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MICROORGANISMS AND THE PATENT OFFICE: TO DEPOSIT OR NOT TO DEPOSIT, THAT IS THE QUESTION

INTRODUCTION

The revolution in biotechnology¹ is one of the most important developments affecting industry in the twentieth century.² New techniques have been developed to create novel life forms.³ Many companies have been formed to exploit these advances in biotechnology,⁴ while other corporations are expanding into this area.⁵ To protect their investments in these new ventures, companies have relied on the seventeen-year monopoly granted inventors under the Patent Act of 1952 (Act).⁶

1. 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. See I. Cooper, *Biotechnology and the Law* § 1.01, at 1-1 (1982); Demain, *Industrial Microbiology*, 214 *Science* 987, 991-94 (1981).

2. *Biotech Comes of Age*, *Bus. Wk.*, Jan. 23, 1984, at 84, col. 1 (technological revolution that may rival even the development of the computer).

3. See I. Cooper, *supra* note 1, § 1.01, at 1-1; Blattner, *Biological Frontiers*, 222 *Science* 719, 719 (1983); Falkinham, *Principles of Genetic Engineering*, in *Genetically Engineered Microorganisms & Cells: The Law & Business II-1 to -24* (I. Kayton ed. 1981).

4. Since 1980, over 100 companies have been formed to exploit the new technology. Norman, *Another Biotechnology Company Bites the Dust*, 217 *Science* 1016 (1982); *Biotech Come of Age*, *Bus. Wk.*, Jan. 23, 1984, at 84, col. 1.

5. See, e.g., Culliton, *Monsanto Gives Washington U. \$23.5 Million*, 216 *Science* 1295 (1982); Walsh, *Cornell, Three Companies Plight Biotech Troth*, 220 *Science* 287 (1983). The increased interest in biotechnology is not limited to the United States. See Dickson, *German Firms Move Into Biotechnology*, 218 *Science* 1287 (1982); Dickson, *France Boosts Biotechnology*, 217 *Science* 516 (1982); Schmeck, *Report Says Japan Could Lead in Commercial Biotechnology*, *N.Y. Times*, Jan. 27, 1984, at A9, col. 3.

6. 35 U.S.C. §§ 1-376 (1976). The seventeen-year monopoly allows the inventor to exclude all others from making, using or selling his invention. 35 U.S.C. § 154 (1976). The cost of developing microorganisms is very high. "Without a proprietary position, such as a patent right, few industrial firms will be keen on spending millions of dollars for research." I. Cooper, *supra* note 1, § 1.02, at 1-15. This is analogous to the situation in the pharmaceutical industry where, without patent protection, the development of new drugs would be unprofitable. *Id.* at 1-15 n.16. The availability of patents to cover the newly developed microorganisms will encourage more investment because of the greater chance for a sizable return. *Id.* at 1-15 & n.16.

Some of the patents that have been obtained by companies working in biotechnology include: U.S. Pat. No. 4,362,816 (1982) (process for creating new microorganisms that can produce insulin, assigned to The Upjohn Company); U.S. Pat. No. 4,350,769 (1982) (microorganism that produces a thickening agent for aqueous sys-

Prior to the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*,⁷ a living microorganism could not be patented because the organism was a "work of nature."⁸ The inventor was limited to claiming such inventions as a process, method or mixture using the microorganism.⁹ In *Chakrabarty*, however, the Court held that the man-made living bacteria in question was patentable subject matter.¹⁰ The invention was found to be patentable because the bacteria had "markedly different characteristics from any found in nature and [had] . . . the potential for significant utility."¹¹ Additionally, the discovery was the inventor's, not "nature's handiwork."¹² This decision expanded the

tems, assigned to Merck & Co., Inc.); U.S. Pat. No. 4,259,444 (1981) (microorganism that can digest crude oil, assigned to the General Electric Company).

7. 447 U.S. 303 (1980).

8. *Id.* at 309-10; *accord* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948). In *Funk Bros.*, the Supreme Court held a patent claiming a mixture of bacteria invalid for want of invention because one could not claim or patent a natural phenomenon. *Id.* at 131-32. Although the organisms expressed a trait not exhibited in nature, these were natural properties of the organisms and the discovery of the traits did not warrant the issuance of a patent. *Id.* at 130-31.

9. *See, e.g.*, *Tabuchi v. Nubel*, 559 F.2d 1183, 1184 (C.C.P.A. 1977) (patent allowed for a method that produced citric acid using a yeast from the strain *Candida*); *Ex parte* Schmidt-Kastner, 153 U.S.P.Q. (BNA) 473, 474 (Pat. Bd. App. 1963) (patent allowed for a process the production of actinomycin F1 using a novel microorganism); U.S. Pat. No. 1,260,899, at 3 (1918) (patent allowed for lactic acid bacillus mixed with inert material).

10. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). In *Chakrabarty's* patent applications, in addition to claiming a process using a new microorganism and the process creating the new organism, he claimed a new form of the bacterial genus *Pseudomonas* capable of digesting crude oil. *In re Chakrabarty*, 197 U.S.P.Q. (BNA) 72, 73 (C.C.P.A.), *cert. dismissed*, 439 U.S. 801 (1978), *aff'd on rehearing sub nom. In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *aff'd sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The patent examiner rejected the claim to the microorganism because, in his opinion, the organisms were "products of nature" and as such could not be patented. 197 U.S.P.Q. (BNA) at 74. The Patent and Trademark Office Board of Appeals affirmed the rejection on the grounds that a living organism could not be the proper subject of a patent. *Id.* The Court of Customs and Patent Appeals (now part of the Court of Appeals for the Federal Circuit) reversed, holding that living matter could be the subject of a patent. *Id.* at 75.

11. 447 U.S. at 310.

