LEGISLATION FOR THE PATENTING OF LIVING ORGANISMS: SPECIFICITY, PUBLIC SAFETY AND ETHICAL CONSIDERATIONS

INTRODUCTION

Perhaps when the first patent act was passed in 1790,[1] its authors foresaw that difficulties would arise in the interpretation and application of the law. Certainly they expected it to be applied to unforeseen inventions: encouragement for such progress was the explicit constitutional mandate which gave Congress the authority to grant patent protection.[2] However, since all of the twists and turns that "Science and the useful Arts"[3] can take are unforeseeable, laws made to govern the introduction of new technologies into society cannot be left static or allowed to bind man and his government to rules that become arcane due to those twists and turns. The present patent laws apply to "any machine, manufacture, or composition of matter."[4] Today, our patent system is left with the unacceptable choice of either applying such laws to the unforeseen products of the modification of life itself or denying patent protection to an important and developing industry. This note will discuss problems and solutions that Congress should consider in order to adapt the patent laws to the living products of bio-technology.[5]

BACKGROUND TO THE PROBLEM

Bio-technology is the scientific field which uses living organisms and their components as tools or products in research and development. It applies to the manipulation of both natural and man made, or man modified, substances. Manipulation of biological organisms is not new.[6] It has, for centuries, been used for the selective breeding of animals and plants into improved stock and has led to the development of "miracle" hybrid plants and "prized" livestock which help to feed an overpopulated world. All of these developments have occurred solely from the use of nature's own reproductive processes, with man only supplying the additional element of guidance. It was not until the early

1. *See* In re Bergy, 596 F.2d 952,959 (C.C.P.A. 1979) [hereinafter cited as Bergy].
2. "[The Congress shall have the Power] to promote the Progress of Science and the useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ." U.S. Const. art. I, § 8, cl. 8.
3. *Id.*
4. "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1976).
5. The author would particularly like to thank Dr. Gerald H. Bjorge, Deputy Commissioner of Patent and Trademarks, for his helpful conversations of July 30 and 31, 1979 which contributed to the direction and scope of this note, and also Dr. Chandler Fulton, Professor of Biology, Brandeis University, for his input on the academic community's concern about these issues as well as his clarification of much of the technical aspects involved. A note of special thanks goes to Dr. Alan Barr, Post Doctoral Research Associate of the Department of Mathematics, California Institute of Technology; Mr. Martin Edelman and Mr. David Parchem.
6. In the middle of the 1800's, an Austrian monk, Gregor Mendel, laid the foundations for modern genetics through his studies with plants. The first understandings of heredity, the passing of traits from parents to child, grew out of his work. J. A. Mazzeo, *The Design of Life*, at 137-150 (1967) [hereinafter cited as Mazzeo].

1950's that science discovered the chemicals which enable living cells to reproduce and to pass on traits to their offspring, and thereby opened the door to genetic engineering.[7]

All living creatures contain within their cells strings of a chemical called deoxyribose nucleic acid (DNA).[8] This DNA is made up of smaller units of other chemicals in much the same way that a toy wall may be composed of a child's building blocks. Certain sub-sections of these strings constitute self-contained entities called "genes" and, somehow, the DNA within those genes acts as an instruction set. These instructions govern which chemicals the cell synthesises, the way in which the cell reacts to stimuli, and the circumstances under which it will grow, reproduce, or metamorphosise. By adding, deleting, or recombining the DNA of living cells, the characteristics of those cells and the higher level organisms which they constitute can be manipulated. It is this changing of the genetic structure of living things that is known as genetic engineering, of which "recombinant DNA" techniques are a primary tool.

In 1972, Dr. Ananda M. Chakrabarty, a Staff Microbiologist of General Electric Research and Development Center,[9] filed for a patent on a new organism he had created which could eat oil spills. Eight years later, after several Patent and Trademark Office hearings and appellate court decisions,[10] the question as to whether he or anyone else can be given a patent on a non-plant living organism is still unanswered and has, for the second time, been granted certiorari by the Supreme Court of the United States.[11] In the meantime, corporations and research laboratories have been investing millions of dollars into work that will produce a plethora of "genetically engineered" organisms and which will change the face of industrial technology as well as man's view of his existence.

RATIONALE FOR PATENTING THE LIVING PRODUCTS OF BIO-TECHNOLOGY

The primary goals of patent laws are to encourage advancement of the sciences and useful arts and to open the development of such fields to the public's view.[12] It is highly desirable to pursue both goals for the living products of bio-technology.

