INTERNATIONAL HARMONIZATION BROUGHT ABOUT BY THE AMERICAN INVENTOR'S PROTECTION ACT COMPELS EARLY RELEASE OF THE BIOLOGICAL DEPOSIT

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I. INTRODUCTION

The passage of the American Inventor's Protection Act of 1999[1] ("AIPA") has brought about one of the most significant changes in the United States patent system since the enactment of the Patent Act of 1952.[2] The practice of the United States Patent and Trademark Office ("USPTO") has long been to maintain the secrecy of pending patent applications until the corresponding patent issues. However, as of November 29, 2000, patent applications will be published 18 months from the earliest filing date for which a benefit is sought, unless some exceptions apply.[3] For example, if the applicant requests no publication and certifies that the disclosed invention will not be the subject of a foreign patent application, the patent application

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1 *See American Inventor's Protection Act of 1999*, Pub. L. No. 106-113, §§ 4001-4808, 113 Stat. 1501A-552 to 1501A-591 (1999) (codified as amended in scattered sections of 35 U.S.C. (1994 & Supp. 2001)) [hereinafter AIPA].

2 *See Patent Act of 1952*, Pub. L. No. 593, §§ 1-293, 66 Stat. 792, 817 (1952) (codified as amended in scattered sections of 35 U.S.C. (1994 & Supp. 2001)).

3 *See* AIPA, *supra* n. 1, at § 4502 (codified as amended at 35 U.S.C. § 122(b)(1) (1994 & Supp. 2001)).

will not be published at the end of the 18 month period.[4] This early publication requirement is modeled after the patent systems of Japan, Europe, and various other countries that publish patent applications 18 months after their effective filing date.[5]

The rights of the applicant who files abroad, or who voluntarily publishes his application, are greatly enhanced by sections 4504 and 4505 of the AIPA. Section 4504 gives such an applicant the provisional right to receive a reasonable royalty from any party who infringes the published claims during the publication date of the application and the issuance of the patent.[6] This provisional right vests when the patent issues, but is not available unless the claims of the published application are substantially similar to the claims of the issued patent.[7]

Section 4505 amends 35 U.S.C. § 102(e)[8] to give published patent applications the same prior art effect as a patent issued by the USPTO.[9] That is, a published application will be considered prior art with respect to any subsequently filed patent applications.[10] The owner of the published application, therefore, may exclude others from patenting the same invention.

Of prime importance to the biotechnology industry is section 4805 of the AIPA, which requires the Comptroller General to conduct a study and submit a report to Congress related to biological deposits in support of biotechnology patents.[11] The study must include:

> (1) an examination of the risk of export and the risk of transfers to third parties of biological deposits, and the risks posed by the change to 18-month publication requirements made by this subtitle;

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4 *See id.* at § 4502 (codified as amended at 35 U.S.C. § 122(b)(2) (1994 & Supp. 2001)). Other exceptions include that an application shall not be published if the application is: no longer pending, subject to a secrecy order, a provisional application, or an application for a design patent. *See id.*

5 Donald S. Chisum, *The Harmonization of International Patent Law*, 26 John Marshall L. Rev. 437, 440 (1993).

6 *See* AIPA, *supra* n. 1, at § 4504 (codified as amended at 35 U.S.C. § 154(d) (1994 & Supp. 2001)).

7 *See id.*

8 *See* 35 U.S.C. § 102 (1994 & Supp. 2001) (prescribing the novelty conditions for patentability and loss of rights to a patent). Section 102(e) specifically addresses the effects of previously filed patent applications on U.S. patentability. *See id.*

9 *See* AIPA, *supra* n. 1, at § 4505 (codified as amended at 35 U.S.C. § 102(e) (1994 & Supp. 2001)).

10 *See id.*

11 *See id.* at § 4805.

(2) an analysis of comparative legal and regulatory regimes; and

(3) any related recommendations.[12]

The AIPA requires the USPTO to consider the recommendations submitted by the Comptroller General when it drafts regulations affecting biological deposits.[13]

This article will conduct a study similar to the study mandated by section 4805 by addressing the risks posed when a biological deposit is made available to third parties after the 18 month publication of a patent application referencing the deposit. An examination of the laws in Europe and Japan concerning accessibility of biological deposits during the period between patent application publication and patent issuance will also be addressed. A recommendation will be made on whether samples of the deposited biological material should be made accessible to third parties prior to issuance of the patent. Furthermore, this article will suggest safeguards that may be taken to avoid the risks posed to biotechnology inventors.

II. BIOLOGICAL DEPOSIT REQUIREMENT

Depositing biological material has developed into an acceptable means of meeting disclosure requirements for obtaining a patent in countries around the world. In the United States, rules pertaining to biological deposits have emerged from various court decisions[14] and from the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure ("Budapest Treaty"),[15] to which the United States is a party.

A. Development of the Biological Deposit Requirement

Microorganisms have been used in patented inventions for over a century.[16] Since the beginning of the biotechnology patent era, researchers

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12 *See id.*

13 *See id.*

14 *See, e.g.*, *Amgen, Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200 (Fed. Cir. 1991); *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985).

15 *See Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure* (Apr. 28, 1977), 32 U.S.T. 1241 [hereinafter *Budapest Treaty*].

16 Brandi L. Wickline, Note, *The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions*, 24 Vand. J. Transnatl. L. 793,

have patented processes and mixtures using microorganisms that are readily available to the scientific community.[17] As the biotech field became more advanced in the 1940s and 1950s, researchers began to create and patent artificially modified strains of microorganisms and processes for making, and using, those microorganisms.[18] Since artificially created microorganisms often could not be produced without undue experimentation, patent applicants found it difficult to meet the enablement and/or best mode requirements of a particular country's patent laws.[19] Presuming the approval of patent offices and courts, biotechnology inventors began depositing samples of the microorganisms disclosed in their patent applications with a

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796 (1991). *See also* U.S. Patent No. 141,072 issued to Pasteur (Jul. 22, 1873) (patented a biologically pure yeast culture as a new article of manufacture).

17 John E. Schneider, Note, *Microorganisms and the Patent Office: To Deposit or Not To Deposit, That is the Question*, 52 Fordham L. Rev. 592, 595 (1984). *See also* U.S. Patent No. 4,155,811 issued to Nubel (May 22, 1979) (patented a process for producing citric acid by fermenting a yeast belonging to the genus Candida); U.S. Patent No. 3,627,641 issued to Mancy (Dec. 14, 1971) (patented a process for producing an antibiotic by fermentation using two strains of Streptomyces venezuelae); U.S. Patent No. 1,260,899 issued to Harris (Mar. 26, 1918) (patented a process using lactic acid bacillus mixed with inert material); U.S. Patent No. 952,418 issued to Collett (Mar. 15, 1910) (bacteria mixed with cocoa).

18 Schneider, *supra* n. 17, at 595-596. Researchers produced the artificially modified strains to improve antibiotic technology.