12. *Id.* The Court did not address the question whether naturally occurring microorganisms were the proper subject of a patent. A companion case, *Parker v. Bergy*, 444 U.S. 924 (1980), raised the issue, but the appeal was dismissed as moot when Bergy withdrew the claim to the microorganism. *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980); *see* I. Cooper, *supra* note 1, § 2.08, at 2-23. The court below, however, in dicta, had found the new organism isolated from nature to be the proper subject of a patent because what was claimed was a biologically pure culture of the organism and the organism did not exist in a pure state in nature. *In re Bergy*, 596 F.2d 952, 976 (C.C.P.A. 1979), *dismissed as moot sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980). The Patent Office appears to have adopted this position as it has allowed patents claiming biologically pure cultures of microorganisms isolated from nature. *See, e.g.*, U.S. Pat. No. 4,371,622 (1983) (microorganism isolated from Danubian mud); U.S. Pat. No. 4,328,316 (1982) (microorganisms isolated from Indian soil); U.S. Pat. No. 4,315,989 (1982) (microorganism isolated from soil).

protection that an inventor can obtain for a new microorganism and has spurred the increased commercial interest in biotechnology.¹³

An inventor claiming or using microorganisms faces an unusual problem in satisfying the "enablement" requirement of the Act.¹⁴ The Act requires an inventor to include in his patent application "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."¹⁵ As a result, the enablement requirement helps fulfill the overall purpose of the Act which is "To promote the Progress of Science and the useful Arts"¹⁶ by encouraging inventors to share their acquired knowledge with the public.¹⁷

A writing, known as the specification, normally satisfies the enablement requirement.¹⁸ If a patent claims or uses a microorganism, however, a specification alone may not necessarily satisfy the enablement requirement.¹⁹ To solve this problem, the Patent and Trademark Office (Patent Office) and the courts have developed a deposit requirement for patents involving microorganisms.²⁰ If a patent relies on a microorganism that is not known or readily available to the public, a culture or sample of the microorganism must be placed "in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted."²¹ In this manner, enablement is accomplished because using both the specification and the

13. See *supra* notes 4-6 and accompanying text.

14. See *In re Argoudelis*, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970) (written description of the inventor's process alone insufficient because of the unique aspect of using microorganism); *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959) (same).

15. 35 U.S.C. § 112 (1976).

16. The purpose of the Act is found in U.S. Const. art. I, § 8, cl. 8.

17. *Sony Corp. of Am. v. Universal City Studios*, 52 U.S.L.W. 4090, 4093 (U.S. Jan. 17, 1984) (The purpose of the patent and copyright laws is to motivate inventors and writers by granting them a limited monopoly and to allow public access to the products of their genius when the monopoly expires.); *A.F. Stoddard & Co. v. Dann*, 195 U.S.P.Q. (BNA) 97, 103 (D.C. Cir. 1977) ("The *quid pro quo* which supports the patent grant is the requirement of a full disclosure regarding the invention; indeed, the very purpose of the patent system is to encourage disclosures."); *Flick-Reedy Corp. v. Hydro-Line Mfg. Co.*, 146 U.S.P.Q. (BNA) 694, 697 (7th Cir. 1965) (same), *cert. denied*, 383 U.S. 958 (1966); *Ex parte Hull*, 191 U.S.P.Q. (BNA) 157, 159 (Pat. Bd. App. 1975) (same).

18. See 35 U.S.C. § 112 (1976). A specification must be included in all patent applications. *Id.* § 111 (1976).

19. *In re Argoudelis*, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970); *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959).

20. *In re Argoudelis*, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970); Manual of Patent Examining Procedure § 608.01(p)(C) (1981) [hereinafter cited as MPEP].

21. MPEP, *supra* note 20, § 608.01(p)(C).

microorganism, a person skilled in the art can make and use the claimed invention.²²

Since the development of the deposit requirement, significant changes in technology have occurred.²³ Techniques have been developed by which new organisms can be created.²⁴ Using these techniques, it is possible for another scientist to faithfully duplicate a process and thereby consistently achieve the same results as the original inventor.²⁵ Thus, it may be possible to develop the microorganism²⁶ based on the specification alone.²⁷ Additionally, problems such as the cost of the deposit and the lack of a clear standard for the deposit have arisen. As a result, if the process can be faithfully reproduced, a deposit should not be required. When a deposit is needed, the requirement should be modified.

This Note addresses the question of when a deposit should be required for patents involving microorganisms. Part I explores the history and purpose of the deposit requirement. Part II describes recent changes in technology. Part III examines some of the problems of the deposit requirement. In conclusion, Part IV offers suggestions to overcome these problems.

I. THE DEPOSIT REQUIREMENT

Inventions using microorganisms have been patented for over one hundred years.²⁸ The patents usually claimed new processes,²⁹ methods³⁰ or mixtures³¹ using known or readily-available microorganisms.³² In the 1940's and the 1950's, with the development of new

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

23. See *infra* pt. II.

24. See *infra* pt. II.

25. See *infra* note 76 and accompanying text.

26. While this Note focuses primarily on patents claiming microorganisms such as bacteria, utility patents claiming other living organisms such as plants may be subject to the deposit requirement as well. Neagley, Jeffrey & Diepenbrock, *Section 101 Plant Patents—Panacea or Pitfall?*, in 1 Am. Pat. Law Ass'n Selected Legal Papers A1, A25 (1983); see U.S. Pat. No. 4,378,655 (1983) (utility patent on new variety of plant in which a deposit was made of the seed from the starting organism). Thus, the discussion of the deposit requirement applies to those patents as well as those claiming microorganisms.

27. See *infra* note 76 and accompanying text.

28. In 1873, Pasteur patented a biologically pure culture of yeast as a new article of manufacture. U.S. Pat. No. 141,072 (1873).

29. *E.g.*, *In re Mancy*, 182 U.S.P.Q. (BNA) 303, 304 (C.C.P.A. 1974); *Ex parte Schmidt-Kastner*, 153 U.S.P.Q. (BNA) 473, 473-74 (Pat. Bd. App. 1963).

30. See *Tabuchi v. Nubel*, 559 F.2d 1183, 1184 (C.C.P.A. 1977).

31. *E.g.*, U.S. Pat. No. 1,260,899 (1918) (lactic acid bacillus mixed with inert material); U.S. Pat. No. 952,418 (1910) (bacteria mixed with cocoa).

32. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 129 (1948) (six microorganisms used in the mixture were well-known in the art).

antibiotics, inventors began to use new and rare microorganisms in the processes or methods claimed in their applications.³³ Because the organisms used were not generally available to the public, these patent applications raised the question whether merely describing the microorganism used, and where and how it was found, satisfied the enablement requirement.³⁴ The Patent Office adopted the position that a description alone did not satisfy enablement because, without public access to the microorganism, the invention could not be made and used by one skilled in the art.³⁵ The Patent Office, therefore, required inventors to place samples or cultures of the organisms in depositories accessible to the public.³⁶

The Court of Customs and Patent Appeals in *In re Argoudelis*³⁷ affirmed the need for the deposit requirement. The court found that, given the state of the art, the inventors could not "sufficiently disclose by written word how to obtain the [new] microorganism . . . from nature."³⁸ The screening process used in isolating the new organism was unpredictable.³⁹ As a result, a great deal of time and experimentation might be necessary to find the organism, if it could be found at all.⁴⁰ If so, this would constitute "undue experimentation."⁴¹ If duplicating an invention requires "undue experimentation," the enablement requirement is not satisfied.⁴² An inventor, however, could over-

33. Levy and Wendt, *Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications*, 37 J. Pat. Off. Soc'y 855 (1955).

34. See *id.* at 856.

35. See *id.* See *supra* note 19 and accompanying text.

36. See Levy and Wendt, *supra* note 33, at 857; *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148, 151 (Pat. Bd. App. 1959) (failure to deposit microorganism or to disclose its source rendered specification insufficient); *cf.* *Ex parte* Moersch, 104 U.S.P.Q. (BNA) 122, 124 (Pat. Bd. App. 1954) (failure to disclose the method of making a key starting compound for a chemical process rendered specification non-enabling).

