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The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions

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Abstract

Patenting the fruits of biotechnological research often involves problems unique to that scientific field, especially when the resulting inventions employ micro-organisms that cannot be described easily because of their novelty to the field. The importance of satisfactorily resolving these problems increases because most developed states now allow biotech inventors to patent the novel organism itself. In response to the concern that words are often inadequate to identify completely these microbes, states began allowing biotech patent applicants to deposit a sample culture of the novel micro-organism as a supplement to the written description. This Note addresses the shortcomings of the deposit requirement due, in part, to its nonuniform development among developed states. The Note begins by following the development of the requirement in the United States, certain European states, and the European Patent Convention. The Note also addresses the genesis of patenting the micro-organisms themselves and the various attempts at solving the attendant problems of deposit. The Note concludes by evaluating the current situation and proposing some potential solutions.

Table of Contents

I. INTRODUCTION

Perhaps one of the more noteworthy industrial developments in recent history[1] is the biotechnology revolution.[2] The "potential fruits" of biotechnological research contribute to the growing importance of the science of biotechnology, both economically and socially.[3] To stimulate research and accelerate progress in this field, states have relied heavily upon the patent system to offer protection for products resulting from

1. *See Biotech Comes of Age*, BUS. WK., Jan 23, 1984, at 84 (describing biotechnology as a technical revolution that may come to rival even the development of the computer); L. ORSENIGO, THE EMERGENCE OF BIOTECHNOLOGY: INSTITUTIONS AND MARKETS IN INDUSTRIAL INNOVATION 63-69, 126 (1989) (discussing the growth in biotechnological activities worldwide).

2. "Biotechnology, the use of living organisms in a manufacturing or productive role, is actually a new term for an old industry. People have always sought to use the abilities and characteristics of other organisms to improve society. For example, through the development of breeding techniques and the cultivation of various hybrid animals and plants, existing species have been improved and new species developed." John E. Schneider, Note, *Microorganisms and the Patent Office: To Deposit or Not To Deposit, That is the Question*, 52 FORDHAM L. REV. 592, 592 n.1 (1984).

3. *Biotechnological Inventions: A Position Paper of the International Chamber of Commerce*, 18 INT'L REV. INDUS. PROP. & COPYRIGHT L. 223 (1987) [hereinafter *Position Paper*]. "The Position Paper . . . elaborated by the IIC [International Review of Industrial Property and Copyright Law] Working Party on the Legal Protection of Biotechnological Inventions . . .with slight amendments . . . was adopted as a statement of the International Chamber of Commerce [ICC] at the 47th session of the Executive Board of the ICC on December 2, 1986." *Id.* at 223 n.1.

biotech research.[4] Initially, these new biotech products incorporated only those micro-organisms that were known and readily available to researchers in the field. Additionally, because of their common use within the biotech field, these micro-organisms could be described specifically.[5] With the development of antibiotics, however, came the need to employ strains of micro-organisms that had been modified artificially to produce a desired result.[6] The modified micro-organisms, or microbes as they often are denoted, were increasingly difficult to describe in words because they were not previously known or available. To cope with the problem caused by the inability to provide a sufficient written disclosure of their invention, inventors began to supplement their patent applications by depositing samples of the novel microbes with a culture depositary.[7] As states began to recognize that the new strain itself might be patentable, the importance of the so-called deposit requirement increased dramatically.[8]

Unfortunately, the deposit requirement, combined with conditions existing prior to and developments occurring since its implementation in the United States and several European states, frequently exact a high price from biotechnological inventors. All too often, inventors may be required to forfeit valuable property rights in inventions, which, absent the deposit requirement, they could not have been forced to surrender.[9]

This Note addresses the parallel development of the deposit requirement in the United States, certain European States, and the European Patent Convention.[10] The Note also addresses the allowance of patent claims relating to micro-organisms themselves.[11] The Note then discusses various attempts to solve some of the problems raised by the issue of deposit[12] and concludes by assessing and evaluating the present state of practice.[13]

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4. *Id.* at 223.

5. *See infra* note 16 and accompanying text.

6. *See* Donald Levy & Lucile B. Wendt, *Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications*, 37 J. PAT. OFF. SOC'Y 855 (1955).

7. *See infra* note 21 and accompanying text.

8. *See generally* Levy & Wendt, *supra* note 6, at 856-87; *Ex Parte* Kropp, 143 U.S.P.Q.(BNA) 148, 152-53 (Pat. Bd. App. 1959) (failure to deposit micro-organism or to disclose its source rendered specification insufficient).

9. *See infra* note 83 and accompanying text.

10. *See infra* part II.

11. *See infra* part III.

12. *See infra* parts IV, V(B)(3).

13. *See infra* part VIII.

II. DEVELOPMENT OF THE DEPOSIT REQUIREMENT

Inventions incorporating micro-organisms[14] have been recognized as patentable subject matter for over a century.[15] For several decades, the microbes used in these inventions were known and readily available to researchers in the biotech field.[16] As a result of rapid advances in antibiotic development during the 1940s and 1950s,[17] researchers began using artificially modified strains of micro-organisms designed to improve and increase the yields of antibiotics.[18] Many of the organisms used in the production of antibiotics were neither familiar to other biotech researchers, nor isolatable from known and publicly available sources without undue experimentation.[19] It was increasingly difficult for patent applicants in the biotech field to meet the enabling disclosure and best mode requirements of a particular state's patent laws.[20] To facilitate compliance with these provisions, applicants began supplementing patent applications by depositing samples with a recognized culture depositary of the

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14. Microbiological inventions can come within any of four statutory classes of inventions, see 35 U.S.C. § 101. Examples include:

1. *Machines*—a laboratory pipetting machine, a zone reader . . .;
2. *Manufacture*—a biologically pure culture of a novel microbe, a cloned gene;
3. *Composition of matter*—a chemical compound made by a microbiological process, a biologically pure culture of a novel microbe, a cloned gene;
4. *Process*—a microbiological process for preparing a chemical compound, a process for purifying nucleotide sequences.

ROMAN SALIWANCHIK, LEGAL PROTECTION FOR MICROBIOLOGICAL AND GENETIC ENGINEERING INVENTIONS 4 (1982).

15. Louis Pastuer patented a biologically pure yeast culture as a new article of manufacture in 1873. U.S. Pat. No. 141,072 (1873). Schneider, *supra* note 2, at 595 n.28 (citing U.S. Pat. No. 141,072 (1873)). *See also* Donald G. Daus, *Patents for Biotechnology*, 26 IDEA 263 (1986).

16. *See* Schneider, *supra* note 2, at 595.

17. *See generally* Levy & Wendt, *supra* note 6.

18. *See* Daus, *supra* note 15, at 264.

19. *See generally* SALIWANCHIK, *supra* note 14, at 68.

20. *See, e.g.*, JOSEPH STRAUS & RAINER MOUFANG, DEPOSIT AND RELEASE OF BIOLOGICAL MATERIAL FOR THE PURPOSES OF PATENT PROCEDURE: INDUSTRIAL AND TANGIBLE PROPERTY ISSUES 13 (1990). For example, British patent law requires that the application "disclose the invention in a manner . . . clear enough and complete enough for the invention to be performed by a person skilled in the art." Patent Act 1977 § 14(3) (1977) (Eng.), *reprinted in* 33 HALSBURY'S STATUTES, at 143 (4th ed. 1987). Similarly, in the United States the requirement is that the specification be concise enough "to enable any person skilled in the art to which it pertains. . . to make and use the same." 35 U.S.C. § 112 (1988). German patent law requires that the disclosure meet a "reproducibility" standard. *See* Baker's Yeast Decision, 1975 GRUR 430 (BGH 1975), *reprinted in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L. 207, 212 (1975).

relevant micro-organism.[21] Hoping that the courts and patent offices of the various states would approve, inventors worldwide adopted the deposit practices.[22]

A. *The United States*

In the 1970 *In re Argoudelis* decision,[23] the United States Court of Customs and Patent Appeals (CCPA) approved the deposit requirement.[24] The court confirmed that requiring a sample to be deposited was necessary to guarantee full compliance with the enabling disclosure requirement.[25] Unlike the German courts, the CCPA found unnecessary the requirement that the general public be granted access to the deposited culture prior to the patent grant.[26] Instead, the CCPA stated explicitly that the purpose of section 112 is not to compel an applicant whose invention involves the use of a novel micro-organism to "surrender his starting materials to the general public before filing, whereas an applicant in the other arts need tell the public nothing until his patent issues."[27]

The *Argoudelis* court did not address the required timing of the deposit in relation to the application's filing. The Patent and Trademark Office (PTO) has since assumed that the sample could be deposited no later than the time the application was filed.[28] The United States Court of Appeals for the Federal Circuit (CAFC)[29] determined otherwise in *In re Lundak*.[30] The CAFC decided that an applicant need not make a deposit until the time the patent has issued, provided the PTO's right to demand a sample during the examination procedure remained secure.[31]

