

Comments for Issues
Center for Advanced Study on Intellectual Property
The University of Washington School of Law

Introduction

It is essential for U.S. inventors, in particular for U.S. universities and public research organizations, to go forward with substantive law harmonization to reduce the cost of procuring patents worldwide. Many rights in inventions created by U.S. research institutions are lost outside the United States for cost and technical reasons, including lack of a grace period in many non-U.S. jurisdictions.

Substantive patent law harmonization will remove redundant examination of the same application, as is currently done by several offices, and will substantially reduce application and examination costs by allowing one office to cite the examination result of another office. Substantive harmonization can create a single patent prosecution, eliminating multiple translation and office action costs.¹ Further, through harmonization, the U.S. patent system can be improved and made simpler and more manageable for U.S. inventors.

In other countries, such as Japan and European countries, patent systems, particularly the novelty and priority rules, are simple and readily understood from the language of the patent statutes. The majority of applications are filed by inventors' employers, who can prosecute patents with limited assistance from patent attorneys. This practice substantially reduces the cost of patent prosecution. Changes in the U.S. system could achieve similar results.

(1) Priority

The best patent system, for a number of reasons, is a first-to-file system with a one-year grace period for filing patent applications. Thus, the United States should abandon the first-to-invent system in favor of awarding the patent to the first-to-file. If it is necessary to maintain a first-to-invent rule for political reasons, the United States should allow only inventors who are qualified for small entity status as of the filing date to take advantage of the first-to-invent rule.

A first-to-file system that all other countries follow is very simple and easy to understand. In principle, an invention must be new and nonobvious when it is

¹ The current international patent application system is incomplete because it requires prosecution with national offices after completing the international procedure. The cost for filing applications in different languages and prosecuting patents in multiple national offices is too great for public funded research institutions and universities. Thus, most research institutions give up pursuing foreign patents unless they find licensees to cover all prosecution cost before the expiration of 30 months from the application to enter the national procedure.

filed with a patent office.² Any disclosure of an invention forfeits the right to patent regardless of who disclosed the invention. Some countries provide for a grace period system. Grace period systems in other countries prevent patent offices from taking account of a disclosure of an invention for patentability only if the invention is filed within the grace period and the disclosure falls into one of limited categories.³ Even if an invention is new and nonobvious, a patent is granted to the first-to-file if more than one application is filed for the same invention.⁴ Filing an application creates an affirmative priority right to obtain a patent and a defensive right for preventing later inventions from obtaining a patent with respect to both claimed and unclaimed subject matter.

To adopt a first-to-file model, the United States should revise Section 102 to specify that the novelty and nonobviousness must be examined as of the filing date, although a grace period system makes it possible to remove any disclosure of the invention within a one-year grace period from the priority date. The United States should award a patent to the first-to-file regardless of the invention date. It follows that even if a disclosure during the grace period of the first-to-file is later than a third party's another disclosure during the grace period of the second to file, the United States should award a patent to the first-to-file. An inventor can no longer eliminate a reference by establishing an early invention date when a reference prior to the grace period is cited against her invention. An inventor can no longer establish an invention date to obtain a patent when a third party filed for the same invention earlier than she filed.

The impact of this change is minimal. Although the language of the current U.S. patent statute does make the adoption of a first-to-invent priority rule clear, the U.S. has implemented in practice a first-to-file system much as described above. The practice adopted by the USPTO and Federal Circuit supports the view that the U.S. has a first-to-file system. This is because the majority of applications are examined and rejected with respect to novelty as of the filing date under Section 102(a) or as of the critical date that is one year prior to the filing date under Section 102(b), as discussed in more detail below.

Discrepancy between the statute and the practice misleads U.S. inventors, creates needless complexity in the system, and causes other countries to criticize the U.S. system for following a first-to-invent system, when in practice the United States follows a first-to-file system.

The U.S. should bring statutory provisions into line with U.S. practice to clarify how the U.S. system implements a first-to-file model. In particular, the U.S.

² E.g., European Patent Convention (EPC), Article 54; Japanese Patent Law (JPL), Article 29.

³ E.g., EPC Article 55, JPL Article 30.

⁴ E.g., EPC Article 60, Paragraph 2, JPL Article 36.

should revise the priority and novelty provisions of the patent statute. In return, the U.S. should ask other countries to adopt a non-restrictive one-year grace period for filing patent applications.

A grace period for filing patent applications is important for universities and public research institutions in the U.S. and worldwide. These organizations promote publication and timely presentation of scientific and technical results of research activities. Requiring patent applications to be filed prior to the scholarly presentation of results enforces on universities and public research institutions a pattern of secrecy that is adverse to the openness the patent laws are designed to promote in industry.

a. Section 102(a): Novelty Provision

The United States is considered to follow a first-to-invent system because the novelty provision, Section 102(a) of the Patent Act, requires that the novelty of an invention be determined based on the invention date. However, like all other countries that follow the first-to-file system, the USPTO adopts the practice of determining novelty based on the filing date. This is because U.S. case law indicates that filing an application with USPTO constitutes constructive reduction to practice.⁵ The current U.S. system makes it possible for an inventor to eliminate a prior art reference by showing an earlier invention unless the subject matter is claimed in a U.S. patent.⁶ However, unsophisticated inventors often fail to take advantage of this practice because they do not keep records to show an earlier invention. Further, this practice may cause a delay in examination because examiners must await the disposal of an early application disclosing the subject matter.⁷ Otherwise, the early application may be amended to claim the subject matter, which results in double patenting on the same subject matter for different parties.

b. Section 102(b): Statutory Bars

The majority of applications are rejected under Section 102(b), instead of Section 102(a). Sections 102 (b) and (d) function like the priority and novelty provisions under the first-to-file system because they reject the patentability of inventions based on the filing date, with the bar date being one year prior to the filing date.⁸ Since the 1829 *Pennock* Supreme Court decision,⁹ inventions have been excluded from the definition of first inventions if they were publicly used or on sale prior to the filing date. Introduction of a grace period by the Patent Act of 1839 made it possible for inventors to obtain patents on publicly known inventions only if an application was filed within the grace period.¹⁰ Thus, the majority of patents are awarded by novelty of the filing date, with the exception of

⁵ E.g., *Hazeltine Corp. v. United States*, 820 F.2d 1190, 2 U.S.P.Q.2d 1744 (Fed. Cir. 1987)

⁶ CFR Title 37, Chapter 1, Subchapter A, Part 1, Subpart B, Section 1.131.

⁷ Manual of Patent Examining procedure Section 706.02(f).

those filed under the grace period. The notion of the “first-to-invent” may mislead an unsophisticated inventor because the ordinary meaning of the “first-to-invent” should mean issuing a patent to the true and first inventor regardless of novelty on the filing date.

c. Section 102(g): Priority Provision

The United States is also considered to follow a first-to-invent system because a patent is granted to an inventor who can show an earlier invention date according to the priority rule provided in Section 102(g) in an interference proceeding. This practice also introduces significant uncertainty in U.S. patents because the inventor of a secret prior invention can challenge the validity of patents that are issued to first-to-file but second-to-invent inventions.

Involvement in an interference proceeding often results in a significant delay in obtaining a patent. A survey indicates that only a small proportion of applicants take advantage of the first-to-invent priority rule because of the high cost associated with the interference proceeding.¹¹ Although a first-to-invent model is advocated for giving a fair opportunity to small inventors, individual inventors and public research institutions seldom are able to afford such an expensive proceeding unless an industry sponsor covers the costs. Further, U.S. case law requires applicants to produce corroborative evidence with respect to the complex legal concepts required to show priority.¹²

To eliminate the delay in examination and the uncertainty in U.S. patents, the United States should eliminate the first-to-invent practice that allows inventors to predate a prior art reference and establish priority through an interference proceeding. If this option is not possible, the United States should at least limit inventors who can take advantage of the first-to-invent practice to those who are qualified for small entity status as of the filing date. Further, to minimize the uncertainty introduced by the first-to-invent, those who take advantage of the exception of the first-to-file must submit evidence of conception and reduction prior to the filing date when they originally file applications. Despite the notion that the first-to-invent system is fair to small inventors, it has in fact been used mainly by industry patent applicants and owners, because showing priority is expensive and extremely difficult unless inventors are familiar with the

⁸ Adelman etc., *Cases and Materials on Patent Law*, 206 (1998). However, these provisions serve a philosophically different role in the first-to-invent system from the first-to-file system as their functions are keyed with the patent-defeating activity, which removes the priority.

⁹ *Pennock v. Dialogue*, 27 U.S. 1, 2 Peters 1, 7 L. Ed. 327, (1829)

¹⁰ Patent Act of 1839. Cj/ 88. 5 Stat/ 353-355 (March 3, 1839), reprinted in Donald S. Chisum, *Chisum on Patents*, Appendix 13 (1978, Supp. 2001).

