee may look at that next Congress.<sup>150</sup>

Under the CTEA, copyrights in works created by individual authors on or after January 1, 1978, were extended to a term of life plus seventy years;<sup>151</sup> works-made-for-hire created on or after January 1, 1978, were extended to

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<sup>145</sup> See Copyright Term Extension Act of 1995, H.R. 989, 104th Cong. (1995); Copyright Term Extension Act of 1996, S. 483, 104th Cong. (1996) (as amended).

<sup>146</sup> See S. REP. NO. 104-315, at 33-35 (1996) (minority views of Mr. Brown); *id.* at 37-38 (minority views of Mr. Kohl).

<sup>147</sup> See Patry, *Protecting the Idle Rich*, *supra* note 17, at 923-24 (describing the political stalemate); Laurence R. Helfer, *World Music on a U.S. Stage: A Berne/TRIPS and Economic Analysis of the Fairness in Music Licensing Act*, 80 B.U. L. REV. 93, 132-39 (2000) (describing legislative efforts to enact the FMLA).

<sup>148</sup> See Lydia Pallas Loren, *Paying the Piper*, 3 J. SMALL & EMERGING BUS. L. 231, 235 (1999) ("Many in the legislature expressed the view that the FMLA balanced out the lengthening of copyright by giving small businesses a slight break from having to pay license fees when they wanted to play the radio.").

Given that the FMLA was considered a political trade-off for copyright term extension, it should be noted that this compromise is threatened by the ruling of the World Trade Organization that the FMLA violates the United States' international obligations under the TRIPs Agreement. See United States — Section 110(5) of the U.S. Copyright Act, WT/DS160/R (WTO 2000). Should Congress choose to repeal or amend the FMLA in response to this ruling, it should also reconsider its support for copyright term extension.

<sup>149</sup> Pub. L. No. 105-298, 112 Stat. 2827 (1998).

<sup>150</sup> 144 CONG. REC. H9952 (daily ed. Oct. 7, 1998).

<sup>151</sup> 17 U.S.C. § 302(a) (2000).

the shorter of ninety-five years from first publication or 120 years from creation;<sup>152</sup> and works registered for copyright before January 1, 1978 were extended to ninety-five years from the date of first publication.<sup>153</sup> Following the precedent established in 1831, the Act extended the terms of all existing and future copyrights, but it did not revive copyrights which had already fallen into the public domain.<sup>154</sup>

The effect of these multiple extensions on the replenishment of the public domain has been dramatic. Under the 1909 Act, all works published before 1922 would have entered the public domain on or before January 1, 1978, the effective date of the 1976 Act. Since that time, due to copyright extensions, only one additional year of copyrighted works (works first published in 1922) has entered the public domain; and under the CTEA, no published works will enter the public domain for the next eighteen years.

#### B. *Private Laws*

Beginning in 1789, several authors petitioned Congress to grant copyrights to individual works by means of private bills.<sup>155</sup> Despite a favorable recommendation from the special Committee to whom the petitions were referred, however, none of these private bills were enacted.<sup>156</sup> With the passage of the Copyright Act of 1790, the need for private legislation largely disappeared. Over the next one hundred years, however, Congress saw fit to enact nine private copyright laws for individual works.<sup>157</sup> Only two of these laws, however, granted an extension of the copyright term provided for in the general copyright law.

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<sup>152</sup> *Id.* § 302(c).

<sup>153</sup> *Id.* § 304(a) (for works in their first term on Jan. 1, 1978, an initial term of twenty-eight years, followed by an automatic renewal term of sixty-seven years); 17 U.S.C. § 304(b) (“Any copyright in its renewal term at the time that the Sonny Bono Copyright Term Extension Act becomes effective shall have a copyright term of 95 years from the date copyright was originally secured.”). The CTEA became effective on Oct. 27, 1998. Pub. L. No. 105-298, § 106, 112 Stat. 2829.

<sup>154</sup> 17 U.S.C. § 304(b) (2000).

<sup>155</sup> See 1 PATRY, *supra* note 27, at 25-27 & nn.76-77, 80.

<sup>156</sup> *Id.* at 26-29 & nn.78-80, 84-85.

<sup>157</sup> See *id.* at 27 n.80 (describing private laws); COPYRIGHT ENACTMENTS, *supra* note 32, at 73-77 (collecting private laws).

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The first three private laws<sup>158</sup> were for the benefit of John Rowlett of Philadelphia, whose book, *Rowlett's Tables of Discount or Interest*,<sup>159</sup> was originally copyrighted on February 4, 1802.<sup>160</sup> The first act, signed into law on May 24, 1828, extended the copyright on Rowlett's book for fourteen years, provided that Rowlett comply with the formalities of notice, registration and deposit.<sup>161</sup> The second act, passed in 1830, clarified that the notice requirement only applied to those copies in Rowlett's possession at the time the first Act was passed.<sup>162</sup> Finally, in 1843, the copyright was extended for another fourteen years.<sup>163</sup> All told, it appears that Rowlett enjoyed fifty-six years of copyright protection.<sup>164</sup>

What impelled Congress to twice extend Rowlett's copyright? In a forward to a later edition, Rowlett explained that he had invested a great deal of time and money in ensuring the accuracy of the first edition, and had lost money publishing it.<sup>165</sup> In subsequent years, however, the work

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<sup>158</sup> An Act to continue a copy-right to John Rowlett, ch. 145, 6 Stat. 389 (May 24, 1828); An Act to amend "An Act to continue a copyright of John Rowlett," ch. 13, 6 Stat. 403 (Feb. 11, 1830); An Act supplemental to the act of the twenty-fourth May, one thousand eight hundred and twenty-eight, to continue a copyright to John Rowlett, ch. 140, 6 Stat. 897 (Mar. 3, 1843).

<sup>159</sup> JOHN ROWLETT, *ROWLETT'S TABLES OF DISCOUNT OR INTEREST* (1st ed. 1802); see 6 Stat. 389 (1828); 6 Stat. 403 (1830). In the 1843 Act, the title was listed as "Rowlett's Tables of Discount *and* Interest." 6 Stat. 897 (1843) (emphasis added). As its name implies, the bulk of Rowlett's book was a compilation of mathematical tables, and it is possible that this portion may not have satisfied the constitutional standard of originality set forth in *Feist Publications, Inc. v. Rural Telephone Service Co.*, 499 U.S. 340 (1991), which holds that a compilation of facts or data cannot be copyrighted unless the facts or data are selected or arranged in an original manner. *Id.* at 357-59.

<sup>160</sup> 6 Stat. 897 (1843).

<sup>161</sup> 6 Stat. 389 (1828).

<sup>162</sup> 6 Stat. 403 (1830).

<sup>163</sup> 6 Stat. 897 (1843).

<sup>164</sup> Read literally, the extension provided by the 1828 Act would have expired on May 24, 1842; and the 1843 Act revived as well as extended Rowlett's copyright, effective Feb. 4, 1844, leaving a lapse of some twenty months. The last act, however, used the phrase "prolonged and continued forward," which implies that Congress believed that the copyright was still in force. This would have been true if the first extension had taken effect when Rowlett's original renewal term expired, on Feb. 4, 1830, rather than on the effective date of the first act. It appears, therefore, that both Rowlett and Congress assumed that the first extension added a full fourteen years to Rowlett's copyright.

<sup>165</sup> "[N]otwithstanding this uncommonly costly work . . . has been so extensively and so liberally patronized, it has not yet so much as paid with Interest, the heavy loss of nearly Four Thousand Dollars, besides six years of Time, (from 1799 to 1805,) sustained on the first edition of 7000 copies; . . . to say nothing of compensation or profit, for almost a lifetime of care, toil, and

was deemed so valuable that second-hand copies were being sold at auction for high prices;<sup>166</sup> and many pirated editions appeared during the initial term.<sup>167</sup> Rowlett sought the extensions so that he could recover some of the money he had lost on the first edition.<sup>168</sup> The record thus reveals a problem that continues to trouble copyright theorists to this day: protecting the investment of time and money spent in compiling a database that can easily be copied by free-riders.<sup>169</sup>

In two other instances, Congress “privatized” copyrights that had previously been in the public domain.<sup>170</sup> Each of these acts was for the benefit of a widow of a prominent American.<sup>171</sup> In both instances, the books

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sacrifice.” JOHN ROWLETT, *ROWLETT’S TABLES OF DISCOUNT OR INTEREST* vii (5th ed. 1836).

<sup>166</sup> “[W]hen, after a lapse of 26 years, the Book had become scarce, and in great demand, it appeared that a great number of copies had been sought for in every quarter, and picked up as they could be found, *second hand*, at various prices, from 10 to 25 dollars per copy.” *Id.* at 18.

<sup>167</sup> Even the pirates acknowledged the scarcity and value of Rowlett’s work. The preface to one unauthorized edition states: “This inestimable work was then patronized to an extent unparalleled in this country. It now maintains a reputation above every work of the kind, and has become so scarce that rarely, if at all, can a copy be found for sale; and if met with, an exorbitant price is always demanded for it.” JOHN ROWLETT, *ROWLETT’S TABLES OF DISCOUNT OR INTEREST* 3 (reprint; Portland, Maine, Jan. 1, 1826).

<sup>168</sup> “[I]t was evident the Book had proved itself useful *beyond doubt*, . . . and a Copy was laid before Congress for inspection, soliciting a continuance of Copyright — a special Act for this work was passed accordingly, and from that period *alone*, may be dated a *hope of reimbursement*, and peradventure before I die, *Interest* on the loss, if not something for compensation.” *ROWLETT’S TABLES*, *supra* note 165, at 18.

<sup>169</sup> See, e.g., Amy C. Sullivan, *When the Creative is the Enemy of the True: Database Protection in the U.S. and Abroad*, 29 *AIPLA Q.J.* 317 (2001); Jonathan Band & Makoto Kono, *The Database Protection Debate in the 106th Congress*, 62 *OHIO ST. L.J.* 869 (2001); Paul J. Heald, *The Extraction/Duplication Dichotomy: Constitutional Line-Drawing in the Database Debate*, 62 *OHIO ST. L.J.* 933 (2001); Malla Pollack, *The Right to Know?: Delimiting Database Protection at the Juncture of the Commerce Clause, the Intellectual Property Clause, and the First Amendment*, 17 *CARDOZO ARTS & ENT. L.J.* 47 (1999); Jane C. Ginsburg, *Copyright, Common Law, and Sui Generis Protection of Databases in the United States and Abroad*, 66 *U CIN. L. REV.* 151 (1997); J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 *VAND. L. REV.* 51 (1997).

<sup>170</sup> An Act for the relief of Mistress Henry R. Schoolcraft, ch. 16, 11 Stat. 557 (1859); An Act for the relief of Mrs. William L. Herndon, ch. 99, 14 Stat. 587 (1866).

<sup>171</sup> Henry Rowe Schoolcraft was an Indian Agent for the U.S. Government. He spent thirty years living among Indian tribes in the Michigan territory and elsewhere, and negotiated several treaties with them. See *Mole Lake Band of Chippewa Indians v. United States*, 126 Ct. Cl. 596, 607-09, 611-12 & n.32

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were written by government employees in the course of their duties<sup>172</sup> and were “published under order of Congress,”<sup>173</sup> and were therefore not subject to copyright. Moved by the financial plight of the authors’ widows, however, Congress granted to each “the exclusive right to republish the book” for a period of fourteen years.<sup>174</sup>

In one private law, Congress purchased the copyright of a book describing a new method of navigation, and placed the work in the public domain.<sup>175</sup> The other three private laws from this period restored the copyrights of authors who had relied on the economic incentive provided by copyright but had inadvertently failed to comply with one or more of the necessary formalities.<sup>176</sup> There are no reported decisions challenging the validity of any of these nineteenth-century private laws.

Only one private copyright law was enacted in the twentieth century. In 1971, Congress passed a law extending, and in some instances reviving, the copyrights in all editions of Mary Baker Eddy’s *Science and Health*, for a term of seventy-five years from the effective date of the Act or from the date of first publication, whichever was later.<sup>177</sup> The book had originally been published in 1875, and had been revised numerous times before Eddy’s death in 1910.<sup>178</sup> Under this extraordinary legislation, the copy-

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(1953). For a scathing critique of his role in these negotiations, see *United States v. State of Michigan*, 471 F. Supp. 192, 215-16, 226-30 (W.D. Mich. 1979). William Lewis Herndon was an officer in the U.S. Navy who became the first American to explore the Amazon basin. For his background, and an account of his final voyage, see GARY KINDER, *SHIP OF GOLD IN THE DEEP BLUE SEA* 22-25 (1998).

<sup>172</sup> Schoolcraft’s six-volume treatise, *History, Statistics, Conditions and Prospects of the Indian Tribes of the United States*, was commissioned by Congress and originally published in 1851-57. Herndon’s book, *Exploration of the Valley of the Amazon*, was his report, in narrative form, of an expedition he was ordered to undertake by the Navy in 1851. “His report so far surpassed his superiors’ expectations that Congress . . . published ten thousand copies” in 1854. KINDER, *supra* note 171, at 23.

<sup>173</sup> 11 Stat. 557 (1859); 14 Stat. 587 (1866).

<sup>174</sup> 11 Stat. 557 (1859); 14 Stat. 587 (1866).

<sup>175</sup> An Act for the purchase of the copyright of a work by Thomas H. Sumner, wherein he describes his new method of ascertaining a ship’s position at sea, ch. 187, 10 Stat. 810 (Aug. 2, 1854).

<sup>176</sup> An Act for the relief of Levi H. Corson, ch. 57, 9 Stat. 763 (Feb. 19, 1849); An Act for the relief of William Tod Helmuth, of New York, ch. 534, 18 Stat. 618 (June 23, 1874); An Act for the relief of Judson Jones, ch. 29, 30 Stat. 1396 (Feb. 17, 1898).

<sup>177</sup> An Act for the relief of Clayton Bion Craig, Arthur P. Wuth, Mrs. Lenore D. Hanks, David E. Sleeper, and DeWitt John, Priv. L. No. 92-60, 85 Stat. 857 (Dec. 15, 1971).

<sup>178</sup> *United Christian Scientists v. Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1154-55 (D.C. Cir. 1987).

rights would have been extended to at least the year 2046, 171 years after first publication and 136 years after the death of the author. Moreover, as the Court of Appeals later noted:

[B]y providing that subsequently published editions are each to be protected for 75 years from the date of first publication, it may empower First Church to maintain the copyright for an indefinite period in variant editions of Science and Health which it does not choose to publish. . . .

Should First Church remain content to publish only the 1906 edition of the text it currently publishes, it would hold copyrights in, and thus publication control over, all other variant editions, whose publication it could suppress indefinitely.<sup>179</sup>

The constitutionality of the law was challenged in court by dissident members of the Christian Science Church, who wished to promote and publish variant editions of the Church's basic text.<sup>180</sup> The law was struck down on the grounds that it violated the Establishment Clause of the First Amendment.<sup>181</sup> Although the Court did not find it necessary to rule on the argument that the law also violated the "limited Times" provision of the Copyright Clause,<sup>182</sup> its opinion is replete with skeptical references to the extraordinary duration of the copyrights granted by the law.<sup>183</sup>

In sum, the history of private copyright legislation reveals only one work for which Congress successfully extended the term of copyright. There is an important reason, however, why that single example should not be considered persuasive precedent for term extension generally. In an era in which bankers and merchants had to calculate interest by hand, Rowlett's production of accurate interest tables required a truly monumental investment of time, labor and money that far exceeded the typical copyrighted work.<sup>184</sup> In Rowlett's day, the investment of time, labor and

<sup>179</sup> *Id.* at 1157 & n.22.

<sup>180</sup> *Id.* at 1155-56.

<sup>181</sup> *Id.* at 1161-71.

<sup>182</sup> *Id.* at 1171 n.104.

<sup>183</sup> *Id.* at 1169-70 ("Moreover, the copyright granted by means of Private Law 92-60 is exceptional in scope and duration. Even if not construed as a copyright in perpetuity, it purports to confer rights of unprecedented duration. . . . Scant authority, if any, exists for such a dramatic departure from copyright practice.") *See also id.* at 1157 & n.22; 1159 ("an unusual measure of copyright protection by unusual means") & n.28; 1160 ("an extraordinary grant of power").

<sup>184</sup> Rowlett hired a team of assistants to perform each mathematical computation three times, by different methods. The three lists were examined twice each for errors by different teams, and the page proofs were examined four times. ROWLETT'S TABLES, *supra* note 159, at 6-7. Rowlett claimed that he

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money was at least arguably an acceptable basis for copyright protection.<sup>185</sup> Now that the Supreme Court has firmly rejected the “sweat of the brow” doctrine as inconsistent with the Copyright Clause,<sup>186</sup> however, the conceptual underpinnings of Rowlett’s copyright claim have been eroded. Likewise, while such a large investment of time, labor and money might have been entitled to protection under a broad reading of the misappropriation doctrine of *International News Service v. Associated Press*,<sup>187</sup> in recent years the pre-*Erie INS* doctrine has been greatly restricted.<sup>188</sup> Rowlett’s case, therefore, provides little support for the notion that Congress may serially extend all existing copyrights without heed to the “limited Times” provision of the Copyright Clause.

### III. PATENT TERM EXTENSION AND THE CONSTITUTION

#### A. Utility Patents

##### 1. General Laws

In accordance with the established practice in England, all colonial and state patents prior to 1789 were granted by means of private laws for the benefit of specific individuals.<sup>189</sup> It is therefore unsurprising that fourteen petitions for patent rights were presented to Congress during its first

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had “expended in the undertaking a sum of money beyond ordinary bounds in works of this bulk and kind.” *Id.* at 8.

<sup>185</sup> See Paula Baron, *Back to the Future: Learning from the Past in the Database Debate*, 62 OHIO ST. L.J. 879, 912-28 (2001) (describing how copyright cases prior to 1850 effectively provided protection for databases).

<sup>186</sup> See *Feist Publ’ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340 (1991); see also Jane C. Ginsburg, *No “Sweat”? Copyright and Other Protection of Works of Information After Feist v. Rural Telephone*, 92 COLUM. L. REV. 338 (1992).

<sup>187</sup> 248 U.S. 215, 239-40 (1918) (“defendant . . . admits that it is taking material that has been acquired by the complainant as the result of organization and the expenditure of labor, skill and money, and which is salable by the complainant for money, and that defendant in appropriating it and selling it as his own is endeavoring to reap where he has not sown, and . . . is appropriating to itself the harvest of those who have sown.”). See Wendy J. Gordon, *On Owning Information: Intellectual Property and the Restitutionary Impulse*, 78 VA. L. REV. 149 (1992).

<sup>188</sup> See *Nat’l Basketball Ass’n v. Motorola, Inc.*, 105 F.3d 841, 850-53 (2d Cir. 1997) (misappropriation claim limited to time-sensitive information, appropriated by free riders, in such a way that the existence of plaintiff’s product or service is threatened); Gary Myers, *The Restatement’s Rejection of the Misappropriation Tort: A Victory for the Public Domain*, 47 S. C. L. REV. 673 (1996).

<sup>189</sup> See Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 4)*, 78 J. PAT. OFF. SOC’Y 668 (1996). It is worth noting that many statutes were enacted in England in the late eighteenth century extending the duration of particular patents, including James Watt’s patent on the steam engine. See Walterscheid, *supra* note 25, at 327-31.

session under the new Constitution.<sup>190</sup> Congress rejected all of these private bills in favor of general legislation, the Patent Act of 1790; which, as noted above, authorized patents to be granted for a maximum term of fourteen years.<sup>191</sup>

As patents granted under the Act began to expire in the early 1800s, many inventors began to complain that the fourteen-year term was too short a time in which to profit from exploitation of their inventions.<sup>192</sup> Between 1805 and 1814, Congress considered and rejected several proposals to enact a general renewal term for patents of between seven and fourteen years.<sup>193</sup> “Instead, it chose to act only on a case-by-case basis with regard to petitions for extension or renewal of particular patents.”<sup>194</sup> Between 1808 and 1836, eleven private laws were passed granting term extensions for individual patents. These private laws are discussed below.<sup>195</sup>

In 1832, in response to the growing number of private petitions for extension or renewal, Congress passed a statute specifying the conditions under which it would consider such petitions.<sup>196</sup> That statute provided “that application to Congress to prolong or renew the term of a patent shall be made before its expiration,”<sup>197</sup> and further added that:

The petition shall set forth particularly the grounds of the application. . . . [and] it shall be accompanied by a statement of the ascertained value of the discovery, invention, or improvement, and of the receipts and expenditures of the patentee, so as to exhibit the profit or loss arising therefrom.<sup>198</sup>

Although this statute standardized the form of petitions, “it did not give any assurance that the petition would be granted. In other words, extension or renewal still necessitated a special act of Congress.”<sup>199</sup>

Four years later, Congress enacted a general revision of the patent laws.<sup>200</sup> The 1836 Act retained the fourteen-year patent term,<sup>201</sup> and it

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England, of course, did not have a Constitution limiting the duration of patents and copyrights to “limited Times.”

<sup>190</sup> See EDWARD C. WALTERSCHEID, *TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798-1836*, 82-87, 107-08 (1998).

<sup>191</sup> An Act to promote the progress of useful Arts, § 1, 1 Stat. 109, 110 (Apr. 10, 1790).

<sup>192</sup> See WALTERSCHEID, *supra* note 190, at 309-13.

<sup>193</sup> *Id.* at 337-40.

<sup>194</sup> *Id.* at 313.

<sup>195</sup> See notes 235-286 and accompanying text.

<sup>196</sup> Act of July 3, 1832, § 2, 4 Stat. 559 (1832).

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> WALTERSCHEID, *supra* note 190, at 344.

<sup>200</sup> Act of July 4, 1836, ch. 357, 5 Stat. 117 (1836).

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included a procedure by which any patentee could petition a three-person Board for a seven-year extension of his or her term.<sup>202</sup> The statute provided:

And if, upon a hearing of the matter, it shall appear to the full and entire satisfaction of said board, having due regard to the public interest therein, that it is just and proper that the term of the patent should be extended by reason of the patentee, without neglect or fault on his part, having failed to obtain, from the use and sale of his invention, a reasonable remuneration for the time, ingenuity, and expense bestowed upon the same, and the introduction thereof into use, it shall be the duty of the Commissioner to renew and extend the patent . . . for the term of seven years from and after the expiration of the first term. . . . *Provided however*, that no extension of a patent shall be granted after the expiration of the term for which it was originally issued.<sup>203</sup>

The application of this section to patents issued under the 1836 Act presents no constitutional difficulty, as the right to apply for a single seven-year renewal term became part of the expected reward for prospective patentees.<sup>204</sup> But this provision applied retroactively to existing patents, as well as to patents issued under the 1836 Act. Once again, therefore, Congress expressed its view that it could extend the term of patents and copyrights, so long as they had not yet expired at the time of the extension.

The process of hearing petitions for extensions under the 1836 Act proved to be burdensome for the Patent Office. In 1861, therefore, Congress decreed “[t]hat all patents hereinafter granted shall remain in force for a term of seventeen years from the date of issue, and all extension of such patents is hereby prohibited.”<sup>205</sup> By its terms, this enactment was not retroactive. Thus, when a general revision was passed in 1870, the right to petition for an extension under the 1836 Act was limited to those patents granted prior to March 2, 1861.<sup>206</sup> Consequently, “[t]he last extension of

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<sup>201</sup> *Id.*, § 5, 5 Stat. 119.

<sup>202</sup> *Id.*, § 18, 5 Stat. 124-25. It is clear from the statutory language that a patent could only be renewed once, “for the term of seven years from and after the expiration of the first term.” *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> In this respect, the 1836 Act is no different from the Copyright Acts of 1790, 1831, and 1909, all of which provided for an initial term and a single renewal term of fixed duration.

<sup>205</sup> Act of Mar. 2, 1861, ch. 88, § 16, 12 Stat. 246, 249 (1861).

<sup>206</sup> Patent Act of 1870, § 63, 16 Stat. 198, 208 (1870).

the kind was granted in 1875 and expired in 1882.”<sup>207</sup> Aside from this grandfather clause, both the 1870 Act<sup>208</sup> and the 1952 Act<sup>209</sup> provided for a single term of seventeen years.

In the twentieth century, special term extension acts were passed in the wake of the World War I<sup>210</sup> and World War II.<sup>211</sup> These Acts authorized the Commissioner of Patents to extend patents owned<sup>212</sup> by war veterans,<sup>213</sup> “on the theory that their service would have in many cases precluded them an opportunity to exploit their patents during that period.”<sup>214</sup> Although the Acts allowed extensions that exceeded the terms

<sup>207</sup> 2 ERNEST BAINBRIDGE LIPSCOMB III, WALKER ON PATENTS § 8:8, at 498 (3d ed. 1985).

<sup>208</sup> Patent Act of 1870, § 22, 16 Stat. at 201.

<sup>209</sup> Pub. L. No. 82-593, § 4, 66 Stat. 792, 804 (1952) (codified at former 35 U.S.C. § 154).

<sup>210</sup> Act of May 31, 1928, ch. 992, § 1, 45 Stat. 1012 (1928). Only six patents were extended under the 1928 law. *See* Extension of Reissued Patent No. 19,023, Hearings Before the Committee on Patents on H.R. 2994, 78th Cong. (Oct. 13, 1943) at 2. One aggrieved veteran appealed to the Court of Customs and Patent Appeals, but the appeal was dismissed on procedural grounds. *See In re Horton*, 58 F.2d 682 (C.C.P.A. 1932).

<sup>211</sup> Pub. L. No. 81-958, ch. 444, 64 Stat. 316 (1950). It is unknown how many patents were extended under this Act, but one veteran had no fewer than twenty-four patents extended. *See* Application of Walker, 195 F.2d 531, 532 (C.C.P.A. 1952); *see also* Barrett v. United States, 405 F.2d 502, 503 n.1 (Ct. Cl. 1968) (noting patent was extended by six years under 1950 Act).

<sup>212</sup> The 1950 act applied only to patents “still owned” by the veteran-inventor, or to patents assigned to the veteran of which the veteran was “continuously thereafter the sole owner.” In a series of decisions, the Court of Customs and Patent Appeals interpreted the phrase “still owned” to require continuous and sole ownership, and it affirmed the denial of several extensions on that ground. *See* Application of Field, 190 F.2d 268 (C.C.P.A. 1951) (patent owned by corporation of which veteran owned 79% of stock); Application of Miller, 193 F.2d 339 (C.C.P.A. 1951) (patent assigned to corporation for period of twenty-two months and reassigned to veteran); Application of Blood, 197 F.2d 545 (C.C.P.A. 1952) (patent issued to corporation of which veteran owned 52% of stock and later assigned to the veteran); Application of Sutherland, 197 F.2d 556 (C.C.P.A. 1952) (patent held in trust by two veterans for the benefit of themselves and four others). Congress subsequently amended the act to provide that “[n]o person shall be held not to be the sole owner of a patent within the meaning of this Act, by reason of any interest of his spouse in such patent.” Pub. L. No. 82-437, ch. 540, 66 Stat. 321 (1952).

<sup>213</sup> In *Application of Martin*, 195 F.2d 303 (C.C.P.A. 1952), the Court of Customs and Patent Appeals held that service in the Merchant Marine, operating under the control of the U.S. Navy, was not service “in the military or naval forces of the United States” within the meaning of the 1950 Act.

<sup>214</sup> S. REP. NO. 81-1190, reprinted in 1950 U.S.C.C.A.N. 2667, 2667. Consequently, both acts were restricted to veterans who could demonstrate that they had lost income from the patent as a result of their service. *See* Appli-

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of service of the patentees,<sup>215</sup> this was considered necessary because of the delay in enacting them following the wars.<sup>216</sup> These Acts can thus be justified as restoring the term reasonably expected to be enjoyed by the patentees, rather than increasing it.

In 1984, Congress again acted to mitigate the consequences of circumstances beyond the control of the patentee by enacting the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>217</sup> commonly known as the Hatch-Waxman Act. The Act provided for the extension of patents for human drug products, medical devices, and food additives subject to regulatory review by the Food and Drug Administration.<sup>218</sup> The extension is equal to the period during which the product was under regulatory review,<sup>219</sup> subject in most cases to a maximum extension of five years.<sup>220</sup> The extended patent term may not exceed fourteen years follow-

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cation of Walker, 195 F.2d 531 (C.C.P.A. 1952) (affirming denial of extension where income from patent had increased during the war years).

<sup>215</sup> Act of May 31, 1928, § 1(F), 45 Stat. at 1013 (“The period of extension of the patent from the expiration of the original term thereof . . . shall in no case exceed a further term of three times the length of his said service in the military or naval forces”); Pub. L. No. 81-958, § 1, 64 Stat. at 317 (“The period of extension of such patent shall be a further term from the expiration of the original term thereof equaling twice the length of the portion of his said service . . . during which his patent was in force.”).

<sup>216</sup> See CONF. REP. NO. 81-1880, *reprinted in* 1950 U.S.C.C.A.N. 2669, 2669 (“The Senate amendment to the bill would have reduced the period of the proposed extension of patents for veterans of World War II from twice the period of their service between certain dates to a length of time only equaling the period of service between those dates. This would have inadvertently deprived many veterans of their rights because in many cases the period represented by the Senate amendment would have already expired.”).

As a consequence of the delay, these Acts in some cases revived expired patent rights in addition to extending them. Both Acts, however, contained savings clauses that preserved the rights of those who had manufactured infringing devices after the expiration of the original term and before the extension was obtained. Act of May 31, 1928, § 1(H), 45 Stat. at 1013; Pub. L. No. 81-958, § 4(c), 64 Stat. at 318.

<sup>217</sup> Pub. L. No. 98-417, Title II, 98 Stat. 1585, 1598 (1984) (codified as amended in 35 U.S.C. § 156).

<sup>218</sup> See 35 U.S.C. § 156(f) (2000).

<sup>219</sup> *Id.* § 156(c). The regulatory review period is reduced by “any period . . . during which the applicant . . . did not act with due diligence,” *Id.* § 156(c)(1), and by one-half of the period between which testing was begun and an application for approval was submitted to the FDA, *Id.* § 156(c)(2).

<sup>220</sup> *Id.* § 156(g)(6) (2000). If the patent issued after the date of enactment, or the patent issued before the date of enactment but no testing had occurred before that date, the maximum extension is five years. § 156(g)(6)(A-B). If the patent issued and testing was begun but approval was not obtained before the date of enactment, the maximum extension is two years.

ing FDA approval,<sup>221</sup> and a patent may receive only one such extension.<sup>222</sup> Like the veterans' extensions, the Hatch-Waxman Act can be justified as merely restoring the term intended by Congress and reasonably expected to be enjoyed by the patentees, rather than increasing it.

In 1994, in legislation implementing the Uruguay Round of the General Agreement on Tariffs and Trade,<sup>223</sup> Congress changed the basic term for all newly-issued patents<sup>224</sup> from seventeen years from the date of issue to twenty years from the date of filing.<sup>225</sup> Existing patents and pending applications were automatically given the greater of the two periods.<sup>226</sup> For these patents, the statute extends the term of the patent only if the patent issued less than three years from the date of filing. In a case decided shortly after the amendment, the Federal Circuit commented:

The purpose of the URAA was not to extend patent terms, although it has the effect in some cases, but to harmonize the term provision of United States patent law with that of our leading trading partners . . . .<sup>227</sup>

Nonetheless, Congress recognized that extending the terms of existing patents might be unfair to those who had relied on the previous expiration date. It therefore provided that if, prior to the effective date, a person had

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§ 156(g)(6)(C). A statutory loophole exempts some products which do not fall into any of the above categories from any maximum period of extension. *See Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 528-29 (Fed. Cir. 1990).

<sup>221</sup> 35 U.S.C. § 156(c)(3) (2000).

<sup>222</sup> Extension is permitted only if "the term of the patent has never been extended" under the Act. 35 U.S.C. § 156(a)(2) (2000).

<sup>223</sup> *See generally* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (Dec. 8, 1994) (codified in scattered sections of the United States Code).

<sup>224</sup> Section 534(b)(1) of the URAA provides: "Subject to paragraph (2), the amendments made by this subtitle take effect on the date that is 6 months after the date of enactment of this Act and shall apply to all patent applications filed in the United States on or after the effective date." Pub. L. No. 103-465, § 534(b)(1), 108 Stat. at 4990. The URAA was passed on Dec. 8, 1994; so the effective date of the term extension provisions was June 8, 1995. For a discussion of an ambiguity with regard to the effective date, see 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.04[6], at 16-221 n.4 (2001 ed.).

<sup>225</sup> "[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States." 35 U.S.C. § 154(a)(2) (2000).

<sup>226</sup> "The term of a patent that is in force on or that results from an application filed before [the effective date] . . . shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. § 154(c)(1) (2000).

<sup>227</sup> *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996).

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commenced acts or made a substantial investment toward acts that became infringing because of the extension, the normal remedies for infringement would not apply.<sup>228</sup> Instead, the person would be allowed to continue the infringing acts upon payment of an “equitable remuneration” to the patentee.<sup>229</sup>

This brief history of patent terms reveals three noteworthy features. First, while patent terms have been increased from a maximum of fourteen years from issuance to a maximum of twenty years from filing, copyright terms have been increased from a maximum of twenty-eight years from first publication to a maximum of ninety-five years from first publication for older works, the greater of ninety-five years from first publication or 120 years from creation for works made for hire, and life of the author plus seventy years for the works of individual authors. In 1790, a copyright could last twice as long as a patent; today, a copyright lasts five or six times as long as a patent. If the Constitution can be read to require proportionality between copyright terms and patent terms, the Sonny Bono Copyright Term Extension Act would seem to exceed it.<sup>230</sup>

Second, both of the veterans’ extensions and the Hatch-Waxman Act were intended to be compensatory for some delay beyond the control of the patentee, rather than a true increase in the basic term of a patent.

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<sup>228</sup> 35 U.S.C. § 154(c)(2) (2000).

<sup>229</sup> *Id.* § 154(c)(3).

The Uruguay Round Agreements Act also added a provision increasing the term of a patent to compensate for delays in issuance caused by an interference proceeding, a secrecy order, or appellate review of the denial of a patent. Pub. L. No. 103-465, § 532(a), 108 Stat. at 4984 (codified in former 35 U.S.C. § 154(b)). This subsection was in effect for just five years; in 1999 it was repealed and replaced with a new section adjusting the patent term for these and other delays in prosecution of a patent beyond the control of the patentee. Pub. L. No. 106-113, Div. B, § 1000(a)(9) [S. 1948, Title IV, § 4402(a)], 113 Stat. 1536, 1501A-557-58 (Nov. 29, 1999) (codified at 35 U.S.C. § 154(b)). Neither of these sections presents constitutional difficulties, however, because both were applied prospectively only, i.e., only to applications filed on or after their effective dates. *See* Pub. L. No. 103-465, § 534(b)(1), 108 Stat. at 4990 (“Subject to paragraph (2), the amendments made by section 532 take effect on the date that is 6 months after the date of enactment of this Act [Dec. 8, 1994] and shall apply to all patent applications filed in the United States on or after the effective date.”); Pub. L. No. 106-113, Div. B, § 1009(a)(9) [S. 1948, Title IV, § 4405(a)], 113 Stat. at 1501A-560 (“The amendments made by section 4402 and 4404 shall take effect on the date that is 6 months after the date of the enactment of this Act [Nov. 29, 1999] and . . . shall apply to any application filed on or after the date that is 6 months after the date of the enactment of this Act.”).

<sup>230</sup> *See* Edward C. Walterscheid, *The Remarkable—And Irrational—Disparity Between the Patent Term and Copyright Term*, 83 J. PAT. & TRADEMARK OFF. SOC’Y 233 (2001).

Third, until 1994 relatively few subsisting patents were extended for non-compensatory reasons by general acts of Congress. The 1836 Act only allowed patentees to apply for an extension; it did not automatically grant an extension to all existing patents.<sup>231</sup> The 1861 Act enacting a seventeen-year term did not apply retroactively. The recent exception is the URAA, which applied retroactively to those patents in force which issued within three years of filing. Although the effect of this change was hotly debated, a 1994 study found that approximately 75% of existing patents would have their terms extended by the URAA, by an average of 253 days.<sup>232</sup> However, while the URAA did extend most patents, its principal purpose was to change the measurement of patent terms from the date of issuance to the date of filing.<sup>233</sup> Some members of Congress even believed that the change would result in a significant reduction of patent terms.<sup>234</sup> Unlike the CTEA, it cannot be said that term extension was the primary motivating factor for the URAA legislation. Thus, although Congress has occasionally asserted the power to extend the terms of existing patents, none of those occasions provides a precedent for the across-the-board term extension of the Sonny Bono Copyright Term Extension Act.

## 2. *Private Laws*

The first private law extending a patent was enacted by Congress in 1808.<sup>235</sup> The patentee was Oliver Evans, and the patent described a combination of five machines used in the operation of a flour mill.<sup>236</sup> His patent was destined to become one of the most litigated patents in U.S. history, generating twelve reported decisions between 1807 and 1822.<sup>237</sup>

<sup>231</sup> In 1846, it was reported that only ten patents had been extended under § 18 of the 1836 Act, out of 14,526 patents that had been issued prior to that time. *Wilson v. Rousseau*, 45 U.S. (4 How.) 646, 708 (1846) (Woodbury, J., dissenting).

<sup>232</sup> See Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 *AIPLA Q.J.* 369, 391-92 (1994).

<sup>233</sup> *Id.* at 376-81 (explaining that the GATT extension was motivated in part by the problem of “submarine” patents, and that the incentive to engage in submarine patenting is defeated by a term measured from date of filing).

<sup>234</sup> *Id.* at 381.

<sup>235</sup> An Act for the relief of Oliver Evans, 6 Stat. 70 (1808). By this time, only two delegates to the Constitutional Convention of 1787 remained in Congress, both in the Senate. Three other members of the Senate had been representatives in the First Congress. See BENTON, *supra* note 47, at 21-25 (listing delegates); BIOGRAPHICAL DIRECTORY, *supra* note 47, at 51-52 (listing members of First Congress), 74-76 (members of 10th Congress).

<sup>236</sup> See P.J. Federico, *The Patent Trials of Oliver Evans*, 27 *J. PAT. OFF. SOC'Y* 586, 590-93 (1945); WALTERSCHEID, *supra* note 190, at 158-59.

<sup>237</sup> See *Evans v. Jordan*, 13 U.S. (9 Cranch) 199 (1815); *Evans v. Eaton*, 16 U.S. (3 Wheat.) 454 (1818); *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822); *Evans v.*

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In order to fully appreciate the significance of those decisions, it is helpful to examine the chronology of his attempts to obtain an extension.

Evans' original patent was the third patent issued by the federal government; its effective date was January 7, 1791,<sup>238</sup> and under the terms of the 1790 Act, its original expiration date was January 7, 1805. On December 21, 1804, Evans presented a petition to Congress seeking to have the term of his patent extended by seven years.<sup>239</sup> The House Committee of Commerce and Manufactures described the petition as follows:

The petitioner represents, that, owing to the great extent of the United States, and the difficulties usually attending the introduction of improvements in new countries, he has not yet been able to collect any considerable sums from his patent; and having found it necessary to impose on himself a condition not to expend in new inventions and discoveries any more than the net profits derived from old ones, he finds himself compelled to ask for the extension of his patent right for the improvement in merchant flour mills, with a view that he may appropriate the proceeds towards completing his further inventions on steam engines . . .<sup>240</sup>

On January 22, 1805, the Committee recommended that the extension be granted, and further recommended that Congress amend the 1790 Act to allow for term extensions.<sup>241</sup> Both recommendations were rejected.<sup>242</sup>

On December 31, 1805, Evans again petitioned Congress, this time seeking an extension "for such term as you, in your wisdom, may deem best."<sup>243</sup> He reiterated the arguments he had made in his previous peti-

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Hettick, 20 U.S. (7 Wheat.) 453 (1822); *Evans v. Chambers*, 8 F. Cas. 837 (C.C.D. Pa. 1807) (No. 4,555); *Evans v. Weiss*, 8 F. Cas. 888 (C.C.D. Pa. 1809) (No. 4,572); *Evans v. Robinson*, 8 F. Cas. 886 (C.C.D. Md. 1812) (No. 4,571); *Evans v. Jordan*, 8 F. Cas. 872 (C.C.D. Va. 1813) (No. 4,564); *Evans v. Eaton*, 8 F. Cas. 846 (C.C.D. Pa. 1816) (No. 4,559); *Evans v. Kremer*, 8 F. Cas. 874 (C.C.D. Pa. 1816) (No. 4,565); *Evans v. Eaton*, 8 F. Cas. 856 (C.C.D. Pa. 1818) (No. 4,560); *Evans v. Hettick*, 8 F. Cas. 861 (C.C.D.C. 1818) (No. 4,561).

<sup>238</sup> Federico, *supra* note 236, at 589-90; WALTERSCHEID, *supra* note 190, at 158.

<sup>239</sup> Federico, *supra* note 236, at 598; WALTERSCHEID, *supra* note 190, at 347.

<sup>240</sup> American State Papers, No. 186, 1 Misc. 416 (1805).

<sup>241</sup> *Id.*

<sup>242</sup> Federico, *supra* note 236, at 599 & n.39; WALTERSCHEID, *supra* note 190, at 347 & n.60.

<sup>243</sup> American State Papers, No. 196, 1 Misc. 434, 435 (1805). Walterscheid erroneously states that Evans sought an extension for a full fourteen-year term. WALTERSCHEID, *supra* note 190, at 348. He apparently based his belief on language used earlier in the petition, in which Evans asked for "the exclusive right of his own inventions for another term." American State Papers, No. 196, 1 Misc. at 434. As the language quoted in the text indicates, how-

tion, that he had not been “well-rewarded” for his invention, and that he had “already expended more than the net profits arising from his invention” in working on improvements to steam engines; and he stated his intention to spend \$9,000 in refining and introducing his steam engines.<sup>244</sup> Congress did not act on this petition.<sup>245</sup>

The following year, Evans tried a different tactic. On December 19, 1806, he presented an anonymous petition to Congress, arguing that patent rights ought to be granted to inventors and their heirs and assigns forever; or at least for the greater of the life of the inventor or fifty years from the date of the grant.<sup>246</sup> A bill was prepared authorizing three renewal terms of seven years each for existing patents, and two renewal terms for expired patents.<sup>247</sup> The House took no action on the bill, and it died at the end of the session.<sup>248</sup>

In April 1807, an infringement action that Evans had filed three years earlier came up for trial.<sup>249</sup> The defendant, Benjamin Chambers, did not deny infringement, but argued that the patent was invalid because the face of the patent document did not recite the allegations of the petition that Evans had presented when applying for his patent.<sup>250</sup> Evans’ attorney was surprised by the argument, and asked that the case be held over to the October term.<sup>251</sup> Evans immediately wrote to Thomas Jefferson seeking his advice,<sup>252</sup> and Jefferson replied, stating his opinion that a ministerial error was not sufficient to invalidate the patent.<sup>253</sup> Nonetheless, when the

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ever, Evans left the duration of the renewal term he sought to the discretion of Congress.

<sup>244</sup> American State Papers, No. 196, 1 Misc. at 434-35.

<sup>245</sup> Federico, *supra* note 236, at 599.

<sup>246</sup> WALTERSCHEID, *supra* note 190, at 310-11 & nn.19-20.

<sup>247</sup> *Id.* at 338. The extent to which Evans’ petition influenced the content of the bill is unclear, as the Committee that reported it was appointed eight days before Evans’ petition was presented. *Id.*

<sup>248</sup> *Id.*

<sup>249</sup> Federico, *supra* note 236, at 601; WALTERSCHEID, *supra* note 190, at 159.

<sup>250</sup> Federico, *supra* note 236, at 601; WALTERSCHEID, *supra* note 190, at 159.

<sup>251</sup> Federico, *supra* note 236, at 602; WALTERSCHEID, *supra* note 190, at 160.

<sup>252</sup> The letter is quoted in Federico, *supra* note 236, at 601 n.44; and in WALTERSCHEID, *supra* note 190, at 159-60. Walterscheid adds: “The idea of writing to the President of the United States concerning what had transpired in a federal court and fully expecting a reply at the hand of the President would seem highly audacious today, but in the circumstances it was not unreasonable, particularly when it is recalled that Jefferson was the Secretary of State who had issued the patent in question and he was quite familiar with the requirements of the Patent Act of 1790.” *Id.* at 159 n.47.

<sup>253</sup> Jefferson’s reply is quoted Federico, *supra* note 236, at 601; and in WALTERSCHEID, *supra* note 190, at 160-61.

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case came up for decision in October, the court held that the patent was invalid.<sup>254</sup>

According to one scholar, “[i]t was immediately recognized that, if accepted as binding on the federal government, the views expressed by the Circuit Court would render invalid all fifty-seven patents issued under the Patent Act of 1790.”<sup>255</sup> Evans could not appeal to the U.S. Supreme Court, however, because the amount in controversy did not meet the \$2000 amount that was then required.<sup>256</sup> Instead, Evans presented another petition to Congress, seeking a reissue of his patent on the grounds that the decision had prevented him from receiving the economic reward to which he was entitled.<sup>257</sup> The Committee to whom the petition was referred recommended that it be granted, because “the defect in his patent was caused by those appointed to issue it, from a misapprehension of the provisions of the law merely.”<sup>258</sup> Congress approved a private bill granting Evans a new patent of fourteen years, and President Jefferson (who, as Secretary of State, had been responsible for issuing the patent in the first place) signed it into law on January 21, 1808.<sup>259</sup>

Evans’ reissued patent was problematic for at least two reasons. First, as one scholar has noted:

In thus authorizing a new patent for a full term Congress went beyond the necessities of the occasion. The most that Evans lost by the decision of the court was the right to collect from those who had infringed prior to the expiration of the first patent, over three years before the act was passed. While the total of these sums may have been substantial, this total would be far greatly exceeded by the value of fourteen years in the future, with the steadily growing use of the inventions. . . . [T]he decision of the court was a fortunate accident enabling Evans to secure the extension for which he had petitioned two successive Congresses without result.<sup>260</sup>

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<sup>254</sup> *Evans v. Chambers*, 8 F. Cas. 837 (C.C.D. Pa. 1807) (No. 4,555).

<sup>255</sup> WALTERSCHEID, *supra* note 190, at 163. This statement is based on the subsequent report of a congressional committee, which quotes a letter from James Madison, then Secretary of State, which states “a compliance with [the decision] would admit the invalidity of all the patents issued in the same form since the commencement of the Government.” *American State Papers*, No. 231, 1 Misc. 646 (1807).

<sup>256</sup> Federico, *supra* note 236, at 604.

<sup>257</sup> *Id.* at 604-05 & n.49; WALTERSCHEID, *supra* note 190, at 348.

<sup>258</sup> *American State Papers*, No. 231, 1 Misc. 646 (1807).

<sup>259</sup> An Act for the relief of Oliver Evans, 6 Stat. 70 (1808).

<sup>260</sup> Federico, *supra* note 236, at 605.

Second, Congress had not merely extended Evans' patent; it had revived a patent that had already expired three years earlier. To protect the rights of those who had relied on the expiration of the original patent, Congress included a proviso, stating "[t]hat no person who shall have used the said improvements, or erected the same for use, before the issuing of the said patent, shall be liable for damages therefor."<sup>261</sup> The construction of this clause became a major issue in litigation that would eventually reach the U.S. Supreme Court. Parties who had begun practicing the improvements during the intervening three years argued that the clause immunized them from suit during the entire term of the reissued patent; whereas Evans argued that it only immunized them for the use of the improvements during those three years.

The first reported decision involving Evans' revived patent was *Evans v. Weiss*.<sup>262</sup> Weiss had been licensed to use the improvements during the original term of the patent and had expanded his use after the patent expired.<sup>263</sup> Construing the proviso for the first time, Justice Bushrod Washington held that Evans was entitled to recover royalties from Weiss for continued use during the second term.<sup>264</sup> In so doing, he rejected the argument that "such a construction would render this an ex post facto law, and consequently repugnant to the constitution."<sup>265</sup>

In *Evans v. Robinson*,<sup>266</sup> the defendants challenged the constitutionality of the private law on similar grounds. The court responded to these arguments as follows:

[T]hat in the opinion of the court the act referred to is not an ex post facto law, for that relates to criminal cases only; that it does not impair the obligation of contracts, or interfere with any rights previously acquired by the community; . . . that congress have the exclusive right by the constitution to limit the times for which a patent right shall be granted, and are not restrained from renewing a patent or prolonging the time of its continuance; more especially in the present case, where the patent granted in the first instance had been decided by judicial authority to be null and void on account of some defect in the patent.<sup>267</sup>

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<sup>261</sup> 6 Stat. at 71.

<sup>262</sup> 8 F. Cas. 888 (C.C.D. Pa. 1809) (No. 4,572).

<sup>263</sup> *Id.* at 888.

<sup>264</sup> *Id.* at 889.

<sup>265</sup> *Id.*

<sup>266</sup> 8 F. Cas. 886 (C.C.D. Md. 1813) (No. 4,571).

<sup>267</sup> *Id.* at 888.

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The court also concurred with Justice Washington's construction of the proviso.<sup>268</sup>

In *Evans v. Jordan*,<sup>269</sup> the defendants argued that they had constructed their flour mills after the expiration of the first patent and before the date of the second; that it would be unjust to subject them to royalties for using improvements which they had commenced using when they had a right to do so; and that the proviso ought not to be construed to reach an unjust result.<sup>270</sup> In the course of its opinion, the court, in dicta, remarked on Congress' power under the Patent and Copyright Clause:

To that department is confided, without revision, the power of deciding on the justice as well as the wisdom of measures relative to subjects on which they have the constitutional power to act.<sup>271</sup>

That this statement was merely dicta, however, is clear from the court's subsequent observation that "[the] construction of the constitution which admits the renewal of a patent is not controverted."<sup>272</sup> Being divided on the proper construction of the proviso, the court certified the question to the U.S. Supreme Court.<sup>273</sup>

The Supreme Court, in an opinion by Justice Washington, upheld his previous construction of the proviso.<sup>274</sup> It stated:

[T]his Court would transgress the limits of judicial power by an attempt to supply, by construction, this supposed omission of the legislature. The argument, founded upon the hardship of this and similar cases, would be entitled to great weight, if the words of this proviso were obscure and open to construction. But considerations of this nature can never sanction a construction at variance with the manifest meaning of the legislature, expressed in plain and unambiguous language.<sup>275</sup>

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<sup>268</sup> *Id.*

<sup>269</sup> 8 F. Cas. 872 (C.C.D. Va. 1813) (No. 4,564).

<sup>270</sup> *Id.* at 873.

<sup>271</sup> *Id.*

<sup>272</sup> *Id.* at 874.

<sup>273</sup> *Id.*

<sup>274</sup> *Evans v. Jordan*, 13 U.S. (9 Cranch) 199 (1815).

<sup>275</sup> *Id.* at 203.

Although the defendants made allusions to the Constitution in their argument,<sup>276</sup> they did not argue that the extension was beyond Congress' power under the Patent and Copyright Clause.<sup>277</sup>

The constitutionality of the revived patent was expressly raised in a later case, *Evans v. Eaton*.<sup>278</sup> The reporter states:

The plaintiff having closed his evidence, a motion was made to nonsuit the plaintiff. It was contended, that after the expiration of the plaintiff's privilege granted to him by this state, the right to his invention became vested in the people of the state, by an implied contract with the government; and that therefore congress could not, consistently with the constitution of the United States, grant to the plaintiff an exclusive right to the invention.<sup>279</sup>

The Circuit Court, in an opinion by Justice Washington, rejected this argument, saying:

Neither the premises upon which this motion is founded, nor the conclusion can be admitted. It is not true that the grant of an exclusive privilege to an invention for a limited time, implies a binding and irrevocable contract with the people, that at the expiration of the period the invention shall become their property. The state has a perfect right to renew the grant at the end of the period or refuse to do so; and in the latter case, it is a matter of course that the invention may be used by any person who

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<sup>276</sup> The defendants argued: "A law to oblige them now to abandon their property or to pay what Mr. Evans may choose to exact, is in the nature of an ex post facto law; and although it may not be absolutely unconstitutional, yet [it] is so far within the spirit of the constitution, that this Court will not give such a construction to the proviso if it can possibly be avoided. . . . To deprive a person of the use of his property is equivalent to depriving him of the property itself." *Id.* at 200.

<sup>277</sup> Contemporary writers, however, suggested that the decision might violate the Due Process clause. Federico states: "While it can readily be said today, considering over one hundred years of legal development, that the *Evans v. Jordan and Morehead* decision is questionable, even contemporary writers felt constrained to criticize the decision. Phillips in his *Law of Patents for Inventions* . . . suggests that the special act, as interpreted by the courts, was of doubtful constitutionality." Federico, *supra* note 236, at 611-12 (citing WILLARD PHILLIPS, *LAW OF PATENTS FOR INVENTIONS* (1837)). Federico also notes that in an 1813 letter, Thomas Jefferson expressed his view that the proviso had been misinterpreted. *Id.* at 612 & n.73 (quoting the letter).

<sup>278</sup> 8 F. Cas. 846 (C.C.D. Pa. 1816) (No. 4,559), *rev'd on other grounds*, 16 U.S. (3 Wheat.) 454 (1818), *on remand*, 8 F. Cas. 856 (C.C.D. Pa. 1818) (No. 4,560), *aff'd*, 20 U.S. (7 Wheat.) 356 (1822).

<sup>279</sup> 8 F. Cas. at 846.

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chooses to do so. In like manner may congress renew a patent right or decline to do so. But even if the premises were true, still there is nothing in the constitution of the United States which forbids congress to pass laws violating the obligation of contracts, although such a power is denied to the states individually.<sup>280</sup>

Although it appears that the defendants' argument was premised on the Contracts Clause of the Constitution,<sup>281</sup> rather than on the "limited Times" language of the Patent and Copyright Clause, this language strongly indicates that the court would have found such an argument to be without merit. The case was later appealed to the Supreme Court,<sup>282</sup> remanded for retrial,<sup>283</sup> and appealed again,<sup>284</sup> but the contention that the revived patent was unconstitutional was not raised in any of the subsequent proceedings.

Although the renewal of Evans' patent had been contentious and problematic,<sup>285</sup> Congress continued to grant patent extensions through private acts. Prior to July 4, 1836, when the Patent Office was given the authority to grant a seven-year extension, Congress extended the terms of ten more patents.<sup>286</sup> Six of these extensions were enacted after the origi-

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<sup>280</sup> *Id.* at 848-49.

<sup>281</sup> U.S. CONST. art. I, § 10, cl. 1 ("No state shall . . . pass any Bill of Attainder, ex post facto law, or Law impairing the Obligation of Contracts . . .").

<sup>282</sup> *Evans v. Eaton*, 16 U.S. (3 Wheat.) 454 (1818). Reversing a directed verdict by Justice Washington, the Court held that Evans' patent covered all five improvements individually, as well as the combination of the five improvements. *Id.* at 506-12.

<sup>283</sup> *Evans v. Eaton*, 8 F. Cas. 856 (C.C.D. Pa. 1818) (No. 4,560). Justice Washington again directed a verdict in favor of the defendant, this time on the ground that the patent did not sufficiently explain how Evans' hopperboy was an improvement over prior similar machines. *Id.* at 859-60.

<sup>284</sup> *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822). This time the court affirmed, ruling "that if it be a patent for an improvement, it is void, because the nature and extent of the improvement is not stated in the specification." *Id.* at 432. By this time, the revived patent had expired, and Oliver Evans had been dead for three years. Federico, *supra* note 236, at 681; WALTERSCHEID, *supra* note 190, at 354.

In a companion case, the Supreme Court affirmed a jury verdict for the defendant, who was found to have used a prior similar machine, rather than Evans' improvement. *Evans v. Hettick*, 20 U.S. (7 Wheat.) 453 (1822), *aff'g* 8 F. Cas. 861 (C.C.E.D. Pa. 1818) (No. 4,562).

<sup>285</sup> In addition to the litigation noted above, over a dozen petitions were filed in Congress between 1810 and 1813 seeking to limit the application of Evans' revived patent. See Federico, *supra* note 236, at 609-10, 661-62, 666-73; WALTERSCHEID, *supra* note 190, at 351-54.

<sup>286</sup> Interestingly, one of the extensions was An Act to extend the time of Oliver Evans' patent for his improvement on steam engines, 6 Stat. 147 (1815).

nal patent had expired. Even after 1836, patentees whose applications for extension were rejected by the Patent Office continued to turn to Congress for relief.<sup>287</sup> Some of these extended patents were challenged in court, and the resulting decisions indicate that Congress has plenary authority to extend patent terms under the Constitution. The majority of these reported decisions involved four patents.

Thomas Blanchard's patent was originally issued on September 6, 1819, and was reissued on January 20, 1820.<sup>288</sup> On June 30, 1834, after the original patent had expired,<sup>289</sup> Congress passed a special act extending the patent for fourteen years.<sup>290</sup> That act, however, inadvertently gave the date of the patent as January 12, 1820, rather than January 20.<sup>291</sup> In *Blanchard v. Sprague* (1838), this variance was held to be fatal.<sup>292</sup> Congress immediately corrected its error, passing an amended act on February 6, 1839.<sup>293</sup> Blanchard refiled his infringement action, and Sprague raised

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The others are listed in the argument of the plaintiff's counsel in *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 543 (1852). Walterscheid states that only six additional extensions were granted during this period, *supra* note 190, at 354. He appears to have relied upon a congressional study published in 1979 in which this figure was given. See CHRISTINE P. BENAGH, *THE HISTORY OF PRIVATE PATENT LEGISLATION IN THE HOUSE OF REPRESENTATIVES*, 96th Cong. (1979), at 7 & n.69.

<sup>287</sup> At least five additional special extensions were passed by Congress between 1836 and 1847. See *Bloomer v. McQuewan*, 55 U.S. (14 How.) at 543-44 (cases listed in argument of counsel). One of these was an amendment correcting a clerical error in a previous extension. See An Act to amend, and carry into effect, the intention of an act entitled "An Act to renew the patent of Thomas Blanchard," 6 Stat. 748 (1839). Of the remaining four, two were extended after the expiration of the original patent. See An Act for the relief of William Gale, 6 Stat. 895 (1843); An Act for the relief of Samuel K. Jennings, 6 Stat. 899 (1843).

<sup>288</sup> See *Blanchard v. Sprague*, 3 F. Cas. 645, 646 (C.C.D. Mass. 1838) (No. 1,517) (Story, J.).

<sup>289</sup> The exact expiration date of the original patent is open to question. Ordinarily, a reissued patent would expire fourteen years from the date of the original patent, or Sept. 6, 1833. The reissued patent, however, granted rights "for the term of fourteen years from the sixth day of January, A.D. 1819," which would place the expiration date on Jan. 6, 1833. *Id.* In extending the patent, however, Congress appeared to assume that the original patent did not expire until fourteen years from the date of the reissued patent, or Jan. 20, 1834. See note 293, *infra*. In any case, it is clear that Congress did not pass the extension until after the original patent had expired.

<sup>290</sup> See An Act to renew the patent of Thomas Blanchard, 6 Stat. 589 (1834).

<sup>291</sup> *Id.*

<sup>292</sup> 3 F. Cas. 645, 646-48 (C.C.D. Mass. 1838) (No. 1,517).

<sup>293</sup> See An Act to amend, and carry into effect, the intention of an act entitled An Act to renew the patent of Thomas Blanchard," 6 Stat. 748 (1839). This act extended the patent for fourteen years from Jan. 20, 1834, *id.*, indicating

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the issue of the constitutionality of the extension.<sup>294</sup> Writing for the Circuit Court, Justice Story stated:

[I]t is suggested that the grant of the patent by the act of congress of 1839, is not constitutional; for it operates retrospectively to give a patent for an invention, which, though made by the patentee, was in public use and enjoyed by the community at the time of the passage of the act. But this objection is fairly put at rest by the decision of the supreme court in the case of the patent of Oliver Evans. For myself, I have never entertained any doubt of the constitutional authority of congress to make such a grant. The power is general, to grant to inventors; and it rests in the sound discretion of congress to say, when and for what length of time and under what circumstances the patent for an invention shall be granted. There is no restriction, which limits the power of congress to enact, where the invention has not been known or used by the public. All that is required is, that the patentee should be the inventor.<sup>295</sup>

In two subsequent cases involving the same patent, counsel for the defendants conceded that Congress had the constitutional power to extend patents.<sup>296</sup>

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that Congress assumed the original patent expired fourteen years from the date of the reissued patent.

<sup>294</sup> *Blanchard v. Sprague*, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1,518).

<sup>295</sup> *Id.* at 650. The Court also held that damages could only be recovered from the date of the amended act (Feb. 6, 1839), even though the language of the amended act granted the extended patent from Jan. 20, 1834, and contained a proviso exempting only those persons who had constructed the invention between the expiration of the original patent and the date of the first special act (June 30, 1834). *See* 6 Stat. at 748. Justice Story wrote: "The act of congress . . . ought to be construed not to operate retrospectively, or ex post facto, unless that construction is unavoidable; for even if a retrospective act is, or may be constitutional, . . . that interpretation is never adopted without absolute necessity." 3 F. Cas. at 650.

<sup>296</sup> *See* *Blanchard's Gun-Stock Turning Factory v. Warner*, 3 F. Cas. 653, 656 (C.C.D. Conn. 1846) (No. 1,521) ("In the exercise of the power conferred by the constitution, congress may, without doubt, extend, or make provision by law for the extension of the exclusive privilege to inventors, beyond the term originally limited, if that is deemed too short to afford them an adequate reward or encouragement.") (argument of Roger S. Baldwin, for defendant); *Blanchard v. Haynes*, 3 F. Cas. 628, 628 (C.C.D. N.H. 1848) (No. 1,512) ("It was admitted that congress had the constitutional right to confer a new and further term on the patentee. Such cases have frequently occurred."). In the latter case, however, two of the three cases cited for the proposition involved reissued patents (which expire at the same time as the original patent), rather than extensions. *See* *Stimpson v. West Chester Rail-*

William Woodworth obtained a patent on December 27, 1828.<sup>297</sup> Woodworth died six weeks later; but in 1842, on the application of his administrator, the patent was extended under the 1836 Act for seven years,<sup>298</sup> or until December 27, 1849. On February 26, 1845, Congress passed a special act extending the patent for an additional seven years.<sup>299</sup> In *Bloomer v. Stolley*,<sup>300</sup> the second extension was challenged in court, on the ground that Congress could only extend patents by general legislation, rather than by special legislation.<sup>301</sup> The court rejected this argument, saying:

There would seem to be no doubt that the constitutional power in question might have been fully exercised by congress in making special grants. . . . Congress adopted a system for the sale and granting of public lands, but no one doubts that it may make special grants of land by law. This has been done; and the same principle applies to the granting of an exclusive right to an inventor. The machinery through which this right is ordinarily applied for, and obtained, may be dispensed with, and the title may be conferred by legislative grant; and this may be done in regard to the extension of an exclusive right by congress, the same as originally granting it. No constitutional restriction appears against the exercise of this power by congress. . . . There is no prohibition in the law against a second extension, while provision is made for a first extension, should the inventor bring himself within it.<sup>302</sup>

The court also rejected an argument that the extension could not be applied retroactively to licensees under the first patent, who arguably had relied on the expiration date of the patent in investing in the invention. The court said:

The true answer to the case put is, the expenditure made by the licensee, or any other person, was made with a presumed knowledge of the law the congress had the power to extend the patent; and, with this knowledge, the risk of a renewal of the patent was incurred.<sup>303</sup>

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road Co., 45 U.S. (4 How.) 380, 381 (1846); *Grant v. Raymond*, 31 U.S. (6 Pet.) 240 (1832).

<sup>297</sup> *Bloomer v. Stolley*, 3 F. Cas. 729, 730 (C.C.D. Ohio 1850) (No. 1,559).

<sup>298</sup> *Id.*

<sup>299</sup> An Act to extend a patent heretofore granted to William Woodworth, 6 Stat. 936 (1845).

<sup>300</sup> 3 F. Cas. 729, 730 (C.C.D. Ohio 1850) (No. 1,559).

<sup>301</sup> *Id.* at 730.

<sup>302</sup> *Id.* at 730-31.

<sup>303</sup> *Id.* at 731.

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It should also be noted that Woodworth's extended patent came before the U.S. Supreme Court on three occasions, with nary a suggestion by the Court that the extension might violate the "limited Times" provision of the Constitution.<sup>304</sup>

A truly extraordinary situation was presented in the case of *Jordan v. Dobson*.<sup>305</sup> John Goulding obtained a patent on December 15, 1826, and it expired fourteen years later, on December 15, 1840.<sup>306</sup> As the Supreme Court later explained:

Omission of the original patentee seasonably to apply for an extension of his patent was occasioned through erroneous information given to him by the commissioner, and not from any negligence or fault of his own. Acting upon information from that source, the inventor did not file the application until it was too late to give the notice required by law, and the time for presenting such an application having expired. The commissioner had no power to grant his request. Deprived of any legal remedy under the general laws for the protection of inventors, he applied to Congress.<sup>307</sup>

On May 30, 1862, more than twenty-one years after the original patent had expired, Congress passed a special act authorizing the Commissioner of Patents to entertain Goulding's application for a seven-year extension, with a proviso that the extension would not restrain those who had begun

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<sup>304</sup> See *Wilson v. Rousseau*, 45 U.S. (4 How.) 646 (1846); *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539 (1852); *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340 (1863).

In *McQuewan*, plaintiff's counsel considered the power of Congress to extend patents to be so well established that he stated: "It is not deemed necessary by the appellants to present any authorities to meet the point argued by the appellees, that an act of Congress, extending a patent for seven years, is unconstitutional and void." 55 U.S. (14 How.) at 544. It appears, however, that the constitutional argument was not based on the "limited Times" provision, but on the Due Process Clause of the Fifth Amendment. In dicta, the court stated:

[I]t can hardly be maintained that Congress could lawfully deprive a citizen of the use of his property after he had purchased the absolute and unlimited right from the inventor. . . . And a special act of Congress, passed afterwards, depriving the appellees of the right to use them, certainly could not be regarded as due process of law.

*Id.* at 553. The court avoided the question, however, by construing the extension not to apply to those who had purchased the invention during the original term. *Id.* at 554.

<sup>305</sup> 13 F. Cas. 1092 (C.C.E.D. Pa. 1870) (No. 7,519).

<sup>306</sup> *Id.* at 1093.

<sup>307</sup> *Agawam Co. v. Jordan*, 74 U.S. (7 Wall.) 583, 608 (1868).

using the invention in the interim.<sup>308</sup> The revived patent issued on August 30, 1862.<sup>309</sup> When Goulding's assignees sued Dobson for infringement, Dobson argued that the extension was unconstitutional. The Circuit Court rejected this argument, saying:

It has been further contended . . . that the act of congress of May 30, 1862, under which the patent was extended, was unauthorized and went beyond the power of congress, because the patent had expired in 1840, and the invention had become the property of the public, and because, therefore, the act was in effect taking property which belonged to the public and giving it to an individual. It assumes that every person had a right of property in Goulding's invention immediately after the expiration of his first patent, even before any attempt to appropriate it. It puts a right to appropriate that which is common, and in which there can be no private property until there has been an actual appropriation, on the footing of property acquired. And it overlooks the express grant of power to congress by the constitution. . . . This is a large power. It is not said when those limited times shall commence, how long they shall continue, or when they shall end. All that is left to the discretion of congress. I see no reason why, under this commission, congress may not secure to an inventor an exclusive right to his invention for a limited period, beginning at any time after the invention is made, and after it became publicly known. Congress may be trusted, and they are trusted, to take care that in protecting the inventor, the public shall not be injured. . . . I am not aware that it has ever been seriously thought that congress has not power, after a patent has expired, to provide for its extension.<sup>310</sup>

Again, a subsequent case involving the same patent came before the U.S. Supreme Court,<sup>311</sup> and no argument or suggestion was made that the revived and extended patent was unconstitutional.

A similar situation was presented in *The Fire Extinguisher Case*.<sup>312</sup> William A. Graham's original patent application was filed in the patent office on November 23, 1837.<sup>313</sup> The Commissioner refused to grant the

<sup>308</sup> An Act for the Relief of John Goulding, 12 Stat. 904 (1862).

<sup>309</sup> *Jordan v. Dobson*, 13 F. Cas. at 1093.

<sup>310</sup> *Id.* at 1095 (citing *Blanchard v. Sprague*) (*supra* notes 288-295 and accompanying text); *Evans v. Eaton* (*supra* notes 278-284 and accompanying text); *Blanchard's Gun-Stock Turning Factory v. Warner* (*supra* note 296); and *Blanchard v. Haynes* (*id.*).

<sup>311</sup> *Agawam Co. v. Jordan*, 74 U.S. (7 Wall.) 583 (1868).

<sup>312</sup> *Graham v. Johnston*, 21 F. 40 (C.C.D. Md. 1884).

<sup>313</sup> *Id.* at 40.

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patent on the grounds that the specifications did not disclose a practicable device.<sup>314</sup> Graham was unable to travel to Washington to demonstrate his device, and he died in 1857 without obtaining a patent.<sup>315</sup> In 1874, a similar patent was invalidated on the ground that Graham was the first inventor.<sup>316</sup> Graham's administrator filed another application in the patent office, "but was refused upon the ground that in consequence of the long delay the invention had gone into public use."<sup>317</sup> On June 11, 1878, Congress passed an act permitting Graham's heirs to revive the application.<sup>318</sup> In a subsequent infringement suit, the defendant argued that the revival of Graham's application violated the Due Process Clause of the Fifth Amendment.<sup>319</sup> The court rejected this argument, saying:

[T]he constitutional power of congress for securing to [inventors] the exclusive right to their inventions has only one restriction, viz., that is shall be for limited times. With regard to the terms upon which the exclusive right shall be granted, the time when the application for the original grant or for any renewal or extension of it shall be made, it has been frequently held that the regulations in these matters are merely self-imposed restrictions on the constitutional power of congress, which it can at its pleasure disregard in any particular case. . . .<sup>320</sup>

The right which the public has acquired to use the thing invented, by reason of the applicant for a patent failing to do something prescribed by congress, and the necessity for which congress might, by previous legislation, have dispensed with, have never been held to be a vested right. The cases of *Evans v. Eaton*; *Evans v. Jordan*; *Bloomer v. Stolley*; [and] *Jordan v. Dobson* hardly leave this question debatable.<sup>321</sup>

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<sup>314</sup> *Id.* at 41.

<sup>315</sup> *Id.*

<sup>316</sup> *Id.* See *Northwestern Fire Extinguisher Co. v. Philadelphia Fire Extinguisher Co.*, 18 F. Cas. 394, 397-400 (C.C.E.D. Pa. 1874) (No. 10,337).

<sup>317</sup> *Graham*, 21 F. at 41.

<sup>318</sup> An Act for the relief of the heirs of William A. Graham, 20 Stat. 542 (1878).

<sup>319</sup> *Id.* at 42 ("It is contended by the respondents that this patent is void because congress had no constitutional power to act; that is, by the general acts of congress on the subject of patents . . ., the applications of Graham and his administrator were declared abandoned, and all right to prosecute them was denied, it resulted that the public had acquired the right to use the inventions, and that right could not be taken away without the law being repugnant to the declaration of the constitution that no person shall be deprived of his property without due process of law.").

<sup>320</sup> *Id.*

<sup>321</sup> *Id.* at 43 (citations omitted).

Although this decision involved a revived patent application, rather than an extension, the ruling demonstrates that the court did not consider that the general public had any kind of vested right to practice inventions that were in the public domain.

Throughout the second half of the nineteenth century, Congress continued to pass private patent extensions.<sup>322</sup> Some of these extensions were passed to make amends for the negligence of a public official;<sup>323</sup> but others were based simply on congressional disagreement with the determination of the Commissioner;<sup>324</sup> while others were based on the failure of the inventor to receive adequate compensation for his invention during the patent term.<sup>325</sup> In 1879, however, “the House Committee on Patents began to cut off the flow of petitions based upon inadequate compensation.”<sup>326</sup> It did so by requiring an inventor to demonstrate “reasons not only beyond his control but beyond the control of a man of reasonable prudence and foresight.”<sup>327</sup> As a result, “the heyday of private patent petitions ended with the century.”<sup>328</sup>

Only one private patent extension was passed in the first half of the twentieth century. In 1928, Louis V. Aronson, President of Art Metal Works, Inc., received a patent for a pocket cigar lighter.<sup>329</sup> In 1932, the patent was held valid and infringed by two competing lighters manufactured by the Evans Case Company.<sup>330</sup> On remand, however, the defendant was permitted to amend its answer to allege inequitable conduct by

<sup>322</sup> See Benagh, *supra* note 286, at 9-10.

<sup>323</sup> See, e.g., An Act for the relief of David Bruce, 11 Stat. 546 (1858). Benagh explains that “the Patent Office had lost the application.” Benagh, *supra* note 286, at 9.

<sup>324</sup> See, e.g., An Act for the relief of Oliver C. Harris, 9 Stat. 734 (1848). According to Benagh, “[t]he Commissioner’s refusal was based upon a finding that the invention in question was of insufficient novelty and importance. The committee disagreed, pointing out that when, as part of the fire restoration of the Patent Office, descriptive models were chosen to be re-built on the basis of value, interest, and importance to the public, the petitioner’s invention was among those re-built.” Benagh, *supra* note 286, at 9.

<sup>325</sup> See, e.g., An Act for the relief of George G. Bishop, and the Legal Representative of John Arnold, deceased, 10 Stat. 776 (1854). Benagh states that “although few . . . ever became law,” petitions for private extensions based on inadequate compensation “easily out numbered any other patent petitions” between 1848 and 1880. Benagh, *supra* note 286, at 9.

<sup>326</sup> Benagh, *supra* note 286, at 9.

<sup>327</sup> H.R. REP. NO. 45-177 (1879), *quoted in* Benagh, *supra* note 286, at 9.

<sup>328</sup> Benagh, *supra* note 286, at 10.

<sup>329</sup> U.S. Patent No. 1,673,727 (June 12, 1928). The patent was reissued in 1933. U.S. Patent No. RE 19,023 (Dec. 12, 1933).

<sup>330</sup> See *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 61 F.2d 122 (2d Cir. 1932). Although the suit was brought against a retailer, “[t]he suit was defended by the Evans Case Manufacturing Company, as manufacturer of the

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Art Metal Works.<sup>331</sup> The district court rejected the defense;<sup>332</sup> but on appeal the Second Circuit, in an opinion by Judge Martin T. Manton, held that the plaintiff had affirmatively misrepresented the scope of the prior decision, and denied all relief on that basis.<sup>333</sup> At the same time, a third lighter manufactured by Evans was held to be non-infringing.<sup>334</sup> Five years later, in 1939, Judge Manton resigned his office and was convicted of conspiracy to obstruct justice and to defraud the United States, based in part upon his having solicited money from Evans in return for favorable decisions on the two 1934 appeals.<sup>335</sup> On motion of Art Metal Works, the two decisions were vacated<sup>336</sup> and reargued, with Art Metal Works prevailing in both cases.<sup>337</sup> Despite ultimately having prevailed, Art Metal Works successfully argued to Congress that the seven-year delay between the original finding of infringement in 1932 and the decisions on re-argument of the Second Circuit in 1939 warranted a patent term extension of seven years.<sup>338</sup> According to one commentator, “[t]his was a classic exam-

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alleged infringing devices.” *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 52 F.2d 951, 953 (E.D.N.Y. 1931).