As a direct result of *Lundak*, an applicant is not divested automati-

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21. *See* Daus, *supra* note 15, at 264.
22. STRAUS & MOUFANG, *supra* note 20, at 13.
23. 434 F.2d 1390 (C.C.P.A. 1970).
24. *Id.* at 1392-93.
25. *Id.* at 1392. For the enabling requirement, see 35 U.S.C. § 112.
26. *Id.* at 1392-93.
27. *Id.* at 1393.
28. STRAUS & MOUFANG, *supra* note 20, at 46.
29. The United States Court of Appeals for the Federal Circuit (CAFC), an Article III court, was created by the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25, which merged the former Court of Customs and Patent Appeals (CCPA) and the Court of Claims. Congress' primary objective in creating the CAFC was "to eliminate a persistent disparity in patent law standards among courts of appeals deciding patent cases." PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 198-99 (3d ed. 1990).
30. 773 F.2d 1216 (Fed. Cir. 1985).
31. *Id.* at 1222-24. *See also* STRAUS & MOUFANG, *supra* note 20, at 46.

cally of property rights in the micro-organism simply upon the filing of a patent application.[32] Moreover, the applicant can establish during the course of the examination procedure that a deposit is unnecessary because the specification provides a sufficient written description.[33] The United States patent law gives an applicant for a microbiological-type patent greater control over the disposition of the deposited sample prior to the patent grant or refusal. The applicant, however, may not restrict further the public's access to the sample after a patent is granted.[34]

B. *The Federal Republic of Germany*

Indeed, the deposit practice did begin to gain widespread acceptance.[35] In 1967, the German Federal Patent Court (BPatG) became the first court to confirm the practice when it held that to constitute an enabling disclosure, a sample culture must be deposited no later than the date on which the applicant files an application.[36] The BPatG also held that the name of the depositary institution where the organism is deposited must be designated in the application before the deposit is considered valid.[37] Eight years later, the Federal Court of Justice (BGH) confirmed these rulings, in the *Baker's Yeast* decision.[38] The BGH added the requirement that the deposited culture must be available to any third party from the time the application is published, thereby insuring that the invention is capable of being reproduced.[39]

C. *Great Britain and the European Patent Convention*

Under the British Patents Act of 1977, a patent applicant must provide, within the application, a description of the invention sufficient to enable a person skilled in the particular art to practice the invention.[40] When a microbiological invention employs an unfamiliar micro-organism, a sample culture of the microbe must be deposited on or before the

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32. *See* STRAUS & MOUFANG, *supra* note 20, at 46-48.
33. *Id.* at 47.
34. *Id.* at 49-50.
35. *See generally id.* at 13-15.
36. *Id.* at 13 (citing BPatGE 9, 150).
37. *Id.*
38. 1975 GRUR 430 (BGH 1975), *reprinted in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L. 207 (1975). *See also* STRAUS & MOUFANG, *supra* note 20, at 53-56.
39. 1975 GRUR 430 (BGH 1975), *reprinted in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L., at 214-15. *See also* STRAUS & MOUFANG, *supra* note 20, at 53-54.
40. Patents Act 1977 § 14(3) (1977) (Eng.), *reprinted in* 33 HALSBURY'S STATUTES, at 143 (4th ed. 1987).

date upon which the British application is filed.[41] The application must include the depositary's name, the sample culture's identification number,[42] and the deposit date.[43] This information, however, may be submitted up to two months after the original filing date.[44] In pertinent respects, the British system resembles the German and the United States systems.[45]

The European Patent Convention (the EPC), signed at Munich in 1973 and entered into force in 1977,[46] has become an increasingly important and influential single-application patent system. Under the EPC, if an invention requires the use of a micro-organism that neither is readily available to the public, nor is capable of being sufficiently described in the application, the inventor must deposit a culture of the micro-organism no later than the filing date and must describe in the application any relevant characteristics of the organism. The inventor has up to sixteen months after the filing date to submit information regarding the micro-organism's location.[47] An applicant's compliance with these re-

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41. SALIWANCHIK, *supra* note 14, at 152.

42. The accession number is the identification number assigned to the culture by the repository upon deposit. Each accession number refers to only one culture deposit and only one deposit date. *Id.*

43. *Id.*

44. This British requirement of the deposit date differs from United States practice, which requires that the repository name and the accession number be contained in the application when filed, but does not require the disclosure of the deposit date. *Id.*

45. *See generally id.* at 151-52. All three systems require a sample culture to be deposited when a written description of the micro-organism does not fulfill disclosure requirements. Furthermore, the applicant must supply identifying information with respect to the deposited sample at some point in the application process. *See supra* notes 24-25, 28-30, 35-36, 41-43 and accompanying text.

46. *See generally id.* at 142. At the time of filing, the applicant must designate the states in which patents are desired. The number of states designated by the applicant may be reduced, but not increased, during the patent process. Convention on the Grant of European Patents, Oct. 5, 1973, art. 79 [hereinafter European Patent Convention], *reprinted in* M. VAN EMPEL, THE GRANTING OF EUROPEAN PATENTS 339, 355 (1975). *See also id.* art. 79(3) and Rule 14, *reprinted in* VAN EMPEL at 355, 383 (prohibiting reduction of designated countries if a third party asserts a right to ownership of the invention).

47. European Patent Convention Rules 28 (1) and (2) state:

> 1. If an invention concerns a microbiological process or the product thereof and involves the use of a micro-organism which is not available to the public, the European patent application and the resulting European patent shall only be regarded as disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art if:
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> a. a culture of the micro-organism has been deposited in a culture collection not later than the date of filing of the application;

quirements constitutes "the unreserved and irrevocable consent of the applicant to the culture deposited being made available to the public in accordance with [the EPC Rules]."[48]

The EPC has harmonized the majority of the member states' national patent laws. Nevertheless, because member states are not required to incorporate the EPC recommendations into their own laws, each state's patent laws will reflect particular national preferences.[49]

The German, British, and EPC deposit procedures share a common requirement that deposit be made upon application for patent. In Europe, generally, from the time of deposit forward, the depositor has no right to restrict public access to a sample of the deposited culture.[50] In contrast, the United States allows deposit to be withheld until the patent grant. This United States practice insures that if a patent does not issue, the inventor will have lost no property rights in the invention. Upon issuance of a valid United States patent, however, the inventor can impose no restrictions on public access to the deposit.[51]

III. PATENTABILITY OF MICRO-ORGANISMS

A. *Background*

A recent development impacting the deposit mechanism's importance is the recognition that novel micro-organisms themselves may be patentable subject matter under the patent law.[52] Prior to the 1980s, the basic legal principles constituting the foundation of United States biotechnological intellectual property law developed primarily to accommodate the

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b. the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism;

c. the culture collection, the date when the culture was deposited and the file number of the deposit are given in the application.

2. The information referred to in paragraph 1(c) may be submitted within a period of two months after the filing of the application. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the culture deposited being made available to the public in accordance with this Rule.

European Patent Convention, *supra* note 46, Rule 28(1)-(2), *reprinted in* VAN EMPEL at 386-87.

48. European Patent Convention, *supra* note 46, Rule 28(2), *reprinted in* VAN EMPEL at 387.

49. *See* STRAUS & MOUFANG, *supra* note 20, at 14.

50. *See supra* notes 23-27, 39-45 and accompanying text.

51. *See supra* notes 28-39 and accompanying text.

52. *See generally* I.L. Fuller, *Intellectual Property Rights Associated with Biotechnology—An International Trade Perspective*, 16 AIPLA Q. J. 529, 533-34 (1988-89).

pharmaceutical industry.[53] Decades of patenting processes and compositions involving micro-organisms necessarily begged the question of whether the micro-organism itself could be the subject of a patent claim under existing patent law theory and practice.[54] Considerable opposition to the idea of patenting life led to fierce debate on this topic.[55] Those opposed to the patenting of the micro-organism bolstered their position by reference to the well-accepted doctrine that laws of nature, physical phenomena, and undeveloped ideas are not patentable.[56] This argument, however, failed to satisfy biotechnological inventors, who, while developing a patentable process, often developed a completely novel micro-organism.

B. Chakrabarty *in the United States and* Baker's Yeast *in Germany*

The United States Supreme Court addressed the micro-organism patentability issue in the landmark case of *Diamond v. Chakrabarty*.[57] Chakrabarty had developed a genetically modified oil-eating bacterium that he wanted to patent.[58] The PTO allowed the claims relating to the method of bacteria production and the inoculum comprised of the carrier material and bacteria,[59] but rejected the claim relating to the bacterium itself.[60] The CCPA reversed on the authority of an earlier case, which held that "the fact that micro-organisms . . . are alive . . . [is] without legal significance" in patent law,[61] and that a patent should not be denied merely because micro-organisms are living things.[62]

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53. Geoffrey M. Karny, *Intellectual Property in the 1990s: Patenting Higher Life Forms, in* THE BUREAU OF NATIONAL AFFAIRS, BIOTECHNOLOGY LAW FOR THE 1990S: ANALYSIS AND PERSPECTIVE 1 (BNA 1989). *See generally* Levy & Wendt, *supra* note 6.