37. 434 F.2d 1390, 1392-93 (C.C.P.A. 1970).

38. *Id.* at 1392.

39. See *id.* (screening for microorganisms may take a short time or a long time, if the organism can be found at all); *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959) (same).

40. *Argoudelis*, 434 F.2d at 1392.

41. See *id.*; *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148, 153 (Pat. Bd. App. 1959).

42. See *In re* Honn, 364 F.2d 454, 463 (C.C.P.A. 1966) (if extensive experimentation is needed to create claimed compound, specification is insufficient to support claims) (citing *Prutton v. Fuller*, 230 F.2d 459, 463 (C.C.P.A. 1956)); *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959). The fact that some experimentation or testing may be required, however, does not render the specification non-enabling. *Tabuchi v. Nubel*, 559 F.2d 1183, 1187-89 (C.C.P.A. 1977) (screening a known group of microorganisms to find the one that works best is not undue experimentation); *In re* Geerdes, 491 F.2d 1260, 1265 (C.C.P.A. 1974) (testing to select proportions and particle sizes from a given group is not undue experimentation).

come this problem by making the microorganism starting material available to the public.⁴³ Thus, a person skilled in the art could freely obtain a sample of the organism, and by following the patent specification, duplicate the invention.⁴⁴

II. CHANGES IN TECHNOLOGY AFFECTING THE DEPOSIT REQUIREMENT

When the Patent Office announced the deposit requirement, the organisms used by inventors, while rare, already existed in nature.⁴⁵ The inventor isolated and identified the organism as opposed to creating a new organism from a set procedure.⁴⁶ The method used was as follows: Based on prior experience, a scientist examined a sample of a substrate, such as soil, to detect the presence of microorganisms.⁴⁷ Any microorganisms present were isolated from the substrate, and their traits studied and catalogued.⁴⁸ The organisms were then tested for any useful characteristics, such as the production of antibiotics.⁴⁹ If the microorganism exhibited a useful trait, the scientists attempted to develop the organism commercially.⁵⁰ The process using the microorganism or the new and useful product of the process was the subject of any patent issued.⁵¹

Another process used at that time did not discover pre-existing organisms but instead sought to create new organisms. This process, however, did not ensure that the same organism would always be produced.⁵² The process exposed known organisms to mutation-inducing agents, such as radiation or chemicals.⁵³ After exposing a culture of a selected organism to the mutation agent, the culture was tested to

43. *Argoudelis*, 434 F.2d at 1392-93.

44. In return for obtaining a sample of the microorganism during the life of the patent, the user may be required to pay a royalty to the inventor. See *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."). After the patent expires, however, anyone can reproduce the invention without charge. *Id.*

45. See *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148, 149 (Pat. Bd. App. 1959) (microorganism isolated from soil sample found on farm in Pennsylvania).

46. *Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970); I. Cooper, *supra* note 1, § 1.01[1], at 1-4 to -6. Isolation of microorganisms is still used today. See U.S. Pat. No. 4,315,989 (1982).

47. See I. Cooper, *supra* note 1, § 1.01[1], at 1-4; U.S. Pat. No. 4,315,989 (1982).

48. I. Cooper, *supra* note 1, § 1.01[1], at 1-4 to -5.

49. *Id.* at 1-4.

50. See *id.* at 1-6.

51. See *supra* notes 29-31 and accompanying text.

52. Behringer, *Microorganism Patents*, 63 J. Pat. Off. Soc'y 128, 133-34 (1981) (mutation is a "shot-in-the-dark approach").

53. See I. Cooper, *supra* note 1, § 1.01[1], at 1-6; Behringer, *supra* note 52, at 133-34; Demain, *supra* note 1, at 991; Falkinham, *supra* note 3, at I-31 to -32.

see if the resulting organisms exhibited any new and useful traits.⁵⁴ If so, the organisms were isolated and developed.⁵⁵

The rarity of the sampled substrate or the unpredictability of the mutation agents, however, prevented the results of the isolation process or mutation experiments from being readily duplicated.⁵⁶ Regardless of how accurately the isolation or mutation process was described, no one skilled in the art could consistently duplicate the results.⁵⁷ The patents using the organisms found by these processes therefore could not be enabling without a deposit of the organism.⁵⁸

Advances in technology, however, have allowed more predictability in the development of new microorganisms. In 1953, Watson and Crick discovered deoxyribonucleic acid (DNA) to be the basic genetic material of living organisms.⁵⁹ Since then scientists have sought to understand how DNA functions.⁶⁰ By understanding the structure and function of DNA, scientists hoped to discover ways to manipulate the genetic compositions of different organisms to create new and useful forms of life.⁶¹ In the late 1970's and early 1980's, several methods were developed to accomplish this goal.

One method uses natural or laboratory-induced gene transfer methods to transfer the traits of one organism into another, thereby creating a new organism.⁶² The new organism has the traits of both.⁶³ The patent issued to Ananda Chakrabarty is an example of this procedure.⁶⁴ In developing his new microorganism, Chakrabarty used plasmids⁶⁵—small, independent, self-replicating segments of DNA that

54. See I. Cooper, *supra* note 1, § 1.01[1], at 1-2, 1-6; Behringer, *supra* note 52, at 133-34; Falkinham, *supra* note 3, at II-2.

55. See Falkinham, *supra* note 3, at II-2.

56. See *In re Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970) (isolation process may take a long or short amount of time if the organism can be found at all); Behringer, *supra* note 52, at 133-34.

57. See *In re Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970) (inventor "cannot sufficiently disclose by written word how to obtain the microorganism starting material from nature"); *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959) (reproduction of the invention would require extensive screening that may or may not isolate the same organism).

58. See *In re Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970); *Ex parte Kropp*, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959).

59. Fox, *The DNA Double Helix Turns* 30, 222 *Science* 29 (1983); Watson and Crick, *Molecular Structure of Nucleic Acids*, 171 *Nature* 737 (1953).

