Comments

PATENTING MICROORGANISMS: WORKING THE BUGS OUT OF THE INTERNATIONAL DEPOSITARY AUTHORITY

Mark Twain once wrote: "A country without good patent laws is just a crab and can't travel any way but sideways and backways."[1] If his statement has any merit, the world is but a paralytic crab with respect to the modernistic era of genetic engineering.[2]

Genetic experimentation has become an international commonplace.[3] Developments in genetic research have already provided society with dynamic technological advances. Pharmaceutical laboratories, for example, have developed vaccines from genetically altered microorganisms which have helped diminish many types of poultry, bovine and porcine diseases.[4] Microorganisms have been created which synthesize human insulin.[5] Future experiments are predicted to accomplish even greater advances.[6] Developments through genetic experimentation undoubtedly will provide society with alternative fuel supplies, chemicals to

1. *Quoted in* Whale, *Patents and Genetic Engineering* 14 INTELL. PROP. L. REV. 93 (1982). It was Judge Rich of the Court of Customs and Patent Appeals (CCPA) speaking through the United States Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S. Pat. Q. 193 (1980) who saved the U.S. patent system from being "just a crab" with respect to products of new technology. *Id.*

2. Teschemacher, *Patentability of Microorganisms per se*, 13 INT'L REV. INDUS. PROP. & COPYRIGHT L. 27, 28 (1982).

3. After World War II, the technology for producing penicillin and streptomycin by fermentation was introduced by the United States and caused revolutionary developments in Japan. Today over twenty antibiotics invented by Japanese scientists are in production in this country and the microbial strain used is the key to each product or process. Hayashi, *A Japanese Perspective on Patenting Microorganisms*, 7 AM. PAT. L.A.Q.J. 306 (1979).

4. These experiments have international significance. Many of the major pharmaceutical industries derive a substantial portion of their profits through international sales. The economic benefits of providing a uniform international patent system would be attractive to these industries. *See* Reinbold, *Bacteria Tycoons Start a Real Growth Industry*, N.Y. Times, Feb. 3, 1980, at E8, col. 3.

5. *See* Aharonowitz & Cohen, *The Microbiological Production of Pharmaceuticals*, SCI. AM., Sept. 1981, at 151.

6. "[One] main reason for the excitement is recent advances in identifying genes called

aid in food production and, possibly, a cure for cancer.[7]

The laws regulating and protecting these experiments and their subsequent inventions continue, however, to sputter at an inchoate stage. Although a few countries have enacted statutes that recognize the patentability of man-made microorganisms, there is little uniformity within the patenting process.[8] The Budapest Treaty was conceived in 1977[9] to help create some uniformity.[10] The Treaty established a system of depositaries[11] for the collection and maintenance of microbial products, which are the subject of inventions, where patent protection has been sought.[12] Recently, several member nations have expressed discomfort with the safety and functioning of the system of depositaries. Some countries have gone so far as to enact regulatory laws which undermine one of the original objectives of the Treaty.[13]

This Comment will explore the patent laws governing man-made life forms and discuss two major areas of international con-

---

oncogenes—that appear to be involved in producing cancer." San Diego Union, Feb. 20, 1983, at A1, col. 4.

7. A cancer cell is a cell that has lost the ability to control its growth and division. It is now known that viruses cause this unregulated division. Many researchers hope that experiments with interferon, a chemical derived from humans with the aid of microorganisms, will yield a product that will interrupt the growth of these cancer cells. J. WATSON, MOLECULAR BIOLOGY OF THE GENE 684 (1977).

8. *See* Whale, *supra* note 1, at 106.

9. Budapest Treaty on the International Recognition of the Deposits of Microorganisms for the Purposes of Patent Procedure, April 28, 1977, T.I.A.S. No. 9768 [hereinafter cited as Budapest Treaty]. The Budapest Treaty was subsequently amended in 1981. As of March 1, 1982, the signatories were: Bulgaria, France, Federal Republic of Germany, Hungary, Japan, Liechtenstein, Philippines, Spain, Switzerland, United Kingdom, United States of America and the USSR. The following countries are likely future members: Australia, Austria, Czechoslovakia, Denmark, Egypt, Finland, Democratic Republic of Germany, Indonesia, Italy, Luxemburg, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Senegal, Sweden and Yugoslavia. W. BIGGART, B. BRUNSUOLD, D. CONLIN, I. KILEY & R. SCHWAAB, GENETIC ENGINEERING WORLDWIDE THE LAW AND BUSINESS 14-15 (1982) [hereinafter cited as PATENT RESOURCES GROUP, INC.].

Editor's note: As of publication, the Budapest Treaty has not been listed in any other treaty service.

10. This Treaty will be discussed at length later in this Comment; *see infra* text § III. At this point it should be noted that prior to the enactment of this treaty, many of the major countries established their own laws with regard to patenting microorganisms; *see also* Lederer, *A Perspective on Patenting Microorganisms*, 7 AM. PAT. L.A.Q.J. 288 (1980).

11. Budapest Treaty, *supra* note 9. The depositaries are collection laboratories which contain facilities designed to store microorganisms; *see also infra* text accompanying notes 129-145.

12. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 12.

13. Germany and Korea presently restrict exportation of patented microorganisms. In Germany the patent applicant has a legal right to prohibit third parties from removing microbial samples from territories covered by German patent law. *Id.* at 80-81.

cern: the dangers of uncontrolled transportation of potentially harmful microorganisms; and the suppressive effect on international patenting caused by sovereign supervision over the transportation of microbial inventions.[14] A cursory examination of domestic and international patent laws will illustrate the lack of uniformity of the various patent systems. The unique nature of the patenting of life forms will then be discussed. This inquiry will establish the need for uniformity in patenting man-made life forms.

A detailed discussion of the Budapest Treaty will follow, and arguments for and against the depositary system will be addressed. Those opposed can cite the Paris Union Convention[15] as international precedent.[16] Moreover, these same nations assert sovereign scrutiny over the importation and exportation of patented life forms is essential to prevent international infringement, maintain domestic mores and ensure worldwide safety. The nations favoring the system maintain that international depositaries are essential to encourage communication of novel information.[17]

Imaginative and invaluable products are being discovered every day. A proper system of international patent protection is essential to purvey the suitable incentive to reach these goals. Authorities must therefore create a more appropriate international patenting system for man-made microorganisms. In conclusion, provisions for an amplified treaty, which could alleviate many of the concerns presented, will be proposed. A revised treaty should put Mark Twain's crab back on course.

I. THE DOMESTIC AND INTERNATIONAL PATENT SYSTEMS

A. Origins

Historically, legal minds have recognized the inherent "right" of originators to at least receive credit when others utilize their

14. *See infra* text accompanying notes 238-269.

15. *See* Landau, *Multinational Corporations and Lesser Developed Countries—Foreign Investment, Transfer of Technology, and the Paris Union Convention: Caveat Investor*, 5 U. DAYTON L. REV. 105, 136 (1980).

16. "The international obligation of countries that have approved a treaty to give internal effect to its provisions is a prerequisite for the fruitful and almost global cooperation among the 88 states of differing political and economic structures which, today, adhere to the Convention for the Protection of Industrial Property concluded in Paris in 1883 and ultimately revised in Stockholm in 1967." Gansser, *Violations of the Paris Convention for the Protection of Industrial Property*, 63 J. PAT. OFF. SOC'Y 138 (1980).

17. *See infra* text and accompanying notes 57-63.

ideas.[18] An idea which spawns a marketable product provides a valuable contribution to society. These originators deserve to be rewarded for their contributions.[19] Moreover, worthwhile ideas benefit society only when the results of the ideas are made widely available.[20] Once available, the new information will increasingly enable others to invent more novel products.[21]

Patent law was the progeny of that area of property law which recognized the need to govern both the *incentives* for and the *availability* of new ideas.[22] The function of the law is to provide an incentive for experimenters to develop ideas which benefit society.[23] When the law fails, new ideas are lost or never even "born." A law that does not properly protect an inventor's property right hardly encourages the development of subsequent ideas.[24]

In the United States, patent law was the creation of Congress.[25] Other countries, under the authority of their constitutions, similarly have created statutory law designed to encourage experimentation.[26] Most countries accomplish this task by granting the experimenters an *exclusive right* to their inventions for a limited

18. Ideas in and of themselves are not patentable subject matter. It is the resulting product of that idea which may be legally protected. OFF. TECH. ASSESSMENT REP. ch.12, at 237 (1981).

19. The U.S.A. Patent Act of 1793, authored by Thomas Jefferson, embodied the philosophy that ingenuity should receive liberal encouragement. 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871).

20. The most common element of the patent statutes around the world is *enablement*. This means that most countries would not recognize a product as being patentable unless the invention's full description *enables* others with similar skills to reproduce it. PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

21. The term "inventing around the invention" is often used to explain how many novel products are created through improvement of prior art. *See* OFF. TECH. ASSESSMENT REP., *supra* note 18, at 244.

22. Patent law was the legal system designed to provide government-sanctioned remedies and a means to protect inventors' rights in their unique contributions to society. I. KAYTON, KAYTON ON PATENTS 1-1 (1980).

23. G. COPLEIN, CURRENT DEVELOPMENTS IN PATENT LAW 31 (1980).

24. There is a great expense in developing ideas into novel products. For an overview of the procedures involved, see B. LANDIS, PATENTS, COPYRIGHT, TRADEMARKS AND TRADE SECRETS FOR CORPORATE COUNSEL AND GENERAL PRACTITIONERS 92 (1979).

25. The federal patent statutes are derived from the United States Constitution. Article 1, § 8 reads: "The Congress shall have [the] power . . . 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 . . . ." L. TRIBE, AMERICAN CONSTITUTIONAL LAW 57 (1978).

26. G. FLONZ, CONSTITUTIONS OF THE COUNTRIES OF THE WORLD 9 (1975). According to Article 73, § 9, "[t]he Federation of the Federal Republic of West Germany shall have the exclusive power to legislate . . . industrial property rights, copyrights and publishers' rights . . ." *Id.* at 35.

period of time.[27] During this period, the experimenter's new invention becomes published and accessible to the public as long as that person receives compensation from anyone who uses, makes or sells the invention.[28] Compensation is generally received in the form of royalties supplied by the company which utilizes the invention to create other marketable and unique products.[29] These procedures, however, only apply to those products which are patentable.