54. *See* Karny, *supra* note 53, at 1.

55. *See generally id.*

56. See Parker v. Flook, 437 U.S. 584 (1978) (method of updating alarm limits during catalytic conversion through use of mathematical formual not patentable); Gottschalk v. Benson, 409 U.S. 63 (1972) (method for converting binary coded decimal information to pure binary numbers for use in programming computers not a patentable process); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (discovery that certain strains of bacteria can be mixed safely not patentable because it is discovery of a natural phenomenon).

57. 447 U.S. 303 (1980).

58. *Id.* at 305 & n.2, 306.

59. These two claims were found to be proper subject matter under 35 U.S.C. § 101 as a process and a composition of matter, respectively. *Id.* at 306.

60. *Id.*

61. *Id.* (quoting *In re* Bergy, 563 F.2d 1031, 1038 (1977)).

62. *Bergy*, 563 F.2d at 1038.

The United States Supreme Court affirmed the CCPA decision and rejected the notion that Congress intended to distinguish between patentable and nonpatentable subject matter on the basis of living and nonliving matter.[63] Instead, the Court stated that the proper distinction is between "products of nature, whether living or not, [which are not patentable], and human-made inventions, [which are patentable]."[64]

The German Supreme Court also has conceded to micro-organism patentability.[65] The International Chamber of Commerce, approving this view, advocated that all developed states extend patent protection to, or at least not automatically withhold protection from, micro-organisms.[66] This position corresponds to that of the United States, the EPC, and Japan.[67] By recognizing micro-organisms as patentable subject matter, national patent laws have expanded the scope of protection available to biotechnological inventors, simultaneously have sparked commercial interest in biotechnology,[68] and have raised new issues and concerns that remain to be addressed.[69]

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63. *Chakrabarty*, 447 U.S. at 313.

64. *Id.* The Court held that the bacterium was patentable subject matter under 35 U.S.C. § 101 because it had "markedly different characteristics from any found in nature and one having the potential for significant utility. [The] discovery is not nature's handiwork, but [Chakabarty's] own." *Id.* at 310.

In so holding, the Court determined that Chakrabarty's micro-organism was either a manufacture or a composition of matter. *Id.* at 309-10.

65. Baker's Yeast Decision, 1975 GRUR 430 (BGH 1975), *reprinted in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L. 207 (1975).

66. *Position Paper, supra* note 3, at 225-26.

67. *Id.* at 226.

68. Between 1980 and 1982, approximately 200 companies were formed to exploit biotechnology. Colin Norman, *Another Biotechnology Company Bites the Dust*, 217 SCIENCE 1016 (1982). *See also* Barbara J. Culliton, *Monsanto Gives Washington U. $23.5 Million* , 216 SCIENCE 1295 (1982). For articles on increased foreign interest, see David Dickson, *German Firms Move Into Biotechnology*, 218 SCIENCE 1287 (1982); David Dickson, *France Boosts Biotechnology*, 217 SCIENCE 516 (1982); Harold M. Schmeck Jr., *Report Says Japan Could Lead in Commercial Biotechnology*, N.Y. TIMES, Jan. 27, 1984, at A9.

69. Examples include questions concerning circumstances under which deposit is necessary, timing of deposit and release, identity of parties to whom a sample can be released, and conditions of release. *See generally infra* notes 24, 30, 40 and accompanying text; *see supra* notes 135, 139, 145 and accompanying text.

IV. THE BUDAPEST TREATY: AN UNSUCCESSFUL ATTEMPT TO HARMONIZE DEPOSIT

As the number of states that required patent applications for biotechnological inventions to be supplemented by deposit increased, so did the burden on applicants hoping to patent inventions in more than one of these states because a separate deposit would be required for each state's application.[70] To relieve this burden and to encourage continued research and development in biotechnology, cooperation was necessary. Cooperation took the form of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty or the Treaty),[71] which concluded in 1977 and entered into force in 1980.[72] As of 1990, twenty-four states had signed the Budapest Treaty.[73] Article 7 of the Treaty provides for the establishment of international depositary authorities in which micro-organisms may be deposited.[74] Article 3 obligates the contracting states to recognize the deposit of a micro-organism in any depositary institution authorized by the Treaty.[75]

The Budapest Treaty heavily regulates procedures, and certain

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70. STRAUS & MOUFANG, *supra* note 20, at 15.

71. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241 [hereinafter Budapest Treaty], *reprinted in* WORLD INTELLECTUAL PROPERTY ORGANIZATION, 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 11 (1980) [hereinafter RECORDS].

72. STRAUS & MOUFANG, *supra* note 20, at 15.

73. *Id.* at 15 n.9. These states are referred to as "Contracting States."

74. Budapest Treaty, *supra* note 71, art. 7, 32 U.S.T. at 1246, *reprinted in* RECORDS at 23.

75. Budapest Treaty, *supra* note 71, art. 3, 32 U.S.T. at 1244, *reprinted in* RECORDS at 17. Article 3 reads, in relevant part:

> *Recognition and Effect of the Deposit of Microorganisms*
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> (1)(a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.
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> . . . .
>
> (2) As far as matters regulated in this Treaty and the Regulations are concerned, no Contracting State may require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

Id.

mechanical aspects of depositing and releasing samples[76] within the depositary institutions. The Treaty, however, has minimal influence on the substantive law of each contracting state. This arrangement is not the one originally intended by the initial participating states. Special interest groups concerned with this issue had hoped for an arrangement that would have bound contracting states with respect to their national law on the issue of releasing samples to third parties.[77] The participating states first had aimed for an arrangement under which no contracting state would have been required to amend the substance of its own patent law,[78] except "that publication constituted the minimum limit in time for the release to third parties (non-release of samples to third parties before publication)."[79] Unfortunately, even this small goal proved unattainable. Some of the participating states' patent laws permit third parties to inspect the files of the patent office prior to an application's publication.[80] The arrangement adopted in the final version of the Treaty enables a third party to obtain a sample of the deposited material prior to publication if, under the patent law of the state concerned, the party is entitled to access to the application.[81]

Hence, according to the Treaty, whether a third party may obtain a sample of the micro-organism is determined solely by the substantive law of the contracting state. Nonetheless, the state's patent office must attest in writing, on a form, the contents of which are fixed by the Assembly of the Budapest Union, that the certified party has the right to demand a sample and that any conditions, prerequisite to the granting of access to the sample, have been fulfilled.[82] Clearly, the Budapest Treaty does very little to harmonize the contracting states' patent laws. The Treaty, however, is useful for applicants who wish to apply for patents in several states because it permits the deposit of only a single sample.

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76. Budapest Treaty, *supra* note 71, Rule 11.3, 32 U.S.T. at 1258-59, *reprinted in* RECORDS at 75, 77.

77. STRAUS & MOUFANG, *supra* note 20, at 43.

78. *Id.*

79. Comment by J.L. Comte, the Chairman of the Main Committee of the Budapest Diplomatic Conference, *reprinted in* RECORDS, *supra* note 71, para. 1236.2, at 360.

80. STRAUS & MOUFANG, *supra* note 20, at 43.

81. Budapest Treaty, *supra* note 71, Rule 11.3(a)(iii), 32 U.S.T. at 1258-59, *reprinted in* RECORDS at 75, 77.

82. *Id. See also* STRAUS & MOUFANG, *supra* note 20, at 43-44.

V. Problems Arising From the Deposit Requirement

Although the deposit requirement eliminates the difficulty involved in providing an adequate written description of a novel micro-organism, it creates new difficulties in other aspects of the microbiological patent process. One major cause for concern among inventors and potential patent applicants arises from the dual nature of the micro-organism, which incorporates both tangible and intangible property.[83] Another problem arises in states that have amended their national patent law to provide for early publication of patent applications, often prior to examination by the patent office.[84]

A. *The Dual Nature of Micro-organisms*

An inventor who creates a new micro-organism simultaneously generates valuable intangible property—the idea embodied in the invention.[85] The micro-organism itself, however, constitutes tangible personal property.[86] Historically, the primary objective of patent law has been to promote advances in science and technology by granting inventors exclusive rights in their inventions in the form of patents.[87] Patent law protects the inventor's intangible property rights by granting the inventor a monopoly of limited scope and duration to make, use, or sell the invention.[88] In exchange for these exclusive rights, the inventor is required to disclose fully the nature of the invention. Upon expiration of the patent, this disclosure enables the public to utilize freely the resourcefulness of the invention. This limited monopoly of an enforceable patent has been viewed either as consideration for the inventor's relinquishing the right to keep the know-how secret or as a reward for making the invention available to the public.[89]

The deposit requirement does not alter the scope of patent protection with respect to the invention claimed, because the deposited sample merely functions as a supplement to, or substitute for, the compulsory written description.[90] Nonetheless, the deposit requirement constitutes an

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83. *See infra* notes 85-101 and accompanying text.