Encouragement of individuals and corporations to develop this field will result not only in individual economic benefits but also social gains in environment and health. The genetic modification of farm crops to increase their productivity

7. J. D. Watson and F. H. C. Crick, using X-ray diffraction techniques, worked out the structure of the deoxyribose nucleic acid (DNA) molecule. *Id.*, at 202-203.
8. *Id.*
9. Bergy *supra* note 1, at 968n.8.
10. Bergy *supra, on remand from* Parker v. Bergy, 483 U.S. 932 (1978) *Mem. vacating,* In re Bergy, 563 F.2d 1031 (C.C.P.A. 1977); In re Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978), *vacated and merged with,* Bergy *supra.*
11. Diamond v. Bergy, *sub nom.,* Parker v. Bergy, 596 F.2d 952 (C.C.P.A. 1979), *cert. granted,* No. 79-136 (U.S. Oct. 29, 1979).
12. Sinclair Co. v. Interchemical Corp., 325 U.S. 327, 330-331 (1945) [hereinafter cited as Sinclair].

in terms of yield, caloric, and nutritional content, as well as the development of grains having special nitrogen-fixing capabilities are cited as possibilities that can be realized in the near future.[13] Several other examples of recent work in this area also serve to illustrate this point:

1. Correction of Cell Defects.

In research done by Rockerfeller University and the National Institutes of Health, individual cells were removed from mice. These cells had been defective since they were unable to produce an important chemical necessary for the survival of the mice due to an error in the DNA structure of the particular gene which contained the instruction. The cells were injected with genes that contained the correct instruction and, successfully, the defective cells began producing the needed chemical.[14] Many human diseases such as hemophilia, sickle cell anemia, and diabetes, are similiarly caused by the inability of human cells to produce certain substances; this research holds the possibility for their eventual cure.[15]

2. Oil Eating Bacteria.

During the early 1970's, General Electric's research laboratories, by transferring genes between bacteria, created a new microorganism capable of "eating" multiple components of crude oil. By spreading the new bacteria onto an oil spill, the entire spill was consumed and turned into food for fish. Before this breakthrough, many different bacteria had to be employed to devour the different oil components of a spill and often these bacteria were not able to co-exist with each other, leaving some part of the spill uneaten. General Electric's discovery can result in the safe elimination of the entire oil spill without resort to dangerous detergents and expensive beach recovery operations.[16]

3. Fuel from Rubbish

The United States Department of Energy is presently scheduled to spend almost two million dollars on as many as twenty research projects aimed at converting wastes to sugar by processes using microorganisms. The sugar will then be converted into alcohol to be used as a fuel[17] via manufactured enzymes.[18]

13. R. Beers & E. Bassett (ed.), *Recombinant Molecules: Impact on Science and Society*, at 1-2 (1977) [hereinafter cited as Beers].
14. N.Y. Times, Sept. 21, 1979, at 26, col. 1.
15. Eventually, the actual cure of individuals strickened with such diseases may be possible by the transformation of the genes of body cells *in vitro* or *in vivo* through the use of virus vectors. Beers *supra* note 13, at 1-2. In the interim, products such as human insulin, human growth hormone, and the natural anti-virus substance, human interferon, which have already been produced via recombinant DNA techniques, hold promise to be grown by bacteria in unlimited supplies. Such drugs should no longer be scarce and expensive for those who need them. N.Y. Times, Jan. 27, 1980, at 1, col. 1.
16. Bergy *supra* note 1, at 968-971.
17. "Where Genetic Engineering Will Change Industry," Business Week, at 160,172 (Oct. 22, 1979).
18. N. Y. Times *supra* note 15, at 31, col. 2.

Thus, bio-technology holds the potential to alleviate many of the ills that plague our society.[19] It is not then surprising that new corporations, including Cetus, Biogen, Genex, and Genetech have already formed with the purpose of doing research and development in this field. Older established corporations are investing heavily into these newer businesses: Koppers Co. has invested two million dollars in Genex; Lubrizal has made a ten million dollar commitment to Genetech; and Socal, together with Indiana Standard and the National & Chemical Corp. have provided thirty million of Cetus' thirty five million capitalization.[20] To date, the field has attracted about 150 million dollars in venture capital.[21] Already some benefits of this research and development have been realized (such as Chakrabarty's oil eating bacterium).