B. Patentable Subject Matter

Patent statutes in most nations require four essential criteria in order to consider an invention patentable.[30] First, an invention must be capable of classification as a machine, process, manufacture or composition of matter.[31] Most countries have found products of nature, scientific principles and mathematical formulas to be unpatentable since such discoveries are only derived from preexistent entities.[32] In other words, the invention must have the attribute of *utility*.[33] Second, the invention must be *novel*: new and useful. The requirements for novelty do not exist under United States law[34] if (a) the inventor is not the applicant for the patent, (b)

27. *See* OFF. TECH. ASSESSMENT REP., *supra* note 18, at 238. A patent gives the creator the right to exclude all others from making, using or selling his invention for the statutory period of time. In the United States the statutory period is 17 years; in West Germany the duration is 18 years. *See also* B. SINNOT, 2C WORLD PATENT LAW AND PRACTICE art. 3, at 2 (1982).

28. *See* OFF. TECH. ASSESSMENT REP., *supra* note 18, at 238; *see also* 35 U.S.C. § 101 (1976).

29. Royalties can be set in a large variety of ways. The following are some of the most common: percentage on sales, fixed sum per unit sold, straight scale versus varying scale, fully paid-up license, use royalty, entire market value rule and a minimum royalty rule. L. PRETTY, PATENT LAW FOR THE BUSINESS LAWYER 45 (1981).

30. G. SPENCER, INTERNATIONAL PATENT LAW AND PRACTICE 44 (1973).

31. In Hartranft v. Wiegmann, 121 U.S. 609 (1887), the United States Supreme Court defines a manufacture or composition of matter to mean a product of human ingenuity "having a distinctive name, character and use." *Id.* at 615.

32. The laws of nature, physical phenomena and abstract ideas have been held not to be patentable in the U.S. Therefore, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not have patented his celebrated $E=mc^2$, nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." Funk Bros. Seed Co. v. Kalo Inoculant Co., 33 U.S. 127, 130 (1948).

33. Ideas have utility only when they are fully developed. "One may not patent a mere idea, although novel and useful; an idea must be reduced to practice and practical methods of making and using it must be described so as to enable the public to use the invention." Wayne v. Humble Oil Refining Co., 175 F. 2d 230, 233 (1949).

34. 35 U.S.C. § 102 (1976). In France, in order for an invention to be considered *novel*,

the invention was previously known or used by others in either the United States or other countries, or (c) the invention's description was previously in a foreign patent or publication.[35] Third, the invention must *not* be obvious to one skilled in the arts.[36] Obviousness can be determined by considering the differences between previously patented inventions and the design claimed for protection. Fourth, the description of the invention must *enable* duplication by reasonably skilled individuals in the same area of technology.[37]

Although these four elements are required in many of the major countries, variations do exist.[38] For example, the definition of "patentable subject matter" under the European Patent Convention[39] is limited to one sentence:[40] "European patents shall be

---

the invention must not be included in the "state of the art." *See* G. SPENCER, *supra* note 30, at 63.

35. *See* 35 U.S.C. § 102 (1976). The West German patent system is composed of two branches: The Patentgesetz, the formal patent law, and the Gebrauchsmustergesets, the petty patent system. The Patentgesetz grants long term monopolies to inventions which fulfill stringent requirements. The Gebrauchsmustergesets grants short term monopolies to products which satisfy less strict novelty requirements. The formal system has novelty requirements similar to the United States patent system. The Gebrauchsmustergesets requires the invention to be novel in arrangement, embodiment or device. *See* E. STRINGHAM, PATENTS AND GEBRAUCHSMUSTER IN INTERNATIONAL LAW 43 (1935). Novelty of arrangement (Anordnumg) distinguishes the originality of the spatial arrangement of the parts of the invention. Novelty of embodiment (Gestalung) refers to inventiveness of form, material, or surface. Novelty of the device (Vorrichtung) takes into consideration the novelty of arrangement and embodiment factors. *Id.*

36. 35 U.S.C. § 103 (1976). The U.S. standard for nonobviousness has been criticized for being inflexible. No degrees or levels of obviousness are recognized by the U.S. statute. The Federal Republic of Germany's requirement of nonobviousness under the Patentgesetz and the Gebrauchsmustergesets has some flexibility. Germany's statute permits a dual standard of recognition. Under the obviousness criteria, Erfindungshoehe mandates that the invention manifest substantial improvement over prior art. *See* Busse, *Probleme des Gebrauchsmusterrechts*, 54 GROR 123, 124 (1952).

37. In West Germany the requirement is that the invention must be susceptible of exploitation in industry and trade. G. SPENCER, *supra* note 30, at 63, 159; *see also* Blumcraft of Pittsburgh v. U.S., 372 F.2d 1014, 178 Ct. Cl. 798 (1967).

38. For the purpose of expediency, the reader is asked to consider these four elements as being the requirements for patentability of the countries discussed in this Comment. A compilation of many different countries' requirements would confuse the reader's understanding of why life forms can be considered patentable. *See* SPENCER, *supra* note 30, at 63.

39. Convention on the Grant of European Patents and Attached Annexes and Draft Guidelines [hereinafter cited as EPC], also known as the Munich Patent Convention, *adopted in* Munich, Oct. 5, 1973, *entered into force* Oct. 7, 1977. J. SINNOTT, 2L WORLD PATENT LAWS 1 (1978). The EPC was designed to grant an option to worldwide inventors for obtaining foreign patents beyond simply filing separate applications in each country. It should be noted that the EPC was created to ease the problems involved in patenting inaminate objects in foreign countries. This Comment deals with the Budapest Treaty which was designed to eliminate the problems in patenting "live" inventions abroad. *See* Winner, *Prac-*

granted for any inventions which are new, susceptible of industrial application and which indicate an inventive step."[41]

The requirements for protecting inventions traditionally applied only to inanimate objects.[42] Within the last decade, however, many countries have recognized that certain genetically engineered microorganisms are also patentable.[43] The current international trend favors the patentability of various life forms.

C. The Patentability of Living Organisms

Although several countries contemplated the patentability of microorganisms as early as the 1920's, it was not until the late 1970's that a few major countries determined certain life forms to be capable of legal protection by patents.[44] West Germany, Japan and Great Britain were among the first countries which regarded microorganisms as *per se*[45] patentable.[46]

The United States has reached a similar conclusion. In 1980, the Supreme Court in *Diamond v. Chakrabarty*[47] held that a live, man-made microorganism could qualify as patentable subject mat-

---

tical Effects of the Patent Cooperation Treaty and the European Patent Convention on Domestic Technology Management and Patent Practice, 62 J. PAT. OFF. SOC'Y 419 (1980).

40. EPC, *supra* note 39, art. 52:1.

41. "The EPC definition is extraordinarily general and broad. Rather than providing a clear, positive definition of patentable subject matter, the EPC takes the approach of narrowing this broad definition by explicitly specifying negative restrictions thereto." PATENT RESOURCES GROUP, INC., *supra* note 9, at 38.

42. "No doubt, when 100 years ago the various patent systems were created, those who drafted the patent laws did not have the intention to provide for inventions which related to anything alive. Neither did they have the intention to exclude such inventions; it is just because they did not contemplate living matter, because the patent system was primarily intended to serve industry and in those days industry did not comtemplate living matter as part of its concerns." Lederer, *supra* note 10, at 296.

43. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 137.

44. In a decision concerning a patent on a process for the manufacture of a medicament useful against tuberculosis and made up of the cultivation of tortoise, the German Patent Office, upheld by the Reichsgericht (the governing body in Germany), did not reject the patentability of a biological process made up of living matter. Lederer, *supra* note 10, at 289.

45. "*Per se*" means, in this situation, that the product will be accepted as long as the Patent Examining Office determines that it is novel, nonobvious and useful.

> Up until about 1979, it was considered that microorganisms *per se* could not be patented in Japan, and the Examination Standards for Inventions of the Applied Microbiological Industry promulgated by the Japanese Patent Office in 1970 stated that microorganisms were unpatentable because they are not industrially applicable.

PATENT RESOURCES GROUP, INC., *supra* note 9, at 97.

46. *See* Whale, *supra* note 1, at 107.

47. 447 U.S. 303, 308 (1980).

ter in accordance with 35 U.S.C. § 101.[48] The United States Supreme Court based its decision on the fact that Chakrabarty's microorganism could be classified as a "manufacture" or "composition of matter" within the meaning of this statute.[49] The Court ruled that a live, genetically engineered microorganism could therefore fulfill the requirements of *utility, novelty, obviousness and enablement*.[50]

The decision in *Chakrabarty* had a profound effect throughout the world.[51] Many other countries have subsequently determined that certain man-made microorganisms are patentable.[52] Microorganisms can now be patented in Austria, Belgium, Great Britain, Italy, Israel, Japan, The Netherlands, Sweden and West Germany.[53] The Soviet Union and Czechoslovakia allow a new strain of microorganisms to be protected by an inventor's certificate,[54] provided that the microorganism is capable of use in an industrial process. The European Patent Office[55] has not directly ruled on the patentability of microorganisms, but undoubtedly will follow the precedent set by these countries.[56] Despite the number of countries which recognize microorganisms as patentable, the lack of interna-

48. *See supra* text accompanying notes 31-37.

49. Diamond v. Chakrabarty, 447 U.S. at 308.

50. Chakrabarty, while employed by the General Electric Company, succeeded through the use of recombinant deoxyribonucleic acid by altering the genetic makeup of some of the bacteria of the genus Pseudomonas. The altered bacteria could degrade crude oil into a food source for marine life, therefore, the product became a unique way of removing oil spills. Prior to Chakrabarty's work, it was found that although various species of Pseudomonas could degrade one out of the four components of hydrocarbons which make up crude oil, the species could not co-exist and therefore would not successfully degrade all the components of crude oil. *Id.*

51. Clark, *Philosopher's Paradise: Should a Microorganism the Product of a Microbiologist be Patentable*, 4 AUCKLAND U. L. REV. 129, 143 (1981).

52. Schlosser, *Patenting Biological Inventions*, 12 U. TOL. L. REV. 925 (1982); *see also* PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

53. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

54. Schlosser, *supra* note 52, at 933-44. Communist countries issue inventor's certificates rather than patents when protecting inventions. The State, not the inventor, owns the novel product in these countries. *Id.*

55. The European Patent Office receives the patent applications of inventors of the nations belonging to the European Patent Convention. The European Patent Office determines whether an application falls under the category of patentable subject matter. A patent search is also performed at this point. Once found patentable, the application is transmitted to designated member-countries, who require translation into their own languages and thereafter issue separate national patents. *See* Winner, *supra* note 39, at 420.

56. The German Federal Supreme Court (BGH) in the 1975 Bäckerhefe (Baker's Yeast) case, having precedent that biology formed part of the technology for which patent protection was available, ruled that microorganisms were patentable. *See* 1975 GRUR 430; GIIC 207 (1975). However, the question whether and to what extent microorganisms can be pro-

tional uniformity of patent procedures is prevalent. The reasons for patenting man-made microorganisms demonstrates the arguments supporting increased uniformity.