The following patents are examples of patents related to non-naturally occurring microorganisms: U.S. Patent No. 4,259,444 issued to Chakrabarty (Mar. 31, 1981) (patented a genetically engineered microorganism having multiple compatible degradative energy-generating plasmids from bacteria of the genus Pseudomonas and the preparation thereof); U.S. Patent No. 4,108,724 issued to Nara (Aug. 22, 1978) (patented an antibiotic prepared using artificially modified strains of Pseudomonas fluorescens); U.S. Patent No. 3,986,928 issued to Marconi (Oct. 19, 1976) (patented an antibiotic complex produced by culturing a novel strain of Pyrenochaeta sp. NRRL 5786 under submerged aerobic fermentation conditions).

Genetic engineering became a practical tool for microbiologists in 1973 when Herbert Boyer and Stanley Cohen revealed a simple technique for splicing genetic material from two different organisms and reinserting the laboratory-made combination of genes into a bacterium. *See, e.g.,* Elizabeth R. Hall & T. Ling Chwang, *Deposit Requirements for Biological Materials*, 14 Hous. J. Intl. L. 565, 569 (1992).

19 Wickline, *supra* n. 16, at 796. For example, United States law requires that the specification describe the invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the invention. The specifications must also provide the best mode contemplated by the inventor of carrying out the invention. *See also* 35 U.S.C. § 112 (1994 & Supp. 2001).

recognized culture depository.[20] The practice of depositing microorganisms gained worldwide acceptance soon after the German Federal Patent Court found the practice to be an appropriate means of satisfying the enablement requirement in 1967.[21]

The United States Court of Customs and Patent Appeals ("CCPA")[22] first approved depositing microorganisms as a means to meet the enablement requirement of 35 U.S.C. § 112 in 1970, with the *In re Argoudelis* decision.[23] There, the applicant could not sufficiently disclose in writing how to obtain from nature the microorganism required for the invention, but deposited the microorganism with a public depository.[24] The CCPA found the written description, which included the name of the public depository when filed, was sufficiently enabling to a person of skill in the art.[25] The CCPA pointed out that the deposited material did not have to be made available to the general public prior to the grant of the patent.[26] Moreover, the disclosure was found to be sufficient to permit a thorough examination by the USPTO because the applicant had ensured access to the deposit after the application was filed.[27]

In *In re Lundak*,[28] the United States Court of Appeals for the Federal Circuit ("CAFC") followed the *Argoudelis* precedent by holding that the applicant's failure to place the biological deposit at a recognized depository until seven days after filing did not violate 35 U.S.C. § 112.[29] By depositing the biological material with colleagues at a university laboratory prior to filing, the USPTO was assured of access to the material during the patent application's pendency.[30] The CAFC also held that the applicant's post-filing

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20 Wickline, *supra* n. 16, at 796-97. The American Type Culture Collection ("ATCC") was the first depository to receive a deposit of biological material from an inventor for the purposes of satisfying the patent disclosure requirement. *See* David J. Weitz, *The Biological Deposit Requirement: A Means of Assuring Adequate Disclosure*, 8 High Tech. 275, 281 (1993).

21 Wickline, *supra* n. 16, at 798.

22 The CCPA is one of the predecessor courts to the United State Court of Appeals for the Federal Circuit ("CAFC").

23 *In re Argoudelis,* 434 F.2d 1390, 1393 (C.C.P.A. 1970).

24 *Id.* at 1392.

25 *Id.* at 1393.

26 *Id.* at 1392.

27 *Id.* at 1393.

28 773 F.2d 1216, 1222 (Fed. Cir. 1985).

29 *Id.*

30 *Id.*

addition of the depository data into the specification did not constitute new matter under 35 U.S.C. § 132.[31]

The CAFC addressed the best mode requirement of 35 U.S.C. § 112, as it applies to biological material, in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*[32] In *Amgen*, the CAFC held that if the best mode of the biological material can be prepared without undue experimentation based on the description in the specification, a deposit is not required.[33] The CAFC, therefore, found a deposit of the biological material is not required for a microorganism when the best mode of creating a microorganism is to insert genetic material into a cell obtained from generally available sources.[34] When, however, the best mode of the invention is incapable of being practiced by one skilled in the art without access to the biological material, the deposit is required.[35]

B. The Budapest Treaty

The Budapest Treaty was adopted by the Budapest Diplomatic Conference on April 28, 1977, and entered into force on August 19, 1980.[36] As of February 1, 2001, 49 countries, known as "Contracting States," had signed the Budapest Treaty.[37] Prior to the Budapest Treaty, biotechnology inventors engaged in the costly practice of depositing biological material in every country patent protection was sought.[38] With the Budapest Treaty, this multi-country deposit practice is eliminated.[39]

The Budapest Treaty requires Contracting States to recognize the deposit of a microorganism with any international depositary authority, regardless of the location of the authority.[40] A "depositary institution" is defined as an institution that provides for the receipt, acceptance, and storage

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31 *Id.* at 1223. Section 132 prohibits adding new matter to the disclosure of the invention after filing. *See* 35 U.S.C. § 132 (1994 & Supp. 2001).

32 927 F.2d 1200 (Fed. Cir. 1989).

33 *Id.* at 1211.

34 *Id.*

35 *Id.*

36 *See Budapest Treaty*, *supra* n. 15, 32 U.S.T. at 1241.

37 *See Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure: Note by the International Bureau*, U.N. WIPO, UN Doc. WO/INF/12 Rev. 8 (2001).

38 *Id.* at 2.

39 *Id.* at 4-5.

40 *See Budapest Treaty*, *supra* note 15, at art. 3(1)(a), 32 U.S.T. at 1244.

of microorganisms, and the furnishing of samples of the microorganisms.[41] A depositary institution capable of storing microorganisms can acquire the status of an international depositary authority when the Contracting State in which it is located makes assurances that the institution will comply with certain requirements set forth in the Budapest Treaty.[42] Included in these requirements are: the authority must issue a receipt to the depositor,[43] and must furnish samples of any deposited microorganism to anyone entitled to such samples.[44] The depositary authority may release samples to any industrial property office of a Contracting State that requires samples for patent procedure purposes, the depositor, and anyone authorized by the depositor.[45]

During the Budapest Diplomatic Conference, a majority of the Contracting States agreed that no country should be required to change its national laws to accommodate special interest groups who desired more uniform laws relating to biological deposits.[46] Consequently, in addition to the previously mentioned parties, the Budapest Treaty permits other parties to obtain samples upon presenting a form to the depositary authority in which the industrial property office of that party's state has certified the party has a right to a sample under the laws of that state.[47] Thus, while the

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41 *See id.* at art. 2(vii), 32 U.S.T. at 1244.

42 *See id.* at art. 7(1)(a), 32 U.S.T. at 1246.

43 *See id.* at art. 6(2)(vi), 32 U.S.T. at 1245.

44 *See id.* at art. 6(2)(viii), 32 U.S.T. at 1245.

45 *Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, Apr. 28, 1977, WIPO Pub. No. 277(E), Rules 11.1-11.2 [hereinafter *Regulations*].

