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Enemies to Innovation: Protecting Biotechnology Inventions

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COMMENTS

ENEMIES TO INNOVATION: PROTECTING BIOTECHNOLOGY INVENTIONS

Elizabeth F. Enayati†

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ENEMIES TO INNOVATION: PROTECTING BIOTECHNOLOGY INVENTIONS

Elizabeth F. Enayati

I. INTRODUCTION

In the words of Joseph Addison,¹ "When men are easy in their circumstances, they are naturally enemies to innovation."² In recognition of this exigency, the Framers of the U.S. Constitution provided a means for motivating and rewarding authors and inventors by incorporating in the Constitution protective provisions for their respective writings and inventions.³

Is the protection that was envisioned in the 1700's adequate for modern technology, specifically, for biotechnology? Not as it stands to date. The world market for biotechnological products is projected to reach between \$40 and \$100 billion within the next 15 years.⁴ At the present market growth rate, the product life-cycle of a drug is 8 - 12 years and getting shorter.⁵ In light of this time-frame, there is an urgency on the part of pharmaceutical companies to obtain fast legal protection for their products.

There is currently a two-and-a-half year wait before a biotechnology-related patent application is reviewed by a Patent Examiner.⁶ This is, in part, due to the lack of Examiners qualified to review such applications. Ultimately, the responsibility falls on the legislature to respond to the increased flow of biotechnology-related patent applications.

Legislative action in response to the increase in biotechnology-related inventions has been slow in coming. There are now plans in effect to expand the chemistry division, adding more Examiners

1. Joseph Addison (1672-1719), English poet, essayist and intellectual who was a major influence on English public opinion. 1 *ENCY. AMERICANA* 155 (1981).

2. B. EVANS, *DICTIONARY OF QUOTATIONS* (1978) (citing J. ADDISON, *THE FREEHOLDER* No. 42).

3. U.S. CONST. art. I, § 8, cl. 8, provides: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

4. Figg, *Biotechnology: Science Fiction Becomes a Legal Reality*, *THE COMPLETE LAW.*, Winter 1986, at 29.

5. *Patently Outdated*, *THE ECONOMIST*, July 18, 1987, at 17.

6. Crawford, *Patent Claim Buildup Haunts Biotechnology*, *SCIENCE*, Feb. 12, 1988, at 723.

with a background in biotechnology-related education.⁷ Failure on the part of the legislature to provide adequate protection for inventions in biotechnology will have the short-term effect of loss of market position for individual inventors and companies, and the long-term effect of discouraging investment in research.⁸

Existing intellectual property laws⁹ are inadequate to protect inventions in biotechnology,¹⁰ and restrict access to information among scientists. For reasons discussed in this comment, current intellectual property law can best protect the needs of the innovative biotechnology frontier in the form of a statutory hybrid of two areas of existing legal protection: patent and copyright law.

This comment includes: 1) definitions of some terms and techniques used in the biotechnology industry; 2) a brief survey of the relevant areas of patent and copyright law, including a synopsis of key cases decided in these fields; and 3) a proposed Amendment to 35 U.S.C. section 1-900, attached as an Appendix.

The Appendix, a proposed Amendment to Title 35, is the focal point of this comment. It has been drafted in an attempt to address the key issues and problems posed by the existing patent and copyright laws which have, in a sense, become "enemies of innovation."

II. TERMS AND TECHNIQUES

A. *Biotechnology*

"Biotechnology" is a term which has been used to describe scientific endeavors for decades. Although not a new term, biotechnology techniques today are new and often controversial.¹¹ Modern

7. The application to the April, 1989 Patent Agent Examination adds the following fields to its list of accepted degrees: biology, botany, food technology, microbiology, pharmacology as well as biomedical and computer engineering. See also *infra* note 120 and accompanying text.

8. *Id.* It is important to bear in mind that there are numerous government agencies involved in the approval of biotechnology and pharmaceutical products, the involvement and impact of which is beyond the scope of this comment. For example, the Food and Drug Administration, the National Science Foundation, the Occupational Safety and Health Administration, the Environmental Health Administration and the National Institute of Health. See also Lavelle, *Biotech: The Unknown Frontier for Lawyers*, THE NAT'L LAW J., Feb. 6, 1989, at 1.

9. Intellectual property laws relevant to this area of discussion shall include patent, copyright and trade secret law.

10. Biotechnology, as used in this comment, is defined as the human manipulation of living organisms with the intent of manufacturing a commercially viable or otherwise utilitarian product.

11. See Comment, *A New Twist in the Double Helix: Admissibility of DNA "Fingerprinting" in California*, 5 COMPUTER & HIGH-TECH. L. J. [this issue] (for a discussion on the admissibility of DNA "fingerprinting" as evidence).

use of the term "biotechnology," particularly as used in this comment, refers to recombinant DNA (deoxyribonucleic acid), monoclonal antibody technology and similar technology primarily used in the pharmaceutical industry. The end-result of such laboratory manipulation may take the form of a genetic sequence intentionally encoded in the DNA. It may also take the form of: 1) a substance which will locate and attach to designated cells; 2) a means of mass producing a particular cell line; or 3) a new chemical marketable as a drug.¹²

Biotechnology research and product development primarily centers around the antibody-antigen reaction. This reaction is a major factor in every individual's immune system. An antibody is a molecule comprised of a particular type of protein¹³ which is produced in response to and specifically binds to discrete particles, antigens,¹⁴ which may be on a cell surface. Antibodies are produced by B-cells, manufactured primarily in bone marrow. Once a B-cell is committed to producing an antibody against a specific antigen, all progeny of that B-cell line are equally committed to the production of the identical antibody.¹⁵

Harvesting the natural by-product of specific cell types, part of a process known as tissue culturing, became routine in the 1950's. The barrier encountered by researchers using such techniques was the finite life-span of a cell in culture. All normal cells have an average life-cycle in culture of approximately eight days.¹⁶ Tumor cells, however, have a potentially infinite life span in culture, and it was soon discovered that by creating a hybrid¹⁷ of a tumor cell with a normal cell, called a hybridoma, the cell lines exhibiting a desired characteristic could be perpetuated almost indefinitely. With the development of hybridoma techniques, monoclonal antibody technology has grown to commercial proportions.¹⁸

12. See *Glossary of Biotechnology Terms*, 1 HIGH TECH. L. J. 253 (1986) for a more complete listing of relevant terms.

13. An antibody is also called an "immunoglobulin" which is itself comprised of a glycoprotein.

14. An antigen is a substance that can induce a detectable immune response when introduced into an animal or human. D. STITES, J. STOBO, J. WELLS, *BASIC CLINICAL IMMUNOLOGY* 694 (6th ed. 1987).

15. *HUMAN HYBRIDOMAS AND MONOCLONAL ANTIBODIES*, (E.G.Engleman, S.K.H.Fong, J.Larrick & A.Raubitschek ed. 1985).

16. B. ALBERTS, D. BRAY, J. LEWIS, M. RAFF, K. ROBERTS & J. WATSON, *MOLECULAR BIOLOGY OF THE CELL* (1983).

17. One cell fused with another, resulting in a cell with some of the characteristics of each contributing cell.

18. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 623 F. Supp. 1344, 1349 (N.D. Cal. 1985) *rev'd*, 802 F.2d. 1367 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987) (for an

Cells which produce an antibody recognizing a known or desired antigen are fused with mouse tumor cells (myelomas). The hybridomas from this fusion result in cell lines of potentially infinite duration which multiply at a rapid rate, thus making harvesting of the desired antibodies commercially feasible.

B. Genetic Engineering

"Genetic engineering" is an area of scientific endeavor different from, though related to, the field of monoclonal antibody and myeloma technology. The term "genetic engineering" typically encompasses any number of techniques used for modifying the nucleotide sequence¹⁹ of a DNA strand.²⁰

One technique used to change the nucleotide sequence is known as "gene splicing." Similar to splicing a piece of film or recording tape, a nucleotide strand of the DNA helix is "cut" (known as "cleavage") using an enzyme specific for that region of DNA. The strand is then replaced with a different string of nucleotides.²¹ This genetic form of "cutting-and-pasting" results in genetically altered, or "engineered" plants and animals.²²

III. PATENT AND COPYRIGHT LAW

Traditionally, protection for inventions and innovations in the pharmaceutical and biotechnological arenas comes from patent law.²³ What is it that makes current patent law inadequate in these

excellent dissertation given by Judge Conti on the current understandings in immunology). One example of the manner in which the above technology is put to use by pharmaceutical and biotechnology companies is drug testing kits.