¹¹ Charles Macedo, *First to File: Is American Adoption of the International Standard in Patent Law Worth the Price?* 18 AIPLA Q. J. 193 (1990).

¹² *Hahn v. Wang*, F.2d 1028, 13 U.S.P.Q.2d 1313 (Fed. Cir. 1989).

case law and develop a routine process to keep a record of research activities.

(2) Patentable Subject Matter

The Federal Circuit's "useful arts" test, focusing only on a "useful, concrete and tangible result," is inconsistent with the Supreme Court's interpretation of "invention" and with CCPA's interpretation of "useful arts," if it is interpreted to include subject matter outside of "technological art." Properly interpreted, the test should function to limit patent eligibility to subject matter (1) that results from the application of the law of nature and (2) that is within technological art. This scope would be perfectly in line with the patent eligible subject matter in other countries, such as Japan and EPC countries.

The "useful, concrete and tangible" test represents the Federal Circuit's attempt to clarify the test restated by the Supreme Court in *Diehr*,¹³ whether the claim is directed to a mathematical formula in the abstract. However the test is overly broad because it is inconsistent with the finely defined scope for patent eligible "invention" defined by the Supreme Court. In *Benson*,¹⁴ and *Diehr*,¹⁵ the Court cited *Funk Bros*,¹⁶ and defined patent eligible subject matter as resulting from the application of the law of nature to produce a new and useful end. This test, restated by the Federal Circuit in *State Street Bank*¹⁷ and *In re Alappat*,¹⁸ fails to reflect the important requirement of "resulting from the application of the law of nature." Thus, to interpret the test consistently with Supreme Court precedent, the useful, concrete and tangible result should mean a result from the application of the law of nature.

The requirement of "application of law of nature" is a central element to define patent eligible subject matter, because it is keyed to distinguish "technological art" from other arts. One old but well-accepted definition for the term "technology" is "the principles, processes, and nomenclatures of the more conspicuous arts, particularly those which involve application of science."¹⁹ One can substitute the law of nature for the term "science" because the task of science is to discover the law of nature. Thus, the Supreme Court's definition implicitly incorporates the "technological art" requirement.

¹³ *Diamond v. Diehr*, 450 U.S. 175, 67 L. Ed. 2d 155, 101 S. Ct. 1048, 209 U.S.P.Q. 1 (1981)

¹⁴ *Gottschalk v. Benson*, 409 U.S. 63, 34 L. Ed. 2d 273, 93 S. Ct. 253, 175 U.S.P.Q. 673 (1972)

¹⁵ *Diamond v. Diehr*, 450 U.S. 175, 188 (1981)

¹⁶ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 92 L. Ed. 588, 68 S. Ct. 440, 76 U.S.P.Q. 280 (1948)

¹⁷ *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 47 U.S.P.Q.2d 1596 (Fed. Cir. 1998)

¹⁸ *In re Alappat*, 33 F.3d 1526, 31 U.S.P.Q.2d 1545 (Fed. Cir. 1994)

¹⁹ John Thomas, *The Patenting of the Liberal Professions*, 40 Boston College Law Review 1139, 1167 (1999).

Moreover, CCPA, one of the Federal Circuit's predecessor courts, interpreted the copyright and patent clause to support the requirement of "technological art." In *Bergy*, Judge Rich, who authored *State Street Bank*, limited the scope of patent eligible subject matter by interpreting the term "useful art" in the Constitution to correspond to "technological art."²⁰ Accordingly, in light of the Federal Circuit's own precedent and the Supreme Court precedent, the test should be interpreted to exclude subject matter that does not result from the application of the law of nature and thus to exclude non-technological art, however practical or useful it may be.²¹

Coincidentally, the *Funk Bro.*, *Benson*, *Diehr* definition is perfectly in line with the definition used by many other countries. For example, although the European Patent Convention (EPC) does not provide any positive definitions of patent eligible subject matter,²² it limits the exclusion of patent eligibility to definitions falling within the excluded categories as such.²³ Thus, the results of application of discoveries, scientific theories, etc. should meet the patent eligibility requirement. To distinguish the excluded categories as such from those that are patent eligible, European Patent Office (EPO) case law also requires claims to be directed to subject matter in "technological art."²⁴ This definition of requiring the application of the law of nature and technological art follows the long-standing German practice that requires technical character in claimed subject matter.²⁵

Further, these requirements of the application of the law of nature and technological art are also in line with requirements for patent eligible subject matter under the Japanese Patent Law (JPL). The Japanese Patent Law defines an invention, with patent eligible subject matter, as an advanced technological idea using a law of nature.²⁶ This statutory definition includes two important elements: (1) the claimed subject matter must relate to technological art; and (2) the claimed subject matter must result from an application or utilization of a law of nature, instead of from

²⁰ In re *Bergy*, 596 F.2d 952, 201 U.S.P.Q. 352 (CCPA 1979) ("The constitutionally stated purpose of granting patent rights to inventors for their discoveries is the promotion of progress in the 'Useful Arts' rather than in science....[T]he present day equivalent of the term 'useful art' employed by the Founding Father is 'technological arts'.")

²¹ Donald Chisum, *Chisum on Patents*, Section 1.01 (1978, Supp. 2001).

²² European Patent Convention Article 52 (2).

²³ *Id.*, Article 52(3).

²⁴ EPO Decision T 0935/97.). For a general discussion, see Raph Lunzer, Singer: *The European Patent Convention* 113 (Revised English Edition, 1995).

²⁵ Friedrich-Kerl Beier, *Future Problems of Patent Law*, 3 IIC Studies, 421 (1972).

²⁶ Japanese Patent Law, Article 2, Paragraph 2.

the law itself.²⁷

The “technological contribution” test cited by USPTO appears to indicate a test that was recently adopted by an EPO panel²⁸ and endorsed by the European Commission.²⁹ The test is analogous to the test expressly rejected by the U.S. Supreme Court in *Diehr*,³⁰ on the grounds that it dissected the claims into old and new elements and then ignored the old elements as general teaching on the use of data processing means. The test led to a conclusion of lack of eligibility when the remaining elements were found to be of an administrative, actuarial or financial character. Obviously, as *Diehr* Court correctly pointed out,³¹ EPO confused the question of patent eligibility with the question of novelty. Thus, although the technical feature test is proper, the test was improperly applied by not analyzing a claimed invention as a whole. As discussed above, both the EPC and the U.S. Patent Act use the requirement of the application of the law of nature and technological art. Properly interpreted, the “technological character” test under the EPC should be in line with the test under the U.S. Patent Act.

In short, in light of the Supreme Court’s precedent and the Federal Circuit’s own precedent, the test for patent eligibility under the U.S. Patent Statute should be in line with the tests under the EPC, JPL and the patent statutes of many other countries. Computer software and business methods implemented by software are patent eligible subjects because they result from the application of the law of nature by utilizing hardware resources of computers. However, business method as such, when independent from computer implementation, does not result from the application of the law of nature. The United States should not support the definition of patent eligible subject matter that covers business method as such. Such scope is inconsistent with the Supreme Court’s definition of invention and CCPA’s definition of useful art even if the scope may be supported by the overly broad statement in *State Street Bank*, which amounts to nothing more than *dicta*.³²

(3) Disclosure Requirement

a. Enablement and Written Description

The United States should clarify the distinction between the enablement and written description requirements with respect to the different policy

²⁷ For more explanations of “statutory invention” under JPL, see JPO Draft Revised Examination Guideliens for Industrially Applicable Inventions (2001).

²⁸ T0931/95 available at <http://www.european-patent-office.org/dg3/biblio/t950931eu!.htm> (4/8/01).

²⁹ Stefan Schohe, *What’s Happening in Europe: Business Patent Value*, Unpublished Manuscript Presented at CASRIP Representing Technology Startup Seminar in Munich, Germany, January 16, 2001.

³⁰ *Diamond v. Diehr*, 450 U.S. at 188.