Without patent protection for undertaking expensive investments and time consuming research, the incentive to continue this research and development and to market the results will be greatly reduced. As had been true with plant breeding and research prior to the passage of the first Plant Patent Act,[22] genetic engineering is presently dependent largely upon Government funds or the limited endeavors of private researchers.[23] By placing bio-technology upon the same basis of economic equality which the rest of the industry enjoys, it will not be discriminated against in the allocation of industrial resources and funds. Additionally, since many foreign countries already provide patents for new microorganisms,[24] the continued absence of such protection in the United States will encourage bio-industries to develop overseas, where they can recover profits from their efforts.[25]

The second goal of the patent laws concerns the public disclosure of new inventions and discoveries. Normally, this simply insures that other researchers will have speedy access to the most recent developments in a field, thus assuring its further rapid advancement. By negating any possibility of keeping a patented item a trade secret, patent laws encourage the marketing and licensing of these new advances, thus bringing their benefits to the public.[26]

19. As a caveat to what genetic engineering, or any technology, can and cannot do, the following portion of a paper delivered at the Tenth Miles International Symposium on Recombinant Molecules is worth giving thought to:

"At first the argicultural applications seem not merely acceptable, but exciting and wonderful. But let us take a step back in time and look at the 'Green Revolution', which involved introducing a new genetic variety of rice to under-developed countries. Because this new rice required special fertilizer and a different growing season, and had stalks which were unsuitable for use as fodder or thatch, the rich farmer got richer and the poor got poorer. Changing a crop may affect the economy and the ecological environment, but it cannot change the political conditions. Any increase in welfare becomes illusory. Although there are people in the United States who go hungry, it is not because we do not know how to grow enough food. No matter how much food is produced, it will not keep people from starving until it is distributed to the people who need it." F. R. Warshaw, "Gene Implantation: Proceed with Caution," Beers *supra* note 13, at 508.

R. F. Beer's own introduction to this collection of papers makes the point more succintly, "[A]ny technology, including genetic engineering, designed to increase the productivity of the earth can do no more than buy the time necessary for man to discover and design the proper solution of institutional and behavoiral reform to obliterate the underlying cause, namely, unlimited growth." Beers *supra* note 13, at 5.

20. "Where Genetic Engineering Will Change Industry" *supra* note 17, at 160.
21. N.Y. Times *supra* note 15, at 1, col. 2.
22. Plant Patent Act of 1930, ch. 312, 46 Stat. 376; *See* S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930) *and* H. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930).
23. On the National Institutes of Health list of 191 research centers that have set up institutional biosafety committees in accordance with Recombinant DNA Research Guidelines, only about one dozen appear to be commercial. N.Y. Times *supra* note 15, at 31, col. 6.
24. For example, Great Britain has granted Chakrabarty's bacterium a patent. *See* Bergy *supra* note 1, at 969n.9.
25. "Where Genetic Engineering Will Change Industry" *supra* note 17.
26. 325 U. S. at 331.

However, when dealing with bio-technology, the disclosure aspect of the patent laws offers a second important benefit. The controversy surrounding "recombinant DNA" research has been great; so too has been the fear: fear both as to its safety, and to the ethical dilemmas which manipulation of human genetics will pose. There is no better way to monitor the developments, directions and expectations of a technological field than by disclosure of the state of its art. Such disclosure will provide government and society the maximum lead time possible to effectively deal with those safety and moral problems which do appear.

Not only economic incentive, but sound public safety and ethical considerations argue that the living products of bio-technology be granted the protection of the United States patent laws.

A LEGISLATIVE APPROACH TO THE PROBLEM

Whether or not, on the current appeal of the patentability issue before the Supreme Court,[27] it is decided that the present patent laws already include non-plant living organisms as patentable subject matter, pressure for legislation in this area will continue to grow. Although patent protection for living organisms is highly desirable, an analysis of the present patent law together with an examination of bio-technology reveals four key areas that may result in problems:

Lack of Specificity. Living organisms are difficult to describe with specificity. Therefore, difficulties will be encountered in defining patent property and in determining when an infringement has taken place.

Public Safety. Extending patent protection to microorganisms will have the effect of encouraging research and development in the area of recombinant DNA. This raises concern of an accidental escape of a novel but dangerous microorganism.