46 Joseph Straus & Rainer Moufang, Deposit and Release of Biological Material for the Purposes of Patent Procedure: Industrial and Tangible Property Issues 43 (Anthony Rich Trans., 1990). The Summary Minutes of the Main Committee of the Budapest Diplomatic Conference states that the Contracting States should not be obliged to change the rules of its national law in order to be able to ratify the Treaty. *See Records of the Budapest Diplomatic Conference; for the Conclusion of a Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, U.N. WIPO, at 360, WIPO Doc. 332 (E) (1980).

47 *Regulations*, *supra* n. 45, Rule 11.3. Rule 11.3(a) states:

> 11.3 Furnishing of Samples to Parties Legally Entitled
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> (a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as "the certified party"), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

Budapest Treaty regulates the procedures for the deposit and release of samples of biological deposits, it has minimal influence on the substantive laws of each Contracting State.

C. Current United States Law

The USPTO has prescribed guidelines relating to deposits of biological material,[48] thereby ensuring that biotechnology inventors filing applications in the United States are aware of how to meet the enablement and best mode requirements of 35 U.S.C. § 112. According to 37 C.F.R. § 1.801, the term "biological material" includes "material that is capable of self-replication either directly or indirectly."[49] As specified in 37 C.F.R. § 1.802, the "[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public or can be made or isolated without undue experimentation."[50]

Although the deposit need not be made before the filing of a patent application, 37 C.F.R. § 1.809 indicates that if the patent examiner determines a deposit is needed and has not been made, the claims must be rejected

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> (i) that an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
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> (ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;
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> (iii) either that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.

Id.

48 *See* 37 C.F.R. § 1.800 *et. seq*. (2000).

49 *Id.* at § 1.801.

50 *Id.* at § 1.802.

under 35 U.S.C. § 112.[51] Unless the applicant subsequently submits the deposit to an appropriate depository during pendency of the application, or convinces the USPTO that no deposit is required, the patent application will be abandoned.[52] Acceptable depositories according to 37 C.F.R. § 1.803 include any International Depositary Authority established under the Budapest Treaty or any other depository recognized as being suitable by the USPTO.[53]

Prior to the enactment of the AIPA, the United States refused to make patent applications accessible to the public before the grant of the patent.[54] The first publication of a patent application in the United States was, therefore, the publication of the actual patent once patent protection was granted. Accordingly, samples of a biological deposit were not available in the United States to the public until issuance of the patent. AIPA changes this practice by requiring the publication of applications after 18 months, subject to some exceptions.[55] The USPTO is expected to make additional guidelines and amendments to the present guidelines in response to the 18 month publication requirement of the Act. One of the most important issues the USPTO will face in promulgating the guidelines is whether to release biological deposit samples to third parties upon publication of the application, or wait until after the patent issues.

III. TIMING OF RELEASE OF BIOLOGICAL DEPOSIT IN AN 18 MONTH PUBLICATION SYSTEM

In the 1960's the number of inventors seeking patents increased dramatically.[56] Consequently, the period of examination of patent applications filed in various patent offices in Europe increased to, on average, several years because those offices were unprepared for the rapid growth in filings.[57] As a consequence, inventors had to make commercial decisions in a state of uncertainty as to whether they might eventually infringe rights

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51 *See id.* at § 1.809(a).

52 *See id.* at § 1.809(c).

53 *See id.* at § 1.803(a).

54 An exception to this rule allowed third parties to access abandoned applications cited in issued patents. *See* 37 C.F.R. § 1.14(a)(2) (2000).

55 *See* AIPA, *supra* n. 1, at § 4502 (codified as amended at 35 U.S.C. § 122(b) (1994 & Supp. 2001)).

56 Wickline, *supra* n. 16, at 808.

57 *Id.*

protected by an ensuing patent.[58] Inventors desiring to make competing inventions were deterred from doing so because they feared that their time and money would be wasted if they later infringed a then-pending patent.[59] In hopes of eliminating this uncertainty, European states developed the practice of "laying open an invention," i.e., early publication of the patent application before the patent is granted.[60] In 1961, the Netherlands became the first state to engage in early publication.[61] Other states, such as Sweden and the Federal Republic of Germany, shortly followed.[62]

Early publication of patent applications is now common practice throughout the world, as evidenced by its inclusion in the AIPA.[63] However, regional and national patent procedures continue to differ as to when biological deposits are made available to third parties.[64] For example, two of the most prominent patent systems in the world differ in that the European Patent Convention ("EPC") releases samples of a biological deposit before a patent is granted, while the Japanese patent system releases those samples only after a patent has issued.[65] An analysis of the underlying rationales for the EPC and Japanese release requirements may be used in conjunction with United States policy to determine how the United States should approach biological deposit releases.

A. The European Patent Convention

1. Development of the Release Requirement

The Convention on the Grant of European Patents was adopted by several European states at Munich in 1973, and entered into force on October 7, 1977.[66] The EPC established a uniform patent system in Europe that

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58 *Id.*

59 *Id.*

60 *Id.* at 808-09.

61 *Id.*

62 *Id.*

63 *See* AIPA, *supra* n. 1, at § 4502, 113 Stat. 1501A-561 (codified as amended at 35 U.S.C. § 122 (1994 & Supp. 2001)).

64 *See, e.g.*, Straus & Moufang, *supra* n. 46, at 42.

65 *Id.* at 42.

66 Joseph Greenwald & Charles Levy, *Protection of Intellectual Property Rights: Convention on the Grant of European Patents (European Patent Convention)*, 1 Basic Documents of Int'l Econ. L. 983 (1994). Austria, Belgium, Cyprus, Denmark, Finland,

permits a patent applicant to obtain patent protection in all the member states with a single application filed with the European Patent Office ("EPO").[67] The EPO performs one centralized search and examination to determine whether to grant a European patent.[68]

From the beginning, the Implementing Regulations of the EPC recognized the need for biological deposits to ensure that inventions are sufficiently disclosed for them to be carried out by a person skilled in the art.[69] Rule 28 of the Implementing Regulations of the EPC as originally drafted required a microorganism deposited with a recognized culture collection agency whenever the microorganism cannot be adequately described to enable a person skilled in the art to carry out the invention.[70] During the negotiations of the Main Committee at the Munich Diplomatic Conference, the committee members generally agreed that deposits should be made no later than the filing date of the application.[71] However, they expressed different views on the latest time at which the applicant should make samples available to third parties.[72]

The French delegation proposed that third parties should not be allowed to obtain samples of the deposited material until the grant of the patent.[73] Otherwise, it was argued, biotechnology inventors would be treated unfairly in comparison with inventors in other technological fields.[74] Furthermore, an early release of the sample would make it easier for others to

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France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, the Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey, and the United Kingdom are currently members of the EPC. *See Accession to the EPC*, *available online at* <http://www.european-patent-office.org/news/pressrel/2000_08_29_e.htm> (accessed Mar. 28, 2002).

67 *See* Greenwald & Levy, *supra* n. 66.