³¹ *Id.*

³² John Thomas, *the Patentability of the Liberal Professions*, 40 Boston College L. Rev. 1139, 1161 (1999).

considerations underlying the two separate requirements. The policy underlying enablement is to assure that inventors provide sufficient information about the claimed invention to enable a skilled person to make use of the invention without undue experimentation.³³ The enablement requirement is potentially at issue for every claim in every patent, because every patent must make the invention sufficiently available to the public as the bargain for the exclusive right.³⁴ In contrast, the policy underlying the written description requirement is to guard against the inventor's overreaching, by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.³⁵ The written description is at issue only in limited circumstances where the entitlement of priority is at issue with respect to amendment, continuation or divisional applications, or an interference proceeding.³⁶

Obviously the confusion between the enablement and written description requirements originates from the difficulty of statutory interpretation, because both requirements rely on the same sentence in the first paragraph of Section 112.³⁷ In other countries, these requirements are provided in separate provisions: one for the disclosure requirement³⁸ and another for the condition of enjoying the benefit of the original filing date or priority date with respect to amended claims,³⁹ or for claims in priority applications⁴⁰ and divisional applications to benefit from the date.⁴¹

Further, the United States should urge other countries to use the enablement provision to reject claims that are too broad scope compared with the scope of disclosure as done by the United States⁴² and Japan.⁴³ The case law in the EPO supports the position that the EPO cannot reject an overly broad claim if the disclosure includes at least one way of carrying out the invention,⁴⁴ although the EPO case law also developed the concept of undue experimentation.⁴⁵ This practice has created a significant problem.⁴⁶ Some scholars suggest the use of EPC Article 84,

³³ *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991).

³⁴ *Supra* note 8, Adelman etc., Patent Law, 567.

³⁵ *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111,1114 (Fed. Cir. 1991)

³⁶ *Supra* note 8, Adelman etc., Patent Law, 567.

³⁷ *In re Barker*, 559 F.2d 588, 591,194 U.S.P.Q. 470, 472 (C.C.P.A. 1977).

³⁸ E.g., EPC Article 83; JPL Article 36, Paragraph 4.

³⁹ E.g., EPC Article 123; JPL Article 17bis, Paragraph 3.

⁴⁰ E.g., EPC Article 87; JPL Article 17bis, Paragraph 3.

⁴¹ E.g., EPC Article 76; JPL Article 17bis, Paragraph 3.

⁴² *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993).

⁴³ JPO, Practices in Examination and Appeals under 1994 Revised Patent Law in Japan (1994); see JPO Draft Revised Examination Guidelines for Industrially Applicable Inventions (2001).

⁴⁴ E.g., T281/86, OJ EPO 1989, 202.

⁴⁵ E.g. T787/89, 1991 EPOR 387.

⁴⁶ Stephen Crespi, *Recombinant DNA Patents in Litigation-A Comparative Study of Some EPO and UK National Court Decisions*, 28 IIC 604 (1997); Paul Cole, *Pioneering Pays- Or Does It?* 200 European Intellectual Property Review, 534 (2000).

which corresponds to the claim definiteness requirement under 35 USC Section 112 Paragraph 2, instead of Article 83, which corresponds to the enablement requirement under Section 112, Paragraph 1.⁴⁷

b. Written Description Standard

The United States should relax its written description standard, which is stricter than those adopted by other countries, with respect to biomolecule sequence inventions. A biomolecule sequence that is described by functional characteristics does not satisfy the written description requirement unless any known or disclosed correlation between that function and the structure of the sequence is disclosed.⁴⁸ Such a description of function does not satisfy the requirement even if it is accompanied by a method of obtaining the claimed sequence.⁴⁹ This strict standard resulted from the Federal Circuit's ruling in *Deuel*⁵⁰ that a process could not render the product of that process obvious, because a description that does not render a claimed invention obvious cannot satisfy the written description requirement.⁵¹

However, the ruling of *Deuel* should take account of the change in the level and general knowledge in the art and thus should not mechanically apply to inventions. USPTO's strict adherence to the *Deuel* ruling results in a significant difference from other offices with respect to the nonobviousness conclusion.⁵² This results in significant difference in enablement and written description conclusions between USPTO and other offices. The standard adherence to *Deuel* makes it too easy to obtain U.S. patents but difficult to issue a patent with a reasonably broad scope. This practice requires U.S. inventors to file more applications with very narrow claims, which has significantly increased prosecution costs. Universities and research organizations cannot afford such expensive prosecution costs. Thus, the United States should overrule *Deuel* and make it possible for U.S. inventors to claim a reasonable scope to cover variations that are understood by one skilled in the art.

c. Best Mode

The United States should remove the best mode requirement because the benefit of the requirement is marginal. Most other countries do not have a best mode requirement. Under the current case law, the best mode is

⁴⁷ Sir Nicholas Pumfrey, *Patent Protection of Broad Claims* (April 20, 2001) (unpublished manuscript, presented at 2001 Fordham International Intellectual Property Law & Policy Conference).

⁴⁸ Guidelines for Examination of Patent Application under the 35 U.S.C. 112 Paragraph 1, "Written Description Requirement", 66 Fed. Reg. 1099 (Jan. 5, 2001).

⁴⁹ *Id.*

⁵⁰ *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995)

⁵¹ *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997)

⁵² Trilateral Project B3b Mutual understanding in search and examination Comparative study on biotechnology patent practices available at: http://www.jpo.go.jp/saikine/tws/sr-3-b3b_bio_search.htm (4/13/01).

determined subjectively by the inventor's state of mind as of the filing date,⁵³ and thus the mode believed to be the best mode might be the worst mode if examined objectively in the view of one skilled in the art. Because there is no requirement to update the best mode once an application is filed,⁵⁴ any better mode developed after the application would not be disclosed. The public might not benefit from the best mode because under current case law inventors are allowed to bury the best mode with other modes,⁵⁵ or employers can conceal information on the best mode from inventors so that they can keep secret the best mode developed by others.⁵⁶

In contrast, the best mode introduces significant uncertainty in the validity of patents because USPTO cannot examine the requirement during the prosecution. Case law is unclear with respect to the relationship between the preferred mode and the claimed subject matter.⁵⁷ The application of the best mode requirement might create a problem in claiming priority under the Paris Convention because a foreign applicant who intends to pursue patent rights in the U.S. must, before filing a priority application in her country, predict what must be disclosed to comply with the best mode requirement.⁵⁸ Further, without the best mode, applicants have enough incentive to disclose the best mode to ensure that such mode is included in the literal claim scope and can be protected.⁵⁹

(4) Claim

It is often difficult for pioneer inventions to identify the field of technology at the time of application. Some inventions may create a completely new field of technology. It is nonsense to require identifying the technological field to which the claimed invention relates.

(5) Unity of Invention

The United States should eliminate a restrictive practice for determining the utility of an invention and adopt the same standard for the unity of invention that has already been adopted to examine international applications under the Patent Cooperation Treaty. This will reduce patent prosecution costs and remove complexity in preparing and examining applications. A uniformity of formality requirements in patent applications is essential to foster collaboration of examination among patent offices, which will lead to a significant reduction of costs for prosecuting patents internationally.

⁵³ *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 923, 16 USPQ2d 1033 (Fed. Cir. 1990).

⁵⁴ *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987).

⁵⁵ *Randomex, Inc. v. Scopus Corp.* 849 F.2d 585, 592, 7 U.S.P.Q.2d 1050,1055 (Fed. Cir. 1988)

⁵⁶ *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995).

⁵⁷ Donald S. Chisum, *Chisum on Patents*, Section 7.05[1] (1978, Supp. 2001).

⁵⁸ Donald S. Chisum, *Elements of United States Patent Law*, 183 (2000).

⁵⁹ Testu Tanabe & Harold Wegner, *Japanese Patent Law* Section 422 (1979) reprinted in *supra* note 8, Adelman, *Patent Law*, 629.

(6) Utility

The United States should keep its utility requirement because other countries provide a similar requirement under the disclosure provision. The industrial applicability standard can be considered to be broader than the utility standard because the former standard excludes medical methods.⁶⁰ The patent systems of other countries provide for immunity against a pharmacist's acts of preparing a patented medicine in accordance with a medical prescription and acts concerning the medicine so prepared.⁶¹ The United States does not exclude medical methods for lack of utility but provides immunity against a medical practitioner's performance of a medical activity using patented medical methods.⁶² However, the narrow scope of immunity and uncertainty in the scope of newly introduced immunity provisions resulted in the confusion in medical practitioners' community.⁶³ Thus, the United States should work with other countries to adopt a uniform scope of immunity to maintain the freedom of medical practitioners to engage in their practice.

Further, other countries maintain the concept of beneficial utility and exclude immoral inventions, the publication or exploitation of which would be contrary to public order.⁶⁴ The concept of beneficial utility to invalidate immoral or illegal inventions exists in the United States, but U.S. courts substantially limit its applicability.⁶⁵

Focusing on the necessity of specific use in subject matter to constitute a patentable invention, the industrial applicability standard in other countries is considered to be narrower than U.S. utility requirement because the former does not require a specific, tangible and credible use. However, those countries require disclosure of a similar degree of specific use to meet the enablement requirement. However, evidence to show such use may be different between the U.S. and other countries.

