

UNITED STATES PATENT AND TRADEMARK OFFICE

INTERIM RULE

***Changes To Implement the Cooperative Research and Technology
Enhancement Act of 2004***

(The “CREATE Act”)

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Testimony of
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Responsive to the captioned publication of an *Interim Rule* by the United States Patent and Trademark Office (“the Office”), the following comments are offered. The Office is congratulated on its promptness in responding to the difficult task of implementing a brand new law that was *immediately* effective upon the signature of the President on December 10, 2004. This task has been made particularly difficult by the statutory *retroactivity* of the new law to a whole class of inventions.

A *retroactive* patent law, as here, may not represent the best public policy for Congress, but it is within the Constitutional authority of that body. *Eldred v. Ashcroft*, 537 U.S. 186, 202-03 (2003)(citing *McClurg v. Kingsland*, 42 U.S. (1 How.) 202 (1843)). While the *Interim Rule* includes an ambitious variety of topics that deserve further discussion, the testimony, here, is focused upon a newly created double patenting regime of 37 CFR § 1.109 (“Rule 109”).

The comments are personal to the author and do not necessarily represent the views or opinions of any colleague or client of any organization with which the author is affiliated. The author is the former Director of the Intellectual Property Law Program and Professor of Law of the George Washington University Law School and currently a partner of Foley & Lardner LLC, [hwegner@foley.com].

EXECUTIVE SUMMARY

The creation of a new double patenting regime in Rule 109(b) for *inventions owned by different parties* is considered in § I, *Double Patenting not Required by Statute*. Rule 109(b) is drafted in a manner that opens the possibility that it may *retroactively* deal with inventions of competitors and related companies who do *not* claim the benefits of the CREATE Act. This *substantive* denial of patent rights goes far beyond what the Office can do under the Administrative Procedure Act (APA).

The creation of a new double patenting regime for inventions of the *same owners* has nothing to do with the CREATE Act. See § II, *Rule 109(a): A New Double Patenting Standard*. Clear questions of violation of the APA are raised. Rule 109(a) also blurs the line on the test of Supreme Court case law for double patenting and needlessly creates confusion for the rights of patentees.

Whether the *Interim Rules* are necessary and comply with the APA is dealt with in § III, *An Unnecessary Regulatory Excursion*. There is simply no emergency that compels an adoption of an *Interim Rule*. The patent sky is *not* falling in any way that requires a dramatic bypass of the APA. The law does not create a brand new regime to favor a class within the patent community, but rather only *restores* the law for that community to a state prior to judicial legislation by the courts in a series of cases culminating in *OddzOn Products, Inc. v. Just Toys, Inc.*, 132 F.3d 1396 (Fed. Cir. 1997). The law restores a freedom from “secret” prior art that was present before such judicial activism; it partially restores a parity with the more favorable laws of Europe and Japan that do not provide a “secret” prior art discrimination.

I. DOUBLE PATENTING *NOT* REQUIRED BY STATUTE

The *Interim Rule* provides a new Rule 109(b) to defeat the patentability of an invention that meets the requirements of patentability under the *statute* but which may be “patentably indistinct” from the invention of an independent third party that happens to be within the ambit

of a joint research agreement: “A double patenting rejection *will* be made in an application *** if the application or *** claims an invention that is not patentably distinct from an invention claimed in a non-commonly owned patent by or on behalf of [a party] to a joint research agreement in which the inventions claimed in the application *** and in the other patent were made as a result of activities undertaken within the scope of the joint research agreement.” 37 CFR § 1.109(b); emphasis added.

A. The Broad Scope of a “Joint Research Agreement”

There are numerous written agreements amongst various companies or organizations that include competitors that may constitute “a joint research agreement” within the meaning of Rule 109(b). Nothing in Rule 109(b) provides a definition of what may be “a joint research agreement”.

The only reference in the *Code of Federal Regulations* from the *Interim Rule* is found in 37 CFR § 1.71(g) that “[t]he specification may disclose or be amended to disclose the names of the parties to a joint research agreement (35 U.S.C. 103(c)(2)(C)).” But, there is nothing in Rule 109(b) that limits the term to the statutory definition or to inventions where the benefit of the statute is claimed.