68 *Id.* Note, however, that there is not truly a European patent yet because enforcement of patents is still on a national basis. *See id.*

69 Straus & Moufang, *supra* n. 46, at 69. *See Convention on the Grant of European Patents*, Oct. 5, 1973, art. 83.

70 Straus & Moufang, *supra* n. 46, at 69.

71 Paul Braendli, *Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents: Report on the Discussions and Decisions of Main Committee I*, 4 IIC 402, 407 (1973) (noting that this is a translation from the original German text of Conference Document M/148/G).

72 *Id.*

73 *Id.*

74 *Id.*

copy the invention at a time when the applicant was not assured of receiving patent protection.[75]

In opposition to the French proposal, the delegation from the Federal Republic of Germany sought to make deposited material available to the public no later than the publication date of the European patent application.[76] Advocates of this position argued that the public could be sufficiently informed of the subject matter of the invention only if it had access to the deposited material.[77] They further argued that the microorganism could constitute the state of the art only if made available to third parties at the time of laying open the application.[78] Ultimately, the German delegation perceived public availability of the deposited material as the only means to prevent double patenting and to remove the legal uncertainty of national patent applications.[79]

The results of the vote of the Main Committee were six votes in favor of the French proposal and nine against.[80] Rule 28, as adopted by the Main Committee, requires deposited material be made available on or before the publication date.[81] It also gave the applicant guarantees against misuse of the deposited material.[82] For example, any third party provided with a sample of the microorganism had to agree to only use the sample for experimental purposes until the patent is refused, withdrawn, or granted.[83] Rule 28 also requires the EPO and the patent applicant to identify any person requesting a sample of the deposited material.[84]

Believing that Rule 28 would not adequately safeguard the interests of inventors, patent experts working in the biotechnology industry formed an informal group known as "MICROPAT."[85] The group drafted proposals for amendments and additions to Rule 28 in 1977, then submitted the proposals

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75 *Id.*

76 *Id.*

77 *Id.*

78 *Id.*

79 *Id.*

80 Straus & Moufang, *supra* n. 46, at 71.

81 Braendli, *supra* n. 71, at 407.

82 *Id.*

83 Straus & Moufang, *supra* n. 46, at 72.

84 *Id.*

85 Albrecht Hüni, *The Disclosure in Patent Applications for Microbiological Inventions*, 8 IIC 499, 500 (1977). Hüni was a leading member of MICROPAT. *See* R. Stephen Crespi, *The Micro-Organism Deposit System in European Patent Law – An Appraisal of Current Proposals*, 24 IIC 1, 4 (1993).

to the EPO.[86] Among the proposals, MICROPAT suggested that the depositor should be allowed to withdraw the deposit in the event he discovers it to be unnecessary for adequate disclosure.[87] MICROPAT also proposed limiting the use of the deposit by third parties to experimental purposes, and restricting the availability of the deposit to residents of the states requiring the deposit.[88]

Probably the most significant proposal presented by MICROPAT was the so-called "independent expert solution."[89] This proposal called for limiting the release of the deposit to an independent expert residing in the state the deposit was made during the period between application publication and patent issuance.[90] The independent expert would be nominated jointly by the depositor and the requester of the sample; or if no agreement could be reached, the President of the EPO would nominate the independent expert.[91] Of these particular MICROPAT proposals, the Administrative Council of the EPO, in 1980, adopted only the independent expert solution (with the exception that the expert could reside in any state).[92]

2. Current Release Requirement Stemming from the Proposed EC Directive

With the intent of creating a uniform, single market in the European Community, the Commission of the European Communities ("EC Commission") issued a proposed directive related to the legal protection of biotechnological inventions in 1988.[93] While some of the EPC member states, e.g., the United Kingdom, France, and Denmark, had modified their national patent laws to be consistent with Rule 28, other states, such as the Federal Republic of Germany, had refused to adopt the independent expert solution.[94]

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86 Crespi, *supra* n. 85, at 4.

87 *Id.*

88 *Id.* at 4-5.

89 *Id.* at 5.

90 *Id.*

91 *Id.*

92 *Id.*

93 *European Commission Proposal for a Directive on the Legal Protection of Biotechnological Inventions*, 1989 O.J. (C 10) 3 [hereinafter *European Commission Proposal*]. *See* Straus & Moufang, *supra* n. 46, at 86.

94 Straus & Moufang, *supra* n. 46, at 85-86.

Therefore, the EC Commission drafted the proposal to eliminate existing discrepancies in the national laws of EPC member states.[95]

In an attempt to more fairly balance the interests between the patent applicant and the general public, Article 15 of the Commission's proposal contained additional provisions not included in Rule 28.[96] Focusing on the purpose of the early publication system (to inform the public of technology that would likely be protected by future patent rights), one provision required closing off the availability of deposited material to experts and third parties if an application is refused or withdrawn.[97] The EPO found this provision unacceptable because of its incompatibility with the "generally accepted doctrine that whatever has become state of the art must forever remain so."[98] Consequently, the Commission amended this provision in September 1990 to state that in the event an application is refused or a patent is revoked, only an independent expert would be allowed access to the deposit.[99]

The EC Commission's proposed directive also required a person requesting a sample of the deposit to agree to use the sample only for experimental purposes.[100] This restriction on use would only be relinquished in states that eventually grant the applicant patent rights.[101] The proposed directive further provided that the requester must not make the sample available to third parties.[102] Another provision extended the concept of using the biological deposit to support the invention disclosure to all inventions using self-replicating material.[103]

Subsequent revisions of the proposed EC Commission directive gave rise to the current version of the directive, which the European Parliament and Council of the European Union adopted on July 6, 1998.[104] Following

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95 *Id.* at 86.

96 *European Commission Proposal*, *supra* n. 93, art. 15. *See* Straus & Moufang, *supra* n. 46, at 86.

97 *European Commission Proposal*, *supra* n. 93, art. 15. *See* Straus & Moufang, *supra* n. 46, at 87.

98 Crespi, *supra* n. 85, at 11.

99 *Id.* at 12.

100 *European Commission Proposal*, *supra* n. 93, art. 15.

101 *Id.*

102 *Id.*

103 *Id.*

104 *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, art. 13, 2 O.J. EPO 101, 116-18 (1999) for the provisions pertaining to the deposit, access, and re-deposit of biological material. The Directive requires members of the European Union to amend their national patent laws to correspond with the Directive by July 30, 2000. *See Notice dated 1 July 1999*

this adoption, the Administrative Council amended the EPC to incorporate the provisions of the EC Commission directive related to the access of biological deposits.[105] In its present form, Rule 28 makes deposited biological material available to anyone from the publication date of the patent application.[106] The sample requester, however, must guarantee the applicant, before the sample is released, that the biological material sampled will not be released to any other party.[107] The requester must also agree to limit the use of the material to experimental research until such time that the patent application is refused or withdrawn, or until the expiration of the patent in the European state it expires in last.[108] The applicant may waive the requirement that the requester take these precautions.[109]

Alternatively, the applicant may rely on the independent expert solution and inform the EPO that samples of the biological material should only be issued to an expert nominated by the requester until the patent is granted, or for twenty years from the filing date if the application fails to issue as a patent.[110] A person cannot be nominated as an independent expert unless he receives applicant approval, or is recognized as an expert by the President of the EPO.[111] A declaration by the nominated expert agreeing to the same restrictions placed on the requester's use of the sample must accompany the nomination.[112] Therefore, the independent expert solution still remains an important aspect of the requirements of Rule 28, as it pertains to the release of biological deposit samples.[113]

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concerning the amendment of the Implementing Regulations to the European Patent Convention, 8-9 O.J. EPO 1999, 573, 573.