D. The Necessity of Patenting Man-Made Microorganisms

The primary objective of a patent system is to stimulate product innovation.[57] A proper legal system stimulates the expression of novel ideas through three methods. First, the potential for exclusive commercialization provides an incentive for the inventor to endure the long, frustrating and expensive process of discovering and developing a product from the stages of research through marketability.[58] The inventor goes through great expense and effort in order to develop the product and to convince others of its unique value to society.[59]

Second, the new knowledge disclosed in a patent application allows other experimenters to improve and to develop the patented product by "inventing around the invention."[60] A patented invention not only makes the expression of a marketable idea available to the public, but also encourages the creation of other ideas which envision modified versions of this product of even greater value.[61] The notion behind encouraging the publication of novel products is to allow others access to new and useful information. Once the information is available, researchers can incorporate the concepts into their own experiments and create even better products.[62]

Third, the patent system saves the time and money of the inventor's competitors. A patent system grants an exclusive property right in the inventor for a limited period of time.[63] This property

---

tected *per se* is still largely unresolved in the international legal practice. *See* Teschemacher, *supra* note 2, at 27, 30.

57. *See* Churchwell, *Patent Law—Subject Matter Patentability-Computers and Mathematical Formulas*, 14 INTELL. PROP. L. REV. 305 (1982).

58. *See* E. PENROSE, THE ECONOMICS OF AN INTERNATIONAL PATENT SYSTEM 8 (1951 & reprint 1973).

59. The inventor cannot isolate himself from the world of politics. OFF. TECH. ASSESSMENT REP., *supra* note 18, at 244.

60. *Id.* at 243.

61. Former President Jimmy Carter stated, "[I]nnovation in the United States badly needs stimulation." Thereafter he made plans to spur innovation, which included, in part, enhancing the transfer of information and strengthening the patent system. Watson, *The Patentability of Living Organisms*, 20 AM. BUS. L.J., 93, 101 (1982).

62. *See* OFF. TECH. ASSESSMENT REP., *supra* note 18, at 244.

63. The term "exclusive" is misleading. Patent law encourages publication of ideas so that others can use them. However, the law excludes those who do not compensate the inventor. *Id.*

right entitles *only the holder* to reap the benefits of a marketed invention. Once a patent is granted, the invention becomes *prior art*[64] to all subsequent products which lack a sufficient degree of inventiveness.[65] Subsequent inventors would be dissuaded from redeveloping prior art as such acts would constitute infringement. Inventors would redirect their resources into other areas of research.[66] Furthermore, both the individual and society will benefit. The time and energy of some of the world's best minds would be streamlined into areas of research in dire need of inventive work.[67]

A patent system is therefore essential to the protection of inanimate objects. Many argue that the patenting of living organisms would have similar positive effects, in addition to providing adequate protection to the applicants.[68] Alternatively, some argue that other types of legal theories would provide superior protection.[69]

The consensus among intellectual property experts is that the patent system will prove to be of major assistance to genetic research.[70] Microorganisms or other man-made life forms deserve the same type of legal protection as chemical compounds.[71] Many countries currently recognize the patentability of chemical products provided that the invention satisfies the requirements of utility, novelty, nonobviousness and enablement.[72] Experimentations in chemistry, although distinct, parallel those in biology in that both

64. For a detailed discussion on the subjects that constitute "prior art," see Chisum, *Foreign Activity: Its Effect on Patentability under United States Law*, 11 INT'L REV. INDUS. PROP. & COPYRIGHT L. 26 (1980); Chisum, *Sources of Prior Art in Patent Law*, 52 WASH. L. REV. 1 (1976). The general rule as to priority of invention is that priority goes to the inventor who first reduced the embodiment of the invention to practice.

65. Fields v. Schuyler, 472 F.2d 1304, 1305 (1972).

66. *See* Collins, *The Significance of Inventorship Determinations for Foreign and Domestic Inventors*, 7 AM. PAT. L.A.Q.J 117 (1979).

67. Whale, *supra* note 1, at 108.

68. *See* Bloom, *Designer Genes and Patent Law: A Good Fit*, 26 N.Y.L. SCH. L. REV. 1041 (1981).

69. An alternative to the patent system is the protection gained through trade secrecy. Unlike patents, trade secrets protect an inventor's new product not through compensation, but through censorship of the novel information. This procedure may prevent infringement, but it also prevents the distribution of new information to society. *See* Rose, *Protecting Trade Secrets* 130 PRAC. L. INST. 9, 11-12 (1981).

70. Talbot, *Introduction to Recombinant-DNA Research Development and Evolution of NIH Guidelines, and Proposed Legislation*, 12 U. TOL. L. REV. 805, 806 (1981).

71. At the present time some countries recognize the patentability of *chemical compounds* created by microorganisms and yet refuse to grant patent protection to the mircroorganism itself. These countries include Switzerland, Liechtenstein, Denmark, Norway, Finland and Spain. PATENT RESOURCES GROUP, INC., *supra* note 9, at 137.

72. *See supra* text accompanying notes 31-37.

use many of the same materials, techniques and theories.[73] Furthermore, product claims are the only means of protecting all forms of manufacture and use.[74] Providing the very best protection would arguably encourage full disclosure by potential patent applicants.[75] Identical products have been derived through different methods.[76] Unless the product is protected, an inventor would not have any recourse against others who produce substantially similar products by different methods.[77] Likewise, patents could be obtained even if a product encompasses prior art[78] as long as it is produced by a different method. Product protection would prevent this problem.[79]

The third supporting authority embodies international policy which encourages uniformity in the patent laws.[80] The general trend of international jurisprudence has favored the patentability of microorganisms.[81] The benefits of making patent information internationally available would be defeated unless most countries were to follow this trend.[82] Inventors would be deterred from filing in countries not following the trend of providing protection to the actual life form.

Finally, without patent protection of the microbial product, *sample submission*[83] would not occur.[84] In many countries, full dis-

73. The growth and reproduction of microorganisms involves many chemical reactions. Microorganisms commonly produce alcohols, acids and aldehydes as byproducts. *See* J. WATSON, *supra* note 7, at 43.

74. OFF. TECH. ASSESSMENT REP., *supra* note 18, at 24.

75. The following example is an abbreviated list of some of the potentially patentable microbial products: new microorganisms, processes for making the new microorganisms, biologically pure cultures of microorganisms, new and old products from new microorganisms, new *uses* for products from new microorganisms, isolated genes and gene sequences on other DNA subunits, synthetic genes, plasmids containing inserted genes, fermentation processes for growing new microorganisms, and new enzymes and reagents and their uses in making microorganisms. Whale, *supra* note 1, at 93.

76. Hayashi, *supra* note 3, at 316.

77. The clause "substantially similar" is used more often in copyright law. A product is classified as substantially similar when it lacks a sufficient amount of creativity. In patent law the product must show a "sufficient degree of inventiveness." *See* text accompanying note 65.

78. Whale, *supra* note 1, at 104.

79. *See* Behringer, *Microorganism Patents*, 63 J. PAT. OFF. SOC'Y 128 (1981).

80. *See* Winner, *supra* note 39, at 419.

81. Work in genetic engineering is taking place overseas. This work originated with the sponsorship of U.S. companies. These countries also follow the U.S. restrictions on DNA research. Hayashi, *supra* note 3, at 306.

82. *Id.*

83. Sample submission means the submission of a pure culture of the microorganism. A pure culture is one that is composed of entirely one genus and species of an organism.

closure of microorganism is best served when the product is submitted to the proper authority.[85] Accessibility to the sample gives the user the ability to reproduce the microorganism without undertaking the expensive process of development.[86]

The conclusions provided by these arguments do not reveal the complete picture. There is authority against providing patents for man-made microorganisms.[87] The major arguments are threefold. The first group opposed to such a system contends that a patent would not provide sufficient protection for unique organisms.[88] Infringements of these inventions could be difficult to detect.[89] When an application is filed, the patent system generally requires the *best mode*[90] of disclosure. Sample submission would probably fulfill this requirement.[91] A person to whom a sample is released could, through genetic experimentation, alter or mutate the genetic makeup into an arguably noninfringing but useful species.[92] Thus, the original patent owner might not be compensated if the mutation goes undetected.[93] Furthermore, in many countries, the burden of proving infringement is often difficult to overcome.[94] This might influence the patent owners not to undergo the expensive process of

84. Schlosser, *supra* note 52, at 944.

85. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

86. Most microorganisms can be easily reproduced if a viable sample is passed to someone with the proper instructions for propagation. The process of altering the DNA sequence, however, can be quite technical, expensive and difficult unless the scientist is familiar with the organism and the type of experiment that is to be performed. *Id.* at 45.

87. *See* Zimmerman, *A Case Against Patents for Living Organisms*, 7 AM. PAT. L.A.Q.J. 278 (1979).

88. Whale, *supra* note 1, at 108.

89. Kiley, *Learning to Live with the Living Invention*, 7 AM. PAT. L.A.Q.J. 220 (1979).

90. The Patent Cooperation Treaty in rule 5.1 (a)(v) contains the requirement that the *best mode* be described in an international application. "Best mode" in this context means depiction that permits the most convenient form of duplication. PATENT RESOURCES GROUP, INC., *supra* note 9, at 66.

91. *See* Whale, *supra* note 1, at 98; *see also* In re Argoudelis, 434 F. 2d 1390 (1970), *reprinted in* 168 U.S. Pat. Q. 99 (1970).

92. The process of genetic engineering involves altering the species genetic makeup to instill desired characteristics. Such altered genetic elements may be artificially inserted by scientists into microorganisms with the result that the recipient microorganism takes on new characteristics which it would not have naturally possessed. These characteristics then become reproduced as part of the normal reproductive process of the microorganism. *See* Watson, *supra* note 61, at 101.

93. It is not clear from the decision in Chakrabarty whether induced mutants will be considered patentable subject matter. The Court did not address whether a "derivative" creation gives the original patent owner an action for compensation. *See* Behringer, *supra* note 79, at 134.