84. *See infra* notes 121-37 and accompanying text.

85. John W. Schlicher, *Some Thoughts on the Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, 69 J. Pat. & Trademark Off. Soc'y 263, 275 (1987).

86. *See* Goldstein, *supra* note 34, at 358-59.

87. 35 U.S.C. § 154 (1988).

88. 35 U.S.C. § 112 (1988).

89. *See generally* Straus & Moufang, *supra* note 20, at 23-29.

90. *See, e.g., In re* Lundak, 773 F.2d 1216, 1218 (Fed. Cir. 1985).

unduly intrusive infringement of the inventor's tangible property rights in the micro-organism.[91] The original justification for this deposit practice arose from situations in which a written description was insufficient to satisfy the enabling disclosure or reproducibility requirement.[92] A sample of the organism could supply the descriptive elements that words simply could not capture.[93] The additional burden placed on the inventor by requiring a sample to be deposited is arguably minimal when viewed in light of the simplified disclosure. The inventor's lost property rights could be justified as an additional cost imposed on the inventor in exchange for patent protection. Furthermore, because the Budapest Treaty allows the inventor to make only a single deposit, which will be recognized in all contracting states,[94] the inventor arguably has little cause for complaint. But this lack of grounds for complaint would be true only if a sample deposit were all that is required of inventors of biotechnology.

The additional expense, however, is not the only infringement of rights imposed by the deposit requirement. Because the deposited sample may be released to third parties under conditions established by the patent law of the particular state in which the patent is sought,[95] the Buda-

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91. STRAUS & MOUFANG, *supra* note 20, at 96-100.

92. *See, e.g., In re* Argoudelis, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970).

93. "Ordinarily no problem in this regard arises since the method of preparing almost all starting materials can be set forth in writing . . . and when this is done the specification is enabling to the public . . . . [But] because of the particular area of technology involved, [one] cannot sufficiently disclose by written word how to obtain the microorganism starting material from nature." *Id.* at 1392.

94. *See supra* note 75 and accompanying text.

95. Rule 11.3 of the Budapest Treaty provides:

> (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:
>
> . . . .
>
> (ii) that, except where the second phrase of (iii) applies, [the application has been published];
>
> (iii) *either* that the certified party has a right to a sample . . . 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 [those conditions have actually been fulfilled or are deemed to have been fulfilled]; 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.

Budapest Treaty, *supra* note 71, Rule 11.3(a)(ii)-(iii), 32 U.S.T. at 1258-60, *reprinted in* RECORDS at 75, 77.

pest Treaty forces the inventor to forfeit the right to control physically the disposition of the invention.[96] The self-replicating character of micro-organisms exacerbates this inequitable result[97] because possession of a single microbe provides an individual with the capability of producing an unlimited supply of the organism.[98] As a result, by requiring a biotech inventor to supplement the written description with a sample of the micro-organisms claimed as or employed in the invention, the deposit requirement forces the inventor to disclose not only the intangible know-how of the invention, but also the start-up materials necessary to reproduce the invention.[99]

Consequently, inventors of biotechnology face an unwarranted additional burden, that is not imposed upon inventors in any other field of technology. For example, one commentator compared this burden to a situation that would require the inventor of the first nuclear power facility to guarantee that sufficient supplies of uranium existed for use in the facility or to disclose a method for producing uranium.[100] An inventor who employs a novel micro-organism in an invention is obligated to supply not only the information necessary to reproduce the invention, but also the actual invention.[101] The only readily apparent difference in the two situations is the difficulty encountered when verbally describing the micro-organism. This single difference hardly justifies the substantially different treatment under the same laws.

B. *The Unusual Case of Early Publication*

1. History

Another obstacle faced by inventors of biotechnology involves the early publication of unexamined patent applications, which is unique to certain states.[102] The practice of early publication, commonly known as laying open, is admittedly an exception to the long-practiced principle that an inventor cannot be required to disclose an invention until patent rights have attached.

For nearly 250 years, the tradition in most states with well-developed or developing patent laws had been to balance the applicant's interest in

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96. *See generally Position Paper, supra* note 3, at 229, 231.

97. STRAUS & MOUFANG, *supra* note 20, at 95-96.

98. *See generally* Fuller, *supra* note 52, at 539 (discussing problem of "pocket factories" because of the biological nature of micro-organisms).

99. *Position Paper, supra* note 3, at 229, 231.

100. *See* Schlicher, *supra* note 85, at 275-76.

101. *Id.*

102. *See infra* notes 106-11, 115, 118 and accompanying text.

acquiring sufficient protection of rights in the invention against society's interest in advancing the state of the art.[103] To insure full protection of the applicant's interests, the specification, which discloses the nature of the invention, is not publicly available until patent protection has attached—in other words, the public does not have access to the specification until the application has been examined and a patent has issued.[104] This fundamental principle provides the foundation upon which the patent laws in the majority of developed states had been based.[105]

During the 1960s, several European states began to abandon this principle in favor of an alternative system in which unexamined patent applications are published eighteen months after the filing or priority date.[106] This shift was not precipitated by patent principles, but by external pressures exerted on the European national patent examining offices by the vast number of applications filed during this period.[107] The number of inventors seeking to patent their inventions grew at an alarming rate. This growth overburdened the patent offices and caused delays in the examination process of up to several years.[108] In turn, the delays caused uncertainty for other inventors who desired to commence work on new inventions, but the possibility that their efforts would be wasted if their inventions later would be found to infringe on a then-pending application deterred them. Similarly, corporations hesitated to invest large amounts of money in research and development, fearing the inability to recoup their investment if a similar patent issued in the interim.[109] These conditions were not conducive to industrial growth in the affected states.

The Netherlands was the first state to attempt to mitigate the apprehension felt by both individual and industrial inventors by proposing the Netherlands Patent Bill of 1961.[110] The objective of the proposal was to shorten this period of uncertainty, caused by the backlog in the examina-

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103. STRAUS & MOUFANG, *supra* note 20, at 30.

104. *Id.*

105. *See generally id.* at 26-29.

106. *Id.* at 30.

107. At the end of 1965, 250,000 patent applications were pending in the German patent offices. *Id.*

108. In 1965, granting procedures were taking over five years and, because of the existing backlog at the time, were most certainly to take longer in the future. *Id.*

109. STRAUS & MOUFANG, *supra* note 20, at 30. *See also infra* note 119.

110. Patents Act for the Kingdom of the Netherlands and the Netherlands Antilles of 7th November 1910 § 22C (as amended Jan. 12, 1977 and Dec. 13, 1978), *reprinted in* 2G JOHN P. SINNOTT, WORLD PATENT LAW AND PRACTICE, at Netherlands -12 (1988).

tion process, by allowing the patent office to publish unexamined patent applications within a certain time after their filing date. In 1962, Scandinavia followed the Netherlands lead.[111] In 1964, Sweden suggested that the solution of early publication should apply to the European patent system as well,[112] and the European Community (EC) Working Group on Patents took up the debate.[113] The EC Working Group sought to balance the interests of the public and competitors against the interests of the patent applicant.[114]

In October 1964, the EC Working Group decided in favor of the solution permitting competitors to know of the patent application eighteen months after filing. The essence of this solution later became Article 93 of the EPC.[115] With one exception,[116] all nongovernmental, international organizations accepted this procedure for early publication.[117]

Given the similarity of the EC proposals to those already envisioned by the Federal Republic of Germany for relieving its own patent office, the German system naturally changed in accordance with the new proposal.[118] The losses that might be suffered by applicants as a result of

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111. STRAUS & MOUFANG, *supra* note 20, at 30.

112. *Id.* at 31.

113. *Id.*

114. In the minutes of the meeting of April 15, 1964, a statement summarized the objectives sought to be achieved through early publication:

> If this question is examined in the light of the interests of the public and the competitors, it must be desirable for these to know 18 months after filing of the application *what application they must expect* (emphasis added). The interests of the public on the one hand, and the interests of the applicant on the other: it is from this point of view that the Swedish proposal must be considered, rather than from the point of view of a longer or shorter duration of the preliminary procedure.

Id. at 31 (citing the 12th session, Feb. 26-Mar. 6, 1964, Doc. (EEC) 2.632/IV/64, pp. 44, 46).

115. *Id.* at 32.