105 *Id.*

106 *See Implementing Regulations to the Convention on the Grant of European Patents*, Oct. 5, 1973, Rule 28(3), *as amended by Decision of the Administrative Council of the European Patent Organization of Oct. 11, 2000*, *available online at* <http://www.european-patent-office.org/legal/epc/e/ma2.html> (accessed Mar. 28, 2002) [hereinafter *Implementing Regulations*].

107 *See id*.

108 *See id*.

109 *See id*.

110 *See id*. at Rule 28(4).

111 *See id.* at Rule 28(5).

112 *See id*.

113 Controversy relating to the EC Directive continues, and the Netherlands has begun a lawsuit challenging the validity of the EC Directive, claiming in part that the EC Directive conflicts with international agreements. *See* Patrick Farrant & Vicki Salmon, *Netherlands Seeks End to EU Biotech Directive*, IP Worldwide, July/Aug. 1999, at 3.

B. Japanese Patent Law

The provisions of Japanese patent law addressing the deposit of microorganisms and furnishing samples of microorganisms are Articles 27bis and 27ter, respectively.[114] In contrast to the provisions of the EPC, Article 27ter generally does not permit samples of the deposited material to be released to third parties until the patent is first granted in Japan.[115]

However, samples of the deposited material may be released to third parties before the patent is granted under certain circumstances.[116] One such circumstance occurs when a person is issued an infringement warning by the patent applicant and is then given approval to access a biological deposit.[117] Additionally, a sample may be furnished to a person requiring it to adequately respond to the Japanese Patent Office during the prosecution of another patent application.[118] This situation may arise, for example, when a patent applicant needs to respond to a rejection of their application in light of another application referring to the biological deposit.[119]

Once a patent is granted, samples of deposited material may only be released to a person who agrees to limit his use of the material to testing and experimentation.[120] A person furnished with such a sample is also prohibited from making the sample available to third parties.[121] Currently, a debate is ongoing concerning whether people may be furnished a sample of a sample of biological material for purposes other than experimentation after the expiration of the patent term.[122] And, finally, a distinguishing feature of the Japanese system is that the applicant can withdraw the deposit if the application is withdrawn, rejected, or the patent term has expired.[123]

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114 *Research and Study on the Ideal of the Depository System Pertaining to Patent Applications of Bio-Related Inventions*, 8 IIP Bulletin 68, 68 (1999) [hereinafter *Ideal Depositary System*].

115 *Id.* at 70.

116 *Id. See* Thomas D. Denberg & Ellen P. Winner, *Requirements for Deposits of Biological Materials for Patents Worldwide*, 68 Denv. U. L. Rev. 229, 240 (1991).

117 *Ideal Depositary System*, *supra* n. 114, at 70.

118 *Id.*

119 *Id.*

120 *Id.*

121 *Id.*

122 *Id.*

123 *Id.*

The current Japanese system demonstrates a strong desire to protect the rights of inventors.[124] Supporters of the current system fear that the risk of patent infringement would increase if the public were given access to the deposited material too early.[125] To these supporters, a patent applicant's right to claim compensation from a person who commercially uses the invention after the initial publication of the patent application is insufficient, from the applicant's viewpoint, to warrant the release of deposited material.[126]

IV. PROPOSAL FOR THE RELEASE REQUIREMENT OF THE UNITED STATES

Determining the proper time that the United States should release biological deposits requires weighing the burden early release would place on the inventor against the advantages it would give to society. Accordingly, the following analysis of the appropriate timing for the release of the biological deposits takes into account the different interests of the biotechnology inventor and the government. The following analysis also considers the need for international harmonization of patent laws.

A. Problems Associated with the Early Release of the Biological Deposit

Releasing biological deposits to third parties before patent protection is granted creates several problems for biotechnology inventors and the biotechnology industry in the United States. A biological deposit may be considered tangible property owned by the patent applicant, which are protected by the Fifth Amendment of the Constitution.[127] By placing a biological deposit in the hands of the public before the patent is granted, applicants essentially give up tangible property rights before gaining intellectual property right protection. Non-biotechnology inventors, conversely, are only required to disclose how to make and use their inventions; these inventors are not required to supply the inventions or the means of making the inventions to the public.[128] As the foregoing illustrates,

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124 *Id.* at 71.

125 *Id.*

126 *Id.*

127 *See* U.S. Const. amend. V. *See Biotechnological Inventions: A Position Paper of the International Chamber of Commerce*, 18 IIC 223, 231(1987) [hereinafter *Biotechnological Inventions*].

128 *Biotechnology Inventions, supra* n. 127, at 231.

biotechnology inventors do not receive equal treatment compared to inventors in other areas of technology.[129]

Once the biological deposit becomes publicly accessible, the applicant loses the option of protecting the biological material through trade secret law.[130] Biotechnology applicants, therefore, face a risk that their patents will be rejected after the deposit is released, leaving them without patent protection and no recourse in trade secret protection.[131] Consequently, the inventor's time and effort spent creating a new microorganism or isolating a gene may not be rewarded with a patent and, even worse, may undesirably place others in a better position to compete with the inventor due to the release of the biological material.

Even if a patent subsequently issues, the potential for infringing the patent during the pendency of the application is great. Having access to both the deposited biological material and a copy of the patent application, an applicant's competitor can easily reproduce the applicant's invention. Furthermore, because an applicant's provisional right to a reasonable royalty from an infringer during this period fails to vest until the patent is granted,[132] the royalty they may later receive cannot be used to gain an advantage over competitors. The inability of applicants to enjoin the infringer before the patent is granted prevents applicants from obtaining the advantage in the marketing of their product that they would have had if their product had been released without any competition. The absence of such competition could have allowed an applicant's brand to gain recognition and develop a good reputation. Unfortunately, consumers of products such as pharmaceuticals may come to recognize the infringer's brand more so than the applicant's brand. As such, the profit potential of an applicant's brand would be reduced even if an injunction were later obtained. Similarly, biotechnology researchers may associate the invention with the infringer rather than an applicant, resulting in the loss of an applicant's ability to license his contributions to the biotechnology industry.

Another risk posed to an applicant is that a biological deposit sample may fall into the hands of a competitor in a country where an applicant, for various reasons, will not receive patent protection.[133] For example, the high

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129 *Id.*

130 Chisum, *supra* n. 5, at 440.

131 *Id.*

132 *See* AIPA, *supra* n. 1, at § 4504 (codified as amended at 35 U.S.C. § 154 (1994 & Supp. 2001)).