94. *See* Whale, *supra* note 1, at 108.

litigation.[95]

This first argument can be defeated through international mandates for guidelines and strict regulation.[96] Practices of dangerous genetic alterations will be discouraged if severe sanctions are levied on the violators. Periodic governmental inspections will uncover illegal practices. Additionally, violators will more likely be convicted in those countries having liberal evidence rules.[97]

A second group asserts that patent protection is unnecessary. They maintain that genetic experimentation flourished long before any country recognized its patentability.[98] Therefore, this faction contends that substantial incentives exist in this area of experimentation without providing patent protection to microorganisms.[99] Giving the scientist legal rights for life forms would only burden the already overcrowded patent courts.[100]

This second argument can be attacked constitutionally in many countries. These nations have supreme laws which require the *continual promotion* of scientific progress.[101] Although some incentive[102] did exist prior to the patenting of microbial products, total protection through patents has provided even greater incentives.[103] The additional incentives gained through a patent system would intensify vital cancer, food and energy research. Furthermore, live inventions must receive equal treatment with inanimate inventions, regardless of the supplementary burden placed on the patent courts. Unequal treatment would be a violation of many

95. *Id.*

96. Numerous nations have initiated regulatory measures, demonstrating worldwide concern about and desire for biohazard containment. For example, the European Molecular Biology Organization has established a standing Advisory Committee on Recombinant DNA, which met on Feb. 14 and 15, 1976, to discuss the National Institute of Health's (NIH) guidelines and their suitability for implementation in Europe. While European countries might accept the general principles embodied in the guidelines, certain procedures may not lend themselves to easy adaption because Europe does not have an organization equivalent to NIH. It is therefore not clear who could assume the responsibility of certifying biologically disarmed microorganisms. Comment, *Genetic Manipulations: Research Regulation and Legal Liability Under International Law*, 7 CALIF. W. INT'L L.J. 203, 213 n.5 (1977).

97. *See* Whale, *supra* note 1, at 108.

98. *Id.*

99. OFF. TECH. ASSESSMENT REP., *supra* note 18, at 210.

100. *See* Mossinghoff, *American Bar Association Address*, 63 J. PAT. OFF. SOC'Y 342, 343 (1981). There are presently over 200,000 patent applications and 100,000 trademark applications backlogged in the United States.

101. *See* G. FLONZ, *supra* note 26, at 36.

102. Boyer, *The Age of Molecular Biology*, 7 AM. PAT. L.A. Q.J. 185 (1979).

103. OFF. TECH. ASSESSMENT REP., *supra* note 18, at 240.

nations' constitutions.[104]

The third contingent presents a moral argument against providing patents for man-made microorganisms.[105] This group contends that such a procedure of "re-creation" dehumanizes life and infringes upon their religious values.[106] However, the protests of inhumane experimentation have calmed in recent years. Strict enforcement guidelines regarding the permitted types of genetic experiments have aided the control of dangerous experiments.[107] Furthermore, the patent system does not encourage genetic mutations of higher life forms.[108] Patentable life forms must be capable of exact duplication. Only microorganisms reproduce with such accuracy. Therefore, until cloning methodology is perfected, higher life forms will not be patentable, and experimenters will not be able to obtain the exclusive property right.[109] Also, human ownership through *in vitro*[110] fetal experiments would not be permitted by those nations prohibiting involuntary servitude.[111] It is doubtful that the experimenter would undergo the expensive process without being assured governmental authorization and compensation.[112] Genetic engineering with humans will be subject therefore to strict governmental guidelines.[113]

In summary, major countries now believe that scientific advancement in genetic engineering will be best served if these products are patentable.[114] The impact of the opposing arguments would be intensified if science progresses to the point of precise higher life form duplication. The patentability of higher life forms must be addressed when such techniques become available.[115] A

104. *See generally* G. FLONZ, *supra* note 26.

105. Sears, *The Concept of Societal Consent for Recombinant-DNA Research and Engineering 12* U. TOL. L. REV. 902 (1981).

106. *Id.* A major concern is that patent protection for life forms may set precedent to the patenting of test-tube babies. However, ownership through a patent could not occur in the United States. See U.S. Const. amend. VIII, which prohibits involuntary servitude.

107. Talbot, *supra* note 70, at 806.

108. Kass, *Patenting Life*, 63 J. PAT. OFF. SOC'Y 571, 582 (1981).

109. Patents are an intangible property right, meaning the right to own, use or possess. *See generally* 1 D. CHISUM, PATENTS (1983).

110. *In vitro* means "within glass" and is used to refer to test-tube reproduction. M. FROBISHER, R. HINSDILL, K. CRABTREE, C. GOODHEART, FUNDAMENTALS OF MICROBIOLOGY 124 (1974).

111. *See supra* note 108 and accompanying text.

112. Kiley, *supra* note 89, at 228.

113. Watson, *supra* note 61, at 100.

114. Sparrow, *An International Comparative Analysis of the Patentability of Recombinant-DNA-Derived Organisms 12* U. TOL. L. REV. 926 (1981).

115. Many, but not all countries have excluded animals from patentability. For those

more pressing issue entails devising the proper methodology for patenting microorganisms.

II. THE UNIQUE NATURE OF PATENTING MICROORGANISMS

For the drafter, nothing could be more difficult than to physically conceptualize a life form on paper. Life is continually in motion.[116] Living matter has properties incapable of visual perception.[117] Their qualities and attributes are constantly changing.[118] Most countries have dealt with this drafting problem by creating distinct procedures for patenting live products.

A. A Comparative Analysis

Several distinct foreign procedures for the patenting of microorganisms currently exist.[119] Patent laws around the world require an inventor seeking protection to fully describe and disclose every procedural step and detail surrounding the invention.[120] This disclosure is required because the invention must be reproducible in order to benefit the public.[121] Disclosure of most inanimate inventions can be satisfied by descriptions through words, pictures and diagrams.[122] In order to patent a microbial invention, many coun-

---

which have not, one seeking patent protection may have a difficult time satisfying the disclosure requirement. The higher the order of the organism, the more unpredictable is its reproduction. Thus, even though a living sample of the starting material may be available, there is often no guarantee the offspring will have the same characteristics as the parents. Until the technique of cloning in higher animals becomes perfected, this unpredictability will be a serious obstacle to patentability. *See* In re Merat, 186 U.S. PAT. Q. 471 (1975).

116. *See* M. STRICKBERGER, GENETICS 3 (1976).

117. *Id.*

118. A living organism is constantly exchanging substances with the environment. A tree absorbs water and salt through its roots and absorbs carbon dioxide through its leaves. A mammal absorbs water and food substances in the intestine and oxygen in the lungs. A microorganism also has many properties that go undetected through the microscope. Many are identified by the chemical reactions they produce. J. SMITH, THE THEORY OF EVOLUTION 15 (1975).

119. One of the most interesting systems is the patent system in Yugoslavia. In Yugoslavia, the inventor is given an option to choose between receiving a patent or a certificate of invention. Where a certificate is chosen, ownership devolves to the State. Janic, *Yugoslavia Patent Law and Practice*, *reprinted in* DIGEST OF COMMERCIAL LAWS OF THE WORLD, PATENTS AND TRADEMARKS 2 (G. Kohlik ed. 1980). In the People's Republic of China, inventions are categorized and "awarded" in accordance with their value in industrial use. The inventions are classified into four categories. An invention in the top category receives the greatest cash reward (10,000 yuan). Hsia & Huan, *Laws of the People's Republic of China and Industrial and Intellectual Property*, 5 L. & POL. INT'L BUS. 743, 747 (1973).

120. P. ROSENBERG, PATENT LAW FUNDAMENTALS 13, 15 (1982).

121. 35 U.S.C. § 112 (1976).

122. Schlosser, *supra* note 52, at 933.

tries require the deposit of the microorganism with the proper authority.[123] Presently, the Federal Republic of Germany, Japan, the Soviet Union, Austria, Bulgaria, Hungary, Ireland, the United States, Yugoslavia and the German Democratic Republic require the deposit of the microbial invention.[124] In other countries, the deposit is recommended but not mandatory.[125]

The European Patent Convention[126] also established various laws for the patenting of microorganisms.[127] Rule twenty-eight states:

> If an invention contains a microbial process or the product thereof and involves a microorganism which is not available to the public, the European patent application and corresponding patent shall only be regarded as disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art if: i) a culture of the microorganism has been deposited in a culture collection not later than the date of filing the application; and ii) the application as filed gives such relevant information as is available to the applicant on the characteristics of the microorganism.[128]

The prevailing international viewpoint resolves the technical problems of describing "live" inventions in patent applications by creating procedures that allow deposits of viable samples. Many beneficial aspects subsist by depositing these samples.

---

123. *Id.*

124. *Id.*

125. Although a deposit is not mandatory under Spanish law, they do have strict disclosure requirements. Article 62 of the Spanish Patent Law states: "the description . . . must be so detailed and complete as to be able to be put into practice by a person skilled in the art." *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 126.

The language in Spain is very broad. Compare this with the Soviet Union which makes deposit of the microorganism mandatory. Section 44 of their Patent Law requires that:

> The description of the invention must state the purpose of the invention and must describe the invention in detail including its distinctive features; it shall also contain data on the technical and economic effectiveness of the utilization of the invention, the fields of technology to which the invention relates and where the invention can be utilized, and the claims of the invention.

Id. at 129.

126. *See supra* note 39. The EPC has eleven member countries. They are: Austria, Belgium, France, Germany, Italy, Liechtenstein, Luxembourg, Netherlands, Sweden, Switzerland and the United Kingdom. Other countries not listed here have also been allowed to accede. *See also* Winner, *supra* note 39, at 420.

127. J. SINNOT, *supra* note 39, at 83-84. *See also* B. BEETZ, PRACTICING UNDER THE EUROPEAN PATENT CONVENTION 13 (1978).

128. J. SINNOT, *supra* note 39, at 83.

B. The Benefits of Depositing the Microbial Invention

Having revealed the difficulty of describing life forms on paper,[129] the question now becomes whether the deposit satisfies the requirements of proper disclosure. Practicality and efficiency demonstrate the necessity for such a procedure.

First and foremost, the procedure has been determined to be practical.[130] Microorganisms can be readily reproduced, or reproduce themselves, if propagated from a frozen or lyophilized sample on or in a nutrient media known to cultivate that organism.[131] Therefore, a pure culture, once isolated or produced, can be frozen or lyophilized as a master seed and stored for many years. This procedure is quite practical, as many domestic patent licenses run for periods exceeding fifteen years.[132] A subsequent party could then utilize the invention simply by cultivating the organisms in the appropriate media under the conditions listed in the original patent application.[133]

Second, the procedure of depositing microorganisms conserves time.[134] A more accurate description can be made by depositing the organism, thereby accelerating the patent procedure.[135] If a subsequent user of a patented microorangism were only supplied with a written description, the inventor would be forced to redevelop the product. Although some description must accompany the sample to facilitate cultivation, the written description would be substantially reduced.[136]

---

129. *See* Schlosser, *supra* note 52, at 932.

130. PATENT RESOURCES GROUP, INC., *supra* note 9, at 41.

131. Lyophilization is the process of freeze drying. Some products cannot remain viable if merely frozen and not freeze dried. The type of storage depends upon the particular organism. Most sample cultures of bacteria and viruses are frozen or lyophilized in the nutrient media in which they are propagated. A common sample might contain 10^9 organisms per milliliter. Therefore, when this text refers to "microorganism," it is meant to depict the entire pure culture of microorganisms. *See* Kiley, *supra* note 89, at 228.