19. The nucleotides which comprise the DNA strand are thymine, guanine, adenine and cytosine. These four nucleotides form specific pairs which then arrange in different combinations. The resulting sequence of these nucleotides form the "code" sequence for the "building blocks" of proteins. In 1953, Watson and Crick announced that the DNA molecule structure is that of double helix formed by these nucleotides lining up on opposite strands, and bonding together in a unique manner.

20. DNA, deoxyribonucleic acid, carries the genetic "code" which determines the features of most living organisms. Due to the fact that "genes" are the carriers of the information contained in DNA, the act of changing the nucleotide sequence is also known as "genetic engineering."

21. See generally U. GOODENOUGH, *GENETICS* (2d ed. 1978).

22. See generally *Tomorrow's Animals*, *THE ECONOMIST*, Aug. 15, 1987; See also *What Do You Get If You Cross. . .?*, *THE ECONOMIST*, Aug. 15, 1987.

23. The literature on this topic extends from practical advice to outrage. See Horsley, *Research Pathfinder: Biotechnology and Law*, 1 *HIGH TECH. L. J.* 209 (1986). See also R. SALIWANCHIK, *LEGAL PROTECTION FOR MICROBIOLOGICAL AND GENETIC ENGINEERING*, (1982); Casey & Moss, *Intellectual Property Rights and Biotechnology*, 27 *IDEA* 251 (1986); Daus, *Patents for Biotechnology*, 26 *IDEA* 263 (1985).

fields? The answer is found in the statute, in current Patent Office practice, and in recent cases as discussed below.

Copyright law, though not intuitively applicable to technical innovations such as inventions in biotechnology, contains some provisions and approaches which may be applicable to the field of biotechnology. Specifically, the copyright law contains some statutory definitions and provisions which may be applicable to DNA sequences. Recent copyright cases on the "look and feel" issue may offer some insights into analytical approaches to protecting the end-products of genetic engineering.²⁴

A. Patent Law

1. Statutory Subject Matter

The basic requirements for a successful patent application are that the disclosed invention is: 1) within one of the statutory categories of allowable subject matter; 2) useful; 3) novel; 4) non-obvious; and 5) adequately disclosed so as to enable designated persons to use the invention.²⁵

a. 35 U.S.C. § 101: Appropriate Subject Matter

An invention must fall within one of the statutory subject matters listed under 35 U.S.C. section 101.²⁶ Products of microbiological manipulation or genetic engineering have qualified as a "composition of matter."²⁷

Patents for biotechnology-related inventions may also be obtained as a "process" of obtaining a given composition of matter as well as for the product itself.²⁸ There are problems of scope inherent in obtaining both types of patents.

One example of the problem of scope is found when a patent is obtained on a process for producing an antibody, "Ab." The antibody resulting from the process is specific for antigen "Ag," which deactivates a certain virus. A researcher, working for a competitor pharmaceutical company, identifies a process *different* from the pat-

24. A complete discussion of the "look and feel" issue is beyond the scope of this comment. There is extensive literature and case law available on this topic.

25. See generally D. CHISUM, PATENTS (1987).

26. 35 U.S.C. § 101 (1987) states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

27. See *Diamond v. Chakrabarty*, 447 U.S. 303, 65 L. Ed. 2d 144, 100 S. Ct. 2204 (1980) [hereinafter *Diamond*].

28. CRESPI, PATENTING IN THE BIOLOGICAL SCIENCES 33 (1982).

ented process, which results in production of antibody "Ab." The patented process is not broad enough in scope to prevent the use of the second researcher's process.

The problem of scope, as described in the example above, makes researchers wary of disclosing their invention through patents. Although inventions in biotechnology have been fit into existing statutory categories, the resulting protection is not optimal.

b. 35 U.S.C. § 101: Utility

A further requirement of 35 U.S.C. section 101 is that the invention have utility.²⁹ As defined by Chisum, "Utility. . . means that an invention must perform some function of positive benefit to society."³⁰ Utility must be demonstrated in the specification, cannot be solely based on future use or even further research,³¹ and is usually required to be demonstrated for a Patent Examiner beyond the written specification.³²

c. 35 U.S.C. § 102: Novelty

The novelty requirement of 35 U.S.C. section 102³³ basically

29. See *supra* note 26.

30. CHISUM, *supra* note 25, § 4.01, at 4-2. (Chisum states three tests which an invention must meet to satisfy the utility requirement: (1) it must be operable and capable of use; (2) it must operate to achieve some minimum human purpose; and (3) it must achieve a human purpose that is not illegal, immoral or contrary to public policy).

31. *Id.* at § 4.02(2) (1987) (discussing the Supreme Court case of *Brenner v. Manson*, 383 U.S. 519, 16 L. Ed. 2d 69, 86 S. Ct. 1033, 148 U.S.P.Q. (BNA) 689 (1966) a seminal case in which the court held that a chemical process which produces a compound may be patented only if the compound has "substantial utility," i.e. specific benefit in its currently available form, beyond a mere interest for further scientific research).

32. CRESPI, *supra* note 28, at 103.

33. 35 U.S.C. § 102 (1987) states:

Conditions for patentability; novelty and loss of right to patent: A person shall be entitled to a patent unless—

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the

requires that the inventor named in the patent is, in fact, the actual inventor. A patent cannot issue on an invention which is based on material known at the time of the invention, or which is already in the public domain. An inventor cannot obtain the benefits of a patent grant if the invention was attributed to one other than the inventor named in the patent.

To assure that the patent grant issues to the right person, a Patent Examiner will conduct a search of all "prior art"³⁴ references relating to an invention disclosed in an application. This requirement does not pose unique difficulties for biotechnology inventions.

d. 35 U.S.C. § 103: Non-obvious Subject Matter

There is also a statutory threshold "non-obvious subject matter"³⁵ requirement for inventions. The question is whether the invention teaches "one skilled in the art" something that is not already known or disclosed in prior patents or other publications.³⁶ The "non-obvious" requirement is based upon the level of expertise of a person skilled in the art to which the invention pertains.³⁷ In a young, highly dynamic field such as biotechnology, it is difficult to ascertain the relevant level of expertise, primarily because it is constantly shifting as new processes evolve. Inventors in this area must

applicant for patent, or on an international application by another who has fulfilled the requirements of [international patent], or

(f) he did not himself invent the subject matter sought to be patented, or
(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

34. Prior art is a term of art referring to patents, or other publications generally available, which pertain to the field to which an invention relates.

35. 35 U.S.C. § 103 (1987) states that:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in § 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

36. CRESPI, *supra* note 28, at 76.

37. See *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. (BNA) 416 (Fed. Cir. 1986) (in dicta, the following factors are listed as elements to be considered in determining the level of ordinary skill in the art: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions; (4) rapidity of innovation; (5) sophistication of technology; and, (6) educational level of active workers in the field).

ride out the learning curve for attorneys and Patent Examiners who must remain abreast of the dynamic field to adequately review patent applications.³⁸

The non-obvious requirement, though an issue for every claimed invention, has raised particular problems in the area of genetically engineered plants³⁹ and animals.⁴⁰ Conceptually, it is easy to understand that a genetically engineered animal may be considered obvious: a mouse, is a mouse, etcetera.

Along this same line of review, particularly relevant to inventions in biotechnology, is the prohibition against granting patents on "products of nature."⁴¹ There are several ways to circumvent a "product of nature" objection to an application for a biotechnology invention. One way is to discover a new use, and to obtain a process or method patent for the new use. Another way is to significantly alter the form of the product, thus qualifying the result as a composition of matter.⁴²

Process and method claims have also encountered the non-obviousness obstacle, usually expressed in terms of whether or not the results are "unexpected." For example, in one case, claims were made to the preparation of monoclonal antibodies capable of detecting malignant human renal cells by well-established hybridoma technology.⁴³ The Patent Examiner in the case cited, *inter alia*, the hybridoma method that was discovered by Kohler and Milstein, as reported in Nature magazine ten years prior to the application. The Board, in reversing the Examiner's rejection, emphasized that although the technique was well-known in the field, the results obtained were unexpected and, thus, the inventors were able to obtain a patent.