The statutory definition itself is unclear. Thus, 35 USC § 103(c)(3) states that “[f]or purposes of [35 USC § 103(c)](2), the term ‘joint research agreement’ means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.” But, there are numerous situations, for example, of standards organizations *amongst competitors* which provide ground rules for creating and disclosing innovations “in the field of the claimed invention”. There are often related but completely independent companies that have interlocking directorships or other relationships; they could be considered within the literal scope of the broad wording of Rule 109(b) and not necessarily excluded under 35 USC § 103(c)(2)(C)).

B. Double Patenting Invalidity Ground

It can be imagined that there will be situations where two related companies do *not* wish to invoke the benefits of the new law; yet, their inventions may be subject to a double patenting rejection under Rule 109(b).

C. There is no Statutory Basis for Rule 109(b)

There is nothing in the statutory wording of the new law that in any way, shape or form provides basis for a double patenting rejection against claims amongst different organizations without common ownership.

Rule 109(b) double patenting is a new species of substantive denial of claims that clearly is far more than an “interpretive” rulemaking.

1. An at Best Tortured Double Patenting Legislative History

a. A Silent Legislative History Upon Enactment

While earlier presentations of the CREATE Act made a brief mention of double patenting, there is at best inferential reference to double patenting in remarks on the floor of the House and Senate after June 2004; neither is there *any* committee hearing held in 2004. Congressional intent as reflected in the legislation contemporaneous with final enactment only speaks in a *positive* sense to *grant* patent rights by overruling precedent from the Federal Circuit that had judicially expanded “secret” prior art.

The Chairman of the House of Representatives Judiciary Committee contemporaneously with the full House enactment the purpose of the legislation *without a single mention of double patenting*: “S. 2192 will provide a [] statutory ‘safe harbor’ for inventions that result from the collaborative activities of private, public, and non-profit entities. In so doing, the bill responds to the 1997 *OddzOn Products, Inc. v. Just Toys, Inc.* decision of the Federal Circuit Court of Appeals[, 132 F.3d 1396 (Fed. Cir. 1997),] by clarifying that prior inventions of team members will not serve as an absolute bar to the patenting of the team's new invention when the parties conduct themselves in accordance with the terms of the bill. *** By enacting S. 2192, Congress will help to foster improved communication among researchers, provide additional certainty and structure for those who engage

in collaborative research, reduce patent litigation incentives, and facilitate innovation and investment. *** S. 2192 will ensure that tomorrow's collaborative researchers can enjoy the full measure of the benefits of the patent law. I urge the Members to support the bill.” *Floor Remarks of the Hon. James Sensenbrenner*, 150 Cong. Rec. H10219 (November 20, 2004).

When the CREATE Act was introduced as part of an omnibus appropriations bill, Senator Leahy made the following comments: “I am pleased that we can today include, as part of the Department of Justice Authorization Act, the ‘Cooperative Research and Technology Enhancement Act of 2004,’ the CREATE Act, legislation that I cosponsored along with Senator Hatch, Senator, Kohl, Senator Feingold, Senator Schumer, Senator Grassley, Senator Johnson, and Senator Cochran. This bill will provide a needed remedy to one aspect of our Nation's patent laws. *** [T]he United States Court of Appeal for the Federal Circuit ruled, in *Oddzon Products, Inc. v. Just Toys, Inc.*, [132 F.3d 1396 (Fed. Cir. 1997)], that non-public information may in certain cases be considered ‘prior art’ – a standard which generally prevents an inventor from obtaining a patent. Thus some collaborative teams that the Bayh-Dole Act was intended to encourage have been unable to obtain patents for their efforts. The result is a disincentive to form this type of partnership, which could have a negative impact on the U.S. economy and hamper the development of new creations. *** The ‘CREATE Act’ *** ensur[es] that non-public information is not considered ‘prior art’ when the information is used in a collaborative partnership under the Bayh-Dole Act.” *Floor Remarks of Senator Leahy*, 150 Cong. Rec. S9952, September 29, 2004.

b. A Purpose to “expand[] opportunities for double patenting”

There is *no* Congressional reference to “double patenting” in the context of the CREATE ACT after June 2004. Rather, Senator Hatch explained that the law essentially “expanded opportunities for double patenting.” See *Remarks of Hon. Orin Hatch*, 150 Cong. Rec. S7520-01 at S7520 (2004).