116. The International Inventor's Association refused to accept early publication. *Id.*

117. Although the United States had considered a similar solution, United States industry concluded that the disadvantages of early publication outweighed the advantages. Friedrich-Karl Beier, *The Remedies of the Patent Applicant and His Competitors in Comparison-Balance or Imbalance? A Comparative Law Study*, 20 INT'L REV. INDUST. PROP. & COPYRIGHT L. 407, 418 n.34 (1989).

118. *See* STRAUS & MOUFANG, *supra* note 20, at 32. The official reasons for adopting a system of early publication included:

> The [Government of the Federal Republic of Germany] is of the opinion that this laying-open, which per se is not directly related to the introduction of the deferred examination, is indispensable in the interests of informing the public as early as possible about the applications pending at the Patent Office, because it is only in this way that mistakes in economic planning can be avoided.

early publication were considered justifiable because

> [i]f production has to be stopped after a lengthy period of time because some proprietary right suddenly appears, with priority extending far back into the past, considerable economic losses are incurred. Industry has accepted this disadvantage. . . . It is, however, justified in objecting to this period of uncertainty's lasting too long.[119]

Recognizing that the adoption of early publication marked a break with traditional patent principles, the German government offered the possibility of returning to the traditional system once the burden on the German patent office had returned to a manageable level.[120]

2. Problems Created by Early Publication

In the wake of the EPC's harmonizing effect, publication of unexamined patent applications eighteen months after the filing or priority date became the standard in most European states.[121] Although these revolutionary changes may have aided European industry, they placed the patent applicant in a vulnerable position. Most patents generally will not have issued within eighteen months. Consequently, the inventor's rights in the invention go unprotected for the entire period between publication and the patent grant.[122] In the worst case scenario in which the application is rejected altogether and no patent issues, the applicant has lost not only the opportunity to patent the invention, but also the opportunity to protect the invention as a trade secret because the secrecy of the invention already has been destroyed by the laying open of the application.[123]

Arguably this loss of trade secret protection is reasonable when the application is rejected for substantive reasons, such as improper subject

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. . . .

> [T]he arrangement proposed constitutes the sole possibility of tackling the current difficulties concerning the work load of the German Patent Office and the Federal Patent Court, without at the same time giving up the German examination procedure, which has proven its worth over the decades.

Id. at 33 (citing 1967 Blatt für Patent-, Muster- und Zeichenweser 247-48).

119. *Id.* at 33 n.82 (citing 1967 Blatt für Patent-, Muster- und Zeichenwesen 252).

120. *Id.* at 33.

121. Early publication especially became commonplace after Article 93 of the EPC was enacted in 1973. *Id.* at 30.

122. At the time early publication was first adopted, the Working Group envisaged that a provisional patent would be issued to protect the applicant's interests during the interim period between publication and the grant or rejection of the application. Because the issuance of the provisional patent was to take less than 18 months, the Working Group assumed that the applicant's invention would not go unprotected. *See id.* at 31-32.

123. *See infra* notes 138-41 and accompanying text.

matter. In the case of substantive rejection, the applicant should not be allowed to obtain potentially perpetual protection for an unpatentable invention through the indirect means of trade secret laws.[124] Many applications, however, are rejected for purely procedural reasons.[125] Completely denying protection to an invention that may have been an advance in the state of the art is undoubtedly inequitable.[126] Moreover, this result ignores the long-standing principle of patent law that an inventor must not be made to surrender the technical teaching of an invention to the public domain until the granting of exclusive rights therein.[127] The system of early publication forces the applicant to relinquish rights prior to patent issuance in exchange "for the mere prospect of patent protection."[128] The only way to avoid publication, and thereby preserve the possibility of trade secret protection, is to withdraw the application at least ten weeks prior to its being laid open.[129] Generally, however, not even a novelty report would be available from the examining office within this time. Thus, the applicant is in no better position to assess the patentability of the invention immediately prior to early publication than at the time of filing the application.[130]

3. Attempts to Deal with the Special Problems of Biotechnological Inventions

Additional problems result for the inventor of biotechnology when early publication is combined with the deposit requirement. Important questions arise regarding the release of samples to third parties. For example, when is the sample to be made available to third parties, and under what conditions? Rule 28 of the Implementing Regulations of the European Patent Conventions (Rule 28) originally intended to ensure that samples would be released to third parties without restriction from

124. "The decision of Congress to adopt a patent system was based on the idea that there will be much more innovation if discoveries are disclosed and patented than there will be when everyone works in secret." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 496 (1974) (Douglas, J., dissenting).

125. *See* STRAUS & MOUFANG, *supra* note 20, at 37.

126. *Id.*

127. *See id.* at 36.

128. *Id.* at 37 (citation omitted).

129. Under the European patent system, the possibility of preventing the applicant's publication exists up until ten weeks before the eighteenth month after the application is filed. *Id.* at 36 n.92.

130. Until 1981, search reports giving the applicant at least an indication of the patentability of the invention were available by the eighteenth month in 85% of European patent applications. From 1981 to 1987, the percentage dropped to 48%. *Id.*

the time of publication.[131] The Munich Diplomatic Conference[132] supplemented Rule 28 to make release of the micro-organism after publication dependent upon certain conditions.[133] Amendments were added to Rule 28 in 1979,[134] when the so-called expert solution was adopted. The expert solution provides that access to the deposited sample be restricted to an expert appointed by an interested third party who requires a sample between the time of early publication and the time of patent issuance or rejection.[135]

Rule 28, as it currently reads, provides the applicant with the option to invoke the expert solution simply by informing the European Patent Office (EPO). This solution, however, only applies up until the time a patent issues or the application is rejected.[136] If a patent issues, the pat-

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131. STRAUS & MOUFANG, *supra* note 20, at 70. The draft text for Rule 28 has been published in the Preparatory Documents for the Munich Diplomatic Conference (*Vorbereitende Dokumente für die Münchner Diplomatische Konferenz*) issued by the Government of the Federal Republic of Germany, Bonn 1972, at 222-23. STRAUS & MOUFANG, *supra* note 20, at 70 n.194.

132. STRAUS & MOUFANG, *supra* note 20, at 71-72.

133. These conditions stipulated that the person receiving a sample:

> [M]ust undertake . . . not to make the culture issued available to third parties before the patent application has been refused or withdrawn or is deemed to be withdrawn, or before the expiry of the European patent in all the designated Contracting States; furthermore, the samples issued and also cultures derived from those samples may only be used for experimental purposes until such time as the patent application is refused or withdrawn or is deemed to have been withdrawn, or up to the date of the publication of the mention of the grant of the Euorpean patent.

STRAUS & MOUFANG, *supra* note 20, at 71-72.

134. These amendments incorporated some of the proposals made by MICROPAT in 1977. MICROPAT was an informal group set up by industry to study the problems of patenting procedures for microbiological materials. *See* STRAUS & MOUFANG, *supra* note 20, at 72-74.

135. *See id.* at 75-76. The amendments prompted considerable discussion as to which type of expert solution should be adopted: whether it should apply if no patent issued after publication, and if so, for how long the restriction should apply. *See id.* at 76-77.

136. The Administrative Council of the European Patent Office which proposed the amendment to Rule 28 commented:

> Since the expert solution is restricted to the period between publication of the European patent application and the patent grant [or rejection or withdrawal], it cannot be judged according to whether it does perfect justice to all the aims of the patent system in general. Since, according to the proposed version of Rule 28, the deposited micro-organisms become directly available after the conclusion of the granting procedure, we can in particular disregard the question of whether an expert solution with no time limitation would not be an intolerable obstacle to further research even if taking into account the property rights of the applicant.

STRAUS & MOUFANG, *supra* note 20, at 80 (citation omitted).

ent will resume protection when protection via the expert solution ceases. If no patent issues, the sample becomes available to all requesters the moment at which the application is withdrawn or rejected.[137]

C. *Timing of Release*

Although the prevailing view endorses deposit as a necessary evil for completion of microbiological patent applications,[138] debate still rages among states over the release of culture samples. The controversy concerns when, and under what conditions, the sample culture must be made available to third parties.[139] Several underlying concerns complicate the issue of release. Because the practice of laying open necessarily involves the publication of the patent specification, those states laying open applications have assumed, somewhat arbitrarily, that the sample must be made publicly available in order for the publication to be complete.[140] These states justify this requirement on the grounds that a deposit is necessary because disclosure of the invention cannot be adequately set out by using only words. Hence, the sample constitutes a necessary part of the specification that must be published, or released, at the time the application is laid open.[141]

Treatment of the biotech inventor differs greatly from that of inventors in other fields, with the former at a great disadvantage with regard to tangible property rights in the deposited sample. Clearly, all inventors seeking patents in states whose laws provide for early publication are subject to having their applications laid open before a patent issues. Moreover, because of the peculiar nature of biotechnological inventions, early publication gives third parties not only access to a written description of the invention, but also possession of the invention itself. Because patent protection usually will not have attached at the time of publication, the inventor potentially lacks recourse for several months, or even years, against potential misuse of the deposited sample.[142]

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137. For various critiques of Rule 28's expert solution, see STRAUS & MOUFANG, *supra* note 20, at 81-86.