38. See Rauh and Jaenichen, *Novelty and Inventive Step in Inventions having Proteins or DNA Sequences as their Subject Matter*, 70 J. PAT. OFF. SOC'Y 313 (May 1988) (in which the authors conclude: "[A] protein can no longer be considered new if the parameters indicated in the state of the art are sufficient to unambiguously identify it, and accordingly to indicate further parameters would only protect a new definition, but not now [sic] a new product.").

39. See Comment, *Patents, Plants & Biotechnology — Policy and Law*, 14 WESTERN STATE U. L. REV. 529 (1987).

40. See *supra* note 22.

41. For a complete discussion of this issue, including relevant cases, see CHISUM, *supra* note 25, at § 1.02(7). See also Bjozicevic, *Distinguishing "Products of Nature" From Products Derived From Nature*, 69 J. PAT. OFF. SOC'Y 415 (1987).

42. See, e.g., *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 3 U.S.P.Q. 2d (BNA) 1481 (N.D. Cal. 1987), *on motion for reconsideration*, 678 F. Supp. 1429, 6 U.S.P.Q. 2d (BNA) 1018 (N.D. Cal. 1988) (in which the court held that a purified and concentrated form of naturally occurring molecules, Factor VIII:C, was not a product of nature, hence patentable).

43. *Ex parte Old*, 229 U.S.P.Q. (BNA) 196 (PTBA 1985).

It is not difficult to identify the obstacles facing a research scientist who has discovered a commercially viable, antibody-producing mutant microorganism. As the field develops, patents on inventions using hybridoma technology will become narrower in scope to satisfy the statutory requirements. Due to the ambiguity and inadequacy of existing laws, the courts have been forced to draw and enforce their own guidelines.

To date, the Supreme Court has heard only one case in this area of intellectual property law, *Diamond v. Chakrabarty*,⁴⁴ discussed below. From that single case, it can be surmised that the court is willing to look at the degree of human intervention involved in an invention, or innovation, in making its determination whether or not the statutory threshold questions of novelty and non-obviousness have been satisfactorily answered.

The proposed Amendment found in the Appendix, is designed to reduce, if not eliminate, such technically cloaked judicial guesswork. However, until such an amendment is implemented, the practitioner must be ever vigilant and diligent in ferreting out the guidelines for obtaining patents in biotechnology from the cases as they are decided. Legislative activism on the part of patent attorneys may be the best way to assure that guidelines are clear and that protection is in the inventor's best interest.

2. The Patent Application Process

Once it is determined that an invention for which a patent is sought falls within the statutory subject matter requirements, the difficult process of filing an acceptable application begins. The furor over the inadequacy of current patent law for protecting the interest of scientists, pharmaceutical companies and consumers reaches a deafening roar concerning the application requirements.

Three basic filing requirements are enumerated in 35 U.S.C. section 111.⁴⁵ Historically, these requirements, specifically the enabling disclosure requirement,⁴⁶ raised serious obstacles to patent

44. *Diamond*, 447 U.S. 303.

45. 35 U.S.C. § 111 (1987) states: "1) a specification as prescribed in section 112 of this title; 2) a drawing as prescribed by section 113 of this title; and 3) an oath by the applicant as prescribed by section 115 of this title."

46. 35 U.S.C. § 112 (1987) states:

The specification shall contain 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 which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. . .

applications for inventions in biotechnology. As discussed below, a series of cases has given some definitive resolution to the questions of when, and what materials to deposit to satisfy the enabling disclosure requirement.⁴⁷

There are factors which are changing the application process for biotechnology inventions. For example, patent attorneys are becoming more familiar with the language necessary to write valid claims as they see more biotechnology-related cases through their practice. The disclosure requirements can be satisfied with more certainty now that they are understood and generally accepted. In an area of law which was historically dominated by engineers,⁴⁸ the language of the biochemist and hybridoma technician was as foreign as an unexplored country.

3. Recent Patent Cases

a. 35 U.S.C. §§ 102 and 103

Two cases seemingly collide over the issue of what constitutes "anticipated" or "obvious" subject matter under Sections 102 and 103: *Ex parte Old*⁴⁹ and *Ex parte Goodall*.⁵⁰ In the former case, the claims of the applicant's patent covered monoclonal antibodies recognizing enumerated human renal cell antigenic systems, cell lines producing specified antibodies, and a method for differentiating between malignant and normal cells. All three types of claims were rejected on the basis of prior patents disclosing the preparation of monoclonal antibodies and disclosing polyclonal antibodies which react with cell surface antigens such as those in the claims in Old's patent. The Board reversed this rejection, allowing all claims, stating:

Although this technique underlying hybridoma technology is well recognized, nevertheless, the results obtained by its use clearly are unpredictable. Hybridoma technology is an empirical art in which the routinier is unable to foresee what particular antibodies will be produced and which specific surface antigens

47. See Aisenberg, *Depositing Cell Lines to Satisfy Enablement Requirements*, 27 IDEA 149 (1986); *In re Argoudelis*, 434 F.2d 1390, 168 U.S.P.Q. (BNA) 99 (CCPA 1970) (hereinafter Argoudelis). But see Schneider, *Microorganisms and the Patent Office: To Deposit or not to Deposit, That is the Question*, 52 FORDHAM L. REV. 592 (1984).

48. See 37 C.F.R. § 10.7 (1988) (which specifies the qualifications required for someone practicing before the Patent and Trademark Office).

49. *Ex parte Old*, 229 U.S.P.Q. (BNA) 196 (PTBA 1985) [hereinafter Old].

50. *Ex parte Goodall*, 799 F.2d 867, 231 U.S.P.Q. (BNA) 831 (PTBA 1986) [hereinafter Goodall].

will be recognized by them.⁵¹

The Board further noted, as did the appellants, that:

. . . if the art of monoclonal antibodies to cancer antigens were routine and predictable then the Kohler-Milstein discovery [cited as the publication which makes Old's, invention obvious] would make obvious all monoclonal antibodies to cancer antigens and the field of cancer immunology would have routinely produced cancer cures.⁵²

Thus, the Board held that, as with chemical products, if an end-product of a known process is a demonstrably unexpected result of that process, that end-product may properly be patented.

Disregarding the guidelines of *Old*, the Board in *Goodall* came to a contrary decision. It rejected a patent application containing claims for a monoclonal antibody specific to a hepatitis-B surface antigen. The basis for the Board's rejection was that the invention was anticipated under Section 103.⁵³

The prior art relied upon by the Board in sustaining the Examiner's rejection was a patent disclosing the formation of hybridomas from an antigen and cell line apparently identical to those used by the appellant. The Board held that, although the processes were not identical, the resulting antibodies would have been obvious from the antibody disclosed in the prior art.⁵⁴ Unfortunately, the opinion is not rich in the Board's explanation of its method for arriving at its conclusion. It is possible that the appellant could have won this case had it demonstrated that the monoclonal antibody was an unexpected result of the prior art processes.

The most recent case addressing, inter alia, section 102 and 103 requirements is *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*⁵⁵ In this case, Hybritech had filed suit against Monoclonal Antibodies, Inc. alleging that immunometric assays⁵⁶ which utilized monoclonal antibodies and which were marketed and sold by

51. *Old*, 229 U.S.P.Q. at 200.

52. *Id.*

53. It is worth noting that claim 1, upon which the rejection of all claims was based, was for the monoclonal antibody itself, not the process. The Board, in dictum, stated: "[E]ven were claims to appellants' hybridoma and antibody found to be allowable, the patentability of the process of producing the hybridoma and the antibody and using the antibody would still be in question." *Goodall*, 231 U.S.P.Q. at 831.

54. *Id.* at 832.

55. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 623 F. Supp. 1344, 227 U.S.P.Q. 215 (N.D. Cal. 1985) *rev'd*, 802 F.2d. 1367 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987) [hereinafter *Hybritech*].

56. Immunometric assays are techniques for quantitatively measuring the antibody to antigen responses, usually in the form of a kit containing the necessary reagents. Generally,

Monoclonal Antibodies, Inc., infringed a Hybritech patent. The Hybritech patent was on a process for determining the presence or amount of antigen in a fluid sample using a "sandwich" or "two-site" method.⁵⁷ Monoclonal Antibodies, Inc. successfully defended against the infringement claim. The Hybritech patent was declared invalid under Sections 102, 103 and 112.⁵⁸

On appeal,⁵⁹ the decision was reversed. After admonishing the District Court for adopting, as its opinion, Monoclonal's pre-trial brief and findings of fact, Judge Rich, for the Court, applied the classic *Graham v. John Deere Co.*⁶⁰ test to determine "obviousness" under Section 103; i.e., whether the claimed invention would have been obvious at the time the invention was made. The factual inquiries necessary in such determinations are: 1) scope and content of prior art; 2) level of ordinary skill in the art; and 3) difference between the prior art and the claimed invention.⁶¹ The Court also stressed the importance of secondary considerations⁶² in evaluating the obviousness rejection.

The *Hybritech* decision set forth some clear standards for inventions in biotechnology. The Court made the statement, "The mere existence of prior art disclosing how to measure the affinity of high affinity monoclonal antibodies is insufficient to support a holding of obviousness."⁶³ It then concluded that since Hybritech claimed the *process* employing monoclonal antibodies, and not merely the antibody itself, this was sufficient to distinguish it from some prior art references.

On the other hand, the Court stated that while the seminal work of Kohler and Milstein "paved the way for a supply of monoclonal antibodies,"⁶⁴ it did not suggest the use of monoclonal antibodies in the manner used in the Hybritech patent. This statement, combined with testimony at the trial to the effect that the

these are either diagnostic tools used in clinical laboratories or research tools used in research laboratories.

57. *Hybritech*, 623 F. Supp. at 1346.

58. *Id.* at 1356-57.

59. *Hybritech*, 802 F.2d 1367, 1385.

60. *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966) [hereinafter *Graham*].

61. *Hybritech*, 802 F.2d at 1379-80; *See also Graham*, 383 U.S. at 17 (1966).

62. *Hybritech*, 802 F.2d at 1380 states: "Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered BEFORE a conclusion on obviousness is reached and is not merely 'icing on the cake.'" [citations omitted] [Emphasis in original].

63. *Id.* at 1381.

64. *Hybritech*, 802 F.2d at 1380.

Hybritech diagnostic kits embodying the disputed invention unexpectedly solved a long-standing problem, led the Court to find that the Hybritech invention was not obvious.⁶⁵

b. 35 U.S.C. § 112

The landmark decision of *In re Argoudelis, DeBoer, Eble and Herr*,⁶⁶ sets the stage for the current practice of depositing cultures of microorganisms in a public depository prior to filing an application. At present, deposit is necessary to satisfy the enablement requirements of Section 112.⁶⁷

The applicant in *Argoudelis* claimed two new antibiotic compounds and a microbiological process. Prior to filing with the Patent and Trademark Office (PTO), applicants deposited two agar plates of the microorganism producing the antibiotic compounds with the U.S. Department of Agriculture. A cover letter was included with the deposit, requesting that the depository withhold distribution of the organism to the public until notified by the inventors. Notification was to be sent pending patent registration. The claims relating to the organism on deposit were rejected by the Patent Examiner as failing to satisfy the Section 112 specification requirements.

The Patent and Trademark Office Board of Appeals (PTBA) agreed with the Examiner, affirming the rejection of the claims. Finding the deposit to be satisfactory disclosure, the Court of Customs and Patent Appeals (CCPA)⁶⁸ reversed.

At issue was whether applicants were required to make the deposited culture available to the public at the time of filing. The Court held that it was unnecessary for the public to have access to the deposited material *prior* to issuance of a patent. It further stated that the "possibility that the disclosure may someday become non-enabling. . . does not render the disclosure insufficient under section 112."⁶⁹ The CCPA recognized that a unique aspect of using microorganisms as starting materials is that a sufficient description of

65. There were eight conclusions of law stated in *Hybritech*, 623 F. Supp at 1355, including invalidation of the *Hybritech* patent under 35 U.S.C. §§ 102(g), 103, 112 and 113 (indefinite claims). The Circuit Court of Appeals, Federal Circuit (hereinafter CAFC) reversed the decision on all conclusions of law.

66. *Argoudelis*, 434 F.2d 1390.

67. See *supra* note 46.

68. The Court of Customs and Patents Appeals [hereinafter CCPA] was the court for appellate review of Patent and Trademark Office [hereinafter PTO] decisions prior to 1982. In 1982, the CAFC was established, replacing the CCPA in all matters.

69. *Argoudelis*, 434 F.2d at 1394.

how to obtain the microorganism from nature cannot be given.⁷⁰

The concurring opinion by Judge Baldwin points out the concern of patent law expressed in Section 112. Considering the fact that patents are the granting of legal monopoly, the public must receive something in return, thus adding a "measure of worthwhile knowledge to the public storehouse."⁷¹ Judge Baldwin then concluded that as long as one of ordinary skill in the art is able to make and use the claimed compounds at the time the patent *issues*, Section 112 is satisfied by the conditional deposit of materials.⁷²

Relying on the dicta in *Argoudelis* (stating that the particular area of technology involved defied description by written word) the PTBA in *Ex parte Jackson*⁷³ affirmed the Patent Examiner's final rejection of a claim for a new species of microorganism which contained neither a deposit number nor adequate description.⁷⁴ Applicants had discovered three bacterial strains producing a new antibiotic. The claim for the end-product antibiotic (claim 1) was allowed, but the process claims (claims 2-6) for producing the new bacterial strains were rejected by the Examiner as failing to adequately disclose the invention under Section 112.

Although applicants had deposited cultures with a recognized depository, claim 2 relied solely upon a written disclosure, not upon the deposited material for purposes of Section 112. The deposited material was identified with claims 3-6. The Board allowed claims 3-6. Unfortunately, claim 2 was the process claim upon which claims 3-6 relied. Since the *starting material* for claim 2 was not deposited, only the end-product of the claim 2 process, the claim failed to satisfy the disclosure requirements of Section 112 and all claims were finally rejected.

Jackson expands on the dicta and holding of *Argoudelis*. The Board clarified the enablement requirement of Section 112 as allowing a person skilled in the art to reproduce the end-products, in this case the claimed antibiotics.⁷⁵ It is apparent that the inventors were attempting to avoid the deposit requirement by filing one patent and depositing only the starting materials for the claimed bacteria.⁷⁶

70. *Id.* at 1392.

71. *Id.* at 1394 (J. Baldwin, concurring).

72. *Id.* at 1396.

73. *Ex parte Jackson*, 217 U.S.P.Q. (BNA) 805 (PTBA 1982) [hereinafter *Jackson*].

74. *Id.* at 806.

75. *Id.* at 809 (Katz, concurring).

76. For example, microbiological manipulation of A results in B bacteria which produces C antibiotic. Depositing only A would, theoretically, allow one skilled in the art to

The conclusion which may be drawn from the *Jackson* decision is that if one starts from a known common bacteria, A, and adequately discloses a method of mutating A, it will be possible to claim both the process and the end-product without depositing the starting material. However, if mutant bacteria A is required to produce the end-product of a claimed process, bacteria B, the starting material of A must be deposited to satisfy the disclosure requirements of Section 112.

The applicant in *In re Lundak*⁷⁷ believed that his cell lines had been deposited with a recognized depository prior to the filing of his patent application. In fact, the deposit was made too late. The Commissioner denied the applicant's petition to change the filing date. In addition, the Commissioner decided that the legal specification requirements of Section 112 were not satisfied by deposit of the cell lines at other Universities prior to filing.

On appeal, the Court held that Section 112 does not require the deposit to precede filing, emphasizing that the deposit requirement adds nothing to the description of the invention as expressly required by Section 112.⁷⁸ This is consistent with the *Argoudelis* decision.