Public Policy on Ethical Questions. Unlike prior subjects of the patent laws, the material of genetic engineering inherently concerns itself with the essence of man himself.

The Inappropriateness of Judicial Solutions. In view of the number and nature of the policies that will have to be developed to accommodate this particular field, the courts are an inappropriate forum for this to be done.

A discussion of each of these problem areas is set forth below.

Specificity Requirements for Living Organisms

The patent law requires that the applicant file a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms, as to enable any person skilled in the art" to make and use the patented item.[28] Because of the difficulty of properly describing a plant, Congress has, however, to a certain extent waived this requirement in the plant patent acts.[29] Such a description need only be as complete as reasonably possible.[30] The making of a proper description for any other living organism is no less difficult than doing so for a plant; a similar provision should be added to the patent laws to provide for all living organisms.

27. Diamond v. Bergy *supra* note 11.
28. 35 U.S.C. § 112 (1976).
29. Kim Bros. v. Hagler, 120 U.S.P.Q. 210,211 (S.D.Cal.,N.D. 1958).
30. 35 U.S.C. § 162 (1976).

There is a conflicting problem which also needs to be addressed to insure order in this area of the patent field. As already pointed out by the Patent and Trademark Office (PTO), "[T]he nature of living things – especially microorganisms – creates a substantial risk that a patent monopoly will exceed its lawful limits. The difficulty of describing and understanding microorganisms creates serious problems in determining whether competitive developments are lawful or infringing."[31]

This problem has already been faced, to some extent at least, with respect to plant patents. Normally, the three requirements for patentability are novelty, utility and nonobviousness. For plant patents, however, the requirement of distinctiveness replaces that of utility.[32] In order for a new variety of plant to be distinctive, it must have characteristics "clearly distinguishable from those of existing varieties."[33] Since characteristics of living organisms tend to blend into each other much as in a continuum, such a distinctiveness requirement is more helpful in defining such patent property than the novelty one alone. For non-plant living organisms, this distinctiveness requirement should be added to the other three, the utility requirement being retained.[34]

Describing characteristics of microorganisms which are "clearly distinguishable" will continue to prove difficult. Instead of gross characteristics such as "red flowers" or "circular seeds" as in the case of plants, elements such as "plasmids" or "ribosomes" will have to be cited. These are parts of a cell that are much too small to be seen except by use of the most powerful microscopes, and even then they may not look different from each other while being very much different. The alternative of describing the distinguishing features in terms of their chemical structures will for a long time remain impractical due to the immense complexity of those structures. Therefore there will be a great temptation to describe new microorganisms in terms of what they do instead of what they are. Because the same processes can be accomplished by vastly different mechanisms, the danger will exist of over-extending a patent holder's rightful monopoly.

A patent claim[35] defines patent property by setting forth the "metes and bounds of the boundaries surrounding the discovery,"[36] and it "apprise[s] the public of what is still left open to them" for further development.[37] For these reasons, the elements of a claim must be set out in substantive terms and not functional ones; they must specify what the patent *is,* not what it *does*. Otherwise, a patent monopoly might be extended beyond the discovery or invention, and would discourage rather than promote invention.[38] Although use of functional

31. Parker v. Bergy, Petition for a Writ of Certiorari to the United States Court of Customs and Patent Appeals, at 9n.12, No. 79-136 (U.S. July 27, 1979).
32. Yoder Bros., Inc. v. California Florida Plant Corp., 537 F.2d 1347,1377 (5th Cir. 1976), *cert. denied,* 429 U.S. 1094 (1977).
33. S.Rep. 315, 71st Cong., 2d Sess. (1930).
34. Often the utility of new plants will not be known until they have been tested in field conditions for a full planting season or more. This is necessary to determine their resistance to deseases and insects, and their adaptability to various weather conditions. Non-plant living organisms will predominantly be used in industrial or similarly sheltered environments.
35. A specification in a patent application describes the new item in its full detail: what it is, how it works, and what its best mode of use is. This can become a very lengthly document. A claim is usually a brief statement which sets out the elements which define the property upon which a patent is being sought. It can and often does refer to the description in the specification.
36. 3 *Deller's Walker on Patents* 40 (1964).
37. 5 *Deller's Walker on Patents* 133 (1972).
38. Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928).

language in a claim may be permitted where it is construed to cover the corresponding structure described in the specification,[39] if the specification itself is unable to properly describe what the invention is, the problem still remains.[40]

With plants, the applicant can be required to furnish specimens for inspection or experiment.[41] However, with non-plant living organisms, such specimens would have to be kept alive and contained. It would seem impractical to do both for the large numbers of organisms that can be expected to be submitted for patents and for the seventeen years that patent monopolies last. Therefore, simple comparisons between allegedly infringing and infringed organisms does not appear to provide the solution.