138. *See supra* notes 21-22; *see also Position Paper, supra* note 3, at 231-33.

139. *See supra* notes 131-37 and accompanying text.

140. The International Chamber of Commerce is of the opinion that "the point at which the full sufficiency of disclosure is of primary significance is not the date of early publication of the unexamined application, but rather the date at which the examined application is published." *Position Paper, supra* note 3, at 231.

141. *See, e.g.*, European Patent Convention, *supra* note 46, Rule 28, *reprinted in* VAN EMPEL at 386-87; Patent Act 1977, *supra* note 20, § 16, *reprinted in* 33 HALSBURY'S STATUTES, at 145-46. *But see* STRAUS & MOUFANG, *supra* note 20, at 104-05.

142. *See Position Paper, supra* note 3, at 233-34.

Indeed, the biotech inventor might be prevented permanently from seeking relief against misuse if a patent does not issue ultimately. If no patent issues, the micro-organism will be left to circulate in the public domain and perhaps provide another inventor with the starting material for a similar invention.[143] In the most unfortunate case involving patent rejection based on procedural defects in the application, the sample may be used to reproduce the very material or process that the original applicant was attempting to patent.[144]

Releasing the sample culture only upon the third-party requester's fulfillment of certain conditions may provide some relief to the inventor. The lack of agreement among states as to a uniform set of conditions, however, has prevented any satisfactory solution. Even in states in which release is not permitted until the patent issues, the question still exists as to what should be the conditions of release.[145]

VI. THE VIABILITY OF TRADE SECRET PROTECTION FOR BIOTECHNOLOGICAL INVENTIONS

Faced with the problems inherent in the patenting of biotechnological inventions and micro-organisms, inventors may attempt to protect their discoveries by alternative means. One alternative to patent protection is the trade secret law. In the United States, an inventor reserves the right to hold in secret any invention and to claim it as a trade secret.[146] Trade secret rights have been recognized in the United States for more than a century.[147] As early as 1883, a circuit court observed that "no constitutional or statutory provision . . . was, or ever has been, necessary to the right of any person to make an invention . . . or to use it when made, or to sell it to someone else."[148] The Supreme Court affirmed the principle

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143. *Id.* at 232-233.

144. *Id.*

145. *See generally id.*; SALIWANCHIK, *supra* note 14, at 147-58.

146. Restatement of Torts provides the most widely relied upon definition of trade secret:

> A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939).

147. *See, e.g., In re* Brosnahan, Jr., 18 F. 62 (W.D. Mo. 1883).

148. *Id.* at 64. The court stated further:

> Such a right has always existed, and would exist now if all patent laws were repealed. It is a right which may be called a natural right, and which, so far as it

that patent law and trade secret law do not necessarily conflict with one another.[149] The Court reasoned that "[t]rade secret law and patent law have co-existed in the country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other."[150]

A. *The Positive Aspects*

Trade secret protection remains an especially attractive option for inventors whose inventions are, for some reason, not patentable. Often these nonpatentable inventions are a source of economic value or competitive advantage that demands some mode of protection against misappropriation by competitors.[151] Trade secret protection is also available to protect inventions whose infringement would be difficult to detect or to prevent.[152] Biotechnological inventors are discovering that the patent laws of many states do not provide sufficient protection against subsequent misuse. Consequently, these inventors are turning to trade secret law for protection.[153]

Even inventors of clearly patentable inventions may have reason to resort to trade secret law.[154] First, trade secret protection continues for as long as the invention remains secret. Patent protection, however, has a limited duration.[155] Second, the costs of trade secret protection are limited to the expenses incurred in keeping the invention secret. The cost of obtaining and enforcing a valid patent generally will be greater.[156] Additionally, competitors have no notice of the trade secret, whereas complete disclosure is a prerequisite to obtaining a patent.[157] Finally, with most microbiological inventions, as long as the micro-organism necessary to practice the invention remains unavailable to competitors, trade secret

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may be regulated by law, belongs to ordinary municipal legislation; and it is unaffected by anything in the constitution or patent laws of the United States.

Id.

149. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 491 (1974).

150. *Id.* at 493.

151. *See* RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939).

152. *See* SALIWANCKHIK, *supra* note 14, at 10.

153. *Id.*

154. *See supra* notes 95-99 and accompanying text.

155. SALIWANCHIK, *supra* note 14, at 12. Realistically, the term of trade secret protection may be less than the 17 years granted by a United States patent, because biotechnology is a "fast-moving area of science." *Id.*

156. A primary cost component of patenting biotechnology is the expense incurred when depositing a micro-organism. *See* Schneider, *supra* note 2, at 602 nn. 93-95.

157. *See* 35 U.S.C. § 112 (1988).

protection also will exist for the invention.[158] Under patent law, if the inventor files in a state whose laws require a culture deposit, the deposited sample may be released. This release of the sample gives competitors access to what was initially the inventor's secret.[159]

B. *The Negative Aspects*

Nevertheless, trade secret protection of biotechnological advances is not without drawbacks. The primary hurdle of this alternative form of protection is that whatever is being claimed as a trade secret must remain secret. Once secrecy is lost, the possibility of trade secret protection is destroyed.[160] Furthermore, trade secret law lacks the scope of protection available under the patent paradigm. Unlike a patent that prohibits others from making, using, or selling the invention during the life of the patent,[161] the law of trade secret recognizes both reverse engineering[162] and independent development[163] as permissible forms of competition. Additionally, publication of a trade secret in an enabling form[164] destroys secrecy.[165] In contrast, although publication prior to the patent

158. For example, disclosure of a microbiological process without making available the key microbe necessary to practice the invention preserves trade secret protection of the process. SALIWANCHIK, *supra* note 14, at 12.

159. *Id.*

160. *Id.* at 13.

161. 35 U.S.C. § 271 (1988).

162. *See* Tabor v. Hoffman, 23 N.E. 12 (N.Y. 1889). The presiding judge stated:

> If a valuable medicine, not protected by patent, is put upon the market, any one may, if he can by chemical analysis and a series of experiments, or by any other use of the medicine itself, aided by his own resources only, discover the ingredients and their proportions. If he thus finds out the secret of the proprietor, he may use it to any extent that he desires without danger of interference by the courts.

Id. at 13. This discovery by analysis of the marketed product constitutes reverse engineering.

163. Most industrial nations of the world have maintained a right of prior user, which permits a trade secret user to practice the invention as a secret without the possibility that a subsequent patentee will be able to assert patent rights against this prior user. A prior trade secret user that is unknown to the patentee will not render the subsequent patent invalid. This approach arguably weakens the protection afforded through the patent grant. SALIWANCHIK, *supra* note 14, at 17 n.8.

164. In the United States, the enabling disclosure is statutorily mandated by 35 U.S.C. § 112. To constitute an enabling disclosure, the description of the invention must be sufficient to enable someone skilled in the particular art of the invention to make or use the invention. *See, e.g.*, W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1556 (Fed. Cir. 1983).

165. SALIWANCHIK, *supra* note 14, at 13. *See, e.g.*, Painton & Co. v. Bourns, Inc., 442 F.2d 216, 224-25 (2d Cir. 1971).

grant bars the inventor from ever receiving a patent on that particular invention, the inventor holding a patent can publish information about the invention without fear that a competitor will use the information.[166] Furthermore, a competitor might be able to obtain surreptitiously the trade secret through theft or breach of a confidential relationship with the inventor.[167] If the invention had been patented, the misappropriating competitor would be liable as an infringer upon subsequent use of the invention.[168]

Clearly, a biotech inventor faces, early in the developmental process, difficult decisions concerning the protection of property rights in the invention.[169] Encouraging inventors to choose the patent route promotes disclosure, benefits the public, and advances biotechnology. If a state's patent law places too many obstacles in the inventor's way, the likelihood of protection by a less efficient means, such as trade secret law, greatly increases.[170]

VII. ARTICLE 15—THE PROPOSED EC DIRECTIVE

In 1985, after publishing a white paper on the "Completion of the Single Market," the Commission of the European Community (the Commission) initiated unification attempts, which included unification of the various patent systems.[171] A primary goal with regard to patent protection for biotechnological inventions was to enable European industry to look to the EC "as a uniform environment for its economic activities."[172] To create a uniform, single market in the EC, the differences among the states in the treatment of biotechnological inventions must be eliminated or at least minimized. More importantly, new differences must not develop.[173]

After assessing the situation, the Commission had no doubt that the differences among states needed to be removed by directive. The Commission proceeded under the arrangement that already had been estab-

166. *See* 35 U.S.C. § 271 (1988).

