Biotechnology and Animal Patents: When Someone Builds a Better Mouse

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BIOTECHNOLOGY AND ANIMAL PATENTS: WHEN SOMEONE BUILDS A BETTER MOUSE

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INTRODUCTION

Biotechnology is a relatively new area of science. A biotechnologist seeks to develop custom made living organisms by manipulating genetic material.[1] Biotechnology has produced a new generation of vaccines that can protect humans and animals against a broader range of diseases than was previously possible.[2] It is responsible for the creation of disease- and insect-resistant plants,[3] as well as the discovery of monoclonal antibodies[4] which are used to diagnose, differentiate, and prevent human disease.[5] Moreover, biotechnology has increased supplies of insulin,[6] growth hormone,[7] viral antigens,[8] and interferon.[9]

Despite these discoveries, however, the expanding scope of biotechnology has caused increased public concern. Intrinsic to the technology is the ability to alter the genetic material of plants and animals.[10] Scientists can now create new organisms. Furthermore, the many private companies specializing in this

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1. *See* Smith, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1085-86 (1988).

2. *See generally* Medley, *Issues in Assessing the Environmental Impact of Veterinary Biologics Produced Through Biotechnology*, 43 FOOD DRUG COSM. L.J. 821, 821 (1988) ("These vaccines are markedly different from the conventional . . . [live] . . . vaccines . . . [which] . . . can produce allergic reactions and . . . the actual disease they are intended to prevent.").

3. *Id.*

4. Antibodies are the basis of the human immune system. Scientists use monoclonal antibodies to diagnose diseases such as AIDS, to identify and treat cancerous tumors, to help the success of bone marrow transplants, and to reverse the body's rejection of kidney transplants. Marciniszyn, *What Has Happened Since* Chakrabarty, 2 J. LAW & HEALTH 141, 152 (1987-1988); TABER'S CYCLOPEDIC MEDICAL DICTIONARY 103, 783, 1063 (C. Thomas 15th ed. 1985) [hereinafter TABER'S].

5. Medley, *supra* note 2, at 822.

6. Insulin is a hormone that regulates glucose (blood sugar) metabolism and is secreted by the pancreas. It is commonly used to control diabetes. *Id.* at 855-56.

7. Growth hormone is normally secreted by the anterior pituitary. The hormone stimulates growth and is often used to treat dwarfism. *Id.* at 710.

8. Antigens induce formation of antibodies in the blood. *Id.* at 104.

9. Interferon protects cells from viral infection. *Id.* at 859. *See generally* Zepfel, *Stopping a "Gruesome Parade of Horribles": Criminal Sanctions to Deter Corporate Misuse of Recombinant DNA Technology*, 59 S. CAL. L. REV. 641, 642 n.10 (1986) ("Interferon, produced naturally by virus-infected cells, inhibits virus multiplication.").

10. The term "animal" encompasses any living organism "that requires oxygen and organic foods, is incapable of photosynthesis, has limited growth, and is capable of voluntary movement and sensation." This definition includes bacteria. TABER'S, *supra* note 4, at 95.

technology can patent their creations under *Diamond v. Chakrabarty*.[11] Since research in this field is so expensive and time-consuming, animal patents are important because they are a biotechnical corporation's hope of protecting its investment. Nevertheless, opponents of animal patents say that permitting a person or a corporate entity to own life is repugnant to the morals of society.[12]

This Note explains the requirements of the current patent statute and briefly reviews biotechnology and its importance. It then examines the *Chakrabarty* decision along with its previous and subsequent legal history. Next, it analyzes the most commonly expressed concerns regarding animal patents: public safety, impact on the economy and the ecology, survival of small farms, animal suffering, and philosophical considerations such as the possibility of human-animal hybrids. Finally, the Note concludes that the objections to animal patents are actually objections to biotechnology itself and that the current federal regulatory framework can sufficiently control biotechnology.