Since describing what patented property *is* may be so difficult, additional emphasis should be placed on describing what it is *not*. The use of "negative limitations," as they are called,[42] ought to be changed from a permitted and alternate element of a patent specification to a required one when the specification is of a non-plant living organism. Only when the patent examiner is satisfied that the combination of positive and negative descriptions which the applicant has used reasonably insures that his monopoly will not be over-extended should the patent be issued. The standard used to determine such "reasonable insurance," as well as a compilation of suggested negative limitations that can be expected to be useful in attaining that standard, should be developed by the PTO. Such a standard could be updated as the PTO gains experience in handling this field, and also as the field changes.

Public Safety: Recombinant DNA Research

The granting of patent protection to living organisms will have the effect of encouraging research, development, and commercialization of recombinant DNA products. Since recombining DNA involves the transfer of genetic material from one microorganism to another, and hence the transfer of characteristics from one microorganism to another, there exists the possibility for the creation of a novel and dangerous organism. Such would be the case if the ability to produce toxins or to infect humans were transfered to an organism which could resist the human immunization system. An accidental leak from a laboratory could conceivably result in the release of a new disease.[43]

Although no harm has resulted from recombinant DNA research to date, there still remains widespread uncertainty as to the degree of risk involved.[44] The interests identified are the need to protect laboratory workers,

39. 35 U.S.C. § 112 (1976); In re Swinehart, 169 U.S.P.Q. 226 (C.C.P.A. 1971).
40. Such a problem may exist with respect to the Chakrabarty patent claim that is currently on appeal to the Supreme Court. Should it be granted in its present form, the claim will read, "A bacterium from the *Psuedomas* containing therein at least two stable energy-generating plasmids [gene packages], each of said plasmids providing a separate hydrocarbon degradative pathway [method of digesting hydrocarbons, or oil]."
    As worded, the claim may over extend the rightful patent property. Should somebody invent an artificial plasmid, enabling a bacterium of the genus *Psuedomas* to eat a component of oil not previously possible, the new bacterium would fall under Chakrabarty's patent claim as worded. It shouldn't. Furthermore, should somebody create a distinctively superior bacterium of the genus *Pseudomas* than has Chakrabarty, (i.e. by transplanting several plasmids into it each of which would enable the bacterium to eat detergents and insecticides as well as oil) then such an organism would also fall under Chakrabarty's claim as written. Again, it shouldn't. *See,* 7 Deller's Walker on Patents 319-324 (1972).
41. 35 U.S.C. § 114 (1976).
42. 5 *Deller's Walker on Patents* 212 (1972).
43. S. Lederberg, "The Least Hazardous Course: Recombinant DNA Technology as an Option for Human Genetic, Viral, and Cancer Therapy," Beers *supra* note 13, at 485-494.
44. N.Y. Times *supra* note 15, at 31, col. 1.

the public, and the environment, as well as a public concern for the ethical questions raised by the artificial manipulation of genetics in higher animals.[45] In response to these interests, the National Institutes of Health (NIH) released in 1976,[46] and amended in 1978[47] and 1980,[48] guidelines for conducting recombinant DNA research. Fundamentally, they focus on two remedies: the containment of any potential dangerous organism and the public disclosure of research being done. These guidelines provide that:

a. certain experiments are prohibited;[49]
b. deliberate release into the environment of any organism containing recombinant DNA is forbidden;
c. permitted experiments must be conducted with procedures and equipment intended to prevent the escape of recombinant material;
d. researchers must use biologically weakened organisms unlikely to survive in a non-laboratory environment;
e. institutions must inform the NIH of all recombinant DNA projects being performed there;
f. important records of local Institutional Biosafety Committees must be made available to the public and twenty percent of the committee members must represent the general public and have no connection to the local institute.