60. Blattner, *supra* note 3, at 720; see Gilbert, *DNA Sequencing and Gene Structure*, 214 *Science* 1305 (1981).

61. See Abelson, *Biotechnology: An Overview*, 219 *Science* 611 (1983).

62. Falkinham, *supra* note 3, at II-2.

63. *Id.*

64. U.S. Pat. No. 4,259,444 (1982).

65. *Id.*; Falkinham, *supra* note 3, at II-2 to -3.

occur in many forms of bacteria.⁶⁶ Chakrabarty transferred the plasmids containing the genetic code for several traits from different varieties of bacteria into one host organism.⁶⁷ Thus, a new organism was created having the characteristics of both the donors and the host organism.⁶⁸ Because following the specification would produce consistent results, enablement could be satisfied without a culture deposit.⁶⁹

Other methods that have been developed to alter the genetic composition of microorganisms include the use of natural processes, such as conjugation⁷⁰ and the use of temperate viruses.⁷¹ The use of mutation agents continues to be a major method of producing new organisms.⁷² Scientists now have a better understanding of how mutations occur and have developed more specific mutation agents.⁷³ Thus, the predictability of this process has been improved. Fusion of organisms is another process used.⁷⁴ Finally, scientists have learned to construct artificial hybrid plasmids which have been used to transfer the genetic

66. I. Cooper, *supra* note 1, § 1.01, at 1-3; U. Goodenough & R. Levine, *Genetics* 561 (1974). Plasmids generally occur only in bacteria and carry the genetic code for one or more traits. *Id.* One advantage of using plasmids to transfer traits is that the microorganisms do not suffer any adverse effects. *See id.* (plasmids are "capable of enjoying an autonomous self-replicating status in the host-cell without lowering host-cell viability").

67. U.S. Pat. No. 4,259,444 (1981); Behringer, *supra* note 52, at 128-29; Falkinham, *supra* note 3, at II-2 to -3.

68. *See* Falkinham, *supra* note 3, at II-2 to -3. Chakrabarty transferred the plasmids coding for hydrocarbon digestion and heavy metal resistance from different strains of *Pseudomonas aeruginosa* into one strain creating a new organism capable of digesting crude oil. Such an organism could help control oil spills. *Id.* at II-2 to -3; U.S. Pat. No. 4,259,444 (1981).

69. *See infra* notes 76 and accompanying text.

70. I. Cooper, *supra* note 1, § 1.01, at 1-3. Conjugation is a process by which two cells join to exchange genetic material. *Id.*; U. Goodenough & R. Levine, *supra* note 66, at 395-99. By interrupting the process at a known point, a scientist can select which traits are transferred and which are not. *See id.*

71. I. Cooper, *supra* note 1, § 1.01[2], at 1-9. Temperate viruses are used to insert new traits into microorganisms because the viruses merge their genetic material with the genetic material of the host organism and can be induced to express the new information along with the host's normal genes. *See* U. Goodenough & R. Levine, *supra* note 58, at 399.

72. *See* Demain, *supra* note 1, at 991-93; Falkinham, *supra* note 3, at II-2, *see, e.g.*, U.S. Pat. No. 4,339,539 (1982) (novel microorganism created by mutating known organisms); U.S. Pat. No. 4,266,035 (1981) (microorganism used in the treatment of wastewater developed by mutating a known strain of *Pseudomonas*); Evans & Sharp, *Single Gene Mutations in Tomato Plants Regenerated from Tissue Culture*, 221 *Science* 949 (1983) (improved variety of tomato produced by mutating plant tissue culture); Lyons, *Pace Quickens in the Search for Ideal Plants*, N.Y. Times, Sept. 27, 1983, at C1, col. 1.

73. *See* Demain, *supra* note 1, at 991; Falkinham, *supra* note 3, at II-2.

74. I. Cooper, *supra* note 1, § 1.01, at 1-3; Demain, *supra* note 1, at 991. In this process, the cell walls of the starting organisms are dissolved and the protoplasts

code for traits, such as the production of human insulin, into microorganisms.⁷⁵

The important feature of many of these techniques is that a new organism can be faithfully reproduced relying solely on the specification.⁷⁶ This is in contrast to the earlier processes that did not yield predictable results. Using these new methods, an inventor can create a new organism and describe the process in such full, clear and concise terms that others in the field can achieve the same result solely by following the specification. Thus, enablement may be achieved without a deposit, and accordingly, a culture deposit should not be required for every patent claiming a microorganism.

III. THE PROBLEMS STEMMING FROM THE DEPOSIT REQUIREMENT

In addition to the changes occurring in the technology of creating microorganisms, several problems connected with the deposit requirement have arisen. These problems, coupled with the technological changes that allow enablement at times to be met without a deposit, demand a reconsideration of the deposit requirement.

A. *Limiting the Scope of the Patent*

The scope of protection given to a patent owner depends upon what he claims in his patent.⁷⁷ An inventor must recite in his claims what he believes to be his invention.⁷⁸ In an infringement action, a court will interpret the claims broadly or narrowly, depending upon the nature

merged. I. Cooper, *supra* note 1, § 1.01, at 1-3. The resulting organisms bear the characteristics of both original cells. *Id.* at 1-3 to -4.

75. U.S. Pat. No. 4,387,162 (1983); U.S. Pat. No. 4,371,625 (1983); U.S. Pat. No. 4,362,816 (1982); U.S. Pat. No. 4,349,629 (1982); *see* U.S. Pat. No. 4,332,892 (1982) (process to produce proteins by inserting hybrid plasmids into microorganisms); Falkinham, *supra* note 2, at II-3 to -4. This process involves adding or substituting a foreign gene into a known plasmid and then introducing the hybrid plasmid into an organism that will accept the plasmid. *Id.*; *see* Hitzeman *et al.*, *Secretion of Human Interferons by Yeast*, 219 *Science* 620 (1983); Murai *et al.*, *Phaseolin Gene from Bean is Expressed After Transfer to Sunflower via Tumor-Inducing Plasmid Vectors*, 222 *Science* 476 (1983). Hybrid temperate phages have also been altered to insert new genes into microorganisms. *See* U.S. Pat. No. 4,349,629 (1982).

76. *See* Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 *J. Pat. Off. Soc'y* 455, 458-60 (1983); U.S. Pat. 4,349,629 (1982) (process for creating hybrid plasmids and introducing them into microorganisms).

77. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950); *Ziegler v. Phillips Petroleum Co.*, 483 F.2d 858, 869 (5th Cir.), *cert. denied*, 414 U.S. 1079 (1973).

78. 35 U.S.C. § 112 (1976).

of the patent⁷⁹ and the area of technology.⁸⁰ The scope of a claim may, in some instances, be limited to what is deposited.⁸¹ This has raised a serious concern that the scope of protection an inventor receives for his man-made microorganism may be unnecessarily narrowed.⁸² Such reduced protection may discourage some inventors from seeking patents: The advantages of keeping the organism a trade secret may outweigh the reduced protection of a patent.