<sup>331</sup> *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 61 F.2d 79, 79 (2d Cir. 1932) (granting motion for permission to apply to District Court for leave to amend); *see also* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 2 F. Supp. 292 (E.D.N.Y. 1933) (granting motion for leave to amend).

<sup>332</sup> *See* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 4 F. Supp. 298 (E.D.N.Y. 1933).

<sup>333</sup> *See* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 70 F.2d 641 (2d Cir. 1934). Judge Manton’s opinion was joined by Judge Harrie Brigham Chase; Judge Learned Hand dissented.

<sup>334</sup> *See* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 2 F. Supp. 677 (E.D.N.Y. 1933) (denying motion for preliminary injunction); *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 4 F. Supp. 303 (E.D.N.Y. 1933) (dismissing action), *aff’d*, 70 F.2d 639 (2d Cir. 1934) (opinion by Manton, J., joined by Chase and L. Hand, JJ.).

<sup>335</sup> *See* *United States v. Manton*, 107 F.2d 834, 837, 840-41 (2d Cir. 1939).

<sup>336</sup> *See* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 42 U.S.P.Q. 639 (2d Cir. 1939) (per curiam).

<sup>337</sup> *See* *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 107 F.2d 940 (2d Cir. 1939) (reversing finding of non-infringement of third lighter), *rev’g* 4 F. Supp. 303 (E.D.N.Y. 1933); *Art Metal Works, Inc. v. Abraham & Straus, Inc.*, 107 F.2d 944 (2d Cir. 1939) (adopting opinion at 70 F.2d 645 (2d Cir. 1934) (L. Hand, dissenting)), *aff’g* 4 F. Supp. 298 (E.D.N.Y. 1933).

<sup>338</sup> *See* An Act to extend Reissued Letters Patent Numbered 19,023, 58 Stat. 1095 (Dec. 23, 1944); Extension of Reissued Patent No. 19,023, *Hearings Before the Committee on Patents on H.R. 2994*, 78th Cong. (Oct. 13, 1943). The Act extended the patent seven years from its original expiration date of June 12, 1945. The seven-year extension was held to be valid despite a typographical error by Congress in identifying the date of the reissued patent. *See* *Ronson Patents Corp. v. Sparklets Devices, Inc.*, 102 F. Supp. 123, 124-25 (E.D. Mo. 1951).

ple of the traditional purpose of private legislation, to relieve a private party in circumstances in which the government had incurred a moral or ethical obligation toward the party.”<sup>339</sup>

The development of radar resulted in a similar piece of private legislation. In 1931, Major William R. Blair of the U.S. Army Signal Corps was placed in charge of a project to detect enemy aircraft by noise, infrared waves and radio waves.<sup>340</sup> He conceived “a method and means for determining the position of distant objects by means of reflected radio waves,”<sup>341</sup> and on May 18, 1937, a prototype was demonstrated to military and government officials at Fort Monmouth, New Jersey.<sup>342</sup> With war looming in Europe, Blair “was specifically ordered by his commanding officer to keep the invention secret and not to file a patent application thereon.”<sup>343</sup> When Blair eventually applied for a patent many years later, his application was denied on the ground that the invention had been in public use or on sale for more than one year before the date of the application.<sup>344</sup> In 1950, Congress passed a private law to relieve Blair of the one-year limit,<sup>345</sup> and Blair was issued a basic patent on radar in 1957.<sup>346</sup>

In 1962, in an infringement suit brought by an assignee of Blair,<sup>347</sup> the private law was challenged on four grounds.<sup>348</sup> First, the defendant argued that since the Act preserved the rights of persons manufacturing or using the invention before the passage of the Act, it did not grant an “exclusive right” within the meaning of the Patent Clause of the Constitution.<sup>349</sup> A three-judge district court<sup>350</sup> rejected this argument, relying in

<sup>339</sup> Benagh, *supra* note 286, at 10. See *United States v. Realty Co.*, 163 U.S. 427, 440-41 (1896) (private legislation is “based upon consideration of a moral or merely honorary nature, such as are binding on the conscience or the honor of an individual, although the debt could obtain no recognition in a court of law.”).

<sup>340</sup> [http://www.infoage.org/SCR\\_270.html](http://www.infoage.org/SCR_270.html) (last visited Sept. 10, 2001).

<sup>341</sup> U.S. Patent No. 2,803,819 (Aug. 20, 1957).

<sup>342</sup> Letter from Kenneth C. Royall, Secretary of the Army, to Chan Gurney, Chairman, Senate Armed Services Committee (Apr. 7, 1948), *reprinted in* S. Rep. No. 81-1665, at 11 (1950).

<sup>343</sup> *Radio Position Finding Corp. v. Bendix Corp.*, 205 F. Supp. 850, 852 (D. Md. 1962), *aff'd mem.*, 371 U.S. 577 (1963) (per curiam).

<sup>344</sup> *Id.* at 851; see 35 U.S.C. § 102(b) (2000).

<sup>345</sup> An Act to Correct Possible Inequity in the Case of a Certain Application for Letters Patent of William R. Blair, Priv. L. No. 1008, 81st Cong., 64 Stat. A243 (1950).

<sup>346</sup> U.S. Patent No. 2,803,819 (Aug. 20, 1957).

<sup>347</sup> *Radio Position Finding Corp. v. Bendix Corp.*, 205 F. Supp. 850 (D. Md. 1962), *aff'd mem.* 371 U.S. 577 (1963) (per curiam).

<sup>348</sup> The court characterized the challenge as based on three grounds, *id.* at 852; but as discussed below, the defendant had two different arguments based on substantive due process. See notes 353-363 and accompanying text.

<sup>349</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 852.

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part on the patent term extension cases described above.<sup>351</sup> The court stated:

The direct and indirect expressions of approval of various private laws which have modified the exclusiveness of the grant to the patentee and the long legislative history of the exercise of congressional power to modify the exclusiveness of a patent grant, dating, indeed, from shortly after the adoption of the Constitution, lead us to conclude that Congress did not violate Article I, § 8, cl. 8 of the Constitution in the enactment of Private Law 1008.<sup>352</sup>

Second, the defendant argued “that it and other members of the public acquired a vested right in the invention because of Blair’s failure to seek a patent within the time prescribed by law and the passage of the invention into the public domain,”<sup>353</sup> and that allowing Blair to obtain a patent would deny them that property right in violation of the Due Process Clause of the Fifth Amendment.<sup>354</sup> Relying on *The Fire-Extinguisher Case*,<sup>355</sup> the court rejected this argument.<sup>356</sup> It reasoned:

Private Law 1008 did nothing more than waive the statute of limitations contained in 35 U.S.C.A. § 102(b). In Federal jurisprudence statutes of limitations are not generally considered to create vested rights in those whose obligations are barred from enforcement.<sup>357</sup>

The court’s decision on this point is flawed. The court relied in part on the premise that “not until the Patent Act of 1870 . . . was any time limit

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<sup>350</sup> Between 1937 and 1976, federal law required that a three-judge district court be convened whenever the enforcement, operation or execution of any Act of Congress was challenged as unconstitutional. Former 28 U.S.C. § 2282 (repealed 1976); see CHARLES ALAN WRIGHT, *LAW OF FEDERAL COURTS* § 50, at 316-17.(5th ed. 1994).

<sup>351</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 853-55 (citing *Evans v. Jordan*, 13 U.S. 199 (1815)); *Agawam Co. v. Jordan*, 74 U.S. 583 (1868); and *The Fire-Extinguisher Case*, 21 F. 40 (C.C.D. Md. 1884). These cases are discussed above at notes 269-277 and 305-321, and accompanying text.

<sup>352</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 855.

<sup>353</sup> *Id.* at 855-56.

<sup>354</sup> The court characterized this argument as based on “substantive due process.” *Id.* at 852.

<sup>355</sup> 21 F. 40 (C.C.D. Md. 1884), discussed at notes 312-321 and accompanying text.

<sup>356</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 856 (“defendant is in error when it argues that it and the public had acquired a property right in the Blair invention by reason of Blair’s failure to pursue a timely application for a patent, and that this right is one entitled to the protection of the due process clause.”).

<sup>357</sup> *Id.* at 856.

imposed on an applicant for a patent to make his application,”<sup>358</sup> but this premise was incorrect. While the Patent Act of 1870 allowed a two-year period of public use before making an application,<sup>359</sup> prior to that time *any* public use of the invention before the application would disqualify the applicant from receiving a patent.<sup>360</sup> In addition, the court’s analogy to a statute of limitations is flawed. Statutes of limitation act to preserve the status quo and to protect settled expectations,<sup>361</sup> while granting a patent many years after the public has adopted the invention has the opposite effect of disrupting the status quo and interfering with settled expectations.

Third, the defendant argued that the Private Law violated the Equal Protection component of the Due Process Clause of the Fifth Amendment.<sup>362</sup> The court correctly concluded that Congress had a rational basis to grant Blair individual relief.<sup>363</sup> Finally, the defendant argued that the Private Law violated procedural due process by circumventing the usual interference procedure of the Patent Office in determining priority of invention.<sup>364</sup> The court concluded that the ability to challenge the validity of Blair’s patent in court constituted sufficient process to satisfy the requirements of the Fifth Amendment.<sup>365</sup> On a direct appeal,<sup>366</sup> the U.S. Supreme Court affirmed the decision of the three-judge district court without a written opinion.<sup>367</sup>

In the last half of the twentieth century, several pharmaceutical manufacturers sought patent term extensions to compensate them for the time during which their products underwent regulatory review in the Food and

<sup>358</sup> *Id.* at 856 n.6.

<sup>359</sup> Patent Act of 1870, § 24, 16 Stat. 198, 201 (“not in public use or on sale for more than two years prior to his application”).

<sup>360</sup> Patent Act of 1790, § 1, 1 Stat. 109, 109 (“not before known or used”); Patent Act of 1793, § 1, 1 Stat. 318, 318 (“not known or used before the application”). The Patent Act of 1836 limited disqualifying prior uses to those known to the inventor and not objected to. *See* Patent Act of 1836, § 6, 5 Stat. 117, 119 (“not, at the time of the application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer”).

<sup>361</sup> *See* Tyler T. Ochoa & Andrew J. Wistrich, *The Puzzling Purposes of Statutes of Limitation*, 28 PAC. L.J. 453, 464-66 (1997).

<sup>362</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 856-57; *see* *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954).

<sup>363</sup> *Radio Position Finding Corp.*, 205 F. Supp. at 857 (“We cannot say . . . that Congress had no basis on which to conclude that Colonel Blair was entitled to special relief.”).

<sup>364</sup> *Id.* at 857.

<sup>365</sup> *Id.* at 857-58.

<sup>366</sup> *See* 28 U.S.C. § 1253 (2000) (authorizing direct appeal to the U.S. Supreme Court from the decision of a three-judge district court).

<sup>367</sup> 371 U.S. 577 (1963) (per curiam). The precedential effect to be accorded this summary affirmance is discussed at notes 548-563 and accompanying text.

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Drug Administration.<sup>368</sup> These efforts resulted in several special patent extensions for particular products.<sup>369</sup> The first product to receive such an extension was the artificial sweetener Aspartame, patented by G.D. Searle & Co.<sup>370</sup> During the FDA approval process, questions had arisen concerning the data Searle had submitted with its application. “Although Searle was not at fault, the FDA, to protect the public, formally stayed the approval of aspartame until the validity of the data on aspartame . . . was confirmed.”<sup>371</sup> The stay remained in effect from December 5, 1975, until the FDA approval of aspartame on October 22, 1981,<sup>372</sup> a total of five years, ten months and seventeen days. In 1983, Searle sought and received an extension from Congress equal to the period of the delay.<sup>373</sup>

Over the next two years, four additional products were granted special terms extensions under similar circumstances. FDA approval of the anesthetic drug Forane took more than ten years, leaving it with less than seven years of patent protection.<sup>374</sup> Congress granted an extension of five years and three months,<sup>375</sup> the portion of the delay attributable to investigation of a spurious claim that the drug was carcinogenic.<sup>376</sup> USDA approval of a veterinary drug called Impro was withheld for sixteen years on the basis of a private study later found to contain false and misleading statements, during which time the USDA refused to release the underlying data to the patentee.<sup>377</sup> Congress granted Impro an extension of fifteen years.<sup>378</sup> Two oral hypoglycemic drugs, Glyburide and Glipizide, were found to be safe and effective by the FDA in 1974, but final approval was withheld for ten years over a labeling issue.<sup>379</sup> In 1984, Congress extended

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<sup>368</sup> See generally Richard M. Cooper, *Legislative Patent Extensions*, 48 FOOD & DRUG L.J. 59 (1993).

<sup>369</sup> *Id.* at 64.

<sup>370</sup> *Id.* at 64-65.

<sup>371</sup> *Id.* at 65.

<sup>372</sup> *Id.*

<sup>373</sup> See 35 U.S.C. § 155 (2000). Although this statute is phrased in general terms, the only product which falls within its scope is Aspartame. Under this statute, a total of thirty-two patents covering aspartame were extended. See *Patent Terms Extended Under 35 U.S.C. § 155*, <http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html> (last visited July 14, 1999).

<sup>374</sup> See Cooper, *supra* note 368, at 66.

<sup>375</sup> See 35 U.S.C. § 155A (2000). Once again, although the statute does not identify Forane by name, it is the only drug that satisfies the description set forth in the statute. See *Patent Terms Extended Under 35 U.S.C. § 155A*, <http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html> (last visited July 14, 1999).

<sup>376</sup> See Cooper, *supra* note 368, at 66-67.

<sup>377</sup> *Id.* at 67-68.

<sup>378</sup> See Priv. L. No. 98-34, 98 Stat. 3430 (1984).

<sup>379</sup> See Cooper, *supra* note 368, at 68-69.

five patents covering the two drugs until April 21, 1992,<sup>380</sup> a period of between two years, nine months for the most recent patent, and nearly six years for the oldest patent.<sup>381</sup>

In 1984, Congress addressed the problem more systematically by enacting the Hatch-Waxman Act, which allows the patentee to apply for an extension to compensate for delays in regulatory approval.<sup>382</sup> The Act also streamlined the approval process for generic drugs following patent expiration. As a result, patent owners that had expected to enjoy an extended period of market exclusivity following expiration of the patent, while a generic drug went through the FDA approval process, were now faced with competition immediately upon expiration of the patent.<sup>383</sup> One such patent owner was Warner-Lambert which, as a condition of FDA approval on its cardiovascular drug Lopid, had been required to continue funding a five-year heart attack prevention study in Helsinki, Finland.<sup>384</sup> Warner-Lambert agreed to the condition, expecting that it would have a period of five to seven years of market exclusivity after the patent expired in which to recoup its investment in the study.<sup>385</sup> The Hatch-Waxman Act eliminated this expectation. As Senator Hatch remarked, “[i]n effect, the rules were changed in the middle of the game on this product.”<sup>386</sup> In response, Congress granted Warner-Lambert an extension of three years and six months to the Lopid patent.<sup>387</sup>

Notwithstanding the enactment of the Hatch-Waxman Act, Congress continued to be besieged with requests for term extensions on specific pharmaceutical patents.<sup>388</sup> Some of these requests involved so-called “pipeline” drugs, i.e., drugs which were already under review in the FDA

<sup>380</sup> See Priv. L. No. 98-46, 98 Stat. 3434 (1984).

<sup>381</sup> See *Patent Terms Extended Under Private Laws (Not Codified Into Title 35)*, <http://www.uspto.gov/web/offices/pac/dapp/opla/term/law.html> (last visited July 15, 1999).

<sup>382</sup> See notes 217-222 and accompanying text.

<sup>383</sup> See Cooper, *supra* note 368, at 70-71.

<sup>384</sup> *Id.* at 69-70.

<sup>385</sup> *Id.*; see also 133 CONG. REC. E3209-03 (daily ed. Aug. 3, 1987) (remarks of Hon. Butler Derrick, South Carolina).

<sup>386</sup> 133 CONG. REC. S10,353 (daily ed. July 21, 1987) (remarks of Senator Orrin Hatch, Utah).

<sup>387</sup> See Pub. L. No. 100-418, § 9201, 102 Stat. 1569 (1988).

<sup>388</sup> See Cooper, *supra* note 368, at 73-85 (describing four patent extension requests to Congress during the 1991-1992 term). Extensions were sought of behalf of the anti-inflammatory drugs Ansaid (S. 1165, 102d Cong. (1991) and H.R. 2255, 102d Cong. (1992)) and Lodine (H.R. 4896, 102d Cong. (1992)); the anti-radiation drug Ethiofos (S. 526 and H.R. 1314, 102d Cong. (1991)); and the fat substitute Olestra (S. 1506 and H.R. 2805, 102d Cong. (1991)).

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when the Hatch-Waxman Act was passed.<sup>389</sup> Expecting that most such drugs would be approved relatively quickly, Hatch-Waxman limited patent term extensions for pipeline drugs to a maximum of two years.<sup>390</sup> When some pipeline drugs took longer than expected to gain approval, the drug manufacturers sought relief in Congress. In 1992, the Senate Judiciary Committee expressed concern about the process:

The committee views the dramatic increased interest in patent extension requests as troubling. The patent system was not designed to guarantee every inventor a financial reward for his efforts. Furthermore, the Hatch-Waxman Act provides a uniform and fair mechanism for dealing with a diminished patent life from regulatory delay. In the long run, uncertainty in the length of the patent term may have a chilling effect on competitors.<sup>391</sup>

At the same time, the House Subcommittee on Intellectual Property tried to set forth general standards under which Congress would consider individual patent term extensions.<sup>392</sup> Under the proposal, extensions would be limited to delay beyond the control of the patent holder caused by federal governmental misconduct, or other “action or inaction” by the government “of such a nature as to create a moral or ethical obligation . . . to provide relief.”<sup>393</sup> Despite the proposed guidelines, however, both houses of Congress passed private patent term extensions in late 1992.<sup>394</sup> Only an ironic political stalemate<sup>395</sup> and the adjournment of Congress prevented the extensions from becoming law.<sup>396</sup>

In 1993, Procter and Gamble renewed its efforts to obtain a patent extension for the fat substitute Olestra.<sup>397</sup> Olestra had originally been

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<sup>389</sup> Both Ansaid and Lodine fell into this category. Olestra was also under review in the FDA as a drug, rather than as a food additive. *See* note 399, *infra*.

<sup>390</sup> 35 U.S.C. § 156(g)(6)(C) (2000).

<sup>391</sup> S. REP. NO. 102-414 (1992).

<sup>392</sup> H.R. REP. NO. 102-775 (1992).

<sup>393</sup> *Id.* (text of proposed amendment to H.R. 5475).

<sup>394</sup> *See* Cooper, *supra* note 368, at 84-85.

<sup>395</sup> The House Judiciary Committee opposed granting a patent term extension sought by U.S. Bioscience (for Ethiofos) which was championed by Strom Thurmond, the ranking member of the Senate Judiciary Committee; and the Senate had not approved the patent term extension for Lodine which was supported by William J. Hughes, the Chairman of the House Subcommittee on Intellectual Property. *See* Cooper, *supra* note 368, at 85.

<sup>396</sup> *Id.*

<sup>397</sup> On Feb. 18, 1993, Senator John Glenn (D-Ohio) introduced a bill extending three patents on Olestra, S. 409, 103d Cong. (1993), describing it as “unfinished business from the 102d Congress.” 139 CONG. REC. S1914 (daily ed. July 14, 1993).

patented in 1971,<sup>398</sup> but P&G had not submitted a food additive petition with the FDA until 1987;<sup>399</sup> and P&G was concerned that three subsequent Olestra patents<sup>400</sup> would expire before the FDA approved its use, which would render the patents ineligible for extension under the Hatch-Waxman Act.<sup>401</sup> A bill extending the Olestra patents to December 31, 1997 was passed in the Senate,<sup>402</sup> and was incorporated into a House appropriations bill for the Patent and Trademark Office.<sup>403</sup> Before final passage, however, the Olestra extension was replaced with a more general provision allowing the Patent Office to grant “interim” one-year extensions to any patents which were about to expire if the patented product was still undergoing regulatory review.<sup>404</sup> Under the revised bill, as enacted,<sup>405</sup> a key Olestra patent was extended pending FDA approval.<sup>406</sup>

<sup>398</sup> U.S. Patent No. 3,600,186 (Aug. 17, 1971).

<sup>399</sup> According to a GAO study requested by the House Subcommittee on Intellectual Property, “[v]arious factors have contributed to the extended period of time it is taking to obtain FDA approval of Olestra. . . . Because the FDA lacked a clear approval process for such substances in the 1970’s and 1980’s, P&G pursued approval for Olestra not only as a food additive but also as a drug. Between 1975 and 1985, P&G spent significant time and resources exploring the product’s properties and its potential as a drug. . . . In a 1985 meeting with P&G, FDA officials had explained that the agency had liberalized its attitude toward companies making health claims about food products. In light of this meeting, P&G switched its focus to the food approval path and filed a FAP in April 1987.” General Accounting Office, FDA Premarket Approval: Process of Approving Olestra as a Food Additive, *quoted in* H.R. REP. NO. 102-775, at 15, 17 (1992), *available at* 1992 WL 191650.

<sup>400</sup> U.S. Patent Nos. 4,005,195 (Jan. 25, 1977), 4,005,196 (Jan. 25, 1977) and 4,034,083 (July 5, 1977). Under the seventeen-year term then in effect, these patents were due to expire in 1994.

<sup>401</sup> Under Hatch-Waxman, a patent may be extended only if “the term of the patent has not expired before an application is submitted . . . for its extension,” 35 U.S.C. § 156(a)(1) (2000), but P&G could not submit an application for an extension until after its product had been approved by the FDA. *See* 35 U.S.C. § 156(d)(1) (2000).

<sup>402</sup> 139 CONG. REC. S8735-37 (daily ed. July 14, 1993).

<sup>403</sup> 139 CONG. REC. S15,634 (daily ed. Nov. 10, 1993) (approving Glenn Amendment No. 1161 to H.R. 2632).

<sup>404</sup> 139 CONG. REC. H10,256-57 (daily ed. Nov. 19, 1993). Rep. Brooks explained: “No provision was made [in Hatch-Waxman] for products for which the regulatory review is so long that the 17-year patent expires before approval. The House amendment allows patent holders who are eligible for a patent extension under the 1984 legislation to receive — prior to the expiration of the patent — an interim patent extension while awaiting regulatory approval. When such approval is received, the patent could then be extended pursuant to the [Hatch-Waxman] Act.” *Id.* at H10,257.

<sup>405</sup> Pub. L. No. 103-179, § 5, 107 Stat. 2040 (1993) (codified at 35 U.S.C. § 156(d)(5) (2000)).

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The FDA approved Olestra on January 24, 1996,<sup>407</sup> and the patent was extended for an additional two years under the provisions of the Hatch-Waxman Act.<sup>408</sup>

In 1993, two bills were introduced to grant an additional two-year period of “market exclusivity” to G.D. Searle for oxaprozin,<sup>409</sup> a non-steroidal anti-inflammatory drug (NSAID) marketed under the name Daypro.<sup>410</sup> Oxaprozin was a pipeline drug which had been patented in 1971,<sup>411</sup> but which was not approved by the FDA until 1992.<sup>412</sup> “As a result of this delay, the patent for oxaprozin expired before Daypro could be brought to market.”<sup>413</sup> The 1993 bills died in committee,<sup>414</sup> but two similar bills were introduced in 1995.<sup>415</sup> The language of these bills was

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<sup>406</sup> U.S. Patent No. 4,005,196 (Jan. 25, 1977) was due to expire on Jan. 25, 1994. It received an interim extension, and was reissued on May 24, 1994 as U.S. Patent No. RE 34,617. Later that year, under the terms of the URAA (see notes 223-229 and accompanying text), the term was changed to twenty years from the date of filing, extending the patent to Feb. 12, 1996.

<sup>407</sup> <http://www.fda.gov/bbs/topics/NEWS/NEW00524.html> (last visited July 2, 2001).

<sup>408</sup> U.S. Patent No. RE 34,617 (May 24, 1994). The patent term was extended “for the period of Two years from January 30, 1996, the effective date of *receipt* of permission for commercial marketing or use.” *Id.* at 15 (emphasis added).

Section 5 of Pub. L. No. 103-179 was widely perceived as applying specifically to Olestra. See, e.g., S. REP. NO. 104-343, at 59-60 (1996) (reporting passage of Olestra extension bill); Statement of Peter Barton Hutt before House Subcommittee on Courts and Intellectual Property (May 21, 1998) (listing Olestra as the recipient of a “Statutory Patent Term Restoration” in 1993), <http://www.house.gov/judiciary/42014.htm> (last visited July 2, 2001). It appears, however, that at least one other product, Remeron, received an interim extension under this law. See U.S. Patent No. 4,062,848 (Dec. 13, 1997) (originally due to expire Dec. 13, 1994; extended to Mar. 23, 1996, by the URAA; interim extension granted pending FDA approval; and extended two years from date of FDA approval on June 14, 1996).

<sup>409</sup> S. 1734 and H.R. 3552, 103d Cong. (1993). Instead of extending Searle’s patent, which had already expired, these bills instead prohibited the FDA from accepting or approving a New Drug Application for a generic competitor.

<sup>410</sup> See Statement of Sen. Paul Simon (D-Illinois), 139 CONG. REC. S16,492 (daily ed. Nov. 19, 1993); Statement of Rep. Cardiss Collins (D-Illinois), 139 CONG. REC. E2980 (daily ed. Nov. 19, 1993).

<sup>411</sup> U.S. Patent No. 3,578,671 (May 11, 1971).

<sup>412</sup> <http://www.fda.gov/cder/ob/default.htm> (last visited July 2, 2001).

<sup>413</sup> Statement of Rep. Dennis Hastert (R-Illinois), 141 CONG. REC. E1917 (daily ed. Oct. 11, 1995).

<sup>414</sup> *Bill Summary & Status for the 103rd Congress*, at <http://thomas.loc.gov> (last visited July 2, 2001).

<sup>415</sup> H.R. 2467 and S. 1496, 104th Cong. (1995). Unlike the 1993 bills, the 1995 bills granted Searle a new two-year patent, incorporating by reference the remedies for patent infringement under Title 35.

inserted into an appropriations measure by a conference committee,<sup>416</sup> resulting in a two-year patent revival for oxaprozin.<sup>417</sup>

In 1996, shortly after the Daypro legislation was enacted, four separate attempts were made to pass a patent extension for Lodine that had failed in 1992.<sup>418</sup> The first effort was made in a Senate amendment to a Defense authorization bill<sup>419</sup> and was removed by a conference committee.<sup>420</sup> Similar language was included in an Agriculture appropriations bill<sup>421</sup> and was again removed by a conference committee.<sup>422</sup> One day later, the Lodine extension was inserted into a health insurance bill during the deliberations of a conference committee.<sup>423</sup> After several members of Congress objected that the change had been made improperly,<sup>424</sup> the

<sup>416</sup> H.R. REP. NO. 104-537, at 330-31 (1996). The Conference Committee included two co-sponsors of the Daypro legislation, Rep. John E. Porter (R-Illinois) and Sen. Christopher S. Bond (R-Missouri). It is fair to criticize the Daypro measure as stealth legislation: the Conference Committee report was filed on Apr. 25, 1996, at 1:49 p.m.; it was presented for debate in the House at 3:13 p.m.; the House approved the lengthy appropriations bill at 4:56 p.m.; the Senate approved it at 7:43 p.m.; and the President signed the bill the next day. *Bill Summary & Status for the 104th Congress*, at <http://thomas.loc.gov> (last visited July 2, 2001).

<sup>417</sup> Pub. L. No. 104-134, § 2105, 110 Stat. 1321, 1321-320 (1996); see Notice of Two-Year Exclusivity Period; DAYPRO® Oxaprozin, 61 Fed. Reg. 25636 (May 22, 1996).

<sup>418</sup> See notes 388-396 and accompanying text.

<sup>419</sup> H.R. 3230, § 1080(d), 104th Cong. (as amended in Senate, July 10, 1996). In debating S. 1745, Senators Pryor, Brown and Chaffee introduced an amendment to reconcile the GATT extension with the Hatch-Waxman Act. S. Amdt. No. 4365, 142 CONG. REC. S7113-01 (daily ed. June 27, 1996). Senator Hatch proposed a substitute amendment that included the Lodine provision, which was approved. S. Amdt. No. 4366, 142 CONG. REC. S7113-01 (daily ed. June 27, 1996). Senator Hatch had previously argued that Lodine “was under FDA NDA review for over 8 years, and presents a factual case in many respects similar to Daypro.” 142 CONG. REC. S6594 (daily ed. June 20, 1996). The provisions of S. 1745, as amended, were then incorporated into H.R. 3230, *Bill Summary & Status for the 104th Congress*, at <http://thomas.loc.gov> (last visited July 10, 2001).

<sup>420</sup> H.R. CONF. REP. NO. 104-724, at 801 (1996), reprinted in 1996 U.S.C.C.A.N. 3130, 3308 (deleting § 1080).

<sup>421</sup> H.R. 3603, § 732, 104th Cong. (June 7, 1996); see also 142 CONG. REC. S8608 (daily ed. July 24, 1996) (remarks of Sen. Hatch).

<sup>422</sup> H.R. CONF. REP. NO. 104-726, at 34 (1996) (Amendment No. 121), available at 1996 WL 431982.

<sup>423</sup> H.R. CONF. REP. NO. 104-736, § 281, at 106 (1996), available at 1996 WL 579893.

<sup>424</sup> See 142 CONG. REC. H9778 (daily ed. Aug. 1, 1996) (remarks of Rep. Waxman); 142 CONG. REC. S9463-64 (daily ed. Aug. 2, 1996) (remarks of Sen. Kennedy); *id.* at S9465 (remarks of Sen. Wellstone); *id.* at S9469 (remarks of Sen. Wyden).

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Lodine extension was removed by a concurrent resolution.<sup>425</sup> Finally, after the summer recess the Senate reported a bill to “reconcile” the GATT extension with the Hatch-Waxman Act that included the Lodine provision.<sup>426</sup> This bill was not enacted.<sup>427</sup>

The issue of patent term extensions for “pipeline” drugs continued to occupy Congress during the next four years. In 1996, a bill was introduced granting a two-year extension to any pipeline drugs which had been reviewed by the FDA for more than five years.<sup>428</sup> The principal beneficiary of the legislation would have been Schering-Plough, manufacturer of the antihistamine Claritin, which had received FDA approval in 1993.<sup>429</sup> Claritin was rapidly becoming one of the best-selling drugs ever produced,<sup>430</sup> but it was approaching the end of its patent life.<sup>431</sup> During the next few years, Schering-Plough made several more attempts to extend Claritin’s patent,<sup>432</sup> culminating in two bills which were introduced in

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<sup>425</sup> H. Con. Res. 208, 104th Cong. (1996); see 142 CONG. REC. H9897-98 (daily ed. Aug. 2, 1996); *id.* at S9526; see also *id.* at S9499-501 (debate on S. Con. Res. 68 regarding Lodine).

<sup>426</sup> S. 1277, § 4, 104th Cong. (as amended Oct. 1, 1996); see S. REP. NO. 104-394, at 4, 22 (1996).

<sup>427</sup> *Bill Summary & Status for the 104th Congress*, at <http://thomas.loc.gov> (last visited July 10, 2001).

<sup>428</sup> S. 2154, 104th Cong. (1996).

<sup>429</sup> <http://www.fda.gov/cder/ob/default.htm> (last visited June 30, 2001).

<sup>430</sup> According to Schering-Plough’s website, Claritin had \$1.15 billion in worldwide sales in 1996. <http://www.sgp.com/news/financial/earnings/1-23-97.html> (last visited July 16, 2001). Worldwide sales of Claritin increased to \$3 billion in 2000. <http://www.sgp.com/news/financial/earnings/01-25-01.html> (last visited July 16, 2001).

<sup>431</sup> The patent application covering Claritin was filed on June 19, 1980 and was granted on Oct. 4, 1981. U.S. Patent No. 4,282,233 (Oct. 4, 1981). Without any extensions, the patent would have expired on Oct. 4, 1998. The patent received a two-year extension under Hatch-Waxman and a GATT extension of twenty-two months, and is now due to expire on June 19, 2002. In addition, under a provision added by the FDA Modernization Act of 1997, 21 U.S.C. § 505A(c)(2)(A), Claritin will receive an additional six months of post-patent “market exclusivity” in exchange for having conducted pediatric trials on Claritin. See *FDA Extends Claritin Patent Six Months*, WALL ST. J., Aug. 17, 2000, at B15.

<sup>432</sup> According to Rep. Henry Waxman (D-Calif.), “[i]n 1996, Schering tried unsuccessfully to attach Claritin patent extensions to the omnibus appropriations bill, the continuing resolution and the agriculture appropriations bill.” 144 CONG. REC. E2121-03 (daily ed. Oct. 13, 1998). Subsequently, “[i]n May 1997, the company attempted to add a patent extension amendment to the Omnibus Patent Act of 1997, an effort that was blocked in the Senate Judiciary Committee. In the closing moments of the 1997 congressional session, there was a second attempt to extend the patent through the appropriation process, while a bill was in conference. That effort was also rejected. Last year there was an attempt to add this proposal to the 1998 Omnibus Appro-

1999.<sup>433</sup> The case for the term extensions focused on the fact that “pipeline” drugs had been limited to a two-year extension under Hatch-Waxman, while non-pipeline competitors could receive a five-year extension.<sup>434</sup> The proposed bills faced intense opposition from consumer advocates and the generic drug industry,<sup>435</sup> citing a study which estimated that a three-year patent extension for Claritin would cost consumers \$7.36 billion over a ten-year period.<sup>436</sup> Despite a multi-million dollar lobbying effort by Schering,<sup>437</sup> both bills died in Committee,<sup>438</sup> and an effort to add the legislation to a military construction appropriations bill in 2000 also failed.<sup>439</sup>

In addition to the efforts to obtain patent term extensions by the pharmaceutical industry, several other individual patent term extension

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priations Bill. That initiative failed as well.” Testimony of Bruce L. Downey before House Subcommittee on Courts and Intellectual Property, 1999 WL 20009817 (July 1, 1999).

<sup>433</sup> H.R. 1598 and S. 1172, 106th Cong. (1999). A pharmaceutical industry study identified eight drugs that would have benefitted from the legislation: Claritin (loratidine), Relafen (nabumetone), Daypro (oxaprozin), Cardiogen-82 (rubidium), Eulexin (flumatide), Nimotop (nimopidine), Dermatop (prednicarbate), and Penetrex (enoxacin). PRIME Institute, College of Pharmacy, University of Minnesota, *Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures* (July 28, 1999), tbl. 1, <http://www.house.gov/berry/prescriptiondrugs/schoncharts.htm> (last visited July 16, 2001).

<sup>434</sup> Testimony of Jonathan Spicehandler, M.D., Schering-Plough Research Institute, before House Subcommittee on Courts and Intellectual Property, 1999 WL 20009820 (July 1, 1999).

<sup>435</sup> See, e.g., *Claritin Bill Targeted at Grassroots*, Congress Daily A.M., 1999 WL 27685516 (Nov. 8, 1999); Hearing Before House Subcommittee on Courts and Intellectual Property: Testimony of Bruce L. Downey, 1999 WL 20009817 (July 1, 1999); Testimony of Andrew M. Berdon, 1999 WL 20009818 (July 1, 1999); Testimony of Maura Kealy, 1999 WL 20009824 (July 1, 1999).

<sup>436</sup> PRIME Institute, College of Pharmacy, University of Minnesota, *Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures* (July 28, 1999), *Executive Summary*, <http://www.house.gov/berry/prescriptiondrugs/schondelmeyer.htm> (last visited July 16, 2001).

<sup>437</sup> One consumer organization estimated that Schering has spent \$28 million since 1996 in attempting to obtain a patent extension for Claritin. See Public Citizen Congress Watch, *Schering-Plough Political Money Pushes Claritin Patent Extension and Distorts GAO Report* (Mar. 2001), <http://www.citizen.org/congress/drugs/factshts/patentextension/report.pdf> (last visited July 16, 2001).

<sup>438</sup> *Bill Summary & Status for the 106th Congress*, at <http://thomas.loc.gov> (last visited July 10, 2001).

<sup>439</sup> See Stephen S. Hall, *Prescription for Profit*, N.Y. TIMES MAGAZINE, Mar. 11, 2001, at 59; *Drug Patent Extension Measure is Blocked from Military Spending Bill*, GENERIC LINE, 2000 WL 31703053 (July 14, 2000).

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bills were introduced in the last decade. In 1993<sup>440</sup> and again in 1995,<sup>441</sup> a bill was introduced to renew and extend six patents<sup>442</sup> covering a medical device which had been banned from sale in the U.S. by the FDA from 1972 to 1987.<sup>443</sup> In 1997, a quixotic twelve-year effort to obtain a patent term extension on a stock-market “quotation monitoring unit”<sup>444</sup> ended when the last in a series of twelve bills died in Committee.<sup>445</sup> Finally, in 2000 Senator Judd Gregg (D-N.H.) tried to attach a patent term extension that would have benefitted his alma mater, Columbia University, to two appropriations bills.<sup>446</sup> The patent covered a process for inserting DNA

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<sup>440</sup> See H.R. 3579, 103d Cong. (1993).

<sup>441</sup> See H.R. 2113, 104th Cong. (1995).

<sup>442</sup> The bill would have revived for ten years five patents owned by the Diapulse Corporation of America that had already expired: U.S. Patent Nos. 3,670,737 (June 20, 1972); 3,566,877 (Mar. 2, 1971); 3,464,010 (Aug. 26, 1969); 3,181,535 (May 4, 1965); and 3,043,310 (July 10, 1962). Reviving the latter two patents apparently would have been a futile gesture, since both had been declared invalid in 1967. See *Diapulse Corp. of Am. v. Rochester Leasing Corp.*, 286 F. Supp. 74, 80 (W.D.N.Y. 1967).

In addition, the bill would have extended for ten years U.S. Patent No. 4,226,246 (Oct. 7, 1980), which was assigned to Carba Societe Anonyme, a Swiss corporation. The author assumes this assignee is a successor to Carba, Ltd., a Swiss corporation that was an exclusive distributor of Diapulse machines in Switzerland and Germany in the 1970s. See *Diapulse Corp. of Am. v. Carba, Ltd.*, 626 F.2d 1108, 1109 (2d Cir. 1980).

<sup>443</sup> For a summary of the lengthy dispute between Diapulse and the FDA, see *United States v. Diapulse Corp. of Am.*, 748 F.2d 56 (2d Cir. 1984); Paul Schreiber, *Diapulse Wins 15-Year Feud with FDA to Market Device*, NEWS-DAY, May 18, 1987, at 5.

<sup>444</sup> U.S. Patent No. 3,387,268 (June 4, 1968).

<sup>445</sup> See H.R. 381, 105th Cong. (1997); H.R. 901, 104th Cong. (1995); S. 2013, 103d Cong. (1994); H.R. 3057, 103d Cong. (1993); S. 2689, 102d Cong. (1992); H.R. 2192, 102d Cong. (1991); S. 463, 101st Cong. (1989); H.R. 926, 101st Cong. (1989); S. 1102, 100th Cong. (1987); H.R. 1274, 100th Cong. (1987); S. 1573, 99th Cong. (1985); H.R. 1012, 99th Cong. (1985).

“The patent holder argued that FCC regulations in force at the time his patent was granted effectively denied him use of his patent,” H.R. REP. NO. 102-775, at 17 (1992), available at 1992 WL 191650, but this explanation was expressly rejected by the House Judiciary Committee in 1992. *Id.* at 17-19. The Committee followed the negative recommendation of the Department of Commerce, which explained in a letter that the patent specification and claims attached “no importance” to the use of FCC-approved radio channels in implementing the patented invention. *Id.* at 18.

<sup>446</sup> See Charles R. Babcock, *Senator Tries to Extend Alma Mater’s Patent: Columbia Would Gain \$100 Million a Year*, WASH. POST, May 19, 2000, at E3; Ronald Rosenberg, *Gregg Draws Ire Over Columbia Patent Move*, BOSTON GLOBE, July 13, 2000, at A1.

The initial effort was an Agriculture Appropriations Bill, S. 2536, § 2801, 106th Cong. (introduced May 10, 2000). The Committee report explained: “Since this patent is not subject to Food and Drug Administration review, current

used to manufacture proteins into animal cells.<sup>447</sup> Gregg abandoned the effort when it became clear that the term extension could not be enacted before the patent expired.<sup>448</sup>

What lessons about the meaning of the Patent and Copyright Clause can be drawn from the history of private patent term extensions? This question is analyzed in Section III-C, below.

### B. *Design Patents*

Unlike utility patents, which govern products, processes and machines,<sup>449</sup> design patents are issued for “any new, original and ornamental design for an article of manufacture.”<sup>450</sup> The term of a design patent is fourteen years from the date of the grant.<sup>451</sup> When design patents were first added to the Patent Act in 1842, they were granted for a seven-year term,<sup>452</sup> which could be extended by statute for an additional seven years.<sup>453</sup> In 1861, the term of a utility patent was increased to seventeen years, and extensions were prohibited;<sup>454</sup> but applicants for design patents were permitted to elect a term of either 3.5 years, seven years or fourteen years, which could be extended for an additional seven years.<sup>455</sup> In 1870, the seven-year extension of design patents was repealed, but was preserved for design patents issued prior to the 1861 Act.<sup>456</sup> The initial election of a term of 3.5 years, seven years or fourteen years was carried forward in both the 1870 Act<sup>457</sup> and the 1952 Act.<sup>458</sup> In 1982, Congress replaced the three alternative terms with a single term of fourteen years

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law does not provide a mechanism by which non-profit organizations can seek term extensions.” S. REP. NO. 106-288, at 197 (2000). When the agriculture bill stalled, some of its spending provisions were proposed as an amendment to a Defense Appropriations bill. See Amend. No. 3374 to H.R. 4576, § 2801, 146 CONG. REC. S5033, S5050 (daily ed. June 13, 2000). This amendment was ordered to lie on the table. *Id.* at S5033.

<sup>447</sup> U.S. Patent No. 4,399,216 (Aug. 16, 1983). The draft bills covered an “elemental biologic,” defined as “a genetically engineered cell, or method of making thereof, used in manufacturing five or more new drugs, antibiotic drugs, or human biological products.” S. 2536, § 2801, 106th Cong. (May 10, 2000).

<sup>448</sup> See Editorial, *The Old College Try*, BOSTON GLOBE, July 17, 2000, at A10.

<sup>449</sup> 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

<sup>450</sup> *Id.* § 171.

<sup>451</sup> *Id.* § 173.

<sup>452</sup> See Patent Act of 1842, § 3, 5 Stat. 543, 543-44 (1842).

<sup>453</sup> See Patent Act of 1836, § 18, 5 Stat. 117, 124-25 (1836).

<sup>454</sup> See Patent Act of 1861, § 16, 12 Stat. 246, 249 (1861).

<sup>455</sup> *Id.*, § 11, 12 Stat. at 248.

<sup>456</sup> See Patent Act of 1870, § 74, 16 Stat. 198, 210 (1870).

<sup>457</sup> *Id.*, § 73, 16 Stat. at 210.

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for all design patents.<sup>459</sup> The 1982 amendment was not made retroactive,<sup>460</sup> so it did not result in the extension of any existing design patents. The Uruguay Round Agreements Act, which changed the term of utility patents to twenty years from filing,<sup>461</sup> left the term of design patents unchanged.<sup>462</sup>

Although design patents were supposed to be granted only to ornamental designs on an article of manufacture, several service organizations, such as the Daughters of the American Revolution<sup>463</sup> and the Disabled American Veterans,<sup>464</sup> applied for and received design patents on their badges and insignia.<sup>465</sup> As those design patents began to expire, some of these organizations sought and received special congressional extensions of the terms of their design patents.<sup>466</sup> Often these extensions were not granted until after the original term or previous extension had expired, resulting in renewals of expired design patents as well as extensions. With one exception, these design patent extensions have routinely been granted.<sup>467</sup>

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<sup>458</sup> See Patent Act of 1952, Pub. L. No. 82-593, § 1, 66 Stat. 792, 805 (1952) (codified at former 35 U.S.C. § 173; repealed 1982).

<sup>459</sup> See Pub. L. No. 97-247, § 16, 96 Stat. 317, 321 (1982) (codified at former 35 U.S.C. § 173).

<sup>460</sup> Section 16 reads: “Patents for designs *shall be* granted for the term of fourteen years,” *id.* (emphasis added), indicating that it is prospective only. See also *id.*, § 17(a) (“Sections 3 and 16 of this Act shall take effect on October 1, 1982.”).

<sup>461</sup> See notes 223-229 and accompanying text.

<sup>462</sup> To emphasize that no change was being made, the URAA did clarify that the fourteen-year term was to run “from the date of the grant.” Pub. L. No. 103-465, Title V, § 532(c)(3), 108 Stat. 4809, 4987 (1994) (codified at 35 U.S.C. § 173).

<sup>463</sup> U.S. Patent No. D21,053 (Sept. 22, 1891).

<sup>464</sup> U.S. Patent No. D59,560 (Nov. 1, 1921).

<sup>465</sup> The probable explanation is that it would have been difficult to register these badges and insignia as trademarks prior to the enactment of the Lanham Act in 1946. “The Lanham Act significantly changed and liberalized the common law to ‘dispense with mere technical prohibitions.’” *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 171 (1995).

<sup>466</sup> See, e.g., Priv. L. No. 64-14, ch. 84, 39 Stat. 1260 (1916) (Daughters of the American Revolution); Priv. L. No. 71-3, ch. 126, 46 Stat. 1633 (1930) (same); Priv. L. No. 79-692, ch. 470, 60 Stat. 1241 (1946) (same); Pub. L. No. 74-627, ch. 468, 49 Stat. 1389 (1936) (Disabled American Veterans); Priv. L. No. 81-522, ch. 292, 64 Stat. A69 (1950) (same).

<sup>467</sup> In addition to the design patents discussed at notes 466 and 468-471, see also U.S. Patent No. D25,909 (Aug. 11, 1896) (United States Daughters of 1812), *renewed and extended by* Pub. L. No. 66-398, ch. 170, 41 Stat. 1440 (1921); Pub. L. No. 74-551, ch. 278, 49 Stat. 1257 (1936) (same); U.S. Patent No. D119,187 (Feb. 27, 1940) (Massachusetts Dep’t of United Am. Veterans of

In 1992, the House Judiciary Committee reported a bill to extend design patents for the insignia of the United Daughters of the Confederacy,<sup>468</sup> and the badges of the American Legion,<sup>469</sup> the American Legion Women's Auxiliary,<sup>470</sup> and the Sons of the American Legion.<sup>471</sup> Each of these design patents had been extended several times.<sup>472</sup> The Committee explained its decision as follows:

The Committee is not convinced of the appropriateness of the original decisions, renewed several times since, to utilize design patent laws to protect these insignia and badges. Trademark or some form of sui generis protection may be more appropriate.

However, the Committee takes note of the long precedent for utilization of design patent protection for these emblems, and the fact that such an approach appears to achieve the desired purpose with no detrimental effects upon the public interest. For these reasons, the Committee has recommended renewal and extension of design patent protection for the insignia and badges of these patriotic organizations.<sup>473</sup>

The House bill was not enacted because of disagreement between the House and Senate over several pharmaceutical patents that were also contained in the bill.<sup>474</sup> When the design patent extensions were re-introduced in 1993,<sup>475</sup> Senator Carol Moseley-Braun (D-Ill.) offered an amendment in the Senate Judiciary Committee to remove the extension for the insignia of the United Daughters of the Confederacy, which con-

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the United States of Am., Inc.), *renewed and extended* by Pub. L. No. 89-295, 79 Stat. 1070 (1965).

<sup>468</sup> U.S. Patent No. D29,611 (Nov. 8, 1898), *renewed and extended* by Pub. L. No. 69-242, ch. 327, 44 Stat. 562 (1926); Pub. L. No. 77-220, ch. 369, 55 Stat. 633 (1941); Pub. L. No. 88-213, 77 Stat. 421 (1963); Pub. L. No. 95-168, 91 Stat. 1349 (1977).

<sup>469</sup> U.S. Patent No. D54,296 (Dec. 9, 1919), *renewed and extended* by Pub. L. No. 74-230, ch. 427, 49 Stat. 510 (1935); Priv. L. No. 81-121, ch. 252, 63 Stat. 1121 (1949); Priv. L. No. 87-439, 76 Stat. 1319 (1962); Priv. L. No. 94-39, 90 Stat. 2971 (1976).

<sup>470</sup> U.S. Patent No. D55,398 (June 1, 1920), *renewed and extended* by Pub. L. No. 74-231, ch. 428, 49 Stat. 510 (1935); Priv. L. No. 81-122, ch. 253, 63 Stat. 1122 (1949); Priv. L. No. 87-438, 76 Stat. 1318 (1962); Priv. L. No. 94-40, 90 Stat. 2971 (1976).

<sup>471</sup> U.S. Patent No. D92,187 (Jan. 25, 1934), *renewed and extended* by Priv. L. No. 81-123, ch. 254, 63 Stat. 1122 (1949); Priv. L. No. 87-437, 76 Stat. 1318 (1962); Priv. L. No. 94-38, 90 Stat. 2970 (1976).

<sup>472</sup> See notes 468-471.

<sup>473</sup> H.R. REP. NO. 102-775 (1992).

<sup>474</sup> See notes 388-396 and accompanying text.

<sup>475</sup> S. 409, 103d Cong. (1993) (as introduced).

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tained a replica of the Confederate flag.<sup>476</sup> The amendment passed by a vote of 12 to 3.<sup>477</sup> Later that term, Senator Jesse Helms (R-N.C.) proposed the extension as an amendment to another bill.<sup>478</sup> A motion to table the amendment initially failed 48-52,<sup>479</sup> but Senator Moseley-Braun successfully staged a filibuster and succeeded in persuading the Senate to reconsider<sup>480</sup> and to table the amendment by a vote of 75-25.<sup>481</sup> The other three design patent extensions, for the badges of the American Legion and its two affiliates, were enacted into law.<sup>482</sup>

It has frequently been pointed out that “this recurrent renewal procedure is unnecessary.”<sup>483</sup> The insignia of these service organizations are not really ornamental designs on an article of manufacture; instead, they serve the source-identifying function of a trademark.<sup>484</sup> Specifically, they fall within the Lanham Act’s definition of a collective mark:

The term “collective mark” means a trademark or service mark . . . used by the members of a cooperative, an association or other collective group or organization . . . and includes marks used to indicate membership in a union, an association or other organization.<sup>485</sup>

Accordingly, “the parties currently holding these design patents would apparently lose no rights if the patents were converted into trademarks. In-

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<sup>476</sup> The flag on the insignia is the Stars and Bars, the first national flag of the Confederate States of America, rather than the more familiar Confederate battle flag. U.S. Patent No. D29,611 (Nov. 8, 1898).

<sup>477</sup> See Report on the Activities of the Committee of the Judiciary During the 103d Congress, S. REP. NO. 104-343, at 60 (1996).

<sup>478</sup> See Helms Amend. 610 to S. 919, 103d Cong. (1993), *published at* 139 CONG. REC. S9251 (daily ed. July 22, 1993).

<sup>479</sup> 139 CONG. REC. S9256 (daily ed. July 22, 1993).

<sup>480</sup> 139 CONG. REC. S9268 (daily ed. July 22, 1993). The vote on the motion to reconsider was 76-24.

<sup>481</sup> *Id.* The record of this extraordinary debate is preserved at 139 CONG. REC. S9251-68 (daily ed. July 22, 1993). See also *Freshman Turns Senate Scarlet*, WASH. POST, July 27, 1993, *reprinted at* 139 CONG. REC. E1907 (daily ed. July 28, 1993).

<sup>482</sup> Pub. L. No. 103-179, § 7, 107 Stat. 2040, 2042 (1993).

<sup>483</sup> Benagh, *supra* note 286, at 12.

<sup>484</sup> A trademark is defined as “any word, name, symbol, or device, or any combination thereof, used by a person . . . to identify and distinguish his or her goods . . . from those manufactured or sold by others.” 15 U.S.C. § 1127 (2000).

<sup>485</sup> *Id.* § 1127.

deed, such a measure would eliminate the need to periodically approach Congress for renewal.”<sup>486</sup>

Moreover, Congress has already granted *sui generis* trademark protection to a large number of federally-chartered service organizations in Title 36 of the United States Code.<sup>487</sup> These statutes typically provide that the organization has the “exclusive right” to use the name, badge, emblem, or insignia of the organization;<sup>488</sup> although a few are limited (for no apparent reason other than historical accident) to the name alone.<sup>489</sup> At least two of the organizations which frequently sought design patent extensions have received such protection. The charter of the Daughters of the American Revolution was amended in 1976 to include the exclusive right to use the “seals, emblems, and badges” adopted by them;<sup>490</sup> and the statutes incorporating the American Legion were amended in 1953 to include “the exclusive right to manufacture, and to control the right to manufacture, and to use, such emblems and badges as may be deemed necessary.”<sup>491</sup> In addition, the badges of the American Legion and other veterans organizations are protected by a criminal statute, first adopted in 1940,<sup>492</sup> which states:

Whoever knowingly manufactures, reproduces, sells or purchases for resale, either separately or on or appended to, any article of merchandise manufactured or sold, any badge, medal, emblem, or other insignia or any colorable imitation thereof, of any veterans' organization incorporated by enactment of Congress, . . . or knowingly prints, lithographs, engraves or otherwise reproduces on any poster, circular, periodical, magazine, news-

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<sup>486</sup> Benagh, *supra* note 286, at 12. Registered trademarks which continue to be used may be renewed every ten years upon filing of an affidavit and payment of a fee. 15 U.S.C. § 1058 (2000).

<sup>487</sup> A First Amendment challenge to one such statute was rejected by the U.S. Supreme Court in *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522 (1987). See notes 530-532 and accompanying text.

<sup>488</sup> See, e.g., 36 U.S.C. § 22306 (2000) (American Symphony Orchestra League); *id.* § 30905 (Boy Scouts); *id.* § 80305 (Girl Scouts); *id.* § 130506 (Little League); *id.* § 152907 (National Society, Daughters of the American Colonists); § 170307 (Pearl Harbor Survivors Association); *id.* § 230105 (Veterans of Foreign Wars).

<sup>489</sup> See, e.g., 36 U.S.C. § 22505 (2000) (American War Mothers); *id.* § 50305 (Disabled American Veterans).

<sup>490</sup> Pub. L. No. 94-443, § 2, 90 Stat. 1475 (1976) (now codified, as amended, at 36 U.S.C. § 153104 (2000)).

<sup>491</sup> Pub. L. No. 83-80, ch. 153, § 1, 67 Stat. 82 (1953) (now codified, as amended, at 36 U.S.C. § 21705 (2000)).

<sup>492</sup> Pub. L. No. 76-663, ch. 426, 54 Stat. 571 (1940) (now codified, as amended, at 18 U.S.C. § 705 (2000)).

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paper, or other publication, or circulates or distributes any such printed matter bearing a reproduction of such badge, medal, emblem, or other insignia or any colorable imitation thereof, except when authorized under rules and regulations prescribed by any such organization, shall be fined under this title or imprisoned not more than six months, or both.<sup>493</sup>

The existence of these special civil and criminal statutes demonstrates that the design patent extensions obtained by the American Legion in 1962, 1976 and 1993<sup>494</sup> were wholly unnecessary.<sup>495</sup> Such extensions should be recognized for what they really are: honorary recognition by Congress of patriotic organizations,<sup>496</sup> and private trademark legislation that has little, if anything, to do with traditional patent law.<sup>497</sup>

Analytically, the repeated extension of design patents for these service organizations results in patent protection that is essentially perpetual in duration.<sup>498</sup> If such repeated extensions were granted for any other type of design or utility patent, it is likely that the extension would be invalidated on the ground that perpetual patent protection is unconstitu-

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<sup>493</sup> 18 U.S.C. § 705 (2000). In *United States v. Dettra Flag Co.*, 86 F. Supp. 84 (E.D. Pa. 1949), this statute was challenged “on the grounds that this statute is an unconstitutional delegation of legislative powers by Congress.” 86 F. Supp. at 85. The District Court held the statute was constitutional. *Id.* at 90. See also *American Legion v. Matthew*, 144 F.3d 498 (7th Cir. 1998) (law prohibiting duplication of American Legion’s badge, medal or emblem did not prohibit use of word “Legionaire” as a trademark for caps imitating “the distinctive headgear of the French Foreign Legion.”).

<sup>494</sup> See notes 469-482 and accompanying text.

<sup>495</sup> Cf. *United States v. Dettra Flag Co.*, 86 F. Supp. at 86-87 (“The committee reports in Congress state that the purpose of the Act is to protect these organizations and the public from the unauthorized use of their insignia, . . . [because] patent infringements suits have been ineffective.”).

<sup>496</sup> The honorary aspect of these patent extensions was discussed in the 1993 debate concerning the proposed design patent extension for the United Daughters of the Confederacy. See 139 CONG. REC. S9253 (daily ed. July 22, 1993) (remarks of Sen. Moseley-Braun) (“It is a rare honor given to an organization.”); *id.* at S9254 (“Why would we give an extraordinary honor to a symbol which is counter to the symbol that we as Americans . . . all know and love?”).

<sup>497</sup> *Id.* at S9253 (“it is not only extraordinary but probably inappropriate to have a design patent issued in this regard.”); Benagh, *supra* note 286, at 13 (“It appears, in light of the traditional function of private legislation to honor the equitable and moral debts of the United States, that the original grant of such extensions by Congress may have been erroneous.”).

<sup>498</sup> Cf. *Eldred v. Reno*, 239 F.3d 372, 381 (D.C. Cir. 2000) (Sentelle, J., dissenting) (“there is no apparent substantive distinction between permanent protection and permanently available authority to extend originally limited protection.”).

tional.<sup>499</sup> By contrast, trademarks which remain in continuous use can be protected indefinitely.<sup>500</sup> Indefinite protection for trademarks is constitutionally permissible because trademark law is not based upon the Patent and Copyright Clause,<sup>501</sup> nor is it based on that Clause's incentive rationale, under which the government grants exclusive rights for a limited period of time as an incentive to creation or invention.<sup>502</sup> Instead, trademark law arises solely under the Commerce Clause,<sup>503</sup> and traditionally it is based on a consumer protection rationale, the prevention of confusion among consumers in the market.<sup>504</sup> Thus, if design patent

<sup>499</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) ("Congress may not create patent monopolies of unlimited duration."); see also *United States v. Moghadam*, 175 F.3d 1269, 1281 (11th Cir. 1999) ("the 'Limited Times' requirement . . . forbids Congress from conferring intellectual property rights of perpetual duration.").

<sup>500</sup> 15 U.S.C. § 1058 (2000); *Kohler Co. v. Moen, Inc.*, 12 F.3d 632, 637 (7th Cir. 1993) ("Although patent rights are limited in duration by statute, trademark rights may continue as long as the mark is used to distinguish and identify.").

<sup>501</sup> See *The Trade-Mark Cases*, 100 U.S. 82, 94 (1879) ("While such legislation may be a judicious aid to the common law on the subject of trade-marks, . . . we are unable to see any such power in the constitutional provision concerning authors and inventors, and their writings and discoveries.").

<sup>502</sup> See *Traffix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, \_\_\_, 121 S.Ct. 1255, 1262 (2001) ("The Lanham Act does not exist to reward manufacturers for their innovation in creating a particular device; that is the purpose of patent law and its period of exclusivity."); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 164 (1995) ("It is the province of patent law, not trademark law, to encourage invention by granting an inventor a monopoly over new product designs or functions for a limited time."); *Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1446 (3d Cir. 1994) ("Of course, it is not the purpose of unfair competition law, under the guise of either consumer protection or the protection of business good will, to implement a policy of encouraging innovative designs by protecting them once designed. Those issues are the province of copyright and patent laws.").

<sup>503</sup> See *United States v. Moghadam*, 175 F.3d 1269, 1278 (11th Cir. 1999) ("modern trademark law is built entirely on the Commerce Clause"); *United We Stand Am., Inc. v. United We Stand, Am. New York, Inc.*, 128 F.3d 86, 92 (2d Cir. 1997) ("The history and text of the Lanham Act show that 'use in commerce' reflects Congress's intent to legislate to the limits of its authority under the Commerce Clause.").

<sup>504</sup> See *Park 'N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 198 ("The Lanham Act provides national protection of trademarks in order to secure to the owner of the mark the goodwill of his business and to protect the ability of consumers to distinguish among competing producers."); *Star Financial Servs., Inc. v. Aastar Mortgage Corp.*, 89 F.3d 5, 9 (1st Cir. 1996) ("The purpose of trademark laws is to prevent the use of the same or similar marks in a way that confuses the public about the actual source of the goods or services.").

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extensions for service organizations can legitimately be characterized as private trademark legislation, the “limited Times” provision of the Patent and Copyright Clause would not present a constitutional barrier to their validity.<sup>505</sup>

In order for the “limited Times” restriction of the Patent and Copyright Clause to be meaningful, there must be some way of distinguishing potentially indefinite trademark protection from the protection afforded by patent and copyright law, which can only be granted for “for limited Times.”<sup>506</sup> Traditionally, three doctrines have served to keep trademark law separate from patent and copyright protection.<sup>507</sup> First, a trademark must serve a source identifier; that is, it must serve to distinguish the goods or services of the mark owner from those of others.<sup>508</sup> Second, trademark protection cannot be granted to the functional features of a product.<sup>509</sup>

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<sup>505</sup> See *United States v. Moghadam*, 175 F.3d 1269, 1278 (11th Cir. 1999) (“The Supreme Court’s analysis in the Trade-Mark Cases stands for the proposition that legislation which would not be permitted under the [Patent and] Copyright Clause could nonetheless be permitted under the Commerce Clause.”); *but see id.* at 1280 n.12 (“We assume arguendo, without deciding, that the Commerce Clause could not be used to avoid a limitation in the Copyright Clause if the particular use of the Commerce Clause . . . were fundamentally inconsistent with the particular limitation in the Copyright Clause.”); *cf.* Heald & Sherry, *supra* note 25, at 1160-66 (explaining why trademark law does not exceed implied limits placed on Congress by the Patent and Copyright Clause).

<sup>506</sup> See David S. Welkowitz, *Trade Dress and Patent — The Dilemma of Confusion*, 30 RUTGERS L.J. 289, 299 (1999) (“Trademarks are unlimited in time, while patents have limits in time. . . . If trademarks are perceived as better protection than design patents, then the design patent scheme that Congress has created, with its explicit trade off between incentive and public access, is eviscerated.”); *id.* at 306 (“to the extent there are similarities between the tests, there must be strong discernable lines separating them. Otherwise, the harmonization between patent and trademark will be a false one.”).

<sup>507</sup> See Welkowitz, *supra* note 506, at 306-07.

<sup>508</sup> 15 U.S.C. § 1127 (2000) (defining “trademark” as “any word, name, symbol, or device” used “to identify and distinguish his or her goods . . . from those manufactured and sold by others and to indicate the source of the goods”); *see also id.* (definition of “service mark”); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 164 (1995) (“It is the source-distinguishing ability of a mark . . . that permits it to serve these basic purposes.”); *I.P. Lund Trading ApS v. Kohler Co.*, 163 F.3d 27, 35 (1st Cir. 1998) (“A primary purpose of trade dress or trademark protection is to protect that which identifies a product’s source.”).

<sup>509</sup> *Qualitex*, 514 U.S. at 164 (“The functionality doctrine prevents trademark law . . . from instead inhibiting legitimate competition by allowing a producer to control a useful product feature.”); *Wilhelm Pudenz, GmbH v. Littlefuse, Inc.*, 177 F.3d 1204, 1211 (11th Cir. 1999) (“The functionality doctrine serves the extremely important function of avoiding conflict between the trademark law and the patent law. It does this by denying a perpetual exclusive

Third, trademark infringement requires a showing that there is a likelihood of confusion among consumers in the relevant market.<sup>510</sup>

Application of these doctrines to the insignia and badges of service organizations demonstrates a substantial overlap between their design patent extensions and trademark law. First, the insignia or badges of service organizations often do serve as source identifiers, because they distinguish the goods and services sold or endorsed by those organizations from those of others.<sup>511</sup> On the other hand, at least two cases have held that jewelry displaying the insignia of a fraternal organization does not *necessarily* signify origin or sponsorship by that organization.<sup>512</sup> Second, insignia and badges are not functional under the Supreme Court's definitions of that term. An insignia is not "essential to the use or purpose of the article" on which it appears; nor does it "affect[ ] the cost or quality of the article."<sup>513</sup> Of course, this is true of all design patents, which by definition must be

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right in a wholly functional product feature or configuration under the trademark law, where such a grant under the Patent Act would be unconstitutional.").

<sup>510</sup> *Kohler Co. v. Moen, Inc.*, 12 F.3d 632, 637 (7th Cir. 1993) ("Compared to patent protection, trademark protection is relatively weak because it precludes competitors only from using marks that are likely to confuse or deceive the public."); *W.T. Rogers Co. v. Keene*, 778 F.2d 334, 337 (7th Cir. 1985) ("The trademark owner has an indefinite term of protection, it is true, but in an infringement suit must also prove secondary meaning [i.e., source identification] and likelihood of confusion, which the owner of a design patent need not do; there is therefore no necessary inconsistency between the two modes of protection.").

<sup>511</sup> *See Int'l Order of Job's Daughters v. Lindeburg & Co.*, 633 F.2d 912, 918 (9th Cir. 1980) ("the name 'Job's Daughters' and the Job's Daughters insignia are indisputably used to identify the organization, and members of Job's Daughters wear the jewelry to identify themselves as members. In that context, the insignia are trademarks of Job's Daughters."); *United States v. Dettra Flag Co.*, 86 F. Supp. 84, 86-87 (E.D. Pa. 1949) ("It is proper that Congress should seek . . . to protect the interest of these organizations in self-identification.") (insignia of the American Legion).

<sup>512</sup> *See Job's Daughters*, 633 F.2d at 920 (upholding finding that "consumers did not ordinarily purchase their fraternal jewelry from only 'official' sources"); *Supreme Assembly, Order of Rainbow for Girls v. J.H. Ray Jewelry Co.*, 676 F.2d 1079, 1083 (5th Cir. 1982) (upholding finding that "there is no historical custom or practice . . . that would provide a reasonable basis for buyers of Rainbow jewelry to assume that such jewelry can only be manufactured with Rainbow's sponsorship or approval."). Both cases distinguished *Boston Prof'l Hockey Ass'n, Inc. v. Dallas Cap & Emblem Mfg., Inc.*, 510 F.2d 1004, 1010-12 (5th Cir. 1975), which held that professional sports team logos *do* constitute source identifiers.

<sup>513</sup> *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, \_\_\_, 121 S.Ct. 1255, 1261 (2001); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165 (1995); *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 850 n.10 (1982).

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ornamental and not functional.<sup>514</sup> Some courts have developed the concept of “aesthetic functionality” to try to deal with this problem;<sup>515</sup> and some have suggested that “aesthetic functionality” exists whenever buyers purchase a good merely to display the logo itself.<sup>516</sup> However, the Supreme Court seems to have limited aesthetic functionality to situations in which the “exclusive use of [the design] would put competitors at a significant non-reputation-related disadvantage.”<sup>517</sup> Using this standard, there is no indication that using the insignia of a service organization confers any competitive advantage except to enhance the reputation of the goods on which it appears.

Third, it appears that avoidance of consumer confusion was a significant purpose behind the design patent extensions for these service organizations.<sup>518</sup> Indeed, the test for infringement of a design patent is expressly stated in terms of confusion:

[I]f, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first one patented is infringed by the other.<sup>519</sup>

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<sup>514</sup> 35 U.S.C. § 171 (2000); *Avia Group Int’l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1563 (Fed. Cir. 1988).

<sup>515</sup> See generally *Welkowitz*, *supra* note 506, at 334-43.

<sup>516</sup> See *Job’s Daughters*, 633 F.2d at 918 (“in the context of this case, the name and emblem are functional aesthetic components of the jewelry, in that they are being merchandised on the basis of their intrinsic value, not as a designation of origin or sponsorship.”); *Order of Rainbow*, 676 F.2d at 1083 n.5 (declining to address the issue). The problem with this inquiry is that, as applied, it seems to merely duplicate the source-identification inquiry. See *Welkowitz*, *supra* note 506, at 341-43.

<sup>517</sup> *Qualitex Co.*, 514 U.S. at 165; see *Traffix Devices*, 532 U.S. at \_\_\_, 121 S.Ct. at 1261-62 (explaining use of this standard in cases of aesthetic functionality).

<sup>518</sup> See, e.g., 139 CONG. REC. S8736 (daily ed. July 14, 1993) (remarks of Sen. Glenn) (“Unfortunately, this worthy organization [the American Legion] has frequently fallen prey to profiteers who use the Legion emblems without permission to solicit contributions and to sell counterfeit products.”); cf. *United States v. Dettra Flag Co.*, 86 F. Supp. 84, 86-87 (E.D. Pa. 1949) (“It is proper that Congress should seek to protect the public from frauds perpetrated by imposters. . . . The committee reports in Congress state that the purpose of the Act is to protect these organizations *and the public* from the unauthorized use of their insignia.”) (emphasis added).

<sup>519</sup> *Gorham Co. v. White*, 81 U.S. 511, 528 (1871). This test is still used today, supplemented by the “point of novelty” test, which seeks to determine whether the allegedly infringing product uses the features that distinguish the design from the prior art. *Unidynamics Corp. v. Automatic Prods. Int’l, Ltd.*, 157 F.3d 1311, 1323 (Fed. Cir. 1998).

This test is a combination of the “ordinary observer” test for assessing “substantial similarity” in copyright infringement cases,<sup>520</sup> and the “likelihood of confusion” test for trademark infringement.<sup>521</sup> The distinction, if one exists, is that design patent infringement requires only confusion as to the design itself,<sup>522</sup> whereas trademark requires confusion as to the source of goods bearing the design.<sup>523</sup> Presumably, a perceptive consumer could understand that the source of the goods was different, even though the two designs were identical.<sup>524</sup> However, to the extent that design patent law allows a finding of infringement without a showing of confusion as to source, it resembles the protection afforded by trademark dilution statutes,<sup>525</sup> such as the Federal Trademark Dilution Act.<sup>526</sup> These statutes are based on the theory that even non-confusing uses of a trademark may cause harm to the senior user of a famous mark, by lessening the distinctiveness and thus the commercial value of the mark.<sup>527</sup> While one court has suggested that trademark dilution law may violate the Patent and Copyright Clause as applied to product configurations,<sup>528</sup> the same court indi-

<sup>520</sup> See *Peter Pan Fabrics, Inc. v. Martin Weiner Corp.*, 274 F.2d 487, 489 (2d Cir. 1960) (finding infringement where “the ordinary observer, unless he set out to detect the disparities, would be disposed to overlook them, and regard their aesthetic appeal as the same.”).

<sup>521</sup> See Welkowitz, *supra* note 506, at 344-46.

<sup>522</sup> *Unidynamics*, 157 F.3d at 1323 (“the ordinary observer must be deceived by the features common to the claimed and accused designs that are ornamental, not functional”).

<sup>523</sup> *Unette Corp. v. Unit Pack Co.*, 785 F.2d 1026, 1029 (Fed. Cir. 1986) (“Likelihood of confusion *as to the source of goods* is not a necessary or appropriate factor for determining infringement of a design patent.”) (emphasis added).

<sup>524</sup> *But see* Welkowitz, *supra* note 506, at 327-30 (noting that the expansion of trademark law in allowing evidence of post-sale confusion amounts to a ban on copying).

<sup>525</sup> See Welkowitz, *supra* note 506, at 358-66.

<sup>526</sup> 15 U.S.C. § 1125(c) (2000). See David S. Welkowitz, *Oh, Deere, What's to Become of Dilution? (A Commentary on the New Federal Trademark Dilution Act)*, 4 UCLA ENT. L. REV. 1 (1996).

<sup>527</sup> See *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 539 (1987) (citing Frank Schechter, *The Rational Basis of Trademark Protection*, 40 HARV. L. REV. 813, 825 (1927)). For a critique, see David S. Welkowitz, *Reexamining Trademark Dilution*, 44 VAND. L. REV. 531 (1991).

<sup>528</sup> *I.P. Lund Trading ApS v. Kohler Co.*, 163 F.3d 27, 32 (1st Cir. 1998) (“Kohler has raised serious constitutional concerns”); *id.* at 35 (“Kohler’s constitutional claim [is] that dilution protection of trade dress of product design amounts to an unconstitutional perpetual monopoly under the Patent Clause of the Constitution”); *id.* at 53 (Boudin, J., concurring) (“In the case of patents and copyrights, the foreclosure of competition is deemed a price worth paying . . . but only for a limited time. Is this policy of time-limited protection, constitutional at its core, overcome wherever dilution is

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cated that dilution could constitutionally be applied to non-functional insignia which serve as a source identifier.<sup>529</sup> Similarly, in *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*,<sup>530</sup> the U.S. Supreme Court held that a special trademark statute that did not require a showing of likelihood of confusion could be based on a dilution theory without violating the First Amendment.<sup>531</sup> While there are possible grounds upon which that ruling could be distinguished,<sup>532</sup> it seems likely that a special statute protecting the insignia of a service organization would also be constitutional (at least in the vast majority of circumstances) as an exercise of Congress' power under the Commerce Clause to regulate trademarks.

In sum, the insignia of service organizations serve a trademark function, and renewals and extensions of the design patents for those insignia have more in common with trademark law than with design patent law. As applied to design patents, those renewals and extensions are constitutionally suspect; but if the insignia are viewed as trademarks, the renewals and extensions stand on firm constitutional footing. Consequently, this category of extensions should not be viewed as precedent for the extension of patents and copyrights generally.

### C. Analysis

The history of private patent term extensions can be interpreted in two very different ways. One view is that the Constitution gives to Con-

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threatened—even though no confusion can be proved and any impairment of the trademark may be only potential and directed primarily to protecting the seller rather than the public?”).

<sup>529</sup> *Id.* at 52 (Boudin, J., concurring) (“By contrast to a trademark consisting of a name or insignia, a product design will not often qualify as a trademark inviting protection from dilution.”); *id.* at 52-53 (“Where only a word or symbol is forever preempted, this protective approach toward the trademark may make sense, and in all events does not pose much risk to the policies of the patent and copyright clauses.”).