132. *See* G. SPENCER, *supra* note 30, at 44.

133. The proper patent application is one in which all aspects of the experiment are listed. This would include a description of the microorganisms' nutrient requirements, such as coenzymes, starches, sugars and the corresponding quantities of each. A description of the growth parameters and conditions would also be needed. This description would include the organisms' temperature, acid, base and oxygen requirements as well as all other conditions necessary for the organisms' propagation. *See* H. ZINSSER, MICROBIOLOGY 67 (1976). See also PATENT RESOURCES GROUP, INC., *supra* note 9, at 133 for an example claim of Bacillus Thuringiensis var.

134. "A bug is worth a thousand words"; *see also* Teschemacher, *supra* note 2, at 31.

135. *See* Lederer, *supra* note 10, at 289.

136. Schlosser, *supra* note 52, at 934.

Moreover, the procedure of depositing the sample is less expensive than the written description typically used for inanimate inventions. Fewer hours would be required by the drafting attorneys since they would not be required to fully describe the invention on paper. Additionally, the subsequent users could spend less money developing the patented invention since the product would be available in its completed form.[137]

C. The Need for a Uniform Depositary System

Due to expensive translation and prosecution costs, the cost of patenting internationally continues to inflate at a shocking pace.[138] An inventor who seeks to patent his invention in a particular nation is subject to the domestic laws of that State.[139] Furthermore, the patent laws of many of these nations require the individual deposit of a microorganism for that country's patent purpose.[140] In many cases, deposits made in foreign countries might not be accepted.[141]

In many countries, patent applicants who seek to market their inventions must make individual deposits in *each* country where the inventor wishes the invention protected.[142] Numerous deposits increase the probability of error or omission detrimental to the acquisition of the patent.[143] The inventor, by making deposits in foreign nations, is confronted with unfamiliar languages and currencies. Further, the inventor must contend with unknown depositary officials over confusing technical, legal and administrative depositary requirements.[144] Many problems could be alleviated by the establishment of a uniform system throughout the different countries. The first attempt to create such uniformity in this area was the establishment of the Budapest Treaty.[145]

---

137. *Id.*

138. Winner, *supra* note 39, at 431. A cost estimate for filing foreign applications was $1000 per case as of May 1978. Present figures for non-English-speaking countries average over $2000, and in Sweden and Japan may be as high as $4000. (Estimates based on statements for fees received from foreign associates directed to the firm of Sheridan, Ross, Fields and McIntosh, Denver, Colo., Sept. 1979 through June 1980).

139. G. POLLIZIEN, INTERNATIONAL LICENSING AGREEMENTS 8 (1974).

140. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

141. Schlosser, *supra* note 52, at 935. This would be true in those nations which do not recognize microorganisms as patentable *per se*. For a complete compilation of the countries that recognize microorganisms as patentable *per se*, see PATENT RESOURCES GROUP, INC., *supra* note 9, at 136-37.

142. Schlosser, *supra* note 52, at 935.

143. *Id.*

144. *See* Whale, *supra* note 1, at 107.

145. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 12.

III. THE BUDAPEST TREATY: AN INTERNATIONAL ATTEMPT TO CREATE UNIFORMITY IN THE PATENTING OF MICROORGANISMS

A. Background

The Budapest Treaty[146] was designed to eliminate many of the international problems inherent in the deposit of man-made microorganisms. On April 28, 1977, eighteen nations signed this agreement,[147] which established the International Depositary Authority (IDA).[148] The purpose of the Treaty was to secure a system of depositaries within the member countries which would reduce the expense and confusion of the international patenting of man-made microorganisms.[149] First, the agreement provides one set of rules and requirements for the patenting of microorganisms, which is administered by one organization—the World Intellectual Property Organization (WIPO).[150] This provision facilitates an understanding of applicable patent rules. The patentee need learn only one set of rules, rather than having to learn the regulations of every country in which protection is sought. Second, the Treaty creates *some* uniformity.[151] The patentee is able to obtain exclusive patenting rights in a variety of foreign nations with minimal expense and confusion.[152]

The Treaty provides that an inventor can receive patent protection in all member States with only one deposit.[153] Further, the Treaty mandates that contracting States which allow or require the

146. Budapest Treaty, *supra* note 9.

147. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at i2.

148. *Id.*

149. Under United States patent law, if an inventor publishes his work or places his invention on sale, he has one year after making the invention public to file his patent application. During this year he can test the commercial value of his invention and decide whether it is worth the expense of patenting. Some countries do not allow this grace period. They hold that if an invention has been published or used anywhere in the world before filing the application, patenting is absolutely barred. This example illustrates another reason for establishing a uniform system for patenting inventions. *See* Winner, *supra* note 39, at 422.

150. The World Intellectual Property Organization (WIPO) is an intergovernmental organization with headquarters in Geneva, Switzerland. WIPO promotes the protection of intellectual property throughout the world through the cooperation of various States. It is also responsible for the administration of several unions founded on multilateral treaties. A substantial portion of its activities and resources is devoted to assisting developing countries. *See* WIPO, General Information, WIPO Publication No. 400E (1981).

151. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 12.

152. Schlosser, *supra* note 52, at 935.

153. Budapest Treaty, *supra* note 9, art. 1 (*Establishment of a Union*) (1977).

deposit of the microorganisms,[154] recognize a deposit in any international depositary authority.[155] Such recognition shall include the fact[156] and date of the deposit.[157] By virtue of these rules, an inventor is assured that the exclusive right of the invention will be granted in all member States from the time of filing.[158] This guarantee will continue for the duration of the IDA recognition.[159]

The Treaty is open to all nations which are members of the Paris Union Convention.[160] All States can become members of the Convention.[161] Therefore, the Budapest Treaty likewise remains open to all countries who agree to abide by its provisions.[162] The major provisions of the Treaty demonstrate the effectiveness of a uniform patent system. Problems arise when the Treaty fails to extend its authority over international infringements.[163]

B. Requirements to Acquire IDA Status

In order to acquire IDA status, a depositary must fulfill specific requirements provided by the Treaty.[164] First, an institution must have continual existence within a member State.[165] The Treaty requires samples in each of the depositaries to be closely regulated to protect the patentee's rights.[166] If a depositary were to transfer samples to a non-member State, compliance with this regulation would be virtually impossible. Second, if a depositary within a member country ceased to maintain the proper facilities for these

154. The IDA is governed by an International Bureau. The chief executive of the Bureau shall be the chief executive of the Union and shall represent the Union. Budapest Treaty, *supra* note 9, art. II, §§ 1-4.

155. PATENT RESOURCES GROUP, INC., *supra* note 9, at 12.

156. *Id.* at 19.

157. *Id.*

158. *See supra* note 149 and accompanying text.

159. *See infra* text accompanying notes 178-185 for a discussion of the length of storage of a deposited invention.

160. The Budapest Treaty is open to membership to any country belonging to the Paris Union Convention. Furthermore, Article 9 of the Treaty contains a special provision under which only intergovernmental organizations having authority to grant regional patents to several countries may accept certain obligations under the Treaty. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 14; *see also* Budapest Treaty, *supra* note 9, art. 9 (*Intergovernmental Industrial Property Organization*).

161. Administrative matters will be conducted by the contracting States of the Treaty. One delegate will represent each country. Budapest Treaty, *supra* note 9.

162. *Id.*

163. *See generally* PATENT RESOURCES GROUP, INC., *supra* note 9.

164. Budapest Treaty, *supra* note 9, rule 3 (*Acquisition of the Status of the IDA*).

165. *Id.* art. 6, § 2.3.

166. *Id.* rule 2, § 2.2.

samples, IDA status would be terminated.[167] Third, all institutions must be impartial and objective.[168] Inventors who may wish to deposit in various nations would be discouraged from patenting abroad if a member State were to extend preferential treatment to its citizens.[169] Finally, an institution must accept specified strains of microorganisms for deposit,[170] examine their viability, and store them properly.[171]

Problems develop once the depositary of a particular nation acquires IDA status. The Treaty permits each State to legislate its own laws for acceptance and release of the samples. Germany has expressed legitimate doubt as to the effectiveness of international detection devices for uncovering infringements.[172]

C. Transfer of Deposits

The Treaty regulations provide an essential safeguard for depositors.[173] If an international depositary authority should temporarily or definitely discontinue performance, the State in which the depositary is located must transfer all microorganisms without contamination and all accompanying records to another international depositary.[174] Additionally, the IDA must notify all depositors and the Director General[175] of all action taken.[176] This procedure, vital to the inventor's patent rights, assures the continued maintenance of deposits in an IDA.[177] An inventor must be guaranteed that the patent rights will be maintained for the statutory period. Inventors who are promised continual protection will be encouraged to release their products abroad.

D. Length of Storage and Confidentiality

Another Treaty provision requires that microorganisms be

167. *Id.* art. 8 (*Termination and Limitation of the Status of the IDA*).
168. *Id.* art. 6, § 2.3.
169. *Id.* § 2.5.
170. *Id.*
171. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 20-21.
172. *Id.*; *see also* Budapest Treaty, *supra* note 9, art. 5 (*Import and Export Restrictions*).
173. If a member country refuses to accept a sample, the country must notify the Director General. The Director General will in turn notify the contracting States involved. Budapest Treaty, *supra* note 9, rule 5.2.
174. *Id.* rule 5 (*Storage or Microorganisms*).
175. *Id.* § (a)(4).
176. *Id.*
177. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 16.

stored for at least thirty years.[178] Furthermore, the Treaty requires the IDA to guarantee the secrecy of the inventor's information during this period.[179] The institution shall not reveal whether the microorganism has been deposited.[180] The depositary may only divulge this information to either an authorized individual[181] or one who is legally entitled to this knowledge.[182]

The Treaty, within this section, advocates secrecy, yet mandates no provision for restitution if the confidentiality requirement is violated. The contents of the invention should only be divulged to persons who have either legal rights or permission from the inventor to gain access to the information.[183] The Treaty has allowed each nation to retain jurisdiction over infringement suits within its boundaries.[184] However, these laws contain substantial disparity as to the proper legal remedies involved.[185] For example, an inventor in England might find the relief granted for a secrecy violation in other countries to be inadequate. If the English inventor were to find other nations' laws improper, he could be discouraged from releasing the information beyond English boundaries. A compilation of such examples would have a profound effect on an international patent system.