The cause for this concern is the Patent and Trademark Office Board of Appeals (Board) decision in *Ex parte Jackson*.⁸³ The Board held that an inventor attempting to claim an entire species of naturally occurring microorganisms would be limited instead to the three different organisms deposited and mutations of those organisms.⁸⁴ This decision severely limits the scope of a patent claiming microorganisms when a deposit is required and is a shift from the cases involving chemical patents in which an inventor may be able to claim an entire class of compounds.⁸⁵ As a result, similar organisms "discovered" by another scientist might be found to lie outside the scope of the patent and be non-infringing.⁸⁶

While the microorganisms claimed in *Jackson* were naturally occurring, the language in the opinion appears broad enough to encompass man-made microorganisms as well.⁸⁷ The problem of applying *Jack-*

79. The claims in a "pioneer patent," which covers a wholly new function or device, are entitled to very liberal construction, providing a broad scope of protection. *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 561-62 (1898); *Ziegler v. Phillips Petroleum Co.*, 483 F.2d 858, 870 (5th Cir.), *cert. denied*, 414 U.S. 1079 (1973). When the patent is merely an improvement on an existing invention, the claims are construed more narrowly and the inventor is given more limited protection. *Connell v. Sears, Roebuck & Co.*, 559 F. Supp. 229, 245 (N.D. Ala.), *aff'd in part*, 722 F.2d 1542 (Fed. Cir. 1983); *see Ziegler v. Phillips Petroleum Co.*, 483 F.2d 858, 870 (5th Cir.), *cert. denied*, 414 U.S. 1079 (1973).

80. If the technology has been well developed, the claims will be narrowly construed. *Connell v. Sears, Roebuck & Co.*, 559 F. Supp. 229, 246 (N.D. Ala.), *aff'd in part*, 722 F.2d 1542 (Fed. Cir. 1983).

81. Elman, *Patent Examiners Cite Unpublished Appeals Decision in Denying Broad Species Claims*, Genetic Engineering News, May/June 1983, at 13, col. 1 (patent claims limited to microorganism deposited); Schmidt, *Microorganisms are Entitled to Generic Claims as Much as Anything Else*, 2 Biotechnology L. Rep. 126 (1983) (same).

82. Schmidt, *supra* note 81, at 131.

83. 217 U.S.P.Q. (BNA) 804 (Pat. Bd. App. 1982).

84. *Id.* at 807-08.

85. Schmidt, *supra* note 81, at 128-31; *see In re Fischer*, 166 U.S.P.Q. (BNA) 18 (C.C.P.A. 1970) (patentee allowed to claim class of chemicals by defining the basic characteristics of the class).

86. *See* Schmidt, *supra* note 81, at 131; *cf. Ziegler v. Phillips Petroleum Co.*, 483 F.2d 858, 868 (5th Cir.) (court will determine if the infringing product is the same as the patented invention), *cert. denied*, 414 U.S. 1079 (1973).

87. *Ex parte Jackson*, 217 U.S.P.Q. (BNA) 804, 809 (Pat. Bd. App. 1982) (Katz, Examiner-in-chief, concurring) ("Even considering the newly developing biological

son to the claims of the inventor of a man-made organism is that, unlike the inventors in *Jackson*, he has shown how, in effect, to create a new species of organism.⁸⁸ He should be entitled to claim the entire species resulting from his process if the specification alone is enabling.⁸⁹ If the inventor of a man-made microorganism believes that his claims would be severely limited, he may choose to forego seeking a patent and instead maintain his invention as a trade secret.⁹⁰ This would contravene the purpose of the Act, which is to encourage inventors to disclose their discoveries so that others can learn from and build upon their inventions.⁹¹

B. *The Cost of Depositing Microorganisms*

The cost of establishing and maintaining a microorganism deposit is perhaps the biggest practical problem with the deposit requirement.⁹² This cost may deter inventors from seeking a patent. No other patent applicant faces this cost, which runs from \$380 to over \$870 per deposit, depending upon the type of protection sought.⁹³ This cost has risen considerably over the past few years and may continue to rise.⁹⁴ In light of the high cost of obtaining a patent,⁹⁵ the fact that a deposit

engineering techniques, at this time it is just not feasible to expect one skilled in the art to 'manufacture' the necessary microbe."); see Schmidt, *supra* note 81, at 131.

88. Schmidt, *supra* note 81, at 131.

89. See *id.*

90. See I. Cooper, *supra* note 1, § 1.02, at 1-16 to -17; Schmidt, *supra* note 81, at 131.

91. See *supra* note 17 and accompanying text.

92. See I. Cooper, *supra* note 1, § 5.04[2], at 5-54 to -55. One author has stated that while the cost presents a problem, it is cheaper to pay the deposit fee than it is to prepare "a response to an office action rejecting the application . . . for lack of a deposit." *Id.* at 5-55.

93. The fees listed are for the American Type Culture Collection (ATCC), one of the two major depositories in the United States. The \$380 fee is for inventors seeking U.S. patents. An additional \$300 fee is required if the depositor wants to be informed of all recipients of the deposit. The fee is \$870 for those filing under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, T.I.A.S. No. 9768. American Type Culture Collection, Patent Culture Depository (1981) [hereinafter cited as ATCC Pamphlet].

The other major depository in the United States is the Agricultural Research Culture Collection (NRRL) [hereinafter cited as ARS Collection]. The fee for depositing a culture at the ARS collection is \$500 regardless of the type of protection sought. ARS Patent Culture Collection *Initiation of Fees*, 1033 Official Gaz. Pat. Off. 22 (Aug. 23, 1983) [hereinafter cited as ARS Collection Fees].

94. Prior to 1983, the ARS Collection did not charge any fees for depositing microorganisms for patent purposes. See ARS Collection, *Procedures and Policies for Deposition of Cultures for Patent Purposes in the Agricultural Research Culture Collection (NRRL)* 1 (1979).

95. In addition to the deposit fees, other expenses connected with a patent application include Patent Office fees that can exceed \$1000. See 35 U.S.C.A. § 41

can increase that cost by five to ten percent may present a significant obstacle to many new biotechnology companies. To achieve and maintain a strong market position and thereby attract more customers and investors,⁹⁶ these companies should establish extensive patent portfolios.⁹⁷ Biotechnology companies usually have very limited capital with which to develop a patent portfolio. Needlessly increasing the cost of securing a patent would unnecessarily cause some companies to fail and force others to pursue other forms of protection such as trade secrets.