133 The EC Commission recognized this problem when it proposed requiring the requester of the deposit to agree to only use the deposit for experimental purposes and to not give the deposit to other parties. Straus & Moufang, *supra* note 46, at 89.

cost of filing patent applications leaves most applicants with no alternative but to limit the number of countries in which they file. Moreover, some European states, particularly underdeveloped states, do not have a patent system, while other states refuse to grant patents for biological material or processes incorporating such material. Once a competitor gains access to the biological deposit in one of these states, he will most likely be able to reproduce the biological material and thereby practice an applicant's invention. The competitor might then take commercial advantage of an applicant's invention, or the competitor could circumvent the patent by genetically modifying the microorganism sampled.[134]

To avoid such risks, a biotechnology inventor may feel compelled to abandon the patent application before the biological deposit is released to third parties, i.e., before the publication of the patent application.[135] The incentive to abandon the patent application would be especially strong for applicants finding it difficult to convince the USPTO that their inventions are patentable. Due to the large volume of patent applications pending before the USPTO, an applicant may have received only one Official Action from the USPTO when faced with the decision of whether to abandon the application. At this stage in prosecuting the patent, an applicant will most likely not have enough knowledge to make such a crucial decision. Despite the possibility of obtaining a patent, an applicant may decide to abandon the application and decide that trade secret protection is a better choice, thus ensuring that his competitor will not be able to access his biological material.

B. The Most Suitable Release Requirement for the United States

1. Promoting Innovation in the United States

Despite the risks, releasing biological samples upon patent publication is the best route for the United States to take. The Framers of the United States Constitution recognized the necessity of the patent system when it gave Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[136] The primary purpose of this clause is to encourage people to invent and make advances in

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134 Crespi, *supra* n. 85, at 3.

135 Chisum, *supra* n. 5, at 440.

136 *See* U.S. Const. art. I, § 8, cl. 8.

technology. To achieve this purpose, the government gives limited monopolies to inventors of useful, novel, and non-obvious inventions in exchange for a detailed disclosure of how to make and use the invention. The patent system, therefore, encourages disclosure of inventions to the public, which in turn promotes further innovation based on such inventions.

Making the biological deposit available to third parties 18 months after the earliest application filing date advances the goal of the Patent Clause by enabling third parties to improve on the technology disclosed in the application. The 18 month period gives applicants a head start in making improvements to their invention, while at the same time encouraging others to modify the invention to solve new problems. Applicants, therefore, do not contemporaneously receive a patent in exchange for the disclosure of the invention, but receive the right to make a claim for a reasonable royalty against any party infringing the application during its pendency.[137]

Not releasing the biological deposit at the same time the application is published would defeat the purpose of early publication. As stated in the legislative history of the AIPA, Congress's intent in requiring early publication of patent applications filed abroad was to permit American inventors to have access to technology of foreign competitors at a much earlier date.[138] It follows, then, that an application that relies on a biological deposit to adequately disclose the invention necessarily requires the release of the biological deposit to stimulate further innovation from the application's publication. Supporting this argument, opponents of the current Japanese procedure of releasing the deposit upon grant of a patent fear that a third party will not be able to carry out the invention without the deposit, even after the application has been publicly disclosed.[139]

In 1995, the USPTO requested comments concerning the 18 month publication proposal, which included a question relating to whether the deposit of biological material should be accessible to the public.[140] The majority of the comments received by the USPTO supported making such deposits available to the public upon publication of the patent application.[141]

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137 *See* AIPA, *supra* n. 1, at § 4504 (codified as amended at 35 U.S.C. § 154(d)(1) (1994 & Supp. 2001) (the patent applicant only receives this right if the application actually issues as a patent and the claims of the application and the patent are substantially the same)).

138 *See* H.R. 287, 106th Cong. (1999).

139 *Research and Study on the Ideal of the Depository System Pertaining to Patent Applications of Bio-Related Inventions*, 8 IIP Bull. 68, 71 (1999).

140 *Changes to Implement 18-Month Publication of Patent Applications*, 60 Fed. Reg. 42352, 42358 (1995) (proposed Aug. 15, 1995).

141 *Id.*

Several comments advocated that access to the deposits should be limited in the same manner as they are limited in Europe or Japan, or that access should be limited to experimental use.[142]

The USPTO subsequently held public hearings concerning the proposed 18 month publication of patent applications. A representative for the Alliance for American Innovation, representing over 3,000 independent and small business inventors, favored the early release of deposits of biological material.[143] Conversely, only one independent inventor appeared to oppose making deposits publicly accessible.[144] These comments indicate that inventors may be willing to have their biological deposits released to third parties despite the dangers the release would pose. Biotechnology inventors most likely realized that accessibility to other inventors' biological deposits will give them the building blocks they need to make further advances in the biotechnology field. If applications are abandoned prior to publication to maintain trade secret protection, however, this will serve to stifle the innovation the AIPA is meant to promote.

2. Promoting International Harmonization

Making samples of the biological deposit accessible to third parties will serve to harmonize the United States deposit system with the deposit system of the EPC.[145] The need for harmonization became apparent in the late 1980's in decisions of the EPO Technical Board of Appeal, e.g., case T 0039/88.[146] In that case, the patent applicant appealed a decision of the Examining Division concerning a European patent application filed on October 25, 1983, which claimed priority from a United States application filed on November 18, 1982.[147] The Examining Division refused the application, finding that one of the claims pertained to a microorganism not

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142 *Id.*

143 Before The United States Department of Commerce Patent and Trademark Office In RE: Public Hearing and Request for Public Comment on Issues Associated with Implementation of Eighteen-Month Publication of Patent Applications (1995), *available online at* <http://www.uspto.gov/web/offices/com/hearings/18month/hearings/transcript.html> (providing statement of Mr. Litzsinger, Vice President of the Alliance for American Innovation) (accessed on January 22, 2002).

144 *Id.* (providing statement of Mr. Riley).

145 *Implementing Regulations to the Convention on the Grant of European Patents*, Oct. 5, 1973, Rule 28.

146 Case T 0039/88, OJ EPO 499 (1989).

147 *Id.* at 499.

sufficiently described in the application, and that it was uncertain whether the microorganism had been deposited in accordance with Rule 28(3) EPC.[148]

When the European patent application was published on June 27, 1984, the corresponding application in the United States remained pending; the United States patent did not issue until June 4, 1985.[149] The Board found that while the deposit had been made with a recognized International Depositary Authority in the United States, the applicant had failed to accompany the deposit with a written statement indicating that the deposit was made under the Budapest Treaty or under Rule 28 EPC.[150] Therefore, during the gap in time between the European publication and the United States publication, there was no legal guarantee that the deposit requirement for the microorganisms was fulfilled by making samples available on the date of publication of the European patent application.[151] The fact that the applicant could consent to any requests for samples did not satisfy the legal guarantee, as one purpose of Rule 28 EPC is to remove the need for such consent.[152]

In its decision, the Board made a concession and determined that it would be unfair to punish the applicant for the deposit system's lack of clarity when the applicant filed the European application.[153] The Board mentioned that the deposit system under Rule 28 EPC was not clarified until much later.[154] In 1986, the EPO published a notice explaining the proper manner to bring a deposit filed for other purposes in line with EPC requirements: convert the deposit into a deposit under Rule 28 EPC, or under the Budapest Treaty, no later than the European filing date.[155]

The problems faced by the Board resulting from inconsistencies between the United States and the EPC deposit systems may be resolved by releasing deposits in the United States at the date of publication in the United States. Applicants that do not want to have their deposits released can agree not to file a patent application in a foreign country on the same subject matter as filed in the United States.[156] This declaration already serves to

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148 *Id.*

149 *Id.*

150 *Id.*

151 *Id.*

152 *Id.*

153 *Id*.