Of most interest in *Lundak* are the statements made in a footnote to the majority opinion:

[We] observe that it is the public interest in the progress of the useful arts that is benefitted as new technologies evolve. An interpretation of the statute to deny patent rights in microbiological inventions would be contrary to law. . . The PTO must continue to adapt its procedures to facilitate the advance of science and technology.⁷⁹

Perhaps this footnote was in response to the Commissioner's seemingly harsh treatment of *Lundak* by neither allowing him to change his original filing date, nor allowing his deposits with a University

reproduce both B and C. The Board in this case broke the chain of events into two sub-chains: A results in B; B produces C; therefore, both A and B must be deposited.

77. *In re Lundak*, 773 F.2d 1216, 227 U.S.P.Q. (BNA) 90 (Fed. Cir. 1985) (hereinafter *Lundak*).

78. *Id.* at 95; *But see* Old, 229 U.S.P.Q. (BNA) 196 (PTBA 1985) (in which the Board held that the monoclonal antibodies which were the subject matter of the claimed invention, being indisputably reduced to practice prior to the filing date and which were to be deposited at a recognized depository and which were presently being maintained at an institution of reknown and integrity, satisfied 35 U.S.C. § 112 requirements, stating, "No more can be asked of applicant.").

79. *Lundak*, 227 U.S.P.Q. at 93.

to compensate for a bona fide error.⁸⁰ Or perhaps it is a signal by the Court that, at least in the area of biotechnological inventions and discoveries, the PTO needs to be more flexible and less bureaucratic in its approach.

To summarize the deposit requirements, materials must be deposited when they supplement the written description of the invention contained in the application. Usually, this deposit requirement arises when a microorganism, cell line or hybridoma necessary for replicating a claimed process is not readily available to the public. A deposit will be considered timely if it is made prior to issuance of a patent on the matter.⁸¹

In drafting the proposed Amendment found in the Appendix, these strong and often conflicting notions of fairness versus facilitation of the advance of science were key issues to be resolved. As was clearly expressed in *Lundak*, conflicts between the interests of the public in scientific advancement and the private interests of an inventor in personal advancement and economic gain, permeate this area of law. In fact, it is in the public's interest that scientific advances are recognized and protected under the Constitution.⁸² Legislative action is appropriate to alleviate tensions created by such conflict.

c. *The Scope of Biotechnology Protection:
Diamond v. Chakrabarty*

*Diamond v. Chakrabarty*⁸³ is the only U.S. Supreme Court case to date specifically addressing the scope of legal protection as it extends to inventions in biotechnology. It is the subject matter of numerous reviews, analyses and subsequent court decisions.⁸⁴ As a key case in the area of biotechnology, it merits mention in any discussion of law as applied to discoveries or inventions in biotechnology.

The issue before the court was strictly limited to whether Chakrabarty's microorganism constituted a "manufacture" or "composition of nature" within the meaning of section 101.⁸⁵

80. Lundak had apparently believed his cell line had been deposited before filing, when in fact it was not made until seven days after filing. *Id.* at 92.

81. For an excellent discussion of the deposit requirement, complete with examples, see Wiseman, The Need for Deposits, A.B.A., Ann. Meeting (Aug. 11, 1987).

82. U.S. CONST. art. I, § 8, cl. 8.

83. *Diamond*, 447 U.S. 303.

84. For a list of references see *Research Pathfinder: Biotechnology and Law*, 1 HIGH TECH. L. J. 233 (1986).

85. See *supra* note 26.

Chakrabarty had created a new microorganism by fusing four different plasmids. The end-product was a microorganism which could be used to degrade crude oil spills. Indisputably the product of human manipulation, the fact that the "invention" was a living organism made it appear as though it was a "composition of nature."⁸⁶

The impact of the *Chakrabarty* decision on the future of legal protection for inventions and innovations in biotechnology is potentially far-reaching. The basic holding is that for inventions in biotechnology, the relevant query lies in distinguishing between products of nature and man-made inventions. The query does not end with the mere determination that a claimed invention is either living or inanimate.⁸⁷

At the very least, the *Chakrabarty* holding concedes that future inventions in biotechnology will be afforded some protection. Still to be determined is the amount of protection a court will be willing to grant. The legislature is taking up the fight for such leading-edge biotechnology inventions, with numerous bills affording or limiting the rights to inventions in biotechnology.⁸⁸ The scope of protection is broadening, but it remains to be seen whose interests are being protected in the process.

B. Copyright Law

It has been proposed that genetically engineered organisms are within the bounds of copyright protection.⁸⁹ There is a strong argument for allowing scientists to copyright the DNA sequence of a "new" organism: just as a composer may be able to copyright the sequence of notes transcribed on a sheet of paper, so, too, may a scientist copyright the nucleotide sequence comprising the key element of the "new" organism.⁹⁰

86. See Daus, *Patents for Biotechnology*, 26 IDEA 263, 276 (1985).

87. *Id.* at 277.

88. The most recent bills presented concerning animal patenting issues are those introduced by Rep. R.W. Kastenmeier on March 22, 1989: "Transgenic Animal Patent Reform Act" (HR 1556); and "Transgenic Animal Regulatory Reform Act" (HR 1557). The bills propose to grant an exception to the patent laws to allow farmers the right to breed and sell patented animals without the threat of infringement. *Two Bills and OTA Report Address Animal Patenting Issues*, 37 Pat. Trademark & Copyright J. (BNA) No. 923, at 521 (March 23, 1989). The issues raised by the grant of patent protection for genetically altered animals are too numerous to be adequately addressed in this comment.

89. Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982) (Kayton analogizes DNA sequences of genetically engineered works to computer programs. Kayton applies the statutory copyright requirements to protecting amino acid sequences which comprise DNA strands).

90. An organism formed by fusing or genetically engineering nucleotides into a known

Although it is easier to obtain a copyright (there is no intense review of the materials registered under copyright laws) and the protection is granted for a longer period of time,⁹¹ patent protection is usually preferred over the protection of copyright laws. The primary reason for this preference is that the scope of protection provided under patent law is broader than that provided under copyright laws.⁹²

1. Statutory Subject Matter

Subject matter of copyright protection, as outlined in 17 U.S.C. section 102,⁹³ essentially need satisfy only two criteria for registration: 1) the work must be original; and, 2) the work must be "fixed" in a tangible medium of expression. Compared with the requirements for obtaining patent protection, the scrutiny by the Registrar of Copyrights is de minimus. The effect given such protection has basically been developed through common law, and is beyond the scope of this discussion.

Modern copyright law has been challenged recently with respect to protection of computer software. On its face, a straightforward application of an "original work" (the computer program), "fixed" in a medium (the computer code) leads to copyright protection. The issue has arisen, however, whether the "look and feel," or how the software actually appears to the end user, is also protected under copyright law.⁹⁴ A seminal case, *Whelan Associates, Inc. v.*

and intentional sequence is expressed in a manner as unique as the musical expression of notes on a sheet of paper. For proof, look around at the variety in expression in the human race.

91. See 17 U.S.C. § 302 (1987) (Copyright protection basically extends for the life of the owner plus fifty years, whereas most patents have a term of 17 years from the date of issuance. In the case of joint work, the term is fifty years beyond the life of the last surviving author. In the case of anonymous, pseudonymous or work for hire, as would exist in a corporation, the term is 75 years from the year of first publication, or 100 years beyond the year of its creation, whichever expires first).

92. A side-by-side analysis between patent protection and copyright protection is beyond the scope of this discussion. One distinction, however, is that after the intensive review of patent applications, the patent holder receives a presumption of validity for the patent. The copyright registrant has no such presumption upon registration. Also, patent law provides protection against "innocent infringers," whereas copyright law does not provide protection against independent creation.

93. 17 U.S.C. § 102(a) (1987) states: "Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device."

94. The term "look and feel" usually refers to the look of the screen when the computer program is in operation, how the various "menus" prompt the user, or even how the information being supplied by the user is stored and accessed by the hardware of the computer.