167. *See, e.g.*, Forest Lab., Inc. v. Formulations, Inc., 299 F. Supp. 202 (E.D. Wis.), *aff'd in part and rev'd in part*, Forest Lab., Inc. v. Pillsbury Co., 452 F.2d 621 (7th Cir. 1971).

168. *See* 35 U.S.C. § 271(a) (1988).

169. *See* Roman Saliwanchik, *Microbiological Inventions: Protect by Patenting or Maintain as a Trade Secret*, 19 DEVELOPMENTS IN INDUSTRIAL MICROBIOLOGY 273-277 (1978).

170. *See, e.g., Position Paper, supra* note 3, at 231.

171. *See* STRAUS & MOUFANG, *supra* note 20, at 86.

172. *Id.*

173. *Id.*

lished within the EPC framework. Fortunately for the inventor of biotechnology, the Commission implicitly acknowledged that Rule 28 does not strike a fair balance between the interests of the inventor and the interests of the general public and competitors.[174] The Commission's proposal, embodied in article 15 of the Directive,[175] proposes four substantial changes to be made in the Implementing Regulations of the EPC, yet retains, in principle, the expert solution contained in Rule 28.[176]

The first proposed modification would extend the deposit requirement to all inventions employing self-replicating material, regardless of whether they involve micro-organisms.[177] This proposal would have far-reaching implications with respect to animal and plant matter, but it does not affect directly the treatment of biotechnological inventions or inventors.

The three remaining proposals are of greater importance to biotech inventors. All three proposed modifications are concerned directly with the release of or access to the deposited material.[178] Article 15(5)(a) of the proposed EC Directive provides that when the patent application is refused, withdrawn, or deemed to be withdrawn such that no patent protection attaches, the deposited material will not be released either to third parties or to neutral experts.[179] This modification is a tremendously welcome improvement over Rule 28. Rule 28 provides that regardless of whether the applicant has chosen the expert solution, in the event that the application fails, the deposited sample, or a culture derived thereform, must be made available to any requesting party.[180]

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174. *Id.* at 86-87.

175. Proposed EC Directive 1989: Working Paper of the EC Council Working Party on Intellectual Property (Patent/Biotechnology), ch. 4, art. 15 [hereinafter Proposed EC Directive], *reprinted in* STRAUS & MOUFANG, *supra* note 20, at 165-67.

176. STRAUS & MOUFANG, *supra* note 20, at 87. The 1988 original official wording of the Directive was modified in 1989. *See id.* at 165 & n.463.

177. *Id.* at 87.

178. *See* Proposed EC Directive, *supra* note 175, art. 15(5)(a), 15(7)(a)(i)-(ii), *reprinted in* STRAUS & MOUFANG, *supra* note 20, at 166.

179. Article 15(5)(a) reads:

> Subject to the provisions of paragraphs 6 and 7, unless the patent application is refused, withdrawn or deemed to be withdrawn, a sample of the deposited material shall be available upon request to any person from the date of publication of the patent application and to any person having the right to inspect the files under the provisions of national patent law prior to the date of publication.

Proposed EC Directive, *supra* note 175, art. 15(5)(a), *reprinted in* STRAUS & MOUFANG, *supra* note 20, at 166.

180. STRAUS & MOUFANG, *supra* note 20, at 87.

To lend credibility to the additional restrictions on the accessibility and availability of the deposited material, the Commission emphasized that the original purpose behind early publication in Europe was to apprise interested parties of pending patent rights, rather than to give those parties an opportunity to exploit those inventions commercially.[181] The Commission also recognized that early publication carries immense disadvantages for biotechnological inventors when access to the deposited material remains unrestricted after publication and upon rejection of the application.[182] The Commission acknowledged that the loss of the inventor's ability to use the invention as a trade secret was a devastating consequence of unrestricted access to the deposited material.[183] Although article 15(5)(a) represents an improvement in existing practice, it fails to solve all problems posed by early publication.[184]

The remaining modifications found in the proposed EC Directive, located in article 15(7)(a), also relate to the nonexistence of patent protection when the patent application fails. Both provisions of article 15(7)(a) impose tighter restrictions on persons requesting and receiving samples of the deposited material than those imposed by Rule 28. Article 15(7)(a)(i) requires that the requester must not grant access of the deposited material to third parties.[185] This obligation remains in force after refusal or withdrawal of the application, or after the expiry of the pat-

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181. *Id.* at 87-88.

182. *Id.* Commenting on this problem, the Commission opined:

> While the possibility of losing the confidential nature of an invention exists for all published but subsequently unsuccessful patent applications, the release of material which greatly facilitates the use of an invention distorts the disclosure rule to the unwarranted advantage of a competitor, because of the greater immediate value of a sample of the deposited material than that of a written description.
>
> In respect of deposited animate matter, therefore, it is necessary to separate the desired notice function of the early publication from the undesirable effects of providing the capability for the public to employ the invention for other than verification or experimental purposes.

STRAUS & MOUFANG, *supra* note 20, at 88 (citation omitted).

183. *See infra* notes 185-88 and accompanying text.

184. STRAUS & MOUFANG, *supra* note 20, at 87-89.

185. Article 15(7)(a)(i) states:

> 7. (a) Any person requesting a sample of the deposit under paragraph 5 or 6 hereof must undertake:
>
> (i) not to make it or any matter derived therefrom available to third parties irrespective of whether the application has been refused, withdrawn or deemed to be withdrawn.

Proposed EC Directive, *supra* note 175, art. 15(7)(a)(i), *reprinted in* STRAUS & MOUFANG, *supra* note 20, at 166.

ent.[186] Article 15(7)(a)(ii) provides that anyone to whom a sample is issued must undertake to use the sample culture, or cultures derived therefrom, for experimental purposes only.[187] This obligation is not limited as to time or place and only ceases to apply when the patent issues.[188] The obligation also will expire when the patent application is refused or withdrawn, in accordance with Rule 28.[189]

When taken together, the two provisions of article 15, paragraph 7 achieve a result equivalent to a direct prohibition on exportation of the sample to states in which a patent has not yet issued.[190] Because the requester must promise to use the material for experimental purposes only and must agree not to transfer the sample or derivatives of the sample to third parties, the mere use of the sample by the requester in a patent-free state poses no greater threat to the inventor's property rights than use within the grantor state.[191] The obligations placed on the requester apply regardless of time or location.[192]

The Commission supports this nonexportation restriction, or its equivalent, that implies a contractual relationship between a patentee and the patent grantor, whereby the patentee receives certain exclusive rights as consideration for disclosure.[193] Under this theory, consideration is illusory "if disclosure takes place in the form of a sample of self-replicating material for the public of that legal territory for which no patent has been granted or applied for."[194] The transfer of the sample to a patent-free state[195] is not imposed by patent law, nor is it in the inter-

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186. *Id. See also* STRAUS & MOUFANG, *supra* note 20, at 88.

187. Article 15(7)(a)(ii) states:

> (a) Any person requesting a sample of the deposit under paragraph 5 or 6 hereof must undertake:
>
> (ii) to use the deposited matter or any matter derived therefrom in any country only for experimental purposes concerning the invention.

Proposed EC Directive, *supra* note 175, art. 15(7)(a)(ii), *reprinted in* STRAUS & MOUFANG, *supra* note 20, at 166.

188. *See* Article 15(7)(b), which reads:

> The undertakings provided in paragraph 7 (a) hereof shall also apply after the grant of the patent unless the patentee has voluntarily abandoned his rights or the patent has expired.

Id.

189. *See supra* note 186 and accompanying text.

190. STRAUS & MOUFANG, *supra* note 20, at 89.

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. A patent-free state is one that either has not granted a patent on the particular invention or does not consider microbiological inventions to be patentable subject matter.

ests of the grantor state. Therefore, the transfer serves no genuine patent purpose and should be kept to a minimum.[196] The proposed Directive, through the provisions of article 15, indicates that the Commission at least implicitly recognized the component of tangible property inherent in biological material, even if they did not express explicitly that view.[197]

VIII. Assessment and Critique of the Existing Systems in the United States and Europe

A. *European States and the European Patent Convention*

By incorporating the expert solution into Rule 28 and by proposing additional restrictions on release, the EPC has made laudable attempts to alleviate the hardship suffered by biotech inventors. Unfortunately, these remedies fail to strike at the root of the problem—the accepted practice of early publication. Although implemented out of the necessity to increase the efficiency of and relieve the burden on European national patent offices, early publication creates complications that neither the expert solution nor the proposed Directive takes into account.[198]

Article 15 of the proposed EC Directive provides that after rejection or withdrawal of an application, the sample deposited in connection with the application will not be subject to release to anyone under any circumstances.[199] Article 15, however, fails to acknowledge that third parties will have had access to the sample since publication. Because patent protection has not attached to the micro-organism, the only protection accorded under article 15(7)(a) is the restriction placed on the requester's use of the sample.[200] Nevertheless, the opportunity to misuse the sample still exists because of the self-replicating nature of micro-organisms. Even if misuse is unlikely, the likelihood is greater than if the deposit had not been released prior to the issuing of a valid patent.[201] Furthermore, under article 15, the applicant does not have the opportunity to prevent the release of deposited biological material in the event a patent is granted, if during the course of examination the deposit was

196. Straus & Moufang, *supra* note 20, at 89.

197. *Id.*

198. *See supra* notes 121-30 and accompanying text.