The cost may be increased further if an inventor is required to make several deposits to ensure the broadest possible scope for his patent in light of *Jackson*.⁹⁸ An inventor may be required to deposit every possible organism created by his process or at least a sufficient number of new microorganisms to show that he has created a process that should be afforded broad scope.⁹⁹ Given the current costs for depositing microorganisms, this can increase significantly the costs of securing patent protection and may discourage some inventors from seeking patents.¹⁰⁰

C. *Lack of a Precise Standard for the Requirement*

While the Patent Office and the two major depositories have some rules concerning the deposit requirement, the rules are incomplete and varied.¹⁰¹ In addition, the Manual of Patent Examining Procedure merely lists guidelines for the preferred way to meet the deposit requirement.¹⁰² Other methods of meeting the requirement are possible.¹⁰³ This lack of standards presents various problems, including the

(1982); 37 C.F.R. § 1.16-1.21 (1983). Attorneys fees can bring the total cost to over \$4000. See Am. Pat. Law Ass'n, Report of Economic Survey 13, 30-31 (Oct. 1983).

96. See *supra* note 6 and accompanying text.

97. See Norman, *supra* note 4, at 1016-17; see also Schmeck, *Report Says Japan Could Lead in Commercial Biotechnology*, N.Y. Times, Jan. 27, 1984, at A9, col. 3 (U.S. companies have difficulty in obtaining capital for later rounds of financing).

98. See *supra* notes 83-86 and accompanying text.

99. See *supra* notes 83-86 and accompanying text.

100. See *supra* notes 83-86 and accompanying text.

101. Among the differences are the fees, see *supra* note 93 and accompanying text, and what organisms will be accepted. The ARS Collection will not accept "[v]iruses and highly pathogenic or especially fastidious microorganisms." *ARS Collection Fees*, *supra* note 93, at 23. The ATCC has no such restriction. See ATCC Pamphlet, *supra* note 93; I. Cooper, *supra* note 1, § 5.03[3], at 5-52.

102. MPEP, *supra* note 20, § 608.01(p)(C); I. Cooper, *supra* note 1, § 5.02[9], at 5-23; Biggart, *Patentability in the United States of Microorganisms, Processes Utilizing Microorganisms, Products Produced by Microorganisms and Microorganism Mutational and Genetic Modification Techniques*, 22 *Idea* 113, 122-23 (1981).

103. See *Feldman v. Aunstrup*, 517 F.2d 1351, 1355 (C.C.P.A. 1975) (deposit that did not meet all the MPEP guidelines for culture deposits found to be acceptable because it fulfilled the purpose of the deposit requirement), *cert. denied*, 424 U.S.

possible release of the deposited organism prior to the issuance of a patent.

If a culture deposit is required it must be made on or before filing a patent application.¹⁰⁴ Normally, during the examination of a patent application, the Patent Office is required to keep secret the application and accompanying materials.¹⁰⁵ The information disclosed to the Patent Office becomes public only if the patent issues.¹⁰⁶ Should a patent not issue, the inventor may retain trade secret rights in the invention.¹⁰⁷ The Patent Office has developed specific rules that are intended to ensure the secrecy of applications before it.¹⁰⁸

Unfortunately, the Patent Office does not possess the facilities to maintain culture deposits.¹⁰⁹ Therefore, other agencies of the federal government,¹¹⁰ private corporations¹¹¹ and institutions¹¹² maintain the deposits. The lack of set procedures for ensuring the confidentiality of deposits means secrecy at these institutions may be difficult to maintain.¹¹³ Even a governmental facility, while acknowledging the necessity for maintaining secrecy,¹¹⁴ has not adopted any rules or procedures to do so.¹¹⁵ When viewed in light of the recent incidents in which companies have obtained their competitors' trade secrets given confidentially to the federal government,¹¹⁶ genuine concern for the secrecy of the deposits arises.

912 (1976); I. Cooper, *supra* note 1, § 5.02[9], at 5-23 to -25, § 5.03, at 5-47 to -52; Biggart, *supra* note 102, at 124-25.

104. MPEP, *supra* note 20, § 608.01(p)(C).

105. See 35 U.S.C. § 122 (1976).

106. See 37 C.F.R. § 1.11 (1983).

107. See, e.g., Aronson v. Quick Point Pencil Co., 440 U.S. 257, 264-65 (1979) (denial of a patent did not affect the inventor's right to enforce a contract for payment of a royalty based on a trade secret disclosure); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 482 (1974) (non-patentable discovery can be protected as a trade secret).

108. See 37 C.F.R. § 1.14 (1983).

109. See I. Cooper, *supra* note 1, § 5.02[8], at 5-22.

110. The ARS Collection is maintained by the Department of Agriculture. Reorg. Plan No. 1 of 1947, 12 Fed. Reg. 4534 (1947), reprinted in 5 U.S.C. app. at 731 (1976) and in 61 Stat. 952 (1947) (all agricultural research functions consolidated under the Secretary of Agriculture).

111. One such corporation is In Vitro International, Inc. See *Acquisition of the Status of International Depository Authority*, Indus. Prop., Nov. 1983, at 306, 307.

112. The ATCC is a private, non-profit corporation. I. Cooper, *supra* note 1, § 5.03[2], at 5-50.

113. This is analogous to the trade secrets situation where the absence of set guidelines or procedures for safeguarding the protected material increases the chance of disclosure. See R. Milgrim, Trade Secrets § 2.04, at 2-27 (1983).

114. See ARS Collection, *Procedures and Policies for Deposition of Cultures for Patent Purposes in the Agricultural Research Culture Collection (NRRL)* 1 (May 1979).

115. *Id.* at 4.

116. Cf. Monsanto Co. v. Acting Adm'r, United States EPA, 564 F. Supp. 552, 567 (E.D. Mo.) (disclosure by the EPA of Monsanto's secret formulas for insecticides

The lack of a clear standard also creates a problem regarding the nature of the deposit. In some cases, the inventor deposited only the organism created or found.¹¹⁷ In another case, the inventor deposited the organism that donated the plasmid he used, as well as the new organism developed using that plasmid.¹¹⁸ In yet another instance, the applicant deposited the starting organism.¹¹⁹ These examples raise the question of which of the many materials used the inventor should deposit to allow others to make and use his invention. If, in hindsight, a court finds that the inventor has failed to deposit the correct material, the patent may be held invalid for failing to fulfill the enablement requirement.¹²⁰

As a result of this possibility, the cost of the deposit again becomes a factor. To ensure meeting the enablement requirement, an inventor may feel compelled to deposit every material or organism used in his invention.¹²¹ This practice increases the cost of the patent because each deposit requires a separate fee.¹²² If the inventor had to make only one deposit based on a clear standard, the cost would be reduced.