E. Redepositing the Microorganism, Maintaining the Patent

The Budapest Treaty also allows the depositor to make a replacement deposit if the original is lost or destroyed.[186] A replacement, for purposes of deposit, is considered to have been made on the date of the original filing.[187] The patentee must sign a statement that the new deposit is identical to the microorganism initially deposited.[188] This safeguard assures the patentee the exclusive right to the invention for the statutory period. Additionally, this

178. *See* Budapest Treaty, *supra* note 9, rule 9 (*Storage of Microorganisms*).

179. The rules for granting release of sample will be discussed at length later in this Comment. *See infra* text accompanying note 287.

180. Budapest Treaty, *supra* note 9, rule 9.2.

181. *Id.* rule 11 (*Furnishing Samples*).

182. *See* Schlosser, *supra* note 52, at 935.

183. The Treaty also requires the depositary to check the viability of the organism (a) promptly after any deposit or transfer; (b) at reasonable intervals, depending upon the species deposited; and (c) at any time requested by the depositor. Budapest Treaty, *supra* note 9, rule 10.1.

184. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 21.

185. Kiley, *supra* note 89, at 229.

186. Budapest Treaty, *supra* note 9, rule 6.2 (*Making a New Deposit*).

187. *Id.*

188. *Id.* rule 6.2(a).

procedure guarantees that the patent information will be available to others during this period.[189] Any controversies concerning the precision of duplication of the original deposit will be resolved by national or regional law.[190]

Disparity between each nation's determination of whether precise duplication occurred could also burden international courts with numerous suits. Theoretically, the inventor could modify the organism before resubmission. This replacement might be considered an "exact duplication"[191] in one country and a "derivative"[192] in another. The problem is exaggerated when the patentee receives additional property rights with a derivative.[193]

F. Depositor's Requirements Under the International Depositary Authority

In order for the deposit to receive patent protection, the depositor must fulfill certain requirements under the Treaty. For example, depositors must sign a written affidavit which includes various declarations. First, inventors must indicate that the deposit complies with the provisions of the Budapest Treaty and the depositor will not withdraw the information for a minimum of thirty years.[194] Second, inventors must release their name and address to enable contact by prospective users and the Director General.[195] Third, inventors must detail the proper propagation, storage and testing conditions for the microorganisms.[196] Fourth, the inventor must indicate the microorganisms' dangerous propensities, or admit to not knowing whether such potential danger exists. The Treaty recommends, but does not require, that the statement contain a scien-

189. *See supra* note 183 and accompanying text.

190. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 31; *see also* Budapest Treaty, *supra* note 9, art. 4(2).

191. "Exact duplication" means isolated from the original culture and patented without any further genetic engineering performed. *See* Whale, *The ABCD's of Patent Infringement*, 62 J. PAT. OFF. SOC'Y 136, 137 (1980). A direct infringement requires doing the *same* thing in the *same* way to get the *same* result. This could be called "umbral" infringement. It forces the defendant to do a microinspection of the patent records. But direct infringement is also doing *substantially* the same thing in *substantially* the same way to *substantially* get the same result. *Id.*

192. "Derivative" means isolated from the original culture but altered in some way through genetic engineering. *See* Behringer, *supra* note 79, at 134.

193. The inventor may make a derivative that has more usefulness in the commercial market than the microorganism originally deposited. *Id.*

194. Budapest Treaty, *supra* note 9, rule 6(a) (*Making the Original Deposit*).

195. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 32-34.

196. *Id.* at 32.

tific description of the organism.[197]

The IDA may refuse to accept the deposit regardless of whether the above requirements are met. For example, the microorganisms might not be of a species for which the IDA gives assurances of patentability. Furthermore, the IDA might also not be suited to handle the properties of a particular organism, or the deposit may be defective for scientific reasons.[198] Therefore, the Treaty does not specify criteria for member countries to determine whether a certain microorganism is patentable subject matter.[199] This question is resolved by the patent laws of each country.[200] However, individual depositaries can specify the categories of microorganisms which would be acceptable. The depositary can transmit this list to the Director General.[201] Therefore, an inventor can discover whether a country would accept his deposit without having to translate foreign laws.

In all cases, once a Treaty depositary accepts an organism, the date of patent protection relates back to the original date of deposit.[202] This benefit can be significant when competing inventors race to obtain exclusive rights to a unique and potentially valuable invention.[203]

G. Accessibility to the Deposited Samples

Opponents of the Treaty predominantly criticize the regulations which direct the furnishing of a deposited sample to subsequent third-party users.[204] Under the rules of the Treaty, third-party users can gain access to deposits in three situations. First, the depositor may directly authorize access to the user.[205] Second, a national granting authority[206] may itself gain access to a deposit. Finally, if the subsequent third-party user does not qualify under these situations but is legally entitled to obtain the sample, he might

197. *Id.*

198. *Id.* at 33.

199. *See supra* notes 31-37 and accompanying text.

200. Budapest Treaty, *supra* note 9, rule 6.1(B).

201. *Id.* rule 3.1 (*Communication*).

202. *Id.* art. 4 (1)(d). The new deposit shall be treated as if it had been made on the date which the original deposit was made, if viable, and where it is made within three months after the depositor received notification of the organisms lack of viability.

203. *See* Watson, *supra* note 61, at 101.

204. Budapest Treaty, *supra* note 9, rule 11 (*Furnishing of Samples*).

205. *Id.* § 11.2.

206. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 23.

also gain access.[207] Apparently, authority under the first two sections does not pose problems if the sample is used only for patent experimentations authorized by the States.[208] Several problems have arisen, however, regarding the third mode of access.

The Treaty does not propose specific laws for access by a third-party user. These regulations are legislated by the country in which the depositary is located.[209] Therefore, although an inventor can acquire protection in all member countries with only one deposit, each country may select those individuals who are entitled to the depositor's samples. Under the third course of access, a party must adhere to the laws of the country in which the sample is acquired, even if the inventor intends to use the sample in another nation.[210] In order to acquire access to a sample in another country, the user must request a sample through an official form which bears an authorized certification.[211] Certification occurs only when the laws of the country in which the depositary is located are fulfilled. Therefore, a State can potentially restrict access to all samples within its depositaries.

A country which restricts access, however, must submit a statement justifying this decision to the Director General and the International Bureau.[212] Furthermore, a person who is unjustifiably denied access to a sample can submit a formal request to the Director General to terminate the institution's status as a member of the IDA.[213] Upon such a request, the Bureau has the duty to investigate the situation and determine whether the complaint is well founded.[214]

These regulations are an effective safeguard against prejudicial restrictions imposed upon foreign users. However, the laws do not have sufficient clarity in all situations. For example, contracting States might justify restrictive actions as being necessary to the health and safety of the nation.[215] Problems arise when certain countries abuse their sovereign privilege. Claims of health and

207. The user may be given permission by a licensee of the original creator. Budapest Treaty, *supra* note 9, § 11.3.

208. *Id.* § 11.1.

209. PATENT RESOURCES GROUP, INC., *supra* note 9, at 25.

210. *Id.*

211. *Id.* at 26.

212. Budapest Treaty, *supra* note 9, rule 3.1.

213. *Id.* art. VIII (*Termination and Limitation of the Status of the IDA*).

214. *Id.* rule 3.1(c).

215. Lederer, *supra* note 10, at 293.

safety violations could entail hints of sovereign prejudice.[216] Such claims would have a deterrent effect on foreign patent applicants. Foreign inventors must be accorded equal treatment in all member countries, otherwise the purpose of the Treaty—to establish a uniform patent system—would be defeated.

The Budapest Treaty also authorizes contracting States to deny access to the depositaries. A contracting nation can impose import and export restrictions on samples located within its depositaries.[217] The Treaty, however, does not provide regulations which can countermand the export and import restrictions of a member country. The Treaty merely encourages each member to restrict access to its depositaries if the limitation is necessary to prevent contamination of the environment and to preserve national security.[218]

The problems of international accessibility present many vital issues. One major question is whether the IDA should have the authority to overrule export and import restrictions. This problem is immediate, since Germany has already passed laws which completely restrict exportation of German samples.[219] The United States is presently contemplating the enactment of similar laws. These laws could have significant ramifications if adopted on a world-wide basis. The principle objective of the Treaty is to encourage transfer of valuable technology. A multitude of restrictive laws would shatter any homogeneity and thwart the Treaty's objectives.

The Budapest Treaty, therefore, falls far short of its goals. The Treaty advocates secrecy, but mandates no provision for uniform enforcement. The Treaty grants inventors a right for resubmission in the case of sample destruction, yet fails to control resubmission abuses. Finally, the Treaty permits multiple patent grants upon one deposit, but does not warrant sample release to each State. The foregoing problems are clearly evidenced by examining underdeveloped and developed nations' exercise of sovereign rights.

IV. THE FAILURES OF THE BUDAPEST TREATY: EXERCISING SOVEREIGN RIGHTS

A developed invention, to be considered patentable, must meet

216. *See* Landau, *supra* note 15, at 140.
217. Budapest Treaty, *supra* note 9, art. 5 (*Export and Import Restrictions*).
218. PATENT RESOURCES GROUP, INC., *supra* note 9, at 29.
219. *Id.* at 81.

the requirement of utility, novelty, nonobviousness and enablement.[220] An invention with societal value must enable others to gain access to the information.[221] Additionally, inventions geometrically accelerate the development of other ideas and new products into the market.[222] The resulting effect propels society forward with creative products which facilitate an easier lifestyle. *International* patents allow the world to gain more information than any individual nation could acquire.

Individual countries, as well as the international community, suffer from the prohibition of access to new information.[223] However, certain situations require the preservation of independence, national security, health and environmental conditions, and demand certain restrictions regarding access to the information.

The Budapest Treaty leaves vital areas of control open to preemption by member nations. Uniformity is advocated but not fulfilled. These shortcomings are evidenced by the past restrictive measures of Third World nations and by those of Germany.

A. Third World Restrictions Under the Paris Union Convention

Industrialized nations have argued against the admission of Third World States in an international patent system.[224] A tremendous disparity of wealth and knowledge exists between developed and underdeveloped countries.[225] Discontent over former colonialism has inspired Third World nations to achieve identity through independent sovereignty. These nations have impeded worldwide transfer by restricting the importation of technology and foreign investment.[226] These States have equated industrialization with colonial dictatorships. Furthermore, they have also prohibited an influx of genetic technology. Genetic experimentation contravenes many Third World nations' ideals of morality.[227]

Industrialized nations have criticized the membership of Third World countries in the Paris Union Convention, contending that

220. *See supra* notes 31-37 and accompanying text.

221. *Id.*

222. In the United States not all improved inventions are patentable. For example, the new use doctrine bars the discoverer of a new use for a known compound from obtaining a patent with composition claims regardless of the level of inventiveness exercised. 1 A. DELLER, DELLER'S WALKER ON PATENTS 244-72 (1964).