199. *See supra* note 179 and accompanying text.

200. Proposed EC Directive, *supra* note 175, art. 15(7)(a), *reprinted in* Straus & Moufang, *supra* note 20, at 166.

201. In the United States, which does not permit release before the patent grant, misuse of a sample prior to patent grant would be impossible, provided the depositor did not distribute samples. *See infra* note 209 and accompanying text.

deemed unnecessary and superfluous.[202]

Few reasonable solutions exist for curing this dilemma. Even the acceptable solutions carry undesirable collateral effects. The most ameliorative solution would be to end completely the procedure of early publication. Although the remedial effects on the rights of biotech inventors would be tremendous, the cessation of early publication would re-impose an enormous burden on the European national patent offices.[203] Unless the backlog in the patent offices could be rerouted, this solution would result in additional problems and delay for inventors, as well as for interested third parties.[204]

Legislative measures taking into account the special dual nature of biological materials could be enacted, as was attempted with article 15. For example, the release of a deposited sample upon the application's publication is not justified by the arguments set forth in support of early publication.[205] Publishing only the application, without releasing samples of the deposited culture, would serve the purpose of apprising interested parties of potential patent rights and would protect fully the inventor's property rights in the deposited material.[206]

Concessions must be made to allow the applicant to reclaim possession of the deposited sample upon realization that deposit is unnecessary to fulfill the disclosure requirement. Penalizing the applicant for underestimating the ability of the written word to sufficiently describe his invention serves no valid purpose.[207]

B. *The United States*

The situation in the United States, with respect to release conditions, is more favorable than that of any other a state.[208] Flaws, however, still exist that render protection for microbiological inventors less effective than ultimately could be possible with proper modifications. The United States has rejected early publication and remained true to the traditional view that an inventor does not surrender property rights in the invention

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202. STRAUS & MOUFANG, *supra* note 20, at 92. *Cf. In re* Lundak, 773 F.2d 1216 (Fed. Cir. 1985).

203. *See supra* notes 107-09 and accompanying text.

204. *See supra* notes 108-09 and accompanying text.

205. *Id.*

206. The claims contained in the application describe the nature and boundaries of the invention, rather than information for actually practicing the invention. *See generally* GOLDSTEIN, *supra* note 34, at 451-53.

207. *See supra* note 96 and accompanying text.

208. *See Position Paper*, *supra* note 3, at 231-32.

until those rights are replaced with patent rights.[209] As a result, the deposited sample is not released until the examination procedure has been completed.[210]

Waiting to release the sample is advantageous to the inventor for several important reasons. First, the inventor's intangible, as well as tangible, property rights are protected fully until the time the patent takes effect. Because the Patent and Trademark Office (PTO) is the only party granted access to the deposited micro-organism during the examination process,[211] the applicant does not risk misuse of the deposited sample by competitors. Both the application and the deposited sample remain confidential during the period prior to the issuance of the patent.[212] Hence, any protection the inventor might obtain under trade secret laws remains intact. Similarly, if for some reason the application is rejected, the sample is not made available to third parties. Therefore, the applicant retains the right to make the final determination as to the invention's disposition.[213] Again, the applicant may choose to seek protection under trade secret laws.

In contrast, after the inventor has obtained the patent rights and the sample is released, the inventor cannot further restrict release of the sample.[214] Simply stated, once a patent issues, the inventor has very limited power to make release dependent upon the fulfillment of certain conditions. At first glance, this result is no different than the situation involving the patenting nonbiotechnological inventions. Indeed, this result arises from the quid pro quo in which the inventor gives up the right to secrecy in exchange for the exclusive right to make, use, or sell the invention for a limited period. Nevertheless, as previously discussed, release of a deposited micro-organism affects not only intellectual property rights, but also tangible property rights.[215] To successfully protect the latter, the inventor must be able to exercise at least a modicum of control over the disposition of the deposited sample. This extra control dictated by the dual nature of biotechnological inventions is accomplished most effectively by allowing the inventor to specify certain conditions upon which release of the deposited sample is predicated.[216]

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209. STRAUS & MOUFANG, *supra* note 20, at 44-49.
210. *Id.*
211. 37 C.F.R. § 1.808(a) (1990).
212. *See In re* Argoudelis, 434 F.2d 1390, 1393 (C.C.P.A. 1970).
213. STRAUS & MOUFANG, *supra* note 20, at 48.
214. 37 C.F.R. § 1.808(a)(2) (1990).
215. *See Position Paper, supra* note 3, at 232.
216. *See* Berge Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. TRADEMARK OFF. SOC'Y 569 (1985).

By refusing to grant this right of minimum control to inventors, the United States patent law produces an anomalous result. A patent applicant's tangible property rights in the deposited material are protected by contract at all times prior to the patent grant or rejection. After the invention passes the rigorous test of patentability, this contractual protection disappears.[217] Consequently, the term of the patent protection afforded to biotechnological inventors effectively is reduced from the statutory term of years to the period of time during which the application is pending.[218] If an underlying purpose of patent law is to draw innovation into the public domain, this scenario of a reduced protection term is completely unacceptable. By underprotecting the inventors' rights affected by the patent process, the system encourages inventors to seek protection under the trade secret laws.[219]

The International Chamber of Commerce has set forth several conditions that it considers to be reasonable and necessary, in light of the concerns raised.[220] These conditions include permitting the released sample to be used for experimental purposes only,[221] prohibiting transfer to third parties,[222] prohibiting exportation of the released sample,[223] prohibiting release of the sample to states where no enforceable rights exist,[224] and imposing restrictions on material derived from the deposited material.[225]

Permitting the patentee to exercise some control over the release of the sample is compelling for several of the same reasons justifying the existence of the deposit requirement.[226] For instance, the difficulty of sufficiently describing the micro-organism in writing is analogous to the difficulty of proving the infringing similarity of a competitor's micro-organism to the micro-organism claimed in the patent. Furthermore, if the invention claimed is a manufacturing procedure that merely employs

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217. *Id.* at 603.

218. *Id.*

219. *See supra* notes 146, 151-59 and accompanying text.

220. *See Position Paper, supra* note 3, at 232-33, 240.

221. *Id.* at 232. This limitation gives the patent owner additional protection in situations in which patent rights would be difficult to enforce.

222. *Id.* This prohibition recognizes the importance of the patentee's ability to keep track of the identity of parties who possess a sample of the deposited material.

223. *Id.* at 232-33. This prohibition prevents use of the sample in a patent-free state and subsequent re-importation of the final product to the original state.

224. *Id.* at 233.

225. *Id.* at 233. This restriction prevents possible mutation of the organism to the point that it falls outside the scope of the patent.

226. *See supra* notes 18-22 and accompanying text.

the deposited micro-organism as an essential element, absent a mandate against exportation of the sample, the manufacture could be carried out in a state in which the invention has not been patented. The final product then could be imported back to the state of origin. When the requester is not restricted from exporting the sample or from taking it to patent-free states, infringement of this type will be extremely difficult, if not impossible, for the patentee to prove.[227]

IX. CONCLUSION

An immediate solution to the problems involved in patenting biotechnological inventions in Europe is not readily apparent.[228] The European states and the EPC should abandon the practice of early publication and return to the traditional system of prohibiting publication prior to patent grant. This solution cannot be effected over night, but it should be adopted as a long term goal for the European states.[229]

Returning to the traditional system alone, however, is not enough. All states must begin to allow inventors to place restrictions on the release of deposited samples to protect their interests sufficiently. Examples of possible restrictions have been set forth herein.[230] The need for greater harmonization in this area cannot be overstated. The failure of any major state to offer sufficient protection of biotech inventors' interests renders the protection afforded by all remaining states irrelevant. The law of the weaker state will prevail and will discourage potential patent applicants in all states. Inventors instead will turn to trade secret laws, which, in the long run, will not be in any party's best interest.[231]

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227. *Position Paper, supra* note 3, at 232-33.
228. *See supra* notes 121-30 and accompanying text.
229. *Id.*
230. *See supra* notes 220-25 and accompanying text.
231. *Position Paper, supra* note 3, at 231.