These guidelines are, however, binding only upon institutions which are accepting government funds. There are other statutory authorities which presently can be used to require private laboratories to comply with the guidelines[50] but, even so, a recent report from the Congressional Research Service has pointed out that, "comprehensive regulation of the products resulting from recombinant DNA research techniques does not appear feasible under current laws."[51] Such regulation would be piecemeal and divided among several federal agencies, each agency limited to regulating only those products, used only for those purposes, which fall under its mandate.

For such reasons, the Carter administration sent draft legislation to Congress in early 1977 which would comprehensively make the NIH guidelines applicable to private institutions.[52] Bills have been introduced into both the House of

45. Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science and Transportation, 95th Cong., 2d Sess., Oversight Report on Recombinant DNA Research and Its Applications, at 2,20-21 (1978) [hereinafter cited as Overight Report], U.S. Dept. of Health, Education and Welfare, 3 Recombinant DNA Research, B-253 [hereinafter cited as Research].
46. 41 Fed.Reg. 27901 (1976).
47. 43 Fed.Reg. 60107 (1978).
48. 45 Fed.Reg. 6724 (1980). It should be noted that each of these amendments have loosened the restrictions on recombinant DNA research. It is conceivable that eventually such regulations may be entirely done away with. Until and unless that happens, it must be assumed that there exists a legitimate risk to be guarded against, and Congress should be given the opportunity to couple patentability of recombinant DNA material with sufficient safeguards to protect against this risk.
49. Examples are the introduction of antibiotic resistant traits to pathological organisms and the formation of recombinant molecules containing genes for the production of dangerous toxins. Oversight Report *supra* note 45, at 13; 3 Research *supra* note 45, at B-273.
50. Toxic Substances Control Act, 15 U.S.C. §§ 2601 *et seq.* (1976); Marine Protection, Research and Sanctuaries Act, 33 U.S.C. §§ 1401 *et seq.* (1976); Solid Waste Disposal Act, 42 U.S.C. §§ 3251 *et seq.* (1976); Federal Walter Pollution Control Act, 33 U.S.C. §§ 1251 *et seq.* (1976); Federal Hazardous Substances Act, 15 U.S.C. §§ 1261 *et seq.* (1976); Hazardous Materials Transportation Control Act. 18 U.S.C. §§ 834 *et seq.* (1976); Occupational Safety and Health Act, 29 U.S.C. §§ 831 *et seq.* (1976); Public Health Service Act, 42 U.S.C. §§ 201 *et seq.* (1976); Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (1976); Consumer Product Safety Act, 15 U.S.C. §§ 2051 *et seq.* (1976).
51. American Law Division, The Library of Congress, Congressional Research Service, Regulation Under Current Law of the Products of Recombinant DNA Research, Oversight Report *supra* note 45, at 99; 3 Research, *supra* note 45, at 359.
52. Oversight Report *supra* note 45, at 3; 3 Research *supra* note 45, at 263.

Representatives[53] and the Senate[54] proposing the same, and Senator Adlai Stevenson is currently drafting a bill to regulate industry's involvement in genetic manipulation.[55]

In view of the enforcement concern, it is preferable that Congress explicitly couple the grant of patentability for living organisms with the adoption of regulations for recombinant DNA work applicable to both public and private institutions. Furthermore, the patent laws themselves should be used to encourage private compliance with such federal regulations.

To obtain a patent, the applicant should be made to demonstrate that he has complied with the appropriate federal guidelines during his research. The item for which a patent is being sought should not be one which the research upon or the marketing of is prohibited for a health, safety, or ethical reason. Once a patent has been issued, provisions should be made for its revocation if use of the product by the patent holder or his licensees violates the regulations governing the commercial use of recombinant DNA products.[56]

There is an additional advantage to enlisting the aid of the patent laws in encouraging compliance with federal regulations. Many of the NIH guidelines possess a scope of concern which is global in nature (such as the release of a new disease). The patent laws also provide a way to coax foreign institutions into following these guidelines, since they would otherwise risk losing the monopolies in the American market on their inventions and hence the financial benefits, to their competitors. Since many foreign laboratories are already complying with guidelines similiar, if not identical, to those of the NIH (such as those promulgated by the United Kingdom),[57] a provision should be added to allow foreign patent applicants to comply with such similiar guidelines in order to satisfy federal requirements.