In light of these problems, changes in the deposit requirement are needed. Additionally, the changes in technology that often make a specification by itself enabling cast doubt on the need for a deposit in every case.

IV. PROPOSED CHANGES IN THE DEPOSIT REQUIREMENT

A. *Elimination of the Deposit Requirement in Some Cases*

Eliminating the deposit requirement in certain circumstances would alleviate many of the problems previously detailed.¹²³ Unfortun-

found to be an unconstitutional taking of plaintiff's property), *probable jurisdiction noted sub nom.* Ruckelshaus v. Monsanto Co., 52 U.S.L.W. 3290 (U.S. Oct. 18, 1983); Airborne Data Inc. v. United States, 216 U.S.P.Q. (BNA) 887, 893-94 (Ct. Cl. 1982) (U.S. Geological Survey disclosed trade secrets of a contract bidder to its competitors despite agreement to the contrary), *aff'd*, 217 U.S.P.Q. (BNA) 297 (Fed. Cir. 1983).

117. See, e.g., U.S. Pat. No. 4,363,876, col. 1 (1982); U.S. Pat. No. 4,350,769, col. 1 (1982).

118. See U.S. Pat. No. 4,362,816, col. 3 (1982).

119. U.S. Pat. No. 4,378,655, col. 10 (1983).

120. See *Shelco, Inc. v. Dow Chemical Co.*, 322 F. Supp. 485, 517 (N.D. Ill. 1970) (failure to include or disclose an essential element relating to the composition, manufacture or use of the invention will render the patent invalid), *aff'd on other grounds*, 466 F.2d 613 (7th Cir.), *cert. denied*, 409 U.S. 876 (1972).

121. See *supra* notes 98-100 and accompanying text.

122. See ATCC Pamphlet, *supra* note 93; *ARS Collection Fees*, *supra* note 93, at 22.

123. See *supra* pt. III. At least one country, Sweden, has amended its patent laws to read that if the specification can enable one skilled in the art to reproduce the

nately, the deposit requirement can be eliminated or avoided only when a narrow set of circumstances exist. The process of creating or isolating the microorganism should be capable of being easily duplicated based upon the specification. The specification should include, among other things: the nature and source of the starting materials, the enzymes or chemical agents used, the steps and conditions for each step of the process, and an explanation of how the organism was induced to exhibit its new traits.¹²⁴ A showing that others skilled in the art, by following the specification, can duplicate the invention faithfully and with little difficulty should be required to ensure that the specification alone is enabling.¹²⁵ On the other hand, patents relying on naturally occurring microorganisms that cannot be readily isolated from nature or man-made microorganisms created by a process that cannot be readily duplicated should still require a deposit. No matter how well the inventor describes the procedure for creating or isolating the organism, if one skilled in the art can not easily follow it or produce the same results, the enablement requirement has not been met.¹²⁶

invention, no culture deposit is required. Ass'n Of Swedish Patent Att'ys, Amendments of the Swedish Patents Act (August 1983) (available in files of *Fordham Law Review*).

124. I. Cooper, *supra* note 1, § 5.06[2], [3].

125. Affidavits or declarations by other scientists skilled in the art that they have read and followed the specification to recreate the invention without difficulty would be sufficient. See R. Saliwanchik, Legal Protection for Microbiological and Genetic Engineering Inventions 122-23 (1982). Affidavits for this purpose are common in patent application procedures. See 37 C.F.R. § 1.132 (1983) (affidavits can be used to traverse a rejection for inoperative specification). The process should work every time or the disclosure is inadequate. *Standard Oil v. Montedison*, 494 F. Supp. 370, 384 (D. Del. 1980), *aff'd*, 664 F.2d 356 (3d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

126. *In re Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970). See *supra* notes 37-44 and accompanying text. Because of the wording of many foreign patent acts, a deposit may be required in cases in which patent protection is sought in those countries. See I. Cooper, *supra* note 1, § 5.02[16], [17], [18]; R. Saliwanchik, *supra* note 125, at 147-59.

Arguably, a deposit may be required in all cases to satisfy the "best mode" requirement of § 112. I. Cooper, *supra* note 1, § 5.04[2], at 5-55. The "best mode" concept stems from the part of § 112 requiring an inventor to set forth the "best mode" contemplated by him for carrying out the invention. See 35 U.S.C. § 112 (1976). The purpose of the requirement is to insure that the inventor discloses the best embodiment of his invention at the time he applies for his patent. See *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962). A deposit might be required under this concept if the invention was a process using a microorganism instead of creating a microorganism. This is because the best way of recreating the process is to obtain a sample of the organism from a public depository. If the invention, however, is not a process using an organism but the organism itself the inventor may satisfy the best mode require-

Not requiring a deposit in certain circumstances would alleviate the problems created by *Ex parte Jackson*.¹²⁷ *Jackson* is viewed as severely limiting the scope of a patent claiming a microorganism.¹²⁸ The Board reasoned in part that the specification and the deposited microorganism did not adequately instruct those skilled in the art how to find the other members of the species being claimed.¹²⁹ This rationale, however, should not apply to the inventor of a man-made microorganism when the specification is sufficiently enabling to eliminate the deposit requirement. Such an inventor has shown how to create a new organism. The process can be used to create other organisms with similar traits.¹³⁰ The inventor has created a new species defined by the traits he has transferred into the organism created. On the other hand, inventors claiming a naturally occurring microorganism, such as the scientists in *Jackson*, have shown how to obtain only the organism claimed and not the rest of the species.¹³¹ Accordingly, *Jackson* would still apply and the rationale for limiting the scope of the patent would still be correct.

B. Postponement of Deposit Until the Patent is Allowed

If a deposit is required, it should be required only after the notice of allowance is issued. In this manner, an inventor would be spared the cost of the deposit until he is sure of receiving a patent.¹³² Additionally, should a patent not issue, it would be easier for an inventor to

ment by disclosing the best way to make and use the organism. *Id.*; Herbert, *Failure to Disclose the "Best Mode": What the Public Doesn't Know Will Hurt Them*, 64 J. Pat. Off. Soc'y 12, 18-19 (1982).

127. 217 U.S.P.Q. (BNA) 804 (Pat. Bd. App. 1982). See *supra* notes 83-91 and accompanying text.

128. See *supra* notes 81-91 and accompanying text.

129. See *Ex parte Jackson*, 217 U.S.P.Q. (BNA) at 806; Schmidt, *supra* note 81, at 127.

130. See Meyer, *supra* note 76, at 460-61.

131. 217 U.S.P.Q. (BNA) at 806. It may be argued that the inventors in *Jackson* had in fact found a new species just as the inventor of a man-made organism has created a new species defined by the traits he has been able to transplant. Therefore a claim to the entire species should be allowed. See Schmidt, *supra* note 81, at 128. This, however, does not resolve the problem of instructing others skilled in the art to find the rest of the species.