223. Landau, *supra* note 15, at 105.

224. *Id.*

225. *Id.*

226. *Id.* at 151.

227. *Id.* at 115.

the Third World's restrictive laws defeat uniformity. Furthermore, technology released from Third World nations is minimal as compared with technological achievement in developed nations.[228]

These arguments were addressed at the revised Paris Union Convention of 1967.[229] The Convention concluded that the advantages of Third World membership outweigh the disadvantages.[230] Third World membership in an international patent system maintains *partial uniformity*.[231] Although these countries retain special sovereign rights, the importation of *some* technology is allowed.[232] The accepted inventions allow advancement, at least, to a minimal degree. If the industrialized countries were to expel Third World nations from the uniform patent system, importation would occur at a far slower pace. Disparity of wealth and ideas would continue to expand.[233] Developed countries would also suffer since the Third World nations would be dissuaded from internationally releasing the few discoveries they do uncover.

Additionally, Third World nations provide adequate reciprocity. Some countries have achieved specialization in areas which remain untouched in developed nations. Multinational corporations now develop natural resources in Third World nations.[234] Therefore, unless these countries are admitted to a uniform system, the incentive to market their resources will be insubstantial. The incentive to have these countries market abroad is essential to decrease the huge disparities between Third World nations and the industrialized countries.

The examples set by the Paris Union Convention should be regarded as legal international precedent to the Budapest Treaty. The arguments presented demonstrate the reasons for unrestricted membership to the Paris Union Convention. Members of the Paris

228. Whatever the ultimate causes may be, the underdeveloped nations depend for their growth on the techniques of the advanced countries . . . the third world nations can not achieve more than a few firms in each industry. Hence the third world nations must rely more and more upon the techniques and products imported from developed countries. *Id.* at 112.

229. *See* Gansser, *supra* note 16, at 148.

230. *Id.*

231. If these countries are admitted, at least some technology will travel between developed and underdeveloped nations. These nations do not prohibit all importation. *See* Landau, *supra* note 15, at 134.

232. *Id.*

233. *Id.*

234. Patents granted by Third World nations are mostly received by foreign corporations. *Id.* at 106.

Union Convention are invitees of the Budapest Treaty.[235] The Convention passed special laws[236] which have encouraged Third World nations to join the uniform patent system.[237] The Budapest Treaty should, likewise, encourage nations to adopt the uniform system of patenting life forms. Germany's restrictive laws, however, pose a threat to the uniform system.

B. Germany's Exercise of Restrictions Under the Budapest Treaty

Germany is one member of the Budapest Treaty which has passed confined laws.[238] The development of these restrictive regulations was triggered by the shortcomings of other German patent laws. In Germany, as in many other European countries under the European Patent Convention, the file of a patent application is open to the public at any stage of the examination procedure.[239] The German laws differ from United States patent rules in that the release of information is allowed only after a patent has been granted.[240] In the United States, information is protected once legally available to the public.

Germany's laws were founded on the principle that information should be disclosed at the earliest possible date: the point of publication of an unexamined application. A deposited microorganism is considered part of disclosure and, consequently, should be released at the point of application.[241] Therefore, under current German law, a sample will be released to third-party users without patent protection. Applicants may, however, require recipients to identify themselves and agree not to transmit samples to subsequent users.[242] Third-party users must also agree to use the sample in a manner conforming to German patent law.[243] Apparently, Germany feels secure that German citizens will abide by these

235. Budapest Treaty, *supra* note 9, art. 9 (*Intergovernmental Industrial Property Organizations*).

236. The laws included changes in: 1) national treatment; 2) right of priority; 3) independence of patents; 4) compulsory licensing and forfeiture; and 5) importation of articles and products manufactured by a process patented in the importing country. *See* Landau, *supra* note 15, at 139.

237. *Id.*

238. The others include the United Kingdom, Switzerland, Liechtenstein, Sweden and Italy. *See* PATENT RESOURCES GROUP, INC., *supra* note 9, at 136.

239. *See* Lederer, *supra* note 10, at 292.

240. *See* Feldman v. Aunslup, 517 F.2d 1351 (C.C.P.A. 1975).

241. Lederer, *supra* note 10, at 292.

242. *Id.* The decision in BGH "Bäckerhefe" GRUR 430 (1975) which confirmed this rule is still current law.

243. Budapest Treaty, *supra* note 9, rule 11.3(a)(iii).

laws. The recent German export and import restrictions, however, suggest that the government was not willing to trust the citizens of other nations. Germany's position is founded on several arguments.

1. *Compensation for Infringements Abroad.* If a product is a viable microorganism, transfer of the invention is quite simple. Microorganisms multiply exponentially when proper environmental conditions are maintained.[244] Thus, an unauthorized user who acquires a microorganism from the IDA could transmit the product with little opportunity for objection by the original patentee.[245] Unauthorized transmission is more probable when the subsequent user is in another country.

In many situations, the original patentee and the depositary have virtually no opportunity to effectively police the unauthorized use of inventions. Following the original deposit, once an infringing product appears in another member country's market, an action for compensation becomes available as a legal remedy.[246] In many situations, however, the original microorganism could be genetically altered, which may deny the original patentee compensation.[247]

The current international law classifying the types of "derived" organisms which are protected is unclear.[248] Through the discovery of recombinant DNA[249] and the subsequent advances in technology, genetic alterations are not terribly difficult.[250] The DNA sequences of one organism can be artificially introduced into the DNA sequences of another microorganism, eventually produc-

244. *See* H. ZINSSER, *supra* note 133, at 68.

245. G. TAYLOR, THE BIOLOGICAL TIME BOMB 9 (1968).

246. One of the reasons for allowing sample submission for the deposit of microorganisms is that they can be reproduced in virtually equivalent form as the original. The arguments against allowing samples for higher life forms arise because these organisms do not duplicate with such exactness. *See* Zimmerman, *The Case Against Patents for Living Organisms*, 7 AM. PAT. L.A.Q.J. 278 (1979).

247. *See* Behringer, *supra* note 79, at 134.

248. *Id.* at 133-34.

249. Recombinant DNA is the DNA of one organism inserted into the gene sequence of another. In bacteria, the DNA is isolated from small circular loops in their cytoplasm called plasmids. These plasmids can be isolated from the bacterial cell and cut open by a restriction endonuclease enzyme. From another organism (plant, frog, fly or man) the DNA of the cells can also be isolated through the use of these enzymes. When the pieces of DNA are mixed *in vitro* and recombined, a new bacteria can be created with an entirely different genetic sequence. For a visual description, see Talbot, *supra* note 70, at 804, 805.

250. *See* Behringer, *supra* note 79, at 137.

ing an organism which is quite different.[251] A similar experiment with recombinant-DNA was used by Chakrabarty to yield oil eating bacteria.[252] Furthermore, alterations of the microorganism can now be synthesized without destroying the basic utility of the invention. Although the microorganisms could be genetically different, the new microorganisms might be as useful an invention as the original patented product. Therefore, unless the patent law applies to organisms "derived from"[253] the original deposit, the patentee's original idea could be infringed upon without providing a cause of action.

Presently, only the European Patent Convention, whose members are invitees of the Budapest Treaty,[254] has passed a provision which restricts uncompensated "derived organisms."[255] The European Patent Convention defines a "derived culture" as one which still exhibits those characteristics of the deposited culture which are essential to effectuate the invention.[256] Therefore, Germany justifies the laws restricting access to their depositaries on the grounds that their government cannot effectively control the unauthorized appropriation of an inventor's microorganism outside Germany. Although Germany can police patent infringement more effectively within its boundaries, a total ban on importation and exportation is much too stringent.

2. *Potential Safety Hazards*. Germany also maintains that the purposes of these measures were to promote national security, health and environmental safety. Microorganisms can be altered to benefit society but can also be altered to create potentially dangerous forms. Segments of DNA from a pathogenic organism, transmuted into the DNA of a patented bacteria, can procreate an organism that produces a disease for which there is no known cure.[257] Most countries prohibit this type of dangerous experimentation,[258] but the hazard would be even more prevalent if such or-

251. The Monsanto Corporation has recently found a way to transfer a genetic trait from a bacterium to a plant cell. San Diego Union, Jan. 19, 1983, at A19, col. 4.

252. *See* Diamond v. Chakrabarty, *supra* note 49, at 310.

253. Budapest Treaty, *supra* note 9.

254. *Id*. art. 9.

255. PATENT RESOURCES GROUP, INC., *supra* note 9, at 35. The European Patent Convention derived much of its substantial law from the 1963 Strasbourg Convention. This Convention is also open to any member of the Paris Union. *Id*.

256. Teschemacher, *supra* note 2, at 40.

257. *See* Sears, *supra* note 105, at 902.

258. Talbot, *supra* note 70, at 806.

ganisms were to find their way into the hands of terrorist groups. If the patentee or the depositary is unable to police the transfer of the patented organism within another country, the problem becomes, in fact, a real one. Therefore, until sufficient safeguards exist in all member countries, import and export restrictions may be the most practical methods of control.

3. *Other Problems with the Depositary System*. Another risk embodied in the present depositary system is the possibility that a deposited culture may arrive at a depositary in a nonviable condition in which no deposit date can be secured.[259] If a deposit date is not secured, the resulting invention will not be protected.[260] Under the Budapest Treaty, the legal consequences of an initial negative viability test are left to the discretion of each nation.[261] The Treaty only safeguards the loss of viability of a deposit *after* the original sample has been accepted.[262] The Treaty provides that if the original deposit is lost or destroyed, a depositor may supply an identical substitute culture without loss of the original date of deposit.[263] The procedure does not extend protection to a deposit which *before* acceptance, and through no fault of a depositor, is not deemed viable.

Additionally, various countries might prohibit certain claims on the ground that the deposited organism is not considered patentable subject matter. Therefore, even if an inventor seeks to market his invention in *all* member nations, the microorganism must be of the type which will be accepted. The protection would be limited solely to those countries which regard the microorganism as patentable. Moreover, an inventor will expect the invention to be protected by virtue of acceptance in other member States. A uniform rule is therefore necessary.[264]

Another problem concerns the lack of uniformity regarding the *periods of time* for which culture deposits must be maintained.[265] Many countries require maintenance of the cultures throughout the life of the patent;[266] others require maintenance be-

259. Budapest Treaty, *supra* note 9, art. 4(1)(a).
260. *Id.*
261. PATENT RESOURCES GROUP, INC., *supra* note 9, at 31.
262. *Id.*
263. *Id.*
264. Hayashi, *supra* note 3, at 306.
265. PATENT RESOURCES GROUP, INC., *supra* note 9, at 21.
266. *Id.*

yond the life of the patent.[267] The requirement for maintenance subsequent to the patent life reflects the policy that a culture should remain available after the life of the patent. If the product becomes unavailable, the original patentee could retain his exclusive rights well beyond the life of the patent, as the sole person able to use and experiment with the microorganism.