<sup>530</sup> 483 U.S. 522 (1987).

<sup>531</sup> *Id.* at 539-40.

<sup>532</sup> First, the statute at issue in *SFAA* only prohibited unauthorized use of the word “Olympic” and certain Olympic symbols “for the purpose of trade, to induce the sale of any goods or services, or to promote any theatrical exhibition, athletic performance, or competition.” Former 36 U.S.C. § 380 (now codified, as amended, at 36 U.S.C. § 220506 (2000)). The Court relied on these limitations in upholding the statute, 483 U.S. at 536-41, and it indicated that purely expressive uses might still be protected by the First Amendment. *Id.* at 536 n.14 (citing *Stop the Olympic Prison v. United States Olympic Committee*, 489 F. Supp. 1112 (S.D.N.Y. 1980)). Second, given that the Court expressly concluded that a likelihood of confusion existed, 483 U.S. at 539, the portion of the opinion discussing trademark dilution could be dismissed as dicta.

gress complete discretion over whether and how long patent terms may be extended.<sup>533</sup> Certainly that is the import of the many opinions rejecting constitutional challenges to private patent term extensions,<sup>534</sup> including opinions written by Justices Story<sup>535</sup> and Washington.<sup>536</sup> Indeed, those opinions hold that Congress can even revive an expired patent;<sup>537</sup> and the question was considered so well-settled that in some instances counsel simply conceded the point.<sup>538</sup> This view is supported by general statements on the subject of Congress' power by the U.S. Supreme Court,<sup>539</sup> and bolstered by the fact that during the patent term extension debates of the last

<sup>533</sup> See 2 ERNEST BAINBRIDGE LIPSCOMB III, *WALKER ON PATENTS* § 8:8, at 496 (3d ed. 1985) ("It has been held that patents may be extended by Congress at any time, either before or after their expiration."); 2 ANTHONY WILLIAM DELLER, *WALKER ON PATENTS* § 238 (1937) (same); 2 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 835, at 642 (1890) ("In this country the propriety of such extensions in special cases has always been conceded."); *id.* § 845 at 655 ("Congress may extend a patent by special act . . . at any time before or after the expiration of the original term.").

Similarly, the leading contemporary treatise simply states that "Congress itself on occasion extended patents by special act," and notes many examples of general term extension provisions, without discussing or mentioning the possibility that such term extensions might be unconstitutional. See 5 CHISUM ON PATENTS, *supra* note 224, § 16.04[1] at 16-187 & nn.4-5; § 16.04[5] (Hatch-Waxman Act); and § 16.04[6] (URAA).

<sup>534</sup> See, e.g., *Evans v. Robinson*, 8 F. Cas. 886, 888 (C.C.D. Md. 1813) (No. 4,571) (Congress is "not restrained from renewing a patent or prolonging the time of its continuance."), discussed at notes 266-268 and accompanying text; *Bloomer v. Stolley*, 3 F. Cas. 729, 731 (C.C.D. Ohio 1850) (No. 1,559) ("congress had the power to extend the patent"), discussed at notes 297-303 and accompanying text; and *Jordan v. Dobson*, 13 F. Cas. 1092, 1095 (C.C.E.D. Pa. 1870) (No. 7,519) ("It is not said when those limited times shall commence, how long they shall continue, or when they shall end. All that is left to the discretion of Congress."), discussed at notes 305-310 and accompanying text.

<sup>535</sup> See *Blanchard v. Sprague*, 3 F. Cas. 648, 650 (C.D.D. Mass. 1839) (No. 1,518) ("it rests in the sound discretion of Congress to say, when and for what length of time and under what circumstances the patent for an invention shall be granted."), discussed at notes 288-295 and accompanying text.

<sup>536</sup> See *Evans v. Eaton*, 8 F. Cas. 846, 848-49 (C.C.D. Pa. 1816) (No. 4,559), *rev'd on other grounds*, 16 U.S. (3 Wheat.) 454 (1818), *on remand*, 8 F. Cas. 856 (C.C.D. Pa. 1818) (No. 4,560), *aff'd*, 20 U.S. (7 Wheat.) 356 (1822), discussed at notes 278-284 and accompanying text.

<sup>537</sup> *Evans v. Eaton*, *Evans v. Robinson*, *Blanchard v. Sprague* and *Jordan v. Dobson* all involved patents that had expired prior to their extension by Congress.

<sup>538</sup> See notes 296 & 304 and accompanying text.

<sup>539</sup> See *Pennock & Sellers v. Dialogue*, 27 U.S. 1, 16-17 (1829); *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843). These opinions are discussed at notes 616-627 and accompanying text.

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two decades, apparently there was not a single suggestion in Congress, even by opponents of one or more extensions, that such extensions might be unconstitutional.<sup>540</sup> If this view is correct, then the only course open to opponents of copyright term extension is to argue that copyrights are somehow different than patents, such that copyrights may not be extended even though patents may be.<sup>541</sup> Such an argument is obviously an uphill climb; but Nimmer and others have argued that such a limitation may be found in the First Amendment, reasoning that copyright law imposes restrictions on freedom of speech,<sup>542</sup> whereas patent law does not.<sup>543</sup>

The opposite view is that, despite the raft of relatively broad pronouncements, the question has not been settled. This view relies on the fact that the U.S. Supreme Court has never squarely addressed the meaning of the phrase “limited Times” or the issue of whether patent (or copyright) term extension is constitutional under the Patent and Copyright Clause. While individual members of the U.S. Supreme Court, sitting as Circuit Judges, have expressed their opinions,<sup>544</sup> the issue has never been addressed in a written opinion by the Court as a whole.<sup>545</sup> Several cases involving extended patents have been heard by the Court; but in each of those cases, the issue of whether the extension violated the Patent and Copyright Clause was either never raised<sup>546</sup> or was conceded by the appellant’s counsel.<sup>547</sup> Under this view, the U.S. Supreme Court could treat all of the previous examples of patent term extension and the circuit court

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<sup>540</sup> By contrast, the constitutionality of copyright term extension was repeatedly raised as an issue by opponents of the Copyright Term Extension Act. *See* notes 23 & 146 *supra*.

<sup>541</sup> *Cf.* Heald & Sherry, *supra* note 25, at 1153 (“Congress’s justifications for patent extensions are not necessarily applicable to copyright.”).

<sup>542</sup> *See* 1 NIMMER ON COPYRIGHT, *supra* note 43, § 1.10[C][1], at 1-85; *see also* Lawrence Lessig, *Copyright’s First Amendment*, 48 UCLA L. REV. 1057 (2001); Neil Weinstock Netanel, *Locating Copyright Within the First Amendment Skein*, 54 STAN. L. REV. 1 (2001); *cf.* Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, Inc., 515 U.S. 557, 569 (1995) (First Amendment “unquestionably shield[s] [the] painting of Jackson Pollock, music of Arnold Schoenberg, or Jabberwocky verse of Lewis Carroll.”).

<sup>543</sup> *But see* Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99 (2000) (noting First Amendment difficulties raised by decisions allowing patent protection of computer software).

<sup>544</sup> *See* notes 535-536 and accompanying text.

<sup>545</sup> The Supreme Court did summarily affirm the decision in *Radio Position Finding Corp. v. Bendix Corp.*, 205 F. Supp. 850 (D. Md. 1962), *aff’d mem.*, 371 U.S. 577 (1963). *See* notes 340-367 and accompanying text. The precedential effect to be given to this summary affirmance is discussed at notes 548-563 and accompanying text.

<sup>546</sup> *See* notes 276-277, 282-284, 304, 311 and accompanying text.

<sup>547</sup> *See* notes 296 & 304 and accompanying text.

opinions upholding them as non-binding authority, and address the issue on a clean slate.

The choice between these two views depends in large measure on how one interprets the Supreme Court's summary affirmance in *Radio Position Finding Corp. v. Bendix Corp.*<sup>548</sup> Unlike denials of certiorari, which do not carry any precedential weight,<sup>549</sup> summary affirmances are ostensibly decisions on the merits which are binding on lower federal courts.<sup>550</sup> Some scholars have questioned whether summary affirmances should be given any precedential effect, noting that prior to 1988 summary dispositions essentially served the same function as petitions for certiorari.<sup>551</sup> Despite this widely-acknowledged reality,<sup>552</sup> the Supreme Court has indicated that summary dispositions are entitled to a "limited precedential effect";<sup>553</sup> but it has cautioned that "the precedential effect of a summary

<sup>548</sup> 205 F. Supp. 850 (D. Md. 1962), *aff'd mem.*, 371 U.S. 577 (1963). See notes 340-367 and accompanying text.

<sup>549</sup> See *United States v. Carver*, 260 U.S. 482, 490 (1923) (Holmes, J.) ("The denial of a writ of certiorari imports no expression of opinion upon the merits of the case, as the bar has been told many times."); *accord*, *Teague v. Lane*, 489 U.S. 288, 296 (1989); *Missouri v. Jenkins*, 515 U.S. 70, 85 (1995).

<sup>550</sup> See generally 16B CHARLES F. WRIGHT, ARTHUR MILLER AND EDWARD B. COOPER, FEDERAL PRACTICE AND PROCEDURE, JURISDICTION § 4003 (1996); ROBERT L. STERN, EUGENE GRESSMAN, STEPHEN M. SHAPIRO & KENNETH S. GELLER, SUPREME COURT PRACTICE §§ 4.28-4.29 (7th ed. 1993).

<sup>551</sup> See Erwin N. Griswold, *Rationing Justice—The Supreme Court's Caseload and What the Court Does Not Do*, 60 CORNELL L. REV. 335, 345 (1975) ("In most cases there is no longer any practical distinction between appeal and certiorari."); Philip B. Kurland, *Jurisdiction of the United States Supreme Court: Time For a Change?*, 59 CORNELL L. REV. 616, 624 (1974) ("The fact is that the Court doesn't seem to treat appeals any differently from the way it treats petitions for certiorari."); see also WRIGHT, MILLER & COOPER, *supra* note 550, § 4003, at 18 ("Most observers outside the court had come to believe that the actual practice was to treat appeals in substantially the same way as petitions for certiorari"); STERN, GRESSMAN, ET AL., *supra* note 550, § 4.26, at 211 ("one function of the jurisdictional statement was similar to that of the petition for certiorari, to induce the court to hear oral argument.").

<sup>552</sup> See *Hogge v. Johnson*, 526 F.2d 833, 836 (4th Cir. 1975) (Clark, J., concurring) ("during the eighteen Terms in which I sat [on the U.S. Supreme Court] . . . appeals from state court decisions received treatment similar to that accorded petitions for certiorari and were given about the same precedential weight."); Harold B. Wiley, *Jurisdictional Statements on Appeals to the U.S. Supreme Court*, 31 A.B.A. J. 239, 239 (1945) ("Jurisdictional statements and petitions for certiorari now stand on practically the same footing."). At the time, Wiley was a deputy clerk at the U.S. Supreme Court.

<sup>553</sup> *Anderson v. Celebrezze*, 460 U.S. 780, 784 (1983); see also *Edelman v. Jordan*, 415 U.S. 651, 671 (1974) ("these three summary affirmances obviously are of precedential value in support of the contention . . . . Equally obviously,

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affirmance extends no further than the precise issues presented and necessarily decided by those actions. A summary disposition affirms only the judgment of the court below, and no more may be read into our action than was necessary to sustain the judgment.”<sup>554</sup> Consequently, lower court judges must examine the jurisdictional statement as well as the opinion below to determine which issues, if any, were necessarily decided by the Court.<sup>555</sup>

The jurisdictional statement on appeal in the *Bendix* case presented eleven questions grouped into four categories.<sup>556</sup> Six of the questions specifically concerned “the precise scope of authority delegated to the Congress by the patent clause of the Constitution,”<sup>557</sup> including arguments that the private law did not “promote the progress of science and useful arts”<sup>558</sup> and violated the “limited Times” requirement.<sup>559</sup> Significantly, however, it appears that none of these arguments were raised at the district court level. In the lower court, the only argument based on the Patent and Copyright Clause was Congress’ alleged failure to grant “an exclusive right,”<sup>560</sup> not an alleged violation of the “limited Times” provision. The other arguments raised below were based upon the Due Process Clause of the Fifth Amendment, not upon the Patent and Copyright

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they are not of the same precedential value as would be an opinion of this Court treating the question on the merits.”).

<sup>554</sup> Anderson, 460 U.S. at 784 n.5; *accord*, *Montana v. Crow Tribe of Indians*, 523 U.S. 696, 714 n.14 (1998); *see also* *Mandel v. Bradley*, 432 U.S. 173, 176 (1977) (per curiam) (“The District Court erred in believing that our [summary] affirmance in [a prior case] adopted the reasoning as well as the judgment of the three-judge court in that case.”).

<sup>555</sup> *See* *Mandel v. Bradley*, 432 U.S. 173, 176 (1977) (per curiam) (“Because a summary affirmance is an affirmance of the judgment only, the rationale of the affirmance may not be gleaned solely from the opinion below . . . . Summary affirmances . . . reject the specific challenges presented in the statement of jurisdiction.”); *id.* at 180 (Brennan, J., concurring) (to determine the precedential effect of a summary disposition, lower courts “must (a) examine the jurisdictional statement in the earlier case to be certain that the constitutional questions presented were the same and, if they were, (b) determine that the judgment in fact rests upon decision of those questions and not even arguably upon some alternative nonconstitutional ground.”).

<sup>556</sup> Jurisdictional Statement at 2-5, 12, *Bendix Corp. v. Radio Position Finding Corp.*, 371 U.S. 57 (1963) (No. 645). The statement presented twelve numbered questions, one of which was withdrawn in the accompanying brief. *Id.* at 12 n.9.

<sup>557</sup> *Id.* at 12.

<sup>558</sup> *Id.* at 2-3 (Questions Presented Nos. 1 and 4).

<sup>559</sup> *Id.* at 3 (Question Presented No. 3).

<sup>560</sup> *See* notes 349-352 and accompanying text. This argument was renewed on appeal. *See* Jurisdictional Statement, *supra* note 556, at 3 (Question Presented No. 5).

Clause.<sup>561</sup> Consequently, the Court might have declined to give the appeal plenary consideration because it considered the arguments based on the Patent Clause to have been waived.<sup>562</sup> The arguments based on substantive and procedural due process were renewed on appeal in the U.S. Supreme Court,<sup>563</sup> and must therefore be considered to have been rejected; but, as noted above, a summary affirmance does not necessarily affirm the reasoning of the court below. In addition, the case did not involve the extension of an existing patent, but the granting of a patent to the original inventor despite a delay of several years. Consequently, the three-judge District Court's approval of dicta from prior Circuit Court opinions cannot be considered to have received the imprimatur of the U.S. Supreme Court.

Assuming the issue is analyzed as one of first impression, how should the Court construe the phrase "for limited Times"? Textually, it should be noted that the phrase is worded in the plural form ("for limited Times" rather than "for a limited Time"); but this can easily be explained as merely granting Congress the power to prescribe different times for patents and copyrights,<sup>564</sup> to prescribe different times for different categories of "writings"<sup>565</sup> or "discoveries,"<sup>566</sup> or to allow renewal terms when authorized at the outset of the initial term.<sup>567</sup> Beyond this observation, there are three possible interpretations of the phrase. The broadest possible interpretation is that Congress is only prohibited from granting a perpetual exclusive right, but that it may grant an exclusive right (or an extension) for any finite (and therefore limited) term.<sup>568</sup> The narrowest interpretation is that whatever "limited Times" Congress chooses to bestow upon patents or copyrights, those times cannot be extended retroactively for any

<sup>561</sup> See notes 353-365 and accompanying text.

<sup>562</sup> Cf. *Tacon v. Arizona*, 410 U.S. 351, 352 (1973) (per curiam) ("Upon reviewing the record, . . . it appears that these broad questions were not raised by the petitioner below. . . . We cannot decide issues raised for the first time here.").

<sup>563</sup> Jurisdictional Statement, *supra* note 550, at 4-5 (Questions Presented Nos. 8-11).

<sup>564</sup> Compare 35 U.S.C. § 154(a)(2) (twenty-year patent term) with 17 U.S.C. § 302(a) (life-plus-seventy year copyright term).

<sup>565</sup> Compare 17 U.S.C. § 302(a) (life-plus-seventy year term for individual authors) with 17 U.S.C. § 302(c) (ninety-five years from first publication or 120 years from creation for works made for hire).

<sup>566</sup> Compare 35 U.S.C. § 154(a)(2) (twenty-year term for utility patents) with 35 U.S.C. § 173 (fourteen-year term for design patents).

<sup>567</sup> See, e.g., Copyright Act of 1790, § 1, 1 Stat. 124, 124 (1790; repealed 1831) (providing for fourteen-year initial term and fourteen-year renewal term); Patent Act of 1836, §§ 5, 18, 5 Stat. 117, 119, 124-25 (1836) (fourteen-year initial term; seven-year renewal term).

<sup>568</sup> See notes 571-574 and accompanying text.

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reason.<sup>569</sup> An intermediate position would be that Congress can extend the terms of patents and copyrights for some purposes but not for others.<sup>570</sup>

While there is widespread agreement that Congress cannot grant an exclusive right that is expressly perpetual,<sup>571</sup> the vast majority of commentators further agree that, in order to be meaningful, the phrase “for limited Times” must be interpreted to prohibit ostensibly finite terms that would, as a practical matter, amount to the same thing.<sup>572</sup> Thus, “extension of protection to a term of several hundred years would at some point present a ‘line-drawing’ problem as to what period of years is tantamount to perpetual protection.”<sup>573</sup> Likewise, if Congress were to grant twenty-year term extensions at regular intervals, at *some* point those extensions must be held to violate the Patent and Copyright Clause. Otherwise, Congress could accomplish indirectly what it is expressly prohibited from accomplishing directly.<sup>574</sup>

The narrow interpretation, by contrast, finds support in the Supreme Court’s opinion in *Graham v. John Deere Co.*,<sup>575</sup> in which the Court described the Clause as follows:

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<sup>569</sup> See notes 575-597 and accompanying text.

<sup>570</sup> See notes 598-608 and accompanying text.

<sup>571</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“Congress may not create patent monopolies of unlimited duration.”); *Eldred v. Reno*, 239 F.3d 372, 377 (D.C. Cir. 2001) (“If the Congress were to make copyright protection permanent, then it surely would exceed the power conferred upon it by the Copyright Clause.”); *United States v. Moghadam*, 175 F.3d 1269, 1281 (11th Cir. 1999) (“the ‘Limited Times’ requirement . . . forbids Congress from conferring intellectual property rights of perpetual duration.”); 1 NIMMER ON COPYRIGHT, *supra* note 43, § 1.05, at 1-66.13 (“A federal copyright statute that purported to grant copyright protection in perpetuity would clearly be unconstitutional.”); Patry, *Protecting the Idle Rich*, *supra* note 17, at 910 (“Any effort to grant a perpetual copyright would violate the clause.”).

<sup>572</sup> See, e.g., 1 NIMMER ON COPYRIGHT, *supra* note 43, § 1.05, at 1-66.13 (“Furthermore, it seems likely that a grant of copyright protection for what is nominally a ‘limited time’ but is in fact the equivalent of perpetual protection (e.g., a one thousand year term) would likewise be held invalid.”); Heald & Sherry, *supra* note 25, at 1172 (“Given the seriousness with which the framers viewed the granting of exclusive rights, it is unlikely that they intended the limited-time provision to be rendered a dead letter by linguistic manipulation.”).

<sup>573</sup> 1 NIMMER ON COPYRIGHT, *supra* note 43, § 1.05, at 1-66.13.

<sup>574</sup> See *Eldred v. Reno*, 239 F.3d 372, 382 (D.C. Cir. 2001) (Sentelle, J., dissenting); Peter Jaszi, *Caught in the Net of Copyright*, 75 OR. L. REV. 299, 303 (1996) (describing the CTEA as “down payment on perpetual copyright on the installment plan.”).

<sup>575</sup> 383 U.S. 1 (1966).

The clause is both a grant of power and a limitation. . . . The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. *Moreover, Congress may not authorize the issuance of a patent whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.* Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must ‘promote the Progress of . . . useful Arts.’ This is the standard expressed in the Constitution, and it may not be ignored.<sup>576</sup>

Construing the phrase “for limited Times” in light of this language, it seems that the proper interpretation is that whatever “limited Time” is provided, that time cannot be extended after it has expired, because to do so would be “to remove existent knowledge from the public domain.”<sup>577</sup> Under this view of the Patent and Copyright Clause, the private term extension granted to Thomas Blanchard<sup>578</sup> clearly violated the Constitution. Blanchard’s patent had already expired, and the knowledge that it disclosed had entered the public domain.<sup>579</sup> This view would also invalidate the patent extensions granted to Oliver Evans,<sup>580</sup> John Goulding<sup>581</sup> and William Graham,<sup>582</sup> effectively undermining all but one of the nineteenth-century precedents upholding patent term extension.<sup>583</sup> With one exception, Congress itself appears to have acquiesced in this view in recent years.<sup>584</sup> Thus, if *Graham* correctly expresses the Supreme Court’s view

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<sup>576</sup> *Id.* at 5-6 (emphasis added). The Court immediately added that “Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim.” *Id.* at 6. This observation begs the question as to just what “the limits of the constitutional grant” are.

<sup>577</sup> *Id.* at 6.

<sup>578</sup> See notes 288-296 and accompanying text.

<sup>579</sup> See *Bonito Boats, Inc. v. Thunder Craft, Inc.*, 489 U.S. 141, 152 (1989) (“We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law.”).

<sup>580</sup> See notes 235-284 and accompanying text.

<sup>581</sup> See notes 305-311 and accompanying text.

<sup>582</sup> See notes 312-321 and accompanying text.

<sup>583</sup> The sole remaining exception is the patent of William Woodworth, discussed at notes 297-304 and accompanying text.

<sup>584</sup> From 1962 until 1976, Congress repeatedly extended the terms of existing copyrights on an ostensibly “interim” basis, so that those copyrights would be able to receive the benefit of the extension made in the 1976 Act. See

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of the Patent and Copyright Clause (as it must be presumed to do),<sup>585</sup> the only remaining question is whether Congress has the power to extend a patent (or a copyright) *before* it has expired.

The Supreme Court has made it clear that an author or inventor does not have a natural right to his or her invention or work of authorship once it is disclosed to the public.<sup>586</sup> In *Graham*, the Court reviewed Thomas Jefferson's views concerning monopolies<sup>587</sup> and inferred from them the following principle:

The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited, private monopoly.<sup>588</sup>

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notes 116-133 and accompanying text. This action would have been unnecessary had Congress believed it had the power to revive expired copyrights. Likewise, the CTEA did not attempt to extend copyrights which had already entered the public domain. *See* note 154, *supra*. Finally, during the patent term extension debates in the 1980s and 1990s, Congress was careful to extend only patents which had not yet expired. The one exception was the drug Oxaprozol, which received a two-year period of “marketing exclusivity” after its patent had expired. *See* notes 368-448 and accompanying text.

It should be noted that Congress has also renewed several expired design patents on the insignia of service organizations; however, as explained above, those renewals are more properly viewed as private trademark legislation rather than as patent term extension. *See* notes 449-532 and accompanying text.

<sup>585</sup> In recent years, the Court has repeatedly emphasized that the Patent and Copyright Clause limits the manner in which Congress may act. *See, e.g.,* *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 346 (1991) (“Originality is a constitutional requirement.”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“the [Patent] Clause contains both a grant of power and certain limitations upon the exercise of that power.”).

<sup>586</sup> *See* *Wheaton v. Peters*, 33 U.S. 591, 654-61 (1834).

<sup>587</sup> The Court explained: “Because of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution . . . are worthy of note.” 383 U.S. at 7. For a different view of Jefferson's contributions, see Edward C. Walterscheid, *The Use and Abuse of History: The Supreme Court's Interpretation of Thomas Jefferson's Influence on the Patent Law*, 39 IDEA J.L. & TECH. 195 (1999); Edward C. Walterscheid, *Patents and the Jeffersonian Mythology*, 29 J. MARSHALL L. REV. 269 (1995).

<sup>588</sup> *Id.* at 9; *see also* *Feist*, 499 U.S. at 346 (“Originality is a constitutional requirement.”).

This view follows from the fact that, under the Clause, patents and copyrights may be granted only “[t]o promote the Progress of Science and useful Arts.”<sup>589</sup> Elsewhere, the Court has explained that “[a]s employed, the terms ‘to promote’ are synonymous with the words ‘to stimulate,’ ‘to encourage,’ or ‘to induce.’”<sup>590</sup> A retroactive term extension, however, does not stimulate, encourage or induce anyone to produce anything new.<sup>591</sup> Instead, it merely serves to grant an additional reward to an author or inventor (or his or her heirs or assigns) after the fact, for having produced something valuable in the past.<sup>592</sup> In general, therefore, the extension of existing patents and copyrights violates the principles underlying the Patent and Copyright Clause, as expressed in *Graham*, even if the extension is granted before the initial term has expired.<sup>593</sup> Construing the phrase “for limited Times” to forbid retroactive extension therefore vindicates the incentive rationale embodied in the Patent and Copyright Clause.

Construing the phrase “for limited Times” to forbid retroactive extensions also serves the purposes of the Clause in other ways. One of the important purposes of the Patent and Copyright Clause is to limit the imposition of monopoly-like costs upon the public;<sup>594</sup> another is to ensure that there is a rich public domain of materials available for future authors and inventors to borrow from and build upon in fashioning new works and

<sup>589</sup> U.S. CONST. art. I, § 8, cl. 8; *see also Feist*, 499 U.S. at 349 (“The primary objective of copyright is not to reward the labor of authors, but ‘[t]o promote the Progress of Science and useful Arts.’”).

<sup>590</sup> *Goldstein v. California*, 412 U.S. 546, 555 (1973).

<sup>591</sup> *See Heald & Sherry*, *supra* note 25, at 1169 (“The retroactive extension of the copyright term cannot possibly provide any incentive for Gershwin — or even a living author — to create an already existing work.”). Even a proponent of strong intellectual property protection who believes that intellectual property is “under strenuous attack” agrees. *See Doris Estelle Long, First, “Let’s Kill All the Intellectual Property Lawyers!”: Musings on the Decline and Fall of the Intellectual Property Empire*, 34 J. MARSHALL L. REV. 851, 867 (2001) (“it is difficult to see how an extra twenty years of protection after the author’s death incentivizes creation. In the absence of such incentivization, the harm to the public domain by removing these works for additional periods of time seems unjustified.”) (emphasis in original).

<sup>592</sup> *See Heald & Sherry*, *supra* note 25, at 1170 (“Although it is entirely possible that the recipient of the income stream will do something beneficial with their extra profit, this possibility is as irrelevant now as it was in 1623 and 1709. Congress must buy American citizens something when it imposes monopoly-like costs upon them.”).

<sup>593</sup> *Id.* at 1169 (“It would be difficult to imagine a more overt violation of the Quid Pro Quo principle than [the] CTEA.”).

<sup>594</sup> *Id.* at 1154-55 (“the notion of limiting the term of protection was likely one mechanism by which the framer sought to minimize monopoly costs and assure the valuable inventions and writings would inevitably belong to the public.”); *id.* at 1160-62.

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inventions.<sup>595</sup> Placing copyrighted works in the public domain at the end of a specified period of time serves both of these purposes. If the phrase “for limited Times” is construed to allow repeated extensions, the public will continue to suffer monopoly costs without obtaining anything new, and the public domain will not be replenished with a steady stream of new works, allowing it to become stagnant.<sup>596</sup>

The narrow interpretation also avoids entangling the courts in the inherently arbitrary line-drawing question of whether a particular term does or does not “Promote the Progress of Science and useful Arts.”<sup>597</sup> Instead, it provides a non-arbitrary bright-line rule: whatever term is selected by Congress, it cannot be extended retroactively. Such a rule would reduce the incentive for existing patent and copyright owners to besiege Congress with self-serving requests for term extension, since they would not receive any benefit from such an extension until years after the legislation had passed.

The intermediate view requires a careful examination of the various circumstances which prompted Congress to act by means of private legislation, to determine if the extensions which have been upheld share any characteristics which distinguish them from term extension generally.<sup>598</sup> It appears that in most instances, Congress acted to restore to the inventor

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<sup>595</sup> *Id.* at 1165-66; L. RAY PATTERSON & STANLEY W. LINDBERG, *THE NATURE OF COPYRIGHT: A LAW OF USER'S RIGHTS* 50-51 (1991); Jessica Litman, *The Public Domain*, 39 *EMORY L.J.* 965, 968 (1990); *see also* *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 151 (1989) (“The ultimate goal of the patent system is to bring new designs and technology into the public domain”).

<sup>596</sup> Under the 1909 Act, all works published before 1922 would have entered the public domain on or before Jan. 1, 1978, the effective date of the 1976 Act. Since that time, due to copyright extensions, only one additional year of copyrighted works (works first published in 1922) has entered the public domain; and under the CTEA, no published works will enter the public domain for the next eighteen years.

<sup>597</sup> Opponents of term extension argue that the CTEA does not “Promote the Progress of Science” because the present value of an additional twenty years at the end of a seventy-five year term (or a life-plus-fifty-year term) is essentially zero. *See* Affidavit of Hal R. Varian, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), *available at* <http://cyber.law.harvard.edu/eldredvreno/varian.pdf> (last visited Nov. 30, 2001) (noting that the total present value of \$1 per year in years 76-95 is 1 cent). While persuasive, such evidence raises the difficult question of where a court (as opposed to a legislature) should draw the line: how large must the marginal incentive to authors be in order to make a given term extension constitutional?

<sup>598</sup> *Cf.* Heald & Sherry, *supra* note 25, at 1152 (“there are circumstances suggesting that these patent extensions were consistent with a limiting purpose of promoting innovation.”). For a similar proposal, *see* *Merges & Reynolds*, *supra* note 25, at 64-68.

some period of time which he or she had expected to receive under existing law, but which had been lost due to circumstances beyond the inventor's control. This was the case with Oliver Evans (administrative error),<sup>599</sup> Louis Aronson (judicial corruption),<sup>600</sup> William Blair (war),<sup>601</sup> and all of the pharmaceutical patent term extensions of the late twentieth century (delay in FDA approval).<sup>602</sup> While Congress may have, in some cases, gone beyond what was necessary to compensate the patent owner,<sup>603</sup> in each case its intention was to vindicate the patent owner's expectation interest, rather than to grant the patent owner an additional subsidy.<sup>604</sup> Only during the period between 1844 and 1879 did Congress take the position that a patent owner was entitled to "adequate compensation" for his or her invention, instead of merely the opportunity to earn such compensation during the term originally granted;<sup>605</sup> and that period can be explained as a historical aberration which has subsequently been repudiated by Congress.

Under the intermediate view, therefore, the patent term extension cases discussed above stand for the proposition that the principles underlying the Patent and Copyright Clause are not violated by a statute whose purpose and effect is to ensure that an author or inventor receives the benefit of his or her bargain. If an author or inventor relied upon the existing term, but did not receive the benefit of the full term for reasons beyond his or her control, then Congress may constitutionally extend the exclusive right (before its expiration)<sup>606</sup> to compensate the author or in-

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<sup>599</sup> See notes 249-259 and accompanying text.

<sup>600</sup> See notes 329-339 and accompanying text.

<sup>601</sup> See notes 340-346 and accompanying text.

<sup>602</sup> See notes 368-417 and accompanying text.

<sup>603</sup> See notes 215-216 & 260 and accompanying text.

<sup>604</sup> Cf. Heald & Sherry, *supra* note 25, at 1162-63 & 1171-72 (arguing that under the Intellectual Property Clause, any grant of exclusive rights must be in the form of quid pro quo, rather than in the form of gift-plus-hope).

<sup>605</sup> See Benagh, *supra* note 286, at 8-9; *id.* at 11 ("There was a period in the mid-nineteenth century when the Congress attempted to assure adequate compensation to every inventor with the device of private legislation, but the concept of guaranteed income proved to be too time-consuming and open to frivolous claims.").

<sup>606</sup> This view leaves open the question of whether Congress may constitutionally revive an exclusive right that has already expired. That question is not presented by the CTEA, which expressly applies only to copyrights which have not yet entered the public domain. However, even if all such revivals are prohibited, Congress may use direct subsidies to compensate authors or inventors who may not have received the benefit of their bargain. See note 608 and accompanying text.

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ventor for the lost time.<sup>607</sup> Otherwise, Congress is without power to extend an exclusive right under the Patent and Copyright Clause.

Two additional points concerning the intermediate view must be emphasized. First, the bargain which the author or inventor accepted was the *opportunity* to earn money by exploiting his or her exclusive right for a limited period of time, not the *guarantee* that he or she would profit financially during that time. Thus, Congress cannot constitutionally extend patents or copyrights merely by asserting that circumstances have changed. For example, while it is certainly true that digital technologies and international markets present both new opportunities and new challenges to copyright owners, those changes have not deprived copyright owners of the benefit of their bargain, because those changes have not prevented copyright owners from earning money through licensing of their copyrighted works. If the owner of an exclusive right was able to receive royalties during the entire period of time promised to him or her by Congress, then Congress cannot extend that period retroactively. Only if the owner was actually prevented from exploiting his or her work for a period of time, for reasons comparable to those which prompted Congress to act in previous cases, may Congress act to extend the limited time by a comparable period.

Second, placing limits on the ability of Congress to extend patents and copyrights does not leave Congress entirely without recourse. It may, if it wishes, grant a direct subsidy to an author or inventor; but it may not do so indirectly by reviving or extending his or her exclusive right, except in the limited circumstances described above. This limitation therefore helps ensure political accountability by ensuring that such subsidies are debated openly, rather than disguised in the form of patent or copyright term extensions.<sup>608</sup>

#### IV. ELDRED V. RENO

##### A. *District Court Opinion*

Shortly after the CTEA was enacted, a lawsuit was filed in the District of Columbia to enjoin the Attorney General from enforcing criminal copyright penalties with respect to works that otherwise would have en-

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<sup>607</sup> See *Merges & Reynolds, supra* note 25, at 65 (“where extensions are based on some specific and identifiable government error . . . they are less suspect than they would be if based on other considerations.”). Under this view, all of the private term extensions granted to utility patents in the twentieth century would be valid, with the possible exception of the two-year period of “market exclusivity” granted to the patentee of Oxaprozin.

<sup>608</sup> This point is made and explained in greater detail in Heald & Sherry, *supra* note 25, at 1174-75.

tered the public domain.<sup>609</sup> The lawsuit was filed by Eric Eldred, an individual who publishes public domain works on the Internet under the name Eldritch Press.<sup>610</sup> Eldred was later joined by nine other plaintiffs who regularly publish or use public domain works.<sup>611</sup> The Second Amended Complaint alleged three theories under which the CTEA was unconstitutional: that it violated the Patent and Copyright Clause of the Constitution;<sup>612</sup> that it violated the the First Amendment;<sup>613</sup> and that it violated the Public Trust Doctrine.<sup>614</sup>

The district court summarily rejected all three theories.<sup>615</sup> With regard to the Patent and Copyright Clause, the court relied upon dicta from two U.S. Supreme Court cases: *Pennock & Sellers v. Dialogue*<sup>616</sup> and *McClurg v. Kingsland*.<sup>617</sup> First, it quoted from Justice Story's opinion for the Court in *Pennock*, in which he stated:

The constitution of the United States . . . contemplates, therefore, that this exclusive right shall exist but for a limited period,

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<sup>609</sup> Complaint, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), available at [http://cyber.law.harvard.edu/eldredvreno/complaint\\_orig.html](http://cyber.law.harvard.edu/eldredvreno/complaint_orig.html) (last visited Oct. 31, 2001). As amended by the No Electronic Theft Act, Pub. L. No. 105-147, 111 Stat. 2678 (1997), the Copyright Act provides criminal penalties for making or distributing copies having a total retail value of more than \$1000. 17 U.S.C. § 506(a)(2) (2000). If the copies have a total retail value of more than \$2500, penalties can include up to five years' imprisonment, and up to ten years' imprisonment for subsequent offenses. 18 U.S.C. § 2319(b) (2000).

<sup>610</sup> <http://eldritchpress.org> (last visited Oct. 31, 2001).

<sup>611</sup> The nine included three publishers: Dover Publications, Inc., Higginson Book Co. (genealogy & history), and Tri-Horn International (golf); three users of public domain sheet music: Jill A. Crandall (church choir director), Luck's Music Library (retailer) and Edwin F. Kalmus & Co. (publisher); two users of public domain movies: American Film Heritage Association (non-profit association devoted to film preservation) and Moviecraft, Inc. (commercial film archive); and Copyright's Commons, a non-profit public domain advocacy organization based at Harvard's Berkman Center for Internet & Society. See Second Amended Complaint, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), available at [http://cyber.law.harvard.edu/eldredvreno/complaint\\_amd2.html](http://cyber.law.harvard.edu/eldredvreno/complaint_amd2.html) (last visited Oct. 31, 2001).

<sup>612</sup> *Id.* at 11-14 (Count One); see U.S. CONST. art. I, § 8, cl. 8. The complaint specifically alleged both that retroactive extensions violated the "limited Times" provision and that they did not "promote the progress of science and useful arts." Second Amended Complaint at 13.

<sup>613</sup> *Id.* at 15 (Count Three).

<sup>614</sup> Second Amended Complaint at 14-15 (Count Two).

<sup>615</sup> See *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999), *aff'd*, 239 F.3d 372 (D.C. Cir. 2001), *petition for reh'g and reh'g en banc denied sub nom.*, *Eldred v. Ashcroft*, 255 F.3d 849 (D.C. Cir. 2001).

<sup>616</sup> 27 U.S. 1 (1829).

<sup>617</sup> 42 U.S. 202 (1843).

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and that the period shall be subject to the discretion of congress.<sup>618</sup>

This statement is dicta as applied to term extension. In *Pennock*, the Court held that a patent was invalid if the invention had been known or used by the public prior to the application.<sup>619</sup> In so holding, the Court emphasized both the incentive and public domain rationales underlying the Clause,<sup>620</sup> and it specifically held that “it would materially retard the progress of science and useful arts” if an inventor could retain a monopoly for a period of years before applying for a patent.<sup>621</sup> Thus, although the dicta supports a broad reading of Congress’ power under the Patent Clause, the opinion as a whole seems to support a narrower interpretation of that Clause.

The district court then cited *McClurg* for the proposition that “Congress has authority to enact retrospective laws under the copyright clause.”<sup>622</sup> *McClurg* involved the question whether an 1839 amendment to the Patent Act could be applied retroactively to a patent issued in 1835. The Court stated:

Whether the exceptions are well taken or not, must depend on the law as it stood at the emanation of the patent, together with such changes as have been since made; for though they may be retrospective in their operation, that is not a sound objection to their validity; the powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution, and as there are no restraints on its exercise, there can be no limitation of their right to modify them at their pleasure, so that they do not take away the rights of property in existing patents.<sup>623</sup>

The Court explained that under *Pennock*, any public use of the invention prior to the date of the patent application would have invalidated the patent.<sup>624</sup> The amendment in question enacted a two-year grace period for applying for a patent, and immunized from liability any person who had

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<sup>618</sup> 27 U.S. at 16-17; see 74 F. Supp. 2d at 3.

<sup>619</sup> 27 U.S. at 18-19.

<sup>620</sup> *Id.* at 19 (“While one great object was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was ‘to promote the progress of science and useful arts;’ and this could be done best, by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible.”).

<sup>621</sup> *Id.*

<sup>622</sup> 74 F. Supp. 2d at 3 (citing *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843)).

<sup>623</sup> 42 U.S. at 206.

<sup>624</sup> *Id.* at 207 (“On this construction of the acts of 1793 and 1800, Harley’s patent would have been void.”).

purchased or used the newly-invented machine prior to the date of the patent application.<sup>625</sup> In upholding the amendment, the court held only that it did not leave either party any worse off than they would have been under the former law.<sup>626</sup> The case did not present any question of the extension of an existing patent, or the reduction of the public domain. As applied to term extension, therefore, the passage quoted is once again dicta. Moreover, the premise of the quote, that “there are no restraints on [Congress’] exercise” of power under the Patent and Copyright Clause, has been rejected by the U.S. Supreme Court in later years.<sup>627</sup> *McClurg*, therefore, does not support the broad reading given to it by the district court.

Two additional statements by the district court indicate its approval of the broadest possible interpretation of Congress’ power. The district court stated that “the introductory language of the copyright clause does not limit” Congress’ power.<sup>628</sup> This statement is inconsistent with the Supreme Court’s view of the Clause, as expressed in *Graham v. John Deere Co.* and other cases.<sup>629</sup> The district court also stated “[w]ithin the discretion of Congress, any fixed term is a limited time because it is not perpetual. If a limited time is extended for a limited time then it remains a limited time.”<sup>630</sup> Under this view, any period short of an expressly perpetual term would be constitutional.

With regard to the First Amendment, plaintiffs argued that copyright is a content-neutral speech restriction that is subject to intermediate scrutiny.<sup>631</sup> It attempted to distinguish previous cases which held that the First Amendment was not a defense to copyright infringement. For example, in *Harper & Row Publishers, Inc. v. Nation Enterprises*,<sup>632</sup> the U.S. Supreme

<sup>625</sup> *Id.* at 208 (citing Patent Act of 1839, § 7, 5 Stat. 353, 354 (1839)).

<sup>626</sup> *Id.* at 209 (“This [amendment] relieved [plaintiff] from the effects of former laws and their constructions by this court . . . while it puts the person who has had such prior use on the same footing as if he had a special license from the inventor to use his invention; which . . . would justify the continued use after it issued without liability.”).

<sup>627</sup> See notes 575-585 and accompanying text.

<sup>628</sup> 74 F. Supp. 2d at 3 n.6 (citing *Schnapper v. Foley*, 667 F.2d 102, 112 (D.C. Cir. 1981)).

<sup>629</sup> See notes 575-585 and accompanying text.

<sup>630</sup> 74 F. Supp. 2d at 3 n.7.

<sup>631</sup> Memorandum in Support of Plaintiff’s Motion for Judgment on the Pleadings at 32-35, *Eldred v. Reno*, 74 F. Supp. 2d 1 (D.D.C. 1999) [hereinafter Plaintiff’s Memorandum], available at <http://cyber.law.harvard.edu/eldredvreno/legaldocs.html> (last visited Oct. 31, 2001). See *Turner Broad. Sys., Inc. v. Federal Communications Comm’n*, 520 U.S. 180, 189 (1997); Neil Weinstock Netanel, *Locating Copyright Within the First Amendment Skein*, 54 STAN. L. REV. 1 (2001).

<sup>632</sup> 471 U.S. 539 (1985).

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Court held that First Amendment considerations were adequately reflected in existing substantive limitations on copyright, including the idea/expression dichotomy and the fair use doctrine.<sup>633</sup> As the plaintiffs pointed out, however, those cases involved copyrights which were conceded to be valid; whereas term extension involves the threshold issue of whether the copyright was validly extended in the first place.<sup>634</sup> In other words, while the First Amendment interest in reproducing someone else's words remains high over time, the countervailing governmental interest in restricting such copying does not.<sup>635</sup> The district court rejected this argument, holding flatly that "there are no First Amendment rights to use the copyrighted works of others."<sup>636</sup>

With regard to the Public Trust Doctrine, the plaintiffs in *Eldred v. Reno* argued that the granting of a copyright for a period of years "vest[s] in the public a future remainder interest in the right to use the copyrighted work";<sup>637</sup> and that this future interest is public property, which cannot be transferred to a private entity "when the primary purpose of the legislative grant is to benefit a private interest."<sup>638</sup> An assessment of this argument requires an examination of the origins and legal basis of the Public Trust Doctrine.

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<sup>633</sup> 471 U.S. at 560. In so holding, the court relied in part on an influential article by Melville B. Nimmer, *Does Copyright Abridge the First Amendment Guarantees of Free Speech and Press?*, 17 UCLA L. REV. 1180 (1970). In response, Neil Netanel has argued that while "Nimmer's conclusions may have been plausible in 1970, . . . courts have largely ignored subsequent developments in both copyright law and First Amendment doctrine." Netanel, *supra* note 631, at 4.

<sup>634</sup> Plaintiff's Memorandum, *supra* note 631, at 47-48. It is worth noting that Nimmer was of the opinion that retroactive term extension violated the First Amendment. Nimmer, *supra* note 633, at 1195; see 1 NIMMER ON COPYRIGHT, *supra* note 43, § 1.10[C][1], at 1-83.

<sup>635</sup> Restricting copying for a limited period of time encourages creation by allowing the author to earn royalties. But the decision to create a new work is made based on the term of copyright that exists at the time of creation. While prospective term extension may encourage more works to be created in the future, retroactive term extension cannot increase the supply of existing works.

<sup>636</sup> 74 F. Supp. 2d at 3 (citing *United Video, Inc. v. Federal Communications Comm'n*, 890 F.2d 1173, 1191 (D.C. Cir. 1989)).

<sup>637</sup> Plaintiff's Memorandum, *supra* note 631, at 53. See also *Merges & Reynolds*, *supra* note 25, at 62-63.

<sup>638</sup> Plaintiff's Memorandum, *supra* note 631, at 56 (quoting *Lake Michigan Fed'n v. United States Army Corps of Eng'rs*, 742 F. Supp. 441, 445 (N.D. Ill. 1990)). See also Maureen Ryan, *Cyberspace as Public Space: A Public Trust Paradigm for Copyright in a Digital World*, 79 OR. L. REV. 647, 704-19 (2000).

In *Illinois Central Railroad Co. v. Illinois*,<sup>639</sup> the U.S. Supreme Court invalidated an Illinois statute conveying submerged lands underlying Lake Michigan to the Illinois Central Railroad. The Court held that navigable waters were public property, “held in trust for the people of the state”;<sup>640</sup> and that such property “cannot be alienated except . . . when parcels can be disposed of without detriment to the public interest.”<sup>641</sup> The Court stated:

The state can no more abdicate its trust over property in which the whole people are interested, like navigable waters and soils under them, so as to leave them entirely under the use and control of private parties, except . . . when parcels can be disposed of without impairment of the public interest in what remains, than it can abdicate its police powers in the administration of government and the preservation of peace. . . . So with trusts connected with public property, or property of a special character, like lands under navigable waters; they cannot be placed entirely beyond the direction and control of the state.<sup>642</sup>

There are several difficulties in extending the Public Trust Doctrine announced in *Illinois Central* to the right to use works scheduled to enter the public domain upon the expiration of a copyright. First, the Public Trust Doctrine was developed in the context of navigable waters.<sup>643</sup> While in some instances the doctrine has been extended to other public lands and natural resources,<sup>644</sup> it has not previously been extended to intangible property.<sup>645</sup> The argument that it can be so extended is based on the fact

<sup>639</sup> 146 U.S. 387 (1892).

<sup>640</sup> *Id.* at 452.

<sup>641</sup> *Id.* at 455-56.

<sup>642</sup> *Id.* at 453.

<sup>643</sup> *Id.* at 452 (“That the state holds the title to the lands under the navigable waters of Lake Michigan, within its limits, in the same manner that the state holds title to soils under tide water, by the common law, we have already shown;. . . . It is a title held in trust for the people of the state.”); *but see* *Phillips Petroleum Co. v. Mississippi*, 484 U.S. 469, 476-80 (1988) (public trust doctrine extends to non-navigable tidal waters as well as to navigable waters).

<sup>644</sup> *See* Richard J. Lazarus, *Changing Conceptions of Property and Sovereignty in Natural Resources: Questioning the Public Trust Doctrine*, 71 IOWA L. REV. 631, 649-50 (1986) (“the trust doctrine has steadily emerged from the watery depths to embrace the dry sand area of a beach, rural parklands, a historic battlefield, wildlife, archeological remains, and even a downtown area.”) (citing cases); *see also* Ryan, *supra* note 638, at 697-99.

<sup>645</sup> Perhaps the closest analogy is the electromagnetic spectrum of broadcast frequencies, which has been characterized by Congress as a “public trust” obligating broadcast licensees to operate in the public interest. *See* *Red Lion Broad. Co. v. Federal Communications Comm’n*, 395 U.S. 367, 383 (1969)

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that the language used by the U.S. Supreme Court in *Illinois Central* is illustrative rather than exclusive;<sup>646</sup> but this fact, by itself, says little about where the line should be drawn. Second, while the Public Trust Doctrine has historically been applied to the states, it is unclear whether it also applies to the federal government.<sup>647</sup> Third, while the legal basis of the Public Trust Doctrine is somewhat unclear, plaintiffs argued that it is an interpretation of the Due Process Clause of the Fifth Amendment.<sup>648</sup> Arguably, both the Fifth and Fourteenth Amendments apply to takings of public property for private purposes, as well as takings of private property for public purposes.<sup>649</sup> But to the extent that the Public Trust Doctrine is based on the Due Process Clause, it runs into the Supreme Court's summary affirmance in *Radio Position Finding Corp. v. Bendix Corp.*<sup>650</sup> The three-judge district court in that case specifically held that the public did *not* acquire a vested right in an invention in the public domain that was protected by the Fifth Amendment;<sup>651</sup> and the question was specifically presented to and rejected by the U.S. Supreme Court on appeal (albeit in a summary disposition).<sup>652</sup> However, while this summary affirmance may

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(quoting S. REP. NO. 86-562, at 8-9 (1959)), *reprinted at* 1959 U.S.C.C.A.N. 2571.

<sup>646</sup> 146 U.S. at 453 (“property in which the whole people are interested, *like* navigable waters and soils under them”) (emphasis added); *id.* at 454 (“trusts connected with public property, or property of a special character, *like* lands under navigable waters”) (emphasis added).

<sup>647</sup> *Compare* United States v. 1.58 Acres of Land, 523 F. Supp. 120 (D. Mass. 1981) (public trust doctrine applies to the federal government); *In re Steuart Transportation Co.*, 495 F. Supp. 38, 40 (E.D. Va. 1980) (same) *with* District of Columbia v. Air Florida, Inc., 750 F.2d 1077, 1083 (D.C. Cir. 1984) (declining to address the issue).

<sup>648</sup> Plaintiff's Memorandum, *supra* note 631, at 59-60 (citing Richard A. Epstein, *The Public Trust Doctrine*, 7 CATO J. 411, 426-27 (1987)); *see* U.S. CONST. amend. V.

<sup>649</sup> Epstein, *supra* note 648, at 426 (“The public trust doctrine is the mirror image of the eminent domain clause. Both are designed to place limitations upon the power of legislature to divert property, whether held privately or in common. . . . In principle the public trust doctrine should operate at the constitutional level, as a parallel to the eminent domain clause.”). Of course, the Fifth Amendment contains an express “takings” or eminent domain clause, whereas the Fourteenth Amendment does not; but the U.S. Supreme Court has held that the Due Process Clause of the Fourteenth Amendment includes protection against takings of private property. *See* Chicago, Burlington & Quincy R.R. Co. v. Chicago, 166 U.S. 226, 236 (1897).

<sup>650</sup> 205 F. Supp. 850 (D. Md. 1962), *aff'd mem.*, 371 U.S. 577 (1963).

<sup>651</sup> *See* notes 353-361 and accompanying text.

<sup>652</sup> *See* Jurisdictional Statement at 5, *Bendix Corp. v. Radio Position Finding Corp.*, 371 U.S. 57 (1963) (No. 645) (Question Presented No. 11: “Does the expiration of the limitation period contained in 35 U.S.C. § 102 . . . create a

be binding on lower courts,<sup>653</sup> it would not be an obstacle to the U.S. Supreme Court's reconsideration of the issue, which was never fully argued.<sup>654</sup> While none of these three problems is insurmountable, it would take a court of extraordinary courage and vision to bridge all three gaps in a single bound. It is therefore unsurprising that the district court summarily rejected this argument, holding simply that "the public trust doctrine applies to navigable waterways, not copyrights."<sup>655</sup> The plaintiffs chose not to appeal this portion of the ruling.<sup>656</sup>

### B. Court of Appeals Opinion

On appeal, the D.C. Circuit held 2-1 that neither the First Amendment nor the Copyright Clause "constrains the Congress from extending for a period of years the duration of copyrights."<sup>657</sup> First, it held that under the Supreme Court's opinion in *Harper & Row*<sup>658</sup> and the D.C. Circuit's own opinion in *United Video, Inc. v. Federal Communications Commission*,<sup>659</sup> "copyrights are categorically immune from challenges under the First Amendment."<sup>660</sup> Next, the court rejected the new argument that the "originality" requirement of the Copyright Clause<sup>661</sup> prohibited retroactive term extension, distinguishing "between a new grant of copyright — as to which originality is an issue — and the extension of an existing grant."<sup>662</sup> With respect to the latter, the court stated succinctly: "[a] work with a subsisting copyright has already satisfied the requirement of originality and need not do so anew for its copyright to persist."<sup>663</sup> In so hold-

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substantive right in the public such that the statutory limitation period cannot be waived without violation of Fifth Amendment Due Process?"); see also *id.* at 4-5 (Questions Presented Nos. 9-10, based on "the Fifth Amendment requirements of substantive and procedural due process").

<sup>653</sup> See notes 548-563 and accompanying text.

<sup>654</sup> See STERN, GRESSMAN, ET AL., *supra* note 550, at § 4.28.

<sup>655</sup> 74 F. Supp. 2d at 4.

<sup>656</sup> Appellant's Opening Brief, *Eldred v. Reno*, 239 F.3d 372 (D.C. Cir. 2001) (No. 99-5430), available at <http://eon.law.harvard.edu/openlaw/eldredvreno/appealbrief.html> (last visited Oct. 31, 2001).

<sup>657</sup> 239 F.3d at 373. On appeal, plaintiffs abandoned their argument based on the Public Trust Doctrine, while adding an argument that copyright term extension violated the originality requirement of the Copyright Clause as well as the "limited Times" provision and the First Amendment. Appellant's Opening Brief, *Eldred v. Reno*, 239 F.3d 372 (D.C. Cir. 2001) (No. 99-5430), available at <http://eon.law.harvard.edu/openlaw/eldredvreno/appealbrief.html> (last visited Oct. 31, 2001).

<sup>658</sup> See notes 632-633 and accompanying text.

<sup>659</sup> 890 F.2d 1173 (1989).

<sup>660</sup> *Eldred v. Reno*, 239 F.3d at 375.

<sup>661</sup> See *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 345-46 (1991).

<sup>662</sup> 239 F.3d at 377.

<sup>663</sup> *Id.*

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ing, however, the court did recognize that *Graham v. John Deere Co.*<sup>664</sup> “would indeed preclude Congress from authorizing . . . a copyright to a work already in the public domain.”<sup>665</sup> Thus, the court drew a distinction between extensions of copyright prior to their expiration (which it held permissible) and revivals of expired copyrights (which, by negative implication, might be unconstitutional).

Finally, the court addressed the Constitutional requirement that copyrights be issued only “for limited Times.” The Court expressly recognized that a perpetual copyright would violate the “limited Times” provision,<sup>666</sup> but it rejected the argument that the Copyright Clause placed any further restriction on the power of Congress. It noted that in *Schnapper v. Foley*,<sup>667</sup> the D.C. Circuit stated “[w]e cannot accept appellant’s argument that the introductory language of the Copyright Clause constitutes a limit on congressional power,”<sup>668</sup> and it therefore declined to interpret the “limited Times” provision in accordance with the preamble.<sup>669</sup> The problem with this reasoning, as Edward Walterscheid has argued, is that it rewrites the language of the Constitution to read that Congress shall have power “to secure for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>670</sup> That is not what the Clause says; it says that Congress has power “to promote the progress of science and useful arts,” and then it prescribes the means by which that power may be exercised. To interpret the “limited Times” restriction to permit term extensions that do not promote progress would violate the very terms of the constitutional grant.<sup>671</sup>

Unfortunately, this argument (that the “limited Times” provision must be interpreted in the light of the preamble to the Copyright Clause) was sidetracked in the Court of Appeals by a contentious procedural argument, precipitated by an apparent (in hindsight) strategic error. Plaintiffs were aware of the D.C. Circuit’s language in *Schnapper v. Foley*, and they tried to avoid it by claiming in their brief they were not questioning its correctness. As the Court characterized the plaintiff’s argument:

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<sup>664</sup> 383 U.S. 1 (1966). See notes 575-585 and accompanying text.

<sup>665</sup> 239 F.3d at 377.

<sup>666</sup> *Id.*

<sup>667</sup> 667 F.2d 102 (D.C. Cir. 1981).

<sup>668</sup> *Id.* at 112.

<sup>669</sup> 239 F.3d at 378.

<sup>670</sup> Walterscheid, *Term Limits*, *supra* note 25, at 392-93.

<sup>671</sup> See *Eldred v. Ashcroft*, 255 F.3d 849, 855 (D.C. Cir. 2001) (Sentelle, J., joined by Tatel, J., dissenting from denial of rehearing en banc) (“This interpretation of *Schnapper* erases from Article I half of the Copyright Clause — indeed, that half which defines the very power bestowed.”).

The plaintiffs, however, disclaim any purpose to question the holding of *Schnapper*; indeed, they expressly acknowledge “that the preamble of the Copyright Clause is not a substantive limit on Congress’ legislative power.” Their argument is simply that “the Supreme Court has interpreted the terms ‘Authors’ and ‘Writings’ in light of that preamble, and that this court should do the same with ‘limited Times.’”

The problems with this argument are manifest. . . . [O]ne cannot concede that the preamble “is not a substantive limit” and yet maintain that it limits the permissible duration of a copyright more strictly than does the textual requirement that it be for a “limited Time.”<sup>672</sup>

By trying to avoid the language in *Schnapper* rather than challenging it directly, the plaintiffs wrote themselves into a logical corner. This could have been considered harmless error, because an amicus brief submitted by the Eagle Forum Education and Legal Defense Fund expressly argued that this language from *Schnapper* was dictum.<sup>673</sup> But the majority maintained that it should not consider the argument made by the amicus, saying “that argument is rejected by the actual parties to this case and therefore is not properly before us.”<sup>674</sup> Thus, what should have been a debate about the substantive limits imposed by the Copyright Clause turned into an argument about the proper scope and function of an amicus brief and a factual dispute over whether the amicus’ argument had been adopted by the plaintiffs.<sup>675</sup> The majority stated that an amicus brief “cannot exceed the scope of appeal to implicate issues that have not been presented by the parties to the appeal”;<sup>676</sup> while the dissent maintained that there is a “difference between introducing issues not raised by the parties on the one hand and making new arguments for issues otherwise properly raised on the other.”<sup>677</sup> The most persuasive point supporting the dissent’s position is that Circuit Rule 29 specifically states that an amicus brief “must avoid repetition of facts or legal arguments made in the

<sup>672</sup> *Eldred v. Reno*, 239 F.3d at 378.

<sup>673</sup> See Brief of Amicus Curiae Eagle Forum Education and Legal Defense Fund, *Eldred v. Reno*, 239 F.2d 372 (D.C. Cir. 2001) (No. 99-5430) [hereinafter Eagle Forum Brief] at 5-6, available at <http://cyber.law.harvard.edu/eldredvreno/legaldocs.html> (last visited Oct. 31, 2001).

<sup>674</sup> 239 F.3d at 378.

<sup>675</sup> These arguments were amplified on petition for rehearing. See notes 692-707 and accompanying text.

<sup>676</sup> 239 F.3d at 378 (quoting *Resident Council of Allen Parkway Vill. v. United States Dep’t of Housing and Urban Dev.*, 980 F.2d 1043, 1049 (5th Cir. 1993)).

<sup>677</sup> *Id.* at 383 (Sentelle, J., dissenting in part).

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principal . . . brief and focus on points not made or adequately elaborated upon in the principal brief.”<sup>678</sup>

Despite erecting this procedural roadblock, the majority nonetheless proceeded to discuss the argument that it insisted was improperly raised. In doing so, the majority made three major points. First, it asserted that the CTEA was “necessary and proper” to the goal of promoting progress in two ways: it “give[s] copyright holders an incentive to preserve older works, particularly motion pictures in need of restoration,”<sup>679</sup> and it “matches United States copyrights to the terms of copyrights granted by the European Union.”<sup>680</sup> Second, it asserted that by making the Copyright Act of 1790 applicable to existing state copyrights, the First Congress (of which many of the Framers were members) conclusively indicated that it had the power to extend existing copyrights.<sup>681</sup> Third, it relied on *McClurg v. Kingsland* for the proposition that retroactive legislation was within Congress’ power under the Patent and Copyright Clause.<sup>682</sup>

Judge Sentelle dissented in part from the majority opinion, expressing his view that retroactive (but not prospective) term extension violated the Copyright Clause.<sup>683</sup> Citing the approach taken by the Supreme Court in *United States v. Lopez*,<sup>684</sup> he attempted to determine “whether the rationale offered in support of such an extension has any stopping point or whether it would lead to the regulation of all human activity.”<sup>685</sup> He explained:

The majority acknowledges that “[i]f the Congress were to make copyright protection permanent, then it surely would exceed the power conferred upon it by the Copyright Clause.” . . . However, there is no apparent distinction between permanent protection and permanently available authority to extend originally limited protection. The Congress that can extend the protection of an existing work from 100 years to 120 years, can extend that protection from 120 years to 140; and from 140 to 200; and from 200 to 300; and in effect can accomplish precisely what the majority admits it cannot do directly. This, in my view, exceeds the proper understanding of enumerated powers reflected in the Lopez principle of requiring some definable stopping point.<sup>686</sup>

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<sup>678</sup> *Id.*

<sup>679</sup> *Id.* at 379 (citing S. REP. NO. 104-315, at 12 (1996)).

<sup>680</sup> *Id.* (citing EU Council Directive 93/98, art. 7, 1993 O.J. (L 290) 9).

<sup>681</sup> *Id.* at 379.

<sup>682</sup> *Id.* at 380.

<sup>683</sup> *Id.* at 380-84 (Sentelle, J., dissenting in part).

<sup>684</sup> 514 U.S. 549 (1995).

<sup>685</sup> 239 F.3d at 381 (Sentelle, J., dissenting in part).

<sup>686</sup> *Id.* at 381-82.

In response to the majority's three points, Sentelle stated first that "[t]he government has offered no tenable theory as to how retrospective extension can promote the useful arts."<sup>687</sup> Moreover, even if preservation of existing works was a proper goal, "the means employed by Congress here are not the securing of exclusive rights for a limited period, but . . . the extension of exclusivity previously secured",<sup>688</sup> and even if harmonization of terms with Europe was desirable, "[n]either the European Union nor its constituent nation states are bound by the Constitution of the United States."<sup>689</sup> In other words, the fact that Europe has adopted a longer term (and made it retroactive) does not by itself give Congress authority to disregard the limits imposed by the U.S. Constitution. Second, Judge Sentelle distinguished the first Copyright Act, saying:

The enactment by the first Congress in 1790 regularizing the state of copyright law with respect to works protected by state acts preexisting the Constitution appears to me to be sui generis. Necessarily, something had to be done to begin the operation of federal law under the new federal Constitution. The Act . . . created the first (and for many decades only) federal copyright protection; it did not extend subsisting federal copyrights enacted pursuant to the Constitution.<sup>690</sup>

Judge Sentelle did not specifically respond to the majority's reliance on the dictum of *McClurg v. Kingsland*.<sup>691</sup>

### C. *Opinion on Petition for Rehearing*

Stung by the majority's stated refusal to fully consider the argument raised by the amicus, plaintiffs petitioned the D.C. Circuit for rehearing

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<sup>687</sup> *Id.* at 382. In so stating, Judge Sentelle seems to have fallen victim to the common misunderstanding that copyright exists to promote the "useful Arts." As used in the eighteenth century, the phrase "useful Arts" referred to the technological arts promoted by patent law, while the term "science" referred more broadly to the store of knowledge that was promoted by copyright. See Alan L. Durham, "Useful Arts" in the Information Age, 1999 B.Y.U. L. REV. 1419, 1424-25; WALTERSCHEID, *supra* note 190, at 19.

<sup>688</sup> 239 F.3d at 382 (Sentelle, J., dissenting in part).

<sup>689</sup> *Id.* at 384. Moreover, as others have pointed out, the CTEA does not completely harmonize U.S. copyright terms with those in the European Union. For works made for hire and works created before 1978, it increases the U.S. term of protection from seventy-five years to ninety-five years from first publication, far greater than the European term of seventy years for works made for hire.

<sup>690</sup> *Id.*

<sup>691</sup> See notes 622-627 and accompanying text.

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and for rehearing en banc.<sup>692</sup> That action drew an even stronger rebuke from the panel majority:

First, in their brief the plaintiffs-appellants themselves took the position, diametrically opposed to that of the amicus, “that the preamble of the Copyright Clause is not a substantive limit on Congress’ legislative power”; when expressly offered the opportunity at oral argument to adopt the position of the amicus, the plaintiffs-appellants did not do so. . . .

Second, the point advanced by the amicus . . . implicates discrete terms of the Clause that are not otherwise at issue. . . .

Third, because the plaintiffs-appellants did not take the same tack as the amicus, the Government did not on brief address the district court’s interpretation of this court’s decision in *Schnapper*. . . .

Finally, . . . even if we considered the amicus’s position we would not reach a different result in this case.<sup>693</sup>

With these remarks, the panel majority voted to deny the petition for rehearing.<sup>694</sup> A majority of the judges in active service on the D.C. Circuit voted to deny the petition for rehearing en banc.<sup>695</sup>

Judge Sentelle, joined by Judge Tatel, dissented from the denial of en banc rehearing. He maintained that “the decision . . . is worthy of en banc review on both circuit-specific procedural grounds and fundamental constitutional grounds.”<sup>696</sup>

First, procedurally the Court’s opinion in this case effectively eliminates any role for amicus curiae in the practice of this circuit, when it holds that an argument raised by an amicus may not be considered by the court. . . .

Second, and more importantly, the Court’s construction of the Copyright Clause of the Constitution renders Congress’s power under Art. I, § 8, cl. 8, limitless despite express limitations in the terms of that clause.<sup>697</sup>

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<sup>692</sup> See Appellant’s Petition for Rehearing and Suggestion for Rehearing En Banc, *Eldred v. Ashcroft*, 255 F.3d 849 (D.C. Cir. 2001) (No. 99-5430), available at <http://eon.law.harvard.edu/openlaw/eldredvreno/legaldocs.html> (last visited Oct. 31, 2001).

<sup>693</sup> *Eldred v. Ashcroft*, 255 F.3d 849, 850-51 (D.C. Cir. 2001).

<sup>694</sup> *Id.* at 852.

<sup>695</sup> *Id.*

<sup>696</sup> *Id.* (Sentelle, J., joined by Tatel, J., dissenting from denial of rehearing en banc).

<sup>697</sup> *Id.* at 852, 854.

With regard to the first point, the dissenting judges rebutted the majority's contention that the amicus' argument "was effectively renounced by appellants."<sup>698</sup> They pointed out that the amicus brief was submitted two weeks after the appellants' opening brief,<sup>699</sup> and they quoted the relevant passage from the oral argument on which the majority relied:

THE COURT: Have you adopted any point — any arguments that appear in any of these amicus briefs? Or maybe — I don't remember — there is more than one, but in any brief other than your own?

LESSIG: Well, in particular, Mr. Jaffe's brief is a brief that makes textualist arguments that we believe are quite strong in this way.

THE COURT: Is there any place in which you have adopted them, in your briefs?

LESSIG: We formally acknowledge them in our briefs. I don't believe we have, Your Honor, no.<sup>700</sup>

As this transcript demonstrates, at no time did appellants' counsel renounce the arguments made by the amicus. He simply conceded that plaintiffs "did not formally acknowledge them in our briefs," i.e., in writing. Contrary to the majority's characterization, the plaintiffs were never "expressly offered the opportunity at oral argument to adopt the position of the amicus,"<sup>701</sup> much less did they decline to do so. Instead, as the dissenting judges stated, the transcript "illustrates that appellants had not explicitly adopted amicus's arguments in brief but had no problem taking advantage of amicus's argument."<sup>702</sup>

The majority and dissenting judges also engaged in a metaphysical debate about whether the amicus' argument was or was not a distinct argument from the one made by the appellants.<sup>703</sup> Judge Sentelle concluded this portion of the opinion by saying:

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<sup>698</sup> *Id.* at 853.

<sup>699</sup> *Id.*

<sup>700</sup> *Id.* at 853 n.1. The syntax suggests that Mr. Lessig's penultimate sentence was phrased in the form of a question, i.e., "[Did] we formally acknowledge them in our briefs[?]"

<sup>701</sup> *Id.* at 851.

<sup>702</sup> *Id.* at 853.

<sup>703</sup> Compare *id.* at 851 ("the point advanced by the amicus . . . implicates discrete terms of the Clause that are not otherwise at issue.") with *id.* at 854 ("Contrary to the suggestion of the panel majority, appellants' argument did implicate the 'preamble' of the Copyright Clause, just not in the same fashion as the amicus.").

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Under the panel's holding, it is now the law of this circuit that amici are precluded both from raising new issues and from raising new arguments. If allowed to stand, this holding will effectively bar future amici from adding anything except possibly rhetorical flourish to arguments already outlined and embraced by the parties.<sup>704</sup>

In the remainder of the dissenting opinion, the dissenting judges reiterated Judge Sentelle's points that the majority's interpretation placed no substantive limit on Congress' power;<sup>705</sup> and that the government had not met its burden of demonstrating how retroactive term extension advances the constitutional purpose:

I accept that extending copyright terms for future works may well increase creative efforts at the margin. Once a work is published, however, extending the copyright does absolutely nothing to induce further creative activity by the author — and how could it? The work is already published. A simple finding by Congress to the contrary is not sufficient to demonstrate that the exercise of that power is “necessary and proper.”<sup>706</sup>

The majority responded to this point by asserting that “Preserving access to works that would otherwise disappear — not enter the public domain but disappear — ‘promotes Progress’ as surely as does stimulating the creation of new works.”<sup>707</sup>

It is true that Congress expressed some concern about encouraging the preservation of so-called “orphan” films: films that were deteriorating rapidly but which were not being properly preserved, allegedly because it was not economically worthwhile to do so.<sup>708</sup> There are two responses to this concern. First, the CTEA is not narrowly tailored to serve this objective; it extends all existing copyrights, whether or not the work is in any danger of deterioration. It was not economically marginal films which prompted Hollywood to seek term extension, but the highly profitable landmark films of the 1930s and 1940s. Extending copyright terms indiscriminately merely serves to reward those corporate copyright owners who allowed the films to deteriorate in the first place, without requiring any

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<sup>704</sup> *Id.* at 854.

<sup>705</sup> *Id.* (“The majority never explained how a precedent that would permit the perpetuation of protection in increments is somehow more constitutional than one which did it in one fell swoop.”).

<sup>706</sup> *Id.* at 855.

<sup>707</sup> *Id.* at 851-52 (quoting *Eldred v. Reno*, 239 F.3d at 379).

<sup>708</sup> S. REP. NO. 104-315, at 13 (1996).

restoration efforts at all.<sup>709</sup> Second, the primary obstacle to film restoration today is unduly lengthy durations of copyright. Often those who would like to restore films from the 1920s cannot sort out the tangle of eighty-year-old contractual assignments<sup>710</sup> (drafted before the age of television, videotape and DVDs<sup>711</sup>) to clear the rights. If these films were allowed to enter the public domain sooner rather than later, they would not disappear; instead, they could be restored by organizations such as the American Film Heritage Association, one of the plaintiffs.<sup>712</sup> Of course, if it was simply a question of which policy would best serve the public interest, it would be within Congress' purview to make the choice. But the Framers specified the means by which progress was to be advanced: encouraging the creation of new works by granting an exclusive right of limited duration, and placing the work in the public domain for others to use (and to restore) at the end of that limited time.<sup>713</sup> To borrow a phrase from the U.S. Supreme Court, "[t]his result is neither unfair nor unfortunate. It is the means by which copyright advances the progress of science and art."<sup>714</sup>

## V. CONCLUSION

The view of the Patent and Copyright Clause expressed in *Eldred v. Reno*, that Congress may extend a patent or copyright for any finite term it chooses, does violence to the language and purpose of the Clause, as it has been interpreted by the U.S. Supreme Court. The alternative position that

<sup>709</sup> See Heald & Sherry, *supra* note 25, at 1171 ("the legislation is in the form of gift-plus-hope, not quid pro quo.").

<sup>710</sup> It can be difficult, for example, to determine which parties owned the right of renewal and whether that renewal was properly exercised. See, e.g., *Epoch Producing Co. v. Killiam Shows, Inc.*, 522 F.2d 737 (2d Cir. 1975) (resolving copyright dispute concerning D.W. Griffith's *BIRTH OF A NATION* (1915)).

<sup>711</sup> Often a contract containing an assignment of rights is ambiguous as to whether it does or does not cover new technological means of distribution, rendering it difficult to determine from whom the rights need to be acquired. See, e.g., *Boosey & Hawkes Music Publishers, Ltd. v. The Walt Disney Co.*, 145 F.3d 481 (2d Cir. 1998); *Cohen v. Paramount Pictures Corp.*, 845 F.2d 851 (9th Cir. 1988).

<sup>712</sup> Cf. Brief of Amicus Curiae The Internet Archive in Support of Petitioners, at 9-12, *Eldred v. Ashcroft*, *petition for cert. filed*, 70 U.S.L.W. 3292 (U.S. Oct. 11, 2001) (no. 01-618), available at <http://eol.law.harvard.edu/openlaw/eldredvashcroft/cert/archive-amicus.html> (last visited Feb. 3, 2002).

<sup>713</sup> See Heald & Sherry, *supra* note 25, at 1165 ("The Intellectual Property Clause is designed to encourage a dual benefit through the grant of exclusive rights to authors and inventors: a present benefit in the form of public access to a new work . . . , and a future benefit of free access to the work when it falls into the public domain.").

<sup>714</sup> *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 350 (1991).

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retroactive term extension is absolutely forbidden by the Patent and Copyright Clause has an appealing simplicity; but it is difficult to maintain in light of the long history of patent term extensions which were upheld in the mid-nineteenth century. A closer examination of those extensions, however, suggests an intermediate position: that Congress may extend patent and copyright terms in limited circumstances, in order to vindicate the expectation interest of authors and inventors who, for reasons beyond their control, did not receive the term of years promised to them at the time the copyright or patent was granted. That position, however, does not support the indiscriminate twenty-year term extension provided by the Sonny Bono Copyright Term Extension Act.

In rejecting a constitutional challenge to the CTEA, the D.C. Circuit not only misinterpreted the Patent and Copyright Clause, but it cast a cloud of confusion over the role of an *amicus curiae* in constitutional litigation, and it unfairly criticized plaintiffs' appellate counsel for allegedly renouncing an argument made by an *amicus* and relied upon by the dissenting judge. It is difficult to understand why the majority chose to rely on this dubious procedural irregularity. Indeed, in granting certiorari, the U.S. Supreme Court expressly declined to review the procedural aspect of the decision below.<sup>715</sup> In deciding the case on its merits, the Court should look beyond the broad dicta of the patent term extension cases discussed above, and should instead interpret the "limited Times" limitation in a manner that is more consistent with the purposes of the Patent and Copyright Clause.