The legislative history shows a minimal and at best uniformed understanding of the CREATE Act by the legislature. While the new law *disqualifies prior art* for purposes of obviousness, the only legislative

history in the Senate through June 2004 is a statement by the floor leader of the Senate bill that became the CREATE Act: It suggests that the new law permits the claiming of “obvious” inventions which comprise “‘nonstatutory’ and ‘obviousness-type’ double patenting”; he applauds the new legislation as providing “expanded opportunities for double patenting”. *Id.* (“[T]he CREATE Act will enable different parties to obtain and separately own patents with claims that are not patentably distinct ***. The courts and the U.S. Patent and Trademark Office term this ‘nonstatutory’ and ‘obviousness-type’ double patenting. This is not the first time that Congress has amended the patent laws in a manner that has expanded opportunities for double patenting.”)

The floor leader’s remarks provide the explanation that “The Patent Law Amendments Act of 1984 first created the opportunity for double patenting for patents issued to different inventors that were owned by one entity or which were commonly assigned. In the legislative history for the Patent Law Amendments Act of 1984, Congress indicated its expectation that any newly created opportunities for double patenting would be treated no differently than double patenting for patents issued to the same inventor. We do the same today with respect to the remedial provision in the CREATE Act, but discuss the form of disclaimer that is required of the patent owner whenever double patenting exists.” *Id.* at S7520-21.

Additionally, the floor remarks refer to a nonexistent doctrine of “double patents”. Thus, the statement is made that that “[a]t its core, the double patenting doctrine addresses the situation where multiple patents have issued with respective claims in the different patents that meet one or more of the relationship tests set out by the courts. Double patenting can arise when the two involved patents are determined not to relate to independent and distinct inventions. *It can also arise if a claim in a later-issued patent would not be novel with respect to a claim in a first-issued patent. A third type of double patenting – and perhaps the most common – is where a claim in a later-issued patent is obvious in view of a claim in a first-issued patent.* Whatever the relationship that forms the basis for the double patenting, the current principles governing double patenting should be applied to all such situations involving the issuance of double patents where the provisions of the CREATE Act apply. The double patenting

doctrine exists as a matter of policy to prevent a multiplicity of patents claiming patentably indistinct inventions from becoming separately owned and enforced. Thus, it applies to situations where multiple patents have issued, even if the patents are filed on the same day, issue on the same day and expire on the same day. All that is required for double patenting to arise is that one or more claims in each of the involved patents is determined to represent double patenting under established principles of law. The double patenting doctrine can invalidate claims in any later or concurrently issued patent if those claims are determined to represent double patenting with respect to any of the claims in a first-issued patent. For clarity, any later or concurrently issued patent that creates double patenting can simply be termed a ‘patentably indistinct patent’ with respect to the first-issued patent.” *Id.* at S7521; emphasis added.

To be sure, the Office cites in the *Interim Rule* specific wording in a 1983 *House Committee Report* that is *briefly* quoted, 70 Federal Register 1821, but more completely states that the double patenting *intended in the 1983 legislation* should only apply *if the exemption of the legislation were sought*: “Congress intends to extend th[e] exemption [of 35 USC § 103(c)] to ‘joint research agreement’ inventors, who may represent more than one organization, again subject to the same double patenting principles. Parties to a joint research agreement who seek to benefit from the Act must identify themselves in the application for patent or a valid amendment thereto. *** The doctrine of ‘obviousness-type double patenting,’ a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patents. See, e.g., *In re Berg*, 140 F.3d 1428, (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 943-44 (CCPA 1982). Further, a ‘terminal disclaimer’ of the type required when double patenting is determined to exist for two or more claimed inventions must be filed for any such patent claiming the benefit of [35 USC] § 103(c). Such a terminal disclaimer is sufficient if it disclaims the ability of the patent owner to separately enforce the patent that, but for this Act, would have been invalid for obviousness-type double patenting. Congress intends that parties who seek to benefit from this Act to waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection.

Further, Congress intends that parties with an interest in a patent that is granted solely on the basis of the amendments made pursuant to this Act to waive requirements for multiple licenses. In other words, the requirements under current law for parties to terminally disclaim interests in patents that would otherwise be invalid on ‘obviousness-type’ double patenting grounds are to apply, *mutatis mutandis*, to the patents that may be issued in circumstances made possible by this Act.” H.R. Rep. No. 108-425; parallel citations omitted; emphasis added.