Utility is an important concept because it determines how early an inventor can apply for a patent with respect to subject matter in an unpredictable art. Thus, the United States should urge other countries to adopt a uniform standard with respect to evidence of a specific, substantial and credible use.

⁶⁰ EPC Article 52(4); JPL Article 29.

⁶¹ Community Patent Convention (CPC), Article 27(c); JPL Article 69 (3).

⁶² 35 USC Section 287(c).

⁶³ Brett G. Alten, NOTE: *Left To One's Devices: Congress Limits Patents on Medical Procedures*, 8 Fordham I. P., Media & Ent. L.J. 837 (1998). However, many commentators criticize the immunity. E.g., Cynthia M. Ho, : *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. Section 287(c)*, 33 U.C. Davis L. Rev. 601 (2000).

⁶⁴ EPC Article 53(a); JPL Article 32.

⁶⁵ *Juicy Whip, Inc. v. Orange Bang, Inc.* 185 F.3d 1364, 51 U.S.P.Q.2d 1700 (Fed. Cir. 1999).

(7) **Hilmer Doctrine**

The United States should eliminate the *Hilmer* Doctrine and stop distinguishing an affirmative priority effect to obtain a patent from a defensive effect to defeat the patentability of later inventions. U.S. courts introduced this distinction through statutory interpretation to limit the extent of secret prior art, sections 102(e) and (g), by refusing to give subject matter in U.S. applications the patent defeating effect as of the foreign priority date.

Under the first-to-file model followed by other countries, an application with a patent office gives any subject matter disclosed in the specification both priority right to obtain a patent and the right to defeat the patentability of later applications.⁶⁶ This is because applicants are allowed to amend claims to cover any subject matter disclosed in the specification. If the priority right is limited to claimed subject matter, patent offices cannot dispose of later filed applications until any early application disclosing the subject matter claimed in the later application is disposed of. Otherwise, double patenting on the same subject matter occurs when an applicant amends the claims in the early application to cover the subject matter claimed in the later application. However, other countries share with the United States the same concerns over secret prior art. Thus, they use subject matter in unpublished applications only for the purpose of novelty.⁶⁷

Many commentators have pointed out the illogical problems resulting from application of the *Hilmer* doctrine.⁶⁸ The strongest argument is that application of *Hilmer* results in the issuance of patents to obvious inventions.⁶⁹ The *Hilmer* doctrine is also extensively criticized for violating the priority right provision under the Paris Convention as well as the non-discrimination policy provision as to the place of invention under WTO TRIPS.⁷⁰ This problem is somewhat remedied by the expansive estoppel doctrine used in interference proceedings.⁷¹ Some commentators view *Deckler* as essentially overruling *Hilmer*.⁷²

⁶⁶ For a general discussion of prior rights, see Gerald Paterson, *The European Patent System, The Law and Practice of the European Patent Convention*, 386 (1992).

⁶⁷ E.g., EPC Article 56; JPL 29 bis.

⁶⁸ Donald S. Chisum, *Elements of United States Patent Law*, 104 (2000); Harold Wegner, *TRIPS Boomerang-Obligations for Domestic Reform*, 29 *Vand. J. Transnat'l L.* 535 (1996); Kevin L. Leffel, Comment, *Hilmer Doctrine and Patent System Harmonization: What Does A Foreign Inventor Have At Stake?*, 26 *Akron L.Rev.* 355 (1992).

Donald S. Chisum, *Elements of United States Patent Law*, 104 (2000).

⁷⁰ Paris Convention Article 4. WTO TRIPS Article 27, Paragraph 1.

⁷¹ *In re Deckler*, 977 F.2d 1449, 24 U.S.P.Q.2d 1448 (Fed. Cir. 1992). Kate Murashige, *The Hilmer Doctrine, Self Collision, Novelty and the Definition of Prior Art*, 26 *J. Marshall L.Rev.* 549 (1993).

⁷² Charles E. Van Horn, *Effects of GATT and NAFTA on PTO Practice*, 77 *J. Pat. & Trademark Off. Soc'y* 231, 234 (1995), Robert Armitage, *The Foreign-Based Inventor's Unprecedented Opportunities under the URRRA 6-93* (21 Annual Intellectual Property Workshop 1995). Both articles are cited and commented on in *Supra* note 8, Adelman etc., *Patent Law*, at 844.

There is no justifiable reason to keep the *Hilmer* doctrine over criticisms from U.S. trade partners. First, disclosure of patentably indistinguishable inventions brings no benefits to the public. Second, the *Hilmer* court's major concern in using the foreign priority date for a patent defeating effect was to prevent the expansion of secret prior art.⁷³ However, the scope of secret prior art was substantially reduced by the introduction of 18-month publication under the 1999 AIPA. The risk will be further reduced if the chance to establish a secret prior invention date is limited to small inventors as an exception to the first-to-file principle.

Accordingly, to clarify the holding of *Deckler* and remove the suspicion of violating the Paris Convention and WTO TRIPS, Section 102(e) and 102(g) should be revised to remove the *Hilmer* Doctrine.

(8) Prior Right: Section 102(e) / Double Patenting

The United States should urge other countries to adopt its practice and allow examiners to cite subject matter disclosed in unpublished early applications, both for novelty and nonobviousness purposes. Other countries' practice allows issuance of multiple patents with different patent terms with respect to obvious variations. However, disclosure of such obvious variations gives no contribution to the state of art. Other countries' practice gives an opportunity for owners to extend a patent term up to 18 months with respect to an obvious variation of subject matter in an early application by filing an application for the variation before the publication of the early application.

Obvious variations very likely constitute equivalents under the doctrine of equivalents. Thus, once a patent is issued on the subject matter in the early application, variations should be protected with the early subject matter under the doctrine of equivalents. They should not be protected by separate patents.

(9) Grace Period

The United States should urge other countries to adopt a uniform grace period. A first-to-file system without a grace period provides "disincentives" for universities, public research organizations, and government agencies to be open and prompt in reporting research results in the scientific literature. Without a grace period, these organizations either are denied access to the patent system or must adopt corporate methods controlling information, both of which practices are adverse to innovation in the public

⁷³ In re *Hilmer*, 359 F.2d 859, 877, 149 U.S.P.Q.480 (1966) (The practical potential effect of pushing back the date of the unpublished, secret disclosure, which ultimately will have effect as prior art references in the form of U.S. patents, by the full one-year priority period of section 119.)

interest. This argument is not merely for U.S. universities but applies worldwide.

Under the first-to-file system that all other countries follow, any disclosure forfeits a right to patent. However, the majority of other countries provides for a grace period and excludes pre-filing disclosure of an invention from the prior art in examining the invention.⁷⁴ Among those countries that provide for a grace period, 57% adopt 6 months and 30% adopt one year as their grace period.⁷⁵ 52% provide a grace period starting from the actual filing date and 45% provide a grace period starting from the priority date under Paris Convention.⁷⁶ Most other countries adopt a disclosure specific grace period in which only certain categories of disclosure are qualified to take advantage of a grace period.⁷⁷ The most popular categories of disclosure qualified for claiming a grace period includes (1) experimental use; (2) disclosure by an applicant; (3) disclosure by a third party; (4) abuse of right; (5) display at international exhibition; and (6) presentation at a science meeting.⁷⁸

Even in a country adopting a disclosure-specific grace period, for example Japan, a significant portion of applicants takes advantage of the grace period system.⁷⁹ Among four categories available to claim a grace period, (1) experimental use; (2) publication disclosure; (3) presentation at a science meeting; and (4) display at exhibition,⁸⁰ disclosure at a science meeting is most frequently cited to claim a grace period.⁸¹ A survey revealed Japanese applicants' willingness to expand the grace period to harmonize with the U.S. grace period and also revealed criticism against the limited scope of the grace period under the European Patent Convention.⁸²

In contrast, European applicants are more reluctant to provide a more general scope of grace period.⁸³ Industry experts emphasized the disadvantages of a grace period in introducing legal uncertainty.⁸⁴ Since most other countries adopt a disclosure specific grace period, the novelty

⁷⁴ According to the survey conducted by AIPPI Japan Group, 87% of 177 national and regional patent systems provide for some type of grace period systems. AIPPI Japan Group, Report: A Study of Grace Period and other Conditions of Patentability in National and Regional Patent Systems, 1 (December, 2000)[hereunder, AIPPI Study].

⁷⁵ *Id.* at 2.

⁷⁶ *Id.* at 3.

⁷⁷ *Id.* at 4.

⁷⁸ *Id.* at 4.

⁷⁹ *Id.* at 26.

⁸⁰ JPL Article 30.

⁸¹ *Id.* at 28.

⁸² *Id.* at 33.