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<sup>715</sup> *Eldred v. Ashcroft*, petition for cert. granted, 70 U.S.L.W. 3324 (Feb. 19, 2002), order amended, 70 U.S.L.W. \_\_\_, 2002 WL 257111 (Feb. 25, 2002) (limiting grant of certiorari to Questions 1 and 2 (no. 01-618)).



-----Original Message-----

From: "Kingwell, Brian" <bgkingwell@smart-biggar.ca>

To: THOMAS KOWALSKI <T\_KOWALSKI@vedderprice.com>

Sent: 10/23/2011 8:25:17 PM

Subject: RE: Personal favor

Hi Tom,

Good luck with the session, and living with the legislative changes. Here is some information on prior user rights in Canada:

Section 56 of our Patent Act provides that any person who has acquired the invention prior to the relevant date<sup>1</sup> has the right to use and sell the invention without being accountable to the patentee. The Federal Court has held that where the claim of the patent is to a product, s. 56 would encompass products that were manufactured outside of Canada prior to the relevant date but were not brought into Canada until subsequent to the relevant date, so long as the products were in existence prior to the relevant date and the purchaser in Canada was irrevocably bound to purchase the products prior to the relevant date.<sup>2</sup> In addition, in the case of pharmaceutical products, the Federal Court has recently held that for a defendant to take advantage of the exemption provided by s. 56, bulk material acquired prior to the relevant date must be in a usable form as of that date such as to be formulated into tableted drugs.<sup>3</sup>

Where a patent includes both apparatus and method claims, a person who has purchased, constructed or acquired the patented apparatus before the relevant date may continue to use the apparatus to practice the patented process following the grant of the patent.<sup>4</sup> However, it is uncertain at present whether s. 56 of the Patent Act would apply to a patented method or process per se used prior to the relevant date.

<sup>1</sup> The relevant date depends on the date the application for the patent was filed. If the application was filed before October 1, 1989, the relevant date is the date the patent was granted. If the application was filed after October 1, 1989 but before January 1, 1994, the relevant date is the date the application was laid open for publication. If the application was filed after January 1, 1994, the relevant date is the earlier of the Canadian filing date or the convention priority date (the "claim date").

2 Lido Industrial Products Ltd. v. Teledyne Industries Inc. (1981), 57 C.P.R. (2d) 29 at 54 (F.C.A.), leave to appeal to S.C.C. refused (1981), 50 C.P.R. (2d) 183 (S.C.C.).

3 Merck & Co. Inc. v. Apotex Inc., 2006 FC 524 at paras. 136-137, rev'd in part 2006 FCA 323

4 Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada, [1970] S.C.R. 833 at 835-842.

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-----Original Message-----

From: "ALP\_ME" <alp\_me@shigapatent.com>

To: THOMAS KOWALSKI <T\_KOWALSKI@vedderprice.com>

Cc: <takei.norihide@shigapatent.com>

Sent: 10/24/2011 7:17:55 PM

Subject: RE: Personal favor

Dear Mr. Kowalski:

Thank you for your e-mail of October 22, 2011, concerning Prior User Rights in Japan and more generally Asia.

We found that AIPPI (International Association for the Protection of Intellectual Property) Japan provided a research report concerning Prior User Rights in various countries including Japan, Taiwan, China, and Korea on March, 2011.

However, unfortunately, since this report is written in only Japanese and may not reflect the latest situation of each country, regarding Prior User Rights in Asian countries other than Japan, please directly contact attorneys in the countries in question. This report can be obtained from the following URL ([http://www.aippi.or.jp/report/h22\\_report\\_01.pdf](http://www.aippi.or.jp/report/h22_report_01.pdf)).

Prior User Rights in Japan is recognized under Japanese Patent Law, Article 79 (a free and non-exclusive license by virtue of a prior use). The doctrinal basis for such a right is derived from industrial policy, i.e., from an economical standpoint and partially from the viewpoint of fairness of a prior user. The basic rule governing industrial property law in Japan is the "first-to-file" system and, as an exception, a prior user's right is admitted only when the prior user has used the patented invention in question for commercial purposes or has made serious preparations for such use prior to the filing date (or priority date) of the patentee's patent application. Of course, the effects of the patent right do not extend to the private use and the use only for experimentation or research as stipulated in Japanese Patent Law, Article 69, Paragraph 1. . In addition, the effects of the patent right do not extend to products existing in Japan prior to

the filing date (or priority date) of the patentee's patent application as stipulated in Japanese Patent Law, Article 69, Paragraph 2, Number 2.

Article 79: A person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared.

Article 69: (1) A patent right shall not be effective against the working of the patented invention for experimental or research purposes. (2) A patent right shall not be effective against the following products: (i) vessels or aircrafts merely passing through Japan, or machines, apparatus, equipment or other products used therefor; and (ii) products existing in Japan prior to the filing of the patent application. (3) A patent right for the invention of a medicine (refers to a product used for the diagnosis, therapy, treatment or prevention of human diseases, hereinafter the same shall apply in this paragraph) to be manufactured by mixing two or more medicines or for the invention of a process to manufacture a medicine by mixing two or more medicines shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

Specifically, Article 79 stipulates that if a third party who has been using or preparing to use the invention for business purposes in Japan independently from the patentee in question (Herein, "independently" means that the third party made the invention independently from the patentee without knowing the invention made by the patentee) before the filing date or, if any is applicable, the priority date of the patentee's patent application, the third party can obtain a free and non-exclusive license within the scope of the invention which the third party was already using or preparing to use before the filing date or, if any is applicable, the priority date.

(i) Herein, "preparing for the working" recited in Article 79 is construed to correspond to actual (practical) business embodiments where the third party has not started his business by using the patented invention but has an intention to immediately use the patented invention and this intention can be objectively recognized and represented (e.g., the production of a prototype of the patented products, the construction of a factory for producing the patented products, and the like).

(ii) Herein, "extent of the invention of such business worked or prepared" is construed to include not only actual business embodiments where the third party has been using or preparing to use the patented invention in Japan at the time of the filing date (or the priority date) of the patentee's patent application, but also embodiments which are modified within the extent of the technical idea (or the invention) expressed from the actual business embodiments without losing identity to the expressed technical idea.

For example, when a third party has been producing a stainless-steel perforated knife for cooking before the filing date of the patentee's patent application and if the essential part of the patented invention is to create holes along the side of the knife to avoid vegetables sticking thereto and if the change of the materials of the knife from "stainless-steel" to "ceramic" is an unimportant and non-essential part of the patented invention, such change may be included in the "extent of the invention of such business worked or prepared".

The above two points (i) and (ii) are based on a well-known Japanese supreme court decision. Whether a third party can obtain the right of a prior use against the patented invention is a tricky issue and should be considered on a case-by-case basis.

For more information, we found that AIPPI provided a research report which can be seen at the following URL ([https://www.aippi.org/download/yearbooks/Annuaire%201988\\_V.pdf](https://www.aippi.org/download/yearbooks/Annuaire%201988_V.pdf)), and pages 158 to 161 thereof would be greatly useful to further understand Prior User Rights in Japan.

If you have any additional questions or requests, please feel free to contact us.

Very truly yours,

Norihide TAKEI

Patent Attorney

NT

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-----Original Message-----

From: Trevor Cook <Trevor.Cook@twobirds.com>

To: THOMAS KOWALSKI <T\_KOWALSKI@vedderprice.com>

Sent: 10/24/2011 1:22:00 AM

Subject: RE: Personal favor

Dear Tom

Most if not all European jurisdictions have a prior user defence. That in the UK provides:

Right to continue use begun before priority date

64.-(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention -

- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or

- (b) makes in good faith effective and serious preparations to do such an act,

has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

(2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may -

- (a) authorise the doing of that act by any partners of his for the time being in that business, and

- (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

Discussion in the English case law has focused on two aspects of the section;

1) What constitutes "effective and serious preparations"?

2) What is meant by "that act"? It cannot mean exactly the same act, as that would be too narrow to make the section of any use, but the courts have also held it does not extend as far as anything within the scope of the claim in issue. They have settled on "substantially the same act".

I enclose an extract from a new edition of one of my books commenting on the section (please excuse the formatting as it is cut from the publisher's version of the text) and also the most recent case in which the section has been considered.

Sincerely

Trevor

**From:** Florian Schmidt-Bogatzky <Florian.Schmidt-Bogatzky@twobirds.com>

Monday - October 24,  
2011 6:17 AM

**To:** 'THOMAS KOWALSKI' <tkowalski@vedderprice.com>, Oliver Jan Jüngst<Oliver.Jan.Juengst@twobirds.com>

**Subject:** RE: AW: Personal favor

Dear Tom,

Please find below some remarks regarding the private prior use right in German patent law. Just let me know in case you would like to receive more with respect to certain details or aspects.

The private prior use right is dealt with in section 12 of the German Patent Act. According to this provision the patent does not confer the right to the patentee to prevent a person who, at the time of filing of the application, had already begun to use the invention in Germany, or had made the necessary arrangements for doing so, from continuing such use for the needs of his own business in own or foreign facilities. Such prior use right can only be inherited or transferred together with the business.

As Oliver indicated, there is often a discrepancy or dispute as to whether a prior use right can be successfully asserted against infringement. There is a lot of case law dealing with single questions in certain fact patterns. The following can be said in general:

Time of use:

The use of the invention must have been taking place in Germany at the time the patent application is filed. If priority was claimed in the application, the date thereof is the decisive one.

Possession of the invention:

According to case law the person entitled to a prior use right has to be in possession of the invention in question at the relevant point in time. The use rights should only maintain what is presently owned at the time in question. It is necessary that the person entitled knows that he is using an invention, something new. Attempts to solve a known technical problem are generally not sufficient here and neither is mere knowledge of the invention without actually using it. It should be noted that a possession of the invention can also be demonstrated by arrangements for immediate use. In this case the arrangements have to indicate that the user is seriously intending to work the invention immediately, and it has also to be possible to infer from the arrangements that the party in question is in possession of the invention as a whole.

Good Faith:

The user needs to have gained knowledge of the invention independently or have acquired such knowledge through a third party or direct from a later applicant, so long as that occurred in good faith. Good faith is present if the user knows that his action does not harm the inventor's interests. It is not present if the user unlawfully acquired knowledge of the invention or if he had doubts about the legitimacy of acquiring such knowledge. A prior use right cannot be obtained if the person in question has acted in an unfair or illegal way with respect to the patentee. In

particular, an illegal taking of the used inventive thought from the applicant prevents the prior use right from getting existent. In other words, the ownership of the invention must be required in a fair, legal way.

Range of use:

The user must have used the invention in his own business, in his own interests and for his own needs. That would include the use of the invention by employees or the like. Use on behalf of a third party does generally not suffice. By "use", the law means the acts of use that are described in sections 9 and 10 of the German Patent Act. These are the acts which are normally the exclusive rights of the patentee. According to this, prior use includes producing, offering for sale, marketing, using, importing or possessing of an invention. It should be noted that only a use in Germany itself can lead to a prior use right. The provision is not apply to prior use acts abroad, e.g. in Europe. The use is not necessarily have to be a massive, intensive use. Quantities generally do not play a role here. However, on the other hand, the production of prototypes or the like alone does not lead to a prior use right. But there is also older case law, according to which the production, e.g., drawings as direct material for practicing the invention where perceived as sufficient.

The prior user is only allowed to use the invention in the manner he did before the patent application was filed and is not permitted to change the manner once a patent has been granted. Quantitative adaptations, though, can be made subject to the development of the business in question. Prior use of the invention must correspond to the scope of the patent to the extent that if the party concerned did not have the prior user's right, continuing to use the invention would result in infringement of the patent.

If the prior user deliberately discontinues working the invention, the prior user's right lapses. However, according to case law, it does not harm if the use is only interrupted, e.g., due to business development.

I hope the above is of help. Please let me know if you have any questions.

Best regards  
Florian

>>> "VINATIER-GILCHRIST Jacqueline" <VINATIER-GILCHRIST@plass.com>  
10/24/11 4:00 AM >>>

Dear Tom,

Cyra is out of the office and transferred your question about Prior User Rights in France to me.

In France, this exemption to what would usually qualify as infringement acts is called "prior personal possession" and is defined at Article L613-7 of the French IP Code:

"Any person who, within the territory in which this Book applies, at the filing date or priority date of a patent was, in good faith, in possession of the invention which is the subject matter of the patent shall enjoy a personal right to work that invention despite the existence of the patent.

The right afforded by this Article may only be transferred together with the business, the enterprise or the part of the enterprise to which it belongs."

As you can see, several conditions must be met:

- the person must be "in possession" of the invention;
- prior to the filing date or priority date of the patent ;
- this possession must be on the French territory.

There is still some debate about what is needed to prove this prior possession: is a merely theoretical knowledge enough or does Article L615-7 require that the invention has been reduced to practice (or even that there have been serious and effective preparations to exploit the invention)?

The effects of these provisions are that said person can then personally work the patented invention for his own benefit. This person cannot licence the invention to any third party, and the exemption cannot be transferred to a third party (unless it is transferred together with all the assets of the company to which it is attached).

I hope this answers your questions.

Please do not hesitate to get back to us if we can be of further assistance.

Best regards,

Jacqueline.

Jacqueline VINATIER-GILCHRIST, Ph.D.

Conseil en Propriété Industrielle - French Patent Attorney

Mandataire agréé près l'Office Européen des Brevets - European Patent Attorney

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>>> Tagliafico Giulia <Giulia.Tagliafico@sigma-tau.it> 10/24/11 4:06 AM >>>

Dear Tom,

Sorry for the delay, but during the WE I had some family duties to accomplish.

Prior User Rights in Italy are secured by Art. 68(3) of the Industrial Property Code, which states:

"Chiunque, nel corso dei dodici mesi anteriori alla data di deposito della domanda di brevetto o alla data di priorità, abbia fatto uso nella propria azienda dell'invenzione può continuare a d usarne nei limiti del preuso. Tale facoltà è trasferibile soltanto insieme all'azienda in cui l'invenzione viene utilizzata. La prova del preuso e della sua estensione è a carico del preutente."

"Whoever, during the twelve months preceding the date of filing of the patent application or the priority date, have used in their company the invention may continue to do so within the bounds of such prior use. This capacity may be transferred only with the company in which the invention is used. The burden of proof of prior use and its extent is charged to the prior user."

(non-official English translation)

Other similar dispositions exist in UK for example, but, as far as I know, there is no unanimously recognized analogous principle in the EU.

In the last draft of Unitary European Patent there are some dispositions of this kind, but the text has obviously no legal value yet.

I hope this helps.

Best regards

Giulia

**From:** Jack de Wit <j.de.wit@rijkszwaan.nl> Sunday - October 23, 2011 6:33 AM

**To:** "THOMAS KOWALSKI" <tkowalski@vedderprice.com>

**CC:** <k.van.den.hof@rijkszwaan.nl>, <PvanSomeren@arnold-siedsma.nl>

**Subject:** Re: Urgent personal request

Hi Tom,

You might already have seen these.

[http://www.epo.org/law-practice/legal-texts/html/caselaw/2010/e/clr\\_vi\\_h\\_4\\_3\\_1.htm](http://www.epo.org/law-practice/legal-texts/html/caselaw/2010/e/clr_vi_h_4_3_1.htm)

[http://www.epo.org/law-practice/legal-texts/html/caselaw/2010/e/clr\\_i\\_c\\_2\\_8.htm](http://www.epo.org/law-practice/legal-texts/html/caselaw/2010/e/clr_i_c_2_8.htm)

[http://www.ipmall.org/hosted\\_resources/IDEA/34\\_IDEA/34-2\\_IDEA\\_207\\_Strobel.pdf](http://www.ipmall.org/hosted_resources/IDEA/34_IDEA/34-2_IDEA_207_Strobel.pdf)

Sincerely,

Jack de Wit

Business support Research & Development

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P.O. Box 40 | 2678 ZG | De Lier | The Netherlands

T: +31 (0)174 532 300 | M: +31 (0)6 535 00 103 | F: +31 (0)174 515 334 | E:  
j.de.wit@rijkszwaan.nl

W: <http://www.rijkszwaan.com>

Chamber of Commerce Haaglanden: 27214459 0000

**From:** Petri van Someren <PvanSomeren@arnold-siedsma.nl>

Sunday - October 23,  
2011 3:27 AM

**To:** THOMAS KOWALSKI <tkowalski@vedderprice.com>, Kevin van den Hof  
<k.van.den.hof@rijkszwaan.nl>

**Subject:** Re: Urgent personal request

Dear Tom,

Prior use is found in Article 55 of our Netherlands Patent Act, which reads as follows:

1. Any person who, in the Netherlands, Curacao or Sint Maarten, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter of a patent application filed by another on the filing date thereof or, if the applicant has a right of priority under Article 9(1) or Article 87 of the European Patent Convention, on the filing date of the priority application, shall, notwithstanding the patent, continue to have the right to perform the acts referred to in Article 53(1), this right being based on prior use, unless his knowledge was obtained from matter already made or applied by the applicant or from the applicant's descriptions, drawings or models.

2. Paragraph (1) shall apply mutatis mutandis to that part of the continental shelf contiguous to the Netherlands, Curacao or Sint Maarten, in which the Kingdom has sovereign rights, but exclusively to the extent that such acts are associated with and performed during the exploration for or recovery of natural resources.

3. Anyone who, in good faith, has already manufactured or applied or commenced implementation of his intention to manufacture or apply, in or for his business, the subject matter of a European patent granted to another before the date on which a corrected translation was filed under Article 52(7) was registered in the patent register, will be authorized to perform such acts as meant in Article 53(1) as far as these acts do not infringe upon the exclusive right of the patent holder, which right in this case is determined by the content of the claims and the description and drawings intended for the interpretation thereof in the previous incorrect translation into Dutch.

4. The right referred to in paragraph (1) may only be assigned to other persons with said business.

Please note that the article was changed somewhat as compared to what you can find for example on <http://www.ivir.nl/legislation/nl/patentact1995.html>. This has to do with a change in status of the Antilles. I have tried to provide a translation of the changes.

This is all I can provide for now. May be Kevin has something more to offer in English.

Regards,

Petri

Verstuurd vanaf mijn iPad

>>> "Anna Grzelak" <[grzelak@wtspatent.pl](mailto:grzelak@wtspatent.pl)> 10/23/11 11:37 AM >>>

Dear Tom,

Please find some information of Prior User Rights in Poland. I do not know the rules relating to Prior User Rights In all countries in Europe (most likely this subject is differently regulated in UE countries) but I will look into the EPC if there are some "answers" for patents granted by EPO and come back to you later.

If you would like to call me today I am available on my mobile or on skype [anna.grzelak.wts](mailto:anna.grzelak.wts). Please do not hesitate to ask.

Sincerely,

Anna

>>> "Anna Grzelak" <[grzelak@wtspatent.pl](mailto:grzelak@wtspatent.pl)> 10/23/11 12:20 PM >>>

Dear Tom,

In my opinion (but I am not expert in this field ;) ) EPC do not has special regulations concerning "Prior Use Rights" and national Law in each contracting states decides in such situations. The base for my opinion is in Art 3 EPC- European patent has the same effect as national patent.

Please find attached the scan of very good text book on EPC by Derk Visser concerning his comments on Art 3 EPC in which he states situations the EPC overrules national laws.

I hope this is somehow helpful.

Regards,

Anna

## **Prior User Rights in Poland**

The INDUSTRIAL PROPERTY LAW\* (Polish Patent Law –“Prawo własności przemysłowej” further cited as PWP) provides under special circumstances so called “Prior User Rights”(Art. 71) as well as “Afterwards User Rights”(I am not sure if this is good translation of the term?)(Art. 75):

### **“Prior User Rights” for patents**

#### ***Article 71***

*1. Any person who, on the date according to which the priority for the grant of a patent is determined, has exploited the invention on the territory of the Republic of Poland in good faith, may continue to exploit it in his enterprise free of payment to the extent to which he had previously exploited the invention. This right shall also belong to a person who at the same date had already made substantial preparations for the exploitation of the invention.*

*2. The rights referred to in paragraph (1) shall, at the request of the person concerned, be recorded in the Patent Register. The rights may be transferred to another party only together with the enterprise.*

The PWP provides the possibility to use the invention by the person/enterprise who is not entitled to the patent under some circumstances:

- good faith,
- the invention has been exploited on the territory of the Republic of Poland at the time of priority is determined,
- the invention can be further exploit but only to the extent to which it had previously exploited ( this is a kind of statutory license), any extension of the needs agreement of the owner of the patent (e.g. no further licensing possible by the “Prior User Rights”);
- this right can be registered in the patent office register on the request of the person concerned – which usually is the “Prior User Rights” owner
- this right may be transferred to another party only together with the enterprise (by the enterprise it should be understood in the meaning of material objects)
- 

According to the Art 284 PWP the “Prior Use Rights” are settled in the civil law procedure:

#### **Article 284**

The following cases, in particular, shall be decided in civil law procedure in accordance with the general principles of law:

(vii) for ascertainment of the right to exploit an invention, a utility model or an industrial design in the cases referred to in Articles 71 and 75,

---

### **“Prior User Rights” for utility models**

The same rules applies to utility models based on Art 100 PWP

#### ***Article 100***

---

1. Subject to paragraph (2), the provisions of Articles: 25, 28, 29, 35-37, 39-52, 55-60, 62, 66-90 and 92 shall apply accordingly to utility models and rights of protection for utility models.

2. In the case of a utility model, the period provided for in Article 60 shall be 10 years.

---

### **“Prior User Rights” for industrial designs**

The same rules applies to industrial designs based on Art 118 PWP

#### ***Article 118***

1. Subject to paragraph (2), the provisions of Articles: 35-37, 39, 41, 42, 46, 49, 50, 55, 66(2), 67, 70-81, 90 and 92 shall apply accordingly to industrial designs and to rights in industrial design registration.

---

**“Afterwards User Rights”** – applies for patents Art 75, (utility models-Art 100, and industrial designs Art. 118)

#### ***Article 75***

1. A person who, acting in good faith, was granted or acquired the patent subsequently transferred to the entitled person under Article 74, or, being in good faith, acquired a license and has exploited the invention for at least one year before a proceeding for the transfer of the patent has been instituted, or within that period has made substantial preparations necessary for exploiting the invention, may, subject to payment in favour of the entitled person of compensation at the amount as determined, continue to exploit that invention in his enterprise to the extent to which he had exploited it at the date of institution that proceeding.

2. The right to exploit the invention, referred to in paragraph (1) shall, at the request of the person concerned, be recorded in the Patent Register. The right may be transferred to another party only together with the enterprise.

#### ***Article 74***

Where a patent application has been filed or a patent obtained by a person not entitled thereto, the entitled person may demand that the patent granting proceeding be discontinued or the patent granted be revoked. He may also demand that a patent be granted in his favour or that the patent already granted be transferred to him against reimbursement of the incurred costs of filing of the application or of granting the patent.

## **SUMMARY**

### **Prior Use in Australia**

Sect. 119 of the Australian Patents Act 1990 (Cth) (the “Patents Act”) provides a ‘prior use’ defence to patent infringement which allows a third party who was utilizing the patented product or process before the priority date of a claim to continue using the patented product without infringement. This may occur in situations where the third party had obtained the subject matter of the invention from information that became publicly available with the patent owner’s consent in prescribed circumstances. Such circumstances include, for example, disclosure to a recognised learned society or at a recognised international exhibition.

The prior use defence is limited to prior use of the invention (or definite steps in preparation to use it) in Australia, which it makes clear that the defence is not available to parties that can only show prior use of the invention overseas.

The Patents Act includes a broad definition of the term ‘exploit’ and uses this to define the conduct in respect of which the defence may be applied. The Patents Act also grants prior users the right to dispose (in whole but not in part) of their entitlement to exploit claimed inventions without infringing. This recognises the fact that parties who develop technology will not necessarily commercialise the technology themselves, but may choose to assign rights to technologies to another party.

## PATENTS ACT 1990 - SECT 119

### Infringement exemptions: prior use

(1) A person may, without infringing a [patent](#), do an act that [exploits](#) a product, method or process and would infringe the [patent](#) apart from this subsection, if immediately before the priority date of the relevant claim the person:

- (a) was [exploiting](#) the product, method or process in the [patent](#) area; or
- (b) had taken definite steps (contractually or otherwise) to [exploit](#) the product, method or process in the [patent](#) area.

Note 1: This section applies in relation to a [patent](#) granted as a result of an application filed on or after the commencement of Schedule 6 to the [Intellectual Property Laws Amendment Act 2006](#) (which repealed and substituted this section).

Note 2: [Section 119](#) of this Act as in force before the commencement of that Schedule continues to apply in relation to [patents](#) granted as a result of earlier applications.

(2) Subsection (1) does not apply if, before the priority date, the person:

- (a) had stopped (except temporarily) [exploiting](#) the product, method or process in the [patent](#) area; or
- (b) had abandoned (except temporarily) the steps to [exploit](#) the product, method or process in the [patent](#) area.

Limit for product, method or process derived from [patentee](#)

(3) Subsection (1) does not apply to a product, method or process the person derived from the [patentee](#) or the [patentee's](#) predecessor in title in the [patented](#) invention unless the person derived the product, method or process from information that was made publicly available:

- (a) by or with the consent of the [patentee](#) or the [patentee's](#) predecessor in title; and
- (b) through any publication or use of the invention in the prescribed circumstances mentioned in paragraph 24(1)(a).

Exemption for successors in title

(4) A person (the *disposer*) may dispose of the whole of the disposer's entitlement under subsection (1) to do an act without infringing a [patent](#) to another person (the *recipient*). If the disposer does so, this section applies in relation to the recipient as if the references in subsections (1), (2) and (3) to the person were references to:

- (a) the disposer; or
- (b) if the disposer's entitlement arose because of one or more previous applications of this subsection--the first person:

(i) who was entitled under subsection (1) (applying of its own force) to do an act without infringing the [patent](#); and

(ii) to whom the disposer's entitlement is directly or indirectly attributable.

#### Definition

(5) In this section:

**"exploit"** includes:

(a) in relation to a product:

(i) make, hire, sell or otherwise dispose of the product; and

(ii) offer to make, hire, sell or otherwise dispose of the product; and

(iii) use or import the product; and

(iv) keep the product for the purpose of doing an act described in subparagraph (i), (ii) or (iii); and

(b) in relation to a method or process:

(i) use the method or process; and

(ii) do an act described in subparagraph (a)(i), (ii), (iii) or (iv) with a product resulting from the use of the method or process.

## **Explanatory memorandum which explains why the certain changes were made to Section 119 in 2006:**

### PROBLEM OR ISSUE IDENTIFICATION

A patent is granted to the first person to apply to protect an invention. An invention is patentable if it is new and inventive. In order to determine whether an invention is new, it is compared with information publicly available anywhere in the world. Once a patent has been granted the patent owner (patentee) has the right to prevent others from using the invention while the patent is in force. A person who uses a patented invention without the permission of the patentee is said to 'infringe' the patent and can be sued by the patentee. Section 119 of the Patents Act provides a defence to an infringement action where a third party had been secretly using the invention before the patentee applied for the patent. If the use was not public then it cannot be used to show that the invention was not new and thereby invalidate the patent.

It has long been accepted that a patent should not deprive a party from continuing to do what they were doing before the patent was granted. On the other hand an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge. Section 119 attempts to provide a balance between the rights of the patentee and those of the third party. It is intended to safeguard the rights of third parties who have independently used an invention before the priority date (the date from which an invention is regarded as being new) of an application for a patent.

The issue is particularly important to research-based organisations, especially where the technology is complex and involves substantial investment and long lead times to develop an invention so that it is commercially viable. In such circumstances it is likely that the organisation would keep their research secret and not apply for patent protection for a new product or process initially because they would waste a large proportion of the patent term before they had put their product on the market. Without the benefit of section 119, the grant of a patent to another for that product or process would prevent the organisation from continuing with the development of the product or process and recouping the costs of the R&D.

Another important issue is where a company makes many inventions in the course of its research. Most companies employ a selective patenting strategy where they will apply for patents only in respect of certain inventions. The choice will be based on a number of factors including cost and the competitive nature of the industry. A company is more likely to seek patent protection for inventions which can be copied easily to prevent their competitors from free-riding on the developments. However it is important for the company to be able to use and commercialise those inventions for which it does not have patents as they may have devoted considerable resources to their development. Section 119 permits companies to do this and hence this enhances competition where the products are subsequently available to consumers.

Concerns have been raised that the section does not provide the protection intended and this can inhibit competition. In particular it is not clear whether the prior use must be in Australia or whether it can be use anywhere in the world. If the use is not restricted to use in Australia, then the benefits of section 119 would extend to a person or company making or using an invention overseas. This would mean that competing R&D performed overseas could detrimentally affect subsequent R&D performed in Australia. The restriction of the use

to Australia will protect Australian firms from possible claims of use in obscure jurisdictions overseas and consequential litigation.

Also it is not clear whether the provision is limited to commercial use, in which case a person who has developed a product or process but who has not taken definite steps to commercialise it will not be protected. This would be very serious for the majority of Australian companies that carry out research. If a company makes a development and does not apply for a patent, does not publish the development or does not use it commercially before a third party, generally an overseas company, applies for a patent in Australia, the company will not be able to continue with the development without the benefit of section 119. This would lessen competition in the market provided by such R&D companies.

A further concern is whether the right should be limited to the actual prior user or whether it can be assigned or licensed. The actual prior user is the person or business regarded as the inventor of the invention. An invention made during the course of a person's employment will belong, in the majority of cases, to the employer. If the rights given by section 119 are not capable of assignment otherwise than in conjunction with the business concerned, they are of little value, especially to a university or research organisation whose only opportunity to exploit its work is by licensing or assignment. It is very common in Australia for the commercial exploitation of the products of R&D work to be carried out by a different party from that which conducted the R&D.

Also section 119 limits the use to making a product or using a process and it is not clear whether this extends to other aspects such as selling the product. The right would be of little value if the end product could not be sold and thereby provide a return on the investment in the R&D used to create it.

#### **OBJECTIVE**

To clarify the scope of the rights provided under section 119 of the Patents Act to provide the correct balance between the rights of a patentee and those of a third party who has independently used an invention before the priority date of the patent.

#### **IDENTIFICATION OF OPTIONS**

The Government has three options to clarify the scope of section 119 and balance the rights of patentees and third parties. These are:

##### Option 1

Retain section 119 in its current form.

##### Option 2

Adopt the recommendation of the IPCR Report that section 119 is amended to make it clear that the prior use is only in the patent area (i.e. Australia), that this use includes experimental use and that the benefit of the right is limited to the actual prior user.

This option serves to clarify the scope of the section without making any material changes. The IPCR Committee was divided as to whether the right should be limited to the actual prior user, with the majority considering that it should be so limited to avoid it becoming a de facto patent right.

##### Option 3

Amend section 119 to make it clear that the prior use is only in the patent area, that the benefit of the right extends to assignees but not to licencees and that the use encompasses acts which would. When a patent right is assigned, the right is transferred completely to a third party and the right owner does not retain any interest in the right. When a patent right

is licensed, the licensee is authorised to use the right according to the terms of the licence. However the patent owner retains the right and may licence it to others on the same or different terms. This means that the benefit of the section would extend to selling the product. (A patent gives the patentee the exclusive right to make, hire, sell, use or import the invention. A person who does any of these acts without the patentee's permission is said to 'infringe' the patent.)

There are 3 key differences between this option and option 2. The first is that the benefit extends to assignees. This is consistent with the minority view of the IPCR Committee who noted that the innovation process often required changing corporate arrangements. The second is that the use does not specifically refer to experimental use. Reference to experimental use could cause confusion because experimental use in terms of the infringement provisions of the Patents Act has generally been taken to refer to experimenting with an invention that has been patented. It does not refer to experiments made in order to develop an invention prior to patenting, which is the context in which the IPCR Committee considered experimental use. The third difference is to extend the nature of the use to acts otherwise constituting infringement. Submissions to the IPCR Committee expressed concern that the section did not extend to selling the product. Since section 119 provides a defence against infringement, it is reasonable to extend the use to all acts that constitute infringement.

#### IMPACT ANALYSIS:

Impact group identification The same groups would be affected by the implementation of any one of the three options. These groups include:

- i. industry and the research sector including both users of the patent system and other producers who are competitors of those users, and IP professionals such as patent attorneys and lawyers ('industry')
- ii. consumers including those who use patented products and processes ('consumers')
- iii. any agency or group involved in the administration of the patent system including IP Australia, other Government agencies and the courts ('government')

The following qualitative analysis considers the impact in terms of costs and benefits for the identified groups for each of the three options.

#### Option 1: Retain the current section 119

##### Costs

##### Industry

- Several submissions to the IPCR Committee indicated that the section does not give the protection intended and this can inhibit competition. For example if the use is not restricted to Australia but can be anywhere in the world, then the benefit will extend to competing R&D performed overseas to the detriment of R&D performed in Australia.
- The benefit of section 119 could also extend to non-secret use overseas since novelty and inventive step considerations in Australia currently only have regard to prior use in Australia. This would mean that overseas applicants for patents in Australia are in an advantageous position compared with local applicants because they do not have to keep their inventions secret. (This will be addressed when the novelty and inventiveness tests are amended as recommended to include prior acts anywhere in the world.)
- Uncertainty as to whether the section includes non-commercial use means that businesses may not be able to use or commercialise their inventions developed in the course of R&D but for which they have not sought patent protection. Businesses therefore may not reap the full benefits from their R&D.

- Uncertainty as to the scope of the section may lead to costly and time-consuming court actions. The uncertainty affects the prior users in terms of what they can continue to do. It also affects patent holders who may commence infringement actions only to find that the 'infringer' can claim the defence against infringement under section 119.

#### Consumers

- If non-commercial use is excluded this will lessen competition in the market that would have

resulted from commercialisation of the R&D, leading to fewer products being available at higher prices.

- The section is limited solely to making a product or using a process and does not seem to include other aspects of exploitation. A business could therefore satisfy the requirements of the section but not be able to sell the product. Again this could result in reduced competition

in the market.

- It is very common for commercial exploitation of the products of R&D work to be carried out by a different party to that which conducted the original R&D. If the benefit under section 119 is limited to the actual prior user, and does not extend to the assignee or successor in title, then it is of no value and many inventions will not be commercialised.

Again this will lessen competition in the market.

#### Government

- Uncertainty as to the scope of the section may lead to costly and time-consuming court actions.

- The option will not meet the Government's objective of increasing the certainty of the patent system. The Government believes that the patents legislation should provide certainty to both users of the patents system, in terms of the extent of the rights they have, and to third parties, who need to know what they can and cannot do in the light of the grant of a patent. Any uncertainty will be detrimental to both users and third parties and could be harmful for competition. Interest groups have identified a number of issues relating to the lack of certainty as to the scope of section 119.

#### Benefits

##### Industry

- Retention of the section gives a prior secret user of an invention some protection to balance the very extensive rights accorded to the patent owner of that invention.

- Section 119 encourages innovation in Australia by affording protection to Australian innovators who may have developed inventions but where they have been prevented from applying for patent protection. For example a business may have made a number of inventions during the course of R&D and, for cost reasons, has had to select only some for patent protection. The business will be able to continue to develop those inventions in the face of later patents, most of which will be granted to overseas firms.

- The two major ways recognised in law whereby an inventor can protect an invention are via patent protection or by maintenance of secrecy. There may be sound commercial reasons why a business chooses secrecy, such as where the invention can be reverse engineered.

Section 119 recognises the rights of businesses in such circumstances and protects them from the threat of infringement actions so that they can continue to exploit their inventions and gain a return from their investment.

- Limiting the prior use to the actual prior user benefits patent holders because the opportunities to commercialise competing inventions will be reduced.

#### Consumers

- If businesses can continue to develop their innovations in the circumstances described above, this will increase competition in the market by providing a greater range of products at lower prices than if section 119 did not exist.

#### Government

- No legislative change will be needed.

#### Option 2: Adopt the recommendation of the IPCR Report

#### Costs

#### Industry

- This option will limit the prior use to the actual user and so will be of no value to many research organisations which are not able to commercialise their own inventions.
- Specific reference to experimental use could create uncertainty as to the ambit of the section because experimental use is not generally regarded as constituting infringement in other circumstances within the provisions of the Patents Act. Experimental use generally refers to use after the grant of a patent rather than before a patent application is made. Businesses therefore may be uncertain as to what further protection the amended section would give them and patent holders will not be sure whether the use will constitute an infringement of their patent.

#### Consumers

- As discussed under option 1, limiting the use to the actual prior user may lessen competition in the market.
- The option does not address the issue of whether the section includes other aspects of exploitation with consequent costs to consumers as for option 1.

#### Government

- Legislative change will be required.

#### Benefits

#### Industry

- The benefits of option 1 also apply to this option.
- Limiting the prior use to use in Australia will ensure that firms operating in the jurisdiction of the Australian patent area will not be disadvantaged by the grant of patents in Australia, the majority of which are granted to overseas applicants. It will protect these firms from possible claims of use in obscure jurisdictions overseas and consequential litigation.
- By including experimental use, businesses in Australia will be able to reap the full benefits from their R&D where they have not commercialised an innovation prior to patent protection being granted.
- The increased certainty that the prior use is limited to use in Australia and that it includes experimental use will encourage further investment in R&D.

#### Consumers

- The benefits will be as for option 1.
- Including experimental use will mean more innovations are developed leading to increased competition and lower prices.

#### Government

- The scope of the section will be clearer which will reduce the likelihood of costly and time-consuming court action. Section 119 was introduced into the Patents Act in 1990 and there has been little reported activity under this section to date. However submissions to the IPCR Review pointed to the lack of clarity of the section.
- The changes will increase the certainty of granted patents which will help to encourage investment and technology transfer.

Option 3: Amend section 119 to limit prior use to the patent area, to extend the right to assignees and to specify that the use encompasses acts constituting infringement.

## Costs

### Industry

- There may be uncertainty as to whether the section includes non-commercial use as discussed under option 1. However the Government response will indicate that the use is not restricted to non-commercial use. It is not necessary to specify the nature of the use in the section because this may place undue limitation on its scope. The Court will determine whether the section applies in any particular case, and it is appropriate for the Court to determine whether, in all the circumstances, a particular use falls within the section. The discussion above indicates the problems that may occur if reference is made to experimental use. Similar problems could occur if other types of use are specifically referred to in the section.

- Extending the benefit to assignees may disadvantage patent holders because this increases the likelihood of competing inventions being commercialised. Further extension to permit selling of the product will increase this competition to the patent holder's invention. However the competition will be from only a single competitor.

### Consumers

- There will be not net costs to consumers.

### Government

- Legislative change will be required.

### Benefits

#### Industry

- The benefits as described under options 1 and 2 also apply to option 3.
- Extending the right to assignees will benefit many research-based organisations that do not commercialise their own inventions. This provides an incentive for further R&D to take place because the organisation can profit from its work and hence this will stimulate innovation.
- Clarification of the section by this option will provide more certainty both for prior users and patent holders in terms of what the section provides as a defence against infringement.

#### Consumers

- The benefits of option 1 also apply to option 3.
- The clarification that the section encompasses acts constituting infringement means that businesses can fully exploit their inventions by selling their products. This will increase competition by increasing the range of products available to consumers and will lower prices.

#### Government

- The benefits of option 2 also apply to option 3.
- Government research organisations will benefit because they will be able to assign their technology.

## CONSULTATIONS

- The terms of reference of the IPCR required the Committee to consult with stakeholders and invite submissions from all interested parties and to hold hearings to afford interested parties the opportunity to make oral submissions.

- The Committee sought comments and written submissions on an Issues Paper released in September 1999 and met with groups and individuals to discuss issues of concern. It produced an Interim Report in April 2000, which presented the Committee's preliminary views on options for achieving the objectives, and sought further written submissions from interested parties. Some parties sought extra time to submit their comments and as a consequence the Committee was allowed additional time to deliver its final report.

- The review process also included public consultations and seminars and a roundtable discussion with experts on patents.

- Following publication of the final report, IP Australia sought comment from various interest groups (including the Institute of Patent and Trade Mark Attorneys of Australia (IPTA), the Advisory Council on Intellectual Property (ACIP), the Australian Federation of Intellectual Property Attorneys (FICPI Australia) and the Law Council) on the recommendations in relation to patents.
- An interdepartmental committee, with representatives from IP Australia, the Department of Industry, Science and Resources, the Attorney-General's Department, the Department of Communications, Information Technology and the Arts, the Department of Treasury, the Department of Foreign Affairs and Trade and the Australian Competition and Consumer Commission, was formed to consider the recommendations and make recommendations to Government.

#### CONCLUSION AND RECOMMENDED OPTION

Section 119 attempts to balance the rights of a patentee with those of a third party who has secretly used an invention before the priority date of the patent. Submissions to the IPCR Committee expressed concerns that the section was not achieving this objective and consequentially has a detrimental effect on competition. The submissions also identified some lack of clarity as to the scope of the section. Options 2 and 3, which suggest amendments to section 119, will both assist in achieving these outcomes. At the same time neither of these options limit the patentee's rights to gain patent protection and exploit their invention.

Adoption of option 3 is likely to provide the greatest benefit to third parties. Currently the prior user right can only be assigned in conjunction with the business. Option 3 will permit assignment of the right per se thereby enabling Australian research-based organisations to assign their inventions to others to further develop and bring to the market. This will stimulate indigenous innovation as well as benefiting consumers in providing increased choice in the market. Enabling the right to be assigned but not licensed will limit the prior use to a single entity and this provides a balance with the patentee's interests in maintaining an exclusive right in the market for the product. Option 3 also provides certainty that the new products can be sold by clarifying that the prior user right extends to all acts that may constitute infringement, and that it is not limited solely to the making of a product or the using of a process.

Adoption of option 3 will also mean that the prior user right is limited to prior use in Australia. This will help to ensure that Australian firms that have previously developed technology in Australia but have chosen not to publish it or seek patent protection are not disadvantaged by the 90% of Australian patents granted to overseas applicants. Prior use anywhere in the world could lead to an obscure use being cited as a defence to infringement that would lead to costly and time-consuming litigation. Amendment of section 119 to indicate that the prior use includes experimental use may be unnecessarily limiting because the section is not presently limited to commercial use.

In view of this, and also considering the costs and benefits outlined above, it is recommended that the Government endorses option 3 to amend section 119 to make it clear that the prior use is only in the patent area, that the benefit of the right extends to assignees but not to licencees and that the use encompasses acts which would otherwise constitute an infringement of the patent.

#### IMPLEMENTATION AND REVIEW

Amendments will need to be made to the Patents Act to implement option 3. Drafting

instructions have been prepared. An evaluation of the revised requirements of section 119 will be undertaken 5 years after implementation of the legislation to assess how well it has met its objectives.

# Prior User Rights

By CARL SHAPIRO\*

Many inventions are discovered independently, but at roughly the same time, by two or more individuals or organizations. Famous examples include the light bulb, the telephone, and the integrated circuit. Independent invention is common for minor technological improvements. How should property rights to an invention be defined and awarded in such cases?

Patent law has struggled with this question for many years. The basic rule in the United States is that the patent is awarded to the first inventor, but this system can create some peculiar results.

Suppose Firm A invents something and files for a patent. Slightly later, before the invention is made public, Firm B independently invents the same thing. Firm A receives the patent and can prevent Firm B from developing the invention. In legal terms, a party accused of patent infringement cannot defend itself by showing it discovered the same invention independently. Would such an *independent invention defense* be desirable?

Alternatively, suppose that Firm A invents something, but decides *not* to file for a patent, perhaps because Firm A does not believe this invention is sufficiently novel and nonobvious to be patentable. Instead, Firm A uses the invention internally as a trade secret. Later, Firm B invents the same thing and files for a patent. Under U.S. law, Firm B is awarded the patent and usually can prevent Firm A from practicing the invention. In legal terms, Firm A, despite achieving and using the invention before Firm B obtained its patent, has no *prior user rights*. Would granting such rights be desirable?

Since 1999, U.S. law has provided for some prior user rights for patents on business methods, and Congress is considering legislation (H.R. 2795) that would greatly expand prior user rights.

This paper explores the effects of awarding prior user rights. We abstract away from the details of which party discovered the invention before or after another, viewing slight differences in timing as random. With this abstraction, there is no difference between the independent invention defense and prior user rights.

Suppose two firms are conducting research and development (R&D) directed at a given invention. Prior user rights come into play only if *both* firms successfully discover the invention. In that event, without prior user rights, each firm has a 50-percent chance of getting the patent and obtaining a monopoly over the patented invention. Call monopoly profits  $\pi_M$  and welfare under monopoly  $W_M$ . With prior user rights, both firms have the right to use the invention, so duopoly results. Call each firm's duopoly profits  $\pi_D$  and duopoly welfare  $W_D$ . Assume combined duopoly profits are less than monopoly profits,  $2\pi_D < \pi_M$ , and welfare is less under monopoly than duopoly,  $W_M < W_D$ . So, the ex post effects of prior user rights are clear: if both firms discover the invention, prior user rights enhance competition, reduce joint profits, and increase welfare.

What about the ex ante effects of awarding prior user rights? Prior user rights reduce the return to achieving the invention. If the firms' R&D expenditures without prior user rights are socially excessive, awarding those rights has favorable ex ante and ex post effects. Stephen Maurer and Suzanne Scotchmer (2002) make this point in a static model with free entry in which each firm, by paying a fixed amount, can discover the invention with certainty, so all R&D expenditures by multiple firms are duplicative. We show the attractiveness of prior user rights extends well beyond situations in which equilibrium R&D expenditures are excessive.

## I. R&D Expenditure Levels with Independent Projects

Suppose two firms are engaged in R&D competition, each choosing how much to spend on

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R&D. Greater expenditures increase the chance of success, with diminishing returns. The cost of achieving a success probability  $p$  is  $C(p)$  with  $C(0) = 0$ ,  $C'(p) > 0$ , and  $C''(p) > 0$ . Success by one firm is independent of success by the other.

Two patent policy instruments are available: patent lifetime,  $T$ , and the strength of prior user rights. There is no discounting, the invention is useful during  $[0, 1]$ , and the patent remains in force during  $[0, T]$ . After the patent expires, the market is competitive, the firms earn zero profits, and welfare is  $W_C$ . Stronger prior user rights are modeled by an increase in the probability,  $\alpha$ , that prior user rights will be granted if both firms achieve the invention. Stronger prior user rights correspond to policy changes that lower the requirements for such rights to be granted, such as Congress is currently considering. If both firms are successful, each receives a flow payoff of  $\pi_B = \alpha[\pi_D] + (1 - \alpha)[\pi_M/2]$  during  $[0, T]$ , for a payoff of  $\pi_B T$ . Flow welfare is  $W_B = \alpha[W_D] + (1 - \alpha)[W_M]$  during  $[0, T]$  and  $W_C$  during  $[T, 1]$ . If only one firm is successful, that firm's payoff is  $\pi_M T$ , and welfare is  $W_M T + W_C(1 - T)$ .

A single firm whose rival's success rate is  $q$  chooses its own success rate  $p$  to maximize  $\pi(p, q) = p(1 - q)T\pi_M + pqT\pi_B - C(p)$ . The first-order condition for this firm is  $\pi_p(p, q) = T[(1 - q)\pi_M + q\pi_B] - C'(p) = 0$ . In the symmetric equilibrium,  $[C'(p)/T\pi_M] = 1 - p[1 - (\pi_B/\pi_M)]$ . The equilibrium success rate depends on the policy parameters,  $T$  and  $\alpha$ . Welfare is

$$W(p, T, \alpha) = p^2[TW_B + (1 - T)W_C] \\ + 2p(1 - p)[TW_M + (1 - T)W_C] - 2C(p).$$

**THEOREM 1:** *Suppose each firm chooses its R&D investment level, with greater investment increasing the chance of success, and with success at one firm independent of success at the other. Prior user rights are socially optimal if and only if the ratio of deadweight loss to profits is higher under monopoly than under duopoly.*

Prior user rights are an attractive feature of the patent system if duopoly delivers returns to innovators more efficiently, in terms of deadweight loss, than monopoly (see the deadweight loss to profit ratio test in Louis Kaplow, 1984.)

Richard Gilbert and Shapiro (1990) show this condition holds if profits and welfare are concave in output, a very weak condition.

## II. Diversification of Research Approaches

We now use the model from Partha Dasgupta and Eric Maskin (1987) to study how prior user rights affect firms' decisions to allocate fixed research budgets across R&D projects. Each of two firms can adopt an approach that is less correlated with its rival, but doing so reduces its probability of success. Dasgupta and Maskin established conditions under which the market is biased toward overly correlated project choices, but did not study prior user rights.

The first firm selects a project  $x \in [0, 1/2]$  and the second firm selects a project  $y \in [0, 1/2]$ . Higher values correspond to projects that are less likely to succeed: the probability of success for project  $z$  is  $p(z)$ , with  $p(0) > 0$ ,  $p'(z) < 0$ , and  $p''(z) < 0$ . Higher values of  $x$  and  $y$  correspond to research projects that are less correlated; the correlation between the two projects equals  $1 - (x + y)$ . The probability that both firms succeed is  $B(x, y)$  and the probability that only the first firm succeeds is  $A(x, y)$ . Imposing symmetry, the probability that only the second firm succeeds is given by  $A(y, x)$ .

The first firm picks  $x$  to maximize  $\Pi = A(x, y)\pi_M + B(x, y)\pi_B$ , giving the first-order condition  $A_x(x, y)\pi_M + B_x(x, y)\pi_B = 0$ . Since  $A(x, y) + B(x, y) = p(x)$ ,  $A_x(x, y) + B_x(x, y) = p'(x) < 0$ . Substituting into the first-order condition,  $A_x(x, y)\pi_M + [p'(x) - A_x(x, y)]\pi_B = 0$ , or  $A_x(x, y)[\pi_M - \pi_B] + p'(x) = 0$ . Since  $\pi_M > \pi_B$ , if  $x$  is chosen optimally, we must have  $A_x(x, y) > 0$  and  $B_x(x, y) < 0$ . Since  $\partial^2\Pi/\partial x\partial\pi_B = B_x(x, y) < 0$ , prior user rights reduce  $\pi_B$  and cause the first firm to increase  $x$ . Prior user rights reduce the return if both firms are successful and, thus, cause each firm to select a less correlated research approach.

The symmetric equilibrium is characterized by  $A_x(x, x)\pi_M + B_x(x, x)\pi_B = 0$ . Welfare is given by  $W(x, y, \alpha) = W_M(A(x, y) + A(y, x)) + W_B B(x, y)$ . The direct effect of awarding stronger prior user rights is positive, so stronger prior user rights raise welfare if their indirect effects are also favorable for welfare, which will be true if the equilibrium is biased toward overly correlated projects.

**THEOREM 2:** *Suppose that each firm picks from a menu of R&D projects. Projects at one firm that are more likely to succeed are also more highly correlated with the other firm's projects. Strengthening prior user rights raises welfare if  $(\pi_B/\pi_M) > [(W_B - W_M)/W_M]$ .*

Strengthening prior user rights raises social welfare if each firm is biased toward joint versus sole discovery. The firm's trade-off is reflected in the ratio  $\pi_B/\pi_M$ . The social trade-off is reflected in the ratio  $(W_B - W_M)/W_M$ . If  $\pi_B/\pi_M > (W_B - W_M)/W_M$ , the equilibrium is biased toward joint discovery, and prior user rights help correct for this bias. With no prior user rights,  $\alpha = 0$ ,  $\pi_B/\pi_M = 1/2$ , and  $W_B = W_M$ , so the inequality in theorem 2 is satisfied.

**COROLLARY 2A:** *At least some prior user rights are socially optimal.*

Since  $\pi_B$  decreases with  $\alpha$  and  $W_B$  increases with  $\alpha$ , the inequality in theorem 2 will be satisfied for all values of  $\alpha$  if it is satisfied at  $\alpha = 1$ . Therefore, we also have:

**COROLLARY 2B:** *Full prior user rights are socially optimal if  $(\pi_D/\pi_M) > [(W_D - W_M)/W_M]$ .*

Luís Cabral (1994) shows that this condition is satisfied in Cournot duopoly with linear demand and constant marginal costs. With homogeneous products and Bertrand competition, however, we have  $\pi_D = 0$  and  $W_D > W_M$ , so this inequality is not satisfied. If competition is sufficiently severe, each firm will see little value in being one of two inventors, even though there is a social benefit of having a second inventor. Therefore, full prior user rights can cause the market to be biased toward projects that are less likely to succeed, but less correlated. In that case, the indirect effect of stronger prior user rights on welfare is adverse, but full prior user rights may still be optimal due to their favorable direct effect.

**III. Allocation of R&D Budgets across Markets**

We now ask how prior user rights affect firms' decisions to allocate their fixed R&D budgets across markets. Following Cabral

(1994), each of two firms allocates its R&D budget between a smaller market, in which innovation is easier, and a larger market, in which innovation is harder. Success by one firm is independent of success by the other.

A firm that allocates a fraction  $x$  of its R&D budget to the smaller market will achieve the innovation in that market with probability  $p(x)$ , where  $p'(x) > 0$  and  $p''(x) < 0$ . The larger market involves a lower probability of success,  $p(1 - x)/\sigma$ , where  $\sigma > 1$ , but a proportionately larger payoff,  $\sigma\pi_M$  or  $\sigma\pi_B$ .

Suppose that the other firm is expected to allocate a fraction  $y$  of its budget to the smaller market. Therefore, the other firm is expected to succeed in the smaller market with probability  $p(y)$  and in the larger market with probability  $p(1 - y)/\sigma$ . The payoff to the first firm is

$$p(x)p(y)\pi_B + p(x)(1 - p(y))\pi_M + \frac{p(1 - x)}{\sigma} \frac{p(1 - y)}{\sigma} \sigma\pi_B + \frac{p(1 - x)}{\sigma} \frac{1 - p(1 - y)}{\sigma} \sigma\pi_M.$$

Total welfare in the symmetric Nash equilibrium is

$$W(x, \alpha) = p(x)^2W_B + 2p(x)(1 - p(x))W_M + \left(\frac{p(1 - x)}{\sigma}\right)^2 \sigma W_B + 2 \frac{p(1 - x)}{\sigma} \frac{1 - p(1 - x)}{\sigma} \sigma W_M.$$

Stronger prior user rights cause the firms to shift R&D resources into the larger market, where discovery by the rival is less likely, so prior user rights are less likely to come into play. Cabral (1994) proves the market is biased against R&D in the larger market if and only if  $(\pi_B/\pi_M) > [(W_B - W_M)/W_M]$ , so we have:

**THEOREM 3:** *Suppose each firm allocates its R&D budget between a smaller market and a larger market, in which innovation is more difficult. Stronger prior user rights cause the firms to shift their R&D budgets toward the larger market. Some prior user rights are always so-*

cially optimal. Full prior user rights are socially optimal if  $(\pi_D/\pi_M) > [(W_D - W_M)/W_M]$ .

Even if the inequality in Theorem 3 is not satisfied, full prior user rights may be optimal due to their favorable direct effect on welfare.

#### IV. Concluding Remarks

When nearly simultaneous, independent invention occurs, awarding one inventor a patent and the other the right to use the invention has very attractive properties. Competition is enhanced, innovation is rewarded with relatively little deadweight loss, and the private and social incentives to be the sole versus joint inventor are generally better aligned than in the absence of such rights.

The attractiveness of prior user rights is even stronger if we take into account the fact that a single patent lifetime is set for all industries and inventions, despite huge differences across inventions in their expected profit-to-cost ratios. Prior user rights *automatically* reduce the rewards precisely for those inventions with a high profit-to-cost ratio, since these are the inventions most likely to be discovered simultaneously. These are also the inventions that the patent system is most likely to overreward. From a Bayesian perspective, the fact that an invention was discovered independently by two or more parties is evidence that the profit-to-cost ratio for that invention was relatively high, so reducing the reward based on market power is attractive.

The appeal of prior user rights is especially great today, given mounting evidence that the patent system is out of balance, as argued by the Federal Trade Commission (2003), the National Academies of Science (2004), Adam Jaffe and Josh Lerner (2004), Shapiro (2004), and Mark Lemley and Shapiro (2005). Prior user rights can partially correct for problems caused when patents are issued for obvious or nearly obvious inventions, and for inventions that are not truly novel.

The main potential drawback associated with prior user rights is that they may encourage inventors to keep their inventions secret rather than disclosing them in patent applications. Vincenzo Denicolo and Luigi Franzoni (2004) develop a model in which a second party, who duplicates and patents an inven-

tion he knows had previously been discovered but kept secret, should be granted the right to exclude the inventor from using his invention. The effectiveness of patent disclosures is in doubt, however, especially in industries where scientists and engineers are instructed not to read patents for fear of triggering liability for willful infringement. Plus, the current patent system rewards applicants who are most aggressive in seeking patents over those who simply use their own inventions internally as trade secrets. The effects of encouraging inventors to adopt trade secret versus patent protection are not well understood. Further work is needed to compare the benefits of prior user rights, as described here, with any costs that result from inducing some inventors to seek trade secret rather than patent protection.

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# Prior User Rights: Appendix<sup>\*</sup>

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## R&D Expenditure Levels with Independent Projects

Discounting could easily be incorporated into this model by redefining  $T$  to represent the ratio of the value of an annuity that lasts for the lifetime of the patent to the value of a perpetuity.

### A. Proof of Theorem #1

If the patent lifetime  $T$ , is set optimally, given  $\alpha$ , we must have  $\frac{dW}{dT} = \frac{\partial W}{\partial p} \frac{\partial p}{\partial T} + \frac{\partial W}{\partial T} = 0$ , so

$\frac{\partial W}{\partial p} = -\frac{\partial W}{\partial T} / \frac{\partial p}{\partial T}$ . The welfare impact of strengthening prior user rights is given by

$\frac{dW}{d\alpha} = \frac{\partial W}{\partial p} \frac{\partial p}{\partial \alpha} + \frac{\partial W}{\partial \alpha}$ . Substituting for  $\partial W / \partial p$ , we get  $\left. \frac{dW}{d\alpha} \right|_{T=T^*} = \frac{\partial p}{\partial \alpha} \frac{\partial W}{\partial T} / \frac{\partial p}{\partial T} + \frac{\partial W}{\partial \alpha}$ , so

$\left. \frac{dW}{d\alpha} \right|_{T=T^*} > 0$  if and only if  $\frac{\partial p}{\partial \alpha} \frac{\partial W}{\partial T} / \frac{\partial p}{\partial T} + \frac{\partial W}{\partial \alpha} > 0$ . Since  $\frac{\partial W}{\partial T} < 0$ , we have  $\left. \frac{dW}{d\alpha} \right|_{T=T^*} > 0$  if and

only if

$$\frac{\partial W}{\partial \alpha} / \left[ -\frac{\partial W}{\partial T} \right] > \left[ -\frac{\partial p}{\partial \alpha} \right] / \frac{\partial p}{\partial T}.$$

We now proceed to establish that this inequality is met.

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<sup>\*</sup> This is the Appendix to my paper, "Prior User Rights," (2006), *American Economic Review Papers and Proceedings*, May, vol. 96, no. 2. The paper and appendix together are available at my web site at <http://faculty.haas.berkeley.edu/shapiro/prior.pdf>. This Appendix alone is available at <http://faculty.haas.berkeley.edu/shapiro/priorapp.pdf>.

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The left-hand side of this inequality is easy to calculate. As noted above,  $dW_B/d\alpha = W_D - W_M$ ,

so  $\frac{\partial W}{\partial \alpha} = p^2 T(W_D - W_M)$ . From the definition of  $W(p, T, \alpha)$  we also get

$-\frac{\partial W}{\partial T} = p^2(W_C - W_B) + 2p(1-p)(W_C - W_M)$ . Therefore, we have

$$\frac{\frac{\partial W}{\partial \alpha}}{[-\frac{\partial W}{\partial T}]} = \frac{pT(W_D - W_M)}{p[W_C - W_B] + 2(1-p)[W_C - W_M]}.$$

We now look more closely at the  $p(T, \alpha)$  function to obtain an expression for the right-hand side of above inequality.

Using the condition that defines the symmetric equilibrium level of  $p$ , we get

$$\frac{\partial p}{\partial T} = \frac{(1-p)\pi_M + p\pi_B}{C''(p) + T(\pi_M - \pi_B)} \quad \text{and} \quad -\frac{\partial p}{\partial \alpha} = \frac{pT(\pi_M/2 - \pi_B)}{C''(p) + T(\pi_M - \pi_B)} \quad \text{so we have}$$

$$\left[-\frac{\partial p}{\partial \alpha}\right] / \frac{\partial p}{\partial T} = \frac{pT(\frac{\pi_M}{2} - \pi_B)}{(1-p)\pi_M + p\pi_B}.$$

So, we have  $\left.\frac{dW}{d\alpha}\right|_{T=T^*} > 0$  if and only if

$$\frac{(W_D - W_M)}{p[W_C - W_B] + 2(1-p)[W_C - W_M]} > \frac{\frac{\pi_M}{2} - \pi_B}{(1-p)\pi_M + p\pi_B}.$$

Substituting using  $W_B = (1-\alpha)W_M + \alpha W_D$  and  $\pi_B = (1-\alpha)\pi_M/2 + \alpha\pi_D$ , this becomes

$$\frac{(W_D - W_M)}{p[W_C - (1-\alpha)W_M - \alpha W_D] + 2(1-p)[W_C - W_M]} > \frac{\frac{\pi_M}{2} - \pi_D}{(1-p)\pi_M + p[(1-\alpha)\pi_M/2 + \alpha\pi_D]}.$$

Collecting terms, this becomes

$$\frac{(W_D - W_M)}{(2-p)[W_C - W_M] - \alpha p[W_D - W_M]} > \frac{\pi_M - 2\pi_D}{(2-p)\pi_M - \alpha p[\pi_M - 2\pi_D]}.$$

Inverting both sides and simplifying gives

$$\frac{W_C - W_M}{W_D - W_M} < \frac{\pi_M}{\pi_M - 2\pi_D}.$$

Inverting again and simplifying gives  $\frac{2\pi_D}{\pi_M} > \frac{W_C - W_D}{W_C - W_M}$ . Defining the monopoly deadweight loss

as  $DWL_M = W_C - W_M$  and the duopoly deadweight loss as  $DWL_D = W_C - W_D$ , granting stronger

prior user rights raises welfare if and only if  $\frac{DWL_M}{\pi_M} > \frac{DWL_D}{2\pi_D}$ , as asserted in the text.

### ***B. Ratio of Profits to Deadweight Loss***

Gilbert and Shapiro (1990) show that the ratio of deadweight loss to profits rises with price if profits and welfare are both concave in output. Here we establish an alternative sufficient condition. The material in this section was developed jointly with Joseph Farrell.

Call the demand function  $X(p)$ . Assume that output can be produced at constant marginal cost  $c$ . Denote by  $L(p)$  the deadweight loss if the price is  $p$ . [For this subsection alone,  $p$  denotes price, not the probability of discovery.] Denote by  $\Pi(p) = (p - c)X(p)$  the total profits if price is  $p$ . Under what circumstances is the ratio  $L(p)/\Pi(p)$  increasing in price  $p$  in the range  $c \leq p \leq p^M$ , where  $p^M$  is the monopoly price?

The ratio  $L(p)/\Pi(p)$  is increasing in  $p$  if and only if  $L'(p)/\Pi'(p) > L(p)/\Pi(p)$ . We look at each of these ratios in turn.

By definition,  $L(p) = \int_c^p [X(t) - X(p)]dt$ , so  $L'(p) = (p - c)[-X'(p)]$ .

$\Pi'(p) = (p - c)X'(p) + X(p) = X(p) - L'(p)$ . Therefore, we get

$$\frac{\Pi'(p)}{L'(p)} = \frac{X(p) - L'(p)}{L'(p)} = -1 + \frac{X(p)}{-(p-c)X'(p)} = -1 + \frac{p}{p-c} \left[ \frac{X(p)}{-pX'(p)} \right] = -1 + \frac{1}{mE(p)}, \text{ where}$$

$m \equiv \frac{p-c}{p}$  is the Lerner Index and  $E(p) \equiv -\frac{pX'(p)}{X(p)}$  is the absolute value of the elasticity of

demand. Inverting this equation, we get  $\frac{L'(p)}{\Pi'(p)} = \frac{mE(p)}{1-mE(p)}$ . Assuming that  $\Pi'(p) > 0$  for

$p < p^M$ , we know that  $mE(p) < 1$  in this range; only at  $p = p^M$  do we get  $mE(p) = 1$ .

We now look at the first-order approximations to  $L'(p)/\Pi'(p)$  and  $L(p)/\Pi(p)$  for values of  $p$  near  $c$ . We express these in terms of  $m$ , which is zero at  $p = c$ . Using the above calculation, we

have  $\frac{L'(p)}{\Pi'(p)} \approx mE(c)$  for values of  $p$  near  $c$ . From the definition of  $L(p)$ , for values of  $p$  near

$c$  we get the approximation  $L(p) \approx \frac{1}{2}[p-c][X(c) - X(p)] \approx \frac{1}{2}[p-c][-(p-c)X'(c)]$ . Some

simple algebra shows that this expression is approximately equal to  $\frac{1}{2}mE(c)\Pi(p)$ . Therefore,

for values of  $p$  near  $c$ , we have  $\frac{L(p)}{\Pi(p)} \approx \frac{1}{2}mE(c)$ . We have thus shown that in the neighborhood

of  $p = c$ , the ratio  $L'(p)/\Pi'(p)$  rises with  $p$  twice as rapidly as does the ratio  $L(p)/\Pi(p)$ .

Both of these ratios approach zero as  $p \rightarrow c$ . This reflects the fact that the deadweight loss is second-order small in  $p - c$  when price is near marginal cost.

Using  $\frac{L'(p)}{\Pi'(p)} = \frac{mE(p)}{1-mE(p)}$ , we know that  $L'(p)/\Pi'(p)$  rises with  $p$  if  $mE(p)$  rises with  $p$ , i.e. if

$\left(\frac{p-c}{p}\right)E(p)$  rises with  $p$ . Suppose that this condition is satisfied.

Now suppose that  $d[L(p)/\Pi(p)]/dp = 0$  for some value of  $p$ , as it must if  $L(p)/\Pi(p)$  is ever to decline with  $p$ , since  $L(p)/\Pi(p)$  is increasing with  $p$  near  $p = c$  (and we are assuming all functions are smooth). Call  $p_0$  the lowest value of  $p$  at which  $d[L(p)/\Pi(p)]/dp = 0$ . So, for  $p < p_0$ ,  $L(p)/\Pi(p)$  is increasing, which we know requires that  $L'(p)/\Pi'(p) > L(p)/\Pi(p)$ .

We must have  $L(p)/\Pi(p) = L'(p)/\Pi'(p)$  at  $p = p_0$ . Since  $L(p)/\Pi(p)$  is locally constant with respect to  $p$  at  $p = p_0$ , and since  $L'(p)/\Pi'(p)$  is increasing in  $p$  (by assumption), this could only happen if  $L'(p)/\Pi'(p)$  were *less* than  $L(p)/\Pi(p)$  for values of  $p$  just below  $p_0$ . But this contradicts the fact that  $L'(p)/\Pi'(p) > L(p)/\Pi(p)$  for  $p < p_0$ . We have therefore proven:

**If  $\left(\frac{p-c}{p}\right)E(p)$  rises with  $p$ , then the ratio of deadweight loss to monopoly profits also rises with  $p$  for prices between marginal cost and the monopoly price.**

### *C. Uniqueness and Stability of the Symmetric Equilibrium*

For ease of notation, we write  $k = 1 - \frac{\pi_B}{\pi_M}$ , so the first-order condition is  $\frac{C'(p)}{T\pi_M} = 1 - kp$ . Note

that  $1/2 \leq k \leq 1$ ; when  $\alpha = 0$ ,  $\pi_B = \pi_M / 2$  and  $k = 1/2$ , and when  $\alpha = 1$ ,  $\pi_B = \pi_D$ , and  $k = 1 - \pi_D / \pi_M$ .

The first-order condition for the choice of  $p$  is given by  $C'(p)/T\pi_M = 1 - kp$ . The slope of the first firm's best response function is therefore given by  $dp/dq = -kT\pi_M / C''(p)$ . The symmetric equilibrium is stable if and only if the first firm's best-response schedule is steeper than the second firm's at that point. Since the payoffs are symmetric, this is true if and only if the absolute value of the slope of the  $p$  best-response curve is greater than unity at the symmetric equilibrium. So, we get stability of the symmetric equilibrium if and only if  $kT\pi_M > C''(p)$  at the point where  $C'(p)/T\pi_M = 1 - kp$ . The necessary and sufficient condition for stability,  $kT\pi_M > C''(p)$ , can be written as  $kpT\pi_M > pC''(p)$ . From the first-order condition, we have  $kpT\pi_M = T\pi_M - C'(p)$ , so the stability condition can be written as  $T\pi_M - C'(p) > pC''(p)$  or  $T\pi_M > C'(p) + pC''(p) = C'(p)[1 + E]$  where  $E \equiv pC''(p)/C'(p)$  is the elasticity of the cost function with respect to the success probability. Dividing this inequality by  $T\pi_M$  gives  $[C'(p)/T\pi_M][1 + E] < 1$ . Finally, substituting using the first-order condition we get the necessary and sufficient condition for stability as  $(1 - kp)(1 + E) < 1$ .

We now provide a sufficient condition for the symmetric equilibrium to be the only equilibrium.

The equation defining the symmetric equilibrium is  $\frac{C'(p)}{T\pi_M} = 1 - kp$ .

Suppose there were an asymmetric equilibrium with  $p > q$ . Then we must have

$C'(p)/T\pi_M = 1 - kq$  and  $C'(q)/T\pi_M = 1 - kp$ . Taking ratios of these two first-order conditions, we would have  $C'(p)(1 - kp) = C'(q)(1 - kq)$ . There can be no such asymmetric equilibrium if the function  $C'(p)(1 - kp)$  is monotonic in  $p$ . This expression is decreasing in  $p$  if and only if  $pC''(p)/C'(p) < kp/(1 - kp)$ , which we can write as  $E(1 - kp) < kp$ . This is the same as the stability condition,  $(1 + E)(1 - kp) < 1$ .

To illustrate using an example, suppose that  $C(p) = [\gamma p + \beta p^2 / 2]T\pi_M$ , so

$C'(p) = [\gamma + \beta p]T\pi_M$  and  $C''(p) = \beta T\pi_M$ . Then the symmetric equilibrium level of  $p$  is given

by  $p^* = \frac{1 - \gamma}{k + \beta}$ . An interior equilibrium requires that  $p^* > 0$ , so  $\gamma < 1$ , and that  $p^* < 1$ , so

$\beta + \gamma > 1 - k$ . The condition for stability is that  $\beta < k$ . So long as these three conditions are satisfied, we have a stable interior equilibrium.

## Diversification of Research Approaches

### A. Proof of Theorem #2

We are interested in exploring the welfare effects of granting stronger prior user rights.

Differentiating with respect to  $\alpha$ , we get

$$\frac{dW(x, \alpha)}{d\alpha} = \frac{\partial W(x, \alpha)}{\partial x} \frac{dx}{d\alpha} + \frac{\partial W(x, \alpha)}{\partial \alpha}.$$

As usual, the direct effect of awarding stronger prior user rights is positive, since

$\partial W / \partial \alpha = B(x, y) \partial W_B / \partial \alpha = B(x, y)(W_D - W_M) > 0$ . The text establishes that  $dx / d\alpha > 0$ , so a sufficient condition for stronger prior user rights to raise welfare is that  $\partial W / \partial x > 0$  at the equilibrium.

Using the definition of  $W$ , we have  $W(x, y, \alpha) = W_M(A(x, y) + A(y, x)) + W_B B(x, y)$ .

Differentiating with respect to  $x$ , we have  $W_x(x, y, \alpha) = W_M(A_x(x, y) + A_x(y, x)) + W_B B_x(x, y)$ . By symmetry,  $A_x(y, x) = A_y(x, y)$ . So

$W_x(x, y, \alpha) = W_M(A_x(x, y) + A_y(x, y) + B_x(x, y)) + (W_B - W_M)B_x(x, y)$ . Evaluating this at a symmetric point where  $x = y$  gives

$$W_x(x, x, \alpha) = W_M(A_x(x, x) + A_y(x, x) + B_x(x, x)) + (W_B - W_M)B_x(x, x).$$

Since  $A(x, y) + B(x, y) = p(x)$ , we know that  $A_y(x, y) + B_y(x, y) = 0$ . By symmetry,

$B(x, y) = B(y, x)$ , so  $B_x(x, x) = B_y(x, x)$ . Therefore we must have

$A_y(x, x) + B_y(x, x) = A_y(x, x) + B_x(x, x)$ . Since the left-hand side of this expression is zero, the right-hand side must also equal zero, so we get

$$W_x(x, x, \alpha) = W_M A_x(x, x) + (W_B - W_M)B_x(x, x).$$

From the condition characterizing the symmetric equilibrium,  $A_x(x, x)\pi_M + B_x(x, x)\pi_B = 0$ .

Solving this for  $B_x(x, x)$ , substituting, and simplifying gives

$$W_x(x, x, \alpha) = W_M A_x(x, x) \left[ 1 - \frac{W_B - W_M}{W_M} \frac{\pi_M}{\pi_B} \right]$$

at the symmetric equilibrium. Therefore,  $W_x(x, x, \alpha) > 0$  at the symmetric equilibrium if and only

$$\text{if } \frac{\pi_B}{\pi_M} > \frac{W_B - W_M}{W_M}.$$

Note: Proposition 3 in Dasgupta and Maskin (1987) provides conditions under which the market research portfolio consists of projects that are too highly correlated, so that  $dx/d\alpha > 0$  in my notation. However, they assume that welfare is the same whether one or both firms are successful:  $W_B = W_M$  in my notation. This condition holds at  $\alpha = 0$ , so Proposition 3 in Dasgupta and Maskin (1987), combined with the definition of prior user rights adopted in this paper, implies Corollary #2A, i.e., that some prior user rights are optimal. However, their

analysis must be extended, as shown here, to study the effects of stronger prior user rights away from  $\alpha = 0$ .