Because there is absolutely nothing in the *statute* that provides even a vague hint or suggestion of double patenting, the at best odd history here should be relegated to the scrap heap of “the ever-available snippets of legislative history[.]” *F.C.C. v. NextWave Personal Communications Inc.*, 537 U.S. 293, 305 (2003)(Scalia, J.).

The legislative history has nothing to do with the *statutory* wording. where “the text of the statutory reservation clearly excludes [the subject matter], we have no occasion to resort to legislative history.” *BedRoc Ltd., LLC v. U.S.*, 541 U.S. 176, ___, 124 S. Ct. 1587, 1595 (2004)(Scalia, J.)(citing *Lamie v. U.S. Trustee*, 540 U.S. 526 (2004); *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000); *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999); *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 254 (1992)).

2. Legislative History Excerpts do not Interpret Statutory Wording

It is well settled that legislative history is used, where appropriate, to *interpret* ambiguities in the statute. But, insofar as double patenting is concerned, there is not one whit of wording in the *statute* that in any way suggests a broadening of the scope of double patenting. Rather, the intention of the legislation that everyone can agree upon is that the legislation was designed to statutorily overrule the judicial activism of a Federal Circuit panel opinion in *OddzOn* that is focused upon by the House and Senate sponsors of the legislation when it was ultimately enacted.

More importantly, there is no ambiguity in the statute that in any way compels interpretation to require a double patenting rejection.

D. Rule 109(b) Goes Beyond the Case Law

Double patenting against inventions which are not “independent and distinct” from each other is outside the statute, but clearly is permitted and authorized by Supreme Court case law. There is nothing in the 1952 Patent Act that in any way suggested that the case law rejections and doctrines antedating the 1952 Patent Act were somehow eliminated by this codification of some principles in that enactment. Yet, the Supreme Court double patenting case law all revolved around *commonly owned* inventions.

E. Reaction out of Proportion to any Real Need

The *Interim Rule* proceeds from the implicit premise that the university Technology Licensing Offices (TLO's) and corporate America are being given a boon through the new law, that they are getting a special loophole that requires a balance of an onerous double patenting regime – one that is even more draconian than against common assignee inventions. Thus, a common assignee double patenting situation permits effective separate alienability of exclusive rights through the proper construction of an agreement; thus, the rule against severing assignment of related inventions is completely circumvented through exclusive licensing instead of an outright assignment.

The exclusive license bypass of the double patenting proscription on separate alienability has been commonplace since the advent of the terminal disclaimer to obviate double patenting rejections forty years ago. There has been no outcry nor any problem noted though this policy. Yet, now, *through an Interim Rule*, the licensing bypass is *maintained* for common assignee situations but *eliminated* under the *Interim Rule* for the inventions that have different owners.

No special benefit is given to the TLO's and their corporate partners that is not enjoyed under the historic patent law of the United States up until recently, nor is there any special benefit given, here, that is not uniformly enjoyed under the Japanese patent law or under the European Patent

Convention: Historically, the United States proscribed the use of “secret” prior art for obviousness under 35 USC § 103(a) via 35 USC §§ 102(e), 102(f) and 102(g). It was only through judicial legislation over the past forty years that such “secret” prior art was created for the United States, with the ultimate act of judicial legislation in this area being the notorious panel decision, *OddzOn Products, Inc. v. Just Toys, Inc.*, 132 F.3d 1396 (Fed. Cir. 1997). Indeed, the legislative history is absolutely crystal clear on *one* point, that the evil being attacked through the new law is the *OddzOn* decision.

American innovation is comparatively at a disadvantage vis a vis Europe and Japan where – like the United States of more than forty years ago – there was *no* “secret” prior art for obviousness determination. Neither Europe nor Japan has seen fit to emulate the judicial legislation of the United States, and neither Europe nor Japan has seen a problem with the freedom from “secret” prior art. In fact, the absence of “secret” prior art may be seen as a *benefit* by promoting patents amongst competitors. Europeans and Japanese also have a strategic advantage for *United States* patenting under the American “secret” prior art of 35 USC § 102(g), as this provision bars incremental improvements over *American* innovations but not over European or Japanese (or other foreign) innovations.