BACKGROUND

The Patent Statute

The United States Constitution grants Congress the expansive power to foster the progress of arts and sciences by granting authors, inventors, and artists exclusive rights to their achievements for a limited time as a reward for their efforts.[13] The primary purpose of patents is to encourage the development and advancement of arts and sciences that will result not only in individual economic gains, but in benefits to the public's health and the environment.[14] The current patent statute, the Patent Act of 1952,[15] specifically requires that three criteria be met before a patent is granted: subject matter, utility, and novelty.[16]

The subject matter element of the statute[17] requires the invention to be either a process,[18] machine,[19] manufacture,[20] or composition of matter.[21]

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11. 447 U.S. 303 (1980).

12. *See Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 64-66 (1987) [hereinafter *Hearings*] (statement of John A. Hoyt, President, Humane Society of the United States).

13. U.S. CONST. art. I, § 8, cl. 8.

14. *See generally* Note, *Legislation for the Patenting of Living Organisms: Specificity, Public Safety And Ethical Considerations*, 7 J. LEGIS. 113 (1980).

15. 35 U.S.C.A. § § 101- 376 (West 1984).

16. 35 U.S.C.A. §§ 101-102 (West 1984).

17. 35 U.S.C.A. § 101 (West 1984).

18. The term "process" is defined as a method, art, or process, and includes any new use of any known machine, process, material, composition of matter, or manufacture. 35 U.S.C.A. § 100 (West 1984).

19. A machine is an apparatus of connected rigid bodies functioning in a predetermined manner to produce physical effects by the direct application of force. AMERICAN HERITAGE DICTIONARY 751 (2d college ed. 1982). "Machine," however, is also meant to embrace various types of mechanisms; therefore, the term "apparatus" more readily conveys the intended meaning of the patent statute. *See* E. LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 2:7, at 134-35 (2d ed. 1984).

20. In *Chakrabarty*, the Court defined manufacture as "'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties,

"Utility" requires that an invention be operative and neither frivolous, against public policy, nor harmful to the public's welfare.[22] The invention must be capable of accomplishing its proposed purpose[23] and a patent application will not be approved for a useless product.[24] The invention must have a legitimate purpose in a stated industry, but it may possess utility without being commercially successful.[25]

An invention is novel for statutory purposes if the identical subject matter does not exist in prior art.[26] It must not have been used or known by others in the United States or in foreign countries, nor been described in a printed publication, nor previously been patented or in public use or for public sale in the United States more than a year before the discovery of the invention by the filing inventor.[27] The patent statute contains two further requirements: the invention must not be obvious to someone possessing ordinary skill in the invention's subject matter,[28] and the patent applicant must comply with the disclosure and claiming specifications of United States Code section 112.[29]

Biotechnology

The Science Behind the Technology

Deoxyribonucleic acid (DNA) is a complex molecule which directs an organism's construction and function. The largest substructure of mammalian DNA is a chromosome.[30] Every cell contains several chromosomes, each comprised of thousands of individual genes. Genes are the basic subunit of DNA.[31] Biotechnology involves the science of gene splicing, otherwise known

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or combinations, whether by hand-labor or by machinery.'" *Chakrabarty*, 447 U.S. at 308 (quoting American Fruit Growers, Inc. v. Brogdex Corp., 283 U.S. 1, 11 (1931)).

21. Composition of matter includes "all compositions of two or more substances and . . . [sic] all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids." *Id.* (quoting Shell Development Co. v. Watson, 149 F. Supp. 279, 280 (D.C. Cir. 1957)).

22. R. BUCKLES, IDEAS, INVENTIONS, AND PATENTS: HOW TO DEVELOP AND PROTECT THEM 16 (1957) ("[I]t must be useful, not frivolous nor contrary to public policy, nor inimical to the public welfare.").

23. J. CLAYBROOK, PATENTS 193 (1927) ("But where it appears that a patented device is not capable of being used to effect the object proposed . . . the patent is void for want of utility.").

24. R. BUCKLES, *supra* note 22, at 16 ("A patent will not be issued for a useless device or product, nor for a machine which will not operate.").