*Jaslow Dental Laboratory, Inc.*⁹⁵ has held that copyright protection may be extended beyond the specific code of the computer program. The problems encountered in this area of copyright law find mirror images in patent protection for biotechnology. The present state of copyright law as it pertains to computer software and firmware is in a state of morass similar to that of patent law as it pertains to biotechnology, with modern courts struggling to establish clear guidelines for resolution.⁹⁶

Congress recognized the problem of protecting computer-related products under the Copyright Act of 1946 and has enacted legislation to extend protection into an especially troubled area of law: mask works.⁹⁷ Although appended to the Copyright Act as found in Title 17, the Semiconductor Chip Act defines and describes new subject matter of protection, provides for a severely limited duration (ten years as compared with the life-plus-fifty years for other copyright protected works) and enumerates the scope of protection.⁹⁸

2. Recent Copyright Cases

There are three recent, significant cases concerning the scope of copyright protection for computer software: *Whelan Associates, Inc. v. Jaslow Dental Laboratory, Inc.*,⁹⁹ *Broderbund Software, Inc. v. Unison World*,¹⁰⁰ and *Digital Communications Associates, Inc. v.*

95. *Whelan Associates, Inc. v. Jaslow Dental Laboratory, Inc.*, 797 F.2d 1222, 230 U.S.P.Q. (BNA) 481 (3rd Cir. 1986) [hereinafter *Whelan*].

96. See *Design Patents: A New Form of Intellectual Property Protection for Computer Software*, 70 J. PAT. OFF. SOC'Y 12 (1988) (which discusses the current trend of protecting software through design patent laws). The use of design patent law to protect inventions in biotechnology remains an unexplored area, and is beyond the scope of this comment.

97. See 17 U.S.C. §§ 901-914 (1987) (known as the Semiconductor Chip Act of 1984); 17 U.S.C. § 901a(2)(A) and (B) (1987) defines mask work as: "A series of related images. . .having or representing the predetermined, three-dimensional pattern of metallic, insulating, or semiconductor material. . .in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product."

98. This author is unaware of any cases, to date, which have been brought under the Semiconductor Chip Act. This may be an indication that the scope of protection provided is adequate for resolving necessary issues. For a more complete discussion of the issues arising under 17 U.S.C. §§ 901-914 (1987), see Pinheiro & LaCroix, *Protecting the "Look and Feel" of Computer Software*, 1 HIGH TECH. L. J. 411 (1987). See also Kastenmeier & Remington, *The Semiconductor Chip Protection Act of 1984: A Swamp or Firm Ground?* 70 MINN. L. REV. 417 (1985).

99. *Whelan*, 797 F.2d 1222.

100. *Broderbund Software, Inc. v. Unison World*, 648 F. Supp. 1127, 231 U.S.P.Q. (BNA) 700 (N.D. Cal. 1986) [hereinafter *Broderbund*].

Softklone Distributing Corporation.¹⁰¹ Each case has been discussed in several articles and commentaries since their respective decisions. However, the final outcome of this "family" of cases is significant to the potential applicability of copyright law to inventions in biotechnology.

The *Whelan*¹⁰² case was the seminal case in a string of so-called "look and feel" cases as applied to computer software. It extended protection of a copyright beyond the literal code subject to copyright, to a program written in a different computer language. In biotechnology, this would be analogous to the situation described previously in which a researcher was able to "mimic" the effects of a specific monoclonal antibody, "Ab," using a process other than a patented process.

The second case in this area, *Broderbund*,¹⁰³ deals with alleged audiovisual copyright infringement.¹⁰⁴ The Court in that case took a large step towards granting "look and feel" protection of computer programs. The Unison defense was primarily based upon the axiom that if an idea is indistinguishable from its expression, the expression cannot obtain protection under copyright laws.¹⁰⁵ The invocation of this merger doctrine poses a major obstacle to the protection of biotechnology inventions under copyright laws. For example, if it can be shown that the only way to make antibody "Ab" is by genetically engineering one specific amino acid sequence in a DNA strand, that sequence would fall outside the appropriate subject matter requirement.

The court in *Digital*¹⁰⁶ agreed with *Whelan's* conclusion that copyright protection of a computer program extends beyond the lit-

101. *Digital Communications Associates, Inc. v. Softklone Distributing Corporation*, 659 F. Supp. 449, 2 U.S.P.Q. (BNA) 1385 (N.D. Ga. 1987) [hereinafter *Digital*].

102. In *Whelan*, the defendant, Jaslow, had originally hired the plaintiff, Whelan, to write a program for its dental prosthetics business. In addition, Jaslow had agreed to market Whelan's program. Jaslow eventually wrote a program for a different computer system which performed the same functions in essentially the same manner (i.e., the menus were almost identical). Jaslow's defense primarily consisted of the fact that the programs were written in two different languages, therefore the allegedly infringing program was significantly different from the copyrighted program.

103. *Broderbund*, 648 F. Supp. 1127.

104. In *Broderbund*, the plaintiff, Broderbund, claimed that the overall appearance, structure and sequence of defendant's (Unison) computer program infringed their copyright. Unison challenged that the menu screens of the plaintiff's program were the idea, since any interactive computer program in the particular area of application would look substantially similar. The court rejected this argument, considering for comparison, *inter alia*, other computer programs which did not have an identical screen structure.

105. *Broderbund*, 648 F. Supp. at 1131.

106. *Digital*, 659 F. Supp. 449.

eral source and object code to include its structure, sequence and organization.¹⁰⁷ However, the *Digital* court expressly rejects a broad reading of *Broderbund*, stating that "copyright protection of a computer program does not extend to screen displays generated by the program."¹⁰⁸

In light of the, albeit cautious, broadening of copyright protection in the field of computer software, it is evident that the importance of protecting innovation and expression is a factor weighted heavily by the courts. It follows, therefore, that inventions in biotechnology should be given equal consideration.

In the recent decisions cited above, courts and legislature have worked together to broaden the scope of protection in the young, dynamic and complex computer industry. The biotechnology industry is no less lucrative, no less complex and certainly no less deserving of legislative action in its behalf. Against this background, the Amendment to Title 35 found in the Appendix, is proposed.

IV. DISCUSSION OF PROPOSED TITLE 35 AMENDMENT

In the discussion surrounding the passing of the Semiconductor Chip Protection Act of 1984, the House stated that:

The purpose of the legislation is to protect semiconductor chip products in such a manner as to reward creativity, encourage innovation, research and investment in the semiconductor industry, prevent piracy, while at the same time protecting the public.¹⁰⁹

These same goals are reflected in the proposed Amendment to Title 35 as set forth in the Appendix.

A. *Statutory Subject Matter*

1. Definitions

The present definitions of patentable subject matter found at 35

107. *Id.* at 455. The plaintiff sought protection of a status screen display for a software package. It had obtained copyright registration on the computer program, user's manual and each status screen display. Defendant, without copying either the underlying computer program or user's manual, created a status screen substantially similar to that of the plaintiffs'. Plaintiffs sued for infringement of its copyrights on both the computer program and status screen displays. The court refused to find infringement of the computer program, but did hold that the status screen displays were capable of copyright protection and, as such, were infringed by the defendant's status screen displays.

108. *Id.*

109. H.R. REP. NO. 781, 98th Cong., 2D Sess. 1, 3 (1984), reprinted in 1984 U.S. CODE CONG. & ADMIN. NEWS 5750, 5752.

U.S.C. section 101, as discussed above, are broad in scope and provide little guidance for inventors seeking to protect inventions in biotechnology. The copyright statute is equally devoid of any definition of biotechnology. A clear definition of what is the appropriate subject matter for legal protection is essential for a meaningful statutory provision.

The definition of "biotechnology" found in proposed Amendment Section 190 provides a basis for discerning proper subject matter under the patent law. Notably, it contains mens rea requirements which become the foundation of the statute. The intent requirements incorporated into the definition of "biotechnology" are an expression of a concept behind patent and copyright laws that ideas and products of nature are not subject matter afforded protection. Under the proposed Section 190, an inventor may still obtain patent protection, absent a showing of intent, by demonstrating a useful result.