In any event, it is clear that there has been no major crisis under the European or Japanese models without “secret” prior art: Indeed, the contrary is true, as the American TLO’s have enthusiastically sought the present legislation to overrule *OddzOn* for their joint research projects.

F. Rule 109(b) Violates the Rule of *In re Gay*

There is nothing in the wording of the statute that requires a double patenting rejection. The imposition of a double patenting basis for denying a patent in Rule 109(b) is therefore clearly contrary to the result that the PTO should only go as far as is required to implement a statutory requirement; it should not exceed the statutory requirement. See *In re Stephens*, 529 F. 2d 1343, 1345 (CCPA 1976)(Miller, J.)(citing *In re Gay*, 309 F.2d 769 (1962)(Miller, J.)(“A specification need be no more specific under [37 CFR § 1.71(b)] than is required by the enablement provision of 35 U.S.C. §

112.”). See also *In re Locher*, 455 F.2d 1396, 1400 n.1 (CCPA 1972)(Rich, J.) (“[A]s we pointed out in *In re Gay*, F.2d 769, 774 (CCPA 1962), ‘No direct statutory basis exists for this requirement other than *** [the description, how-to-make, and how-to-use requirements of the first paragraph of 35 U.S.C. § 112], which it appears to implement,’ and we accordingly treat this rejection as one made under the how-to-make requirement of *the statute*.”)(original emphasis)

II. RULE 109(a): A NEW DOUBLE PATENTING STANDARD

A. A New Standard for Double Patenting

Certainly in the absence of following the Administrative Procedure Act, it is highly improper to introduce a new rule and a new statement of double patenting in new Rule 109(a): “A double patenting rejection will be made in an application *** if the application *** claims an invention that is not patentably distinct from an invention claimed in a commonly owned patent.” 37 CFR § 1.109(a). The previous regulation, 37 CFR § 1.130(b), states that “[w]hen an application *** claims an invention which is *not patentably distinct* from an invention claimed in a commonly owned patent ***, a double patenting rejection will be made in the application ***.” (emphasis added).

Clearly, the regulation must be viewed in the history of the judicial case law of the Supreme Court that was maintained as part of the codification of the patent law in 1952. See *In re Weber*, 580 F.2d 455, 459 (CCPA 1978)(Rich, J., concurring) (“35 U.S.C. § 121 deals with a matter of PTO practice known as ‘requirements for division’ prior to the 1952 Patent Act which, for the first time, provided a statutory provision on this subject. It did so, under the heading ‘Divisional Applications,’ by giving the Commissioner a discretionary, unappealable power to *restrict* an application to one of several *claimed* inventions when those inventions were found to be ‘independent and distinct.’ 35 U.S.C. § 121, first sentence; see also P. J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. p. 1, at p. 34 (1954).”).

B. Consonance with the “Independent and Distinct” Standard

Particularly in the context of a joint research agreement amongst a university and a corporate sponsor, there will often be both new products that are produced and often several different processes for making that product. It is important that the historic understanding of the patent law be honored that patents to *both* the product and the process may be valid *without double patenting* if they are “independent and distinct” under the historical precedents.

The *Interim Rule* if anything blurs and obfuscates this historical precedent. Thus, double patenting has a rich history that is traced back to judicial legislation of the Supreme Court that was brought forward through the 1952 Patent Act. For example, the Supreme Court, in the context of product and process patents, held that if both a process and the resulting product were new, then both were patentable. *Rubber Co. v. Goodyear*, 76 U.S. (9 Wall) 788, 796 (1870). Along these line, the practice before the 1952 Patent Act was noted by senior members of the Patent Office who were part of the operation at the time of enactment in their opinion in *Ex parte Zoss*, 114 U.S.P.Q. 309, 310 (Patent Office Board of Appeals 1956), which cites to the leading case, *In re Cady*, 77 F.2d 106 (CCPA 1935).