⁸³ Joseph Straus, *The Grace Period in Patent Law: A Look at Europe* (April 20, 2001) (unpublished manuscript, presented at 2001 Fordham International Intellectual Property Law & Policy Conference).

⁸⁴ Albrecht Hueni, Comments on the Introduction of an International Period of Grace, 16 IIC 580 (1985).

depends on a determination of whether a pre-filing disclosure is qualified for one of the listed categories. This will result in a significant uncertainty in patent validity. Further, when a pre-filing second disclosure occurs, the restrictive system requires determination of whether the second disclosure originates from an earlier pre-filing disclosure that is qualified for the listed categories. This increases administrative costs and may result in a significant examination delay.⁸⁵ However, those who advocate for the adoption of a grace period point to the change in socio-economic environment resulting from the participation of universities and research organizations and emphasize the necessity to develop a system to encourage early academic publication while maintaining a right to patent.⁸⁶

Participation by universities in the patent system is vital for science and technology innovation in this country because the research undertaken can have an important effect on markets and the direction of public support. Without patent positions, universities are pretty much at the mercy of corporate markets in introducing new work. Without patent backing, potential investors have little incentive to invest in inventions that may challenge existing markets, or which, once developed, are merely duplicated by others unwilling to take the risk of developing the invention into a commercial product. However, without a worldwide uniform grace period, U.S. research organizations' rights are lost outside the United States and may not take advantage of the U.S. grace period because licensees often prefer to receive a worldwide license. In short, to maintain active participation by university and public research organizations, the United States should not move to a file-to-file model without a generous scope of grace period.

The non-restrictive grace period available under the current U.S. system is preferable to the disclosure of a specific grace period available under the patent systems of some other countries because it avoids the legal uncertainty argued by European industry experts. For legal certainty and assistance in examination, it is preferable to ask inventors to submit documents related to pre-filing disclosures. However, all applications should be examined based on the prior art as of the date one year prior to the filing date as is done by USPTO under the current U.S. patent statute. Even if a disclosure specific grace period is adopted, patent offices should not examine the qualification for a grace period and should leave the issue for an opposition proceeding or an invalidity proceeding.

If other countries are resistant to an idea of general scope grace period, the United States should urge them to provide for a grace period at least with respect to the following disclosures in addition to display in

⁸⁵ Joseph Straus, Remarks at 2001 Fordham International Intellectual Property Law & Policy Conference (April 20, 2001) (Transcript available from Fordham).

⁸⁶ Straus, *supra* at note 83, The Grace Period in Patent Law, at 4-5.

international exhibition under the Paris Convention: (1) the abuse of right; (2) presentation at an official or officially recognized science meeting; and (3) experimental use. Particularly, inclusion of the second disclosure is essential for reconciling competing needs in universities and public research organizations.

A one-year grace period is preferable to a 6-month grace period because this term is appropriate for preparing patent applications and thus has been adopted for the period of priority under the Paris Convention. Further, the grace period should start from the priority date, instead of from the actual filing date, so that inventors can take advantage of both Paris priority and the grace period. This will give public research institutions enough time to investigate the technology transfer opportunities and to decide whether to file an application.

The scope of patent eligible subject matter has expanded significantly over the last two decades. This has led to inclusion of subject matter that was developed by universities and public research institutions. In addition, the enactment of the Bayh Dole Act⁸⁷ and its equivalents in the United States and other countries has made it necessary for universities and public research institutions to acquire rights in the fruits of their research and encourage commercialization of the fruits through technology transfer.⁸⁸ Technology transfer offices in these institutions have started to play an important role in patent procurement and enforcement, although they were almost non-existent when the patent harmonization negotiation started.

Because industry-licensees prefer to obtain an international license, technology transfer offices are unable to take full advantage of the grace period under the United States patent system. Although the introduction of provisional application significantly eased the burden of preparing an application in timely fashion prior to presentation at a science meeting, technology transfer offices are often forced to make an important filing decision without being given sufficient time to explore the chance of technology transfer. Lack of a grace period in other countries also makes it difficult for these offices to communicate with prospective licensees. Accordingly, unless a uniform grace period is adopted in other countries, particularly in major markets for industry-licensees, the utility of the grace period available under the U.S. patent system is marginal. Thus, adoption of a grace period in other countries is essential to promote technology transfer activities by U.S. universities and public research organizations.

⁸⁷ The Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (Codified as amended at 35 U.S.C. Sections 200-211, 301-307 (1994)).

⁸⁸ Rebecca S. Eisenberg, *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663 (1996).

(10) Non Documentary Prior Art

The United States should remove the geographical restrictions that limit the definition of prior art. It is a common practice for scientific meetings and conferences to publish submitted papers and proceedings through the Internet. This practice has introduced a difficult question as to whether information on the Internet that is not printed out constitutes a printed publication and, if the information qualifies only as known information, whether the information is qualified as being known in this country. It is very difficult to identify where information on the Internet is known. Rather than introducing complex questions by limiting non-documentary prior art to domestic knowledge, the United States should stop distinguishing non-documentary prior art by the place of disclosure. The U.S.'s current practice may violate the spirit of non-discriminative policy under TRIPs.⁸⁹

European countries refused to adopt such restrictions when they enacted the EPC.⁹⁰ Japan has recently removed the restrictions to avoid such a conclusion.⁹¹

(11) Statutory Bars

The United States should simplify the novelty and priority provision under Section 102 by merging Sections 102(a) and (b) under the first-to-file system with a one-year grace period and eliminating Sections 102(c) and (d). Statutory bars were originally developed to prevent inventors from exploiting an invention while keeping the invention secret.⁹² However, adoption of a first-to-file priority provision that fairly corresponds to Section 102(b) under the current U.S. Patent Act motivates inventors to file applications within the grace period once their inventions are publicly known or used.

a. Section 102(c)

Adopting a first-to-file system renders Sections 102(c) useless because a first-to-file model inherently motivates inventors to file an application with USPTO as early as possible. Under the current patent statute, the following two situations may fall under Section 102(c) but not under Section 102(b): (1) non-commercial secret use of an invention; and (2) public use with an inventor's act that gives rise to an abandonment during

⁸⁹ WTO TRIPS, Article 27.

⁹⁰ EPC Article 54, Paragraph 2.

⁹¹ JPL, Article 29, Paragraph 1.

⁹² *Pennock v. Dialogue*, 27 U.S. 1, 2 Peters 1, 7 L. Ed. 327, (1829).

the grace period.⁹³ With respect to the first situation, allowing inventors to keep their inventions secret without commercial exploitation would not conflict with the policy for preventing inventors from extending the patent term. Thus, there is no justifiable reason to punish an inventor by eliminating the right to obtain a patent if he decides to take the risk of an early application filed by a third party by waiting to file an application. With respect to the second situation, an inventor should have an absolute right during the grace period to decide whether or not to apply for a patent regardless of his or her act that may lead to a third party's reliance on the inventor's interest to seek a patent.

d. Section 102(d)

The United States should eliminate Section 102(d) because the goal of Section 102(d) is well served by the priority right system under the Paris Convention.⁹⁴ Section 102(d) aims to require foreign applicants who obtain patent protection abroad to promptly file with USPTO for patent protection.⁹⁵ However, the Paris Convention gives the same motivation by requiring foreign applicants to file an application within one year from the foreign filing date. More over, Section 102(d) unfairly discriminates against inventions made outside the United States by imposing an additional bar. Thus, it may violate the non-discrimination provision in WTO TRIPS.⁹⁶ In short, Section 102(d) is not necessary, may cause criticisms from U.S. trade partners, and thus should be removed.

c. Section 102(b): Secret Use and Experimental Use

The United States should eliminate the inventor's secret commercial use bar and experimental use exception, because these doctrines make the application of priority and novelty provisions unnecessarily complex. In other countries, the rule of novelty is very simple and easily understood by inventors. Subject matter in public knowledge as of the filing date is not patentable for lack of novelty unless the subject matter falls within a category for claiming a grace period. Regardless of the nature of use, no use of the invention gives rise to a lack of novelty as long as the invention is kept secret. Regardless of the purpose of use, any public use gives rise to a lack of novelty even though such use may be qualified for exclusion under a grace period system.

In contrast, the novelty rule under the U.S. Patent System is complicated and difficult to understand because a public use may not constitute "public use" under the patent statute if the use falls within the experimental use exception.⁹⁷ A secret use may constitute "public use" under the patent

⁹³ Donald Chisum, Chisum on Patents, Section 6.03[1][c][ii](1979, Supp. 2001).

⁹⁴ Donald Chisum, *Foreign Activity: Its Effect on Patentability under United States Law*, 11 IIC 26, 44-47 (1980).

⁹⁵ Donald Chisum, Chisum on Patents, Section 6.04[1](1978, Supp. 2001).