### ***B. Second-Order Condition and Best-Response Functions***

As calculated by Dasgupta and Maskin, using my notation,

$$B(x, y) = (x + y)p(x)p(y) + [1 - (x + y)](p(x) + p(y))/2 \text{ and}$$

$$A(x, y) = [1 + (x + y)]p(x)/2 - [1 - (x + y)]p(y)/2 - (x + y)p(x)p(y).$$

The second-order condition for the first firm is  $A_{xx}\pi_M + B_{xx}\pi_B < 0$ . A sufficient condition for this to hold (which is necessary if  $\pi_B$  is sufficiently small) is that  $A_{xx} < 0$ . Direct calculations show that  $A_{xx}(x, y) = p'(x)[1 - p(x) - p(y)] + p''(x)[1 + (x + y)(1 - p(y))]/2$ . This expression is negative if  $p(x)$  and  $p(y)$  are each no larger than one-half, which they must be if  $p(0) \leq 1/2$ . However, we could have if  $p(x) + p(y) > 1$  and if  $p''(x)/p'(x)$  is small. In that case, the second-order condition is not satisfied, and the first firm should increase  $x$  to a higher level at which the first-order condition again holds to find the optimal level of  $x$ , avoiding a local minimum at a lower value of  $x$ .

The first-order condition for the first firm is  $A_x(x, y)\pi_M + B_x(x, y)\pi_B = 0$ . This firm's best-response function is downward sloping if  $A_{xy}(x, y)\pi_M + B_{xy}(x, y)\pi_B < 0$ , which we write as

$$\pi_M[A_{xy}(x, y) + B_{xy}(x, y)] - B_{xy}(x, y)[\pi_M - \pi_B] < 0. \text{ Since } A(x, y) + B(x, y) = p(x),$$

$A_y(x, y) + B_y(x, y) = 0$ , and  $A_{xy}(x, y) + B_{xy}(x, y) = 0$  as well, so this inequality is satisfied if and only if  $B_{xy}(x, y) > 0$ . Since  $B_{xy}(x, y) = p'(x)[p(y) - 1/2] + p'(y)[p(x) - 1/2] + (x + y)p'(x)p'(y)$ , this inequality is satisfied so long as  $p(x)$  and  $p(y)$  are each no larger than one-half, which they must be if  $p(0) \leq 1/2$ .

### **Allocation of R&D Budgets Across Markets: Proof of Theorem #3**

The welfare effect of strengthening prior user rights is given by

$$\frac{dW}{d\alpha} = \frac{\partial W}{\partial x} \frac{dx}{d\alpha} + \frac{\partial W}{\partial \alpha}.$$

As usual, we know that the  $\partial W / \partial \alpha > 0$ , because  $\partial W_B / \partial \alpha = W_D - W_M > 0$ .

We show here that each firm will shift away from the smaller market and towards the larger market as prior user rights are strengthened. Formally, we show that  $\partial x / \partial \alpha < 0$ . The first firm picks  $x$  to maximize  $\pi(x, y, \alpha)$ . Since  $d\pi_B / d\alpha = \pi_D - \pi_M / 2 < 0$ ,  $\partial x / \partial \alpha < 0$  if and only if  $\pi_x(x, y, \alpha)$  rises with  $\pi_B$ .

Differentiating  $\pi(x, y, \alpha)$  with respect to  $\pi_B$  gives  $p(x)p(y) + \sigma[p(1-x)/\sigma][p(1-y)/\sigma]$ .

Differentiating this with respect to  $x$  gives  $p'(x)p(y) - p'(1-x)p(1-y)/\sigma$ . This is positive if and only if  $[p'(x)/p'(1-x)] > [p(1-y)/p(y)]/\sigma$ . We now show that this expression is

positive at the symmetric equilibrium, i.e.,  $\frac{p'(x)}{p'(1-x)} > \frac{p(1-x)}{p(x)} \frac{1}{\sigma}$  at the symmetric equilibrium.

In a symmetric equilibrium, Cabral shows (Equation A.4) that we must have

$$\frac{p'(x)}{p'(1-x)} = \frac{\pi_M - (\pi_M - \pi_B)p(1-x)/\sigma}{\pi_M - (\pi_M - \pi_B)p(x)}. \text{ So, we are attempting to show that}$$

$$\frac{\pi_M - (\pi_M - \pi_B)p(1-x)/\sigma}{\pi_M - (\pi_M - \pi_B)p(x)} > \frac{p(1-x)/\sigma}{p(x)}. \text{ Cross-multiplying and simplifying, this is equivalent}$$

to  $p(x) > p(1-x)/\sigma$ , i.e., that the equilibrium probability of success is greater in the smaller market, a condition that Cabral establishes.

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### 3.6 PUBLIC USE

#### 3.6.1 *General*

Public prior use is the term used to refer to the availability of an actual product or method to the public (as opposed to a description in a document) before the date of filing of the application. Disclosure by means of public use of the product or process imposes more demands on the evidence of availability and the assessment of the contents than the more usual written disclosure and commonly requires extensive evidence. The assessment of the content of a written disclosure is a matter of interpretation of text, while that of public prior use often requires analysis of a product (D-V,3.1.3.1). Public prior use in opposition proceedings is normally complicated by the facts and evidence in general being only available to the opponent and not to the proprietor, influencing the desired degree of proof (see the notes to Art.117).

A product or method disclosed by prior public use is regarded as part of the state of the art if the following matters in relation to the alleged use are proved: When, What, How, Where and by Whom (D-V,3.1.2, T93/89 r.8.1, T194/86). In those public prior use cases where practically all evidence in support of the public prior use lies within the power and knowledge of the opponent, i.e. in the majority of cases, he has to prove his case up to the hilt (T472/92 hn.1). A single sale is sufficient to render the article sold available to the public, provided the buyer is not bound by an obligation to maintain confidentiality (T482/89.) The opposition division may request a list of clients and dates of sale to prove availability of the product.

#### 3.6.2 *Accessibility and analysability*

Decision G1/92 deals with various aspects of public prior use. The composition or internal structure of a product, whether chemical or other, forms part of the state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether or not particular reasons can be identified for such analysis. This is based on Art.54(2), which does not make any distinction between different means for making available information (r.1.2) and on the fact that the possibility of access to information makes it public, irrespective of whether there is any reason to search for it (r.2). Characteristics which are only revealed when the product is exposed to interaction with specific outside conditions, e.g. reactants or the like, in order to prove a particular effect or result or to discover potential results or capabilities, go beyond what is disclosed by the product per se as they are dependent on deliberate choices being made. Typical examples are the application of a known substance as pharmaceutical and the use of a known compound for a particular purpose based on a new technical effect (G2/88). Thus, such characteristics cannot be considered as having already been made available to the public (r.3). (G1/92, overruling T93/89 (adhesive on paper; only available if there is reason for analysis) and T461/88 r.6.3 (program on microchip too expensive to analyse), broadening T406/86 (available only if analysis is simple)).

Opinion G1/92 must be read together with the later decision T952/92, because several passages of G1/92 not relating to the question referred to the Enlarged Board of Appeal are contrary to established case law and, when read in isolation, would lead the reader astray. Some issues have been put right in T952/92.

The degree of burden involved in analysing a prior sold product is in principle irrelevant to the determination of what constitutes the state of the art (T952/92 r.2.2, contrary to G1/92 r.1.4). The possibility of a complete analysis of a prior sold product so as to enable an exact reproduction of such product is not necessary for destroying the novelty of a claimed product (T952/92 r.2.3 last par., contrary to the requirement of complete analysis following from G1/92 r.1.4). Information as to the composition and internal structure of a prior sold product is made available if direct and unambiguous access to such information is possible by means of known analytical techniques which were available for use by a skilled person before the relevant filing date (T952/92 r.4.3).

G1/92 shifts the emphasis in the assessment of public prior use from the existence of the product to the technical teaching that may be directly and unambiguously derived from the product. Teaching that is not available by such deriving does not form state of the art. Hence, it is possible for an existing, publicly available product to be patented (as a product claim) based on a new teaching relating to the product. For example, an available polymer without an available method of manufacture is not part of the state of the art if an analysis of the polymer does not reveal the chemical process by which it was made. Similarly, a microbiological product does not belong to the state of the art if there is a high probability of variation upon reproduction of such microbes and a skilled person cannot establish the identity of the reproduced product or the prior art product because intrinsic or extrinsic features of those products are not accessible (T977/93).

**4 Extent of disclosure**

**4.1 GENERAL**

The contents of a document are what a skilled person would have read in it at the time of its publication or, where Art.54(3) applies, the date of filing, or priority where appropriate (C-IV,9.3). The knowledge of the skilled person must not be supplemented by knowledge which might have been obtained between the date of deemed assessment of the prior art and the filing or priority date of the patent in issue.

A document disclosing a chemical compound and its manufacture makes this compound available to the public in all desired grades of purity provided the required purification methods are known. Hence, the feature of a certain purity does not make a claim related to a known compound novel. Purity is an important issue in pharmaceuticals, for example where a compound is a racemate, i.e. a mixture of two isomers, one of the isomers producing the therapeutic effect and the other isomer causing only side-effects. (T990/96 hn.1)

**4.2 IMPLICIT DISCLOSURE**

A document discloses not only subject-matter derivable directly and unambiguously from that document but also any features implicit to a person skilled in the art from what is expressly mentioned in the document. For example, a disclosure of the use of rubber in circumstances where its elastic properties are used, even if this is not explicitly stated, takes away the novelty of the use of an elastic material. (C-IV,9.2)

Other examples are: e.g. mains electricity implicitly discloses 230V @ 50 Hz; copper implicitly discloses a non-ferrous metal.

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The degree of burden involved in analysing a prior sold product is in principle irrelevant to the determination of what constitutes the state of the art (T952/92 r.2.2, contrary to G1/92 r.1.4). The possibility of a complete analysis of a prior sold product so as to enable an exact reproduction of such product is not necessary for destroying the novelty of a claimed product (T952/92 r.2.3 last par., contrary to the requirement of complete analysis following from G1/92 r.1.4). Information as to the composition and internal structure of a prior sold product is made available if direct and unambiguous access to such information is possible by means of known analytical techniques which were available for use by a skilled person before the relevant filing date (T952/92 r.4.3).

G1/92 shifts the emphasis in the assessment of public prior use from the existence of the product to the technical teaching that may be directly and unambiguously derived from the product. Teaching that is not available by such deriving does not form state of the art. Hence, it is possible for an existing, publicly available product to be patented (as a product claim) based on a new teaching relating to the product. For example, an available polymer without an available method of manufacture is not part of the state of the art if an analysis of the polymer does not reveal the chemical process by which it was made. Similarly, a microbiological product does not belong to the state of the art if there is a high probability of variation upon reproduction of such microbes and a skilled person cannot establish the identity of the reproduced product or the prior art product because intrinsic or extrinsic features of those products are not accessible (T977/93).

**4 Extent of disclosure**

**4.1 GENERAL**

The contents of a document are what a skilled person would have read in it at the time of its publication or, where Art.54(3) applies, the date of filing, or priority where appropriate (C-IV,9.3). The knowledge of the skilled person must not be supplemented by knowledge which might have been obtained between the date of deemed assessment of the prior art and the filing or priority date of the patent in issue.

A document disclosing a chemical compound and its manufacture makes this compound available to the public in all desired grades of purity provided the required purification methods are known. Hence, the feature of a certain purity does not make a claim related to a known compound novel. Purity is an important issue in pharmaceuticals, for example where a compound is a racemate, i.e. a mixture of two isomers, one of the isomers producing the therapeutic effect and the other isomer causing only side-effects. (T990/96 hn.1)

**4.2 IMPLICIT DISCLOSURE**

A document discloses not only subject-matter derivable directly and unambiguously from that document but also any features implicit to a person skilled in the art from what is expressly mentioned in the document. For example, a disclosure of the use of rubber in circumstances where its elastic properties are used, even if this is not explicitly stated, takes away the novelty of the use of an elastic material. (C-IV,9.2)

Other examples are: e.g. mains electricity implicitly discloses 230V @ 50 Hz; copper implicitly discloses a non-ferrous metal.

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**6. “The Patent System and Research Freedom:  
A Comparative Study”**

**Prepared by: Richard Gold & Yann Joly**

**Prepared for: The World Intellectual Property Organization**

**Submitted: August 2, 2010**

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## I. Scope and Definitions

### A. Scope and Issues

One of the primary goals of the patent system is to encourage research of all kinds – basic, applied and translational – by both granting rights to inventors and by excluding or limiting those rights so as to enable others to use and improve existing inventions. As legislatures and courts around the world have recognized, the exclusions and exceptions placed on patent rights are far from an oversight: they are essential to achieving the appropriate set of policies that best foster research and development.<sup>1</sup> This chapter investigates patent exclusions and exceptions which affect research and development in science and technology.

This chapter investigates two types of legal rules through which patent law affects research: 1) those that determine what can and cannot be patented (exclusions); and 2) those which exclude certain acts or certain actors from liability for infringement (exceptions).

The “patent system aims to promote scientific and technological progress by granting exclusive rights in new discoveries. But the enforcement of these exclusive rights against subsequent researchers can sometimes interfere with further progress in the field of the invention.”<sup>2</sup> It thus becomes essential to understand both the effect of patent rights in providing an incentive to undertake research and on making subsequent research more difficult, time consuming or expensive. Exclusions and exceptions do not exist in isolation: they work within the context of legal rules governing what can be patented, the scope of patent rights and the means to enforce those rights, as well as practices that exist over the use and enforcement of patent rights.

Part I of this Chapter sets out important definitions and concepts. Part II then deals with exclusions and Part III with exceptions. Each of these parts begins by setting out the international instruments that deal with exclusions or exceptions – as the case may be –, including regional agreements. Before identifying commonalities and distinctions between countries from various regions, national provisions from a representative sample of countries will be set out in a tabular form. The presentation of these sample national provisions aims at achieving a balance between clarity and conciseness, on one hand, with exhaustiveness, on the other. Countries were selected to represent a variety of exclusions in different world regions.

This chapter’s discussion of exclusions includes both specific, statutory, provisions as well as national interpretations of the requirements for patentability under national or regional law. Often, different countries use different routes to excluding some subject matter. For example, methods of medical treatment or business methods are excluded in some jurisdictions by

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<sup>1</sup> *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010) (U.S.); *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 102 (Canada); *Daiichi Pharmaceutical Co., Ltd. v. Shiono Chemical K.K. & Choseido Pharmaceutical K.K.* (Japan) discussed in Shammad Basheer & Coenraad Visser, *Background Information from Asia* (2010) [unpublished], p. 23 [Asian Report].

<sup>2</sup> Rebecca S. Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use” (1989) 56 U. Chi. L. Rev. 1017, p.1086.

specific exclusion while in others through the interpretation of one or more of the criteria of patentability. Thus, in order to undertake a complete study of exclusions and exceptions, one must pay attention not only to formal exclusions, but also those that arise through the interpretation of other patent rules, such as those pertaining to the criteria for patentability.

The discussion of exceptions includes the prior user exception, the non-commercial user exception, the experimental use exception and the exception for submission of information to the government (*Bolar/Safe Harbor*). For the prior user exception, a link between the first-to-file system, trade secrets and research will be made. The non-commercial user exception will be distinguished from the experimental use exception. As for experimental use exceptions, a distinction will be drawn between those that allow experiments *on* inventions and those that allow experiments *on* and *with* inventions. Distinctions will also be made based on the sources of experimental use exceptions (statutory vs. judicial) and on whether or not commercial purposes are allowed.

Part IV ties these sections together by focusing on the motivation behind major groups of exclusions and exceptions. It ends by discussing the overarching concept of balance that permeates judicial and policy treatments of patent law. Chapter IV plays particular attention to the experimental use exception/*Bolar* exception and disclosure/secretcy dualisms. It concludes by discussing the necessary relationship between the exclusions and exceptions needed to create successful research environments.

## B. Definitions

**Description requirement – Enablement requirement:** While these two expressions might refer to different concepts, some jurisdictions do not differentiate between the two. The expression “description requirement” will hereby refer to all forms of description requirements, including what some distinguish as an enablement requirement.

**Fundamental knowledge:** Fundamental knowledge is derived from “experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.”<sup>3</sup>

**Applied Knowledge (Practical applications):** Applied knowledge results from an “original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.”<sup>4</sup>

**Research:** As previously explained, one of the purposes of the patent system is to stimulate research of all kinds. Because the goal of this chapter is to study the relationship between research and the patent system, it is necessary to define what constitutes research. This will allow the reader to better understand the relationship which certain exclusions or exceptions have with research.

According to the *Oxford English Dictionary*, research may be defined as “the systematic study of materials and sources in order to establish facts and reach new conclusions.” In other words,

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<sup>3</sup> *The Measurement of Scientific and Technological Activities*  
Frascati Manual 2002 Proposed Standard Practice for Surveys on Research and Experimental Development (2002, OECD publishing).

<sup>4</sup> *Ibid.*

research may be defined as an organized investigation of physical or non-physical material, concepts or sources, in order to reach a conclusion.

Research may be applied or fundamental. Applied research is “concerned with action” and is “likely to be effective in real circumstances,” while fundamental research is concerned with abstract concepts and *not directly applicable results*. “The primary criterion of success in applied research is contribution to the solution of specific practical problems.”<sup>5</sup> “[Fundamental] research, on the other hand, is successful when it discovers new phenomena or new ideas of general interest.”<sup>6</sup> The distinction between applied research and fundamental research does not map on to the distinction between what is patentable and what is not. There is some applied research – such as methods of surgery – that are not universally patentable and some fundamental research – such as DNA sequences – that are patentable in many jurisdictions.

## II. Exclusions Affecting Research

This part of the chapter discusses how patentability exclusions may affect research. These exclusions originate from both national and international laws. Consequently, this section will discuss both the international legal framework to which countries adhere (**Part A**) and national regimes (**Part B**).

### A. International Legal Framework

While international legal agreements do not deal specifically with research and patents, several instruments affect the ability of nations to enact specific exclusions. Thus, this Part A focuses on what international legal texts say about exclusions from patentable subject matter that may have an impact on research and development. After having discussed the general framework of international agreements (**i**), regional agreements will be examined in order to achieve a thorough understanding of the supranational obligations countries may have pertaining to exclusions affecting research and to learn more about the origin of these exclusions (**ii** to **v**).

#### i) Global Legal Framework

The *Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS)* is an international substantive treaty that imposes certain limitations on the types of exclusions that may have an effect on research. Concluded in 1994 and having come into force in 1995, *TRIPS* encompasses a broad range of intellectual property regimes. Its main purpose is to set minimum standards for intellectual property for members of the World Trade Organization.<sup>7</sup>

Part II, Section 5 of *TRIPS* is dedicated to patents. This section requires member countries to grant patents for inventions (products or processes) in all fields of technology, as long as the

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<sup>5</sup> Nils Roll- Hansen, “Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science” (2009) LSE Centre for the Philosophy of Natural and Social Science – Technical Report 04/09 [Nils Roll- Hansen, “Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science”].

<sup>6</sup> *Ibid.*

<sup>7</sup> Kevin J. Nowak, “Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27” (2005) 26 Mich. J. Int’l L. 899, p. 902 [Nowak, “Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27”].

invention is new, the product of an inventive step and possess an industrial application.<sup>8</sup> In other words, the breadth of patentable subject matter is very broad; only what is not an invention or not capable of meeting the three criteria of novelty, inventive step (or non-obviousness) and industrial application (or utility) can be excluded from patentability.<sup>9</sup> Nevertheless, Article 27 of *TRIPS* provides countries with the ability to enact some exclusions.

The first of these concerns “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”<sup>10</sup> This exclusion does not encompass pharmaceutical products, however, as *TRIPS* explicitly requires that such products be patentable.<sup>11</sup> This exclusion allows, if brought into national law, doctors and healthcare professionals to use the above mentioned methods without the threat of infringing a patent. Similarly, it permits the use of these methods by medical researchers.

Second, member countries may exclude from the realm of patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”<sup>12</sup> However, “[m]embers shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.”<sup>13</sup> Under this provisions, micro-organisms cannot be excluded from patenting, while animals and essentially biological processes for the production of plants or animals may be excluded. As for plants, a system for the protection of plant varieties “[meaning] a plant grouping within a single botanical taxon of the lowest known rank [...],”<sup>14</sup> has to be implemented by member countries.<sup>15</sup> However, the term “plant,” as opposed to the expression “plant varieties” probably refers to a grouping larger than a “single botanical taxon.” Therefore, it seems as though member countries may exclude groupings larger than a “single botanical taxon” from patentable subject matter. As will be explained in the discussion on the *European Patent Convention*, this line of interpretation is consistent with that given by the Board of Appeal of the European Patent Office.

If brought into national law, the exclusion of plants, animals and of essentially biological processes for the production of plants or animals removes an entire field of research from the realm of patentability. All of the aforesaid subject matter may be the subject of research, but may also be used as research tools free from patent infringement.

Now that the common international framework for exclusions has been outlined in sub-part i), sub-parts ii) to v) will focus on regional agreements containing exclusions in Europe, North America, South America and Eurasia.

## ii) Europe

<sup>8</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Annex 1 C of the Marrakesh Agreement Establishing the World Trade Organization article 27 (1) [TRIPS].

<sup>9</sup> *Ibid.*

<sup>10</sup> *Ibid.*, article 27 (3) a).

<sup>11</sup> *Ibid.*, article 70 (8).

<sup>12</sup> *Ibid.*, article 27 (3) b).

<sup>13</sup> *Ibid.*

<sup>14</sup> *International Convention for the Protection of New Varieties of Plants*, 19 March 1991, article 1 (iii) [UPOV 1991].

<sup>15</sup> TRIPS, *supra* note 8 article 27 (3) b).

This sub-part, subpart (ii), will discuss the *European Patent Convention (EPC)*<sup>16</sup> and, to a lesser extent, the *European Biotechnology Directive*,<sup>17</sup> which was meant to increase the competitiveness of European biotechnology research and to clarify certain articles of the *EPC*.

### **The European Patent Convention**

The first *European Patent Convention (EPC)*,<sup>18</sup> concluded in 1973, came into force in 1978.<sup>19</sup> This convention was replaced with a revised version<sup>20</sup> that came into force in 2007.<sup>21</sup> Only the revised version will be studied here, as it is the one currently in effect.

The *EPC*<sup>22</sup> institutes the European Patent Organisation and provides an autonomous legal system through which patents are granted in Europe. It defines rules pertaining to the patent-granting process<sup>23</sup> and promotes the adoption of common patent rules by Member States, especially regarding rules of patentability and validity.<sup>24</sup> However, there is no such thing as a European patent, as the granting of patents remains national. National patent laws also prescribe rules related to “[...] matters of infringement, enforcement, revocation, renewal and litigation [...]”<sup>25</sup>

Articles 52 and 53 of the *EPC* affect research and experimentation by creating exclusions to what can be patented. Because each article contains several provisions, each with its own exclusion, they will be analyzed individually.

#### *Article 52 (1)*

Article 52 (1) of the *EPC* sets forth the four general requirements for patentability: an invention, novelty, the presence of an inventive step<sup>26</sup> and the potential for industrial application.

#### *Article 52 (2)*

Article 52 (2) sets out three types of exclusions relevant to this chapter: namely, the exclusion of “discoveries, scientific theories and mathematical methods,” of “schemes, rules and methods for performing mental acts, playing games or doing business” and of “presentations of information.” These pertain to “abstract and non-technical” concepts.<sup>27</sup>

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<sup>16</sup> *European Patent Convention*, 29 November 2000, [EPC 2000].

<sup>17</sup> *Directive 98/44/EC*, 6 July 1998, [European Biotechnology Directive].

<sup>18</sup> *European Patent Convention*, 5 October 1973, [EPC 1973].

<sup>19</sup> WIPO’s Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights for Europe, (2010), p. 1 [Unpublished] [European Report].

<sup>20</sup> EPC 2000 *supra* note 16.

<sup>21</sup> *Ibid.*

<sup>22</sup> *Ibid.*

<sup>23</sup> *Ibid.*

<sup>24</sup> European Report *supra* note 19 p. 2.

<sup>25</sup> *Ibid.*

<sup>26</sup> EPC 2000 *supra* note 16 article 52 (1).

<sup>27</sup> European Report *supra* note 19 p. 15.

Discoveries or natural substances are generally deemed not patentable. However, a discovery incorporated into an invention may be patented by putting the discovery to practical use.<sup>28</sup> As for natural substances, they may be patented when they have been “isolated from [their] surroundings [and] properly characterized either by [their] structure, by the processes by which [they are] obtained or by other parameters [...]”<sup>29</sup>

The provision proscribing the patenting of “schemes, rules and methods for performing mental acts, playing games or doing business”<sup>30</sup> has been interpreted as forbidding the patenting of “cognitive, conceptual or intellectual processes conducted by the human mind.”<sup>31</sup>

The two preceding paragraphs describe two forms of fundamental knowledge that cannot be patented. These exclusions affect researchers because they permit to make use of that knowledge without risk of patent infringement.

#### *Animal Varieties and Plant Varieties - Article 53 (b)*

Plants and animals are used by researchers in different circumstances. They may be the object of research or mere tools used to perform research. The exclusion of “plant or animal varieties [...]” from patentable subject matter impacts research by eliminating the risk of patent infringement for researchers using them.<sup>32</sup>

The term “plant variety” refers to “individually characterized plants which would have the detailed taxonomy and the reproductive capacity which is required in general for a plant right.”<sup>33</sup> More precisely, “the concept of plant variety under article 53(b) refers to any plant grouping with a single botanical taxon [or classification] of the lowest known rank.”<sup>34</sup> This definition of plant variety can be explained by the intention of member countries to respect the *International Convention for the Protection of New Varieties of Plants*,<sup>35</sup> which allows them to protect plant varieties either by the patent system or by a separate plant variety protection system. However, the 1961 and 1978 versions of the *Convention* do not allow member countries to give dual protection to plant varieties.<sup>36</sup>

Article 53 (b) can be described as “the borderline between patent and plant variety protection” for countries bound by the versions of this convention prior to 1991.<sup>37</sup> Even though some excluded elements may be subject to breeders’ rights, the *International Convention* prescribes some exceptions to these rights that are of interest for researchers, including a research exception.

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<sup>28</sup> *Ibid.*

<sup>29</sup> *Ibid.*, p. 16.

<sup>30</sup> EPC 2000 *supra* note 16 article 52 (2) c).

<sup>31</sup> *Odour Selection/QUEST INTERNATIONAL*, [2007] OJEPO 63, p.72.

<sup>32</sup> EPC 2000 *supra* note 16 article 53 (b).

<sup>33</sup> *Ciba-Geigy/Propagating material application*, T49/83 [1984] OJEPO 112, cited in European Report *supra* note 19 p. 22.

<sup>34</sup> *Plant Genetic Systems/Glutamine synthetase inhibitors*, T356/93 [1995] OJEPO 545 (TBA), cited in European Report *supra* note 19 p. 22.

<sup>35</sup> UPOV 1991, *supra* note 14; *International Convention for the Protection of New Varieties of Plants*, 3 October 1978 [UPOV 1978]; *International Convention for the Protection of New Varieties of Plants*, 1 December 1961 [UPOV 1961].

<sup>36</sup> UPOV 1978 *supra* note 36 article 2 (1); UPOV 1961 *supra* note 36 article 2 (1); European Report, *supra* note 19 p. 22.

<sup>37</sup> European Report, *supra* note 19 p. 24.

The exclusion of “animal varieties” has been defined by Board of Appeal jurisprudence.<sup>38</sup> The term “variety” refers to a “species or a subunit of a species”<sup>39</sup> (as in the case of plants) and only animals in general which constitute an invention may be patented. For example, the patenting of a specific breed of mice would not be acceptable; however, the patenting of transgenic rodents would.

Finally, one must remember that microbiological processes, along with the products originating from them, continue to be eligible to be patented.<sup>40</sup>

#### *Essentially Biological Processes- Article 53 (b)*

Researchers studying or working with biological processes may work, in certain circumstances, without fear of infringing a biological process patent. This exclusion pertains to non-microbiological (1) processes (as opposed to products) (2) for the production of animals or plants (3) that are essentially biological (4).<sup>41</sup>

These cumulative criteria, especially the requirement for the process to be essentially biological, may be considered ambiguous. When does a process cease to be essentially biological? The answer is unclear.<sup>42</sup> The Technical Board of Appeal said that the “drafters [...] had deliberately chosen the adverb ‘essentially’ to replace the narrower term ‘purely.’”<sup>43</sup> One could expect that the addition of an insignificant technical step to crossing or breeding procedures would not make a process eligible for protection by a patent. However, even the answer to this question is uncertain. There is currently a pending case on the issue<sup>44</sup> and it is thus difficult to identify the breadth of this exclusion.

Even though this exception is narrow, biological processes for the production of animals and plants are used in research. Hence, this exclusion could potentially impact this type of research.

#### *Health related exclusions - Article 53 (c)*

Article 53 (c) provides freedom from infringement for those conducting medical research and experimentation by excluding certain subject matter from the realm of patentability. According to this article, “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body” are not patentable. This article only excludes methods (1) of medical or veterinary treatment (2) pertaining to surgery, therapy or diagnostic methods (3)<sup>45</sup> which are “practiced on or in the human or animal body” (4).<sup>46</sup>

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<sup>38</sup> *Ibid.*, p. 20.

<sup>39</sup> *Ibid.*

<sup>40</sup> European Report, *supra* note 19 article 53 (b).

<sup>41</sup> *Ibid.*, p. 25.

<sup>42</sup> *Ibid.*, p. 26.

<sup>43</sup> *Plant Bioscience/Broccoli*, T83/05 (2007) *OJEP* 644 discussed in European Report, *supra* note 19 p. 26-27.

<sup>44</sup> European Report *supra* note 19 p. 27.

<sup>45</sup> *Ibid.*, p. 7-8.

<sup>46</sup> *Salminen/Pigs III*, T58/87 [1989] *EPOR* 125 ; *Siemens/Flow measurement* [1989] *EPOR* 241; T254/87 [1989] *OJEP* 171 discussed in European Report *supra* note 19 p. 12.

The term “surgery” may be defined as a “physical intervention on the human or animal body in which maintaining the life and health of the subject is of paramount importance.”<sup>47</sup> More precisely, surgical methods with curative purposes must be distinguished from surgical methods with non-curative purposes, such as cosmetic surgery. While the later are patentable,<sup>48</sup> the former are not.<sup>49</sup>

The term “therapy” can be defined as “the curing of a disease or malfunction of the human or animal body and includes prophylactic treatments with a view to maintaining health by preventing ill effects that would otherwise arise.”<sup>50</sup> While the exclusion of therapeutic methods may affect research and experimentation, one should note that methods of treatment to prevent pregnancies have not been considered as being within the scope of the exclusion.<sup>51</sup>

The third “method” category is composed of diagnostic methods. According to the Enlarged Board of Appeal,<sup>52</sup> a diagnostic method has 4 steps:

1. “Examination” - Data collection.
2. “Comparison” - Compare to normal values.
3. “Identification” - Identifying any significant deviation from the norm (i.e. symptoms).”
4. “Diagnosis” - The “‘deductive medical or veterinary decision phase’ where the diagnosis for curative purposes is made (which represents a purely intellectual or non-technical exercise).”<sup>53</sup> The diagnosis must be “for curative purposes *stricto sensu*.”<sup>54</sup>

It is the patenting of these four steps *together* that is forbidden. The patenting of one, two or three of these steps is not forbidden.<sup>55</sup> Thus, researchers studying or developing diagnostic tests may very well be open to an infringement action by a holder of a patent on one or a few (but not all) of these steps.

Finally, the three previously described methods must be practiced “*on or in*”<sup>56</sup> a human or animal body in order to be included in the exclusion prescribed in article 53 (c) of the *EPC*. To satisfy this last requirement, a step in the process must involve interaction with the body.<sup>57</sup> More precisely, in the case of diagnostic methods, the exclusion pertains to “steps of a technical nature,” but not to those that are “intellectual exercises.”<sup>58</sup> As for therapeutic methods, these fall within the exclusion if they are direct treatments, for instance if “there is a ‘corresponding functional link’ between the invention and human or animal health.”<sup>59</sup> Even if subject matter can be used for purposes other than those within the exclusion, it cannot be patented.<sup>60</sup> Since *in vitro* diagnostic methods are not practiced *on* the human body,<sup>61</sup> these are

<sup>47</sup> *Diagnostic methods*, G 01/04 (2006) *OJEPO* 334 (EBA) cited in European Report *supra* note 19 p. 9.

<sup>48</sup> *General Hospital Corp/Hair removal method*, T 383/03 (2005) *OJEPO* 159, discussed in European Report *supra* note 19 p. 9.

<sup>49</sup> *Diagnostic methods*, G 01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 25 p. 9.

<sup>50</sup> *Ibid.*, p. 10.

<sup>51</sup> *British Technology Group/Contraceptive Method*, T74/93 [1995] *EPOR* 279 discussed in European Report *supra* note 19 p. 10.

<sup>52</sup> *Diagnostic methods*, G01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 19 p. 11.

<sup>53</sup> European Report *supra* note 19 p. 11.

<sup>54</sup> *Ibid.*, p. 12.

<sup>55</sup> *Ibid.*, p. 11.

<sup>56</sup> *Salminen/Pigs III*, T58/87 [1989] *EPOR* 125; *Siemens/Flow measurement* [1989] *EPOR* 241; T254/87 [1989] *OJEPO* 171 discussed in European Report *supra* note 19 p. 11.

<sup>57</sup> European Report, *supra* note 19 p. 12.

<sup>58</sup> *Diagnostic methods*, G01/04 (2006) *OJEPO* 334 (EBA) discussed in European Report *supra* note 19 p. 13.

<sup>59</sup> *Ela Medical*, T789/96 [2002] *OJEPO* 364 discussed in European Report *supra* note 19 p. 13.

<sup>60</sup> European Report *supra* note 19 p. 13.

not considered as the type of diagnostic methods excluded by the EPC and thus may be patented.

### ***European Biotechnology Directive***

The *European Directive on the legal protection of biotechnological inventions* (the “*Directive*”) was adopted by the European Parliament and Council for the purpose of harmonizing the laws of Member States as they relate to the patentability of biotechnological inventions. In effect, the Directive serves to clarify the nature and scope of exclusions prescribed in the *European Patent Convention*. It has now been translated into the national law of all Member States of the European Union as well as having been adopted, as a regulation, by the member states of the EPC through the *Implementing Regulations of the European Patent Convention*.<sup>62</sup>

The patenting of biotechnological inventions is furthered by the *Directive* and the *Implementing Regulations*. They require their respective member states to protect biotechnological inventions, as long as doing so does not violate *TRIPS* and the *Convention on Biodiversity*.<sup>63</sup> Article 3 of the *Directive* allows the patenting of inventions containing or consisting of biological material. Article 5 allows the use of isolation or of a technical process as a means of patenting human biological material originating from humans. Article 8 extends the protection conferred to biological material by a patent to material derived from that original material or, in the case of a process patent, to what is produced through that process. Article 9 extends the protection of a product including genetic information to “all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.”

In addition to these provisions, the *Directive* contains certain exclusions from patentability. Article 4 reaffirms the exclusion of animal and plant varieties from the realm of patentability. Article 5(1) forbids the patenting of the human body at all stages of development. In addition, for a gene patent to satisfy the industrial application requirement, the “sequence or a partial sequence of [the] gene must be disclosed in the patent application.”<sup>64</sup> Moreover, the extension of protection by articles 8 and 9 does not extend “to biological material obtained from the propagation or multiplication of biological material,” when the biological material has been placed on the market by the patent owner, in a member state or, when the biological material is marketed for purposes of propagation or multiplication, as long as it “is not subsequently used for other propagation or multiplication.”<sup>65</sup> Finally, article 6(2) prescribes that the following shall be deemed unpatentable:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;

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<sup>61</sup> Su-hua Lee, “Patent Protection for Essential Biomedical Inventions and Its Impacts on the Implementation of Public Health” (2010) 5 *AJWH* 115; Isabelle Huys, Nele Berthels, Gert Matthijs & Geertrui Van Overwalle, “Legal Uncertainty in the Area of Genetic Diagnostic Testing” (2009) 27:10 *Nature Biotechnology* 903.

<sup>62</sup> European Report, *supra* note 19 p. 18.

<sup>63</sup> European Biotechnology Directive *supra* note 17 article 1.

<sup>64</sup> *Ibid.*, article 5(3).

<sup>65</sup> *Ibid.*, article 10.

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Since some of these processes and resulting products are used in several medical research fields including stem cell research, their exclusion from patentability thus offers European researchers with freedom from potential patent infringement as compared to researchers in countries in which they are patentable.

It is important to note that the *Directive* (and hence the *Implementing Regulation*) states that a “[process] for the production of [a plant or an animal] is essentially biological if it consists entirely of natural phenomena such as crossing or selection.”<sup>66</sup> This clarifies the exclusion of article 53(b) of the *EPC*, according to which processes that are essentially biological are not patentable. The ambiguity of the term “essentially” is discussed in the section on the *European Patent Convention* and this article clarifies the legislator’s intent.

### iii) North America

The *North American Free Trade Agreement (NAFTA)* is a multilateral agreement between Canada, Mexico and the United States that was concluded in 1994. It creates a trilateral free trade bloc and regulates different aspects of trade between them. With respect to intellectual property rights, its objective is to “provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory.”<sup>67</sup> The exclusions provided for by *NAFTA* are consistent with those in *TRIPS*.

Two optional provisions pertaining to exclusions may affect research. First, parties may implement measures in their national law to prevent abuse of intellectual property rights or anticompetitive measures.<sup>68</sup> Second, according to article 1709, member countries may exclude from patentability certain subject matter, including:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than microorganisms; and
- (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.<sup>69</sup>

However, if a member does not provide patent protection for plants, it must provide protection through a *sui generis* system.<sup>70</sup> Hence, one may conclude that *NAFTA* allows member countries to adopt certain exclusions that may provide freedom to conduct research without infringing. However, it should be noted that these exclusions are not mandatory.

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<sup>66</sup> European Biotechnology Directive *supra* note 17 article 2.

<sup>67</sup> *North American Free Trade Agreement, Canada, Mexico and the United States of America*, 17 December 1992, article 102 [NAFTA].

<sup>68</sup> *Ibid.*, article 1704.

<sup>69</sup> *Ibid.*, article 1709 (3).

<sup>70</sup> *Ibid.*, article 1709 (3).

#### iv) South America

##### **Mercosur**

Mercosur is a regional trade agreement concluded in 1991 between Argentina, Brazil, Paraguay and Uruguay by the *Treaty of Asunción* and updated in 1994 by the *Treaty of Ouro Preto*. Its goal is to integrate the economies of these four countries by facilitating the free movement of goods, people and currency.<sup>71</sup> Bolivia, Colombia, Ecuador and Peru also have associate member status. Venezuela has signed a membership agreement. However, its entry has yet to be ratified by the Paraguayan parliament. Several agreements have been concluded in connection with Mercosur,<sup>72</sup> including the *Protocol of Harmonization of Intellectual Property Norms*.<sup>73</sup> However, this protocol does not cover patents.<sup>74</sup> Rather, it covers trademarks and geographical indications.<sup>75</sup> Other agreements on intellectual property rights have been concluded, including some pertaining to plant varieties, but no explicit mention of exclusions pertaining to research has been found.<sup>76</sup>

##### **The Andean Community of Nations**

The *Andean Community of Nations* (hereinafter: “*Andean Community*”) is a trade bloc consisting of Bolivia, Colombia, Ecuador and Peru. It provides general IP rules for these countries.<sup>77</sup> Founded in 1969 by the *Cartagena Agreement*, the *Andean Community* was referred to as the *Andean Pact* until 1996.

The *Andean Agreements* (hereinafter: “*Decisions*”) of the *Andean Community* prevail over national laws.<sup>78</sup> However, national laws can provide additional protection to intellectual property in addition to that provided in the *Decisions*.<sup>79</sup> Some of these *Decisions* contain exclusions that may affect research.

A common intellectual property regime has been adopted.<sup>80</sup> As were the cases of *NAFTA* and the *European Patent Convention*, inventions deemed patentable are new, involve an inventive step and are industrially applicable<sup>81</sup>.

Article 15 of *Decision 486* negatively defines an invention by proscribing the patenting of:

- a) discoveries, scientific theories, and mathematical methods;

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<sup>71</sup> Laurenda L. Hicks & James R. Holbein, “Convergence of National Intellectual Property Norms in International Trading Agreements”, 12 Am. U. J. Int’l L. & Pol’y 769, 1997, p. 801 [Laurenda L. Hicks & James R. Holbein, “Convergence of National Intellectual Property Norms in International Trading Agreements”].

<sup>72</sup> Denis Boges Barbarosa & Karin Grau-Kuntz, *WIPO’s Study on Exclusions from Patentable Subject Matter and Exceptions and Limitation of the Rights for South America*, p. 5 [unpublished][South American Report].

<sup>73</sup> Laurenda L. Hicks & James R. Holbein, “Convergence of National Intellectual Property Norms in International Trading Agreements”, *supra* note 72 p. 812.

<sup>74</sup> *Ibid.*, p. 812.

<sup>75</sup> *Ibid.*, p. 807.

<sup>76</sup> South American Report, *supra* note 73 p. 5.

<sup>77</sup> *Ibid.*, p. 15.

<sup>78</sup> *Ibid.*

<sup>79</sup> *Decision 689*, 3 August 2008 [*Decision 689*]; *South American Report*, *supra* note 73 p. 15.

<sup>80</sup> *Decision 486 Common Intellectual Property Regime*, 14 September 2000, art. 14 [*Decision 486*].

<sup>81</sup> *Ibid.*

- b) any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;
- c) literary and artistic works or any other aesthetic creation protected by copyright;
- d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;
- e) computer programs and software, as such; and,
- f) methods for presenting information.<sup>82</sup>

Hence, a number of exclusions that provide freedom to conduct research without a license are imbedded in the very definition of “invention”.

## v) Eurasia

### **Eurasian Patent Convention**

This convention on patents was signed in 1994. Its members include the Republic of Azerbaijan, the Republic of Armenia, the Republic of Belarus, Georgia, the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Moldova, the Russian Federation, the Republic of Tajikistan and Turkmenistan<sup>83</sup>. As in previously described conventions, patentable inventions must be new, involve an inventive step and be industrially applicable<sup>84</sup>.

What may not be considered as an invention is set out in rule 3 (3):

- “— discoveries;
- scientific theories and mathematical methods;
- presentation of information;
- methods of economic organization and management;
- symbols, schedules and rules;
- methods for performing mental acts;
- algorithms and computer programs;
- topographies of integrated circuits;
- projects and plans for structures and buildings and for land development;
- solutions concerning solely the outward appearance of manufactured goods and aimed at satisfying aesthetic requirements.”

Fundamental knowledge is, therefore, precluded from being patented.

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<sup>82</sup> *Ibid.*

<sup>83</sup> Eurasian Patent Organization, available online: <http://www.eapo.org/eng/ea/about/members.html>.

<sup>84</sup> Eurasian Patent Convention, September 9 1994, art. 6.

## B. Exclusions Affecting Research

### i) Tables comparing exclusions affecting research (national level)

These tables compare exclusions impacting research in national statutory laws and case law in selected countries. The tables include the name of countries, the existence of general or specific exclusions (e.g.: one cannot patent basic scientific principles, methods of medical treatments or mathematical methods) and the effect of patentability requirements.

#### Europe

	Europe
<b>Patentability requirements</b>	<p>In the case of the <i>European Patent Convention</i>, innovations or discoveries are first required to be an invention before satisfying the other three patentability requirements. Indeed, “European patents shall be granted for any inventions [...] provided that they are new, involve an inventive step and are susceptible of industrial application” (EPC, art. 52 (1)). The European Technical Board of Appeal concurred with this view by declaring that “[a]rticle 52(1) EPC sets out four requirements to be fulfilled by a patentable invention: there must be an invention, and if there is an invention, it must satisfy the requirements of novelty, inventive step, and industrial applicability.” (Duns Licensing Associates, T 154/04 [2002] <i>OJEPO</i> 46)</p> <p>In other words, after identifying the four requirements for patentability in article 52 (1), the <i>European Patent Convention</i> identifies what does not constitute an <i>invention</i> in art. 52 (2). Hence, “discoveries, scientific theories and mathematical methods” as well as “schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers” are not invention and, incidentally, patentable. (EPC, art. 52 (2)). More precisely, even though elements listed in art. 52 (2) are not patentable <i>per se</i>, “paragraph 3 [of art. 52] actually enshrined the entitlement to patent protection for the non-inventions enumerated in paragraph 2 - albeit restricting the entitlement by excluding patentability "to the extent to which the European patent application or European patent relates to such subject matter or activities as such".”(Duns Licensing Associates, T 154/04 [2002] <i>OJEPO</i> 46) Hence, the elements of art. 52 (2) are protected only for their application to the patented subject matter or activities.</p>
<b>Specific exclusions</b>	<p><i>Article 52 (2)</i> Article 52 <i>EPC</i> excludes “discoveries, scientific theories and mathematical methods... schemes, rules and methods for performing mental acts, playing games or doing business... [and] presentations of information” from the realm of patentability (article 52 (2) <i>EPC</i>). As all of these elements may be subject to academic inquiry, their exclusion from the realm of patentability may prevent accidental infringement by researchers.</p> <p><i>Animal Varieties and Plant Varieties - Article 53 (b)</i> Plants and animals are used by researchers in different circumstances. They may be the object of research or the tools used to conduct research. The exclusion of “plant or animal varieties [...]” from subject matter eligible for patenting is of interest because it eliminates some risks of infringement for researchers. (<i>EPC</i> article 53 (b))</p> <p>Plants and animal varieties may not be protected by a patent. In the case of animal varieties, it is difficult to explain why they may not be patented. However, in the case of plants, this exclusion necessarily exists in countries that are bound by the <i>International Convention for the Protection of New Varieties of Plants</i> of 1978 or 1961.</p> <p>However, plants and animals in general are considered patentable. For more information, please see section on the <i>European Patent Convention</i>.</p> <p><i>Essentially Biological Processes- Article 53 (b)</i> Researchers studying or working with biological processes may work, in certain circumstances, without fear of infringing a biological process patent. This exclusion pertains to non microbiological (1) processes</p>

	<p>(as opposed to products) (2) for the production of animals or plants (3) that are essentially biological (4). For more information, please see section on the <i>European Patent Convention</i>.</p> <p><i>Health related exclusions - Article 53 (c)</i> Article 53 c) excludes medical or veterinary methods and experimentation. According to this article, methods (1) of medical or veterinary treatment (2) pertaining to surgery, therapy or diagnostic methods (3) “practiced on or in the human or animal body” (4) are excluded. When researchers use these methods, they cannot infringe a patent. For more information, please see the section on the <i>European Patent Convention</i>.</p> <p><i>European Biotechnology Directive</i> This directive – which only applies to certain of the member states of the EPC – clarifies some ambiguities in the <i>European Patent Convention</i>. For more information, please see the section dealing with that convention.</p>
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United Kingdom	
<b>Patentability requirements</b>	<p>The provisions of this act are based on the <i>European Patent Convention</i> and should be interpreted according to “the EPC and decisions there under.” (<i>Patents Act 1977</i> (U.K.), 1977, c. 37, s. 91 (1), 130 (7), [<i>UK Patent Act</i>]discussed in European Report, <i>supra</i> note 19, p. 4) UK courts have acknowledged this fact and the European Patent Office EPO “has occasionally reciprocated by taking notice of the decisions of national offices and courts so as to avoid the lack of uniformity in the law of the EPC countries.” (European Report <i>supra</i> note 19 p. 4.)</p> <p>“For example, Lord Justice Mustill of the England and Wales Court of Appeal observed in the judgment in <i>re Genentech Inc.'s Patent</i> [1989] R.P.C. 147, pages 262 f.: "This suggestion of a need to identify the invention leads me to a part of the case which I have found most perplexing. Most of the arguments have been concentrated on the three conditions precedent to the grant of a patent set out in paragraphs (a) to (c) of section 1(1) -- and understandably so, given the shape of the old law. But this approach tends to mask a more fundamental requirement which must be satisfied before a patent can be properly be granted, namely that the applicant has made an "invention"." (re <i>Genentech Inc.'s Patent</i> [1989] R.P.C. 147 cited in <i>Duns Licensing Associates, T 154/04 [2008] OJEPO 46</i>)</p>
<b>Specific exclusions</b>	<p>From reading the <i>UK Patents Act 1977</i>, it appears that exclusions are the same as those in the <i>European Patent Convention</i>. For exclusions of article 52 <i>EPC</i>, see s. 1 (2) <i>UK Patents Act</i>. For animal varieties and plant varieties – article 53 (b) <i>EPC</i>, see Schedule A2 s. 4 <i>UK Patents Act</i>. For health related exclusions – article 53 (c) <i>EPC</i>, see s. 4 A <i>UK Patents Act</i>.</p>

## North America

Canada	
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles:</b> Not patentable according to s. 27(8) of the <i>Patent Act</i>.</p> <p><b>Methods of medical and surgical treatment:</b> Methods of medical and surgical treatments are not patentable. As these are objects of research, this rule obviates what would otherwise be the problem of patent infringement by medical researchers. <i>Industries Ltd. v. Commissioner of Patents</i>, [1986] 3 F.C. 40 &amp; <i>Tennessee Eastman Co. v. Commissioner of Patents</i>, [1974] S.C.R. 111 discussed in Canadian Intellectual Property Office, <i>Manual of Patent Office Practice</i>, chapter 17.02.03.</p> <p><b>Biotechnology –Life Forms:</b> Biotechnological inventions can be protected through the Canadian patent system. For instance, unicellular micro-organisms and the processes to produce them are patentable. (<i>Re Application of Abitibi Co.</i> [1982], 62 C.P.R. (2d) 81) Moreover, genes are patentable because they are considered to be chemical compounds and claims covering them extend to the entire organism. (<i>Monsanto Canada Inc. v. Schmeiser</i> [2004], 1 S.C.R. 34)</p> <p>However, whole plants and animals do not constitute patentable subject-matter. This does not affect the patentability of components of whole plants or animals and does not limit the scope of claims over those components to less than the whole plant or animal. Thus, while whole plants and animals cannot be</p>

	<p>patented <i>de jure</i>, they can be patented <i>de facto</i> through claims over incorporated genes or cells. (<i>Monsanto Canada Inc. v. Schmeiser</i> [2004], 1 S.C.R. 34; <i>Harvard College v. Canada</i> (Commissioner of Patents) [2002], 4 S.C.R. 45.) Therefore, when a patent is not inserted into an animal or a plant, it cannot be covered by patent rights. In this regard, Canadian patent law ensures freedom from infringement for researchers working with non-modified plants or animal.</p> <p><b>Methods:</b> “Advances in the concepts” of non-technological fields, “[m]ethods for influencing human interactions or behaviours” and methods of avoiding or reducing income tax are not patentable. (Canadian Intellectual Property Office, <i>Manual of Patent Office Practice</i>, Chapter 12.04.02). This prevents the infringement of patents by researchers performing fundamental research.</p>
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<b>Mexico</b>	
<b>Patentability requirements</b>	Article 16 <i>Industrial Property Law of Mexico</i> says that only inventions are patentable. To see what does not constitute an invention, please see art. 19 <i>Industrial Property Law of Mexico</i> (discussed below).
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles:</b> “Theoretical or scientific principles [...] [f]indings that consist in making public or disclosing something that already existed in nature, even though it was previously unknown to man [...] [d]iagrams, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods” are not patentable (article 19 <i>Industrial Property Law of Mexico</i>). As all of these are subject to research enquiry, they may help prevent the infringement of patents by researchers.</p> <p><b>Methods of treatment:</b> “Surgical and therapeutic treatment or diagnostic methods applicable to the human body and to animals” are not patentable (article 19 <i>Industrial Property Law of Mexico</i>). Thus, the use of these elements in research cannot be prevented by a patent.</p> <p><b>Human body:</b> “The human body and the living matter constituting it” cannot be patented. This provision prevents the patenting of elements that are often subject to scientific enquiry and thereby procures some research freedom for the biomedical research community. (article 16 <i>Industrial Property Law of Mexico</i>)</p> <p><b>Biotechnology:</b> “Biological and genetic material as found in nature” are not patentable. This provision also prevents the patenting of elements often subject to scientific enquiry may affect research. This includes naturally occurring DNA and proteins (article 16 <i>Industrial Property Law of Mexico</i>).</p> <p><b>Life Forms:</b> Animal breeds &amp; plant varieties are not patentable. Plant varieties are, however, protected by the <i>Federal Law on Plant Varieties</i> which has an experimental exemption stipulating that protected plant varieties used “as source or research material for the genetic improvement of other plant varieties” do not constitute infringement (article 5 <i>Federal Law on Plant Varieties</i>).</p>

<b>United States</b>	
<b>Patentability requirements</b>	<p>Much fundamental knowledge has always been considered as not patentable inventions but the distinction between fundamental knowledge and applied knowledge is not always clear as the following cases illustrate:</p> <p><i>Mackay v. Radio Corp.</i>, 306 U.S. 86 (1939): “While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”</p> <p><i>Gottschalk v. Benson</i>, 409 U.S. 63 (1972): “Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. As we stated in <i>Funk Bros. Seed Co. v. Kalo Co.</i>, 333 U.S. 127, 130, “He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”</p> <p><i>Bilski v. Kappos</i>, 561 U. S. ____ (2010): “The Court’s precedents provide three specific exceptions to §101’s broad patent-eligibility principles: “laws of nature, physical phenomena, and abstract ideas.” ... While these exceptions are not required by the statutory text, they are consistent with the notion that a</p>

	<p>patentable process must be “new and useful.”</p> <p>In addition, much fundamental knowledge cannot be patented because of the difficulty in fulfilling the separate description requirement of 35 U.S.C. 112. Indeed, as described in <i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i>, 598 F. 3d 1336 (C.A. Fed., 2010), “[t]he written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function – a problem that is particularly acute in the biological arts. [...] Ariad complains that the doctrine [(for a separate description requirement)] disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the “useful Arts,” U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, <i>see Brenner v. Manson</i>, 383 U.S. 519, 532-36, 86 S. Ct. 1033, 16 L. Ed. 2d 69, 1966 Dec. Comm’r Pat. 74 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, <i>see, e.g., Rochester</i>, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, <i>i.e.</i>, finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law’s interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. ‘[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’ ... Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of “invention”--that is, conceive of the complete and final invention with all its claimed limitations--and disclose the fruits of that effort to the public.”</p>
<p><b>Specific exclusions</b></p>	<p><b>Biotechnology:</b> Genes and microorganisms are patentable as long as they possess utility (<i>Diamond v. Chakrabarty</i>, 447 U.S. 303 (1980), <i>In re Fisher</i>, No. 04-1465 (Fed.Cir. September 7, 2005)), unless they were obvious to try (<i>In Re Kubin No. 09-667,859</i> (Fed. Cir. April 3, 2009)). However, in <i>Association for Molecular Pathology et al. v. United States Patent and Trademark et al.</i>, the District Court for the Southern District of New York held that isolated human genes were not patentable subject matter since they were phenomena of nature. In arriving at this decision, the Court held that genes have both a physical and informational quality: “DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature . . . [its] existence in an ‘isolated’ form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.” The District Court’s decision could be overturned on appeal to the United States Court of Appeals for the Federal Circuit.</p> <p><b>Life Forms:</b> The United States Patent and Trademark Office (USPTO) “now consider[s] non-naturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101”: United States Patent and Trademark Office, <i>Manual of Patent Application Procedure</i>, s. 2105.</p>

### South America

	<p><b>Argentina</b></p>
<p><b>Patentability requirements</b></p>	<p><b>Patentability:</b> Inventions relating to products or processes shall be patentable provided that they are new, involve an inventive step and are susceptible of industrial application. (article 4, <i>Law 24.481</i>).</p> <p>What is not considered to be an <i>invention</i>: See specific exclusions of article 6, <i>Law 24.481</i>.</p>
<p><b>Specific exclusions</b></p>	<p><b>Theoretical/Scientific principles:</b> Argentina’s patent law does not consider “discoveries, scientific theories and mathematical methods” to be patentable (article 6, <i>Law 24.481</i>).</p> <p><b>Scientific literature:</b> Argentina’s patent law does not consider “scientific works” to be patentable (article 6, <i>Law 24.481</i>).</p> <p><b>Intellectual activities – Data presentation:</b> Argentina’s patent law does not consider “schemes, rules or methods for performing intellectual activities, playing games or engaging in economic and business activities; [...] forms of data presentation” to be patentable (article 6, <i>Law 24.481</i>).</p> <p><b>Methods of treatment:</b> Argentina’s patent law does not consider “methods of surgical, therapeutic or diagnostic treatment applicable to the human body or to animals” to be patentable (article 6, <i>Law 24.481</i>).</p>

	<p><b>Living material:</b> Argentina’s patent law does not consider “any kind of live material or substances already existing in nature” to be patentable (article 6, <i>Law 24.481</i>).</p> <p><b>Biological processes:</b> Argentina’s patent law does not consider “biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature,” to be patentable (article 7, <i>Law 24.481</i>).</p>
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	<b>Brazil</b>
<b>Patentability requirements</b>	<p><b>Patentability:</b> “An invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application.” (article 8 of <i>Brazilian Industrial Property Law</i>).</p> <p>What is not considered to be an <i>invention</i>: see specific exclusions (art. 10 of <i>Brazilian Industrial Property Law</i>).</p>
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles:</b> According to Brazilian law, “discoveries, scientific theories, and mathematical methods” are not patentable (article 10 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Scientific literature:</b> According to Brazilian law, “scientific works” are not patentable (article 10 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Intellectual activities:</b> According to Brazilian law, “purely abstract conceptions [...] [,] commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods [...] [,] presentation of information [...] [,] rules of games” are not patentable (article 10 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Methods of treatment:</b> According to Brazilian law, “surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body” are not patentable (article 10 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Living material - Biological processes:</b> According to Brazilian law, “all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes” are not patentable (article 10 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Atomic nucleus:</b> According to Brazilian law, “substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical- chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus” are not patentable (article 18 of <i>Brazilian Industrial Property Law</i>).</p> <p><b>Life forms:</b> According to Brazilian law, “all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability” are not patentable (article 18 of <i>Brazilian Industrial Property Law</i>).</p> <p>“For the purposes of this Law, transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions.” (article 18 of <i>Brazilian Industrial Property Law</i>).</p>

	<b>Chile</b>
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles:</b> According to article 37 of <i>Law N° 19.039</i>, “discoveries or other abstract knowledge” are not patentable (South American Report, <i>supra</i> note 72, p. 22).</p> <p><b>Intellectual activities:</b> According to article 37 of <i>Law N° 19.039</i>, “useful but non-technical creations as business methods and rules of games” are not patentable (South American Report, <i>supra</i> note 72, p. 22).</p> <p><b>Methods of treatment:</b> According to article 37 of <i>Law N° 19.039</i>, “surgical, diagnostic or therapeutic methods and for human or animal body” are not patentable (South American Report, <i>supra</i> note 72 p. 22). However, this does not include “products intended to implement those methods,” which are patentable (South American Report, <i>supra</i> note 72 p. 23).</p> <p><b>Living material - Biological processes – Life forms:</b> According to article 37 of <i>Law N° 19.039</i>, “plants and animals and essentially biological processes for the production of plants and animal [...] [,] parts of living beings as found in nature, natural biological processes and biological material found in nature even though isolated therefrom, including genome or germoplasm” are not patentable (South American Report, <i>supra</i> note 72 p. 22 – 23).</p> <p><b>Juxtaposition - New uses for known products:</b> According to article 37 of <i>Law N° 19.039</i>, “the new applications or formal changes introduced in known products” are not patentable (South American Report, <i>supra</i> note 72 p. 23). However, if a “new application of a known product solves a technical problem not hitherto solved on a (sic) equivalent manner, and furthermore, it is required to proceed formal changes or changes in material of the known product to solve such technical problem,” then it is patentable. (South American Report, <i>supra</i> note 72 p. 23).</p>

	<b>Andean Community</b>
<b>Patentability requirements</b>	<p>This regime applies to Bolivia, Colombia, Ecuador and Peru.</p> <p><b>Patentability:</b> The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable (<i>Decision 486</i> art. 14 ).</p> <p>For what does not constitute an <i>invention</i>, please see art. 15 (specific exclusions).</p>
<b>Specific exclusions</b>	<p>Article 15 of <i>Decision 486</i> defines what an invention is.</p> <p><b>Theoretical/Scientific principles:</b> According to article 15 of <i>Decision 486</i> “discoveries, scientific theories, and mathematical methods” are not patentable.</p> <p><b>Intellectual activities – Data presentation:</b> According to article 15 of <i>Decision 486</i> “plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities [...] [ and] methods for presenting information ” are not patentable.</p> <p><b>Living material - Biological processes - Life form:</b> According to article 15 of <i>Decision 486</i> “[a]ny living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing” are not patentable.</p> <p><b>Juxtaposition and method of treatment:</b> “Plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes [,] diagnostic, therapeutic, and surgical methods for the treatment of humans or animals” (<i>Decision 486</i> article 20) and new uses of already existing inventions cannot be patented (<i>Decision 486</i> article 21).</p> <p><b>Bolivia:</b> Bolivia forbids the patenting of “chemical products or pharmaceutical or therapeutic compositions” (South American Report, <i>supra</i> note 72p. 20). However, if we take into account <i>Decision 486</i>, this exclusion does not seem to be in effect. (South American Report, <i>supra</i> note 72, p. 20).</p>

Asia

	China
Specific exclusions	<p><b>Theoretical/Scientific principles:</b> According to article 25 (<i>Patent Law</i>), “scientific discoveries” are not patentable.</p> <p><b>Intellectual activities:</b> According to article 25 (<i>Patent Law</i>), “rules and methods for mental activities” are not patentable.</p> <p><b>Methods of treatment:</b> According to article 25 (<i>Patent Law</i>), “methods for the diagnosis or for the treatment of diseases” are not patentable.</p> <p><b>Life form:</b> According to article 25 (<i>Patent Law</i>), “animal and plant varieties” are not patentable. However, processes producing animal and plant varieties are patentable.</p>

	India
Patentability requirements	<p>“(j) “invention” means any new and useful—            (i) art, process, method or manner of manufacture;            (ii) machine, apparatus or other article;            (iii) substance produced by manufacture” s. 2 Patent Act</p> <p>For what does not constitute an invention, please see specific exclusions hereunder.</p>
Specific exclusions	<p><b>Theoretical/Scientific principles:</b> According to s. 3(c) (<i>Patent Act</i>), “the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature” is not patentable.</p> <p><b>Known substance with new properties:</b> S. 3(d) (<i>Patent Act</i>): “[T]he mere discovery of a new form of a substance which does not result in the enhancement of a known efficacy of that substance or the mere discovery of a new property or new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [are not patentable]. Explanation: For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”</p> <p>S. 3(e) (<i>Patent Act</i>): “[A] substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance” is not patentable.</p> <p>These paragraphs set minimal standards for the novelty criteria when an invention pertains to known substances.</p> <p><b>Methods for Agriculture:</b> S. 3(g) (<i>Patent Act</i>): “A method of agriculture or horticulture” is not patentable.</p> <p><b>Intellectual activities:</b> S. 3(j,l,m) (<i>Patent Act</i>): “[A] mathematical or business method or a computer program per se or algorithms [...] a mere scheme or rule or method of performing mental act or method of playing game[...] a presentation of information” are all unpatentable.</p> <p><b>Method of Treatment:</b> S. 3(h) (<i>Patent Act</i>): “[A]ny process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products” are not unpatentable.</p> <p><b>Living material - Biological processes - Life form:</b> S. 3(i) (<i>Patent Act</i>): “[P]lants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals” are not patentable.</p>

<b>Indonesia</b>	
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles - Intellectual activities:</b> According to article 7 (c) <i>Law on Patents</i>, “any theory and method in the field of science and mathematics” is not patentable.</p> <p><b>Method of Treatment:</b> According to article 7 (b) <i>Law on Patents</i>, “any method of examination, treatment, medication, and/or surgery applied to humans and/or animals” is not patentable.</p> <p><b>Biological processes - Life form:</b> According to article 7 (d) <i>Law on Patents</i>, “all living creatures, except micro-organism [...] any biological process which is essential in producing plant or animal, except non-biological process or microbiological process” are not patentable.</p>

<b>Japan</b>	
<b>Patentability requirements</b>	<p><b>Patentability:</b> ““Inventions” in this Law means the highly advanced creation of technical ideas utilizing the laws of nature.” Art. 2 Japan Patent Act. According to art. 29 Japan Patent Act, only an invention may be patented.</p> <p>As explained in the <i>Examination Guidelines for Patent and Utility Model in Japan</i> – Japan Patent Office - Part II – Chapter 1, the legal wording used in article 2 of the Japan Patent Act implicitly excludes the patenting of laws of nature, mere discoveries, non technical ideas, solutions of problems impossible to solve, innovations that do not rely on the laws of nature and innovations that are contrary to the laws of nature. Hence, fundamental knowledge is not patentable according to art. 2 of the Japan Patent Act.</p>
<b>Specific exclusions</b>	None

<b>Pakistan</b>	
<b>Patentability requirements</b>	<p>An invention is defined as “any new and useful product, including chemical products, art, process, method or manner of manufacture machine, apparatus or other article; substances or article or product produced by a manufacture and includes any new and useful improvement of any of them and an alleged invention.” Article 2 , <i>Patents Ordinance</i>.</p> <p>What shall be deemed not being an <i>invention</i> is prescribed at art. 7 of the <i>Patent Ordinance</i>.</p>
<b>Specific exclusions</b>	<p><b>Theoretical/Scientific principles:</b> According to article 7 (2) (a) <i>Patents Ordinance</i>, “a discovery, scientific theory or mathematical method” is not patentable.</p> <p><b>Intellectual activities:</b> According to article 7 (2) (c) &amp; (d) <i>Patents Ordinance</i>, “a scheme, rule or method for performing a mental act, playing a game or doing business [...] [or a] presentation of information” is not patentable.</p> <p><b>Method of Treatment:</b> A patent may not be granted “for diagnostic therapeutic and surgical methods for the treatment of humans or animals” (article 7(4)(a) <i>Patents Ordinance</i>).</p> <p><b>Living material - Biological processes - Life form:</b> A patent may not be granted “for animals or plants other than micro-organisms and essentially biological process for the production of animals or plants, but this prohibition shall not apply to microbiological processes or products of such processes” (article 7 (4) (b) <i>Patents Ordinance</i>).</p>

	Republic of Korea
Patentability requirements	<p><b>Patentability:</b> “The definitions of terms used in this Act are as follows: (i) "invention" means the highly advanced creation of a technical idea using the rules of nature”. Art. 2, <i>Patent Act of The Republic of Korea</i>. According to article 29, only an invention may be patentable.</p> <p>Elements that are considered as a inventions because of article 2 of the <i>Patent Act</i> comprise laws of nature, mere discoveries, innovations contrary to the laws of nature, innovations that do not use laws of nature, personal skills, information presentation, aesthetic creations, incomplete inventions, etc. (Korean Intellectual Property Office, <i>Requirements for patentability</i>, January 2010, p. 2 – 4).</p>
Specific exclusions	None

## ii) Common Aspects and Distinctions

This section will identify the commonalities and trends in national patent laws pertaining to exclusions having an effect on research. The commonalities, distinctions and policy underpinnings of specific exclusions will be described first, followed by an analysis on patentability requirements.

### *Specific exclusions*

Most jurisdictions have carved out specific exclusions from patentable subject matter. This section will discuss the effect that specific exclusions may have on scientific research.

**I. Fundamental/Scientific principles:** In most countries, scientific and fundamental principles, along with laws of nature, are explicitly excluded from patentability. This is the case for members of the *European Patent Convention*, Canada, Mexico, Argentina, Brazil, Chile, members of the Andean Community, India, Indonesia and Pakistan.<sup>85</sup> However, the United States, Japan and Korea have not enshrined this exclusion in an explicit provision although case law in the United States supports this exclusion.

**II. Scientific literature:** The specific exclusion for scientific literature, present in Argentina and Brazil,<sup>86</sup> is a logical consequence of the exclusion of fundamental and scientific principles.

<sup>85</sup> EPC 2000, *supra* note 16, art. 52 (2); Patent Act, s. 27 (8); Industrial Property Law of Mexico, article 19 ; Law 24.481 of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Law of the People’s Republic of China, article 25; Patent Act of India, s. (3)(d); Law on Patents of Indonesia, article 7 c); Patents Ordinance No. LXI, s. 7(2) a) (Pakistan).

<sup>86</sup> Law 24.481 of Argentina, article 6 ; Brazilian Industrial Property Law, article 10.

**III. Intellectual Activities:** Abstract concepts, intellectual activities, game playing are not patentable in many countries.<sup>87</sup>

These three types of provisions (I., II. and III.) exclude fundamental knowledge from patentability.

**IV. Methods of medical and surgical treatment:** the vast majority of countries have an exception for methods of medical and surgical treatment.<sup>88</sup> Countries that do not have similar exclusion are the United-States, Japan and the Republic of Korea.

The United States provides medical practitioners and their institutions with immunity from patent infringement in “the performance of a medical or surgical procedure on a body.”<sup>89</sup> This immunity does not apply, however, with respect to “(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.”<sup>90</sup>

In Korea, methods of medical and surgical treatment are considered *not* to be industrially applicable,<sup>91</sup> except if their application is limited to animals.<sup>92</sup> In the case of Japan, methods of medical and surgical treatment are also considered *not* to be industrially applicable.<sup>93</sup>

Finally, the purpose of this exclusion varies amongst jurisdictions. Some countries may have created this exclusion in order to “ensure that people who carry out medical or veterinary treatments are not inhibited by patents.”<sup>94</sup> For other countries, the justification may be public order.<sup>95</sup>

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<sup>87</sup> Canadian Intellectual Property Office, Manual of Patent Office Practice, Chapter 12.04.02.; Law 24.481 of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Act of India, s. (3)(j,l,m).

<sup>88</sup> EPC 2000, *supra* note 16 art. 53 (c); *Industries Ltd. v. Commissioner of Patents*, [1986] 3 F.C. 40 & *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111 discussed in Canadian Intellectual Property Office, *Manual of Patent Office Practice*, Chapter 17.02.03; Industrial Property Law of Mexico, article 19; Law 24.481 of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 20; Patent Law of the People’s Republic of China, article 25; Patent Act of India, s. (3)(h); Law on Patents of Indonesia, article 7 b); Patents Ordinance No. LXI, s. 7(4) a) (Pakistan).

<sup>89</sup> 35 U.S.C. § 287 (c).

<sup>90</sup> *Ibid.*

<sup>91</sup> Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p.7.

<sup>92</sup> Case No. 90Huh250 (Supreme Court, 12 Mar. 1991) cited in Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p.7.

<sup>93</sup> Japan Patent Office, *Examination Guidelines for Patent and Utility Model in Japan – Part II – Chapter 1 – 2.2.1.*

<sup>94</sup> *Wellcome/Pigs I*, T116/85 [1989] EPOR 1; [1989] OJEPO 13; *Telectronics/Pacer*, T82/93 [1996] EPOR 409; *See-Shell/Blood flow*, T182/90 [1994] EPOR 32 discussed in European Report, *supra* note 19 p. 7.

<sup>95</sup> Law 17.164 of Uruguay, article 14.

V. Biotechnology: In some jurisdictions, life forms and/or genome (or genes), as found in nature, are not patentable.<sup>96</sup> Brazil and Chile even explicitly reject the doctrine of isolation, according to which isolated or purified products of nature are patentable.<sup>97</sup> Also, most jurisdictions exclude essentially and /or natural biological processes, for the production of plants or animals, from patentability.<sup>98</sup>

VI. Life forms: In some jurisdictions, only plant and animal varieties are not patentable (ex: the patenting of a specific breed of mice would not be acceptable; however, the patenting of transgenic rodents would),<sup>99</sup> while in other jurisdictions, plants and animals are not patentable in all cases (e.g. varieties or not).<sup>100</sup> For the former, the exclusion of plant varieties clearly allows these countries to respect the *International Convention for the Protection of New Varieties of Plants* of 1978 or 1971.

Although the last three categories (IV., V., VI) of exclusions were initially conceived to protect medical practitioners in their practice (e.g. a doctor performing a diagnostic test on a patient) or to reflect the moral values of a particular society (e.g. patenting life forms is sometimes seen as a slippery slope that could lead to the exploitation of human beings<sup>101</sup>), they can sometimes be invoked on behalf of biomedical researchers. From this perspective, it is obvious that such exclusions have an impact on research.

### ***General exclusions resulting from patentability requirements***

This section will only study patentability requirements which have an effect on research. Some requirements, such as the novelty and non-obviousness requirements, affect research by making what is known available<sup>102</sup>. However, because these requirements do not constitute exclusions *per se*, they will not be analyzed.

<sup>96</sup> Industrial Property Law of Mexico, article 16; Law 24.481 of Argentina, article 6; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15.

<sup>97</sup> Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37.

<sup>98</sup> EPC 2000, 53 (b); Law 24.481 of Argentina; Brazilian Industrial Property Law, article 10; Law N° 19.039 of Chile, article 37; Decision 486, article 15; Patent Act of India, s. (3)(i); Law on Patents of Indonesia, article 7 d); Patents Ordinance No. LXI, s. 7(4) b) (Pakistan)

<sup>99</sup> EPC 2000, 53 (b); Federal Law on Plant Varieties of Mexico, article 5.

<sup>100</sup> Brazilian Industrial Property Law, article 18; Law N° 19.039 of Chile, article 37; Decision 486, *supra* article 15; Patent Act of India, s. (3)(i); Law on Patents of Indonesia, article 7 d); Patents Ordinance No. LXI, s. 7(4) b) (Pakistan)

<sup>101</sup> David B. Resnik, "The Morality of Human Gene Patents" (1997) Kennedy Institute of Ethics Journal 7.1.

<sup>102</sup> A concept of interest is grace periods, as these affect research. A grace period for the disclosure of the invention may be described in the following way: "[t]he inventor is granted a specified period during which he does not prejudice his case by organizing realistic experiments, discussing the inventions with others, etc." (Oppenheim, *infra* note 215 p.184). An invention may voluntarily or inadvertently be disclosed by a person entitled to file a patent or an individual that has obtained, legally or not, information from that person. Some jurisdictions have a narrow grace period. For example, members of the *European Patent Convention* only grant a grace period in case of abuse of a relationship with the applicant (1) or in case of a presentation in an officially recognized exhibition (2). (EPC 2000, *supra* note 16 article 55) Some jurisdictions have a broader grace period. These jurisdictions allow inventors to disclose their invention up to 12 months before an application (Canada, Mexico, the United States, Argentina and Brazil)

As grace periods accelerate the disclosure of information, disclosure in turn accelerates aggregate innovation. (Suzanne Scotchmer, "Cumulative Research and the Patent Law", (1991) 5:1 The Journal of Economic Perspectives 29 ) For this reason, firms may be tempted to prevent disclosure, as the effort of inventing around the patent will be less demanding. Indeed, "[p]atent law requires disclosure for the same reason that innovators dislike it: it is the vehicle by which technical knowledge is passed from the patenting firm to its competitors." (Suzanne Scotchmer, "Cumulative Research and the Patent Law", (1991) 5:1 The Journal of Economic Perspectives 29 ) To the contrary, researchers in universities are encouraged to publish. While they may not publish everything, the

### *Defining what is an invention*

The patentability requirement which has the most impact on research is that an innovation must be deemed an “invention” within the meaning of the national patent law. This may be explained by the fact that most countries require patentable subject matter to be inventions, and specify that fundamental knowledge cannot be described as an invention. While this is done through explicit provisions in most countries, others exclude fundamental knowledge from the concept of invention through interpretation. Finally, some countries simply exclude fundamental knowledge from patentability without referring to what an invention is.