25. G. WOODLING, INVENTIONS AND THEIR PROTECTIONS 117 (1954) ("[A] device, in order to posses utility, must accomplish a practical purpose in the industry. . . . It is unnecessary that the invention be a commercial success.").

26. "Prior art" refers to the fund of publicly accessible or available information. *See* P. ROSENBERG, PATENT LAW FUNDAMENTALS § 7.01, 7-4 (2d ed. 1990). The novelty requirement is found in 35 U.S.C.A. § 102 (West 1984).

27. 35 U.S.C.A. § 102 (West 1984).

28. 35 U.S.C.A. § 103 (West 1984).

29. 35 U.S.C.A. § 112 (West 1984).

30. Chromosomes are linear threads in the cell nucleus containing the cell's genetic information. They are a complex structure of DNA and proteins and their number is constant for each species. TABER'S, *supra* note 4, at 327.

31. *See* TRANSGENIC ANIMAL PATENT REFORM ACT, H.R. REP. NO. 888, 100th Cong., 2d Sess. 23 (1988) [hereinafter PATENT REFORM ACT]. For an in-depth explanation of the structure of DNA, see generally GENES (B. Lewin 3d ed. 1987); H. CURTIS, BIOLOGY (4th ed. 1983).

as recombinant DNA (rDNA) technique. The first experiments in this area were conducted in the early 1970's,[32] and the first mammalian gene transfer was performed in 1980.[33]

Initially, scientists developed gene splicing techniques from experiments conducted on bacteria.[34] Enzymes known as "restriction enzymes" are present in bacterial cells. They are capable of recognizing and cutting out ("cleaving") specific sequences of bacterial DNA.[35] Through the manipulation of these restriction enzymes, scientists have learned to extract a gene from an organism's genetic material. They then link this gene to a "carrier molecule" capable of inserting itself, along with the extracted gene, known as a transgene, into the DNA of a "host organism." This new DNA, a combination of host and foreign gene sequences, is referred to as "recombinant DNA."

It is far more complicated to extract and introduce genes into animals than into bacteria because animals lack the "carrier molecule" found in bacteria. Currently, scientists use three methods to introduce a foreign gene into the host animal. The dominant method is known as microinjection, where the scientist injects purified copies of the desired gene into a fertilized animal egg which he then implants into the female. The process is labor-intensive, tedious and inefficient.[36] Scientists prefer the microinjection method, however, because eggs that successfully incorporate the gene do so uniformly, that is, every cell of the host animal contains the foreign gene. This uniform incorporation makes it much easier for the scientist to control the foreign gene and accurately predicts how the gene generally will affect the animal.[37]

The second gene splicing technique is the viral vector method. The gene is attached to a virus[38] which serves as a carrier molecule. It transports the gene to an embryonic cell and facilitates the incorporation of the gene into the host DNA. This method is more efficient than microinjection,[39] but there are few viruses available with the necessary characteristics to accomplish the task and they can only transport a limited size of DNA. Moreover, the egg cell does not uniformly incorporate the gene; therefore, only some of the animal's cells

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32. *See Hearings*, *supra* note 12, at 226 (statement of Winston J. Brill).

33. *Id.* at 885 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation, National and Environmental Resources Division).

34. Bacteria are relatively simple forms of life. Their DNA generally consists of a single continuous thread of genetic material. H. CURTIS, *supra* note 31, at 310.

35. *Id.* at 320.

36. Only about eighty-five out of every 100 eggs collected are actually suitable for injection. Sixty survive the injection procedure, and only six result in live births. Of the six offspring born alive, only one or two are transgenic. Only one egg cell can be injected at a time and if the injection procedure itself does not destroy the egg, often an egg that actually incorporates the gene does so in a manner lethal to itself. PATENT REFORM ACT, *supra* note 31, at 25, 32.

37. One of the problems associated with biotechnology is the inability to predict from species to species the characteristics that will result from the insertion of a particular gene. For example, mice expressing the human growth hormone grow to twice their normal size. Hogs expressing the same gene do not experience a change in size but do produce leaner meat. *Id.* at 25, 30, 32.