Thus, the wording of 35 USC § 121 and the implementing regulations were to track the then existing practice at the time of enactment of the 1952 Patent Act. In the context of double patenting where two related inventions are to a product and to a method for making the product, the Patent Office codified the practice in *Cady* in the *Manual of Patent Examining Procedure*, MPEP § 806.05(f), *Process of Making and Product Made — Distinctness* [R-3], p. 800-36 (Rev. 3, July 1997). It that states that “[a] process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (1) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products, or (2) that the product as claimed can be made by another and materially different process.” This follows the admonition of the court that “the legal precedents are uniformly to the effect that ‘double patenting is not sustainable when the product can be fabricated by processes other than that secured by the issued process patent[.]’” *Cady*, 77 F.2d at 109 (citing

Providence Rubber Co. v. Goodyear, 76 U.S. (9 Wall.) 788 (1869); *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516 (1870); *Leeds & Catlin Co. v. Victor Talking Machine Co.*, 213 U. S. 301 (1909); *United States ex rel. Steinmetz v. Allen*, 192 U.S. 543(1904)).

The predecessor to the Federal Circuit adopted the rationale of the Second Circuit in *General Electric v. Mallory*: "That double patenting exists here * * * is a new point of law. It rests on the fact that Just's original American application contained disclosure of several processes by which a single result — i. e., the tungsten filament of the patent in suit — could be attained. The Office required division; the issue of the patent at bar was delayed * * * but one divisional application, covering one process only, became No. 878,463 in 1908, four years before the master patent for the product came out of the Office; hence it is said double patenting resulted. There would be force in the argument, if there were but one process, and the only possible result thereof was the single product; but the more philosophical way to view the question is to ask whether the two patents (878,463 and 1,018,502) cover the same invention, when properly construed. *Thomson, etc., v. Elmira, etc., Co.*, 71 F. 396, 18 C. C. A. 145. They do not; one being only for a process of making, and the other for the thing made, with disclosure of another process." *Cady*, 77 F.2d at 109 (quoting *General Electric Co. v. P. R. Mallory & Co., Inc.*, 298 F. 579, 584 (2nd Cir. 1924)).

The same reasoning was affirmed in *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989) (Markey, C.J.). There, the Federal Circuit saw the issue as being so cut and dried that it affirmed the trial court with the passing observation that as to several issues including double patenting, "[w]e find none [of the arguments] persuasive of error in the district court's disposition of any of those issues and *none of sufficient import* to require discussion here of that disposition." *U.S. Steel*, 865 F.2d at 1253; emphasis added; footnote deleted.

As explained by the trial court, "a charge of double patenting will not be sustained if the product can be made by processes other than that secured by the issued process patent or the process can produce other products not protected by the product claim." *Phillips Petroleum Co. v. U.S. Steel Corp.*,

604 F.Supp. 555, 562 (D.Del. 1985) (citing *In re Taylor*, 360 F.2d 232, 235-36 (CCPA 1966); *In re Cady*, 77 F.2d 106, 109 (CCPA 1935)). In the case of parallel processes, see *In re Sutherland*, 347 F.2d 1009, 1016 (CCPA 1965)(Rich, J.)("We find that [the reference] Carpenter claims the blending of latices in the freeze-thaw process whereas appellant claims an entirely unrelated discovery *** in the freezing step of the same old process. Though the two inventions relate to the same basic process and even though they are capable of conjoint use, they are independent and distinct inventions. *Either can be used without the other.*")(emphasis added).

C. Retroactive Penalties should be Proscribed

It should go without saying that a regulation such as new Rule 109(a) should only be applied *prospectively* and only after due notice has been given to the public. Thus, *if* any major change in the regulatory fabric should be put into place, now, more than fifty (50) years after the 1952 Patent Act, then it should be made crystal clear as part of the Response to Comments in any final rulemaking that the new rule applies *only* prospectively and *only* to patent applications having an effective filing date after whatever date in 2005 the new regulations would become effective.

III. AN UNNECESSARY REGULATORY EXCURSION

There clearly was no emergency that required the establishment of an unprecedented *Interim Rule* in violation of the Administrative Procedure Act particularly where, as here, the regulations are substantive in nature and create new categories of patent-defeating activities.

A. No Need to Offset any "Loss" from Overruling *OddzOn*

One could imagine that Congress may wish to provide a balance where it "gives" special rights to a category of the patent community. But, here, the legislation only *restores* the prior law where there had been no "secret" prior art. The United States patent system up until the creation of "secret" prior art – and the European and Japanese systems today – had and have no "secret" prior art, and have operated quite well. Insofar as the

creation of “secret” prior art via 35 USC § 102(f) is concerned, one might imagine, *arguendo*, that there were some driving public policy need that forced the Federal Circuit to judicially legislate, as it did, in the *OddzOn* case. Yet, there was nothing of the sort.