This problem, however, seems unlikely. During the lifetime of the patent, an individual who acquires the sample can establish his own permanent sample through recultivation and storage.[268] Therefore, a post-protection requirement would merely increase the cost and complexity of the patenting process.[269]

Some problems in the Treaty could be easily remedied. Other areas, however, deserve more consideration by the member countries.

V. PROPOSALS FOR AN AMENDED TREATY

Germany's restrictions have caused significant international concern. The United States is contemplating the enactment of similar laws.[270] Although the laws imposed on inventors by Germany would maintain closer scrutiny of potential infringements, the effects deter international dissemination of information. The following suggestions could be more practical for all countries concerned.

A. Penalty Clauses Should be Specified in Greater Detail

The Budapest Treaty does not mandate a uniform set of rules for secrecy violations. The Treaty must dictate more specific penalty clauses for the misuse of the deposited organisms. Additionally, all users should be required to report the status and location of the original deposit to the IDA.[271] Furthermore, if any misuses are discovered, the Treaty should mandate strict penalties to the original user. This may be a harsh rule, especially if the original user is not the individual violating the safety regulations. However, the rule would deter the original users from passing on a sample without authorization.[272] Finally, if the laws were uniformly strict, in-

267. *Id.*

268. Kiley, *supra* note 89, at 228.

269. Teschemacher, *supra* note 2, at 29.

270. Telephone interview with Mr. Koch, Patent attorney from Alexandria, Virginia, specializing in international patent law, Oct., 1982.

271. *See supra* notes 204-14 and accompanying text.

272. *Id.*

ventors would trust foreign depositaries, thus encouraging international marketing of inventions.

B. A Uniform Set of Rules for Patentability Must be Mandated by the Treaty

In order to create uniformity of patent procedures among the member nations, the Treaty must promulgate rules establishing the products which will be recognized as patentable subject matter.[273] The rules should provide a list of microorganisms known to be pathogenic or "potentially"[274] pathogenic which will not be patentable *per se*.[275] Further, the Treaty must be amended to incorporate all elements necessary for patentability.[276] The present Treaty is noticeably vague on this point.[277] This amendment would provide inventors in all member countries with a clear understanding of those inventions which will be recognized as patentable. The clarity would help inventors change research into areas which would yield patentable and eventually profitable inventions. Once made aware of unpatentable microorganisms, it is unlikely that inventors would spend time and money in their research. One objective of the Treaty was to eliminate much of the cost and confusion of patenting abroad. An international definition of patentable subject matter would fulfill this objective.

C. The Treaty Should Extend the Exclusive Rights of the Patented Microorganisms to All "Derived Cultures"

The Treaty must define the term "derived culture."[278] This definition should be more detailed than the one described in the European Patent Convention.[279] This definition would provide the

273. *Id.* at notes 31-37.

274. "Potentially" in this situation should be defined as having the strong possibility of developing into actuality. *See* WEBSTER'S SEVENTH COLLEGIATE DICTIONARY 665 (1969).

275. Not only should the product be excluded from patentability, but also the processes, techniques and components of these organisms should be likewise excluded from patentability. *See* BLACK'S LAW DICTIONARY 1028 (rev. 5th ed. 1979).

276. The Treaty should establish a complete compilation of the requirements necessary for patentability. A uniform rule should be established so that foreign inventors will have a better understanding of rules abroad.

277. Budapest Treaty, *supra* note 9, art. 2 (*Definitions*).

278. The definition could read: A "derivative" organism is an organism received from a specific source or origin having properties and qualities which lack a sufficient degree of inventiveness from previously patented organisms. *See* BLACK'S LAW DICTIONARY, *supra* note 275, at 399.

279. Lederer, *supra* note 10, at 296.

IDA, depositors, and all subsequent users with insight as to which products infringe upon the original deposit. Additionally, the Treaty must guarantee that all users of "derived cultures" be penalized for not compensating the original patentee. Such sanctions would deter unauthorized transfer of samples by third-party users. Therefore, the Treaty would grant the foreign inventor an international property right.[280] Furthermore, a uniform remedy would create an understandable register of the remedies available. If inventors are assured a protectable property right, they would be encouraged to release a new discovery into the international community.

D. Viability Must be Uniformly Established to Take Effect on the Date of the Original Deposit

A patentee should not be penalized if, absent any fault of his own, the IDA does not find his product viable and, therefore, does not grant acceptance.[281] The Treaty allows for a replacement sample without losing the original deposit date. However, when the microorganism loses its viability after deposit, but before acceptance,[282] the IDA does not allow the inventor to retain the original deposit date.[283] It would be more practical if a replacement sample is allowed, under certain circumstances, even if initial viability is not found. A determination of initial nonviability should give a good faith inventor the right to make two additional deposits. This opportunity would safeguard any negligence on the part of the depositary. However, if the third sample were found "inherently"[284] nonviable, the patentee would be bound to redraft his instructions and reexperiment with the organism.

E. Protection Should be Given from the Point of Application

Germany could minimize the risk of uncompensated transfer of samples by providing immediate patent protection once the deposit is made. Germany's law currently requires depositaries to re-

280. *See* Gansser, *supra* note 16, at 168.

281. PATENT RESOURCES GROUP, INC., *supra* note 9, at 33.

282. *Id.*

283. *Id.*

284. "Inherent" in this situation should be defined: "The condition of the essential character is such that it will be habitually repeated under identical conditions." WEBSTER'S NEW COLLEGIATE DICTIONARY 593 (1976). This suggestion may, however, run counter to the requirement that the inventor must reduce the embodiment to practice before protection can be obtained. *See supra* note 64.

lease samples, even if the sample is not protected by a patent.[285] Germany believes that the risk of infringement is greater outside its jurisdiction.[286] Although the effectiveness of German law within its boundaries is unclear, domestic infringement will probably occur once genetic technology advances to the level which has been obtained in the United States. Germany could eliminate the risk by echoing the patent laws of the United States and providing immediate protection from the time of application.

F. Impose Harsh Safety Regulations

If the Treaty imposes stricter safety regulations, member countries would be encouraged to allow accessibility to their depositaries. It is unlikely that member nations, such as Germany, would agree to the International Bureau[287] or WIPO exclusively regulating the accessibility of the samples at the IDA within their country. However, WIPO or the Bureau must a least encourage all member States to allow for accessibility unless a sample poses real dangers.

All of the proposed suggestions would discourage nations such as Germany and the United States from imposing import and export restrictions. The international flow of novel information, which was one of the original objectives of the Budapest Treaty, must be maintained. If Germany prohibits access, other nations will soon follow. Therefore, member countries must take immediate action to prevent a cascade of new restrictions.

VI. CONCLUSION

Genetic engineering could become the genesis of cancer eradication.[288] This former unattainable vision has become a legitimate theory indebted to incentives created by the patent system.[289] Additionally, other valuable microbial inventions are attributed to patent inducement.[290] *International patent systems* would undoubtedly accelerate inventiveness in genetic engineering at even a greater pace than provided by domestic patent systems. Concern

285. *See* Lederer, *supra* note 10, at 296.

286. *Id.*

287. See Budapest Treaty, *supra* note 9, art. 11, for the requirements the Treaty edicts for the International Bureau.

288. *See* M. STRICKBERGER, *supra* note 116, at 570.

289. *See* Behringer, *supra* note 79, at 137.

290. "The important and laudable achievement in insulin copying supports the positive expectations of scientists to the potential benefit of millions of persons now living and yet to be born." Kiley, *supra* note 89, at 224.

over the effectiveness of infringement control has, however, posed a threat to international patent systems.[291] Recent restrictions imposed by members of the Budapest Treaty[292] contravene the objectives established during the origins of patent law.

The origins of patent law demonstrate a major objective for devising a patent system—to encourage the dissemination of novel ideas.[293] In order to be considered patentable, an invention must fulfill several requirements.[294] A majority of industrialized countries maintain that certain living organisms can fulfill the requirements of utility, novelty, nonobviousness and enablement.[295] Additionally, protection of the microorganisms through patents is favored internationally.[296]

The patenting of microorganisms entails unique procedures. Generally, inventors should use the best mode for disclosing inventions to assure an effective patent system.[297] The best mode for disclosing microorganism is the deposit of a viable sample.[298] Individuals wishing to utilize the invention could reproduce it by cultivating the microorganism under the appropriate conditions enumerated in the patent application.[299] This procedure is clearly more practical than an application consisting of only written descriptions.[300]

The Budapest Treaty demonstrates the numerous problems inherent in the depositing of microorganisms.[301] The Treaty has eliminated much of the cost and confusion in the international patenting of microorganisms.[302] However, the Treaty contains several shortcomings. For example, each member nation determines which individuals may gain access to the samples in the depositaries located within its boundaries. This rule has permitted Germany to restrict total importation and exportation of its samples.[303]

Germany has valid arguments to support these restrictions.

291. *See supra* notes 238-69 and accompanying text.
292. *Id.*
293. *See supra* notes 18-29 and accompanying text.
294. *See supra* notes 30-41 and accompanying text.
295. *See supra* notes 31-37 and accompanying text.
296. *See supra* note 56 and accompanying text.
297. *See supra* note 90 and accompanying text.
298. *See supra* note 91 and accompanying text.
299. *See supra* notes 32-33 and accompanying text.
300. *Id.*
301. *See supra* text accompanying notes 270-287.
302. *See supra* text accompanying notes 130-145.
303. *See supra* text accompanying notes 238-243.

International availability of these samples makes infringement more probable.[304] Furthermore, Germany is concerned that infringement is a significant threat to international safety.[305] Moreover, Germany could cite the Paris Conventions' rules, allowing Third World nations to restrict importation of technology, as international legal precedent for its actions.[306]

The limitations imposed by Germany and Third World nations will deter international publication of novel information. Therefore, the Treaty must be amended in order to discourage Germany and other nations concerned from passing restrictive laws.

The Budapest Treaty has been successful in many areas. This agreement has encouraged cooperation between contracting nations to provide uniform patent laws. A uniform system is necessary to make international distribution of information commonplace. Changes are necessary, however, so that the Treaty is not rendered moot through the passage of restrictive laws by contracting States. The problem is immediate, and the World Intellectual Property Organization should call for a meaningful meeting to resolve the numerous conflicts which presently exist.

Steven D. Schroeder

304. *Id.*
305. *Id.*
306. *See supra* text accompanying notes 220-237.