154 *Id.*

155 *Id.*

156 *See* AIPA, *supra* n. 1, at § 4502 (codified as amended at 35 U.S.C. § 122(b)(2)(B)(i) (1994 & Supp. 2001)).

prevent publication of a United States patent application. [157] Accordingly, harmonization would be achieved between the EPC and United States patent laws in critical situations where patent applications are filed in both the United States and in Europe.

In addition to achieving harmonization between the United States and EPC deposit systems, there is a strong need to harmonize patent laws worldwide. Because of the pressing need to achieve uniformity in their patent systems, the EPO, the Japanese Patent Office ("JPO"), and the USPTO have held a Trilateral Conference annually since 1983.[158] In their exchange of information and views regarding patent administration and patent examination practice, each organization has come to realize that globalization of industry and trade will create a need for a worldwide system for granting patents.[159]

Consequently, the United States should not only change its patent laws to provide for early release of biological deposits, but should also attempt to persuade Japan to do the same. The primary goal of the Japanese patent system is to promote national technological development to fulfill Japan's worldwide economic goals.[160] A modification of Japanese law to make biological deposits publicly accessible upon publication of Japanese patent applications would be consistent with the purposes of the Japanese patent system. Making otherwise non-reproducible microorganisms described in a published Japanese patent application available to third parties would promote technological innovation in Japan, assuming that inventors do not choose trade secret protection over patent protection.

By harmonizing the timing of the release of biological deposits in Japan, Europe, and the United States, the world would be one step closer to having a worldwide patent system. An international patent system where only one patent application is filed and one examination and search is performed would reduce the costs to patent applicants and the time required to grant global patent rights.

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157 *See id.*

158 *About Trilateral Cooperation* <http://uspto.gov/web/tws/gen-1.htm> (accessed Nov. 6, 2000).

159 *Id.*

160 Paul Gibbons, Note, *The Application Publication Dilemma: Should the United States Publish Patent Applications Eighteen Months After Filing to Accommodate International Patent Harmonization?*, 20 Suffolk Transnatl. L. Rev. 449, 464-65 (1997).

C. Proposed Safeguards

Although the public has a strong interest in gaining access to a biological deposit upon patent application publication, an inventor's interest in maintaining control over the biological deposit must be ensured. A proper balancing of the inventor's interest and the public's interest leads to the conclusion that safeguards are necessary to protect the inventor's property interest when a biological deposit is released before patent rights are granted.

As discussed previously, inventors have tangible property rights in biological deposits that allow them to prevent others from obtaining and using the deposit. One can argue that in exchange for receiving a patent, the inventor relinquishes this property right by making the biological deposit available to the public. However, when biological deposits are released before a patent is granted, inventors have no guarantee that they will receive patent protection. An inventor's patent application could be rejected or withdrawn subsequent to both publication and release of the biological deposit. Moreover, under the AIPA, inventors may only claim a reasonable royalty from someone who infringes the patent application while it is pending.[161] Accordingly, to help protect inventors' rights, inventors should be able to collect a reasonable fee from the person requesting a sample of the biological material during an application's pendency.

Economists would probably argue that the reasonable fee should be based on what price the applicant and the requester would have agreed to had they exchanged the biological deposit in a voluntary transaction.[162] This price would likely be the fair market value of the biological material.[163] Courts have typically determined the fair market value of property by looking at both existing and potential uses for property.[164] Likewise, the USPTO could determine the reasonable fee by analyzing the most profitable present and future uses for applicant's biological material.[165] Unfortunately, expecting the USPTO to engage in such a detailed analysis each time a biological deposit is requested would be costly and time consuming. The USPTO is currently backlogged with patent applications and should not be burdened with determining such a fee.

Alternatively, the USPTO could establish a reasonable fee system that is partially based on the length of time a requester possesses a sample of

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161 *See* AIPA, *supra* n. 1, at § 4504 (codified as amended at 35 U.S.C. § 154(d)(1) (1994 & Supp. 2001)).

162 *Richard A. Posner*, Economic Analysis of Law 11 (5th ed. 1998).

163 *Id.*

164 *See, e.g.*, *A.A. Profiles v. City of Fort Lauderdale*, 253 F.3d 576, 583 (11th Cir. 2001).

165 *Id*.

a biological deposit during the pendency of the application. A committee (e.g., examiners of biotechnology applications) could be formed to determine an initial fee. The committee could then request comments from biotechnology inventors on what amount should be charged for using deposits for a particular period of time (e.g., charge per month). After weighing all of the suggestions it receives and reviewing royalty fees that are currently being charged for biological material, the committee could finalize a reasonable fee.

The fee charged to requesters should be paid to the applicant to help further the applicant's research efforts. The applicant, who is most knowledgeable on the invention's subject matter, would then be encouraged to make further improvements with this payment. With this additional funding, the applicant would be in a better position to remain competitive with others using the biological material to conduct competing research.

A disadvantage with charging a fee for biological material samples is that third parties may be unwilling to pay for the samples, which could discourage further advances in technology. Biotechnology companies, however, will probably be the parties most interested in obtaining access to the deposited material. These companies allocate a large percentage of their profits each year to conduct research in order to remain competitive. Consequently, an additional fee for the use of a deposited biological material would not likely deter biotechnology scientists at biotechnology companies from requesting the material.

Additionally, safeguards similar to those provided by the EPC should also be considered to protect deposited material. One such safeguard that should be considered is that biological deposits be released to only a requester that agrees not to release the biological material to any other party.[166] The USPTO could include this requirement in its guidelines through use of a sworn statement, signed by the requester. Such an undertaking makes the requester accountable for the security of the deposited material, thereby reducing the possibility that the material will fall into the hands of competitors. If such a requirement were not included, a third party could obtain the biological material without paying a reasonable fee and without being subjected to the same limitations agreed to by the requester. Unfortunately, a contract may not sufficiently deter the requester from giving the biological material to third parties, especially if the requester has little money and could potentially file for bankruptcy. Congress, therefore, should consider enacting a criminal statute to penalize a requesting party if the biological material is provided to a third party in violation of the sworn statement. For example, a statute could classify an unauthorized release of

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[166] *See Implementing Regulations*, *supra* n. 106, at Rule 28(3).

biological material as theft of property, subjecting the requester to prosecution for theft.