Ethical Considerations and Public Policy

Once past the mechanical questions of how living organisms are to be patented and what safety regulations are to be coupled with that patenting, there arises an even more difficult question. The capacity to manipulate the genetics of single cells will lead eventually to the ability to manipulate the genetics of higher animals, including man. On one end of the scale, the patentability of a new oil eating bacterium hardly seems ethically troublesome. At the other end, no one could be permitted to patent a "new" man. Somewhere, the line must be drawn.

The manipulation, control, sale, etc. of many animals are condoned in our society and are protected by state and federal statutes.[58] Given this, there seems to be no *a priori* reason to deny patent protection to the inventor of a new chicken, whether the improvement be the result of genetic engineering

53. H.R. 11192, 95th Cong., 2d Sess. (1978); 3 Research *supra* note 45, at B-1.
54. S. 1217, 95th Cong., 2d Sess. (1978), Research *supra* note 45, at B-123.
55. "Where Genetic Engineering Will Change Industry" *supra* note 17, at 164.
56. If in the future the risk of severe harm form such products does become sufficiently serious, then sanctions for the misuse of patented property might be considered. Although never before so used, the authority for such sanctions might arise under the Patent Clause coupled with the Necessary and Proper Clause of the Constitution. However, unless absolutely necessary, the exercise of such power is to be avoided. The use of sanctions would have a discouraging effect on the patenting of these materials, and it would set bad precedent for the patent property field generally.
57. Interagency Committee on Recombinant DNA Research, Minutes of Meeting, March 29, 1977, at 2-3, 2 Research *supra* note 45, at 353-4.
58. Witness pet licenses, as well as the laws governing the growing, selling, breeding, etc., of farm, pet, and sport animals.

or of old fashioned selective breeding.[59] Farmers who grow and sell the new chicken will reap financial rewards for their efforts. The inventor, also, should prosper as a result of his work.

However, there is a special biological place in nature that man occupies and no development which blurs this distinction, intentional or otherwise, should be encouraged by the government. To crystallize the problem, the following hypothetical may be considered. A genetic engineer "manufactures" a new chimpanzee, equipping it with both vocal cords and an intelligence quotient of about one hundred. The chimpanzee can talk, read, write, reason and, more importantly, it possesses a heightened sense of awareness of its own existence. Considering the serious moral, religious, and legal questions the production of such an animal would raise, it is suggested that these creations are not to be commercially encouraged. Hence, the patent laws should not be so extended.

A question remains of how it is to be decided whether a new animal is to be treated similiar to the "new" chicken (and hence be patentable subject matter) or instead as the above intelligent chimpanzee (and hence be non-patentable). Certain traits could be identified as warning markers for unpatentability. They could be obtained by referring to the most obvious standard of unpatentability available: man. The following are offered as examples of biological characteristics that identify man's humanness: intelligence, the ability to communicate (including but not limited to the capacity for speech), the ability to interact in a social environment, dexterity, visible features (both cosmetic and functional) which make a human look like a human, and the capacity to evoke an emotional response from a human.

The guideline proposed is the following: any animal that is genetically manipulated in such a way that one of these identifying traits is increased or made more discernible shall not be held patentable subject matter. As a matter of public policy, any such increase or discernibility, whether it be intentional or incidental, should trigger the ethical exception clause. The burden of proving that the clause has not been violated should be placed upon the applicant, and the clause may be used in patent prosecutions as an affirmative defense to an infringement charge.[60]

59. The U.S. Court of Customs and Patent Appeals has already been asked to decide this question. In re Merat, 519 F.2d 1390 (C.C.P.A. 1975). It declined to reach the question, instead basing its refusal of the sought for patent upon the failure of the applicant to sufficiently specify what was new and improved in his claimed chicken.

60. Some discussion of the patentability of genes and unicellular organisms is appropriate. Genes are composed of DNA. That is, they are strings of highly complex chemicals. They simply serve a particular purpose in an organisms and no more, much as any other chemical in a living thing does. For example, adrenalin is a complex protein molecule that serves a very important role in the function of a human being. It, in an isolated form, has already been granted a patent. Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912). So has vitamin B-1. Merck & Co. v. Chase Chemical Co., 273 F. Supp. 68, 155 U.S.P.Q. 139 (D.N.J. 1967); Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 116 U.S.P.Q. 484 (4th Cir. 1958). The same logic which applies to these chemicals should apply to the patentability of genes: if someone puts effort into inventing or isolating a new and useful chemical, there is no ethical reason why this effort should not be rewarded and encouraged merely because the chemical is part of the life process.