Many examples may be given to illustrate the general rule according to which most countries require patentable subject matter to be inventions and specify that fundamental knowledge cannot be described as an invention. In the case of the *European Patent Convention*, innovations or discoveries are first required to be an invention before satisfying the other three patentability requirements. Indeed, “European patents shall be granted for any inventions [...] provided that they are new, involve an inventive step and are susceptible of industrial application”<sup>103</sup>. The European Technical Board of Appeal concurred with this view by declaring that “[a]rticle 52(1) EPC sets out four requirements to be fulfilled by a patentable invention: there must be an invention, and if there is an invention, it must satisfy the requirements of novelty, inventive step, and industrial applicability.”<sup>104</sup>

After identifying the four requirements for patentability in article 52 (1), the *EPC* identifies what does not constitute an “invention” in art. 52 (2). Hence, “discoveries, scientific theories and mathematical methods” as well as “schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers” are not invention and, incidentally, patentable.<sup>105</sup> More precisely, even though elements listed in art. 52 (2) are not patentable *per se*, “paragraph 3 [of art. 52] actually enshrined the entitlement to patent protection for the non-inventions enumerated in paragraph 2 - albeit restricting the entitlement by excluding patentability ‘to the extent to which the European patent application or European patent relates to such subject matter or activities as such’.”<sup>106</sup> Hence, the elements of art. 52 (2) are protected only for their application to the patented subject matter or activities. Most other countries also exclude fundamental knowledge by first requiring innovations to be inventions<sup>107</sup> subsequently prescribing fundamental knowledge as not being an invention<sup>108</sup>.

There are some exceptions to this general rule. In some jurisdictions the exclusion of fundamental knowledge is implicit rather than explicit. In Korea and Japan, the term invention

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primary basis for promotion, tenure and research funding, for academic researchers is publishing (John A. Tessensohn & Shusaku Yamamoto, “Japan’s Novelty Grace Period Solves the Dilemma of ‘Publish and Perish’”, (2007) 25:1 *Nature Biotechnology* 55). Therefore, the most prominent effect of grace periods is to allow university researchers to use the patent regime, without impeding academic activities and disclosure of research results. This may explain why HUGO advocates the adoption of a grace period. (HUGO Intellectual Property Committee, Statement on Patenting Issued Related to Early Release of Raw Sequence Data, May 1997.)

<sup>103</sup> EPC 2000, article 52 (1).

<sup>104</sup> Duns Licensing Associates, T 154/04 [2008] *OJEPO* 46

<sup>105</sup> EPC 2000, article 52 (2).

<sup>106</sup> Duns Licensing Associates, T 154/04 [2008] *OJEPO* 46

<sup>107</sup> Industrial Property Law of Mexico, article 16; Law 24.481 of Argentina, art. 4; Brazilian Industrial Property Law, article 8; Decision 486, article 14; Patent Act of India, s. 2; Patents Ordinance No. LXI, s. 2 (Pakistan).

<sup>108</sup> Industrial Property Law of Mexico, article 19; Law 24.481 of Argentina, art. 6; Brazilian Industrial Property Law, article 10; Decision 486, article 15; Patent Act of India, s. 3; Patents Ordinance No. LXI, s. 7 (Pakistan).

refers to a “highly advanced creation of technical ideas utilizing the laws of nature.”<sup>109</sup> In both cases, this definition is understood to exclude the patenting of laws of nature, mere discoveries, non technical ideas, solutions of problems impossible to solve, innovations that do not rely on the laws of nature and innovations that are contrary to the laws of nature.<sup>110</sup>

Finally, some exclude the patenting of fundamental knowledge without referring to the definition of invention. Case law from the United-States precludes the patenting of fundamental knowledge.<sup>111</sup> In Canada, China and Indonesia, however, the patenting of fundamental knowledge is precluded by statutory provisions<sup>112</sup>.

#### *Description requirement*

In a noteworthy case, the United States Court of Appeals for the Federal Circuit stated as follows:

The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function – a problem that is particularly acute in the biological arts. [...] We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. *Id.* at 927-28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in *Eli Lilly and Ariad's* claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries - leaving it to the pharmaceutical industry to complete an unfinished invention. [...] [P]atent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, see *Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S. Ct. 1033, 16 L. Ed. 2d 69, 1966 Dec. Comm'r Pat. 74 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, see, e.g., *Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, *i.e.*, finding and identifying compounds able to affect the mechanism discovered. [...] Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"-that is, conceive of the complete and final invention with all its claimed limitations-and disclose the fruits of that effort to the public.<sup>113</sup>

According to this case, it seems that description requirements also provide a limitation on the patentability of fundamental knowledge. Indeed, patent criteria are closely linked to the description requirements in national patent laws. Abstract ideas are, by their nature, more

<sup>109</sup> Japan Patent Act, article 2.

<sup>110</sup> As explained in the *Examination Guidelines for Patent and Utility Model in Japan* – Japan Patent Office - Part II – Chapter 1; Korean Intellectual Property Office, *Requirements for patentability*, January 2010, p. 2 – 4.

<sup>111</sup> *Mackay v. Radio Corp.*, 306 U.S. 86 (1939); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Bilski v. Kappos*, 95 U.S.P.Q.2D (BNA) 1001 (U.S.C., 2010); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010).

<sup>112</sup> *Patent Act of Canada*, s. 27 (8); Patent Law of the People’s Republic of China, article 25; Law on Patents, art. 7 (Indonesia).

<sup>113</sup> *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (C.A. Fed., 2010)

difficult to describe in a manner that another person skilled in the art will be able to identify and reproduce it based on the disclosure given in the patent application.

### III. Exceptions to Patentee's Rights Affecting Research

This part of the chapter will discuss how exceptions to patentability may affect research. Exceptions that affect research may originate from national or international rules. This section will discuss the international legal framework to which countries adhere (**Part A**), as well as national regimes (**Part B**).

#### A. International Legal Framework

This part will focus on exceptions to patent rights that impact research and development in international legal texts. After having discussed the international framework (**i**), regional agreements will be studied in order to better understand the obligations countries can have pertaining to exceptions a research and the origin of these exceptions (**ii** to **v**).

##### i) Global Legal Framework

Only one general international treaty has provisions containing exceptions that have an effect on research: The *Trade Related Aspect of Intellectual Property Rights Agreement (TRIPS)*.

#### TRIPS

*TRIPS* introduced previously in the section on exclusions, has two provisions which allow the adoption of research exceptions in party states. The general provision is article 30, according to which exceptions to a patentee's rights may be created, provided they "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."<sup>114</sup>

This provision was interpreted in a panel decision on patent protection for pharmaceutical products.<sup>115</sup> Following a complaint by the European Community, provisions in Canada's *Patent Act* pertaining to a stockpiling exception (allowing the manufacture of a pharmaceutical compound before the expiry of a patent in order to distribute that product immediately following the end of the patent's exclusionary period) and for research pursued in order to comply with regulatory requirement.<sup>116</sup> The panel held that three conditions must be fulfilled in order for an exception to be valid. First, it must be limited to the point where it diminishes the rights it question in only minor respects. Second, an "exception must not unreasonably conflict with the normal exploitation" of patents.<sup>117</sup> Finally, an "exception must not unreasonably prejudice the legitimate interests of the patent owner, taking into account interests of third parties."<sup>118</sup> More precisely, legitimate interests are not equivalent to legal interests.<sup>119</sup>

<sup>114</sup> TRIPS, *supra* note 8 art. 30.

<sup>115</sup> *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R, Panel Report, discussed in Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005.

<sup>116</sup> *Ibid.*

<sup>117</sup> *Ibid.*

<sup>118</sup> *Ibid.*

While allowing the adoption of some exceptions, article 30 must also be read in light of article 27(1) according to which the “discrimination as to the place of invention, the field of technology and whether products are imported or locally produced” is proscribed.<sup>120</sup> In other words, an exception cannot discriminate against a specific field of technology. However, this provision does not require the same treatment for all fields of innovation, as the word ‘discrimination’ was purposely used to communicate that legitimate differentiation can take place (e.g. pricing controls, exclusions, exceptions, etc.) as long it is reasonable. This also applies to article 31 of *TRIPS*.<sup>121</sup>

Article 31 enumerates a series of conditions that compulsory licenses should meet in order to be valid under *TRIPS*.<sup>122</sup> Article 31 does not, however, set out the reasons for a compulsory license. So, in theory, it could be used to grant a license to conduct certain types of research that would otherwise constitute infringement provided that the process and terms of that license complied with that article.

Finally, article 6 of *TRIPS* specifies that provisions in the agreement do not extend to exhaustion of rights (except for articles 3 and 4 that deal with discrimination based on citizenship).<sup>123</sup> This means that member countries do not have any obligation pertaining to parallel imports. Researchers, in jurisdictions that allow parallel importing could, therefore, have access to less costly patented products than those in other jurisdictions.

Now that the common international framework for exceptions has been outlined in sub-part **i)**, sub-parts **ii)** to **iv)** will focus on regional agreements pertaining to Europe, North America, South America and Eurasia.

## **ii) Europe**

### ***European Biotechnology Directive***

The *European Biotechnology Directive* prescribes some rules concerning exceptions. The extension of protection by articles 8 and 9 do not extend “to biological material obtained from the propagation or multiplication of biological material,” when the biological material has been placed on the market by the patent owner, in a member state (1) or, when the biological material is marketed for purposes of propagation or multiplication, as long as it “is not subsequently used for other propagation or multiplication” (2).<sup>124</sup> These exceptions are more relevant for farmers than for researchers. However, they may still be useful to the latter. Indeed, as researchers may use patented cell lines, this exception protects them against infringing a patented cell line by using it for the purposes for which it is sold.

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<sup>119</sup> *Ibid.*

<sup>120</sup> *TRIPS*, *supra* note 8 art. 27. Legitimate differentiation can still take place

<sup>121</sup> Kevin J. Nowak, “Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27”, *supra* note 7 at p. 911.

<sup>122</sup> Sara M. Ford, “Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents”, (1999-2000) 15 *Am. U. Int’l L. Rev.* 941, p.959 [Sara M. Ford, “Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents”].

<sup>123</sup> Amit Gupta, “Patent Rights on Pharmaceutical Products and Affordable Drugs : Can Trips Provide a Solution?”, (2003-2004) 2 *Buff. Intell. Pro. L. J.* 127.

<sup>124</sup> *European Biotechnology Directive supra* note 16 art. 10.

### ***Directive 2004/27/EC***

This directive was passed to impose common European standards relating to the registration of generic products. It introduces new time periods for data exclusivity, introduces a new definition of a generic product, and contains “*Bolar*” provisions. According to article 1 (8) of the *Directive*: “Conducting the necessary studies and trials with a view to [satisfying the abbreviated regulatory approval process for generic medicines] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.”<sup>125</sup>

### ***The Community Patent Convention***

This convention was concluded in 1975 between 9 member states of the European Union to allow individuals and companies to obtain a unitary patent throughout the European Union. The *Community Patent Convention* prescribes an exception for experimental use.<sup>126</sup> According to this provision, “[t]he rights conferred by a Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention.”<sup>127</sup> However, the *Convention* never entered into force since it was not ratified by a sufficient number of Member States.

## **iii) North America**

### ***North America Free Trade Agreement (NAFTA)***

Two *NAFTA* provisions pertaining to exceptions may apply to those conducting research. First, parties may implement measures in their national law to prevent abuse of intellectual property rights or anticompetitive measures.<sup>128</sup> Member countries may also prescribe limited exceptions to patent rights.<sup>129</sup> However, these exceptions must not “unreasonably conflict with a normal exploitation of the patent”<sup>130</sup> and must not unreasonably interfere with the legitimate interests of a patent owner.<sup>131</sup> No international jurisprudence on these matters has been found to further delineate the potential scope of exceptions, yet it is certain that such exceptions are optional under *NAFTA*.

## **iv) South America**

### **The Andean Pact**

Article 53 of the *Pact* limits the scope of patent rights and stipulates that a patent owner cannot forbid:

- a) acts carried out in a private circle and for non-commercial purposes;
- b) acts carried out exclusively to experiment with the subject matter of the patented invention;
- c) acts carried out exclusively for the purposes of teaching or scientific or academic research; [...]<sup>132</sup>

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<sup>125</sup> Directive 2004/27/EC, art. 1 8), cited in Sean O’Connor, “Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries”, Research Roundtable: Law & Economics of Innovation, 2008.

<sup>126</sup> European Report *supra* note 19 p. 39.

<sup>127</sup> Community Patent Convention cited by European Report, *supra* note 19 p. 41.

<sup>128</sup> NAFTA, *supra* note 67 art. 1704.

<sup>129</sup> *Ibid.*, art. 1709 (6).

<sup>130</sup> *Ibid.*

<sup>131</sup> *Ibid.*

<sup>132</sup> Decision 486, *supra* note 81 art. 53.

Paragraphs a), b) and c) serve, *prima facie*, to lower the risks of infringement by researchers.

**v) Eurasia**

**Eurasian Patent Convention**

This convention has provisions that have an impact on research. According to Rule 19, acts done for scientific, experimental or private non-profit-making purposes do constitute infringement. Moreover, good faith prior users “shall retain the right to proceed with that use free of charge, provided that the scope thereof is not increased”<sup>133</sup>.

**B. Exceptions Impacting Research**

**i) Table comparing exceptions affecting research (national level)**

These tables compare exceptions that directly or by implication affect research in national statutory law and case law. They include the name of the country, whether or not there is an experimental exception, the scope of any such exceptions and whether or not there are alternatives when there is not experimental exception.

**Europe**

	General Exceptions
Europe	<p>European countries tend to follow some version of what is contained in Article 27 b) of the <i>Community Patent Convention</i>. As explained earlier, the <i>Convention</i> never entered into force. However, it has had a great influence over member countries and member countries of the EU have enacted legislation which parallels its major provisions. (Organisation for Economic Co-Operation and Development, <i>Research Use of Patented Knowledge: A Review</i>, Chris Dent, Paul Jensen, Sophie Waller, and Beth Webster, 2006, p.18.)</p> <p><b>Exceptions Partially Enumerated from Some European Countries:</b></p> <p><b>Experimental Uses – Germany:</b> There is a statutory provision for experimental uses of a patented invention, according to which “[t]he effect of the patent shall not extend to acts done for experimental purposes which are related to the subject matter of the patented invention.” (s.11.2 <i>German Patent Act</i> 1981 cited in Advisory Council on Intellectual Property, <i>Patents and Experimental Use</i>, October 2005, p.41.) According to the Federal Supreme Court, “[s]ince the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.”(<i>Klinische Versuche (Clinical Trials) I</i> (1997) RPC 623 cited in Advisory Council on Intellectual Property, <i>Patents and Experimental Use</i>, October 2005, p.42.) This was reaffirmed in a second case where the court stated that: “According to the memorandum of the agreement, Article 31 allows the invention protected by the Community patent to be used for experimental purposes “for example, to test its usability and possibility of further development.” These examples contain commercially oriented goals. ( <i>Klinische Versuche (Clinical Trials) II</i> (1998) RPC 423 cited in Advisory Council on Intellectual Property, <i>Patents and Experimental Use</i>, October 2005, p.42.)’ In all cases, however, an experimental act qualifies for the exception only if its purpose is “to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use.”(<i>Klinische Versuche (Clinical Trials) I</i> (1997) RPC 623 cited in E. Richard Gold et al., “The Research or Experimental Use Exception: A Comparative Analysis”, (<i>Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005</i>) available on line: &lt; (<a href="http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf">http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf</a>) pp. 1- 52.)</p> <p><b>Exception for the submission of information to the government – Germany:</b> “The rights conferred by a patent shall not extend to ... studies and trials and the consequential practical requirements necessary for</p>

<sup>133</sup> Eurasian Patent Convention, September 9 1994, rule 20.

	<p>obtaining an authorization to market a drug in the European Union or for obtaining an authorization to market a drug in the Member States of the European Countries.” Sean O’Connor, “Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries” Research Roundtable: Law &amp; Economics of Innovation, 2008)</p> <p><b>Experimental Uses – Belgium</b> On the topic of the research exception, it is interesting to note that “(r)ecently, [...] Belgium has adopted an experimental use exception that extends very broadly to research “on and/or with” patented inventions.”(Henrik Holzapfel &amp; Joshua D. Sarnoff, “A Cross-Atlantic Dialog on Experimental Use and Research Tools” American University, WCL Research Paper No. 2008-13.)</p>
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	General Exceptions
United-Kingdom	<p><b>Private Non-Commercial Uses:</b> The private non-commercial use exception allows individuals to use a patent for non-commercial purposes (s. 60 (5) a) <i>UK Patents Act 1977</i>). If “an activity has both commercial and non-commercial benefits, it is necessary to ascertain the subjective intention of the user” (European Report <i>supra</i> note 19 p.39). The user must not be motivated by commercial benefits.</p> <p><b>Experimental Uses:</b> An experimental use exemption is provided by s. 60 (5) b) <i>UK Patents Act 1977</i>. It protects against infringement actions when infringement is done for experimental purposes. “The distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) indicates that experimental purposes in sub-head (b) may yet have a commercial end in view.... I would regard the sort of experimental activity which was considered by the Supreme Court of Canada in <i>Microchemicals Ltd v Smith Kline and French ...</i>, viz, a limited experiment to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent, as being covered by the words ‘for experimental purposes relating to the subject matter of the invention.’” (<i>Monsanto v. Stauffer Chemical</i> [1985] <i>RPC</i> 515 (CA) cited in Trevor Cook, <i>A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research</i>, March 2006, online: <a href="http://www.ipeg.com/_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf">http://www.ipeg.com/_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf</a>) [Trevor Cook].</p> <p>To be eligible for this exception, an act must be experimental. However, trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a [regulatory] body ... that the product works as its maker claims are not ... to be regarded as acts done “for experimental purposes.” (Trevor Cook) Moreover, the question of whether this exception may be used “to improve it, to invent around the patent, or to invent something else” has not been clarified. (European Report, <i>supra</i> note 19 p. 40.)</p> <p>This exception can be used to “1) discover something unknown; 2) test an hypothesis; 3) determine if the invention is workable under varied conditions; and 4) to determine if the patented product can be manufactured in accordance with the patent.” (E. Richard Gold et al., “The Research or Experimental Use Exception: A Comparative Analysis”, (<i>Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005</i>) available on line : &lt; (<a href="http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf">http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf</a>)&gt; pp. 1- 52.)</p> <p><b>Prior User exception:</b> There is a prior user exception in s. 64 <i>UK Patents Act 1977</i>. This allows the prior user to continue using the invention. If the prior use took place “in the course of business, the prior user has the right to authorize the doing of the act by their partners for the time of the business” (<i>European Report, supra</i> note 19, p. 44.) even though this does not allow the prior user to license his right. ( s. 64 (1) <i>UK Patents Act 1977</i>) This right acquired in a business may also be transmitted. ( s. 64 (2) <i>UK Patents Act 1977</i>)</p> <p>However, this exception is very narrow. Indeed, six conditions must be meet in order to benefit from it:</p> <ol style="list-style-type: none"> <li>a. The prior use must have been private. Otherwise, the patent is invalid as it does not respect the novelty requirement.</li> <li>b. A prior use must have been made in the UK.</li> <li>c. The use must have been made in good faith.</li> <li>d. The prior use must have been “serious and effective.” (<i>Lubrizol Corporation v. Esso Petroleum</i> [1998] <i>RPC</i> 727, 770 (CA); <i>Helitune v. Stewart Hughes</i> [1991] <i>FSR</i> 171 discussed in European Report <i>supra</i> note 19, p. 44.)</li> <li>e. There must be a ““chain of causation” between the prior use and the infringing use.”(<i>Hadley</i></li> </ol>

	<p><i>Industries v. Metal Sections</i> (13 Nov. 1998) cited in the European Report <i>supra</i> note 19, p. 44.)</p> <p>f. This is a personal defense that can only be used by the prior user himself.(European Report, <i>supra</i> note 19 p. 44.)</p> <p><b>Exhaustion of Biological Patent:</b> Codified at paragraph 10 of Schedule A2 <i>UK Patents Act</i>, this exception is the same as the one provided by Article 10 of the <i>European Biotechnology Directive</i>.</p> <p><b>Exception for the submission of information to the government:</b> “An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if ... it consist of</p> <ul style="list-style-type: none"> <li>(i) An act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of [the regulatory approval processes of various EU Directives], or</li> <li>(ii) Any other act which is required for the purpose of the application of those paragraphs [of the various EU Directives]” (<i>Patent Act of 1970</i>, s. 60(5) (i) cited in Sean O’Connor, “Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries” Research Roundtable: Law &amp; Economics of Innovation, 2008).</li> </ul>
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### North America

	General Exceptions
Canada	<p><b>Experimental Use:</b> In <i>Micro Chemicals Ltd. v. Smith Kline &amp; French Inter-American Corp.</i>, [1972] S.C.R. 506, the Supreme Court of Canada applied a common law exemption, dating back to the case <i>Frearson v. Loe</i> [(1878), 9 Ch. D. 48.] pertaining to an experimental use of patents. The Supreme Court declared in <i>Micro Chemicals</i> that “[a]n experimental user without a licence in the course of bona fide experiments with a patented article is not in law an infringer.” The court later declared: “I cannot see that this sort of experimentation and preparation is an infringement. It appears to me to be the logical result of the right to apply for a compulsory licence.”</p> <p>Through the former quote, the Supreme Court had imported the experimental use exemption from British law. However, with the latter quote, the Supreme Court shed doubt on the existence of an experimental use exemption for purposes other than applying for a compulsory licence. The existence of the exemption became even more dubious when the federal government abolished s. 43 (1) <i>Patent Act</i>, R.S.C. 1952, c. 203. The Supreme Court expressed doubts on its existence: “The CBAC recognizes that this Court established a common law experimental use exception in the context of research aimed at sustaining a compulsory licence: see <i>Micro Chemicals Ltd. v. Smith Kline &amp; French Inter-American Corp.</i>, [1972] S.C.R. 506. Nonetheless, the scope and nature of this exception is uncertain, particularly since Canada has since eliminated its compulsory licence provisions.” <i>Harvard College v. Canada (Commissioner of Patents)</i>, (2002) 4 S.C.R. 45, para. 174.</p> <p>Four years later, the Federal Court dealt with this issue in <i>Merck &amp; Co. v. Apotex Inc.</i>, [2006] F.C.A. 671, paras. 161-163: “The Supreme Court in <i>Micro Chemicals</i> held it to be significant that the Trial Judge had found that small amounts of the patented compound had been produced, put in bottles, kept by Micro Chemicals and never entered into commerce and no damage was suffered by the patentee and no profits made by Micro Chemicals. [...] In this case, the evidence shows that there has been a use of lisinopril that should be considered in the circumstance of "fair dealing." That is, the use of lisinopril in ongoing research and development of alternate formulae, alternate techniques for tablet making and the like. As to this research and development material, I find that it clearly falls within the "fair dealing" exemption provided by the Supreme Court of Canada in <i>Micro Chemicals</i>.”</p> <p>This interpretation of the Supreme Court case was approved by the Federal Court of Appeal in <i>Merck &amp; Co. v. Apotex Inc.</i>, [2007] 3 F.C.A. 588, para. 109: “I reject this assertion that the <i>Micro Chemicals</i> exception is limited and only applies as an adjunct to the grant of compulsory licences. Although the grant of a compulsory licence was at issue in <i>Micro Chemicals</i>, certainly it did not form the basis of the exemption. Moreover, the case <i>Frearson v. Loe</i> (1878), 9 Ch. D. 48, was relied on by the Supreme Court in <i>Micro Chemicals</i>, and in that case, the grant of a compulsory licence was not at issue. In my analysis, all that is required is that the infringing product was made merely by way of <i>bona fide</i> experiment, and not with the intention of selling and making use of the product in the commercial market.”</p> <p>While the addition a <i>Bolar</i>-type exception in section 55.2(6) of the <i>Patent Act</i> does not undermine the</p>

existence of the common law experimental use exception (*Apotex Inc. v. Merck & Co.*, [2008] F.C.J. 1465), it remains somewhat unclear how broad the common law exception is. The Federal Court of Appeal in *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588 stated at paragraphs that it was 111-112: "...inclined to agree... that this ongoing research should be exempt as it meets the test in *Micro Chemicals*, particularly, because Apotex was trying to establish if it could manufacture a quality product [according to the patent specifications]...In any event, even if this Court applied the United States test [in *Madey v. Duke*] in this case, I am satisfied that Apotex's research was used to satisfy their curiosity as to whether they could in fact manufacture a product with the specifications disclosed in the application of the '350 patent." In particular, it remains uncertain whether Canada has imported the notion of furthering one's business into the Canadian common law exception.

**Private acts, non-commercial use and acts for teaching:** "A patented article may be repaired, modified, or customized without infringement. Extensive repairs or changes that amount to reconstructing the article substantially, however, infringe..." David Vaver, *Intellectual Property Law – Copyright, Patents, Trademark* (Concord: Irwin Law, 1997). See also *Rucker Co v. Gravels Vulcanizing Ltd.* (1985), 7 C.P.R. (3d) 294.

**Prior User Exception:** Section 56 of the *Patent Act* provides that prior users are exempt from patent infringement if they have "purchased, constructed or acquired any invention for which a patent is afterwards obtained" in respect of the use or sale of "the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired." According to the Federal Court of Appeal in *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 78, the article purchased, constructed or acquired need not be in its final state: "It follows for our purposes that the right to use a chemical compound encompasses the right to use and sell compositions that are created by applying the compound to its intended use. The fact that the use of a chemical compound may become incorporated into subsequently created products is therefore immaterial. Accordingly, the form taken by an invention is not governing for the purpose of section 56," provided that the product purchased, constructed or acquired is of the appropriate quality. In addition, s. 56 provides that a prior user's "purchase, construction or acquisition or use of the invention" may invalidate a patent if "it was purchased, constructed, acquired or used for a longer period than two years before the application for a patent" was filed.

Further, if an invention has been publicly disclosed by a third party before the claim date or by the applicant more than a year before the filing date (or a person deriving its knowledge from the applicant), a patent is deemed invalid. *Patent Act*, R.S.C. 1985, c. P-4, ss. 28.2 (1)(a) & 28.2 (1)(b).

**Exception for the submission of information to the government (Bolar exception):** "55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."

Any use of an invention to file information to any federal, provincial or foreign regulator in respect of the sale of any product is exempt from patent infringement. "The Canadian exception is unrestricted as to subject matter of the patent, it applies to medicines, bicycles and anything patented, and unrestricted as to any country not just Canada or province in which regulatory approval may be sought." *Apotex Inc. v. Merck & Co. Inc.* 2008 FC 1185 at para. 21. This exception is thus broader than that in the US as interpreted in *Merck KG v. Integra Lifesciences Ltd.* 545 US 1 (2005). "That United States statute is more restrictive as it speaks only of requirements under United States law and is limited to drugs." *Merck & Co. Inc. v. Apotex Inc.* 2006 FC 524 at para. 154.

This exemption applies to both pre-market and post-market activities undertaken to comply with regulation: *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 100. Further, the provision does not exempt only activity that actually results in submitted information: "Any samples which are reasonably related to the development and submission of information under legislation or regulations are exempt by the provision. It does not limit the exemption to information actually submitted." *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at para. 103.

Section 55.2(1) is "not an exemption from the purpose of the Act, but is an integral part thereof by seeking to balance the rights of patentees with those of the public": *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588

	<p>at para. 102. The section should not, therefore, be given a narrow interpretation but should be interpreted in the same way as provisions granting the patent itself.</p> <p>Further, if an invention has been publicly disclosed by a third party before the claim date or by the applicant more than a year before the filing date (or a person deriving its knowledge from the applicant), a patent is deemed invalid. <i>Patent Act</i>, R.S.C. 1985, c. P-4, ss. 28.2 (1)(a) &amp; 28.2 (1)(b).</p>
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	<p>General Exceptions</p>
Mexico	<p><b>Private Non-Commercial Uses – Acts for Teaching – Experimental Use:</b> According to Article 22 <i>Industrial Property Law</i>, “[t]he right conferred by a patent shall not have any effect against... a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented.” This provision will prevent the infringement of the patent by some researchers.</p> <p><b>Prior User exception:</b> According to Article 22 <i>Industrial Property Law</i> any person who, prior to the filing date, uses “the patented process, manufactures the patented product or undertakes the necessary preparations for such use or manufacture” does not infringe the patent. This exemption might be useful, especially when inventions are kept secret. Because these secret inventions might be the object of research or used as a tool, this may prevent some researchers from infringing a patent.</p> <p><b>Plants:</b> The breeder’s consent is not necessary when the plant is used as research material for improving other plants and for the multiplication of propagating material for personal use (art. 5 <i>Federal Law on Plant Varieties</i>).</p>

	<p>General Exceptions</p>
United-States	<p><b>Experimental Use:</b> Only personal uses of an invention, unconnected with the goals and missions of one’s enterprise, fall within this exception. Patent holders thus have significant discretion about which forms of research to permit. However, rarely do they use that discretion to curtail academic research.</p> <p>Academic activities pertaining to research are considered business activities. As the Court of Appeals for the Federal Circuit ruled in <i>Madey v. Duke University, United States Court of Appeal</i>, 307 F.3d 1351 (2002): “In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.”</p> <p><b>Private Non-Commercial Uses:</b> The owner of a purchased patented item has a right to repair the item – including replacing an essential part of the invention – but not to reconstruct it. Nevertheless, the line between repair and reconstruction is not clear: “Despite the number of cases concerning repair and reconstruction, difficult questions remain. One of these arises from the necessity of determining what constitutes replacement of a part of the device, which is repair or akin to repair, and what constitutes reconstruction of an entire device, which would be neither repair nor akin to repair. Certain situations suggest an obvious answer. For example, if a patent is obtained on an automobile, the replacement of the spark plugs would constitute a permissible repair, but few would argue that the retention of the spark plugs and the replacement of the remainder of the car at a single stroke was permissible activity akin to repair. Thus, there may be some concept of proportionality inherent in the distinction between repair and reconstruction.” <i>Injection Molding Systems Ltd. v. R&amp;D Tool &amp; Engineering Co.</i>, 291 F.3d 780 (Fed. Cir. 2002).</p> <p>See also <i>Madey v. Duke</i> for more on non-commercial research exemption.</p> <p><b>Prior User exception:</b> 35 U.S.C. § 102 establishes a first-to-invent system. Any publication prior to the invention date protects a prior user against patent infringements suits.</p> <p>Under 35 U.S.C. § 273, it is not an infringement for a person to use a “method of doing or conducting business” if that person “had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the</p>

	<p>effective filing date of such patent." Congress enacted section 273 following the United States Court of Appeals for the Federal Circuit's decision in <i>State Street Bank v. Signature Financial Group, Inc.</i>, 149 F.3d 1368 (Fed.Cir. 1998).</p> <p><b>Exception for the submission of information to the government:</b> 35 U.S.C. § 271 (e)(1): “(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the <i>Federal Food, Drug, and Cosmetic Act</i> and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”</p> <p>Research that may result in information being filed under federal food and drug laws does not constitute infringement. To qualify, the researcher need only have the intention of eventually filing an application. The research need not be mandated by federal authorities. 35 U.S.C. § 271 (e)(1) <i>Merck KGaA v. Integra Lifesciences Ltd.</i>, 545 U.S. 193 (2005).</p> <p>The purpose of this provision is to allow generic drug companies to manufacture patented drugs. However, the provision was interpreted broadly by the Supreme Court of the United States as allowing any research where there is a legitimate belief that a filing will be made.</p>
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### South America

	General Exceptions
Argentina	<p><b>Private Non commercial Use – Experimental Use:</b> Article 36 of law 24.481 states that “[t]he right conferred by a patent does not produce any effect against: a) a third party who, in private or academic and non-commercial purposes, perform scientific research or technological purely experimental, testing or teaching and manufactured or used this product or use as the patented process” (South American Report, <i>supra</i> note 73 p. 53).</p> <p><b>Exception for the submission of information to the government:</b> None (South American Report, <i>supra</i> note 73)</p>

	General Exceptions
Brazil	<p><b>Private Non commercial Use:</b> “[...]acts carried out by unauthorized third parties, privately and without commercial purposes, provided these acts do not prejudice the economic interests of the patent holder [...]” are not infringements (art. 43 of <i>Brazilian Industrial Property Law</i>). Hence, this exception pertains to use for private and non commercial purposes.</p> <p><b>Experimental Use:</b> “[...]acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches [...]” are not infringements (art. 43 of <i>Brazilian Industrial Property Law</i>). According to the report on intellectual property laws from South America, this exception needs to be “interpreted extensively” (South American Report, <i>supra</i> note 73 p. 46). However, it is not clear if experimentation may be undertaken for commercial purposes with this provision.</p> <p><b>Prior User Exception:</b> “A person who in good faith, prior to the filing or priority date of a patent application, used to exploit the subject matter thereof within the Country, shall be entitled to continue such exploitation under the same form and conditions, without liability.</p> <p>Paragraph 1 - The right afforded by this Article may only be assigned together with the enterprise or part thereof that is directly related to the exploitation of the subject matter of the patent, by sale or lease.</p> <p>Paragraph 2 - The right afforded by this Article shall not be enjoyed by a person who obtained knowledge of the subject matter of the patent as a result of disclosure, in accordance with Article 12, provided that the application was filed within 1 (one) year of the disclosure.” (art. 45 cited in South American Report, <i>supra</i> note 73 p. 64)</p>

	<p><b>Biological material:</b> “[P]ersons who, in the case of patents related to living matter, use the patented product, without economic purpose, as an initial source of variation or propagation in order to obtain other products” cannot infringe a patent. (South American Report, <i>supra</i> note 73 p. 64).</p> <p><b>Exception for the submission of information to the government:</b> “Article 43 – The provisions of the previous article shall not apply (...) VII - to acts performed by unauthorized third parties related to the invention protected by patent, exclusively for the production of information, data and test results in order to obtain the registration of trade in Brazil or in another country, for the exploitation and marketing of the patented product after the expiry of the periods stipulated in art. 40. (Included by Law 10.196 of 2001)” (South American Report, <i>supra</i> note 73 p. 66).</p>
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	General Exceptions
Chile	Apart from the possibility of parallel imports (art 49, <i>Law N° 19.039</i> ), the exceptions provided under the <i>Chilean Law N° 19.039</i> are not relevant for research.

	General Exceptions
Andean Community	<p>This regime applies to Bolivia, Colombia, Ecuador and Peru.</p> <p><b>Private Non-Commercial Uses:</b> “a) acts carried out in a private circle and for non-commercial purposes” (<i>Decision 486</i>, art. 53).</p> <p><b>Experimental Use:</b> “b) acts carried out exclusively to experiment with the subject matter of the patented invention” (<i>Decision 486</i>, art. 53). “c) acts carried out exclusively for the purposes of teaching or scientific or academic research; [...]” (<i>Decision 486</i>, art. 53).</p> <p><b>Prior User exception:</b> “Without prejudice to the provisions stipulated in this Decision with respect to patent nullity, the rights conferred by a patent may not be asserted against a third party that, in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation.</p> <p>In such case, the said third party shall have the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place.” (<i>Decision 486</i>, art. 55, cited in South American Report, <i>supra</i> note 73p. 74 - 75).</p> <p><b>Biological material:</b> “A patent owner may not exercise the right referred to in the previous article with respect to the following acts: [...] e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.” (<i>Decision 486</i>, art. 53).</p> <p><b>Experimental Use in Ecuador:</b> Ecuador’s intellectual property law adds to the experimental use exemption by specifying that it only covers acts not made for profit (South American Report, <i>supra</i> note 73 p. 51).</p> <p><b>For all exceptions in Peru:</b> “When the limited exceptions provided for in Article 53 of <i>Decision 486</i> of the Andean Community Commission [interfere] unreasonably with the normal exploitation of the patent or causing unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of third parties, the patent holder may exercise the rights provided in Article 52 of that decision.” (South American Report, <i>supra</i> note 73 p. 54 – 55). Here, article 52 prescribes rights conferred by patents. Hence, when the legitimate interests of the patentee are unreasonably prejudiced, exceptions do not apply.</p>

Asia

	General Exceptions
China	<p><b>Experimental Use:</b> According to article 69 (2) (<i>Patent Law of the People's Republic of China</i>), “using relevant patents solely for the purposes of scientific research and experiment” does not constitute infringement.</p> <p><b>Prior User exception:</b> According to article 69 (2) (<i>Patent Law of the People's Republic of China</i>), “having made identical product or having used the identical process or having made necessary preparations for making such a product or using such a process prior to the date of application, and continuing making such product or using such a process only within the original scope,” does not constitute infringement.</p> <p><b>Exception for the submission of information to the government:</b> According to article 69 (5) (<i>Patent Law of the People's Republic of China</i>), “producing, using or importing patented medicine or patented medicinal equipment for the purpose of providing the information as required for administrative examination and approval, and producing and importing the patented medicine or patented medicinal equipment exclusively for the said purpose,” does not constitute infringement.</p>

	General Exceptions
India	<p><b>Experimental Use:</b> According to s. 47(3): “[A]ny machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils”. Unfortunately, this exception has not yet been interpreted by the courts. Moreover, this experimental use exception does not make the difference between experimenting “on” vs. experimenting “with.” (Shamnad Basheer &amp; Prashant Reddy, “The “Experimental Use” Exception Through a Developmental Lens” (2010) 50 IDEA 831. )</p> <p><b>Exception for the submission of information to the government:</b> “For the purpose of this Act, - (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; shall not be an infringement of patent rights.”( Art. 107A (a) of Indian Patent Act) According to a Joint Committee of the Indian Government, “[t]his provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent.” (Joint Comm. Of the Rajya Sabha &amp; the Lok Sabha, comm.. 91, Report on the Patents (Second Amendment) Bill, 1999, (Comm. Print 2001) (India) cited in Shamnad Basheer &amp; Prashant Reddy, “The “Experimental Use” Exception Through a Developmental Lens” (2010) 50 IDEA 831)</p> <p>“Section 107A is wider than the corresponding U.S. provision because it permits the making, constructing, using or selling of a “patented invention” for the purpose of generating regulatory data to comply with both domestic (Indian) drug regulatory law, and any corresponding foreign law. U.S. law on the other hand permits a defense only in so far as the activities are connected with a regulatory submission within the United States.” (Shamnad Basheer &amp; Prashant Reddy, “The “Experimental Use” Exception Through a Developmental Lens” (2010) 50 IDEA 831)</p>

	General Exceptions
Indonesia	<p><b>Experimental Use:</b> There is no patent infringement when an invention is used “for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder.” (<i>Law on Patent</i> art. 16 (3)).</p> <p><b>Prior User exception:</b> “By obeying the other provisions under this Law, a party who exploits an Invention at the time a similar Invention is filed for Patent shall still be entitled to exploit the Invention as a prior user, even though the similar Invention is then granted a Patent.” (<i>Law on Patent</i> art. 13 (1)).</p>

	General Exceptions
Japan	<p><b>Experimental Use:</b> According to art. 69 (1) of the <i>Japan Patent Act</i>, “[a] patent right shall not be effective against the working of the patented invention for experimental or research purposes.”</p> <p><b>Leading cases:</b> “The Tokyo District Court emphasized the incentive to innovate [as a] justification of patent law and the policy purposes underlying section 69(1), namely to strike a balance between the interests of the patentee and the general public and to allow for the improvement of technology and the development of industry. The court held that section 69(1) [experimental use exception] is not limited to experiments or research directed at working improvements to existing technology. The court held that if generic drug manufacturers were required to wait until the expiration of the patent on the brand name drug before they were permitted to undertake the tests and manufacturing necessary to secure regulatory approval, this would grant the patent holder a de facto period of market exclusivity beyond the end of the patent term. This, the court held, is contrary to the very purposes of the patent regime.” [emphasis added] (<i>Daiichi Pharmaceutical Co., Ltd. v. Shiono Chemical K.K. &amp; Choseido Pharmaceutical K.K.</i> discussed in Shamnad Basheer &amp; Coenraad Visser, <i>Background Information on Asia</i>, 2010, p. 23) [Background Information on Asia]</p> <p>“The Tokyo District Court granted a permanent injunction to prevent a third party from experimenting on a patented herbicide for the purpose of obtaining data for regulatory approval and also to prevent use of such data as well as the manufacture, importation, use and sale of the herbicide. This was a hiccup in the Japanese holdings, which was later clarified in <i>Ono Pharma cases</i> and the case of <i>Otuska Pharma</i> (discussed hereunder). The pharmaceutical field had not seen a similar holding. But the Nagoya District Court in the case discussed hereunder extended this trend against a wide interpretation of experimental use of a protected compound.” (<i>Monsanto Co. v. Stoffer Japan K.K.</i>, 1246 Hanrei Jiho 128 (Tokyo Dist. Ct. 1987) discussed in Background Information on Asia p. 23)</p> <p>“The Nagoya District Court decided differently than the Tokyo District Court in <i>Wellcome</i> (discussed hereunder) and <i>Daiichi</i> (discussed above). The Nagoya court found that clinical tests conducted solely for the purposes of obtaining regulatory approval amounted to patent infringement. However, the court refused to grant a preliminary injunction against the generic manufacturer and instead granted compensation for damages.” (<i>Ono Pharmaceutical v. Malco Pharmaceutical K.K.</i> discussed in Background Information on Asia p. 24)</p> <p>“In <i>Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.</i> the Japanese Supreme Court discussed this issue of experimental use exemption and generic drugs. Section 69(1) of the Japanese Patent Law provides an exemption for “the working of the patented invention for experiment and research.” Ono asserted that Kyoto Pharmaceutical is selling the drugs of same efficaciousness as the patented drug during the patent term for the purpose of obtaining data that accompany an application for the approval of manufacture under section 14 of the <i>Pharmaceutical Affairs Law</i>. The Japanese Supreme Court decided that the use of drugs having the technical scope of the patented invention is “working of the patented invention for experiment and research” provided in Section 69(1) of the Japanese Patent Law and would not constitute patent infringement because:</p> <p>The Pharmaceutical Affairs Law stipulates that a prior approval by the Minister of Health and Welfare is to be obtained for the manufacture of drugs for ensuring safety, etc., and that upon carrying out various experiments, data, etc. on the experimental results must accompany an application when requesting such an approval. ... If under the Patent law such experiments are not be interpreted as “experiments” stipulated in Section 69(1) of the Patent Law and therefore such manufacture, etc. are not possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even after the term of the patent expires. This result is against the basis of the patent system mentioned above.[...] it is possible to exclude others from carrying out manufacture, etc. for the experiments required in applying the patent term for a substantial period of time, such extension of the patent term goes beyond what is expected under the patent law as benefits to be given to the patentee.”</p> <p>(<i>Ono Pharms. Co., Ltd. v. Kyoto Pharm. Indus., Ltd.</i>, 24 AIPPI J. 106 (1999) discussed in Background Information on Asia p. 24)</p> <p>“The Japanese Supreme Court has aligned itself with the Tokyo District Court decisions and has held that the use of a patented invention for the purpose of obtaining a licence to market the generic equivalent of a patented medicine will fall within the scope of the statutory exemption. Finally, the Court concluded that experiments to obtain regulatory approval would also qualify as experiments within art. 69(1) of the</p>

	<p>Japanese Patent Law.” (<i>Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuhin K.K.</i>, 22 AIPPI Journal 296 (Nov. 1997) discussed in Background Information on Asia p. 25)</p> <p>“The Tokyo District Court had to determine whether Sawai, a Japanese pharmaceutical company, had infringed Wellcome's patent by applying for manufacturing approval and conducting tests and research on drugs similar to Wellcome's patented drug during the subsistence of the Wellcome patent. The court found that Sawai's research was aimed at achieving technical progress in terms of Article 69(1). Sawai did not earn any direct profit from these activities, nor did it compete in the same economic market as Wellcome. However, activities directed towards manufacturing or selling the product before the expiration of the patent would fall outside of section 69(1).” (<i>Wellcome Foundation Ltd v. Sawai Pharmaceutical</i> discussed in Background Information on Asia p. 26)</p> <p><b>Prior User exception:</b> According to art. 69 (2), “[a] patent right shall not be effective against the following products: (ii) products existing in Japan prior to the filing of the patent application.”</p>
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	<p>General Exceptions</p>
Pakistan	<p><b>Experimental Use:</b> “[A]cts done only for experimental purposes relating to a patented invention” do not constitute infringement (<i>Patents Ordinance No. LXI</i>, art. 30 (5) (Pakistan)).</p> <p><b>Prior User exception:</b> “[A]cts performed by any person who in good faith, before the filling or, where priority is claimed, the priority date of the application on which the patent is granted in Pakistan, was using the invention or was making effective and serious preparations for such use.” (<i>Patents Ordinance No. LXI</i>, art. 30 (5) (Pakistan))</p>

	<p>General Exceptions</p>
Republic of Korea	<p><b>Experimental Use:</b> “The effect of a patent right does not extend to any of the following subparagraphs: (i) Working a patented invention for research or experimental purposes[...].” (<i>Patent Act of the Republic of Korea</i> art. 96 (1) (i))</p> <p><b>Prior User exception:</b> “The effect of a patent right does not extend to any of the following subparagraphs: [...] (iii) articles existing in the Republic of Korea when the patent application was filed.” (<i>Patent Act of the Republic of Korea</i> art. 96 (1) (i))</p> <p>There is also a prior user exception at art. 103: “When filing a patent application, a person who has made an invention without prior knowledge of the contents of an invention described in an existing patent application, or who has learned how to make the invention from such a person and has been working the invention commercially or industrially in the Republic of Korea in good faith or has been making preparations to work the invention is entitled to have a nonexclusive license on the patent right for the invention under the patent application. The nonexclusive license must be limited to the invention being worked, or for which preparations for working have been made, and to the purpose of such working or preparations.”</p>

## ii) Common Aspects and Distinctions

This section will identify the commonalities and trends in national patent laws pertaining to exceptions affecting research. It will also succinctly address the main divergences between studied world regions/individual countries.

While exceptions applying to research and development must comply with the *TRIPS* requirement that they be “limited to certain uses, [ensure] that it does not conflict with the normal exploitation of patents and [that it facilitates] public policies such as the advancement

of science and technology,”<sup>134</sup> there remains considerable room to enact them. Further, while they must not discriminate against a specific field of technology,<sup>135</sup> there is no requirement that they apply in the same way in all fields. The *Bolar* exception provides one example of this as it is often – but certainly not uniformly – limited to pharmaceutical and similar products.

### Prior User

The exception for prior users (e.g.: United Kingdom,<sup>136</sup> Canada,<sup>137</sup> Mexico,<sup>138</sup>, Brazil,<sup>139</sup> China,<sup>140</sup> Indonesia,<sup>141</sup> Japan,<sup>142</sup> Pakistan,<sup>143</sup> Korea,<sup>144</sup> and members of the Andean Community<sup>145</sup>) has an impact on research practices. For example, an individual may discover an invention that is already known elsewhere, such as a trade-secret. In this situation, the prior user exception may help trade-secret holders, since they may be interested in continuing to experiment with the invention without having to obtain permission from the patent holder (as long as it had not been disclosed). The prior user exception is narrow in scope and will only have an impact on research in limited circumstances.

Some countries, such as Chile and Argentina, do not seem to have such an exception.

### Non Commercial Users

Some jurisdictions have a non-commercial user exception. The United Kingdom,<sup>146</sup> Mexico,<sup>147</sup> Brazil<sup>148</sup> and members of the Andean Community<sup>149</sup> have a statutory non-commercial user exemption. As for Canada<sup>150</sup> and the United-States,<sup>151</sup> they have an exception that originates from case law.

This exception may be considered similar to an experimental exception by some. It is, in fact, different. While some researchers may use an invention for non-commercial purposes, not all non-commercial users are *experimenting*. This type of exception often pertains to acts other than experimental act (e.g. repairs in the case of Canada and the United States).

### Experimental Exception

Experimental use exceptions vary in breadth from country to country. The emphasis must be laid on three characteristics that define different types of experimental exceptions: 1) whether it

<sup>134</sup> *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R, Panel Report, discussed in Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p. 28.

<sup>135</sup> TRIPS, *supra* note 8, art. 27.1.

<sup>136</sup> UK 1977 Patents Act, s. 64

<sup>137</sup> *Patent Act*, R.S.C. 1985, c. P-4, s. 56.

<sup>138</sup> Industrial Property Law of Mexico, art. 22.

<sup>139</sup> Brazilian Industrial Property Law, art. 45.

<sup>140</sup> Patent Law of the People’s Republic of China, art. 69 (2).

<sup>141</sup> Law on patents, art. 13 (1).

<sup>142</sup> Japan Patent Act, art. 69 (2).

<sup>143</sup> Patents Ordinance No. LXI, s. 30 (5) (Pakistan).

<sup>144</sup> Patent Act of the Republic of Korea, art. 96 (1) (i).

<sup>145</sup> Decision 486, *supra* note 80 art. 55.

<sup>146</sup> UK 1977 Patents Act, s. 65 (5) b)

<sup>147</sup> Industrial Property Law of Mexico, art. 22.

<sup>148</sup> Brazilian Industrial Property Law, art. 43.

<sup>149</sup> Decision 486, *supra* note 80 art. 53.

<sup>150</sup> David Vaver, *Intellectual Property Law – Copyright, Patents, Trademark* (Concord: Irwin Law, 1997). See also *Rucker Co v. Gravels Vulcanizing Ltd.* (1985), 7 C.P.R. (3d) 294.

<sup>151</sup> *Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*, 291 F.3d 780 (Fed. Cir. 2002).

allows for experimentation *on* or *with* an invention, 2) whether or not the exception applies to experiments with a commercial purpose (the definition of what is commercial or not being itself a source of controversy in some jurisdictions) and 3) whether it is statutory or judicial.

An experimental exception may be designed only to allow experiments *on* an invention, rather than *with* an invention. This distinction is important because, when it is possible to experiment *with* an invention without infringing a patent, researchers have greater access to research tools without a licence, especially when it is difficult to invent around an invention. For example, “[s]ome of the most important genetic research tools are fundamental research platforms that open up new and uncharted areas of investigation.”<sup>152</sup> However, because researchers may constitute an important market, the possibility of experimenting *with* research tools without buying the tool may lower the incentive to improve or develop new research tools.

The expression “relating to the subject-matter of the patented invention” (used by Germany<sup>153</sup> and the United-Kingdom<sup>154</sup>) indicates that an individual may only experiment *on* an invention.<sup>155</sup> The consequence is that an individual may experiment *on* a research tool, but not *with* it.<sup>156</sup> Other countries have different approaches. Some allow researchers to experiment *on* and *with* an invention (Belgium<sup>157</sup>). However, in many countries, the distinction is not made (ex: India,<sup>158</sup> China,<sup>159</sup> etc.).

Another important distinction is whether or not experimental acts are undertaken for a commercial purpose. Some countries do have an exception that covers experimental acts done for commercial purposes (e.g., Germany<sup>160</sup> and the United-Kingdom<sup>161</sup>). Other countries have narrower exceptions covering only non-commercial research. The latter exceptions preclude the use of patented knowledge for commercial research without a license from the patent holder (e.g., Mexico<sup>162</sup>, Argentina<sup>163</sup>). Many countries, however, do not specify if experiments done for commercial purposes are encompassed within the exception (e.g. Brazil,<sup>164</sup> members of the Andean Community,<sup>165</sup> China,<sup>166</sup> Pakistan,<sup>167</sup> etc.).

The third distinction that exists between jurisdictions is that some provide an experimental use exception by statutory means (Germany,<sup>168</sup> United-Kingdom,<sup>169</sup> Brazil,<sup>170</sup> members of the

<sup>152</sup> E. Richard Gold, Yann Joly & Timothy Caulfield, “Genetic Research Tools, the Research Exception and Open Science” (2005) 3:2 *GenEdit*, 1-8.

<sup>153</sup> German Patent Act 1981, s. 11.2.

<sup>154</sup> UK 1977 Patents Act, s. 60 (5) b).

<sup>155</sup> Henrik Holzapfel & Joshua D. Sarnoff, “A Cross-Atlantic Dialog on Experimental Use and Research Tools” American University, WCL Research Paper No. 2008-13. [Henrik Holzapfel & Joshua D. Sarnoff, “A Cross-Atlantic Dialog on Experimental Use and Research Tools”]

<sup>156</sup> Henrik Holzapfel & Joshua D. Sarnoff, “A Cross-Atlantic Dialog on Experimental Use and Research Tools”, *supra* note 171.

<sup>157</sup> *Ibid.*

<sup>158</sup> Patent Act of India, s. 47(3).

<sup>159</sup> Patent Law of the People’s Republic of China, art. 69 (2).

<sup>160</sup> German Patent Act 1981, s. 11.2.

<sup>161</sup> UK Patent Act of 1977, s. 60 (5) b).

<sup>162</sup> Industrial Property Law of Mexico, art. 22.

<sup>163</sup> Law 24.481, art. 36.

<sup>164</sup> Brazilian Industrial Property Law, art. 43.

<sup>165</sup> Decision 486, *supra* note 81 art. 53.

<sup>166</sup> Patent Law of the People’s Republic of China, art. 69 (2).

<sup>167</sup> Patents Ordinance No. LXI., s. 30 (5) (Pakistan).

<sup>168</sup> German Patent Act 1981, s. 11.2.

Andean Community,<sup>171</sup> China,<sup>172</sup> India,<sup>173</sup> Japan,<sup>174</sup> Pakistan,<sup>175</sup> etc.), while others provide an experimental use exception through case law (Canada<sup>176</sup> and the United States<sup>177</sup>). While a certain level of uncertainty exists in both types of jurisdictions, those that provide an experimental use exception through case law tend to show greater uncertainty as to the existence and scope of the exception. For example, in the case of Canada, even the Supreme Court expressed doubts about whether or not this exception existed in 2002.<sup>178</sup> It was not until recently that the existence of that exception was confirmed.<sup>179</sup> Still, its scope remains uncertain. As for Australia, even the existence of an experimental use exception is uncertain.<sup>180</sup>

Uncertainty is not, however, only characteristic of case law experimental use exceptions; statutory experimental use exceptions are also characterized by uncertainty, since in many cases, it is unclear whether or not the exception covers experiments *with* a patented invention or if experimental acts may be done for commercial purposes. This uncertainty impacts clinical trials as these often cross the line between experiments *with* and *on* a patented invention. Indeed, as explained further in the chapter, it is uncertain in many countries whether these fall into the research exception (as opposed to a *Bolar* exception).

Moreover, in many cases, it is unclear what constitutes an *experiment*. Even though the exception only applies to experimental acts, this type of act is not clearly defined in many jurisdictions. This lack of description as to what is an experiment partially explains why in so many cases, it is unclear whether or not the exception in question covers experiments *with* a patented invention or if experimental acts may be done for commercial purposes (ex: India,<sup>181</sup> China,<sup>182</sup> Brazil,<sup>183</sup> members of the Andean Community,<sup>184</sup> etc.).

### **Exceptions for regulatory approval (Bolar/ Safe Harbor)**

Many jurisdictions have an exception that allows individuals to use a patented invention in order to satisfy regulatory requirements. In addition to the “stockpiling case”<sup>185</sup> that deemed Canada’s regulatory review provision acceptable for art. 30 of *TRIPS*, a recent *European Directive*<sup>186</sup> has encouraged many jurisdictions to adopt an exception to patent infringement for regulatory review.

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<sup>169</sup> Patent Act of 1977, s. 60 (5) b).

<sup>170</sup> Brazilian Industrial Property Law, art. 43.

<sup>171</sup> Decision 486, *supra* note 80 art. 53.

<sup>172</sup> Patent Law of the People’s Republic of China, art. 69 (2).

<sup>173</sup> Patent Act of India, s. 47(3).

<sup>174</sup> Japan Patent Act, art. 69 (1).

<sup>175</sup> Patents Ordinance No. LXI, s. 30 (5) (Pakistan).

<sup>176</sup> *Frearson v. Loe* (1878), 9 Ch. D. 48; *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.*, [1972] S.C.R. 506; *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588, par. 109.

<sup>177</sup> *Madey v. Duke University, United States Court of Appeal*, 307 F.3d 1351 (2002).

<sup>178</sup> *Harvard College v. Canada (Commissioner of Patents)*, (2002) 4 S.C.R. 45, par. 174.

<sup>179</sup> *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.A. 588, par. 109.

<sup>180</sup> Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p. 28.

<sup>181</sup> Patent Act of India, s. 47(3).

<sup>182</sup> Patent Law of the People’s Republic of China, art. 69 (2).

<sup>183</sup> Brazilian Industrial Property Law, art. 43.

<sup>184</sup> Decision 486, *supra* note 80 art. 53.

<sup>185</sup> *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WT/DS114/R

<sup>186</sup> Directive 2004/27/EC, *supra* note 127.

While not always limited in this manner, regulatory review exceptions are made to accelerate the sale of generic drugs. According to a Joint Committee of the Indian Government, this type of “provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent.”<sup>187</sup> Moreover, as pointed out by a Japanese court, “[i]f under the Patent law such experiments are not [...] possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even after the term of the patent expires. [...] [S]uch extension of the patent term goes beyond what is expected under the patent law as benefits to be given to the patentee.”<sup>188</sup>

The scope of provisions for regulatory review varies from country to country. Some countries have safe harbour provisions with a broad scope. This is the case in Canada where an individual may “make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.”<sup>189</sup> In the United-States, this provision has a narrower but still large scope: research that may result in information being filed under federal food and drug laws does not constitute infringement.<sup>190</sup> Hungary,<sup>191</sup> Italy,<sup>192</sup> Spain,<sup>193</sup> and Brazil<sup>194</sup> have adopted a similar approach.

Other countries have exceptions that are limited to acts showing the safety and efficacy of new compounds (e.g., exceptions proposed in Belgium, Netherlands, Sweden and the UK), rather than encompassing all research activity that may lead to a product eventually being submitted for regulatory review (e.g. Canada and the United States).<sup>195</sup> Some have no regulatory review exceptions at all (e.g. Argentina and Chile<sup>196</sup>).

A last, small, distinction must be made. Some countries allow the use of patents for regulatory requirements within the jurisdiction itself (e.g. the United-States), while in others, the exception may be used to satisfy domestic as well as foreign regulatory requirement (e.g. India)<sup>197</sup>.

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<sup>187</sup> Joint Comm. Of the Rajya Sabha & the Lok Sabha, comm. 91, Report on the Patents (Second Amendment) Bill, 1999, (Comm. Print 2001) (India) cited in Shamnad Basheer & Prashant Reddy, “The “Experimental Use” Exception Through a Developmental Lens”, (2010) 50 IDEA 831.

<sup>188</sup> *Ono Pharms. Co., Ltd. v. Kyoto Pharm. Indus., Ltd.*, 24 AIPPI J. 106 (1999) discussed in Background Information on Asia p. 24

<sup>189</sup> Patent Act of Canada, art. 55.2 (1).

<sup>190</sup> 35 U.S.C. § 271 (e)(1); *Merck KGaA v. Integra Lifesciences Ltd.*, 545 U.S. 193 (2005).

<sup>191</sup> Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, March 2006, p68 online: [http://www.ipeg.com/\\_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf](http://www.ipeg.com/_UPLOAD%20BLOG/Experimental%20Use%20for%20IPI%20Chapters%201%20to%209%20Final.pdf) [Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*]

<sup>192</sup> *Ibid.*

<sup>193</sup> *Ibid.*

<sup>194</sup> Brazilian Industrial Property Law, art. 43.

<sup>195</sup> Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, *supra* note 207.

<sup>196</sup> South American Report, *supra* note 73 p.66.

<sup>197</sup> Shamnad Basheer & Prashant Reddy, “The “Experimental Use” Exception Through a Developmental Lens” (2010) 50 IDEA 831

## IV. Interactions between Matters of Patentability and Exceptions to Patentee's Rights

### A. Commentary on major exclusions and exceptions

This section covers the major groups of exclusions and exceptions presented in the previous parts of our chapter. It presents the main motivations behind them along with relevant critiques. Case law and legal doctrine from selected countries are used to illustrate our discussion.

#### **Invention definition – Exclusion of Fundamental Knowledge**

Most countries require patentable subject matter to be inventions and specify that fundamental knowledge cannot be defined as an invention. While some countries achieve the same result through different means, all studied jurisdictions exclude fundamental knowledge from the patent regime.

This is a traditional exclusion within patent law.<sup>198</sup> The decision of the United States Courts of Appeal for the Federal Circuit in *Ariad* illustrate the importance of maintaining scientific norms such as “communalism,” a notion based on the importance of collaborating and sharing fundamental results between members of the scientific community without restriction.<sup>199</sup>

However, the traditional exclusion of fundamental research from patentability has not remained unquestioned. In his historical account on “proposals for formal property rights in scientific discoveries,” Robert Merges emphasizes two attempts to bring this type of research within the patent system.<sup>200</sup>

A proposal was introduced into the French Chamber of Deputies, by J. Barthemely in 1922.<sup>201</sup> If that proposal had been adopted, a scientist would have been able to claim part of the profits from the application of a patent based on his discovery of a fundamental principle.<sup>202</sup> Moreover, a scientist would have been able to “obtain a patent of principle. [...] Anyone would be free to utilize the invention or discovery, so long as he or she paid royalties to the scientist who had discovered it.”<sup>203</sup> The same year, another proposal made at the League of Nations’ Committee on Intellectual Cooperation suggested a term of protection identical to that of Barthelemy’s plan: life plus fifty years.<sup>204</sup>

Advocates for a protection regime for fundamental discoveries argue that there is a “quasi-contractual obligation” to remunerate the discoverer of [a] principle.”<sup>205</sup> Critics raise several objections: “First, it is very often difficult to trace the scientific origins of a particular industrial application. Second, there is a significant lag of time between the disclosure of a scientific discovery and the development of the first application [...]. Third, very often it can be assumed that scientific disclosure will be missed by industrialists; they will thus end up paying royalties

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<sup>198</sup> Robert P. Merges, “Scientific Innovation, Philosophy, and Public Policy”, (1996) 13:2 Social Philosophy & Policy 145. [Robert P. Merges, “Scientific Innovation, Philosophy, and Public Policy”]

<sup>199</sup> *Ibid.*

<sup>200</sup> *Ibid.*

<sup>201</sup> *Ibid.*

<sup>202</sup> *Ibid.*

<sup>203</sup> *Ibid.*

<sup>204</sup> *Ibid.*

<sup>205</sup> *Ibid.*

for a scientific discovery which in fact, was not relied upon in creating their industrial application. [Moreover], the very significant burdens on scientific communication that a system of property rights would create represent perhaps, the most severe problem.”<sup>206</sup> Finally, many of these critics argue that it is counter-productive to grant rights “for discoveries that scientist *would have made anyway*.”<sup>207</sup> Indeed, researchers are motivated by other incentives, such as reputation, and promotion. These arguments may explain why none of the studied jurisdictions have chosen to grant property rights over abstract ideas resulting from fundamental research through property rights.

### Specific exclusions

Some specific exclusions having an impact on research may be classified into two different categories. The first category relates to the choice made by all studied jurisdictions to not protect results from fundamental research through property rights. The category includes scientific and fundamental principles, laws of nature, scientific literature, abstract concepts, intellectual activities, mathematical equations, game strategies and data presentations.

The distinction between fundamental knowledge and applied knowledge is not always clear. In fact, some argue that the relationship between fundamental knowledge and applied knowledge has changed over time and that the gap between a discovery and its commercialization is much shorter<sup>208</sup>, and “commercial interest[s]” tend to intervene at an earlier stage.”<sup>209</sup> This changing relationship between the two types of knowledge might explain why there has been some uncertainty regarding the nature of some inventions. This has been the case for biotechnological inventions<sup>210</sup> (especially DNA related inventions) and for computers.<sup>211</sup>

Moreover, research may be “guided both by understanding and by use”,<sup>212</sup> thereby resulting in a mixture of fundamental and applied knowledge. Indeed, “[s]ome of the most important achievements, both in [fundamental] and applied research, have their origin in settings which include both.”<sup>213</sup>

The last two paragraphs may explain why certain exclusions pertain to specific research sectors: some sectors (e.g. genetics, computers) are difficult to categorize within the traditional dichotomy of fundamental knowledge and applied knowledge. This could explain why some jurisdictions, for example, reject the doctrine of isolation in respect of genetic sequences.

Finally, a second category of exclusions will have a particular impact on the practices of biomedical researchers. This category includes methods of medical and surgical treatments, *in*

<sup>206</sup> *Ibid.*

<sup>207</sup> *Ibid.*

<sup>208</sup> Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.13; Robert P. Merges, “Scientific Innovation, Philosophy, and Public Policy”, (1996) 13:2 *Social Philosophy & Policy* 145.

<sup>209</sup> Rebecca S. Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use” *supra* note 2, p. 1018.

<sup>210</sup> Michael S. Carolan, “From patent law to regulation: the ontological gerrymandering of biotechnology”, (2008) 17:5 *Environmental Politics* 749 – 765.

<sup>211</sup> Brienna Dolmage, “The Evolution of Patentable Subject Matter in the United States” (2005-2006) 27 *Whittier L. Rev.* 1023; Sigrid Sterckx & Julian Cockbain, “the patentability of Computer Programs in Europe: An Improved Interpretation of Articles 52 (2) and (3) of the European Patent Convention”.

<sup>212</sup> Nils Roll- Hansen, “Why the distinction between basic (theoretical) and applied (practical) research is important in the politics of science” *supra* note 5.

<sup>213</sup> *Ibid.*

*vivo* diagnostics as well life forms. Although these exclusions were initially conceived to protect medical practitioners in their practice (e.g. a doctor performing a diagnostic test on a patient) or to reflect the moral values of a particular society (e.g. patenting life forms is sometimes seen as a slippery slope that could lead to the exploitation of human beings), they can sometimes be invoked on behalf of biomedical researchers. For instance, the patenting of the transgenic Harvard Oncomouse, a genetically modified mouse useful for cancer research, was contested on the ground of morality in Europe and because it constituted a “higher life form” in Canada. Thus, it appears that these “medical exclusions”, in a number of instances, could have the effect ensuring the ability of biomedical researchers to conduct research without fear of an infringement action.

### **Prior User Rights<sup>214</sup>**

A prior user may be defined as an individual who has “actually used or worked [the invention] prior to the priority date.”<sup>215</sup> Several conditions must be fulfilled before the rights of a prior user may be invoked: 1) a valid patent must have been granted to an individual, 2) the other individual must have been using the invention before the priority date, 3) this prior use does not constitute invalidating prior art, 4) this prior use continues after the grant of the patent and 5) the patent owner sues the prior user for infringement.<sup>216</sup> Prior user rights have been traditionally associated with first-to-file patent regimes.<sup>217</sup>

Proponents of prior user rights make several arguments. First, trade secrets become more attractive because of prior user rights.<sup>218</sup> As previously discussed, there are some advantages to concealing information from competitors. In jurisdictions where prior user rights exist, reliance on trade secrets to protect an invention becomes less risky if someone else patents the invention. In addition, advocates for prior user rights say that they do not decrease the incentive of obtaining a patent,<sup>219</sup> that they may decrease preventive applications of poor quality<sup>220</sup> and that the entire matter is one of fairness.<sup>221</sup> Critics reply that it encourages secrecy<sup>222</sup> and is a source of litigation.<sup>223</sup>

As explained below, countries try to strike a balance between incentives to invent and users’ rights through the patent system, in order to optimize innovation. Because prior user rights diminish the costs associated with trade secret practices by allowing use of patents after it has

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<sup>214</sup> For more information on the requirements for eligibility to prior user rights, please see the following articles: Keith M. Kupferschmid, “Prior User Rights : The Inventor’s Lottery Ticket” (1993) 21 AIPLA Q. J. 213 [Keith M. Kupferschmid, “Prior User Rights : The Inventor’s Lottery Ticket”]; Gary L. Griswold & F. Andrew Ubel, “Prior User Rights – A Necessary Part of a First-to-File System”, (1992-1993) 26 J. Marshall L. Rev. 567. [Gary L. Griswold & F. Andrew Ubel, “Prior User Rights – A Necessary Part of a First-to-File System”]

<sup>215</sup> Charles Oppenheim, “Patent Novelty; proposals for change and their possible impact on information scientists”, (1985) 10 Journal of Information Science 181 [Charles Oppenheim, “Patent Novelty; proposals for change and their possible impact on information scientists”].

<sup>216</sup> Keith M. Kupferschmid, “Prior User Rights : The Inventor’s Lottery Ticket”, *supra* note 214.

<sup>217</sup> Gary L. Griswold & F. Andrew Ubel, “Prior User Rights – A Necessary Part of a First-to-File System”, *supra* note 214.

<sup>218</sup> Keith M. Kupferschmid, “Prior User Rights : The Inventor’s Lottery Ticket”, *supra* note 214; Gary L. Griswold & F. Andrew Ubel, “Prior User Rights – A Necessary Part of a First-to-File System”, *supra* note 214.

<sup>219</sup> *Ibid.*

<sup>220</sup> Keith M. Kupferschmid, “Prior User Rights : The Inventor’s Lottery Ticket”, *supra* note 214.

<sup>221</sup> *Ibid.*; Gary L. Griswold & F. Andrew Ubel, “Prior User Rights – A Necessary Part of a First-to-File System”, *supra* note 214.

<sup>222</sup> *Ibid.*

<sup>223</sup> *Ibid.*

been granted, this exception to patent rights transforms trade secrets into stronger protection mechanisms. This might make trade secrets more attractive, which tend to lower knowledge dissemination. Incidentally, reducing the dissemination of inventions could affect aggregate innovation, research for possible improvements and other forms of research.

### **Experimental Use**

The effects of experimental use exceptions on research may be understood by analyzing its effects on fundamental knowledge and applied knowledge (as defined Part I). New applied knowledge may lead to questioning fundamental knowledge or to application of this knowledge in a new direction. The main purpose of the experimental use exception is to recognize this two-way connection between fundamental and applied knowledge.

The difference between fundamental knowledge and applied knowledge is not obvious in many situations.<sup>224</sup> Therefore, an experimental use exception may serve to compensate for patents granted on subject matter that might fall within the grey zone between fundamental knowledge and applications. From this point of view, an experimental use exception could make available for research fundamental discoveries that could also be considered a valuable research tool by some. For instance, genetic tools that are considered as fundamental knowledge (e.g. genes, etc.) in some jurisdictions could be made accessible for research by a broad experimental use exception while preserving lucrative applications (e.g., genes incorporated into a therapeutic).

As for the exception's effect on applications, it will vary according to its breath. If wide enough, an experimental use exception may make patented applied knowledge available for fundamental research, especially in the case of research tools. Thus, the experimental use exception is often viewed as having the role of promoting open academic research. Contrary to the *Bolar* exception, which is mostly used by private pharmaceutical companies (or universities working closely with them), this exception is perceived as ensuring the necessary freedom of research for scientific progress within the walls of academia. Moreover, as some jurisdictions have experimental use exceptions that cover experimental acts done for commercial purposes, this type of exception can make patented applied knowledge available for applied research.<sup>225</sup> From these observations, it is possible to conclude that experimental use exceptions will also affect research by influencing the availability of patented applied knowledge.

Detractors point to recent studies demonstrating that university researchers generally tend to ignore patents in their research practices,<sup>226</sup> and that private companies rarely launch lawsuits for patent infringement against academics in order to question the necessity of the experimental use exception. Moreover university research has become increasingly commercial and universities themselves now seek and enforce patents quite aggressively when it is to their own advantage. Thus the clear demarcation between “private, commercial research” and “public, non-commercial research” has disappeared during the 20<sup>th</sup> century, making this exception outdated in their view. They feel universities should not be allowed to benefit from an

<sup>224</sup> Australian Government – Advisory Council on Intellectual Property, *Patents and Experimental Use*, October 2005, p.19; Robert P. Merges, “Scientific Innovation, Philosophy, and Public Policy”, (1996) 13:2 Social Philosophy & Policy 145.

<sup>225</sup> *Ibid.*

<sup>226</sup> Mark A. Lemley, “Ignoring Patents”, (2008) Mich. St. L. Rev. 19 ; John P. Walsh, Wesley Cohen & Charlene Cho, “Where Excludability Matters: Material versus Intellectual Property in Academic Biomedical Research” (2007) 36 Research Policy 1184; Final report to the National Academy of Sciences’ Committee Intellectual Property Rights in Genomic and Protein-Related Inventions, by John P. Walsh, Charlene Cho & Wesley Cohen, “Patents, Material Transfers and Access to Research Inputs in Biomedical Research”, (2005).

exception intended to protect fundamental research.<sup>227</sup> It should be noted that the same argument on the disappearing frontier between fundamental research and applied innovations is thus used as a justification by both proponents and detractors of the exception.

Finally, government exceptions could also be used to create greater freedom from infringement for researchers.<sup>228</sup> For example, an experimental use exception could be combined with a governmental use exception that includes governmental affiliated research institutions. If designed with this in mind, research funded by governments that are exempt from patent infringement could allow some researchers to have access to patented knowledge when conducting research supported by government.<sup>229</sup>

Since experimental use exceptions currently in force vary “in [...] nature, scope and judicial interpretation between the various members of the international community”<sup>230</sup> this is an area in which harmonization could make the state of the law clearer to the scientific community. Indeed, as international research collaborations tend to increase, harmonizing this exception would make the understanding of foreign law easier for scientists. Further, as research collaborations often cross national boundaries, harmonising experimental use exceptions would lower legal uncertainty over which law applies and hence lower transaction costs.

The benefits of harmonisation of the experimental use exception may be outweighed, in the opinion of certain countries, by their costs. First, policy makers would need to agree on whether the exception is limited to research on or includes research with the invention.<sup>231</sup> Second, developing countries may prefer broader exceptions as they build a research infrastructure, thus making agreement on the scope of these exceptions difficult.

### **Bolar exemption**

Many jurisdictions have an exception that allows individuals to use a patented invention in order to satisfy regulatory requirements. As previously explained, regulatory review exceptions are generally made to accelerate the sale of generic drugs but may, as in Canada, apply in other settings.

Some countries with broad experimental use exceptions have narrower *Bolar* exceptions (e.g., the United Kingdom, where clinical trials are covered by the experimental use exception,<sup>232</sup> but not the regulatory review exception<sup>233</sup>), while countries with narrower experimental use exceptions tend to have extremely broad *Bolar* exceptions (e.g. Canada, where the scope of the experimental use exception is unclear and the United States). In these countries, the end result is the same: researchers in the health care field enjoy broad protection from patent

<sup>227</sup> David B. Resnik, “Patents and the Research Exemption”, (2003) 299 Science 821.