⁹⁶ WTO TRIPS, Article 27, Paragraph 1.

⁹⁷ *Elizabeth v. Pavement Co.*, 97 U.S. 126, 7 Otto 126, 24 L. Ed. 1000 (1878).

statute if the use is for a commercial purpose.⁹⁸ The statutory bars were introduced with respect to the following three policies: (1) avoidance of detrimental reliance by public, (2) an early disclosure through patent application and (3) prevention of an inventor's attempt to extend the patent term by adding the period of secret use to the statutory 20 years.⁹⁹

However, these policies are well served by adopting the first-to-file system without inclusion of statutory bars because a determination of novelty based on the filing date effectively avoids public reliance, and a first-to-file model gives enough incentive to file early. The third policy has marginal value under the modern intellectual property system, where trade secrets and patents coexist. Under the first-to-file system, an inventor is given an option to protect his invention as a trade secret while taking a risk of a third party's early application. Since patent owners in other countries enjoy the option, U.S. patent owners would be unfairly disadvantaged unless the same option is given under the first-to-file system.

Not only are statutory bars no longer necessary after the adoption of the first-to-file system, they introduce uncertainty because the novelty of the invention depends on whether an activity falls within the definition of a statutory public use or "on sale." Inventors sometime improperly use statutory bars. They carefully draft claims to distinguish subject matter on sale and attempt to extend a grace period.¹⁰⁰ U.S. courts have attempted to avoid this improper use, which has resulted in a complex concept of complete invention to trigger a grace period.¹⁰¹

Moreover, the secret commercial use bar and the experimental use exception mislead U.S. inventors. An inventor's secret commercial use bar is a judicially developed doctrine.¹⁰² Nothing in the language of Section 102(b) suggests that a secret use falls within the definition of "public use" or "on sale" when the use is for a commercial purpose. Although U.S. case law indicates that this bar is applicable only to an inventor's act,¹⁰³ no word in Section 102(b) suggests any discrimination between the inventor's act and the act of another. Thus, U.S. inventors are very likely to be misled into believing that their commercial exploitation of an invention would not prevent them from obtaining a patent if their inventions are kept secret. An inventor's secret commercial use bar is the so-called "secret prior art," which has been extensively criticized because it introduces uncertainty into the validity of U.S. patents.

⁹⁸ *Egbert v. Lippmann*, 104 U.S. 333, 14 Otto 333, 26 L. Ed. 755 (1881).

⁹⁹ Chisum, *Chisum on Patents*, Section 6.02.

¹⁰⁰ *UMC Electronics Co. v. United States*, 816 F.2d 647, 2 U.S.P.Q.2d 1465 (Fed. Cir. 1987)

¹⁰¹ *Pfaff v. Wells Elecs.*, 525 U.S. 55, 142 L. Ed. 2d 261, 119 S. Ct. 304, 48 U.S.P.Q.2d 1641 (1998)

¹⁰² *Egbert v. Lippmann*, 104 U.S. 333, 14 Otto 333, 26 L. Ed. 755 (1881).

¹⁰³ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983)

The experimental use exception is also a judicially developed doctrine and thus Section 102(b) does not explicitly provide such an exception.¹⁰⁴ This exception is known to give inventors enough time to complete an invention. But the complexity of conditions to apply the doctrine have in fact created a pitfall for inventors, who often forfeit their right to patent by failing to meet a condition.¹⁰⁵

In short, the United States should make every pre-filing disclosure a public use and eliminate secret use from public use regardless of the purpose of the use. Elimination of these complex judicial doctrines would make the U.S. patent system simple and manageable by U.S. inventors who are not familiar with judicially created patent law doctrines.

(12) Interpretation of Prior Art Teaching

Many other countries, including European countries and Japan, also allow the use of multiple references to anticipate limited circumstances. Under EPO Guidelines, examiners can combine a separate reference if a primary document refers to another document.¹⁰⁶ Although other countries do not use the term "inherency", many other countries have a similar doctrine to expansively read the teaching of the prior art. Under EPO case law, teaching of the prior art includes not only what is explicitly disclosed but also what is inherent to one skilled in the art.¹⁰⁷ EPO follows the all elements rule to negate novelty but does not follow strict identity between the claimed elements and the structures or act disclosed in the specification.¹⁰⁸ JPO follows a similar rule to allow the use of multiple references and a relaxed identity rule for rejecting claims on basis of lack of novelty.¹⁰⁹ However, a doctrine to find inherency of the end product from a disclosed process only if the end product necessarily results from the process appeared to be unique to the United States.¹¹⁰

Nevertheless, the United States and other countries should eliminate the inherency doctrines because these doctrines prevent applicants from taking advantage of doctrines to prevent hindsight under the nonobviousness standard. These inherency doctrines were developed in the United States as well as other countries to expand the rejection of novelty when their patent statutes did not have a separate requirement of nonobviousness or inventive step.

¹⁰⁴ *Elizabeth v. Pavement Co.*, 97 U.S. 126, 7 Otto 126, 24 L. Ed. 1000 (1878)

¹⁰⁵ *Lough v. Brunswick Corp.*, 86 F.3d 1113, 39 U.S.P.Q.2d 1100 (Fed. Cir. 1996)

¹⁰⁶ EPO Guidelines for Examination, C-IV, 7.1.

¹⁰⁷ T290/86, 1992 Official Journal of EPO, 414 (1992). For a general discussion of the interpretation of teaching in prior art, see Singer, *the European Patent Convention*, 149 (1995).

¹⁰⁸ T198/84, 1985 Official Journal of EPO, 209 (1985). For a general discussion of identity in detail between the claim and prior art, see *supra* note 27, Singer, *the European Patent Convention*, 152 (1995).

¹⁰⁹ Toshiko Takenaka, *The Substantial Identity Rule under the Japanese Novelty Standard*, 9 *UCLA Pacific Basin Law Journal*, 220 (1991).

¹¹⁰ *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 34 U.S.P.Q.2d 1565 (Fed. Cir. 1995).

Patent offices prefer to rely on inherency to avoid the need to show elements to establish prima facie obviousness. The doctrine of analogous art is not applicable under the novelty standard, which allows patent offices to cite any unrelated technology to reject claims.¹¹¹ Such examination practice tends to lead to a rejection using hindsight. Thus, except for a circumstance where a separate reference is explicitly cited in the main reference, if any element is not explicitly disclosed, patent offices should rely on nonobviousness rejection rather than anticipation.

(13) Obviousness Determination

a. Problem Solution Approach

The United States practice in determining obviousness is a better and more objective approach than the problem-solution approach uniformly adopted by EPO and European countries. The serious problem involved in the problem solution approach relates to the steps for objectively determining the problem related to the invention. According to EPO practice, examiners identify the most relevant prior art and compare the claimed subject matter and that of the most relevant prior art to determine the problem objectively.¹¹² This step is more susceptible to hindsight because it requires examiners to look at the invention before addressing the obviousness assessment. European examiners are supposed to forget the solution disclosed in the invention when they define the problem of the invention. However, they often define the problem in terms of the solution because it is difficult to forget once they see the solution.¹¹³

This danger of using hindsight in the problem-solution approach is well represented in a Federal Circuit case, *Monarch Knitting*.¹¹⁴ The Federal Circuit rejected the district court's analysis, which was obviously influenced by arguments advanced by European parties, holding that the problem is defined in terms of the solution of the invention and thus used hindsight.

The problem solution approach can also lead to a grant of patent on a new use of an old product because its examination focuses on the problem related to the invention.¹¹⁵ Definition of a new and nonobvious use as a new problem results in a separate product patent on an old product.

¹¹¹ Chisum, *Chisum on Patents*, Section 3.02[3] (1978, Supp. 2001).

¹¹² Guidelines for Examination in the European Patent Office, Chapter IV, Part C, 9.5, For a general discussion of the problem solution approach, George S. Szabo, *The Problem and Solution Approach in the European Patent Office*, 26 IIC (1995).

¹¹³ G. Knesch, *Assessing inventive Step in Examination and Opposition Proceedings*, 1994 EPI Information 95 (March 1994).

¹¹⁴ *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 45 U.S.P.Q.2d (BNA) 1977 (Fed. Cir. 1998)

¹¹⁵ G2/88, 1990 Official Journal of EPO 93, For a general discussion, Gerald Paterson, *The European Patent System*, 413 (1992).