Another EPC safeguard provides that the requester must only undertake use of the deposited material for experimental purposes until the patent application is refused or withdrawn, or until the expiration of the patent in the country in which it last expires.[167] The USPTO should also consider this safeguard, to ensure that the requester is not given the opportunity to engage in premature commercial exploitation of the applicant's deposit.

One argument against adopting the experimental use provision is that third parties should not be allowed to use the deposited material at all, much less for commercial purposes, if the patent application is refused or withdrawn. However, once the application is published, it becomes part of the prior art that is available to the public.[168] The application's status as prior art is not lost even if the application is later refused or withdrawn.[169] A third party would thus be prevented from later patenting the biological material or the invention described in the patent application because of its status as prior art.

Furthermore, limiting the applicant's control over the experimental research use of the biological material until the expiration of the last enforceable patent seems reasonable. Upon expiration, the patent becomes part of the public domain, but can only benefit society if the patent disclosure is enabling. Since the biological material is necessary for a person having ordinary skill in the art to make and use the invention, the biological deposit is necessary to fulfill the disclosure requirements of the patent application. Therefore, the biological deposit should likewise remain accessible to the public. In effect, applicants would lose their property right in the biological material, but inventors must risk this loss if they want to be awarded an exclusive monopoly for a limited number of years. The EPC allows applicants to waive requiring requesters to agree to such limitations on use,[170] and the USPTO should similarly permit an applicant to waive these requirements.

The EPC also provides an applicant with the option to release biological deposit samples only to an independent expert, nominated by the requester and approved by the applicant or the EPO president.[171] The time period requiring the use of an independent expert endures through patent

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167 *Id.*

168 *See* AIPA, *supra* n. 1, at § 4505 (codified as amended at 35 U.S.C. § 102(e)(1) (1994 & Supp. 2001)).

169 Straus & Moufang, *supra* n. 46, at 137.

170 *See Implementing Regulations*, *supra* n. 106, at Rule 28(3).

171 *See id.* at Rule 28(4).

issuance or, if no patent is issued, for twenty years from the filing date of the patent application.[172] This option limits access biological deposit requesters have to results obtained from experiments performed on the deposited material by the appointed expert.[173]

While adoption of the expert solution by the United States would increase harmonization with the EPC deposit system, it has certain drawbacks that should be considered. Parties interested in conducting experiments on deposited material may not be willing to spend the money necessary to hire an independent expert to perform the required experimentation. Because a requester would have no real control over the expert, the experimentation performed may not meet the requirements of the requester. As well, the expert may have less incentive than the requesting party to attain quick results. Although applicants would probably not approve an expert they believe would secretly infringe pending patents or engage in other illegal actions, applicants cannot be guaranteed that the expert will remain honest. These concerns serve as hindrances to disclosure and, subsequently, to further innovation. Adoption of the expert solution, therefore, would result in only a slight increase in the security provided to applicants, but could significantly discourage innovation. For these reasons, adopting the expert solution in the United States is not recommended.

The United States currently permits anyone to obtain samples of deposited biological material after the corresponding patent issues.[174] The United States appears to have taken the view that once the patent issues, non-infringing use of the deposited material is permissible. In a desire to exclude others from making or using their invention by pursuing patent protection, patent applicants will most likely continue to deposit biological material, despite the possibility that the deposit could be released to the general public if a patent is granted. Accordingly, if the United States elects to permit applicants to restrict the availability of the deposited material to an expert, this restriction should only last until the patent is granted. If no patent is granted, the applicant should be permitted to limit access of the deposited material to the expert for only a reasonable period of time. A reasonable period of time the United States could consider is the twenty-year period of access allowed by the EPC, since it is equivalent to the United States patent term. An additional safeguard could be implemented that requires the independent expert to make the same guarantees as the requester.

Other safeguards that may be considered are those proposed by MICROPAT in 1977, but not incorporated into the EPC. For example,

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172 *See id.*

173 *See id.*

174 *See* 37 C.F.R. § 1.808 (2000).

MICROPAT suggested that depositors should be permitted to withdraw the biological deposit if they later find a deposit is not required to meet EPC disclosure requirements.[175] In this situation, the benefit provided to society by the published application would not be enhanced by the release of the biological deposit. Absent the need for a deposit, applicants should not be expected to deposit their biological material. Including this safeguard in the USPTO guidelines would help ensure that applicants are treated fairly.

MICROPAT also proposed restricting the availability of the biological deposit to residents of countries where patent applications requiring the deposit are filed.[176] This proposal seeks to protect patent applicants from parties that could abuse the deposit system by using the deposited material for their commercial advantage in countries where the applicant does not pursue patent rights. While MICROPAT addressed important concerns with the proposal, the means it chose to alleviate those concerns were inappropriate. Specifically, the proposal gives residents of countries where applications are filed an unfair advantage over non-residents of those countries by denying access to non-residents.

The United States can achieve the same goal promoted by this MICROPAT proposal without engaging in disparate treatment of requesters. For example, the United States could require parties seeking access to a biological deposit to sign a sworn statement agreeing not to import samples of the biological deposit into countries where no patent protection is sought. Requesters who are residents of countries where no patent rights are sought would then have an opportunity to perform experiments but would be limited to performing those experiments in a country where an application has been filed.

V. CONCLUSION

The United States should follow the lead of the EPC, not that of Japan, by releasing biological deposits to third parties once the corresponding patent applications have been published. Two important reasons justify this conclusion. First, early release of biological deposits would encourage further innovation and technological development, thereby satisfying the goal of the patent system envisioned by the Patent Clause and the Congressional 18 month application publication requirement. Second, releasing biological deposits prior to the grant of the respective patents would reduce problems created by a lack of harmonization between the United States and

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175 Hüni, *supra* n. 85, at 514.

176 *Id.* at 513.

EPC deposit systems. Consequently, following the EPC system's lead will be a positive step in harmonizing global patent laws.

Safeguards to protect patent applicants depositing biological material should be incorporated into the USPTO guidelines. For example, the party requesting a biological deposit should be required to pay the patent applicant a reasonable fee for experimental use of the deposit during the pendency of the patent. Additionally, the applicant should be permitted to withdraw biological deposits from public availability if deposits are found not necessary to meet disclosure requirements.

Other recommended safeguards can be drawn from provisions of the EPC. One such safeguard requires the requester to agree not to make the deposit available to third parties. Another safeguard mandates that the requester guarantee that the deposit will only be used for experimental purposes until the application is refused or withdrawn, or until the end of the term of the last-expiring patent that references the deposit. While the United States may consider the expert solution, adopting it is not recommended because potential costs to further innovation outweigh safeguarding benefits.

The AIPA compels the United States to make deposited biological material available to third parties upon publication of a patent application. With appropriate safeguards in place, the early release of deposited material should further the constitutional directive to promote "the Progress of Science and useful Arts."[177]

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[177] U.S. Const. art. I, § 8, cl. 8.