<sup>228</sup> Sean O’Connor, “Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries” Research Roundtable: Law & Economics of Innovation, 2008.

<sup>229</sup> *Ibid.*

<sup>230</sup> Richard Gold, Yann Joly & Timothy Caulfield, “Genetic Research Tools, the Research Exception and Open Science” *supra* note 152.

<sup>231</sup> *Ibid.*

<sup>232</sup> E. Richard Gold et al., “The Research or Experimental Use Exception: A Comparative Analysis”, (*Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005*) available on line : < (<http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf>)> pp. 1- 52.[ E. Richard Gold et al., “The Research or Experimental Use Exception: A Comparative Analysis”,]

<sup>233</sup> Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, apply to Differing Types of Research*, *supra* note 207.

infringement.<sup>234</sup> However, this general rule should be viewed with a degree of caution because it is not clear if the scope of the experimental use exception encompasses clinical trials in some countries (e.g. Argentina, etc.) or because there is no experimental use exception or regulatory review exception in others (e.g. Chile).

## **B. Commentary on Socio-Economic Issues**

What emanates from this study on exclusions and exemption is a common will in all jurisdictions to strike a balance between incentives to invent and users' rights, in order to optimize innovation.

A first balance aims to be struck between secrecy and patents. For instance, the vast majority of jurisdictions require patents to be disclosed and thereby, encourage knowledge dissemination. However, many countries have prior user rights (e.g. United Kingdom, Canada, Mexico, Brazil, China, Indonesia, Japan, Pakistan, Korea and members of the Andean Community) and thus, strengthen trade secrets. Since trade secrets also have a high value<sup>235</sup>, two protection mechanisms are offered to inventors. In the end, some authors have deemed these two mechanisms complimentary as “trade secret law complements patent law in earlier stages of the innovation process by allowing innovators to work on their ideas until they become patentable.”<sup>236</sup> Moreover, it could be that patents “protect patentable inventions, and [trade secrets], the volumes of important, if not essential, collateral know-how associated with such inventions.”<sup>237</sup>

A second balance might be needed between harmonization and diversification. For instance, differences in intellectual property have been observed and harmonization might play a positive role. Indeed, “[...] national innovation systems themselves are becoming internationalized, even if the institutions that support them remain country-specific.”<sup>238</sup> As research and development initiatives tend to globalize, harmonization of national patent laws will make legal issues more accessible to researchers and make collaboration easier. For example, presumptions about whether a university researcher or the university holds a patent in different countries can complicate both the carrying on of joint research and the transfer of any results of the joint research. Other differences may also cause difficulty in ensuring that research collaborations - which the OECD recognizes in its recent Innovation Strategy are key to further innovation - operate smoothly, at least across international borders.<sup>239</sup>

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<sup>234</sup> E. Richard Gold et al., “The Research or Experimental Use Exception: A Comparative Analysis”, *supra* note 232.

<sup>235</sup> Anthony Arundel, “The relative effectiveness of patents and secrecy for appropriation” (2001) 30 Research Policy 611. Wesley Cohen, Richard Nelson & John Walsh, “Protecting their intellectual assets: appropriability conditions and why U.S. manufacturing firms patent (or not)” (2000) NBER Working Paper Series No. 7552.

<sup>236</sup> Nisvan Erkal, “On The Interaction Between Patent Policy and Trade Secret Policy” (2004) Intellectual Property Research Institute of Australia Working Paper No. 14/4.

<sup>237</sup> Karl F. Jorda, “Patent and Trade Secret Complementariness : An Unsuspected Synergy” (2009) 48 Washburn L.J. 1.

<sup>238</sup> Bo Carlsson, “Internationalization of innovation systems: A survey of the literature” (2006) 35 Research Policy 56.

<sup>239</sup> The OECD Innovation Strategy: Getting a Head Start on Tomorrow, May 2010, OECD Publishing.

However, some fear that harmonization might pre-empt the adoption of protective regimes specific to certain types of technologies, and that a “single, global regime would thus require a reduction in the diversity of the innovation systems themselves”.<sup>240</sup>

Further, even within very similar fields, the effect of exclusions and exceptions on research may vary greatly. A good example of this phenomenon is with respect to patents over gene sequences. As used in the development of clinical genetic tests, patents seem not to provide a needed incentive in making new tests available.<sup>241</sup> Moreover, exclusive licensing does not appear to be essential to the marketing of genetic tests.<sup>242</sup> On the other hand, the use of gene sequences as a component of a therapeutic may require a patent to attract investment and development. Thus, excluding gene patents altogether would have significantly different effects in these two markets.

A third observed balance is that between patentees’ rights and user’s rights. Some argue that a stronger patent system – one with fewer exclusions and exemptions that permit researchers to conduct research without a licence – would increase innovation.<sup>243</sup> Others argue that cumulative innovation may actually be hindered by some or too many patents.<sup>244</sup> Some have even argued that “subsidizing imitation may increase the economy-wide rate of technological progress.”<sup>245</sup> Overall, there is no consensus on what strength patents ought to have in order maximize innovation.

Finally, striking a balance may depend on the level of economic development of different jurisdictions. Research resources and infrastructure have an impact on innovation, the ability to identify patent holders and enter into licences. According to a report from the OECD,<sup>246</sup> knowledge networks and human resources play an important role in that regard. Jurisdictions with higher research and infrastructure resources may seek one form of balance between patentees’ rights and users’ rights while those countries with fewer resources may wish to favour user rights more in order to build a scientific infrastructure.. The same can be said of countries with small or inexistent generic medicine production capacities: to fully take advantage of research exceptions and exclusions, jurisdictions must have some research resources. While it could be argued that exclusions and exceptions might help attract research and development resources in developing countries, such an argument is more applicable to a middle-income country than to one with limited scientific infrasture in the first place.

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<sup>240</sup> Bo Carlsson, “Internationalization of innovation systems: A survey of the literature” *supra* note 238.

<sup>241</sup> Julia Carbone, E Richard Gold, Bhaven Sampat, Subhashini Chandrasekharan, Lori Knowles, Misha Angrist & Robert Cook-Degan, “DNA patents and diagnostics: not a pretty Picture”, (2010) 28:8 Nature Biotechnology.

<sup>242</sup> *Ibid.*

<sup>243</sup> Dana Rohrabacher and Paul Crilly, “The case for a strong patent system” (1995) 8:2 Harv. J. L. & Tech. 263.

<sup>244</sup> James Bessen, “Holdup and licensing of cumulative innovations with private information” (2003) 82 Economics Letters 321.

<sup>245</sup> Toshihiko Mukoyama, “Innovation, imitation, and growth with cumulative technology” (2003) 50 Journal of Monetary Economics 361.

<sup>246</sup> The OECD Innovation Strategy: Getting a Head Start on Tomorrow, May 2010, OECD Publishing.

## Conclusion

This chapter analyzed the exclusions and exception that impact on research and development. It examined international and regional legal agreements to identify concrete examples of each of these mechanisms.

What emanates from this study is that incentives to innovate vary in form according to jurisdiction; this is also the case for limitations. For instance, some countries offer stronger experimental use exceptions, while others offer stronger regulatory approval exceptions.

While incentives and limitations may vary, common points may be highlighted. First, all studied jurisdictions exclude fundamental knowledge from patentable subject matter. Second, a balance between disclosure and secrecy is also struck. Finally, most countries have exceptions (although they differ in nature) to accelerate the approval of generic pharmaceuticals for the market, which could otherwise be significantly delayed.

A balance between harmonization and space for diversity might be desirable. Perhaps, this could be attained by setting common objectives, while allowing different means to attain them. In any case, it is clear from this chapter that exceptions and exclusions are considered an integral part of a healthy patent regime in all jurisdictions studied. The tradeoffs sometimes differ, but there is a common will between jurisdictions to ensure that researchers can avail themselves of the necessary freedom to progress in their research. This policy choice is in line with one of the main function of intellectual property which is to promote research that is beneficial to society.

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[End of Annex VI and of document]

**Audiencia Provincial de Barcelona, Sección 15ª, Sentencia de 20 Jul. 2006, rec.  
852/2005**

**Ponente: González Navarro, Blas Alberto.**

**Nº de Sentencia: 375/2006**

**Nº de Recurso: 852/2005**

**Jurisdicción: CIVIL**

**LA LEY 285671/2006**

PROPIEDAD INDUSTRIAL. Patente europea. Acción declarativa de la titularidad de la patente a favor de la entidad actora por gozar de actividad inventiva y novedad. Derecho de impedir a cualquier tercero la utilización del procedimiento objeto de la patente cuando el tercero sabe o las circunstancias hacen evidente que la utilización del procedimiento está prohibida sin su consentimiento. La entidad demandada utilizó un procedimiento incluido en las reivindicaciones de la patente de la actora para obtener loratadina. Si la explotación de la invención excluye los actos experimentales y comprende el proceso de fabricación y la comercialización del objeto de la invención, por contra, el concepto de preparativos serios y efectivos debe venir referido a éstas. La solicitud de la patente no implica la capacidad para explotarla, ni la obtención y envío de muestras supone que se alcanzara la condición que permita fabricar producto a escala industrial y acceder al mercado. Los actos realizados por la demandada muestran una intención real de proceder a la explotación cuando se alcanzara la capacidad para hacerlo, pero no integran ningún preparativo serio y efectivo para explotar su invención. El derecho a impedir a cualquier tercero la utilización del procedimiento objeto de la patente cuando el tercero sabe o las circunstancias hacen evidente que la utilización del procedimiento está prohibida sin su consentimiento, todo lo cual y descartado el derecho de preuso concurre en la entidad demandada. LUCRO CESANTE. Por todos los beneficios que la actora habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la competencia de la demandada, desde la fecha de la publicación de la solicitud PCT de patente hasta que la demandada cese por completo en la infracción. El criterio del perito contable, que excluye los gastos ordinarios del proceso productivo como personal, amortización de maquinaria, etc., pero incluye el coste de la materia prima, para así obtener el margen bruto de la perjudicada mediante su deducción del precio medio de venta del producto en cada año, es correcto, pues los anteriores ya están soportados por la perjudicada con o sin la competencia ilícita del infractor.

*La AP Barcelona manteniendo la declaración de que la entidad demandante es la titular de la patente europea, estima el recurso para declarar que la demandada ha infringido los derechos derivados de la patente debiendo cesar en la fabricación, ofrecimiento o introducción en el comercio de loratadina fabricada mediante cualquier procedimiento comprendido en las reivindicaciones de la patente europea e indemnizar a la demandante por los daños causados.*

### **TEXTO**

En la ciudad de Barcelona, a veinte de julio de dos mil seis

AUDIENCIA PROVINCIAL DE BARCELONA

SECCIÓN DECIMOQUINTA

ROLLO nº 852/2005 - 1ª

JUICIO ORDINARIO 127/2002

JUZGADO DE 1ª INSTANCIA Nº 10 DE BARCELONA

### **SENTENCIA num 375/06**

Ilmos. Sres. Magistrados

D. IGNACIO SANCHO GARGALLO

D. LUIS GARRIDO ESPA

D. BLAS ALBERTO GONZÁLEZ NAVARRO

Vistos en grado de apelación, ante la Sección 15ª de esta Audiencia Provincial, los presentes autos de juicio ordinario num. 127/2002 seguidos ante el Juzgado de 1ª Instancia nº 10 de Barcelona a instancia de la mercantil ROLABO S.L, representada por el Procurador D. Ángel Quemada Cuatrecasas y defendida por el Letrado D. Miguel Montaña Mora, contra MEDICHEM S.A, representada por el Procurador D. Antonio M. Anzizu Furest y defendida por la Letrada Dña. Anna Autó, así como a instancia de MEDICHEM S.A contra ROLABO S.L en virtud de la reconvencción formulada por aquélla, que penden ante esta Sala en virtud de recurso de apelación interpuesto por la parte actora y en virtud de recurso de apelación por vía de impugnación interpuesto por la parte demandada contra Sentencia de fecha 22 de junio de 2005 dictada por el Magistrado-Juez del referido Juzgado.

### **ANTECEDENTES DE HECHO**

**PRIMERO.-** La parte dispositiva de la sentencia apelada es del tenor siguiente:

"Estimando en parte la demanda interpuesta por ROLABO S.L contra MEDICHEM S.A, y desestimando Integramente la reconvencción planteada de contrario, debo declarar y declaro que ROLABO es titular de la patente europea EP 0970050, la cual se encuentra vigente en España, gozando de actividad inventiva y novedad, absolviendo del resto de pedimentos a MEDICHEM por

cuanto ROLABO no puede impedir que MEDICHEM, por haberse acreditado que dicha entidad de buena fe había realizado preparativos serios y efectivos para explotar el objeto de la patente de ROLABO, prosiga la explotación del producto para la que había hecho los dichos preparativos y en la medida adecuada para atender a las necesidades razonables de la empresa. Las costas derivadas de la demanda interpuesta por ROLABO serán a cargo de dicha parte y las derivadas de la reconvencción interpuesta por MEDICHEM serán a cargo de dicha parte"

**SEGUNDO.-** Contra la sentencia mencionada se interpuso recurso de apelación por la representación de ROLABO S.L, mediante escrito del que se dio traslado a la otra parte, que se opuso e impugnó a su vez la sentencia, tras lo cual, verificado el traslado a la apelante y admitido que fue el recurso, se elevaron los autos a esta Sala, previo emplazamiento de las partes. Comparecidas las mismas, se siguieron los trámites legales, señalándose vista para el día 29 de junio de 2006.

**TERCERO.-** En la tramitación de este juicio se han observado las prescripciones legales, salvo los plazos procesales, que no han podido ser atendidos todos.

Ponente el Ilmo. Sr. Magistrado D. BLAS ALBERTO GONZÁLEZ NAVARRO.

### **FUNDAMENTOS JURÍDICOS**

**PRIMERO.-** En el presente proceso se han enfrentado dos posiciones distintas en torno a una misma patente de procedimiento: ROLABO S.L colabora con FARMAHISPANIA en el desarrollo de un proyecto en torno a la loratadina, un principio activo destinado a actuar ante la aparición en humanos de alergias que afectan a las vías respiratorias, ojos o piel, que fue patentada como producto por SCHERING-PLOUGH en 1981, caducando esta patente en el año 2002, ofreciendo como ventaja novedosa una menor producción de electos secundarios. El objetivo era lograr la obtención de loratadina mediante un procedimiento aún más inocuo y económico, lo que ROLABO efectivamente consigue, registrando la invención en varios países. Por ello, la demandante es titular de la patente europea EP 0970050, publicada con fecha 24 de octubre de 2001 y con prioridad de 26 de febrero de 1997, correspondiente a la fecha de la solicitud de la patente británica, así como de la patente US 6093827, con la misma prioridad. MEDICHEM S.A, por su parte, mantiene que el producto, tras el comienzo de sus investigaciones en octubre de 1995, ya fue obtenido en sus laboratorios en mayo de 1996 por un procedimiento sustancialmente idéntico al de ROLABO, que a pesar de haber entablado relaciones con la actora desde 1998 sin embargo no conocía, habiendo registrado su invención en USA mediante una solicitud de fecha tres meses posterior a la de la actora (30 de mayo de 1997), concedida en efecto el 4 de julio de 2000 con el número US 6084100.

Estas circunstancias han tenido plasmación, entre otras cosas en dos procedimientos: el entablado en USA (Tribunales de Nueva York) por MEDICHEM, con fecha 13 de abril de 2001, contra ROLABO, por el que la primera reivindica su prioridad como primer inventor del mencionado procedimiento para la obtención de loratadina, a lo que ROLABO se ha opuesto y formulado reconvencción. Y el proceso que aquí nos ocupa, en el que ROLABO acciona contra la infracción que de su patente viene realizando MEDICHEM, debiendo cesar en ello, destruir la loratadina obtenida mediante el procedimiento patentado por la actora y los medios empleados para ello, abstenerse de ofrecer el producto obtenido con ese procedimiento a terceros, incluyendo el DMF presentado ante las autoridades sanitarias de USA, indemnizarle por los daños y perjuicios causados, notificar y publicar la sentencia a su costa, más costas. MEDICHEM, sin embargo, niega

la infracción y alega la excepción de uso previo previsto en el artículo 54 de nuestra LP , por lo que la demandante no puede impedirle que prosiga con la explotación de su invención, y reconviene además negando la actividad inventiva del procedimiento registrado por ROLABO, por lo que la patente EP 0970050 es nula.

La sentencia de primera instancia abordó primeramente la cuestión de la falta de actividad inventiva de la patente de la actora, para concluir, apoyándose en el perito judicial Sr. Jaime , que sí que concurre esa actividad y la novedad de la invención de ROLABO, por lo que desestimó la reconvencción. Pero, del mismo modo, también desestimó la demanda, pues aunque consideró que el procedimiento empleado por ambas empresas es sustancialmente el mismo y que ROLABO goza de un registro prioritario (26 de febrero de 1997), entendió que, en efecto, MEDICHEM estaba realizando preparativos serios y efectivos para la explotación de su invención en febrero de 1997, lo que enerva el ius prohibendi de la titular.

*Apelan, pues, ambas partes: ROLABO para que se revoque el pronunciamiento que entiende concurrente un caso de uso previo del artículo 54 LP , se condene al pago de la correspondiente indemnización con arreglo a las bases que desglosa, y se revoque en todo caso el pronunciamiento sobre las costas que le fueron impuestas, al ser una cuestión jurídica dudosa; y MEDICHEM para que se revoque la desestimación de su reconvencción, insistiendo en la nulidad de a patente EP 0970050 por carencia de actividad inventiva.*

Así delimitado el objeto del proceso, las cuestiones nucleares a las que seguidamente habremos de dar respuesta son las siguientes:

En primer lugar, determinar si la patente de la demandante es nula o no, pues evidentemente, en caso de nulidad, carecería de sentido abordar una posible infracción por parte de MEDICHEM.

En segundo lugar, establecer si la demandada está verdaderamente amparada por el derecho de uso previo del artículo 54 , pues la práctica identidad en el procedimiento para la obtención de loratadina no está cuestionada, como no lo está tampoco que la fecha de prioridad del registro de la actora es anterior, de forma que el rechazo del uso previo determinará la infracción de la patente de ROLABO.

Concretar, en su caso, la indemnización procedente a cargo de la infractora.

Decidir qué condena en costas es la procedente en este caso.

**SEGUNDO.-** Comenzando, pues, por la patente de la actora, debe admitirse que, como señala la sentencia de la primera instancia, la pretensión de nulidad de MEDICHEM choca frontalmente con sus propios actos: parece difícil justificar una demanda de nulidad de una patente de procedimiento para la obtención de loratadina por considerarla falta de actividad inventiva, cuando la propia reconviniente acudió a USA, tres meses después de la prioridad de ROLABO, a registrar un procedimiento esencialmente idéntico. Para MEDICHEM, la patente europea de ROLABO es nula, pero en USA la suya, que es sustancialmente igual, es válida. Esta contradicción interna en la postura de la demandante reconvenccional se plasma en otros aspectos: dice haber conocido esa presunta carencia a posteriori, pero en ningún momento comunica tal circunstancia ante los tribunales neoyorquinos; rechaza la actividad inventiva de un procedimiento para el que negoció y ofreció una importante suma de dinero a la actora, a fin de obtener una licencia que le permitiera emplearlo en su propio proyecto industrial.

Esta debilidad intrínseca de la reconvención es más que suficiente para desestimarla. No obstante, tampoco desde el punto de vista pericial la demandada, sujeta a la obligación del artículo 217.2 de la LEC , ha demostrado la falta de actividad inventiva de la patente EP 0970050, más concretamente, no ha conseguido enervar las decisiones de la OEP, la Oficina de Propiedad Industrial canadiense, la Oficina de Patentes y Marcas norteamericana o la suiza, que en diversos momentos y a diversas empresas, no sólo a MEDICHEM Y ROLABO, han confirmado la actividad inventiva de este procedimiento por argumentos que, aunque evidentemente no vinculan a los Juzgados y Tribunales de España, son bien significativos desde el punto de vista técnico.

En este sentido, la decisión del Juzgado a quo de apoyarse en el dictamen del perito judicial, Don. Jaime , parece enteramente razonable. Los peritos que las partes traen a juicio en sustento de su posición, sin necesidad de adentrarse en las relaciones personales y profesionales que ya han mantenido con ellas, vienen lastrados al dictaminar por su posible parcialidad, lo que evidentemente no supone que sus apreciaciones no puedan ser compartidas o igualmente desechadas desde el punto de vista argumentativo, pues todo ello abarca la valoración de la pericial con arreglo a la sana crítica, según el artículo 348 de la LEC , pero sí que justifica la atención prestada a informes provenientes de técnicos no relacionados de forma alguna con el interés de los litigantes. La fuerza probatoria de los dictámenes periciales, sienta la STS de 11 de mayo de 1981 , "reside esencialmente, no en sus afirmaciones, ni en la condición, categoría o número de sus autores, sino en su mayor o menor fundamentación y razón de ciencia, debiendo tener por tanto como prevalentes en principio aquellas afirmaciones o conclusiones que vengan dotadas de una superior explicación racional, sin olvidar otros criterios auxiliares como el de la mayoría coincidente o el del alejamiento al interés de las partes". Al no encontrarse normas valorativas de este tipo de prueba en precepto legal alguno, el Juzgador debe atenerse a las más elementales directrices de la lógica humana ante las evidencias técnicas alcanzadas, de manera que, no tratándose de un fallo deductivo, la función del órgano enjuiciador en cada caso para valorar estas pruebas será hacerlo en relación con los restantes hechos de influencia en el proceso que aparezcan convenientemente constatados.

Así el perito judicial ha confirmado las diferencias que ROLABO expresaba que había en su patente sobre el estado de la técnica inmediatamente anterior a su invención, diferencias éstas que, en su conjunto, hacia imprevisible que el procedimiento de la actora funcionara. Este procedimiento, como decimos común en ambas partes, consiste en un acoplamiento cruzado o heteroacoplamiento de McMurry entre una cetona tipo I y una cetona alifática del tipo II. en presencia de titanio de baja valencia generada in situ partir de tetracloruro de titanio y zinc. El Sr. Jaime confirma que la patente de ROLABO presentaba en el anillo de la derecha de la cetona tipo I un átomo de cloro, le falta un doble enlace en el puente del anillo de siete miembros, utiliza tetracloruro y no tricloruro de titanio y zinc, y sobre todo, presenta en el anillo de la izquierda de la cetona tipo I un átomo de nitrógeno en posición 2, por lo que asistimos a una 2-piridil-cetona. De esta forma, concluye el perito judicial, el procedimiento reivindicado por ROLABO supuso el primer acoplamiento de McMurry culminado satisfactoriamente en una cetona piridínica, además del primero que se realizaba satisfactoriamente con tetracloruro de titanio/zinc, nada de lo cual podía deducirse previamente de la bibliografía o de otros acoplamientos anteriores, por lo que la posibilidad de éxito de ROLABO no era evidente.

De la documental aportada con la contestación a la reconvención, resulta que el único intento que consta documentado de llevar a cabo un procedimiento como el relatado con una piridil cetona (esto

es, con un átomo de nitrógeno), se describe en el artículo de G.R Newkome, a pesar de lo cual la actora reconvenzional no lo aporta, haciéndolo en su lugar el Sr. Vicente , perito de la demandada en la reconvencción. Artículo éste que, como resaltó el perito judicial, puso de manifiesto el fracaso en aquél momento del heteroacoplamiento de dos cetonas distintas, una de ellas piridínica, concretamente una 3-piridil-cetona, resaltando así la altura inventiva de la patente cuestionada.

Si en la fecha de prioridad de la patente el intento de un experto de la categoría de Newkome había fracasado, cabe racionalmente concluir que para un experto medio imparcial (y no para algunos de los peritos de que las partes se han valido, autoridades mundiales en materia de reacciones de McMurry o expertos sobrecualificados), el heteroacoplamiento exitoso de una piridil cetona para sintetizar loratadina no era ni mucho menos una posibilidad evidente, por lo que sí que existía actividad inventiva. Teniendo presente esto y la conducta propia de la actora reconvenzional, parece clara la necesidad de confirmar la desestimación de la reconvencción, con el consiguiente reflejo en las costas.

**TERCERO.-** Válida y eficaz la patente de la demandante, por tanto, abordaremos seguidamente si la infracción de MEDICHEM, cuyo procedimiento para la obtención de loratadina está incluido en las reivindicaciones de la patente de ROLABO, de fecha prioritaria, y que ya ha fabricado el producto obtenido, está amparada por un derecho de uso previo, tal y como ha entendido la Sra. Magistrada.

**El artículo 54 de la LP señala lo siguiente:**

**"1. El titular de una patente no tiene derecho a impedir que quienes de buena fe y con anterioridad a la fecha de prioridad de la patente hubiesen venido explotando en el país lo que resulte constituir el objeto de la misma, o hubiesen hecho preparativos serios y efectivos para explotar dicho objeto, prosigan o inicien su explotación en la misma forma en que la venían realizando hasta entonces o para la que habían hecho los preparativos y en la medida adecuada para atender a las necesidades razonables de su empresa. Este derecho de explotación sólo es transmisible juntamente con las empresas.**

2. Los derechos conferidos por la patente no se extienden a los actos relativos a un producto amparado por ella después de que ese producto haya sido puesto en el comercio por la persona que disfruta del derecho de explotación establecido en el apartado anterior. "

Pues bien, las dos partes han ofrecido una interpretación diferente de lo que debe entenderse por "explotación" de la patente, para así perfilar con corrección cuando estamos en presencia de "preparativos serios y efectivos", que es lo que la sentencia recurrida asegura que ya venía desplegando la demandada. ROLABO parte de otro precepto de la LP, al artículo 84, incluido en el Título IX de la Ley , referido a la obligación de explotar y a las licencias obligatorias. Este artículo indica que, para justificar esta explotación, el titular de la patente podrá servirse de un certificado oficial, que se expedirá por el organismo que en cada caso corresponda y deberá ajustarse a los criterios y normas generales que se establezcan reglamentariamente, afirmando que "(e)l certificado de explotación deberá basarse en la inspección del proceso de fabricación en las instalaciones industriales donde la invención esté siendo explotada y en la comprobación de que el objeto de la invención patentada está siendo efectivamente comercializado." Desde esta perspectiva, por tanto, la explotación de la patente se concreta necesariamente en la existencia de un proceso de fabricación en instalaciones industriales y una efectiva comercialización.

Ello excluye que pueda hablarse de explotación cuando el titular tan sólo muestra un proceso para la obtención de la invención o cuando sólo está en condiciones de reproducirla, esto es, está en posesión de la invención, pues nada de ello supone que sea capaz de explotarla, vista la experiencia de que muchos inventos se traducen en la concesión de patentes que, sin embargo, nunca llegan a explotarse. De la misma forma, la solicitud de la patente tampoco implica por se una explotación, como enseña el artículo 133 de la LP, que exige que el titular de la patente ya concedida acredite su explotación o que hace preparativos serios y efectivos a tal efecto como requisito para acceder a las medidas cautelares.

Si es ése el concepto de explotación, los preparativos serios y efectivos vendrán referidos a él: no se señala en la Ley que lo serio y efectivo deba ser la intención del titular de explotar la patente, sino los preparativos que ha dispuesto para fabricar y comercializar, que deben ser serios y efectivos, es decir, más allá de los simples preparativos iniciales. La forma de diferenciarlos, según esta tesis, sería la temporalidad: los preparativos serios y efectivos conducen de forma inminente a la explotación, tal y como realizan otros Tribunales de nuestro entorno, como muestra Gimeno-Bayón en relación a la doctrina contenida en algunas sentencias francesas y británicas.

*Por el contrario, MEDICHEM considera que esta tesis sobre el concepto de explotación, integrado necesariamente por la fabricación del producto y su comercialización efectiva, es demasiado restrictiva, hasta el punto que, de exigirse al favorecido por el uso previo esta explotación antes de la fecha de prioridad de la patente infringida, se daría lugar a la nulidad de la misma por falta de novedad. El concepto de explotación es más amplio según esta otra tesis, que lo localiza en el artículo 64 de la LP, el cual, tras expresar que quien, sin consentimiento del titular de la patente, fabrique, importe objetos protegidos por ella o utilice el procedimiento patentado, estará obligado en todo caso a responder de los daños y perjuicios causados, añade: "Todos aquellos que realicen cualquier otro acto de explotación del objeto protegido por la patente sólo estarán obligados a indemnizar los daños y perjuicios causados si hubieran sido advertidos por el titular de la patente acerca de la existencia de ésta, convenientemente identificada y, de su violación, con el requerimiento de que cesen en la misma, o en su actuación hubiera mediado culpa o negligencia." Para el legislador, por tanto, la fabricación o importación de objetos protegidos por la patente, o la utilización del procedimiento patentado, son actos de explotación, y a ellos vienen referidos los preparativos serios y efectivos, que no guardan relación directa con la inminencia de la explotación, sino con su orientación franca y directa a la explotación de un producto que ya ha sido obtenido.*

Las pruebas disponibles, sobre todo la abrumadora cantidad de documentos que ha aportado MEDICHEM sobre su proyecto, han mostrado perfectamente en qué fase se encontraba a la fecha de prioridad de la patente de ROLABO, que recordemos es de 26 de febrero de 1997. El documento nº 12 de la contestación, la planificación gráficamente expuesta por la demandada en su proyecto de loratadina desde octubre de 1995, es bien claro: asumiendo que MEDICHEM lograra obtener loratadina el 6 de mayo de 1996 (cuestión ésta muy relevante en el pleito norteamericano, pero no en éste, si bien no cabe hacer abstracción de que el Tribunal de Apelación de Nueva York haya declarado finalmente que MEDICHEM antedató ciertas fechas en este proceso de obtención), en febrero de 1997 estaba aún en la que la propia demandada llamó la fase de laboratorio, es decir, en la síntesis y reproducción del producto mediante el procedimiento en cuestión en la planta de I+D, pero sin haber llegado al Technology Transfer, por el que, según se confirmó testificalmente, Investigación y Desarrollo le transfiere al Departamento de Industrialización la tecnología necesaria

para poner en marcha la industrialización, primero en planta piloto y luego en la industrial. De esta forma, de la pequeña cantidad obtenida en la fase anterior, insuficiente para mantener ninguna explotación, se pasa a una escala superior, la cual, una vez validada por su éxito en ocasiones diferentes, culminará con el proceso de fabricación industrial. Concretamente, MEDICHEM estaba en febrero de 1997 con las pruebas de laboratorio, que seguirán realizándose por ejemplo en mayo o junio de 1997, realizándose el Technology Transfer el 17 de julio de este año, según indicó la Dra. Magdalena , Directora del Departamento de I+D, al Sr. Franco , responsable del Departamento de Industrialización (doc. nº 15 contestación). La solicitud de 5 kgr de cicloheptanona, uno de los compuestos de partida para la loratadina, efectuada el 7 de febrero de 1997 al laboratorio indio MOREPEN, fue efectuada para continuar su proceso de I+D, según consta en el documento nº 14 de la contestación, y la solicitud de otro de los precursores, la carbetoxipiperidona, no se efectúa hasta el 10 de septiembre de ese mismo año. En octubre, se continuaban los ensayos en la planta piloto, como muestra el documento nº 17 de la contestación, en la que Sr. Franco informa al Director General de que dos de los tres lotes producidos en el mes de septiembre no salieron bien, estudiándose purificaciones adicionales con I+D. La misma situación se mantenía en el escalado en planta piloto siete meses más tarde, en mayo de 1998, según muestra el documento nº 19 de la contestación, en coherencia con el documento nº 18 de la demandada, que enseña que las pruebas de estabilidad de la loratadina almacenada se acuerdan en marzo de 1998 y se inician en julio de este año. Fue en noviembre de 1998 cuando se presenta el DMF ante las autoridades sanitarias de USA, aunque el mismo día 26 de febrero de 1997 ya había mandado muestras de loratadina a su agente en ese país.

**CUARTO.-** Pues bien, siguiendo las apreciaciones del mismo Profesor Bercovitz, que MEDICHEM ha aportado en apoyo de sus pretensiones, deberemos concluir que el concepto de explotación y preparativos serios y efectivos de nuestra legislación no coincide exactamente con la de nuestro entorno. Así, el actual artículo 37 del Convenio de Luxemburgo sobre la Patente Comunitaria, con el título "Derecho fundado en una utilización anterior y derecho de posesión personal", indicaba que quien "hubiere adquirido, en alguno de los Estados contratantes, un derecho fundado en una utilización anterior de esta invención o un derecho de posesión personal de la misma, disfrutará en este estado del mismo derecho respecto de una patente comunitaria concedida para la misma invención." La utilización del procedimiento patentado no viene limitado por su destino ineludible a la explotación de la patente, mucho menos la mera posesión de la invención; ello ampararía todo el proceso de investigación que la demandada estaba llevando a cabo mediante la utilización del procedimiento patentado por la actora y la obtención reproducible de loratadina.

En Francia también basta con la posesión de buena fe de la invención para conceder el derecho de preuso. En Inglaterra, sin embargo, según el artículo 64 de la Patents Act, el derecho de preuso se concede a quien, "antes de la fecha de prioridad de la patente: a) realice de buena fe un acto que constituiría violación de la patente si ésta estuviese en vigor, o b) realice de buena fe preparativos serios y efectivos para llevar a cabo ese acto (...)", lo que se aproxima al concepto de explotación que da MEDICHEM al cifrarlo en los actos por los que, con arreglo a nuestra LP, el infractor debe indemnizar al titular (la fabricación o importación de objetos protegidos por la patente, o la utilización del procedimiento patentado, según el artículo 64 español).

El concepto de explotación ya aparece expresamente en la Ley de Patentes alemana (art. 12), que sí se pronuncia en términos similares al artículo 54 español: "(n)o se puede invocar la patente contra quien, en el momento del depósito de la solicitud de patente, explotaba la invención en el país o

había realizado preparativos serios y efectivos para su explotación." No obstante, la doctrina pone de relieve cómo la jurisprudencia alemana exige para este derecho de uso previo que el mismo haya consistido en alguno de los actos de explotación que ampara la patente posteriormente solicitada, es decir, que se hace coincidir también el concepto de uso anterior con aquél que, de haber estado vigente la patente, hubiera sido un acto de explotación de la misma, como la introducción en el comercio o el mero ofrecimiento de venta del producto.

A diferencia del sistema norteamericano, en el que patenta quien primero inventa, no quien primero registra, el sistema europeo concede la patente al inventor que primero presenta la solicitud en el registro correspondiente, lo que obliga a hacer alguna previsión para compensar al inventor que también había llegado, de buena fe, de modo independiente y con una inversión generalmente costosa, a la misma invención, pero que acudió al registro más tarde o que simplemente no muestra un interés en patentar, permitiéndole un derecho de explotación de la invención, que al fin y al cabo también es suya. Así lo señala la doctrina al describir el mecanismo corrector que supone este derecho de preuso, totalmente irrelevante en USA, donde los litigios se orientan, con las consiguientes dificultades probatorias, a determinar quién es el que primero llegó al invento, tal y como ha ocurrido con MEDICHEM Y ROLABO, Aunque, desde otro punto de vista, la excepción al ius prohibendi del titular registra debe ser objeto de una interpretación estricta, pues la patente perdería interés si el inventor sabe que terceros que no han hecho accesible el invento al público lo van a poder explotar de todas formas.

Este propósito corrector también anima a nuestra legislación, al artículo 54 de la LP ya expuesto, pero éste no aclara qué debe entenderse por explotación o preparativos serios y efectivos para explotar.

Nuestra LP, ciertamente, emplea conceptos diversos de la explotación: buena muestra de ello es la diferencia entre el artículo 84 y el artículo 64 , que ya hemos puesto de relieve. Pero existen más referencias a la explotación de la patente, y éstas permiten afirmar que, a diferencia de las normas comunitarias, francesas o británicas antes señaladas, nuestro ordenamiento no se detiene en la mera posesión de la invención o en aquellos actos que hubieran constituido una violación de la patente posteriormente solicitada, sino que exige en verdad que exista un proceso de explotación comercial del objeto inventado.

Así, el artículo 5 señala que no pueden ser objeto de patente las invenciones cuya explotación comercial sea contraria al orden público o a las buenas costumbres, considerando el legislador que lo que puede afectar a este orden social básico es la comercialización. De la misma forma, el artículo 7 .c) dice que no se tomará en consideración para determinar el estado de la técnica una divulgación de la invención que, acaecida dentro de los seis meses anteriores a la presentación de la solicitud en el Registro de la Propiedad Industrial haya sido consecuencia directa o indirecta de los ensayos efectuados por el solicitante o por sus causantes, siempre que no impliquen una explotación o un ofrecimiento comercial del invento.

Tenemos un caso de uso previo en el artículo 13 , según el cual, cuando se produzca un cambio en la titularidad de una patente como consecuencia de una sentencia, las licencias y demás derechos de terceros sobre la patente se extinguirán por la inscripción en el Registro de patentes de la persona legitimada, pero tanto el titular de la patente como el titular de una licencia obtenida antes de la inscripción de la presentación de la demanda judicial que, con anterioridad a esa misma inscripción, hubieran explotado la invención o hubieran hecho preparativos efectivos y reales con esa finalidad,

podrán continuar o comenzar la explotación siempre que soliciten una licencia no exclusiva al nuevo titular inscrito. Estas licencias para comenzar o continuar la explotación, que deben solicitarse en un periodo de dos o cuatro meses, parten de la idea de que el titular o el licenciatario anterior ya están en condiciones de explotar la invención, de proceder a su fabricación y comercialización inmediata.

Por su parte, el artículo 58 expresa que, cuando se conceda una patente para una invención cuyo objeto se encuentra en régimen de monopolio legal, el monopolista sólo podrá utilizar la invención con el consentimiento del titular de la patente, pero estará obligado a aplicar en su industria, obteniéndose el correspondiente derecho de explotación, aquellas invenciones que supongan un progreso técnico notable para la misma. Además, si el monopolio fuera establecido con posterioridad a la concesión de la patente, el titular de la misma tendrá además derecho a exigir que el monopolista adquiera la empresa o las instalaciones con las que hubiera venido explotando la invención patentada, abonando un precio que se fijará por acuerdo entre las partes o, en su defecto, por resolución judicial. Todo ello, de nuevo, confirma la idea del legislador sobre cuándo se explota una invención.

El artículo 84 , citado por ROLABO, sobre la certificación de la explotación en base a la fabricación y la comercialización, debe ser puesto en relación con el artículo 83 , que al establecer la obligación de explotar la invención patentada, especifica que ello deberá hacerse mediante su ejecución en España o en el territorio de un miembro de la Organización Mundial del Comercio de forma que dicha explotación resulte suficiente para satisfacer la demanda del mercado nacional, lo que impide considerar como actos de explotación aquellos que no tengan una mínima trascendencia en el mercado.

También interesa destacar el artículo 87 , según el cual, una vez finalizado el plazo establecido en el artículo 83 para iniciar la explotación de la invención protegida por la patente, cualquier persona podrá solicitar la concesión de una licencia obligatoria sobre la patente, si en el momento de la solicitud, y salvo excusas legítimas, no se ha iniciado la explotación de la patente o no se han realizado preparativos efectivos y serios para explotar la invención objeto de la patente, o cuando la explotación de ésta ha sido interrumpida durante más de tres años, añadiendo que "se considerarán como excusas legítimas las dificultades objetivas de carácter técnico legal, ajenas a la voluntad y a las circunstancias del titular de la patente, que hagan imposible la explotación del invento o que impidan que esa explotación sea mayor de lo que es", lo que, interpretado a sensu contrario, significa que las dificultades técnicas objetivas que no tienen contenido legal y que hayan dificultado o imposibilitado la explotación del invento en el mercado nacional no tienen la consideración de excusas legítimas.

En la misma línea, el artículo 90 recoge la posibilidad de que, por motivo de interés público, el Gobierno podrá someter en cualquier momento una solicitud de patente o una patente ya otorgada a la concesión de licencias obligatorias, considerando que existen motivos de interés público cuando la iniciación, el incremento o la generalización de la explotación del invento, o la mejora de las condiciones en que tal explotación se realiza, sean de primordial importancia para la salud pública o para la defensa nacional, o cuando la falta de explotación o la insuficiencia en calidad o en cantidad de la explotación realizada implique grave perjuicio para el desarrollo económico o tecnológico del país. Y antes de solicitar una licencia obligatoria, el interesado podrá pedir la mediación del Registro de la Propiedad Industrial para la consecución de una licencia contractual sobre la misma patente, incluyendo en la solicitud los datos que permiten juzgar sobre la posibilidad de que lleve a

cabo una explotación real y efectiva de la invención patentada, señalando el artículo 94 que cuando, como consecuencia de las negociaciones realizadas con la mediación del Registro de la Propiedad Industrial, las partes hubieran acordado suscribir una licencia sobre la patente, podrán solicitar que no se admitan solicitudes de licencias obligatorias sobre dicha patente durante el plazo necesario para que el licenciataria comience su explotación, sin que en ningún caso podrá ese plazo ser superior a un año y con el deber de justificar mensualmente los trabajos. Este plazo también se asienta en la idea de que la explotación es comercial y trasciende en el mercado.

Y el artículo 127 recoge la posibilidad de que cualquier interesado ejercite una acción contra el titular de una patente, para que el Juez competente declare que una actuación determinada no constituye una violación de esa patente, señalando que el interesado, con carácter previo a la presentación de la demanda, requerirá notarialmente al titular de la patente "para que se pronuncie sobre la oponibilidad entre la misma y la explotación industrial que el requirente lleve a cabo sobre territorio español y frente a los preparativos serios y efectivos que desarrolle a tales efectos". Transcurrido un mes desde la fecha del requerimiento sin que el titular de la patente se hubiera pronunciado o cuando el requirente no esté conforme con la respuesta, podrá ejercitar la acción prevista en el apartado anterior.

**QUINTO.-** Si la explotación de la invención, por tanto, según la entiende el legislador, excluye los actos experimentales, la mera investigación para ejecutar el invento, y comprende el proceso de fabricación y la comercialización del objeto de la invención, es claro que el concepto de preparativos serios y efectivos debe venir referido a éstas. De esta forma, los actos de experimentación tampoco pueden ser considerados como preparativos para explotar, pues aunque exista una intención seria de que esos actos experimentales se traduzcan en una explotación efectiva de un producto ya obtenido con éxito en laboratorio, lo cierto es que muchos de dichos proyectos fenecen en esta fase, son incapaces de dar el paso al proceso industrial y la comercialización posterior; por ende, esta fase de laboratorio no demuestra una capacidad inmediata de explotación, exigiendo la ley preparativos electivos y serios para explotar, no meras intenciones de hacerlo.

*Esto es coherente con las legislaciones que siguen, como la nuestra, el modelo alemán, cuya jurisprudencia, por demás, como recuerda el Profesor Bercovitz, considera que la mera utilización de una invención en el contexto de pruebas de laboratorio, que se circunscriben exclusivamente a comprobar la ejecutabilidad de la invención, no se entiende como un uso previo, a no ser que el resultado tenga ya un aprovechamiento económico o comercial.* Incluso en Francia, que sigue un sistema en principio diferente, la jurisprudencia interpreta el uso previo de forma restringida, exigiendo al beneficiado que acredite que está en condiciones de explotar el invento o, en su caso, que lo iba a explotar en un breve plazo.

La inmediatez, en efecto, no integra la esencia del acto preparatorio serio y efectivo, pero sí que lo adjetiva y permite detectarlo cuando se produce, pues es aquél que muestra la capacidad del inventor de proceder de modo inminente a la fabricación y comercialización del objeto de la invención.

A la vista de cuanto antecede, los actos realizados por MEDICHEM anteriormente descritos muestran una intención real de proceder a la explotación cuando se alcanzara la capacidad para hacerlo, pero no integran ningún preparativo serio y efectivo para explotar su invención; todo ello, debe insistirse sin entrar en la buena fe de la demandada, que en el litigio americano ha sido cuestionada. El análisis de las fases de su proyecto de loratadina enseña que, a 26 de febrero de

1997, MEDICHEM estaba embarcada todavía en la fase de laboratorio, en actos experimentales para lograr pasar a la planta piloto y validar con éxito un proceso de fabricación industrial y posterior comercialización. Ninguno de los actos que esgrime como relevantes a ese efecto lo son en realidad: la solicitud de la patente no implica la capacidad para explotarla, ni la obtención y envío de muestras supone que se alcanzara la condición que permita fabricar producto a escala industrial y acceder al mercado. En consecuencia, discrepamos del criterio expuesto en la sentencia recurrida, que deberá revocada en este punto, al no ser de aplicación el derecho de preuso del artículo 54 de la LP .

**SEXTO.-** Deberemos concluir, pues, que la demanda debe estimarse, ya que el artículo 50 de la LP confiere a ROLABO el derecho de impedir a cualquier tercero la utilización del procedimiento objeto de la patente cuando el tercero sabe o las circunstancias hacen evidente que la utilización del procedimiento está prohibida sin su consentimiento, todo lo cual, visto el historial de negociaciones previas entre las partes, y descartado el derecho de preuso, cabe predicar de la conducta de MEDICHEM, que utilizó un procedimiento incluido sin duda en las reivindicaciones de la patente de la actora para obtener loratadina. Ello se concretará en la estimación de las acciones ejercitadas al amparo del artículo 63 .

En lo que hace a la indemnización de los daños y perjuicios causados, la demanda rectora de la pretensión de ROLABO centraba su reclamación en tres bases:

1. Todos los beneficios que ROLABO habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la competencia de la demandada, desde la fecha de la publicación de la solicitud de patente EP 0970050 (art. 59), es decir, desde el 3 de septiembre de 1998, hasta que la demandada cese por completo en la infracción.
2. Todos los gastos incurridos por ROLABO con relación a los actos de infracción de su patente llevado a cabo por MEDICHEM, como los derivados de las investigaciones para comprobar la realidad de dichos actos, asesoramientos, envío de requerimientos y similares acreditados.
3. El número de horas dedicadas por los directivos y demás personal de ROLABO a comprobar la realidad de la infracción, prepararse para hacerla valer en juicio y las dedicadas a atender las incidencias que se susciten en el curso del procedimiento.

Según el Tribunal Supremo, en sus sentencias de 23 de febrero y 27 de julio de 1998 o 7 de diciembre de 2001 , entre otras, el artículo 64 de la Ley de Patentes dispone en forma imperativa, al emplear la expresión "en todo caso", que, en los supuestos como el que nos ocupa, de utilización del procedimiento patentado sin consentimiento del titular, la obligación de responder de los daños y perjuicios causados: "(s)e trata por tanto- dice la última sentencia mencionada - de una responsabilidad objetiva, que se alinea a la doctrina de esta Sala para otras situaciones jurídicas sobre la estimación de daños y perjuicios inherentes, sin necesidad de prueba directa de los mismos y en cuanto de los hechos demostrados o reconocidos por las partes se deduzca necesaria y fatalmente de los mismos como reales y efectivos (SSTS 10 de junio de 2000, que cita las de 5 de junio de 1985, 30 de septiembre de 1988, 7 de diciembre de 1990, 15 de abril y 15 de junio de 1992, 1 de julio de 1995 y 25 de febrero de 2000), por lo que la obligación reparadora surge como hecho inevitable y sin necesidad imperiosa de la cuantificación, que puede quedar relegado al trámite de ejecución de sentencia." La referida responsabilidad objetiva opera sin necesidad de tener que llevar a cabo requerimiento previo al infractor; se refiere a la fabricación o importación de productos y también, en contra de lo que alega la demandada, a la utilización del procedimiento

patentado; y resulta distinta de la responsabilidad por culpa, también prevista en el artículo 64 , para cuando se realiza cualquier otro acto de explotación del objeto protegido, presumiéndose la culpa desde el momento en que el infractor es advertido por el titular y se le requiere para cesar en la infracción, en cuyo caso si se hace precisa la prueba de los daños y perjuicios que se hubieran causado. Más recientemente, el Tribunal Supremo ha declarado en su sentencia de 1 de junio de 2005; "(a) las anteriores consideraciones procede indicar que en Sentencia de esta Sala de 23 de diciembre de 2004 , se indica que conviene matizar lo declarado por la misma en algunas de sus sentencias, sobre la imperiosa exigencia de acreditar los daños y perjuicios en el proceso de declaración (Sentencia de 20 de febrero de 2001), o sobre la falta de consolidación de la doctrina de los daños "in re ipsa " en estas materias (Sentencias de 29 de septiembre de 2003 y 3 de marzo de 2004), mediante lo resuelto por aquéllas otras que consideran los daños y perjuicios una consecuencia necesaria de la infracción (Sentencias de 23 de febrero de 1998, 17 de noviembre de 1999, 7 de diciembre de 2001 y 19 de junio de 2003), pues raramente podrá darse la infracción que ningún beneficio reporte al infractor, o ningún perjuicio cause al demandado interesado en que cese la ilicitud, si se tiene en cuenta el interés económico que preside estos ámbitos, generalmente vinculadas a actividades empresariales ".

En nuestro caso, debe admitirse que los daños y perjuicios derivados de la utilización por MEDICHEM del procedimiento patentado por ROLABO, con la que incluso estuvo negociando para obtener una licencia (por 500.000 \$ más un 13% sobre las ventas de loratadina), luego frustrada, necesariamente ha causado daños y perjuicios a la demandante. La indemnización debida comprende no sólo el valor de la pérdida que haya sufrido el titular del modelo de utilidad, sino también la ganancia que haya dejado de obtener a causa de la violación, según el artículo 66.1 de la LP .

El daño emergente, siguiendo el criterio del perito Sr. Jorge , que examinó las facturas de ROLABO, comprende en efecto el valor económico de los gastos relacionados con investigaciones, asesoramientos, etc, para confirmar la realidad de la infracción, que sin perjuicio de una posterior liquidación en ejecución de sentencia, importaba a 31 de agosto de 2002 , según el perito, 44.123'83 euros. El coste de oportunidad de las horas incurridas por los empleados de ROLABO y otros en su nombre, con el consiguiente abandono de las tareas propias de su cometido en el proceso productivo o administrativo que les es propio, es de 164.730'71 euros a esa misma fecha, lo que el perito explica de forma racional, incluyendo a personal de FARMAHISPANIA, integrado en el proyecto de la patente infringida, y atendiendo a un número de horas (cuatro empleados, 650, 450, 350 y 90 horas respectivamente) ponderado y prudencial, vista la extraordinaria importancia económica de la invención y el comienzo de estas tareas defensivas años antes.

Para la determinación del lucro cesante, la actora, conforme al artículo 66.2 de la LP , opta por el sistema mencionado en la letra a), esto es, todos los beneficios que ROLABO habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la competencia de la demandada, desde la fecha de la publicación de la solicitud PCT de patente EP 0970050 (lo que ampara el artículo 59 de la LP , en relación con el artículo 11.3 del Convenio de Washington PCT), es decir, desde el 3 de Septiembre de 1998, hasta que la demandada cese por completo en la infracción, lo que a 31 de agosto de 2002 se cifraba en un beneficio bruto de ROLABO de 366.237'13 euros, pero que igualmente deberá ser liquidado de forma definitiva en ejecución de sentencia. Ciertamente, existen otros posibles suministradores de loratadina en el mercado, pero es perfectamente racional afirmar que, siendo el procedimiento que emplea MEDICHEM el mismo

que el patentado por ROLABO, el cliente habría buscado dicho procedimiento y así evitar que las autorizaciones administrativas para comercializar tengan que ser modificadas por un cambio en el procedimiento de obtención.

Por otra parte, al optarse por la letra a) del artículo 66 de la LP , los beneficios contemplados son los previsibles de la explotación de la invención si no hubiera existido la competencia del infractor, es decir, no el beneficio ordinario que ROLABO obtiene por cada kgr de loratadina que vende en su actividad, sino el beneficio adicional previsible si, además, hubiera vendido los kgrs que MEDICHEM puso en el mercado. Por ello, el criterio del perito contable, que excluye los gastos ordinarios del proceso productivo como personal, amortización de maquinaria, etc, pero incluye el coste de la materia prima, para así obtener el margen bruto de la perjudicada mediante su deducción del precio medio de venta del producto en cada año, parece correcto, pues aquél último coste sin duda que se producirá, pero los anteriores ya están soportados por la perjudicada con o sin la competencia ilícita del infractor.

Por el contrario, no es atendible la pretensión de ROLABO, explicitada en su recurso de apelación de modo autónomo, de que en la indemnización se incluyan los perjuicios patrimoniales derivados de la pérdida de clientes en USA como consecuencia de la ilícita competencia de MEDICHEM en ese país, pues modifica los términos del debate, según se configuró en su petición inicial de indemnización de su demanda, que no hacía referencia a ese concepto, sino al lucro cesante del artículo 66.2 .a).

**SÉPTIMO.-** Finalmente, las partes dedican especial atención, lógicamente, al tema de las costas. En ese sentido, de acuerdo con los artículos 398, 397 y 394 de la LEC , consideramos que el caso presentaba serias dudas de derecho en lo referente a la excepción del uso previo, por lo que, tratándose además de una estimación parcial del recurso de la actora, cada parte abonará las costas causadas a su instancia y las comunes por mitad, por lo que se revocará el fallo recurrido en este punto. No se hará condena por las causadas en la alzada.

Sin embargo, consideramos que las circunstancias hacen temeraria la reconvencción formulada por la demandada para obtener la declaración de la nulidad de la patente por falta de actividad inventiva, por lo que las costas derivadas de la reconvencción serán íntegramente impuestas a la demandante reconvenccional en ambas instancias.

## **FALLAMOS**

Que estimando el recurso de apelación interpuesto por la representación de ROLABO S.L contra la sentencia dictada con fecha 22 de junio de 2005 por el Juzgado de 1ª Instancia nº 10 de Barcelona, cuya parte dispositiva obra transcrita en los antecedentes de la presente resolución, **REVOCAMOS** dicha resolución, a salvo de la declaración de la titularidad de ROLABO sobre la patente EP 0970050, que se mantiene, y en su lugar:

**DECLARAMOS** que MEDICHEM realiza actos que constituyen una infracción de los derechos derivados de la patente europea EP 0970050 de ROLABO y que con ello ha causado daños y perjuicios efectivos a la demandante.

**CONDENAMOS** a la demandada MEDICHEM S.A a:

Estar y pasar por esta declaración.

A cesar en la fabricación, ofrecimiento o introducción en el comercio de loratadina fabricada mediante cualquier procedimiento comprendido en las reivindicaciones de la patente europea EP 0970050, incluyéndole descrito en el DMF presentado con el número 13842 ante las autoridades sanitarias de los Estados Unidos.

A destruir la loratadina fabricada mediante cualquier procedimiento comprendido en las reivindicaciones de la patente europea EP 0970050, así como los medios exclusivamente destinados a tal producción o a la realización del producto siguiendo cualquiera de los procedimientos mencionados.

A abstener en lo sucesivo de cualquier acto que suponga una infracción de la patente europea EP 0970050, en particular, a abstenerse del ofrecimiento a PHARMAGENUS, COMBINO PHARM, TEVA o cualquier otro tercero de loratadina fabricada mediante cualquier procedimiento comprendido en las reivindicaciones de la patente europea EP 0970050, incluyéndole descrito en el DMF presentado con el número 13842 ante la autoridades sanitarias de los Estados Unidos.

A indemnizar a ROLABO por los daños y perjuicios sufridos en la siguiente forma: Por todos los beneficios que ROLABO habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la competencia de la demandada, desde la fecha de la publicación de la solicitud de patente EP 0970050 (art. 59), es decir, desde el 3 de septiembre de 1998, hasta que la demandada cese por completo en la infracción, por todos los gastos incurridos por ROLABO con relación a los actos de infracción de su patente llevado acabo por MEDICHEM, como los derivados de las investigaciones para comprobar la realidad de dichos actos, asesoramientos, envío de requerimientos y similares acreditados, y por el número de horas dedicadas por los directivos y demás personal de ROLABO y FARMAHISPANIA a comprobar la realidad de la infracción, prepararse para hacerla valer en juicio y las dedicadas a atender las incidencias que se susciten en el curso del procedimiento. Todo ello se liquidará en ejecución de sentencia, siguiendo las bases expuestas por el perito contable Don. Jorge en su informe, aunque actualizando las cifras obtenidas para cuantificar el perjuicio a la fecha de la liquidación y hasta el completo cese de la infracción.

A notificar la sentencia, a su costa, a las personas interesadas, incluyendo a la Food and Drug Administration de Estados Unidos, a la Agencia Española del Medicamento, a las empresas titulares de autorizaciones de comercialización de loratadina en España, a la empresa TEVA PHARMACEUTICALS y a cualquier otra que, en ejecución de sentencia, se acredite que adquirió loratadina de MEDICHEM.

A la publicación de la sentencia, a su costa, en los periódicos LA VANGUARDIA y EL PAÍS.

Considerando que la cuestión suscitada era jurídicamente compleja y dudosa, cada parte abonará las costas causadas a su instancia y las comunes por mitad. No se hace condena por las costas de la alzada.

Y desestimando el recurso de apelación interpuesto por la representación de MEDICHEM S.A contra la sentencia citada, CONFIRMAMOS dicha resolución en la desestimación íntegra de la reconvencción formulada, imponiendo a la demandante reconvenccional el pago de las costas de ambas instancias con declaración de su temeridad procesal.

Firme que sea esta resolución, devuélvase los autos originales al Juzgado de su procedencia con testimonio de la misma para su cumplimiento.

Así por esta nuestra sentencia, de la que se unirá certificación al rollo, lo pronunciamos, mandamos y firmamos.

**PUBLICACIÓN.-**

Leída y publicada fue la anterior sentencia en el mismo día de su fecha por el Sr. Magistrado Ponente, celebrando audiencia pública. Doy fe.

## *Personal prior use*

### **6.15**

The right to continue to do something that one had already been doing before the priority date was introduced as a defence into UK patent law by PA 1977, s 64. This (as substituted by the Copyright Designs and Patents Act 1988 for a similar but less elegant provision) provides in s 64(1):

- '(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention
- (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or
  - (b) makes in good faith effective and serious preparations to do such an act, has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.'

One major limitation in the section is that personal prior use outside the UK does not count, although within the EU this limitation could perhaps be challenged as constituting a disguised restriction on trade between Member States contrary to TFEU, Article 34.<sup>1</sup> There is no pre-PA 1977 guidance as to its meaning, there having been no need for it, as not only public, but also private prior use could in certain circumstances, pre-PA 1977, invalidate a patent. Private, or secret, prior use can no longer do so.

It is rarely the case, particularly with a process, that an activity continues unchanged. The three English cases on this section have all addressed the application of this section to this particular issue. In *Helitune v Stewart Hughes*,<sup>2</sup> such a defence failed, there being no 'effective and serious preparations', but it was observed, had it been available:

'Section 64 gives what can be called a statutory licence to a person who in good faith either does an infringing act or makes effective and serious preparations to do such an act. The infringing acts referred to are set out in s 60 of the Act and include, where the invention is a product, making, disposing of, offering to dispose of, using and importing the product. Where the invention is a process, infringing acts include using the process and disposing of, offering to dispose of, using or importing a product made by the process.

Section 64(2) confines the statutory licence to the right to continue to do or to do "that act", namely the act which the person had done or had made effective and serious preparations to do. Thus, the right is limited to the particular act of infringement done or for which effective and serious preparation had been made. That conclusion can be illustrated by considering a person who had in good faith imported an infringing product. The section enables him to continue to import the product but not sell it unless the importation amounted to an effective and serious preparation to sell it.

Section 64(1) relates to acts which constitute an infringement and not to any particular product or process. As I have stated the acts are those covered by a patent as set out in s 60. Thus, provided a person has carried out an infringing act before the priority date, he can continue to carry out that act even though the product or process may be different to some degree. This can be illustrated by considering a person who uses an infringing process. The fact that he alters that process after the priority date does not matter. The section states that the doing of that act, namely using an infringing process, shall not amount to an infringement.

I believe that the correct approach is to look first to see what are the acts of the defendant which are alleged to be infringements and which it wishes to continue. Thereafter I must decide whether it carried out those acts in good faith before the priority date or whether it made effective and serious preparations to do so.'

Having once determined the right to exist in the first place, this formulation of what the section would then permit the defendant to do, is broad. But in *Lubrizol Corpn v Esso Petroleum*,<sup>3</sup> another Patents Court judge took a narrower view, observing:

'... I think it is only right to say that I have some doubts, with great respect to Aldous J. as to whether *Helitune* is correct. The act which the alleged infringer is entitled to continue to conduct by virtue of s 64(2) is the act which he was committing before the priority date. It was not an infringement then. It was an act of commerce. It is that specific act of commerce which he is entitled to continue. I have difficulty in accepting that by, for example, manufacturing product A before the priority date, he was thereby given a right to manufacture any product after the priority date. In my view, s 64 is intended to safeguard the existing commercial activity of a person in the United Kingdom which is overtaken by the subsequent grant of a patent. It is not meant to be a charter allowing him to expand into other products and other processes.'

Further observations on PA 1977, s 64 were made in the final hearing at first instance on the same case, by yet another Patents Court judge, in *Lubrizol Corpn v Esso Petroleum*:<sup>4</sup>

'I agree with Laddie J for all the reasons he gave in his decision, and because I do not think the actual language of s 64 is appropriate were Aldous J correct. It is "*the doing of that act*" which is protected, not "*any act which would otherwise be an infringement*".

However there was a slight gloss. I think Laddie J's reference to "existing commercial activity" – the protected act of the section – means an activity which is substantially the same as the prior act or act for which serious and effective preparations were made. In deciding whether the activity is substantially the same all the circumstances must be considered. Both technical and commercial matters must be taken into account. That is important in a case such as the present where there are inherent minor variations in starting materials or the like. If the protected act has to be *exactly* the same (whatever that may mean) as the prior act then the protection given by the section would be illusory. The section is intended to give a practical protection to enable a man to continue doing what he was doing before ...'

Again no 'effective and serious preparations' were found to have been made in *Lubrizol*, so such observations, as with all those above, have limited value as precedents. The Court of Appeal agreed with the views of the Patents Court, in that the preparations in issue had not been 'effective' as at the priority date they were only in preliminary, planning, stages. However, one of the Court of Appeal judges, Aldous LJ, who had when in the Patents Court given judgment in *Helitune*, noted that his own observations in that case as to the scope of the section 'had been read in a way not intended' and agreed with the observations made by the judge at first instance in this case that limiting the protected act to exactly what had been done before would render the protection illusory and that the intent was to give a practical protection to continue doing in substance what had been done before. A more recent analysis of the provision took place in *Forticrete v Lafarge Roofing*<sup>5</sup> where the defendants were allowed to introduce such a plea on amendment as they were able to show an arguable case that they had made 'effective and serious preparations' as to one of the articles in issue but not as to another article said to have been derived from the first, because it was not the same article of commerce as, or in substance the same as, the first.

#### #FootnoteB

- 1 Most other EU Member States also have such a provision, but as with the UK one these are expressed only to relate to local prior use. For a decision of the Federal Supreme Court under the corresponding German provision see *JB GmbH v CML ('Bending Apparatus')* [2003] ENPR 6.
- 2 *Helitune v Stewart Hughes* [1991] RPC 78; [1991] FSR 171. The Judge observed:  
'At the priority date of the patent, the defendant had not sold an active tracker. It had, however, produced a prototype of an active tracker using a laser with a view to its further development. The position had not been reached where the defendant had

decided to sell active trackers, and by the priority date its efforts were concentrated on producing a passive tracker. I do not believe the defendant had reached the state of making effective and serious preparations to sell an active tracker, and, therefore, s 64 does not give it a defence to the action.'

- 3 *Lubrizol Corpn v Esso Petroleum* [1992] RPC 281(Patents Court). This issue was not considered on appeal – [1992] RPC 467(CA).
- 4 *Lubrizol Corpn v Esso Petroleum* [1997] RPC 195 (Patents Court); [1998] RPC 727 (CA).
- 5 *Forticrete Ltd v Lafarge Roofing Ltd* [2005] EWHC 3024 (Ch) (Patents Court). See also *H Lundbeck v Norpharma SpA* [2011] EWHC 907 (Patents Court) at paras [163]–[172] holding a process not to be 'substantially the same' as that undertaken before the priority date of the patent in suit.

**IN THE HIGH COURT OF JUSTICE**  
**CHANCERY DIVISION**  
**PATENTS COURT**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 14/04/2011

Before :

**THE HON MR JUSTICE FLOYD**

Between :

**H. LUNDBECK A/S**

**Claimant/Part 20 Defendant**

- and -

**(1) NORPHARMA SpA**

**Defendants/Part 20**

**(2) INFOSINT S/A**

**Claimants**

- and -

**(3) LUNDBECK LIMITED**

**Third, Fourth and Fifth**

**(4) LUNDBECK PHARMACEUTICALS  
LIMITED**

**Parties/ Part 20 Defendants**

**(5) LUNDBECK GROUP LIMITED**

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**Justin Turner QC and Dominic Hughes** (instructed by **Wragge & Co LLP**) for the **Claimant  
and Part 20 Defendants**

**Andrew Lykiardopoulos** (instructed by **Cumberland Ellis**) for the **Second Defendant**

Hearing dates: 16<sup>th</sup>-18<sup>th</sup>; 21<sup>st</sup> and 23<sup>rd</sup>-24<sup>th</sup> March 2011

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## **Judgment**

Mr Justice Floyd:

### **Introduction**

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1. The claimant H. Lundbeck A/S (“Lundbeck”) brings this action to revoke European Patent (UK) 1 118 614 (“the 614 patent”). The 614 patent now belongs to Infosint A/S, the second defendant, (“Infosint”), as a result of an assignment in 2002 from Norpharma SpA, the first defendant (“Norpharma”). By counterclaim, Infosint alleges infringement of the 614 patent by Lundbeck and the third, fourth and fifth parties, all wholly owned subsidiaries of Lundbeck. No arguments were advanced which made it necessary for me to distinguish between the various Lundbeck companies, so I will refer to them collectively and individually as “Lundbeck”.
2. The 614 patent relates to a method of making 5-carboxyphthalide (5-cbx). 5-cbx is an intermediate compound used in the manufacture of Lundbeck’s anti-depressant drug citalopram.

### **Issues**

3. Lundbeck assert that the 614 patent is invalid for lack of novelty over two papers by a Mobil scientist called Forney and a Danish patent application. However, by the end of the trial, the lack of novelty objection was limited to the Danish application. Lundbeck also contend that the 614 patent is invalid for obviousness over the Forney papers, and that claim 22 is invalid for insufficiency.
4. There are further issues relating to infringement by current and past processes operated by Lundbeck. Lundbeck also contend that they have a defence under section 64 of the Patents Act 1977 (“the Act”) arising out of acts performed before the priority date which they maintain give them a right to continue to do acts which would otherwise infringe.
5. Next there is an issue about the consequences, having regard to section 68 of the Act, of the delayed registration of the assignment from Norpharma to Infosint at the UKIPO.
6. It was agreed that a further group of issues concerning a limitation defence can be dealt with on the hearing of the enquiry as to damages or account of profits, should they arise.
7. As, by the time of the counterclaim, the issues were those of a conventional infringement action, Infosint opened the case and called its evidence first. Mr Andrew Lykiardopoulos appeared for Infosint; Mr Justin Turner QC and Mr Dominic Hughes appeared for Lundbeck.

## **Expert witnesses**

8. Infosint called Dr John Scott and Dr John Moses. Dr Scott is a process chemist. He was the Vice President of Research and Development at Hoffmann La-Roche from 1990-1997 and was then Executive Director of Process Research & Development at Bristol Myers-Squibb from 1998-2003. Since 2003 he has acted as a consultant. He is a highly experienced industrial process chemist, and gave his evidence fairly and impressively. He was called primarily to deal with issues of infringement, but his expertise was such that he could have given all the expert evidence which it was necessary for Infosint to call in this case. He was a little hesitant about areas of the case from which he had been insulated: but when he was unsure he made this plain to the court.
9. Dr Moses is an Associate Professor in Organic Chemistry at the University of Nottingham. Prior to this he was at the School of Pharmacy in London. He has been a member of the Royal Society of Chemistry since 2005. Although he has also worked as an industry consultant, his industrial experience was far less than that of Dr Scott and Mr Ward. I found his approach to the issues a little adversarial, appearing at some points in his evidence to be arguing a legal case on behalf of Infosint, rather than giving technical reasons to support a point of view. It was, in any event, not clear to me why Infosint needed to call two experts in a case involving process chemistry which was entirely within the expertise of Dr Scott. In the end, Lundbeck chose to put nearly all aspects of their validity case to Dr Scott, as they were fully entitled to do. Nevertheless, I have taken account of Dr Moses' points when reaching my conclusions.
10. Lundbeck called Mr Neal Ward and Professor Stephen Davies. Mr Ward is an industrial chemist, currently an independent consultant. Prior to April 2002 he was employed by GlaxoSmithKline as a project manager in Chemical Development, both developing new molecules and improving production processes. Infosint criticised his evidence as "didactic and without compromise" and submitted that he had difficulty seeing things in any way other than his own. I do not think this is fair. He did express confident views. However, he was equally capable of seeing a fair point made against him and agreeing with it. I found his evidence overall to be balanced.
11. Professor Davies is the Waynflete Professor of Chemistry at the University of Oxford and Chairman of the Department of Chemistry. He also founded Oxford Assymetry Company which specialised in preparing compounds with high stereochemical purity. He is an acknowledged expert on stereochemistry. His evidence was originally directed to a narrow point about the technical background to the construction of claim 22. On the pretext that one of Professor Davies' papers had been mentioned by Dr Moses, Lundbeck also asked him to give some evidence in relation to Forney. No criticism was made of Professor Davies as a witness.

## **Fact Witnesses**

12. Infosint called Mr Luigi Zanetti, a former director of Norpharma and Infosint and now a consultant to Infosint. He gave evidence directed to the issue of registration of the assignment of the 614 patent. Mr Zanetti found the process of giving evidence through an interpreter very difficult. It is not possible to say how much this was his fault and how much was the fault of the interpreter, who was provided by Infosint – I

suspect it was a little of each. Despite this I was able to understand the gist of his evidence. His credibility was attacked to a degree by Lundbeck, but I make no criticism of him, given the difficulties he was labouring under. The facts on this part of the case were not really in dispute.

13. Lundbeck called Mr Poul Nielsen and Mr Peter Trickett. Mr Nielsen gave evidence of the processes used by Lundbeck, including those adopted before the priority date. His cross-examination had to be interrupted because it transpired that Lundbeck had given inadequate disclosure of documents relating to the work he carried out before the priority date. The work Mr Nielsen had described turned out not to be the first work he had performed on the relevant reaction. Moreover he had not himself been back to his original notebooks. Given that the work was carried out more than 30 years ago, and he had little actual recollection of the details of the work, this was not an adequate way of ensuring that the court was put in possession of an accurate history.
14. Infosint did not go as far as to suggest that Mr Nielsen was setting out to mislead the court, and I do not think he was. However, the manner which he and Lundbeck set about putting this evidence before the court was, in my judgment, wholly unacceptable. If parties decide to rely on secondary evidence of this kind, they must make sure that the evidence is fairly and accurately put before the court. As a result of these failures by Lundbeck, I am left with no confidence in this Lundbeck story at all.
15. Mr Trickett gave evidence of the history of citalopram production in the UK both before and after the priority date. He was an entirely fair witness.

#### **The skilled addressee or team**

16. The patents are addressed to an industrial process chemist. Such a person will have a degree in chemistry or chemical engineering and some years of practical experience.
17. There was some debate about whether the skilled person was someone having an interest in citalopram, which is discussed in the introduction of the patent and claimed as an end product in claim 22. The argument was that, as the patent mentions the use of 5-cbx as an intermediate for making, amongst other things, citalopram, it follows that the skilled person was to be deemed to be interested in making citalopram.
18. In *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2010] EWCA Civ 819; [2010] RPC 33 at [30] to [70] the Court of Appeal explained that the skilled team required to implement the patent and to understand its teaching was not necessarily the same as the team used to interpret the prior art and as the touchstone for the question of inventive step. This might be so in cases where the invention changed the art or married two unrelated arts together.
19. A similar but not identical point arises in the present case because claim 22 claims the use of 5-cbx made by the claim 1 process in the manufacture of citalopram. I will need to call upon the hypothetical skilled person both to understand the scope of claim 22 and to determine whether the invention of claim 22 is obvious over the Forney papers. For the former purpose the skilled person is plainly aware of and interested in citalopram. But for the purpose of determining whether claim 22 is obvious it seems

to me that it would be quite wrong to assume from the beginning that the skilled person was aware of citalopram, far less that he was interested in it, given that the main prior art references are not in the pharmaceutical field at all. It is quite possible that it would never have occurred to the skilled person to think of citalopram in the context of any given item of prior art. The skilled person's knowledge of or interest in citalopram will depend on the contents of the prior art, where it would lead him and what was part of his common general knowledge.

### **The common general knowledge**

20. The law about the distinction between matter which is part of the common general knowledge, and matter which is merely known or even widely known is stated in *Beloit v Valmet* [1997] RPC 489 at 494-495, relying on the well known judgment of the Court of Appeal in *General Tire v Firestone* [1972]RPC 4. The matter must be "generally accepted as a good basis for further action" amongst those skilled in the art. The distinction is important in the law of obviousness because, although it is in general permissible to combine the contents of an individual published citation with matter which is part of the common general knowledge, it is impermissible to make so-called mosaics of individual citations (unless it would be obvious to do so).

21. Matter which the skilled person would uncover as a matter of routine in the course of work based on a particular disclosure does not form part of the common general knowledge. In *Generics (UK) v Daiichi Pharmaceutical* [2008] EWHC 2413 (Pat); [2009] RPC 4 at [40] Kitchin J said:

"I can readily accept that, faced with a disclosure which forms part of the state of the art, it may be obvious for the skilled person to seek to acquire further information before he embarks on the problem to which the patent provides a solution. But that does not make all such information part of the common general knowledge. The distinction is a fine one but it may be important. If information is part of the common general knowledge then it forms part of the stock of knowledge which will inform and guide the skilled person's approach to the problem from the outset. It may, for example, affect the steps it will be obvious for him to take, including the nature and extent of any literature search."

22. Kitchin J's judgment was approved by the Court of Appeal: [2009] EWCA Civ 646 at [26] to [28]. Jacob LJ said:

"It would be wholly subversive of patents and quite unfair to inventors if one could simply say "piece of information A is in the standard literature, so is B (albeit in a different place or context), so an invention consisting of putting A and B together cannot be inventive." The skilled man reads each specific piece of prior art with his common general knowledge. If that makes the invention obvious, then it does. But he does not read a specific citation with another specific citation in mind, unless the first causes him to do so or both are part of the matter taken to be in his head.