38. The virus used is a tiny and ineffective protein particle whose structure is similar to DNA. *Id.* at 33.

39. Seventy to eighty percent of the eggs incorporate the gene, but only one or two percent of the adults pass the transgene to their offspring because they do not incorporate the gene uniformly. *Id.* at 33.

will have the gene. This makes it much more difficult to control its expression.[40]

The third gene splicing method is the chimera technique.[41] A chimera is produced by substituting some embryonic cells of one organism for the embryonic cells of another. Scientists have already used two closely related species, goats and sheep, to produce a chimera species called a "geep."[42] This process helps scientists study reproduction. The transgene is first introduced by either the viral vector or microinjection method into the embryonic cells of one organism. Some of those embryonic cells are then substituted into the embryonic cells of another organism via the chimera technique. The resulting chimera animals do not, however, incorporate the transgene uniformly and generally cannot pass the gene to their offspring.[43]

Each of these techniques enables scientists to create or alter organisms to exhibit special and unique characteristics not naturally present.[44] With respect to mammalian transfers, however, if more than one gene controls the desired trait, meaningful transfer of that trait into the host organism is currently almost impossible.[45] Although more than one gene generally controls a single trait, those genes do not necessarily occur in sequence. They can be scattered throughout the organism's DNA. It is difficult to identify, locate, and remove all of the genes involved and then successfully rearrange them in the host so that they function synchronously. Even single gene transfers are not always successful because an incorporated gene is not always properly expressed.[46]

It is also important to note that it is not presently possible to remove a native gene and replace it with a recombinant gene. Genes can only be added, and there is even a limit on how much "extra" DNA can be incorporated into an organism's DNA before it becomes unstable. Additionally, since an animal has hundreds of thousands of genes, incorporating a small amount of "extra" DNA usually is not sufficient to change the basic essence, character, and identity of an animal.[47] Finally, scientists must overcome several additional hurdles before they can dramatically alter an animal's natural composition. They must learn which genes control specific characteristics and how to manipulate those genes so they will be expressed predictably. Scientists have yet to develop a truly efficient gene transfer, whereby the animal incorporates the transgene uniformly.[48] Scientists also still must discover how to insert genes into the host

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40. *Id.* at 33-34.

41. "Chimera" is the "mixing of the blood (and blast cells) of embryos of double-egg twins so that even though each twin originally had a different blood group, each now has a mixed group." TABER'S, *supra* note 4, at 312. Blast cells are cells at "an immature stage in cellular development." *Id.* at 205.

42. *See* PATENT REFORM ACT, *supra* note 31, at 34.

43. *Id.*

44. *See* TABER'S, *supra* note 4, at 672, 1460.

45. Manipulating complex characteristics controlled by more than one gene will not be possible for an estimated ten to thirty years. PATENT REFORM ACT, *supra* note 31, at 26.

46. *Hearings*, *supra* note 12, at 886 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation, National and Environmental Resources Division).

47. *Id.* at 44 (statement of Thomas E. Wagner, Director, Edison Animal Biotechnology Center, Ohio State University).

48. The ideal gene transfer technique would have a molecular marker attached to the transgene so the gene's ultimate incorporation into the host DNA could be detected. The method should be reasonably efficient. The percentage of inoculated recipient eggs incorporating the

DNA without interfering with the DNA's normal genetic functions. Thus, absent revolutionary and unanticipated discoveries, only minimal progress in biotechnology is expected because of the enormous obstacles presented by this lack of information.[49]

The Significance of Biotechnology Products

Benefits to Human Health and Well-Being

Animals are the ideal models for studying various human diseases. AIDS research, for example, uses mice and chimpanzees.[50] Animal models presently do not exist for most human cancers, genetic conditions, and infectious diseases because animals do not exhibit these conditions naturally. Transgenic animals[51] with the requisite conditions might be created, however, as soon as scientists perfect techniques for introducing the gene for a human genetic condition.[52] Biomedical research has already created a few animal models. Silkworms have been genetically altered to produce a hepatitis vaccine,[53] and transgenic mice secrete milk containing active human tissue plasminogen activator (t-PA), a compound which dissolves blood clots.[54]