The first class of living organisms that merit discussion are single cell microorganisms. These uni-cellular creatures are, however, more akin to "machines" or "chemical factories" than to what most people consider as life. Plants are organisms which are several rungs of the ladder higher on the scale of life than are microorganisms, and plants have been granted some form of explicit patent protection since 1930 without any ethical concern expressed. Absent any real ethical counter-rationale, all new and useful uni-cellular organisms should be made patentable subject matter, subject to the restrictions on public safety.

Since the use of new inventions for research purposes is generally not subject to patent monopoly rights, researchers should not be hindered in their studies by the patenting of the above materials.

The Need for Legislative rather than Judicial Solutions

Comprehensive public policies are going to have to be developed for the patenting of living organisms. Courts are not suitable places for drawing fine lines in highly technical issues and, furthermore, an adversary judicial context is not the best environment for producing long range public policy. These propositions have been recognized by the courts themselves in reviewing federal agencies in such areas as environmental regulations. The criteria used by reviewing courts in such cases has not been whether or not the agency below made the "correct" decision, but rather whether or not there existed a rational basis for the agency's decision.[61] Most courts in any type of hammering out of patent law for living organisms will be left bereft of the PTO's expertise.[62] They will essentially be left alone to make policy on patent infringements, public safety and morality, while being relatively poorly equipped to make such decisions.

Furthermore, a case by case determination of the law will, in the interim, leave both the PTO and future patent applicants in considerable doubt as to the validity of a specific application. This will have an inhibiting effect on industry which will be magnified since the development of genetic engineering will be moving quickly. Multi-year litigation efforts will not keep up with the field and a case by case handling of outdated questions will do little to promote or regulate it.

Finally, there exists the ultimate question about the patent law to be created: from where shall it be drawn? Since the intent behind the patent law supposedly is that of the Congress,[63] this "congressional intent" will still be the criterion sought for, and will remain elusive in this hitherto-unforeseen field until the Congress itself does decide to speak.

The entire field of bio-technology is highly technical and rapidly advancing. It possesses great promises in health, economic and environmental areas, possesses even greater potential for moral dilemmas, and will have a tremendous impact on our culture. It is the legislature which is the best equipped branch of the government to compile empirical data on all of these areas, to seek advice on the moral issues and cultural impacts and to put this together in a comprehensive public policy.

CONCLUSION

Living organisms should be made patentable subject matter. There are definite advantages to be derived from such action for the researcher, the industry, and the public as well. However, to accommodate the unique problems posed by this unforeseen field, legislation should be enacted specifically to meet the needs and problems of bio-technology.

61. Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976) (en banc), *cert. denied*, 426 U.S. 941 (1977).
62. Patent validity may be challenged in a patent infringement suit in a district court. *See* 35 U.S.C. § 281 *et seq.* (1976), 28 U.S.C. § 1388 (1976). Thus, the questions of patent policy will be faced by other courts than the United States Court of Custom and Patent Appeals and in other ways than by direct appeal from the PTO.
63. *Cf.* Parker v. Flook, 437 U.S. 584 (1978).

The patent specificity requirements as they relate to non-plant living organisms should be changed to more closely resemble those requirements for plants. Standards providing "reasonable insurance" against the possibility of the over extension of patent property should be adopted and should be implemented by the requirement that sufficient limitations be placed in claims as to make clear what the patent does not encompass. These standards should be developed by the PTO and should remain flexible to accomodate the experience gained from their use as well as further advances in the field.

Any move to patent living organisms to encourage commercialized recombinant DNA research and products should be explicitly coupled with legislation establishing safety regulations governing private work in this field. The patent laws should be used to encourage compliance with the regulations by requiring proof of such compliance as an element of a patent application.

With regards to higher animals, an ethical exception should be carved out in order to discourage any blurring of the biological distinction between man and his fellow living creatures. Such an exception should be based on those traits which can be identified as defining what society considers to be "human-ness."

Throughout history, scientific advances have forced changes in society and its institutions. As often as not, these alterations have been disruptive; this has been true not so much from necessity, but because of the failure of society to forsee what would be asked of it and to prepare itself accordingly.

Today science will once again force changes in the way society governs itself. These changes, however, will encompass the way life itself is manipulated and viewed. Rather then merely reacting, society through its government should anticipate what will be required, and then should act in advance to accomodate, without disruption, bio-technology and all its implications.

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