Patent owners often choose a strategy to patent on a new use so as to extend the term of earlier granted product patent.

b. Nonobviousness Assessment

EPO and JPO both adopt a suggestion/motivation test similar to that used by USPTO.¹¹⁶ However, JPO guidelines indicate that examiners can find a motivation or suggestion merely by a close relation of technical fields or similarity of function, work or operation.¹¹⁷ It appears to make rejection easy by using hindsight because it does not require examiners to point out any particular portion of the prior art to show motivation. To avoid such hindsight, the Federal Circuit emphasizes the safeguard function of the suggestion to combine requirement and has required USPTO to identify the principle, known to one skilled, that suggests the claimed combination.¹¹⁸ Thus, the United States should urge other countries to uniformly use a suggestion test and clarify the basis that gives rise to a motivation or suggestion.

c. Secondary Considerations

Further, The United States should urge other countries to give more weight to commercial success. The current practice at EPO and JPO is that examiners tend to give less attention to commercial success than the attention given by USPTO and the Federal Circuit. This may be because of the difficulty in assessing evidence of commercial success with respect to the competency of these patent offices. Also, examiners outside the U.S. often indicate serious concern over the risk of misuse. However, the use of commercial success is more precise and accurately reflects technical merit under the nexus requirement used by the Federal Circuit.¹¹⁹ Other offices may need refinement of rules to examine the risk-minimizing factors as has been done by the Federal Circuit.

Commercial success is particularly significant in some types of inventions such as combination inventions. Because all technical considerations to show *prima facie* obviousness are negative tests, commercial success, which is a positive test, is important to balance the positions of applicants and the patent office in disputing nonobviousness. The use of commercial success is economically sound, although some commentators criticize the extensive use of commercial success in economic perspective.¹²⁰

Because evidence of commercial success is available only with respect to inventions that are on the market, the use of commercial success encourages the introduction of products into the market and secures

¹¹⁶ Singer, the European Patent Convention, 181 (1995); JPO Examination Guidelines, Chapter 2, 2.5(1).

¹¹⁷ JPO Guidelines, 2, 2.5(1) 3) and 4).

¹¹⁸ *In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998).

¹¹⁹ Rochelle Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U.L. Rev. 1 (1998).

¹²⁰ Robert Merges, *Economic Perspective on Innovation: Patent Standards and Commercial Success*, 76 *Cal.L.Rev.* 803 (1988).

reimbursement of investment associated with the commercialization of the invention. Accordingly, other countries should adopt the U.S. practice and should give more weight to commercial success.

d. Definition of One Skilled in the Art

Finally, the United States should adopt the definition of one skilled in the art to include a group of persons where this is more appropriate. This definition has recently been adopted by EPO and JPO to reflect the conduct of inventors in a particular field of technology.¹²¹ For example, in the field of business model inventions, an inventor with a business background very likely hires a computer specialist to develop a business method implemented by computer software on a web site. It is more natural to use a group of inventors to represent the level of ordinary skill in the art, instead of using a single person with knowledge in both business and computer implementation.

(14) Multiple Dependent Claims

For the same reasons stated in (5), USPTO should adopt the same standard used for examining international patent applications under PCT.

(15) Claim Interpretation

a. Peripheral Claiming Approach

The United States is considered to be a paradigm for following the peripheral claiming approach. However, U.S. courts allow claims under the doctrine of equivalents and extend the protection beyond the literal scope.¹²² Thus, United States does not follow the true sense of the peripheral claiming approach if one takes account of the doctrine of equivalents.

A true paradigm of the peripheral claiming approach is Japan prior to a 1998 Supreme Court Decision¹²³ and the United Kingdom prior to joining the EPC, in which systems no claim of doctrine of equivalents is possible. Even under these systems, courts developed doctrines to expansively interpret the language of claims to maintain fairness between patentees and accused infringers.¹²⁴ Although UK courts and Japanese courts developed the doctrines under the scheme of literal infringement, the effect of the doctrines is the same as the doctrine of equivalents.

It is useless to discuss whether a patent system follows the peripheral claiming approach or central claiming approach. A more important issue

¹²¹ Guidelines for Examination in the European Patent Office, Chapter IV, Part C, 9.6.

¹²² *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 137 L. Ed. 2d 146, 117 S. Ct. 1040, 41 U.S.P.Q.2d 1865 (1997)

¹²³ *Tubakimoto Seiko v. T.H.K.*, 1630 Hanrei Jiho 32 (Saiko Saibansho 1998).

¹²⁴ For United Kingdom, see J. A. Kemp, *Patent Claim Drafting and Interpretation* (1983). For Japan, see Toshiko Takenaka, *Interpreting Patent Claims: The United States, Germany and Japan* [hereunder, Takenaka], 17 IIC Studies (1995).

is the extent of protection given by all doctrines to establish infringement. Regardless of the classification of doctrines that expand the protection beyond the strict meaning of claim, it is important to harmonize the extent of protection in different countries, particularly major markets for U.S. patent owners. Harmonization of literal scope is particularly important because it defines the subject matter examined by patent offices.

The United States should maintain the current practice of a peripheral claiming approach with the possibility of claiming infringement under the doctrine of equivalents. A true sense of peripheral claiming tends to encourage applicants to include a number of claims with specific definitions. This will increase administrative costs at examination despite the fact that only fractions of patents are exploited and enforced. After all, it is impossible for claim drafters to have complete information on the prior art and to predict future variations by infringers. To reduce transactional costs, it is much better to let courts handle the scope of infringement through the doctrine of equivalents while the public should bear a risk of uncertainty introduced by the doctrine of equivalents or any doctrines to expand the strict literal scope.

b. Means-Plus-Function Claims

The United States should remove Section 112 Paragraph 6 and interpret means-plus-function claims and step-plus-functions claims in the same manner as structurally defined regular claims. Because Section 112 Paragraph 6 requires examiners and courts to determine whether an element is in means-plus-function format, significant confusion results from the determination, as it is often unclear whether the element was drafted in such a format.¹²⁵ This is particularly true in step-plus-function claims.¹²⁶

Further, in theory, examiners are required to decide the obviousness of equivalents of the structures corresponding to the recited function in the claim. It seems impossible to decide such obviousness. Thus, in *In re Donaldson*, the Federal Circuit's analysis indicates anticipation analysis instead of nonobviousness, even though it found that the claim was nonobvious.¹²⁷

Other countries do not distinguish means-plus-functions claims from other type of claims. Applicants are allowed to use means-plus-function claims only if one skilled in the art reasonably would understand what structures are included to perform the recited function.¹²⁸ The United States should

¹²⁵ *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999)

¹²⁶ *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 50 U.S.P.Q.2d 1225 (Fed. Cir. 1999) —

¹²⁷ *In re Donaldson Co.*, 954 F.2d 732, 29 U.S.P.Q.2d 1845 (Fed. Cir. 1991) —

¹²⁸ T292/85, 1989 Official Journal of EPO 275; JPO's Examination Standard Office, Kaisetsu: Heisei 6 nen Kaisei Tokkyohou no Unyou (Practices in Examination and Appeals under the 1994-Revised Patent Act) 132 (1995).

adopt the same practice and remove confusion resulting from the discriminative interpretation for means-plus-function claims.

c. Product-By-Process Claims

The United States should consider urging other countries to engage in discussion of harmonizing the literal scope of product-by-process claims. The literal scope of product-by-process is unclear as two Federal Circuit decisions conflicts with respect to whether a product-by-process claim extends to a product that is not produced by the recited process.¹²⁹ Other countries interpret product-by-process claims to extend to a product resulting from the recited process.

(16) The Doctrine of Equivalents

a. Infringement by Equivalents

The doctrine of equivalents indirectly relates to the examination procedure, because the availability of the doctrine affects the literal scope of claims that the patent system should select for accomplishing patent policy. In an unpredictable art, such as biotechnology, if a generous scope of equivalents is available, applicants can draft specific and narrow claims to cover only embodiments that were tested and disclosed in the specification, so as to avoid lack of enablement. However, if protection by equivalents is exceptional and thus limited, applicants should be allowed to claim a broad scope covering possible later developments by deciding the equivalency as of infringement time. Otherwise, the policy for rewarding inventors in proportion to the contribution through disclosure of the invention is undermined.¹³⁰ This is because pioneer inventions contribute greatly to the art but can have only a very narrow scope of protection due to lack of information and unpredictability to include variations in the literal scope.

Unless a very relaxed utility, enablement and written description requirement is uniformly adopted, a system without the doctrine of equivalents fails to fairly reward pioneer inventors, particularly in an unpredictable art. Thus, the United States should continue to urge other countries to adopt the doctrine of equivalents or doctrines to extend the protection beyond the literal scope. To cover later developments that have become available because of infringement, the United States should urge other countries to determine equivalency as of infringement time.

However, the timing to include a definition of equivalents has still not matured, because U.S. courts as well as courts in other countries are still in the process of developing the definition of equivalents. Thus, general

¹²⁹ *Comp, Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991) with *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 23 U.S.P.Q.2d 1481 (Fed. Cir. 1992).