Genetic engineering has also helped develop drugs used to treat dwarfism, anemia, rabies, and various cancers.[55] Vaccines for pseudo-rabies,[56] foot and mouth disease,[57] coccidiosis,[58] and scours[59] have been made possible

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transgene and expressing its characteristic should be relatively high. Scientists should be able to exercise control over the number of transgenes actually incorporated into the host DNA and the method should be capable of transferring large pieces of genetic material to the host. *See* PATENT REFORM ACT, *supra* note 31, at 31.

49. *Id.* at 35-36.

50. *See* Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 408 (1988). *See also Hearings*, *supra* note 12, at 468 (statement of Alan E. Smith, Vice President and Scientific Director, Integrated Genetics Inc.); Roberts, *Bill Would Halt Patents on Animals*, L.A. Daily J., Aug. 11, 1987, at 5. Azidothymidine, an antiviral drug, prolongs the life of AIDS patients and is also a product of biotechnology. Marciniszyn, *supra* note 4, at 153-54.

51. Transgenic means "genetically distinct from other animals of its species or breed." PATENT REFORM ACT, *supra* note 31, at 9.

52. Dresser, *supra* note 50, at 408.

53. *Id.* at 409. Hepatitis can lead to liver cirrhosis and liver cancer. The worms produce Recombivax HB which is the first rDNA human vaccine the Food and Drug Administration (FDA) has approved. Marciniszyn, *supra* note 4, at 152-53.

54. Dresser, *supra* note 50, at 409.

55. Schaffer, *Biotech Raises Host of Questions in Legal Circles; Congress to Debate Patent Law Aspects, Beginning Today; Unchartered Territory*, L.A. Daily J., June 11, 1987, at 24. The new, live oral vaccine for rabies is injected into food and left out for wild animals to consume. This vaccine is significantly more effective than current vaccines which entail catching the animals before they can be inoculated. Hopper, *A Legal Frost Over Genetic Testing*, L.A. Daily J., Sept. 24, 1986, at 4.

56. Pseudo-rabies infects about ten percent of the country's hogs and costs hog farmers an estimated one million dollars a month and pork producers sixty million dollars a year. Marciniszyn, *supra* note 4, at 156.

57. Foot and mouth disease is a viral disease which infects horses and cattle. TABER'S, *supra* note 4, at 636.

58. Coccidiosis is a pathogenic condition resulting from a parasitic infestation in the intestines of animals. *Id.* at 347.

59. Scours is diarrhea of livestock. AMERICAN HERITAGE DICTIONARY, *supra* note 19, at 1101.

with the advent of biotechnology.[60] Additionally, there are transgenic organisms capable of converting sewage or plants into methane fuel and eating impurities from precious metals. Scientists have developed crops resistant to pests, bad weather, and poor soil conditions.[61] Genetic engineering has also produced protropin,[62] alpha interferon,[63] and monoclonal antibodies.[64] It is clear that biotechnology holds the promise of a higher quality of life for society, and the availability of animal patents encourages this new and exciting science.

Economic Factors

Biotechnical research is expensive and time-consuming. Patenting living organisms provides protection for investments by allowing the bio-industries to have exclusive rights to their inventions and the profits from them for a minimum of seventeen years.[65] Supporters argue that unless patent protection for transgenic products is available, many corporations will lose their incentive to continue supporting biotechnology because generic companies will copy products and undersell the inventors.[66] Thus, corporations investing in research would not be likely to regain their investment and will be less willing to finance such research in the future. Subsequently, advancements in genetic engineering would be tremendously reduced,[67] compromising our nation's competitive position in the world biotechnical market.[68]

Furthermore, supporters argue that the availability of animal patents in the United States will stimulate foreign investment. Foreign corporations, eager to engage in genetic engineering, are beginning to build facilities in the United States because many European countries have strict regulations discouraging such research.[69] Several foreign chemical corporations, denied

60. Marciniszyn, *supra* note 4, at 152, 153-56.

61. *See generally* Zepfel, *supra* note 9, at 643.