So, for example, if a particular device depends upon expansion of a metal, say brass, and clearly the coefficient of expansion matters to its operation, one can legitimately say that the skilled person knows there are tables of coefficients of expansion and would go to them to see what other metals or alloys had similar coefficients and would therefore probably work. But not so if it was far from evident that the coefficient of expansion mattered.”

23. Relevant aspects of the common general knowledge in this case are the following:
- i) Oleum is the common name for a mixture of sulphur trioxide ( $\text{SO}_3$ ) and sulphuric acid ( $\text{H}_2\text{SO}_4$ ). It can exist with any amount of  $\text{SO}_3$ , although pure  $\text{SO}_3$  would not be called oleum.
  - ii) Oleum was commercially available in various  $\text{SO}_3$  concentrations ranging from 15 to 80%  $\text{SO}_3$ . Those that the process chemist would have on the laboratory shelf might be in the range 20-30%.
  - iii) Pure  $\text{SO}_3$  and oleum are both hazardous chemicals. Both are used very widely in the production of detergents, plastics and dyes. Both chemicals must be treated with care because they produce a corrosive mist containing droplets of  $\text{H}_2\text{SO}_4$ . Overall, as Dr Scott said, oleum would be regarded as a less hazardous reagent than  $\text{SO}_3$ , but this is a matter of degree.
  - iv)  $\text{SO}_3$  is a powerful dehydrating agent. When it reacts with water it forms sulphuric acid so that water is mopped up from the reaction. So pure  $\text{SO}_3$  will become oleum if reacted with less than one mole equivalent of water.
  - v) Formaldehyde ( $\text{CH}_2\text{O}$ ) is an extremely well known chemical reagent. It can conveniently be produced in reactions from paraformaldehyde and trioxane which are solids.
  - vi) Terephthalic acid is the common name for benzene 1,4 dicarboxylic acid. It, too, is an extremely well known chemical reagent used on a large scale in the manufacture of plastics. PTFE (Teflon) is a polymer made from terephthalic acid.
  - vii) Chemical reactions are sensitive to conditions of temperature and pressure, which can affect both the rate of reaction and the degree of conversion.
24. Lundbeck do not assert that either of the cited Forney papers were part of the common general knowledge. They were right not to do so.

### **The 614 patent**

25. The 614 patent is entitled “Process for the preparation of 5-carboxyphthalide” i.e 5-cbx. It has a priority date of 18 January 2000.
26. At [0002] the specification points out that 5-cbx is:

“a useful intermediate in the preparation of several chemical compounds, particularly dyes, resins and drugs. In particular, [5-cbx] is an intermediate useful in the synthesis of citalopram, a well known anti-depressant drug, whose preparation is described in International Patent Application WO 00023431 and the corresponding Italian Patent Application IT1999 MI 0001724, whose contents must be considered as integral part of the present description.”

27. From [0003] to [0008] reference is made to prior art methods of making 5-cbx, including Forney 2. At [0008] the specification says:

“Reaction conditions like these, however, are not suitable for the industrial scale because pressure reactors and strong acidity conditions are required.”

28. At [0009] it is stated that:

“It has now surprisingly been found that by addition of terephthalic acid to fuming sulphuric acid (oleum) containing between 20-33% by weight, of SO<sub>3</sub>, by subsequent addition of formaldehyde to the mixture and by heating, 5-carboxyphthalide is obtained in good yields and in a high degree of purity under easily controllable conditions, in open and however not pressurized reactors, and without any risk in handling the reaction mixtures.”

29. At [0010] the specification states that the invention provides a method in which terephthalic acid is added to fuming sulphuric acid containing 20-33% by weight of SO<sub>3</sub>, subsequently adding formaldehyde thereto, heating the mixture to 120-160°C and isolating the obtained 5-cbx. The range of 120-160°C is not replicated in the claims.

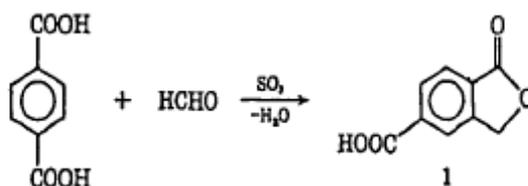
30. At [0011] it is explained that, in a preferred embodiment, solid “forms of” formaldehyde may be used, for example 1,3,5 trioxane. What is meant here is that trioxane is a precursor which produces formaldehyde in the reaction pot. Paraformaldehyde would be another alternative to this.

31. At [0013] the specification gives the following information about temperature and the exothermic (heat generating) nature of the reaction:

“...the mixture thus obtained is treated with 1,3,5-trioxane at a temperature of 30-35°C and subsequently heated at a temperature of 120-145°C, preferably at 130-135°C. Generally, it is sufficient to heat to 120°C so that the temperature of the reaction mixture increases by spontaneous exothermia up to 130-135°C. Preferably, having reached 120°C, it is suitable to wait about 15 minutes in order to verify whether such exothermia has occurred. In the negative, the temperature is brought up to 130-145°C and, after a 2-5 hour heating at this

temperature, there is formed compound III which concurrently dehydrates to give 5-carboxyphthalide.”

32. There are six examples. In each of the examples terephthalic acid is added to oleum followed by 1,3,5 trioxane, as the source of formaldehyde. All the examples use oleum containing between 25 and 27% SO<sub>3</sub>. The temperature ranges of the main heating stage are 135-140; 130-135; 135-145; 130-133; 135-140; 130-133°C.
33. In summary, the skilled person would understand that the chemical reaction being described in the patent was between terephthalic acid and formaldehyde. It involves the elimination of a molecule of water in a medium containing SO<sub>3</sub>, and so can be conventionally depicted thus:



34. The figure above comes, for convenience, from one of the Forney papers. But it is common ground that this is the chemistry which the 614 patent is describing.

### The claims in issue

35. Infosint relies on claim 1 of the 614 patent. It also relies on claim 22 as being independently valid. Claim 1 is to:

“A process for the preparation of [5-cbx] ... in an open and however not pressurised reactor which comprises adding formaldehyde and terephthalic acid ... to fuming sulfuric acid containing 20-33% by weight of SO<sub>3</sub>, heating the mixture at 120-145°C and isolating the [5-cbx] thus obtained.”

36. Claim 22 is to:

“A process for the synthesis of citalopram, in which a process for the synthesis of [5-cbx] according to claim 1 is contained.”

### Construction

37. The approach to construction is not in dispute. It is as stated by Lord Hoffman in *Kirin Amgen v TKT* [2005] RPC 9. The task for the court is to determine what a person skilled in the art would have understood the patentee to have used the language of the claim to mean.
38. In *Virgin v Premium Aircraft* [2009] EWCA Civ 1062, [2010] RPC 8 at [5], Jacob LJ said this, approving a summary by Lewison J of the applicable principles:

“5. One might have thought there was nothing more to say on this topic after *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9. The judge accurately set out the position, save

that he used the old language of Art 69 EPC rather than that of the EPC 2000, a Convention now in force. The new language omits *the terms of* from Art. 69. No one suggested the amendment changes the meaning. We set out what the judge said, but using the language of the EPC 2000:

[182] The task for the court is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. The principles were summarised by Jacob LJ in *Mayne Pharma v Pharmacia Italia* [2005] EWCA Civ 137 and refined by Pumfrey J in *Halliburton v Smith International* [2005] EWHC 1623 (Pat) following their general approval by the House of Lords in *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9. An abbreviated version of them is as follows:

(i) The first overarching principle is that contained in Article 69 of the European Patent Convention;

(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.

(iii) It follows that the claims are to be construed purposively—the inventor's purpose being ascertained from the description and drawings.

(iv) It further follows that the claims must not be construed as if they stood alone—the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.

(v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.

(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol—a mere guideline—is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.

(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.

(vii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.

(vii) It further follows that there is no general "doctrine of equivalents."

(viii) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.

(ix) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge.

39. The Protocol on the Interpretation of Article 69 of the EPC 2000 now requires, as a result of an amendment introduced in EPC 2000, that due account be taken of "any element which is equivalent to an element specified in the claim". The approach approved by Jacob LJ in *Virgin* takes due account of equivalents in sub-paragraph (viii). The provision was certainly in Lord Hoffmann's mind when he gave the leading speech in *Kirin Amgen*: see paragraph [49].

*"open and however not pressurised reactor"*

40. There are two parts to this oddly expressed limitation. An "open" reactor would not, in 2000, connote one which is open to the atmosphere. An open reactor is one vented to atmosphere by a suitable scrubber system (a pollution control device). The term "not pressurised" means that the reactor is at or close to atmospheric pressure. A conventional scrubber system may lead to a slight increase over atmospheric pressure. The experts indicate that this might be about 50 millibars in the reactor. Beyond this, I do not think that "not pressurised" leaves much room for argument. There is no attempt to claim a range of pressures, as in the case of temperatures. Mr Lykiardopoulos said that the contrast was with the sealed glass tubes of Forney 2, given the reference to Forney 2 at [0007] of the specification. That may be so, but it does not justify allowing Infosint to cover, by a process of construction, the whole, or indeed part of the range between atmospheric and whatever pressure would be generated in a sealed glass tube. Neither side ventured any suggestion as to what the skilled person would imagine were the pressures in the sealed glass tubes of Forney 2 in any event. The truth is that the claim requires not only an unsealed reactor: it requires an unsealed and unpressurised one. Accordingly, with the minor exception of the sort of pressures which would be generated by the presence of a scrubber system and similar devices in an open reactor, the claim requires the reactor to be unpressurised.

*"heating the mixture at 120-145°C"*

41. Lundbeck submit that the temperature range means what it says: if the mixture is heated outside this range then there is no infringement. The range was freely chosen by the patentee, and he cannot have meant to cover temperatures outside the range. The reference to a range of 120-160°C at [0010] shows that the patentee knew what he was doing.
42. Infosint submits that the range would not be understood by the skilled reader to be exact and covers temperatures “a few degrees higher than 145°C.” Infosint submits that even a well run process aiming to hit a steady 145°C would be likely to fluctuate a few degrees over. It submits that the skilled person would know (also relying on the reference to the reaction running at 160° at [0010]) that a few degrees would not have a material effect on the way the invention works.
43. I do not think that there is any difficulty about what the numerical upper limit of the claim actually means: it means 145°C. As it is expressed as a whole number, it probably covers 145.4°C as well. Apart from that, I cannot see any basis on which it can sensibly be argued that 145°C means some higher temperature. On that basis a reaction which is conducted at 145.5°C or above does not infringe.
44. There is however a further and related point about whether “heating at” the specified temperature range means that the temperature has to be maintained within the prescribed range for the whole or substantially the whole of the reaction period and if not, for how much of it. The parties were divided on this point as well. Infosint submitted that if any 5-cbx is made by heating for any period (apart from the initial heating up period) at a temperature within the temperature range, then there would be infringement, even if for some of the time the temperature was outside the range. Lundbeck submitted that the temperature must be maintained within the range for the whole period of the reaction.
45. I do not think that Lundbeck’s position represents the meaning that the skilled person would extract from this feature of the claim. Lundbeck’s position allows a party to escape infringement if there is a short temperature spike within a process operated substantially within the range. I did at one point think that Lundbeck’s position could be supported by the closing words of the claim which require the 5-cbx “thus obtained” to be isolated. “Thus obtained” means by heating at 120-145°C. If the 5-cbx at the end of the reaction had been made at temperatures both within and outside the range, it would not be possible to separate out the 5-cbx which had been “thus obtained” because there is no difference between 5-cbx made at one temperature from that made at another. So all the heating must be within the range. In the end I was persuaded by Mr Lykiardopoulos that this is probably too lawyerly a point: a classic case of the “meticulous” approach outlawed by sub-paragraph (ix) of the summary approved by Jacob LJ in *Virgin*. And it was not advanced with any enthusiasm by Mr Turner.
46. I think therefore that one must start by noting that the claim does not specify any period of time for which the reaction must be run at the specified temperature, or indeed any degree of completion of the reaction. There is no reason why a reaction run for ten minutes at the specified temperature *and then stopped* should not be said to be using the patented process, provided that some 5-cbx is made and could be isolated. If such a process is “heating the mixture at 120-145°C”, then there is no

reason why a process in which the reaction mixture is heated outside the range, after a ten minute period within the range, should not infringe as well.

47. I therefore accept Infosint's submission on this question. The skilled person would understand that, provided that he made some 5-cbx within the specified temperature range (ignoring the warming up period) then he will infringe, even if the rest of the 5-cbx is made at a temperature outside the claimed range.
48. Accordingly, if the temperature of the process is set to 145°C, then the process will be likely to infringe, notwithstanding the fact that the temperature went into and out of the range. As Mr Lykiardopoulos submitted, that is in accord with what one would expect.
49. It is arguable that there may come a point where the amount of time that the process is within the range is so small that it can be ignored. Obviously if the time is so short that no 5-cbx is made during that time, then this does not infringe. I did not hear argument on whether there should be a "de minimis" limit and, if so, what it might be. The point is not free of authority: see the observations of Pumfrey J in *Monsanto v Cargill* [2007] EWHC 2257 (Pat) in connection with a product claim. As I do not think that infringement by any of the processes with which I am concerned really turn on this point, I say no more about it here.
50. A further point about whether "heating the mixture" excludes a two-pot process in which a mixture of paraformaldehyde in oleum is added to a preheated mixture of terephthalic acid in oleum was abandoned by the end of the trial. I think that Lundbeck were right to do so. The fact that some of the heating is done before the claimed reaction commences does not mean that the reaction mixture is not heated.

*"citalopram"*

51. The skilled person reading the patent would know that citalopram was a chiral molecule, that is to say a molecule which can exist in two enantiomeric forms: a left-handed and a right-handed form. Normally citalopram will exist in the form of a racemic mixture, i.e. a 50/50 mixture of the two enantiomers. There is often a marked difference in pharmacological activity between enantiomers due to the highly specific interaction which occurs between the drug molecule and the receptor at the site of action. One enantiomer may produce the desired effect, but the other enantiomer, because of the different arrangement of the atoms, does not interact with the receptor either at all or to the same extent.
52. Infosint submit that the skilled reader of the specification would understand claim 22 as extending to citalopram when in the form of either of its isomers.
53. Mr Lykiardopoulos expands on this by referring to the documents cross-referred to in the patent at [0002] and which are to be taken as an "integral part of the present description". The purpose of the incorporation of these documents by reference is to show the preparation of citalopram from 5-cbx. The Italian patent application shows at page 11 that the process there disclosed, which includes 5-cbx as an intermediate, can be used to prepare the two enantiomers of citalopram. The International Patent Application contains a similar passage at page 10 lines 14-18.

54. Mr Lykiardopoulos submits that the patentee is saying “here is a novel process to make 5-cbx which can be used to make citalopram as discussed in these other applications”. Those applications discuss using 5-cbx to make both the racemate and the enantiomers. There is no logical reason why the patentee would be understood to cover one and not the other.
55. Professor Davies expressed the contrary view, making the point that citalopram and the two separated enantiomers are different compounds. That is correct. Nevertheless, words derive their meaning from context. For the purpose of the invention described in the 614 patent, and in that context, the stereochemical form of the citalopram produced is completely irrelevant. In other contexts, it may be incorrect to use the term citalopram to describe anything other than the racemic mixture. In the context of the 614 patent the skilled person would understand it to extend to the enantiomeric forms as well.

## **The prior art**

### *Forney 1*

56. Forney was a scientist working in the Research and Development Laboratories of Mobil Chemical Company in Edison, New Jersey. Forney 1 is a short “Note” appearing in the Journal of Organic Chemistry, a highly respected and peer-reviewed journal. “Notes” are intended for disclosing the important information about a piece of research. A Note will often be followed up by a more detailed paper, in that journal or elsewhere.
57. Forney 1 is entitled “*Reaction of Terephthalic Acid with Formaldehyde in Sulfur Trioxide Media*”. The author explains that terephthalic acid is an aromatic molecule which is strongly resistant to electrophilic substitution – a particular mechanism of chemical reaction. The burden of the disclosure is contained in the third paragraph:
- “We wish to report the condensation of terephthalic acid with formaldehyde in sulfur trioxide media, a process which produces [5-cbx] cleanly and in excellent yield. The reaction is generally free of by-product formation over a fairly wide range of reaction conditions, although terephthaloyloxyacetic acid (2) has been identified (as its dimethyl ester) from reaction in the presence of excess formaldehyde and from reaction media containing <20% SO<sub>3</sub>.”
58. This passage therefore indicates that a range of reaction conditions have been tried and found successful. “Reaction conditions” normally include such matters as temperature and pressure, but include other matters such as relative amounts of reactants and the nature of the solvent. Those two matters are called out for specific mention here. Whilst excellent yields have been obtained, the by-product terephthaloyloxyacetic acid dimethyl ester (“the by-product”) has been observed if the SO<sub>3</sub> concentration in the reaction media falls below 20%. There is a dispute about whether the skilled person would understand the “reaction media” as the whole contents of the reactor or merely the solvent for the reaction. I think it is clear that it means the solvent. Indeed that is what Dr Moses, Infosint’s expert, said in paragraph 10 of his second report (although he later seemed to suggest in cross examination that

this was wrong). Moreover he had no real answer to a point made by Professor Davies that if Forney had meant the percentage of the contents of the reaction vessel, there would be insufficient liquid in the reaction mixture in the main experiment described to form the described slurry.

59. This passage therefore contains a clear implication that the reaction has been tried at SO<sub>3</sub> concentrations in a solvent of 20% or above. Furthermore, it conveys the information that the reaction is generally free of by-product formation unless and until one lowers the SO<sub>3</sub> concentration in the solvent to below 20%.
60. Forney 1 points out that prior routes involved several-step processes or provided a mixture which was difficult to separate. He says that his synthesis is believed to represent the first reported substitution of terephthalic acid with an electron-deficient carbon species.
61. In the “Experimental section” Forney 1 discloses two experiments. The first reaction is on a reasonably large scale – much bigger than one could perform in a glass tube. It would be understood as intended to demonstrate that the reaction works at a preparative scale. It is noted that SO<sub>3</sub> is used in the form of Sulfan B. The skilled person would be able to discover that Sulfan B is 100% SO<sub>3</sub>, in a stabilised form. It is pointed out that the reaction is exothermic. The resultant slurry was heated at 120-130°C and the excess SO<sub>3</sub> distilled off. Forney gives no express indication in this experiment as to the nature of the reaction vessel. The write up is also silent as to pressure. The effect of the evidence was, however, that in the absence of any indication of the use of pressure, the skilled person would assume that the reaction was carried out in what would be regarded as an open, unpressurised reactor. If the reaction being reported was indeed carried out under pressure, then the writer would have been guilty of a serious omission, as such a detail is as important to the reader as the temperature. Furthermore, it is clear that when Forney did use sealed vessels, he said so.
62. A second experiment is directed towards making the by-product. This experiment was conducted in a sealed glass tube. Terephthalic acid, formaldehyde (in a large excess) and sulphuric acid (98%) are reacted together at 150°C. The reaction products were analysed by gas chromatography. They included 83.2% of dimethyl terephthalate, 1.1% of 5-cbx and 15.7% of the by-product.
63. This second experiment therefore discloses that, in the absence of significant amounts of SO<sub>3</sub> and in the presence of a large excess of formaldehyde, the yield of 5-cbx is very low, even in a sealed tube which would raise pressure. 5-cbx is, nevertheless, formed. The second experiment also shows that concentrated sulphuric acid (probably with no significant amount of SO<sub>3</sub>) can be used as the solvent.
64. There was some evidence of the significance of the fact that the by-product reaction was conducted in sealed glass tubes. Mr Ward’s explanation (with which Dr Scott agreed) was that reactions are often conducted in sealed glass tubes when an analysis is being performed, to ensure that no product escapes and to allow accurate analysis of the reaction products. Dr Moses was cross-examined on this, but I was not clear that he disagreed with Dr Scott and Mr Ward. He accepted that this could be one reason for doing the experiment in a sealed tube, but equally it could be because one wanted to pressurise the reaction.

65. I think that the skilled person would infer from the fact that Forney does not at any stage discuss the need for pressure, and his reference to the fairly wide range of reaction conditions where by-product formation does not occur, that pressure is not required for the preparative reactions which Forney describes in the third paragraph of the paper.
66. I would add that the skilled person would understand that the reaction described for making the by-product was entirely consistent with the third paragraph of the paper. Having observed by-product formation when there is excess formaldehyde and where solvents with low  $\text{SO}_3$  concentrations are used, Forney does an experiment with concentrated sulphuric acid and a large excess of formaldehyde. These reaction conditions are designed to maximise the production of the by-product which can be then be isolated and analysed. There is a very clear hint here that the reaction media with 20%  $\text{SO}_3$  would be based on sulphuric acid: i.e. oleum. Lundbeck now accept however that this is not a clear disclosure of oleum for the purposes of a novelty attack.

*Forney 2*

67. Forney 2 is a much longer contribution than Forney 1. It too is concerned with the reaction of formaldehyde and terephthalic acid. Much of it is concerned with questions of the precise chemical mechanism of the reaction which is not relevant to the issues I have to decide. It cross refers more than once to the work reported in Forney 1.
68. Experiments reported in the paper (see Table II) include a run using oleum with a 30%  $\text{SO}_3$  concentration as solvent. Forney 2 reports that the conversion is quite sensitive to the nature of the solvent used for the reaction, but that conversion in 30% oleum and one other solvent were much greater than those using other media. "Relatively high conversions were observed in solvents characterised by their free  $\text{SO}_3$  content" with the exception of methanesulfonic acid. In a strictly non-comparable run with 100%  $\text{SO}_3$  an excellent conversion (recorded as 94%) was achieved.
69. Figure 1 in Forney 2 is a graph of conversion against "mole %  $\text{SO}_3$ " in sulphuric acid and one other solvent. I reproduce it here:

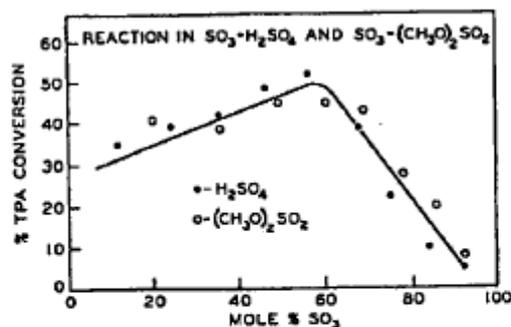


Figure 1.—Yield of 5-carboxyphthalide in sulfuric acid (black dots) and methyl sulfate (open circles) solutions containing varying amounts of  $\text{SO}_3$ . Conditions were: 1 M terephthalic acid and 1 M formaldehyde, reacted in sealed glass tubes for 1 hr at  $150 \pm 0.2^\circ$ .

70. Later the author says: “The conversion in both solvents reaches a maximum at 60 mol % SO<sub>3</sub> content”. The skilled person would understand that, as these reactions were stopped after one hour, the comparison in Figure 1 is simply an indication of rate of reaction in that first hour – a point made elsewhere in the paper (page 691, left hand column). The reactions reported in the Table II runs were conducted for two hours and show near complete conversion at 30% SO<sub>3</sub>, whereas Figure 1 shows less than 50% conversion for this concentration after one hour.
71. There is again a dispute about whether the “mole %” recorded on the x-axis of Figure 1 means mole % in the solvent or mole % in the reaction pot. I prefer the evidence of Mr Ward that what is being shown in Figure 1 is the percentage of SO<sub>3</sub> in the solvent, not the percentage of all the ingredients in the pot. The use of mole % rather than weight % is explained by the fact that there are two solvents being shown on a comparable basis in the Figure. To use weight % would give a misleading comparison.
72. Forney 2’s reactions are all conducted in sealed glass tubes. At page 693 he says this:
- “When the [5-cbx] synthesis is run with a large excess of formaldehyde, or in dilute oleum mixtures, terephthaloyloxyacetic acid appears as a product of the reaction.”
73. This passage echoes the corresponding passage in Forney 1, although it is now expressly made clear that the “reaction media” included oleum. There is a dispute about whether “dilute oleum mixtures” would be understood differently from “<20%” in Forney 1, to which I will return.
74. Finally, other experiments in Forney 2 concerned with added salts all use 30% oleum.

#### *The Forney Patent*

75. Forney applied for (in 1969) and was granted (in 1971) US patent No 3607884. This is not cited as prior art, but for reasons which appear below is relied on by Infosint as part of their response to the obviousness attack as they say it would be found on an obvious search conducted by the reader of Forney 1 or 2. It is therefore convenient to describe its disclosure here as well.
76. The essential disclosure of the Forney patent is that terephthalic acid and formaldehyde dissolved in liquid SO<sub>3</sub> react at atmospheric pressure to produce 5-cbx. Example 1 is effectively the main preparative example which was subsequently published in Forney 1. The patent includes a reference to some prior art (three US patents and an article by Le Blanc *et al*) in which a phthalic acid (not terephthalic) is reacted with formaldehyde in 10-65% oleum. It is said that these references also mention the use of liquid SO<sub>3</sub> but that it is necessary to use pressure equipment. It is against this background that performing the reaction with terephthalic acid and liquid SO<sub>3</sub> at atmospheric pressure is presented as inventive.

#### *The Danish application*

77. The Danish application with which I am concerned is the priority document of Lundbeck's Patent Application PCT/DK00/0585. The Danish Application discloses a method for making 5-cbx. It is available for an attack on novelty only under section 2(3) of the Act. The significance of that fact is that it is therefore not available for obviousness.
78. The Danish Application refers to Forney 1 in the following terms:
- "According to [Forney 1] [5-cbx] is synthesised by reaction of terephthalic acid with trioxane in oleum. During this process, trioxane sublimates and precipitates thereby obstructing the equipment."
79. This is reading more into Forney 1 than was actually expressly disclosed. Read strictly, Forney 1 disclosed "reaction media" containing <20% SO<sub>3</sub> and pure SO<sub>3</sub>. But the disclosure in the Danish application is nevertheless a disclosure of oleum.
80. The Danish application continues by describing its invention as providing a process for the manufacture of [5-cbx] comprising the reaction of terephthalic acid and paraformaldehyde in oleum. It is explained that:
- "... as compared with the prior art process [Forney 1], the process of the invention takes place without precipitation of sublimated trioxane which obstructs the equipment e.g. by precipitating in condensers."
81. The reaction is said to be most preferably carried out at about 120° C. There is no indication of the concentration of SO<sub>3</sub> in the oleum used. The description is silent about pressure.

#### *The 513 application*

82. 513 is a Lundbeck international patent application published in May 1998. It discloses a method of making citalopram from 5-cbx. Its relevance is that Lundbeck seek to combine its disclosure with Forney 1 in an obviousness attack.

#### **Lack of novelty**

##### *Law*

83. Section 2 of the Act which gives effect to Article 54 of the European Patent Convention ("EPC") provides:
- "2.-(1) An invention shall be taken to be new if it does not form part of the state of the art.
- (2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or

elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say-

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.”

84. This part of the law of patents was reviewed by the House of Lords in *Synthon's Patent* [2006] RPC 10. There are two requirements for a claim to be anticipated by a prior document: disclosure and enablement. As to disclosure, Lord Hoffman, who gave the leading judgment, began by citing passages from what he described as two judgments of “unquestionable authority”: the speech of Lord Westbury LC in *Hills v Evans* (1862) 31 LJ Ch (NS) 457 at 463 and the judgment of the Court of Appeal in *General Tire and Rubber Co v FirestoneTyre and Rubber Co Ltd* [1972] RPC 457 at 485-486. In the latter case the Court of Appeal said:

“If the prior inventor’s publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee’s claim if carried out after the grant of the patentee’s patent, the patentee’s claim will be shown to lack the necessary novelty”.

85. At paragraph 22 Lord Hoffmann says this:

“If I may summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: “whether or not a person is working [an] ... invention is an objective fact independent of what he knows or thinks about what he is doing”: *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] R.P.C. 76, 90. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted,

even though the author or maker of the prior art was not aware that he was doing so.”

86. It follows from the above that a generic disclosure will not normally take away the novelty of a subsequent claim to a member of the class. For example disclosure of “fixing means” is not a disclosure of a nail.
87. Mr Turner submits that different considerations apply when one comes to a disclosure of a broad range in a prior art document and an overlapping range in the patent claim. He relies on the decision of the EPO in *Unilever* Case T 666/89. In that case the patent required 8-25% anionic surfactant with 0.001-0.1% cationic polymer. The prior art disclosed 5-25% anionic surfactant (a larger numerical range) and 0.1-5.0% cationic polymer, a small overlap. The Board held the patent nevertheless lacked novelty, despite the fact that a combination of percentages falling within the claim was nowhere specifically taught in the prior art:

“The Respondent also submitted in the course of oral proceedings that, as a matter of law, it was not permissible to cross the legal borderline between novelty, in the strict sense of a clear and specific disclosure in a prior document of the particular narrow combination of claimed ranges in question on the one hand, and the obviousness of choosing such a combination of ranges from that prior art document containing a disclosure of the broader range, on the other hand. In this connection the Board wishes to set out the general legal principles that apply to so-called “selection” patents. The most important one is that under the EPC patents are not granted for inventions for the sole reason that they are “selections”, but only for new and inventive subject-matter of certain defined kinds (Articles 52 to 57 EPC). Selection is in fact only a conceptual tool, used principally in the field of chemical inventions, for deciding novelty in certain situations, which novelty can, however, only be decided under the express provisions of Article 54, and in particular Articles 54(2) and (3) EPC. Article 54 (2) EPC defines the state of the art as comprising “everything made available to the public by means of written or oral description, by use or in any other way”. The term “available” clearly goes beyond literal or diagrammatical description, and implies the communication, express or implicit, of technical information by other means as well. Now it is of course true that in the case of documents the natural mode of communicating information is by written or diagrammatical description. However, this is not the end of the matter in deciding what information content has been made available: cf. G 02/88, OJ EPO 1990, 003, para. 10 of the reasons. One example of the available information content of a document extending beyond this literal descriptive or diagrammatical content is the case where the carrying out of a process, specifically or literally described in a prior art document, inevitably results in a product not so described. In

such a case, the prior art document will destroy the novelty of a claim covering a product; cf. T 12/81, “Diastereomers”, OJ EPO 1982, 296. It is thus content, express and implied, rather than mere form, that is decisive of the issue of novelty in general, and “selection” novelty in particular (cf. T 198/84, “Thiochloroformates”, OJ EPO 1985, 209, para. 4 of the reasons, English version corrected in T 124/87, “Copolymers”, OJ EPO 1989, 491, para 3.2 of the reasons; T 26/85, “Thickness of magnetic layers”, OJ EPO 1990, 22, para. 8 of the reasons).

Clearly, the decision on this issue will depend on the facts of each case. Nevertheless, the Boards’ jurisprudence has generated certain general principles and broadly applicable concepts, sometimes (erroneously) referred to as “tests”. Thus it is clear, (cf. G 02/88 cited above), that matter that is hidden, not in the sense of being deliberately concealed but rather in the sense of being reconditely submerged in a document, will not have been “made available” in the above sense. In the case of overlapping ranges of physical parameters between a claim and a prior art disclosure, what will often help to determine what is “hidden” as opposed to what has been made available, is whether or not a skilled person would find it difficult to carry out the prior art teaching in the range of overlap (T 124/87, OJ EPO 1989, 495, para. 3.4). A similar approach adopted by a Board of Appeal (cf. T 26/85 OJ EPO 1990, 22) for assessing the novelty of a claim in a case where overlapping numerical ranges of certain parameters exist between a claim and a prior art document, is to consider whether a person skilled in the art would, in the light of all the technical facts at his disposal, seriously contemplate applying the technical teaching of the prior art document in the range of overlap. Provided the information in the prior art document, in combination with the skilled person’s common general knowledge, is sufficient to enable him to practise the technical teaching, and if it can reasonably be assumed that he would do so, then the claim in question will lack novelty.

In the Board’s view, there is no fundamental difference between examining novelty in situations of so-called “overlap” or “selection”, and in doing so in other situations, although it may be helpful, in order to verify a preliminary conclusion of a novelty examination in cases of overlap, to investigate whether or not a particular technical effect is associated with the narrow range in question. It needs to be stressed, however that such a particular effect is neither a prerequisite for novelty nor can it as such confer novelty: its existence can merely serve to confirm a finding of novelty already achieved (following T 198/84, OJ EPO 1985, 209, para 7).

The above concept of “seriously contemplating” moving from a broad to a narrow (overlapping) range, while seemingly akin to one of the concepts used by the Boards for assessing inventive step, namely, whether the notional addressee “would have tried, with reasonable expectation of success” to bridge the technical gap between a particular piece of prior art and a claim whose inventiveness is in question, is fundamentally different from this “inventive-step concept” because in order to establish anticipation, there cannot be a gap of the above kind.

In summary, and in dealing with the Respondent’s submission outlined previously, under the EPC novelty must be decided by reference to the total information content of a cited prior document, and in assessing the content for the purpose of deciding whether or not a claim is novel, the Board may employ legal concepts that are similar to those used by them in deciding issues of obviousness, without, however, thereby confusing or blurring the distinction between these two separate statutory grounds of objection.”

88. I derive the following guidance from this passage of relevance to this case:
- a) The term “available” goes beyond the strict literal meaning and includes what is implicit as well;
  - b) On the other hand, matter may be contained in a document but so submerged in it as not to be available (compare *Dr Reddy’s Laboratories v Eli Lilly and Company* [2009] EWCA Civ 1362);
  - c) Novelty in the case of overlapping ranges is no different from novelty in other circumstances.
89. What I find, with great respect, more difficult to follow is the notion that it may be legitimate to find lack of novelty because the skilled person would “seriously contemplate” moving from a broad range to a narrow range. Merely by stating the proposition in that way one can see that it is inconsistent with the approach approved by the House of Lords in *Synthon*. There is no disclosure of the narrower range. Moreover, assuming no specific individual value is disclosed, there are no clear directions to use a value within the narrower range. A person carrying out the disclosure of the prior range will not inevitably fall within the claim of the later patent. If the “serious contemplation” approach is indeed the correct approach in the case of overlapping ranges, then overlapping ranges are a special case in the law of novelty, a proposition which is inconsistent with the third proposition derived from T 666/89 itself.
90. As will appear, however, I have not found it necessary to reach a concluded view on whether the cited EPO decision is correct.

*Lack of novelty over the Danish Application*

91. Lundbeck asserts that the 614 patent is invalid for lack of novelty over the Danish Application. The Danish application does not disclose any specific percentage of SO<sub>3</sub> in sulphuric acid. It just talks about oleum.
92. Mr Turner submitted, firstly, that the Danish application nevertheless disclosed by implication a range of SO<sub>3</sub> concentrations from 1 to 99%. He then submitted, founding himself on the EPO case law which I have referred to above, that the broad range deprived claim 1 of 614 of novelty because the skilled person would seriously contemplate working within the 20-33% range claimed.
93. I think this argument fails at the first hurdle. On no view does the Danish application disclose a range of SO<sub>3</sub> concentrations. It is simply silent on the concentration of SO<sub>3</sub> used. One simply cannot convert an absence of disclosure into the disclosure of a range of concentrations. It is not implicit that the Danish application is referring to a range from 1 to 99% either.
94. It is therefore not necessary for me to decide whether to follow the EPO case law on which Mr Turner relies, particularly as the point does not arise directly. Decisions of an expert tribunal such as the Technical Board of Appeal of the EPO are entitled to respect. On the other hand the court is not bound to follow such a decision. In *Actavis v Merck* [2008] EWCA Civ 444 Jacob LJ likened the EPO to a commodore leading a fleet of ships in a convoy. But he said:

“In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away.”

## **Obviousness**

### *Law*

95. A patent will be invalid on the ground called “obviousness” if the invention is obvious to a person skilled in the art having regard to any matter which formed part of the state of the art: Sections 72(1)(a), 1(1)(b) and 3 of the Act, which enact Article 56 of the EPC.
96. The structured analysis adopted in *Pozzoli v BDMO* [2007] FSR 37, is a helpful guide to the fact finding tribunal, but is not to be regarded as a substitute for the statutory test. The structured approach is as follows:
  - “(1) (a) Identify the notional "person skilled in the art";  
(b) Identify the relevant common general knowledge of that person;
  - (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
  - (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?”

97. Kitchin J concisely summarised the law in *Generics v Lundbeck* [2007] RPC 32 at [72] subsequently approved by the Court of Appeal in that case and the House of Lords in *Conor v Angiotech* [2008] R.P.C. 28 at [42]:

“The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.”

*Over the Forney papers*

98. I have identified the person skilled in the art and the common general knowledge above. The inventive concept of claim 1 is the process for making 5-cbx identified in that claim, as I have construed it. I consider this claim first of all. The differences between the Forney papers and claim 1 are (a) to the extent that it is not made absolutely explicit, the use of an unpressurised open reactor; (b) the use of such a reactor in combination with the 20-33% oleum solvent described in Forney 2.
99. Because lack of novelty was thought still to be in issue, much of the cross examination was conducted on the basis of the individual papers. By the end of the trial it was clear that whether the skilled person started from Forney 1 or from Forney 2, he or she would end up with both papers. That is because anyone sufficiently interested in the Note in Forney 1 would chase up the fuller paper, and anyone interested in Forney 2 would note and follow up the cross-reference to Forney 1. Mr Lykiardopoulos submitted that the evidence also established that the skilled person would at least do a patent name search with the name Forney, and would come across the Forney patent. I think that conclusion is justified as well.
100. The overall picture presented by the Forney work is that the chemical reaction of terephthalic acid with formaldehyde in an SO<sub>3</sub>-containing medium is a robust reaction over a wide range of reaction conditions. Forney demonstrates a preference for 100% SO<sub>3</sub>, but makes it clear that the reaction will give comparably good results with 30% oleum and 30% SO<sub>3</sub> in dimethylsulphate.
101. The evidence established that the skilled person would start by repeating Forney 1's preparative example. This would involve using Sulfan B, i.e. stabilised 100% SO<sub>3</sub> at atmospheric pressure. There is no suggestion that the skilled person would fail to achieve Forney's results.
102. The skilled person would naturally turn to think about whether the reagents described by Forney were the best for his purposes. Dr Scott agreed with Mr Ward that it would be natural to consider alternatives which were less hazardous than 100% SO<sub>3</sub>.

103. Once the skilled person considers the use of an alternative reagent the evidence establishes to my satisfaction that oleum is a natural choice. Firstly, it is, to a degree, less hazardous than 100% SO<sub>3</sub>. Secondly, it did not seem to me from the evidence that there was much of a choice of “SO<sub>3</sub>-containing media” that would occur to the skilled person as being suitable. Oleum is certainly the one that would first come to mind. Thirdly, there is a broad hint in Forney 1 that Forney himself had done experiments in oleum: contrast the third paragraph with the by-product experiment. Fourthly, the skilled person would know that the reaction in 100% SO<sub>3</sub> will produce sulphuric acid: each molecule of water eliminated in the reaction will react with a molecule of SO<sub>3</sub> to form sulphuric acid. The medium is therefore SO<sub>3</sub> in sulphuric acid in any event. Finally Forney 2 makes it clear that the reaction has been tried in 30% oleum and achieved a similar conversion to that achieved with 100% SO<sub>3</sub>, albeit both in sealed tubes.
104. It seems to me, therefore, that the skilled person would have every incentive to try oleum in the place of liquid SO<sub>3</sub>. The real questions are what sort of oleum (i.e. what SO<sub>3</sub> content) would the skilled person use and whether he would use an open and unpressurised reactor.

*What type of oleum?*

105. Mr Lykiardopoulos submitted that the skilled person would not naturally choose an SO<sub>3</sub> concentration in the patented range, for a number of reasons. Firstly, he submitted that Forney warns against “dilute oleum” which the skilled person would understand as encompassing 20-33% oleum. He relied on some answers given by Dr Scott and Mr Ward about the ranges of oleum that they would have on their shelf. So Mr Ward said that 20-30% was the “lower range” as indeed it was. Dr Scott’s answer was that the lowest available form was about 20%. Secondly, Mr Lykiardopoulos submitted that the Figure 1 graph in Forney 2, coupled with the statement about maximum conversion at 60 mol% would point the skilled person towards higher concentrations of SO<sub>3</sub>. Thirdly he points to the fact that SO<sub>3</sub> is said to be “critical to the reaction.”
106. I do not accept these submissions. In the context, which includes Forney 1, the skilled person would understand the reference to dilute oleum as being to oleum containing less than 20% SO<sub>3</sub>. Above this level the product is produced in excellent yield, a conclusion confirmed by the 30% oleum results in Forney 2. The answers relied upon from Mr Ward and Dr Scott were the only ones they could have given, but were divorced from the context of the Forney papers. There is no indication in the Forney papers that by-product formation is a problem at 30% concentration, which is used extensively in Forney 2. There is no “warning” against 30% SO<sub>3</sub>.
107. The reference to the conversion reaching a maximum at 60% also needs to be read in context. Firstly - a fairly minor point - the mol% translates to 55% by weight in the case of oleum. Secondly it must be remembered, as Mr Ward points out, that the comment is made in relation to Figure 1, which only records conversion after one hour. Table II shows that 95% conversion can be achieved in 30% oleum after two hours, which is similar to the results for 100% SO<sub>3</sub> both with and without pressure.
108. Finally the statement that SO<sub>3</sub> is “critical to the reaction” would not be understood as telling the skilled reader that he should adopt a high concentration of SO<sub>3</sub>. The

skilled person would understand that the presence of SO<sub>3</sub> was essential, but that conversion did not depend on concentration. So much would be clear from the fact of 95% conversion at only 30% SO<sub>3</sub>.

109. Armed with a proper understanding of the papers the skilled person would naturally reach for the sort of oleum he is likely to have at his disposal, which is likely to be in the 20-30% range. Although he might try to obtain a more concentrated oleum, that would not detract from the fact that a 30% oleum was a natural choice.

*What type of reactor?*

110. There remains the question as to whether the skilled person would try 30% oleum in an open and unpressurised reactor. There is no specific experimental write-up of such a reaction in any of the Forney documents. Lundbeck's case was that it was obvious to use unpressurised reactions if one could, and the statement about the wide range of conditions for the reaction in the third paragraph of Forney 1 would encourage one to believe that one could.

111. Dr Moses's main answer to this was that, although the skilled person might wish to try to do the reaction with oleum in an open and unpressurised reactor, he would not be confident about the results. His view was that there would be doubt about whether the SO<sub>3</sub> would boil away. If enough of it boiled away the SO<sub>3</sub> concentration might fall below 20% and lead to by-product formation.

112. There is, however, no substance in the concern about the SO<sub>3</sub> concentration falling below 20%. Mr Ward explained that there was no reason why the skilled person would not do the preparative reaction in a round bottomed flask using a reflux condenser. In cross examination Dr Moses said this:

“If I was heating a reaction and trying to keep the reagent concentration above 20%, whatever 20% refers to, I would consider doing it in a sealed vessel. I may consider doing it in an open vessel if I put a condenser on it. I would not know the outcome. I would not be able to reasonably predict whether the SO<sub>3</sub> concentration would drop below 20%. I cannot say that claim 1 is therefore obvious.”

113. I think that, in this passage and elsewhere, Dr Moses was saying that he would not be sure about the precise result. His statement about the final question of obviousness must be read in that light. He did not really have any quarrel with the suggestion that an open reactor was a sensible way to proceed.

114. I think all that would be involved would be the sort of routine process investigation that a skilled industrial process chemist would be obliged to perform as part of his job. The skilled person is not going to use a pressurised reactor if the reaction proceeds satisfactorily under atmospheric pressure. It is true, as Dr Moses emphasised regularly, that one would not be certain, or sure, of what the results would be. As he said, if that were the case, one would not have to run the test. But I gained the impression that the uncertainty with which he was concerned was about how good the conversion would be. He did not advance any coherent reason why the reaction

would not proceed, or why, given the strong statement made in Forney 1, one would not be confident that it would do so.

115. I should add that Mr Lykiardopoulos sought to characterise the necessary testing as a research project. He reminded me of what I said in *Teva v Merck* [2010] FSR 17 at [88]-[98] namely that the court should proceed “with caution” when faced with an obviousness attack based on the suggestion that the skilled person would embark on a research program in the course of which he would discover that a product was effective.

116. I do not think that this is that type of obviousness case at all. Mr Ward explained that in the following exchange:

“Q. He cannot predict the outcome, but he is doing this in order to cover all bases, basically. He picks the papers up and he does a full range of experiments.

A. I would not quite agree that you cannot predict the outcome because I think Forney gives him a very powerful pointer, saying that he can do this over a wide range of conditions. He starts these things with the expectation that he is going to get a lot of positive results rather than a whole host of negative ones.”

117. Mr Lykiardopoulos also pointed to the fact that the patent teaches at [0007] that the invention “allows” the synthesis of 5-cbx with “high yield and purity and easily controllable in the industrial scale”. He submits that it would not be obvious that a process which used 20-33% oleum in an open, unpressurised reactor would achieve these good results.

118. I think this submission seeks an answer to the wrong question, because it incorrectly characterises the inventive concept of the claim. Firstly, to bring the good results into the claim, it is necessary for the results to be obtainable across the breadth of the claim: *Brugger v Medic-Aid* [1996] RPC 635 at 656-657. There is, however, no limitation in the claim about either yield or purity. On the construction of the claim which I have adopted, the claim is infringed whenever the prescribed conditions are used to make 5-cbx, even if the process is not taken to completion, or low purity product is obtained. It follows that it is not legitimate to use the results which the invention “allows” to formulate the question for the purposes of determining inventive step.

119. Secondly, the relative terms “high yield and purity and easily controllable conditions” are nowhere defined. The evidence does not enable me to conclude that these parameters for the claimed process are any better or worse than those obtained using 100% SO<sub>3</sub>. In the opposition proceedings in the European Patent Office, Infosint relied on some experiments which purported to show improvements, but they elected not to rely on such material here.

120. The result is that one cannot approach obviousness on the basis that the claimed process is better, or even as good as Forney’s preferred SO<sub>3</sub> process. It is simply another set of process conditions for performing the same reaction.

121. I have come to the conclusion, therefore, that the skilled industrial process chemist, starting from the Forney work, would arrive at the use of 20-30% oleum in an open and unpressurised reactor without invention. Claim 1 is therefore invalid for obviousness. I would have reached the same conclusion were Forney 1 the only citation to be considered.
122. I have been able to reach this conclusion without relying on the work at Lundbeck before the priority date. In view of the unsatisfactory way in which that material was put before the court, I do not think it would be safe to place reliance on it in the way that Lundbeck would wish. Mr Turner suggested that I could, nevertheless, place reliance on some answers given by Dr Scott, commenting on the work by Lundbeck. He said that I could do so notwithstanding the inaccuracy of the account which was put to him. I think it would be wrong to do so. The material was put to Dr Scott on the footing that this was what Lundbeck had done, and it was reasonable for them to have proceeded in that way. It was hard for Dr Scott to answer that it was not reasonable. He was not given the opportunity of answering the question in the light of a proper explanation of what had happened. Moreover, part of what drove Lundbeck forward was Mr Nielsen's mistaken belief that the preparative example in Forney 1 was oleum, when it was not. It is difficult to place much weight on the work once that mistake had been made. Finally, if the newly disclosed material is indeed the whole of the work which Mr Nielsen did, it seems to have started with a dehydrating agent which is neither oleum nor  $\text{SO}_3$ . This is not consistent with the way in which the experts were agreed the skilled person would proceed, namely by trying what is disclosed first. I do not think there is anything on which either party can rely in the history. I have disregarded it.

### **Claim 22**

123. The inventive concept of claim 22 is the use of the claim 1 process in a process of making citalopram. Lundbeck advance two cases of obviousness of claim 22. The first is that the skilled person seeking to make use of the process of making citalopram disclosed in 513 would need a method for making the disclosed intermediate, 5-cbx. He would be led to perform a search for methods of making 5-cbx, which would uncover the Forney work, with the obvious consequence that he would use the claimed process to make the intermediate, and the rest of 513 to make citalopram. I call this "the searching argument".
124. Lundbeck's alternative case is that claim 22 is a mere aggregation of features. Forney renders obvious the process of claim 1 for making 5-cbx; 513 discloses a process of converting 5-cbx into citalopram. To take these two process steps and perform them in sequence is not an invention: it is a mere aggregation of process steps. I call this "the aggregation argument".

### *The searching argument*

125. It is common ground that all 513 discloses about the way to make 5-cbx is that it:
- "is commercially available and may be prepared by well known procedures (Tirouflet, J.; Bull. Soc. Sci. Bretagne 26, 1959, 35)."

126. So far as the evidence goes, 5-cbx was not commercially available, and the reference, Tirouflet, does not disclose a method of making 5-cbx. It follows that the skilled person who wishes to put 513 into effect must find a way of making 5-cbx.
127. The Beilstein Handbook of Organic Chemistry is the standard reference for the preparation of organic compounds. It was first published in 1881, set up by a German chemist of that name. It is a practical reference source in the sense that it records what chemists have actually made. As Mr Ward put it, “*you can be sure that entries in Beilstein are useful*”. It is now available on-line, but in 2000 the bound volumes would also have been readily available. A search against the formal chemical name for 5-cbx would have uncovered Forney 1 with the indication “(Prep)” which means that the paper gives a preparative method.
128. The Dictionary of Organic Compounds is also a standard reference work which the skilled person would be likely to consult. It was first published in 1934. An entry for “Phthalide-5-carboxylic acid” (5-cbx) in the 1996 edition identifies Forney 1 and gives an indication that it provides a synthesis.
129. For completeness, Mr Ward did a search through Chemical Abstracts. This is a much larger database which catalogues almost every publication in the area of chemistry. In my judgment, the skilled person would be more likely to consult Beilstein and/or the Dictionary of Organic Compounds before resorting to Chemical Abstracts.
130. On the basis of these materials, Lundbeck submit that the skilled person would obviously and inevitably find and read Forney 1. I think that is correct.
131. Infosint answers this case in the following way. The evidence showed that, in addition to Forney, the Beilstein search, whether done manually or on-line, would have turned up a number of other papers. These were not placed before the court, and, for all one knows, might have led the skilled person in other directions.
132. Attractively though this argument was presented by Mr Lykiardopoulos, I am not persuaded by it. Firstly, if there were any material in these other documents which would have rendered Forney’s synthesis less attractive, then I would have expected this material to be put to Lundbeck’s expert. After all, Mr Ward had made clear that he would find Forney 1 and what he would do on finding it. Secondly, it is difficult to see what these other publications could say which would detract from Forney’s plain instruction that he has a robust process for making 5-cbx. The fact that there might be other suggestions would not be sufficient to prevent Forney from being at least one obvious process to use.
133. Accordingly, in my judgment, the skilled person starting from 513 would be led to the other Forney materials and to a process within claim 1 for making 5-cbx. Claim 22 is therefore obvious over 513 and Forney.

*The aggregation argument*

134. It is not therefore necessary for me to deal with the aggregation argument. Mr Turner recognised that it was a more difficult argument both in law and on the facts. It can sometimes be the case that connecting two known processes together in series can be obvious: see the sausage machine case *Williams v Nye* (1890) 7 RPC 602. The EPO

Guidelines for Examination has a similar principle which it expresses in the following way:

“Obvious and consequently **non-inventive combination** of features:

The invention consists merely in the **juxtaposition** or association of known devices or processes functioning in their normal way and not producing any non-obvious working inter-relationship.

Example: Machine producing sausages consists of known mincing machine and that known filling machine disposed side-by-side.” (original emphasis)

135. Equally one can have a claim which identifies two separate and distinct solutions to two separate and distinct problems as in *Sabaf SPA v MFI Furniture Centres Limited* [2004] UKHL 45; [2005] RPC 10. There is no need in those circumstances to show that there was some obvious motive to combine the solutions, if no special advantage flows from the combination. But it is not necessary on the facts of this case to explore these considerations further. For the reasons I have identified in dealing with the searching argument, there was no invention in the present case in combining the teaching of 513 with that of Forney, and it was obvious to do so.

### **Insufficiency**

136. A patent will be invalid for insufficiency (section 72(1)(c) of the Act; Article 123(2) of the EPC) if:

“the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art.”

137. A number of cases have addressed the problem of whether it is enough, where a claim covers a class of products or processes, for the specification of the patent to teach only one, or some but not all, of those products and processes. In *Lundbeck v Generics* [2009] UKHL 12; [2009] RPC 13, the House of Lords held that, in the case of a claim to a single chemical compound (in that case escitalopram), it was necessary only to disclose one way of making it. Lord Neuberger emphasised that statements of general principle in relation to inventions with many embodiments, in which class he included the judgment of the House of Lords in the earlier case of *Biogen Inc v Medeva* [1997] RPC 1, might be irrelevant to a case which consists of a single chemical compound.

138. In *Biogen* Lord Hoffmann explained the principle in the following terms, at 48 line 42:

“... the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved his application in every individual

instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them."

139. In the later case of *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2004] UKHL 46; [2005] RPC 9, Lord Hoffmann explained what was meant by a principle of general application in this context:

"In my opinion there is nothing difficult or mysterious about it. It simply means an element of the claim which is stated in general terms. Such a claim is sufficiently enabled if one can reasonably expect the invention to work with anything which falls within the general term."

*The insufficiency alleged here*

140. Lundbeck attack claim 22 of the 614 patent on the basis of insufficiency only if claim 22 is not invalid for obviousness. The points on insufficiency do not therefore arise. I will deal with them shortly, in case it turns out that my decision on obviousness of claim 22 is wrong.

141. Lundbeck's pleaded case is:

"(a) the Patent discloses a process for producing [5-cbx] and not a process extending to the production of citalopram

(b) in the alternative, insofar as the Patent discloses how to make citalopram from 5-cbx, it does so only by reference to a method described in International Patent Application WO 000243431 and in Italian Patent Application IT1999MI0001724 and not by any other methods. For this reason claim 22 is objectionable insofar as it extends to other ways of making citalopram from 5-cbx."

142. Lundbeck elaborated the first point in the following way. Claim 22 is what Lundbeck call a "reach-through" claim. This is intended to convey the notion that the inventive concept of the claim lies in how to make 5-cbx, not in how to make citalopram from 5-cbx. Lundbeck point out that although the addition of the step of making citalopram narrows the claim in some respects, it enables Infosint to complain of the importation of citalopram made from 5-cbx abroad, when this would not have been possible if the patent only had claims to a process for making 5-cbx. Lundbeck submits that the monopoly in these circumstances extends beyond the contribution to the art.

143. I cannot accept this submission. The technical contribution of claim 22 is making citalopram via 5-cbx made by the process of claim 1. So a monopoly which prevents dealings in citalopram made in that way does not extend beyond the contribution. Points made about the consequent scope of protection have nothing to do with insufficiency.

144. The objection pleaded in sub-paragraph (b) relies on passages in the judgment Lord Hoffmann in *Biogen* as subsequently explained by the House of Lords in *Lundbeck v Generics*. Lundbeck rely on the fact that a process claim needs to be sufficient across its entire breadth. The 614 patent discloses only some ways of making citalopram from 5-cbx, not all the ways.
145. Claim 22 is a claim to the general principle of using 5-cbx made by the claim 1 process to make citalopram. Insofar as it relates to making citalopram from 5-cbx it is claimed in entirely general terms. One could reasonably expect the invention to work with any process which produced citalopram from 5-cbx. As such it would have been enabled provided it taught one method by which to make citalopram from 5-cbx. There is no suggestion that the skilled person would have encountered any difficulty in doing so.

### **Infringement**

146. From a date before the priority date both LUPUK and LUMSAS (Lundbeck's facilities in the UK and Denmark respectively) were operating a process for making 5-cbx. Thereafter other companies, identified below in the way they were referred to at trial, became involved in making 5-cbx for Lundbeck. All of the 5-cbx is now made in India. I deal with each process below.

#### *LUMSAS low temperature process*

147. This was operated in Denmark from 1986 to April 2003, i.e. both before and after the priority date. The reaction mixture is supposed to be heated to 115-145°C for 17-21 hours. This is a one-pot process: all the reactants are heated up in the same open and unpressurised reactor. Whilst there was some debate in the evidence about individual batches, Infosint accepts that Lundbeck have a defence under section 64 (see below) in relation to the operation of this process up to July 2003. It is therefore not necessary to discuss it further.

#### *LUPUK low temperature process*

148. This process was operated in the UK from 1995 to July 2003, again both before and after the priority date. As with the LUMSAS low temperature process, it is accepted that section 64 applies.

#### *LUMSAS and LUPUK high temperature processes*

149. This was a two-pot process, introduced in an attempt to avoid the 614 patent. The oleum and terephthalic acid were first heated to 150°C before paraformaldehyde was slowly added, keeping the temperature at about 150°C and maintaining the temperature at about 150°C thereafter.
150. The difference between a one-pot and a two-pot process is no longer relied on as avoiding infringement. Infosint now accepts, however, that Lundbeck have a defence in relation to these processes on the ground that the temperature exceeds 150°C. There is therefore no infringement here either.

#### *Siegfried*

151. The temperature here was within the claimed range but the pressure was 1.4 to 1.7 bar above atmospheric. These are undoubtedly pressurised conditions. On the view which I have taken of construction there is no infringement.

*CF Pharma*

152. This was a multi-pot process. A mixture of terephthalic acid in oleum is first heated up to the reaction temperature before a mixture of paraformaldehyde in oleum is slowly added. Additional SO<sub>3</sub> is then distilled over into the mixture from a third vessel. Lundbeck accept for the purposes of these proceedings that at least one batch falls within the claims. There is therefore infringement. There is an issue about whether section 64 applies to this process.

*LUPI*

153. These processes were operated at Lundbeck's plant in Italy. The reactor was operated at 0.2 to 0.4 bar above atmospheric.
154. As originally implemented in 2001, the process used 66% oleum. It is common ground that this high oleum process did not infringe.
155. Later, LUPI used an oleum concentration within the claimed range. Dr Scott accepted that the reaction was being run under pressure, but maintained that the reaction was technically equivalent because the extra pressure had no effect on the reaction. He had not, however, done any analysis to determine whether the additional pressure might have a minor effect on impurities or yield. As I have construed the claim, pressurised reaction conditions are not covered. There is therefore no infringement.

*SF Chem*

156. This process is also run at 1.5 to 1.7 bar over atmospheric. The conclusion is the same as for Siegfried and LUPI: pressurised conditions do not infringe.

*Ramdev*

157. There are two Ramdev processes, one run at 140-145°C (up to 26<sup>th</sup> October 2009) and the other at 147-152°C (thereafter). Both are two-pot processes.
158. The first process infringes the claims, subject only to the section 64 defence.
159. The batch records for the post-26<sup>th</sup> October 2009 process reveal:
- i) Trial Bundle G1 tab 12 shows that the recorded temperatures were all above 145°C.
  - ii) Trial Bundle H tab 7 shows that the temperatures were all above 145°C.
160. There is therefore no evidence of any infringement of the claims by these processes.

*Jet*

161. This is a two pot process. The batch record at Trial Bundle H tab 8 shows the process is supposed to run at 145°C but was measured once at 148.1°C, just before the reaction ended. I consider that, on the balance of probabilities, 5-cbx is being made at temperatures within the claimed range. It seems overwhelmingly likely given the intended temperature and the 148.1°C reading, that in practice the temperature would fluctuate above and below the 145°C mark. 5-cbx is accordingly likely to be made within the claimed range.

*Suven*

162. This is run at above 145°C and is two-pot. Trial Bundle I tab 10 reveals a process where the temperature varied with time between 146 and 147°C. The batch record at Trial Bundle H tab 9 reveals slightly higher temperatures. This one is very close to the line, but I think it is just outside the temperature range specified. It does not infringe.

## **Section 64**

163. Section 64 of the Act provides:

“(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention –

(a) does in good faith an act which would constitute an infringement of the patent if it were in force, or

(b) makes in good faith effective and serious preparations to do such an act,

has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.

(2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may–

(a) authorise the doing of that act by any partners of his for the time being in that business, and

(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.”

164. In *Lubrizol Corp. v Esso Petroleum* [1997] RPC 195, Jacob J (as he then was) noted an apparent difference in judicial opinion on the scope of the defence that had arisen between the decision of Aldous J (as he then was) in *Helitune v. Stewart Hughes* [1991] FSR 171 at 205-206 and Mr Laddie QC sitting as a Deputy Judge of the Patents Court (as he then was) in *Lubrizol v. Esso (No.1)* [1992] RPC 281 at 295. Aldous J had appeared to suggest that s.64 provided a general licence under the patent. On appeal in *Lubrizol Corp. v Esso Petroleum* [1998] RPC 727 at page 770, Aldous LJ explained the approach as follows:

"It seems that the words used by me in *Helitune* have been read in a way not intended. Clearly the right given by section 64 cannot be a right to manufacture any product nor a right to expand into other products. However I do not believe that identity is required. I believe that the judge was right in this case when he said:

If the protected act has to be *exactly* the same (whatever that may mean) as the prior act then the protection given by the section would be illusory. The section is intended to give a practical protection to enable a man to continue doing what in substance he was doing before."

165. LUMSAS and LUPUK were operating the processes I have described as their low temperature process from dates before the priority date of the 614 patent. They continued to operate substantially the same processes thereafter until the temperature was changed to the non-infringing high temperature process. I have already recorded the fact that it is common ground that they had a section 64 defence in respect of the importation of citalopram made by those processes. There are really only two issues left on the facts. The first is whether importation of product made from 5-cbx made by the two-pot processes which would otherwise come within the scope of the claims is within the scope of the right given by section 64. The second is whether the importation of the enantiomer, escitalopram, is within that right.

*The two pot process*

166. The two-pot process was introduced by Lundbeck in an attempt, now acknowledged to be inadequate, to avoid the claims of the 614 patent. Mr Turner submitted, firstly, that it was not necessary to enquire into how the citalopram was made before it was imported. The act of importation of citalopram before the priority date gave the right to import citalopram after the priority date even if made by a different process. He says that this is the right approach because the act which gives the rise to the right under section 64 is the act in the United Kingdom – importation of citalopram.
167. Whilst the language of section 64 does not sit entirely happily with the case of infringing importation of the direct product of a process, I am unpersuaded by Mr Turner's submission. The prior act which section 64 refers to is an act which would infringe the patent if it were in force. It makes no sense to characterise this as "importation of citalopram". The only act which infringes is the importation of citalopram made by a claim 22 process. Section 64 therefore gives a right to continue to import citalopram made by a claim 22 process, not a right to import citalopram however made.

168. Mr Turner next submits that the two-pot process does not make any difference, because it is substantially the same commercial process as the one-pot process.
169. Mr Trickett was responsible for introducing the two-pot process at LUPUK. He did so under instructions to change the process for patent infringement reasons. He accepted in cross-examination that making the changes was like starting again. The new process (this is what Mr Trickett called it) involved extra equipment, new timings, a pre-heating step and new pipework. Dr Scott described the new process as “operationally different”.
170. In my judgment Lundbeck are not entitled to a section 64 defence in relation to the importation of citalopram made by two-pot processes. Such processes are not substantially the same as what was done before. To the extent that those processes use the claimed process parameters, they infringe the claims.

*Escitalopram*

171. It is not suggested by Lundbeck that they imported or made serious and effective preparations to import escitalopram by the process of claim 22 before the priority date. The section 64 defence to the importation of escitalopram is based on the importation of racemic citalopram.
172. I do not think there is any difficulty here. The importation of escitalopram is not substantially the same act as the importation of citalopram. As Professor Davies’ evidence makes clear, although escitalopram is contained within racemic citalopram, the two materials have different properties, and are different articles of commerce as a result.

*Pause in production*

173. There was a further point mooted about whether Lundbeck could resume production according to the LUMSAS or LUPUK low temperature processes, which they stopped using in 2003, and still rely on section 64. It does not seem to me that it arises directly, and I therefore do not need to deal with it.

## Section 68 – Limitation of remedy

### *The Law*

174. Lundbeck say that Section 68 of the Act provides them with a partial defence. The point does not arise because the patent is invalid, and for that reason not infringed. Nevertheless I will deal with the point in case I am wrong on validity.
175. Section 68 has been amended. In the section as set out below, the words in square brackets were removed and the words in bold added by the Intellectual Property (Enforcement, etc) Regulations 2006 (SI 2006/1028) coming into force on April 29 2006.
- “68. Where by virtue of a transaction, instrument or event to which section 33 above applies a person becomes the proprietor or one of the proprietors ... of a patent and the patent is subsequently infringed [*, the court ... shall not award him damages or order that he be given an account of profits in respect of such an infringement occurring*] before the transaction, instrument or event is registered, **in proceedings for such an infringement, the court ... shall not award him costs or expenses** unless –
- (a) the transaction, instrument or event is registered within the period of six months beginning with its date; or
- (b) the court ... is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.”
176. In *Siemens v Thorn* [2008] RPC 4 Mann J held that the unamended version of section 68 applies to acts of infringement committed before the section was amended. Although the Court of Appeal allowed an appeal on the non-registration point, the issue of whether or not the amendments to section 68 were retrospective was not the subject of any appeal – see the Court of Appeal’s judgment at [2008] EWCA Civ 1161 at [79]. Infosint did not invite me to differ from Mann J, but reserved an argument that he was wrong for a higher court.
177. The position is therefore that, if the point is a good one, Infosint would not, if the patent had been infringed, have recovered damages or an account of profits for infringements before April 29 2006, and not recover costs thereafter.
178. Section 32(1) requires the Comptroller to maintain the register of patents. Section 32 defines “register” (as a noun) as “the register of patents” and (as a verb) as “to register particulars, or enter notice, of that thing in the register and, in relation to a person, means to enter his name in the register”. Cognate expressions, in which one would include the word “registered” used in section 68, are expressly required to be construed accordingly.

179. Section 33, which is cross-referred to in section 68, is a section which sets out certain effects of registration. For present purposes it is sufficient to note that it is a section which applies by section 33(3)(a) to the assignment of a patent or application for a patent, or a right in it.
180. By Implementing Regulations pursuant to the EPC it is provided that:
- “22(1). The transfer of a European patent application shall be recorded in the European Patent Register at the request of an interested party, upon production of documents providing evidence of such transfer.
85. Rule 22 shall apply to any transfer of the European patent made during the opposition period or during opposition proceedings.”
181. The provisions of the Act which govern the relationship between the European and national phases include:
- “78.-(1) Subject to the provisions of this Act, an application for a European patent (UK) having a date of filing under the European Patent Convention shall be treated for the purposes of the provisions of this Act to which this section applies as an application for a patent under this Act having that date as its date of filing and having the other incidents listed in subsection (3) below, but subject to the modifications mentioned in the following provisions of this section.”
182. Section 78(2) provides that the section applies to sections 30 to 33 of the Act. Section 78(3)(f) includes as one of the incidents referred to in subsection (1):
- “(f) registration of the application in the register of European patents shall be treated as registration under this Act.”
183. Accordingly, although Section 78(3)(f) is not absolutely clear on the point, it would appear that if the applicant succeeds in registering an assignment of an application for a European patent (UK) on the register kept by the European Patent Office, then that will be treated as valid registration under the Act. There is, however, no corresponding provision dealing with the assignment of the European patent. Although the EPO will, by virtue of Rule 85, register such an assignment, there is no provision deeming such registration to be registration under the Act.
184. The scope of the defence afforded by section 68(b) was explained by the Court of Appeal in *Molnlycke v Procter & Gamble* [1994] RPC 49 at 139 in the judgment of Sir Donald Nicholls VC:
- “It is relevant to consider the nature of the responsibility or obligation imposed and its meaning must depend on the conduct or actions which the person on whom the obligation is placed would ordinarily be expected to take to comply with that obligation. The purpose of the registration requirements of the

Patents Act 1977 is to make the subject matter of the application and details of relevant transactions available to the public...

In this context "practicable" means that the applicant for registration must take all the steps which the reasonable applicant acting on competent advice would take in the circumstances to secure registration."

185. In that case an application to register an assignment had been made but not acted on by the Patent Office because of a settled practice of the Office not to register assignments when there were revocation proceedings pending. There was no statutory basis for such a practice. The Court held that a competent agent could properly take the view that she had done all she reasonably could in the circumstances to obtain registration.

*Facts relevant to section 68*

186. The application for the 614 patent was filed by Norpharma on 18<sup>th</sup> January 2000. In February 2002 Infosint was granted an option to purchase a portfolio of patent applications and rights, including the application for the patent in suit. On 18<sup>th</sup> March 2002 Infosint stated that they intended to exercise the option and would pay the consideration to Norpharma by 25<sup>th</sup> March.
187. The patent in suit was granted on 19<sup>th</sup> June 2002. By an assignment dated 22<sup>nd</sup> July 2002 Norpharma purported to assign the application for the patent in suit to Infosint. On 11<sup>th</sup> July 2002, Italian Patent Attorneys acting for Infosint, Dragotti & Associati ("Dragotti"), had written to the European Patent Office to notify it that the "above mentioned patent application" had been assigned from Norpharma to Infosint and asking them to record the assignment "before entering into the national phase". On 25<sup>th</sup> July the assignment was sent to the EPO by Dragotti. On 5<sup>th</sup> August the EPO sent an acknowledgment confirming that as requested "the entries pertaining to the applicant of the above-mentioned European patent application/proprietor of the above-mentioned European patent" had been amended. The registration of the change took effect on 26<sup>th</sup> July 2002.
188. On 29<sup>th</sup> July 2002 Dragotti wrote to patent attorneys in the UK. It was apparent from the letter that the patent had been granted and that it had been assigned from Norpharma to Infosint. The letter also informed the UK attorneys that the recordal of the assignment had been requested at the EPO. The purpose of the letter was to ask the UK attorneys to attend to the "formalities for recordal" of the case in the UK. On 5<sup>th</sup> August 2002 the UK attorneys wrote to the UK Patent Office giving the reference number of the granted patent and heading the letter "Infosint SA". However, the letter only expressly requested the entry of the UK attorneys as the address for service in respect of the Patent. It did not expressly request alteration of the name of the proprietor. Infosint was however recorded as the proprietor in the books and records of the UK agents.
189. On 7<sup>th</sup> August 2002, Dragotti forwarded the EPO acknowledgment concerning the registration of the assignment. This was not, so far as the correspondence shows, forwarded on to the Patent Office here.

190. A similar procedure adopted with agents in the Irish Republic resulted in the Irish register being amended to record Infosint as proprietors.
191. When the 614 patent entered the national phase in the UK it remained in the name Norpharma. Consequently, in the present proceedings Norpharma were named as defendant.
192. In consequence of the commencement of these proceedings, eight years later, on 17<sup>th</sup> May 2010, Infosint requested registration at the UKIPO of the 22<sup>nd</sup> July 2002 assignment. The assignment was registered at the UKIPO on 9<sup>th</sup> June 2010.

*Discussion and conclusion*

193. It is plain on these facts that the registration of the assignment at the UKIPO did not happen within six months of the date of the assignment. Infosint have two answers to this:
  - i) The registration of the assignment at the EPO counts as registration for the purposes of section 68;
  - ii) Alternatively, the defence under section 68(b) applies because it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.
194. On the first point Mr Lykiardopoulos argues that registration of the assignment at the EPO under Rule 85 counts as registration under the Act. So the assignment was registered within 6 months of its date. I am unable to accept this argument.
195. The “transaction, instrument or event” with which this case is concerned is the assignment dated 22<sup>nd</sup> July 2002. It is true that, according to its terms, it is an assignment of the application, not the patent. But by the time it came to be executed the patent had been granted. The assignment thereby operated to convey the title to the patent on that date. It makes no sense to regard it as an assignment of the application, which had by then ceased to exist.
196. It was therefore the assignment of the patent which had to be registered, and which was registered at the EPO. There is no provision which deems such registration to be registration under the Act (unlike section 78(3)(f)). So the assignment needed to be registered here as well. That did not occur.
197. Mr Lykiardopoulos submits that this result does not give effect to the purpose of the provision, which is to put the public on notice of the assignment. He submits that this purpose is satisfied if the assignment is registered at the EPO. I do not agree. Once the patent is granted, it is a bundle of national rights, each separately assignable. It is therefore to the individual national registers that the public are required to look. The public should not be expected to check the EPO register to see whether by any chance an assignment of the patent was registered in the opposition period under rule 85 and then not registered here.
198. I turn therefore to whether section 68(b) provides an answer. The burden of Mr Zanetti’s evidence was that, in the usual course, he would have expected the inventors

to have given instructions to agents to register the assignments in the individual countries to the extent it was necessary to do so, and he thought this had been done.

199. Mr Lykiardopoulos submits that Infosint have done all that was practicable by instructing its agents in this way. He focused on the words of Sir Donald Nicholls VC in *Molnlycke* and submitted that, whatever might have been done by the applicants' agents, the *applicants* had taken all the steps which the reasonable applicant acting on competent advice would take in the circumstances to secure registration.
200. I do not accept that Infosint can avail itself of section 68(b). The defence is only available if it is not practicable to register the assignment. As *Molnlycke* shows, the section requires an investigation of what was done by the applicant and his agents, not just the applicant alone. The fact that the patentee's agent has not succeeded in registering the assignment despite being instructed to do so does not mean that it was not practicable to register the assignment. It would be an odd conclusion if the effect of the section depended on whether the patentee used an employee or an agent to effect registration. Yet on Mr Lykiardopoulos' argument it would make all the difference: in the one case it would be practicable and in the other case it would not.
201. The facts demonstrate that it plainly was practicable to register the assignment, as the registration which was achieved in Ireland shows. It was practicable to register it here as well. The section 68 defence succeeds.

### **Conclusions**

202. My conclusions are that the 614 patent is invalid. If it had been valid the patent would have been infringed by some of the processes relied on. If there had been infringement, the remedies in damages and costs would have been limited by section 68.
203. In slightly more detail:
  - i) Claim 1 is not invalid for lack of novelty over the Danish application.
  - ii) Claims 1 and 22 are invalid for obviousness over the Forney papers.
  - iii) Claim 22 is not invalid for insufficiency.
  - iv) The following processes would not fall within the scope of the claims relied upon, on oleum concentration, temperature or pressure grounds as identified in brackets:
    - a) The LUMSAS and LUPUK high temperature processes (temperature);
    - b) The Siegfried process (pressure);
    - c) The LUPI processes (oleum and pressure);
    - d) The SF Chem process (pressure);
    - e) The Ramdev post-26<sup>th</sup> October 2009 process (temperature);

- f) The Suven process (temperature).
- v) Lundbeck has a section 64 defence in relation to importation of racemic citalopram made by the LUMSAS and LUPUK low temperature processes, but not in relation to escitalopram or any two-pot process.
- vi) Had the patent been valid, there would therefore have been infringement of claim 22 by importation of product made by:
  - a) The CF Pharma process;
  - b) The Ramdev pre-26<sup>th</sup> October 2009 process;
  - c) The Jet process.
- vii) The last conclusion applies whether the product is citalopram or escitalopram, its enantiomer.
- viii) If there had been infringement, the section 68 defence would have succeeded in relation to damages before 29<sup>th</sup> April 2006 and costs on and after 29<sup>th</sup> April 2006.