Jackson, however, may not be as limiting as it appears. The Board did hold that the scope of the claims would include mutations of the strains deposited. 217 U.S.P.Q. (BNA) at 806. Because mutation of patented organisms is the most likely avenue for the development of infringing organisms, this should be sufficient coverage. *Id.*; accord BLR *Interviews Author of Treatise on Patenting Biotechnology Inventions*, 2 Biotechnology L. Rep. 106, 111 (1983).

132. Fees are not required until the deposit is made. See *supra* note 93 and accompanying text. The issuance of a notice of allowance means that the patent

maintain his trade secret because there is less risk of a sample of the microorganism falling into the hands of a third party.¹³³

Arguably, a deposit should be required at the time of filing, to ensure that the organism claimed has actually been created.¹³⁴ This, however, can be accomplished without a deposit. If the Patent Office suspects that the organism claimed does not exist, a sample can be requested.¹³⁵ The Patent Office can then have the culture tested in a governmental laboratory.¹³⁶

C. A Standard for the Deposit

The adoption of a clear standard for culture deposits by the Patent Office and the authorized depositories would help solve many of the problems.¹³⁷ An example of such a set of rules is the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Treaty).¹³⁸ While not requiring all depositors to comply with the Treaty, the two major American depositories, as authorized Treaty facilities, are familiar with the requirements.¹³⁹ Thus, no new rules or regulations would need to be developed.

application has been approved and a patent will issue once the necessary fees are paid and formalities are met. 37 C.F.R. §§ 1.311(a), 1.314 (1983).

133. Not having a deposit in the hands of a third party makes it easier to keep the invention a secret, which is the key to trade secret protection. See I. Cooper, *supra* note 1, § 1.02, at 1-16.

134. Part of the ARS Collection depositing procedure requires the laboratory to test the culture to see if the organism is viable. ARS Collection, *supra* note 114, at 4.

135. 35 U.S.C. § 114 (1976) allows the Patent Commissioner to require an applicant to furnish the Patent Office with models, specimens or ingredients for the purpose of inspection or experimentation.

136. The Patent Office has limited facilities, but it may be able to arrange to have another agency, such as the Department of Agriculture, test the cultures. See I. Cooper, *supra* note 1, § 5.02[8], at 5-22.

137. See *supra* pt. III. Perhaps the one problem that cannot be eliminated is the cost of the deposit.

138. Apr. 28, 1977, T.I.A.S. No. 9768, *reprinted in* 961 Official Gaz. Pat. Off. 21 (1977) [hereinafter cited as Budapest Treaty]. While the Patent Office and the major depositories do follow the Treaty for some applications, there is no requirement that the Treaty be used. See MPEP, *supra* note 20, § 608.01(p)(C).

139. See I. Cooper, *supra* note 1, § 5.02[16]. Recently, a third United States depository, In Vitro International, Inc., has achieved Treaty facility status. *Acquisition of the Status of International Depositary Authority*, Indus. Prop., Nov. 1983, at 306, 307.

Other Treaty facilities include: National Collection of Yeast Cultures (United Kingdom); the Fermentation Research Institute (Japan); the Deutsche Sammlung von Mikroorganismen (Federal Republic of Germany); and the Centraalbureau voor Schimmelcultures (Netherlands). I. Cooper, *supra* note 1, § 5.02[16], at 5-44. A deposit in any of these facilities will satisfy the United States deposit requirement. See

The Treaty rules detail the manner in which the microorganism should be deposited,¹⁴⁰ how long the deposit should be maintained,¹⁴¹ and the procedures for ensuring the secrecy of the deposit.¹⁴² Thus, these rules would eliminate many of the problems with the deposit requirement.¹⁴³ To ensure that the rules are followed, the Patent Office should require that the organism be deposited in a Treaty facility and that the Treaty requirements be satisfied before the patent will issue.

The Treaty does not address what organisms or material should be deposited if a deposit is needed.¹⁴⁴ Moreover, there are currently no clear enablement guidelines covering this point.¹⁴⁵ The Patent Office should provide guidelines to which an inventor can look in order to satisfy enablement. Because of the nature of the inventions, however, set requirements would be difficult to provide. Whether a deposit satisfies the enablement requirement would still have to be judged on a case-by-case basis. The main benefit in providing guidelines, however, is not in giving the inventor a list of requirements. Rather, if an inventor's patent is challenged, he will be able to point to the guidelines and show that he satisfied them to the best of his ability. This would be in contrast to the "shotgun" approach that some inventors use to ensure compliance.¹⁴⁶ The guidelines should be based on common sense: The inventor should deposit organisms or materials that are not readily available or that cannot be made by following the inventor's written procedure.¹⁴⁷ In this manner, the inventor can be assured of satisfying the enablement requirement with the fewest possible deposits.

CONCLUSION

While some patents claiming microorganisms still must meet the deposit requirement, recent developments in biotechnology allow

Feldman v. Aunstrup, 517 F.2d 1351, 1356 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912 (1976).

140. Rules 6, 7, Budapest Treaty, *supra* note 138, at 15-16, *reprinted in* 961 Official Gaz. Pat. Off. at 32-33 (1977).

141. Rule 9, Budapest Treaty, *supra* note 138, at 17, *reprinted in* 961 Official Gaz. Pat. Off. at 33-34.

142. Rules 9.2, 11, Budapest Treaty, *supra* note 138, at 17-19, *reprinted in* 961 Official Gaz. Pat. Off. at 34.

143. See *supra* pt. III.

144. See Budapest Treaty, *supra* note 138.

145. See *supra* notes 117-20 and accompanying text.

146. See *supra* notes 117-20 and accompanying text.

147. *Cf. Ex parte Moersch*, 104 U.S.P.Q. (BNA) 122, 123-24 (Pat. Bd. App. 1954) (specification would have been sufficient had the source of the compound been made known before or at the time of filing).

many inventors to satisfy the enablement requirement with the specification alone. Additionally, serious problems with the deposit requirement exist. These problems reinforce the proposition that a deposit should not be required if it is not needed.

Adoption of a clear set of standards for the deposit, such as the Budapest Treaty, will eliminate many problems for those patents still needing a deposit. Deferring a deposit until the notice of allowance is issued will reduce the problem of possible disclosure prior to the issuance of the patent. Adoption of these suggestions will encourage inventors of new microorganisms to seek patent protection and thus further the purposes of the Patent Act.

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