Precisely *what* public policy reason was there behind the *OddzOn* judicial legislation by a panel of the court? Precisely what public policy concerns were aired as reasons for this judicial legislation? Which scholars clamored for the change? What economic studies were made that showed a need for the result of *OddzOn*? What economists or business persons were cited?

In fact, *there was absolutely no citation of any authority whatsoever to show any public policy need for the change in this case*. As explained by one writer, “[i]n *OddzOn* [], the Federal Circuit ruled that non-public subject matter derived from another pursuant to section 102(f) of title 35 of the United States Code may be used against the patentee as prior art for purposes of an obviousness determination under section 103. Judge Lourie, acknowledging contrary authority, explained the ruling by stating that the court felt constrained by the language of the 1984 amendments to section 103, and the legislative history in support thereof. While a federal court must give effect to statutory language and defer to the expressed intent of Congress, the court's ruling in *OddzOn* [] contravenes the purpose of section 102(f) and the policy behind its enactment.” Brian P. Murphy, *OddzOn Products and Derivation of Invention: At Odds with the Patent Act of 1952?*, 9 Fordham Intell. Prop. Media & Ent. L.J. 529, 529-30 (1999)(footnotes omitted).

Thus, there is no reason for any draconian double patenting regime. Rather, the simple legislative overruling of *OddzOn* should be applauded as the correction of unwarranted and unnecessary judicial activism. (To be sure, it is unfortunate that only *some* aspects of “secret” prior art have been abolished, limited to cases of common ownership or joint research agreements.)

B. The 1995 Model for *Ad Hoc* Implementation

Clearly, patent applicants and patentees have been able to enjoy the benefits of the new law immediately from its December 10, 2004, enactment date *without* regulations. The better approach for an instantly available and retroactive law of this type is to deal with the situation on an ad hoc basis, just as the Office did in 1995 when it was faced with a similar challenge:

On November 1, 1995, a retroactive amendment was made to 35 USC § 103(b) to permit patenting biotechnology processes. Pub.L. 104-41, § 1, 109 Stat. 351. The Office took a wait and see attitude whether regulations would be *required* by the demand for special rules. The PTO correctly decided to wait. Later, the PTO simply acknowledged the existence of the law and created a practice that “[a]n election to proceed under 35 U.S.C. 103(b) shall be made by way of petition under 37 CFR 1.182. The petition must establish that all the requirements set forth in 35 U.S.C. 103(b) have been satisfied.” MPEP § 706.02(n), *Biotechnology Process Applications*; 35 U.S.C. 103(b) [R-1][Rev. 2 May 2004]. Waiting was prudent; experience proved that regulations were *not* required: “In view of the Federal Circuit's decisions in *Ochiai* and *Brouwer*, an applicant's need to rely upon 35 U.S.C. 103(b) should be rare.” *Id.* (citing *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996)).

Clearly, there was no emergency to permit the new rules, particularly not Rule 109. Rule 109 is clearly a substantive rule that effects a change in existing law or policy and which affect individual rights, and hence is not an “interpretive” rule free from the requirement for rulemaking. See *Splane v. West*, 216 F.3d 1058, 1063 (Fed. Cir. 2000)(Clevenger, J.)(quoting *Paralyzed Veterans of America v. West*, 138 F.3d 1434, 1436 (Fed.Cir. 1998), quoting *Orengo Caraballo v. Reich*, 11 F.3d 186, 195 (D.C.Cir. 1993)) (“[S]ubstantive rules’ [are] those that effect a change in existing law or policy or which affect individual rights and obligations. ‘Interpretive rules,’ on the other hand, clarify or explain existing law or regulation and are exempt from notice and comment under section 553(b)(3)(A).... ‘[A]n interpretive statement simply indicates an agency's reading of a statute or a rule. It does not intend to create new rights or duties, but only reminds affected parties of existing duties.’”).

* * *

Thank you for considering this testimony.

Respectfully submitted,

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* I hereby notify the USPTO that I am an attorney of record in reexamination control numbers 90/004,950 and 90/005,200.