Recall that the principle underlying forms of legal protection, such as the patent and copyright laws, is that there is an inherent trade-off between the granting of legal monopoly as a reward to the inventor and the benefit to society derived from the existence of the invention itself.¹¹⁰ The principles of that trade-off are incorporated in the proposed Amendment by allowing a patent based on potential use, as long as there is some *demonstrated* application for the invention.¹¹¹

Proposed Amendment Section 191(a) contains a reiteration of the basic language found in 35 U.S.C. section 101.¹¹² The terms "process", "manufacture" and "composition of matter" were chosen from the 35 U.S.C. section 101 enumerations for their succinct definitions of three important areas of biotechnology protection: a process (such as a new technique in genetic engineering); an article of manufacture (or product such as an antibody); and, a composition of nature (such as a new microorganism). The two-fold process of identifying an invention and its results, assists in identifying those inventions which qualify under this proposed Amendment. Despite the overlap in language between this proposed Amendment Section 191(a) and 35 U.S.C. section 101, the second requirement of biotechnology origin dispels any confusion which may result.

110. Stern, *The Bundle of Rights Suited to New Technology*, 47 U. PITT. L. REV. 1229 (1986).

111. See *supra* notes 30 and 31 and accompanying text.

112. See *supra* note 26.

2. Unanticipated Products/Unexpected Results

The problem of being barred from obtaining a patent on a product obtained by using methods known in the art, similar to the situation in *Ex parte Goodall*,¹¹³ can be resolved through statutory amendment. Proposed Amendment Section 191(b) is drafted to avoid just such situations. This Section works in conjunction with proposed Amendment Section 191(a) to protect an inventor of a process from claims to unanticipated products resulting from use of a patented process.

An inventor should not benefit or extend the life of a patent by withholding information from the public.¹¹⁴ On the other hand, an inventor will be less likely to seek patent protection, and disclose potentially valuable information to the public, if there is uncertainty over whether all modes or forms of a claimed invention have been anticipated and protected. The avoidance and resolution of such conflicts is the purpose of proposed Amendment Section 191(b).

B. *The Application Process*

1. Expedited Review

One of the primary problems identified in legal protection for biotechnology is the extremely slow rate of processing patent applications relative to the rapid rate of growth in the industry. In many instances, this has resulted in reliance on trade secret law for legal protection, instead of patent or copyright protection.

One disadvantage to relying exclusively upon trade secret law for legal protection is that a trade secret is only protected for as long as it is kept secret.¹¹⁵ If a product containing trade secret material is sold, in public use, or offered for sale over one year, the inventor is barred from obtaining patent protection due to the 35 U.S.C. section 102 "novelty" requirement.¹¹⁶

Proposed Amendment Section 192 formally establishes a Biotechnology Group within the PTO. The primary reason for formally establishing a separate biotechnology group,¹¹⁷ is to assure

113. See *supra* note 53 and accompanying text.

114. See 37 C.F.R. § 1.56 (1988).

115. See generally, CALLMANN, UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES (1988).

116. See *supra* note 33 and accompanying text.

117. In April, 1988, the Patent Office was expected to consolidate branches reviewing proteins, diagnostics and asexually produced plants with the organic chemistry and biotechnology examining group to create a biotechnology "supergroup." See Crawford, *supra* note 6, at 723.

that applications for biotechnology patents will receive immediate review. Expedited review is necessary for this proposed form of legal protection to remain viable in this fast-paced industry.

Another reason for establishing a separate group is to attract Patent Examiners with biotechnology backgrounds. To date, in order to practice before the PTO one must satisfy certain technical background requirements.¹¹⁸ Historically, these requirements have been restricted to chemical and engineering fields of undergraduate and graduate studies.¹¹⁹ The establishment of the separate biotechnology group will allow the PTO to accept attorneys with biology backgrounds, and to provide a place for them to exercise their expertise.

2. Deposit Requirement

The benefits and detriments of depositing in biotechnology patent applications, as discussed above, has been the subject of much litigation in this area of law.¹²⁰ At first blush, the deposit requirement may seem to present an undue burden upon an inventor. However, it is a legitimate requirement in instances where a starting material is not known or readily available to the public.¹²¹ The requirement is incorporated into the proposed Amendment Section 194.

The purpose of the enablement requirement of 35 U.S.C. section 112 is to assure that once the patent grant expires, the subject matter of the patent will then become readily available to the public. The trade-off is a legal monopoly now, in return for dedication of the invention to the public in seventeen years. To balance the conflict between placing an undue burden upon an inventor and sabotaging the public's future rights in an invention, a provision is

118. 37 C.F.R. § 10.7 (1988).

119. As part of the application packet for the October, 1988 Patent Agent Examination, issued by the PTO, the U.S. Department of Commerce issued this statement:

A person seeking admission to the examination must demonstrate that he or she possesses the scientific and technical training necessary to enable him or her to render applicants for patents valuable service. A person will be admitted to take the examination if he or she can show that he or she received a bachelor's degree or the equivalent thereof in one of the following subjects from a United States college or university of recognized standing: Applied Physical Science; Electronics; Engineering (Aeronautical, Agricultural, Ceramic, Chemical, including Electrochemical, Civil, Electrical, Engineering Physics, Geological, Industrial, Mechanical, Metallurgical, Mining, Nuclear, Petroleum); General Chemistry; Marine Technology; Organic Chemistry; Physics; Textile Technology.

120. See *supra* note 67 and accompanying text.

121. Lundak, 227 U.S.P.Q. at 93.

included in proposed Amendment Section 194(c), which allows an inventor to petition for a waiver of the deposit requirement.

Consistent with the decision in *Ex parte Jackson*,¹²² an inventor, under the Amendment Section 194, must deposit the determinant element in a process patent with a Federal depository. The rationale behind this seemingly rigid requirement reflects back to the policy statements of the concurring opinion in *Argoudelis*.¹²³ Since it is uncertain whether a new bacteria or new antibiotic will be of value to the public at the expiration of a patent, public policy dictates that there be access to the useful portion of an invention.¹²⁴

By making deposits part of a biotechnology patent application, the PTO may exercise control over the deposit material. The potential of deposited material, as disclosure, becoming non-enabling led to concern over control of deposited material.¹²⁵ By retaining control over deposited materials, the PTO may regulate applications for accessing deposited cultures and thus assuage the concerns of both the PTO and inventors.

As expressed by the court in *In re Lundak*, requiring an applicant to deposit before filing may "easily. . . be subverted by the dishonest, while being unnecessary to the honest."¹²⁶ However, litigation in this area has primarily revolved around the exact time in the application process at which a deposit is absolutely necessary.

It is generally accepted that deposited materials must be available to the public at the time the patent issues.¹²⁷ By allowing an applicant to deposit at any time prior to issue would be arbitrary and unreliable. Thus, proposed Amendment Section 194 requires that an applicant deposit material within six months from the date of filing an application. Proposed Amendment Section 194(b) allows an applicant to petition the Commissioner for extensions of time, not to exceed the date of issuance. This provision provides for consistency and fairness to the inventor.

122. *Jackson*, 217 U.S.P.Q. at 804.

123. *Argoudelis*, 434 F.2d at 1394. *See also supra* notes 71 and 72 and accompanying text.

124. For example, if a bacteria is genetically altered to make a new antibiotic, perhaps only the new antibody will be of feasible commercial value and demand in the future. If only the starting material for the bacteria is available, the progress of technology is pushed back one step further than necessary.

125. *Argoudelis*, 434 F.2d at 1394; *See also In re Metcalfe*, 56 C.C.P.A. 1191, 410 F.2d 1378, 161 U.S.P.Q. (BNA) 792 (CCPA 1969).

126. *Lundak*, 227 U.S.P.Q. 90.

127. *See Argoudelis*, 434 F.2d 1390; *Jackson*, 217 U.S.P.Q. 805.

C. Duration

The duration of a patent is seventeen years from the date a patent issues.¹²⁸ Rights under a copyright registration generally extend for fifty years beyond the life of the author.¹²⁹ Proposed Amendment Section 195 provides for a bifurcated duration: ten years beyond the life of the inventor for any "new and original" invention under proposed Section 191(a); ten years for any "new and useful *improvement*" under proposed Section 191(b).