¹³⁰ Donald Chisum, *Chisum on Patents*, Section 18.04[2][a][I] (1978, Supp. 2001).

language such as that adopted in the Protocol on the Interpretation of EPC Article 69 to require the protection beyond the literal meaning of claim is preferable to specific definitions of equivalents and limitations.

b. Prosecution History Estoppel

The United States should abandon the new rule of prosecution history estoppel, which undermines the well-established practice under a first-to-file model. In other countries, a first-to-file priority rule necessary urges applicants to rush to file an application with patent offices as soon as an invention is complete. Thus, other countries' systems assume giving time to investigate the prior art and commercial value of claims after filing an application and to perfect claims when a request of examination is filed. A significant number of applications are withdrawn from prosecution because they fail to file a request of examination during the statutory period. Further, many applications are originally prepared by inventors themselves and refined by patent attorneys when a request for examination is filed.

Because other countries' patent systems presume the abandonment of these applications and imperfect claims in original applications, these systems guarantee applicants the right to amend claims without any disadvantage even if the original claims are imperfect. This practice makes it possible to disclose inventions early while limiting the prosecution cost as well as administrative costs at patent offices. This practice also helps small inventors and public research organization by enabling them to file an application by themselves.

The new rule of prosecution history estoppel adopted by the Federal Circuit *en banc* in *Festo* undermines this practice of other countries that follow the first-to-file priority rule because any voluntary amendment to narrow the literal scope gives rise to an estoppel bar and completely prevents a claim of the doctrine of equivalents.¹³¹ When prosecution of a U.S. application starts as an international application at other offices, such as JPO or EPO under Patent Cooperation Treaty, foreign applicants are improperly punished if they follow a well-established practice of amending claims when a request of examination is filed. When an application enters the national phase, the prosecution of the international phase at EPO or JPO becomes part of record of U.S. patent prosecution. Amendments filed upon the receipt of the search report¹³² or upon a request of international preliminary examination¹³³ deprive foreign applicants of claims of equivalents.

¹³¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558; 56 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2000)

¹³² Patent Corporation Treaty Article 19.

¹³³ Patent Corporation Treaty Article 34.

Further, a mere clarification of language from a foreign translation may give rise to estoppel if the clarification results in a narrower literal scope with respect to the amended claims compared with that of original claims.¹³⁴ Considering the increased complexity of technology and the difficulty of translation for such complex technology, foreign applicants are more vulnerable to the complete bar against equivalents through the new prosecution estoppel rule.

(17) Inventor-Applicant Restriction

The United States should remove the requirement that a patent be applied for in the name or names of the inventor or inventors. In the modern research and development environment, inventors work in a team and participate in joint activities that give rise to a conception or reduction to practice. However, because of the complexity of case law on inventorship as well as evaluation of contributions by individual inventors in the research activity, employers of inventors often face difficulty in identifying who should be named as inventor(s). Shifting of the U.S. patent system to a first-to-file model requires employers to file application promptly. Employers should be given the flexibility to file an application under their names and to correct inventorship when investigation after filing reveals innocent errors.

Moreover, allowing employers and right successors to file an application will reduce prosecution cost because employers can prosecute patents under their own name when the inventors themselves are not capable of prosecuting patents. Right successors for patents in other countries enjoy flexibility to file under their names and can thus save attorney fees significantly. The same flexibility should be guaranteed to U.S. inventors.

(18) Other Comments

We believe that these issues to be discussed although they are not listed for comments.

a. Prior User Defense

The United States should urge other countries to revise their prior user right provisions so that the activities by universities and public research organizations give rise to a prior user right. A prior user right or defense under a first-to-file model in other countries requires exploitation or investment in the exploitation of an invention to give rise to a right. This requirement unfairly discriminates against universities and research organizations because these organizations do not exploit inventions by their own. They should adopt similar exceptions for activities of these organizations to give rise to a first inventor's defense under the 1999 American Inventors Protection Act.¹³⁵

¹³⁴ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 622 (Linn, J., Dissenting).

¹³⁵ 35 USC Section 273(2).

b. Experimental Use Exemption

The United States and other countries should adopt a uniform scope of experimental use exemption to the enforcement of patents. Expansion of the scope for patent eligible subject matter results in the coverage of exclusive rights to subject matter that is traditionally considered as basic science, such as biotechnology. This expansion makes it possible for public research institutions and universities to obtain patents and transfer the technology, but it limits the freedom to engage in further development once the technology is transferred to industry.

Many other countries expressly provide experimental use exemptions to secure the freedom for research institutions to engage in further development.¹³⁶ Although the United States has a common law "experimental use exemption," recent case law indicates that the scope of the exception is so narrow that it is almost non-existent except for Section 271(e).¹³⁷ Taking account of this exception, WTO TRIPS gives member states options to provide limited exceptions under limited circumstances.¹³⁸

The freedom for researchers in public research institutions to engage in research and development in basic science is essential for the promotion of science and useful arts. Patents should not create any obstacles to hinder their efforts to further developments. The Federal Circuit created such obstacles by refusing to give immunity from patent enforcement with respect to the activity of a university professor to design around the claimed invention.¹³⁹ In contrast, many other countries adopt a broad scope of exemption if the trials and tests are conducted to find new technical features for further developments regardless of the reason for performing the tests or trials.¹⁴⁰ The experimental use exemption of these countries is interpreted by their courts to cover clinical trials to obtain data for a government market.¹⁴¹

Universities and public research organizations should be able to use patent rights to preserve scientific commons that otherwise degrade as corporate entities secure patent rights to improvements but have no

¹³⁶ E.g., Community Patent Convention, Article 27(b); Japanese Patent Law, Article 69(1). For a general discussion of experimental use exception under patent systems in European countries, see David Gilat, *Experimental Use and Patents*, 16 IIC Studies (1995).

¹³⁷ Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L.R. 1 (2001).

¹³⁸ WTO TRIPS Article 30.

¹³⁹ *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 55 U.S.P.Q.2d 1161 (Fed. Cir. 2000)

¹⁴⁰ Andries van der Merwe, *Experimental Use and Submission of Data for Regulatory Approval*, 31 IIC 380 (2000).

¹⁴¹ Judgement of Federal Supreme Court (BGH), July 11, 1995, GRUR 1996, 109 - "Klinische Versuche"; Judgement of Supreme Court of Japan (Saiko Saibansho), April 16, 1999 (Translation is available at <http://www.law.washington.edu/casrip/newsletter/news5i4jp3.htm>.)

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obligation to the inventors of the fundamental technology. This has happened no doubt with PCR in biotechnology, and with any number of computer and Internet related technologies. Therefore, it is essential for U.S. and other countries to adopt a uniform research exception to enforcement of patents.

c. Inventorship and Ownership

The United States and other countries should adopt a uniform definition of inventor and set a simple and inexpensive proceeding to dispute inventorship and/or ownership of the invention. Inventorship is one of the most important concepts because the determination of ownership starts from the inventorship.¹⁴² Different definitions of inventorship lead to different ownership with respect to the same inventions in different countries, and this results in a serious confusion. However, the definition of inventorship is not clear from U.S. case law.

Under the United States patent system, inventors can dispute inventorship in an interference proceeding.¹⁴³ Unfortunately, the interference proceeding is too complex and expensive for small inventors to take advantage of the system. Other countries pay little attention to the notion of inventorship and a very few countries provide an inexpensive system within the patent office for inventorship disputes, enabling the transfer of rights to a lawful owner.

The United States should adopt a system to clarify the share of ownership with respect to a joint invention. The 1984 amendment of the inventorship provision permitted naming as inventor all persons who assisted in the development of an idea, or parts thereof, that originated with others.¹⁴⁴ Such naming, however, should not automatically endow common ownership of the entire invention in equal shares with respect to individual joint inventors regardless of their contribution.¹⁴⁵ No change was made to the ownership provision to remedy an unreasonable consequence in ownership resulting from the post 1984 inventorship rule. Other countries also allow the naming of all persons who contributed any claims to be included in the same patent. These countries provide a system for registering ownership shares held by individual joint inventors. Unless ownership shares are registered, all joint inventors share equally in the ownership of the entire invention.

¹⁴² *University Patents, Inc. v. Kligman*, 762 F. Supp. 1212, 20 U.S.P.Q.2d 1401 (E.D. Pa. 1991); Donald Chisum, *Chisum on Patents*, Section 22.02 (1978, Supp. 2001).

¹⁴³ Donald Chisum, *Chisum on Patents*, Section 2.04 (1978, Supp. 2001).

¹⁴⁴ 35 U.S.C. Section 116.

¹⁴⁵ *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 45 U.S.P.Q.2d 1545 (Fed. Cir. 1998).