The reason for granting a significantly shorter duration for improvement patents is based on the assumption that it is easier to improve upon a known process or product than it is to create a new product or process. There is a strong underlying policy argument to be made for not allowing some to benefit from the effort of others. The distinction between mere "improvement" and novel "invention" is a question of fact which may possibly introduce more uncertainty than the courts are willing to resolve.

The primary reason for providing a duration extending beyond the life of an inventor is to assure that an issued patent has some commercial value. That is, a company will be more likely to pay royalties to an inventor for a patent which will not expire for ten years — assuming the inventor is alive at the time of licensing. However, were the patent grant for the life of an inventor *only*, a licensee's rights to an invention could dissolve at any time. The uncertainty and potentially short license term would significantly, and negatively, impact the economics of biotechnology inventions.

If the duration of a patent is ten years beyond the life of the inventor, as in the proposed Amendment, it is necessary to include some provision for keeping records pertaining to the death of an inventor. Proposed Amendment Section 195(c) provides for optional recordation of the death or related statements concerning an inventor. The Register of Copyrights was established under Title 17, and the need to establish a separate Register for recording the death of inventors seems unwarranted.

Further, if an inventor is not alive to benefit from the invention, a ten year time period will place the invention in public domain sooner. Given the high turn-over rate of products, and the fast pace of developments in the biotechnology industry, the shorter

128. 35 U.S.C. § 154 (1987). Design patents carry a 14 year term.

129. 17 U.S.C. § 302a (1987); Work made for hire has a duration of 75 years beyond the date of publication, or 100 years beyond the date of creation, whichever is shorter. 17 U.S.C. § 302c (1987).

ten year grant will expire about the time a product resulting from a patent peaks on the market.

Given that the average life cycle of a pharmaceutical is between eight and twelve years,¹³⁰ ten years seems to be a fair compromise between industry desires and public needs. The caveat incorporated for products or utilities derived from new or existing process patents is, as noted above, to allow an inventor to enjoy the limited legal monopoly granted by the patent laws before a competitor can obtain an improvement patent.

The counter-argument for short-term protection beyond the life of the inventor is that biotechnology is a high-growth market at the present, and will soon plateau. When it does, the influx of biotechnology inventions into the PTO will decrease, and there will be a need for longer-term protection for adequate competition in the marketplace. If Congress deems it necessary at that time, an amendment to the duration provisions may be made according to need.

V. CONCLUSION

Due to the nature of the industry, inventions in biotechnology require a responsive and flexible system of legal protection. While current patent law appears to grant necessary legal protection, the delay in patent prosecution and the inadequate training of Patent Examiners and attorneys renders patent protection less than optimal. Copyright protection is too limited for the needs of the biotechnology industry. Thus, a hybrid of the two legal monopolies, such as the Amendment herein proposed, seems appropriate.

This proposed Amendment to Title 35 attempts to provide the protection required by the biotechnology industry. The proposed Amendment has a *mens rea* requirement to narrow the scope of protection. That is, a patent on a particular monoclonal antibody directed to one antigen having a specific physiological effect, will not preclude a patent on a different type of monoclonal antibody having the same physiological effect.

The proposed Amendment also establishes a Biotechnology Group within the Patent and Trademark Office to assure that applications are processed rapidly to accommodate the growth rate peculiar to the biotechnology industry. The Group assures that Patent Examiners have the appropriate technological background to give constructive feedback to inventors during the application process.

130. *See supra* note 5.

A balance between the economic needs of scientists and the public interest in the advancement of science can be addressed through appropriate legislation. While statutes, such as the one proposed in this comment, may be useful guidelines, it is up to patent attorneys to assure that the law remains simple enough to be effective. Today, laws either enacted through the legislature or established through the courts, need not be "enemies of innovation."

APPENDIX:

A PROPOSED AMENDMENT TO TITLE 35¹³¹

§ 190 — DEFINITIONS

Biotechnology, as used in this Amendment, shall refer to a process by which the genetic composition of an organism is intentionally altered by means of chemical, biological or other manipulations available to the art, and any end-product thereof; or the process by which an organism known to naturally produce an end-product is intentionally altered to produce an altered end-product, and any resulting end-product thereof; or a product which is the intentional result of a purification process. The term "biotechnology" shall also refer to a chemical, a biological composition, or a microbial, multicellular or monocellular, viral or bacterial organism, of useful or demonstrated potential application in a significant field of human endeavor or need.

§ 191 — PATENTS FOR BIOTECHNOLOGY

(a) Whoever invents or discovers any new and original process, manufacture or composition of matter through the use of or resulting in biotechnology products may obtain a patent therefore, subject to the conditions and requirements of this Title.

(b) Whoever invents or discovers any new and useful improvement on an existing biotechnology invention may obtain a patent thereon, subject to the conditions and requirements of this Title.

(c) The provisions of this Title relating to patents for inventions shall apply to patents for biotechnology, except as otherwise herein provided.

§ 192 — BIOTECHNOLOGY GROUP: ESTABLISHMENT

There shall be in the Patent and Trademark Office a Biotechnology Group dedicated to reviewing applications under this Amendment. The Commissioner shall appoint a Group Director for the Biotechnology Group.

§ 193 — PROCESSING OF APPLICATION

Applications for biotechnology patents shall be reviewed by the special Group established in Section 192. Every reasonable effort shall be made by the Group Director to expedite the issuance of patents under this Section.

131. The following proposed amendment to Title 35 is a combination of 35 U.S.C. and 17 U.S.C., including the Semiconductor Chip Protection Act. Although the bulk of the proposed Amendment is language derived from Title 35, the astute reader will recognize key elements from the other Title. Additional materials are referenced within the text of the statute.

§ 194 — DEPOSIT OF MATERIALS

(a) When an invention or any claims in a patent application covering an invention depend on the use of microorganisms which are not known or not readily available to the public, the applicant shall deposit such material with a Federal depository¹³² not later than six months from the date of filing said application. Failure to deposit within the required time may result in withholding issuance of the patent.

(b) Upon petition by applicant, the Commissioner shall grant an extension of time for depositing any materials required under subsection (b). In no instance shall such extensions be granted beyond the date of issuance.

(c) The deposit requirement may be waived by the Commissioner upon petition by applicant and demonstration by applicant that the requirements of Section 112 of this Title have been sufficiently satisfied so as to enable any person skilled in the art to which the invention pertains, or with which it is nearly connected, to make or use the invention.

§ 195 — DURATION OF PATENT

(a) Biotechnology patents under Section 191(a) shall be for a term of ten years beyond the life of the inventor as measured from the date the patent issues.

(b) In the case of a joint invention, the patent endures for a term consisting of ten years beyond the life of the last surviving inventor.

(c) Any person having an interest in a biotechnology process patent may at any time record in the Patent and Trademark Office a statement of the date of death of the inventor of the patented biotechnology invention, or a statement that the inventor is still living on a particular date. The statement shall identify the person filing it, the nature of that person's interest, and the source of the information recorded, and shall comply in form and content with requirements that the Patent and Trademark Office shall prescribe by regulation. The Patent and Trademark Office shall maintain current records of information relating to the death of inventors of biotechnology inventions upon which patents have been granted, based on such recorded statements.

(d) Biotechnology patents under Section 191(b) shall be granted for a term of ten years as measured from the date the patent issues.

132. Manual of Patent Examining Procedure (MPEP), section 608.01(p)(c)(1985).

(e) No patent shall be filed dependent on an existing process patent within ten years of first issue of said process patent absent an express grant by the owner of said process patent.

(f) Protection under this Amendment shall terminate if the application for biotechnology patent protection is not filed within two years after the date on which the subject matter of the patent is first in public use, sold or offered for sale in this or a foreign country.

§ 196 — GRANT

In the case of biotechnology patents, the grant shall be of the right to exclude others from making, selling or using the product or process, subject to the provisions of section 195.

§ 197 — EFFECT ON ISSUED PATENTS AND PENDING APPLICATIONS

The provisions of this Amendment do not affect patents issued, applications filed, or any other matter initiated before the Patent and Trademark Office prior to the effective date of this Amendment.