62. Protropin is used to treat Turner's Syndrome, which is characterized by an absence or suppression of menstruation, a failure to mature sexually, short stature, webbing of the neck, and impaired intelligence. TABER'S, *supra* note 4, at 67, 404, 1790.

63. *See* Zepfel, *supra* note 9, at 642.

64. *See* Medley, *supra* note 2, at 822.

65. 35 U.S.C.A. § 154 (West 1984). A patent grant may be extended. 35 U.S.C.A. § 155 (West 1984).

66. While companies such as Lubrizol, Koppers Co., and Socal have already invested tens of millions of dollars into new biotechnical companies, generic companies will make enormous profits from genetic research without ever having invested any of their own capital in developing the product. Note, *supra* note 14, at 116.

67. *Id.*

68. *See* Maki & Brownlee, *Patents: Can Higher Life Forms Be Excluded As Non-Statutory Subject Matter?*, Nat'l L.J., Nov. 23, 1987, at 26. Opponents argue, however, that the presence of animal patents in the United States is a disadvantage to the American farmer who will be forced to pay premiums (that his European counterparts will not) to use transgenic animals. *Hearings*, *supra* note 12, at 115 (statement of Cy Carpenter, President, National Farmers Union). It is important to realize, however, that these premiums represent a sharing of the gain between the user and the patent holder. The farmer will not pay a premium if the use of the transgenic animal for which he is purchasing the rights fails to derive a greater economic benefit than the cost of the premium.

69. The European Patent Office (EPO) announced it will not grant animal patents based upon a broad interpretation of the European Patent Convention, which prohibits granting patents for animal and plant varieties. *See* Dickson, *Europe Says no to Animal Patents*, 245 SCIENCE 25 (1989).

patents for the products of their genetic research in their native countries, are looking to the United States to protect their investments.[70] Prohibiting animal patents in the United States would not only result in the loss of foreign investment, but would encourage American corporations to invest and develop overseas. Several other countries already permit animal patents.[71] Additionally, there are indications that the European countries which currently deny animal patents are realizing that they must relax restrictive regulations in order to keep their scientists.[72]

Finally, advocates assert that if biotechnical corporations cannot obtain adequate protection for their transgenic animals, they will rely on trade secrets, restricting the dissemination of engineering techniques[73] and obstructing the production of valuable inventions. Moreover, companies will aim at creating transgenic animals whose transgene is not passed to their offspring. This practice could force buyers to continually replenish their transgenic stock from the suppliers "inventory"[74] and increase the buyer's cost of doing business.

CHAKRABARTY

*Pre-*Chakrabarty *Attitudes Toward Animal Patents*

Prior to *Diamond v. Chakrabarty*,[75] a process within a living organism was patentable subject matter.[76] In *Guaranty Trust Co. of New York v. Union Solvents Corp.*,[77] the Patent and Trademark Office (P.T.O.) stated that the life processes of a bacterial living organism were patentable subject matter under section 101 of the patent statute.[78] Although it did not address the question of whether the organism itself was patentable, the court left the issue open, commenting that a different situation would have been presented had the patent application been for the bacteria per se.[79]

In *Kalo Inoculant Co. v. Funk Bros. Seed Co.*,[80] the Court of Appeals for the Seventh Circuit approved a patent for a mixture of several strains of

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70. BASF and Bayer, two West German companies, are building laboratories in the United States. Dickson, *German Biotech Firms Flee Regulatory Climate*, 244 SCIENCE 1251 (1989). The companies will create new jobs and contribute to the economy.

71. These include Canada, Australia, Brazil, Argentina, Greece, Netherlands, Hungary, Turkey, Japan, New Zealand, Romania, Bulgaria, and Great Britain. PATENT REFORM ACT, *supra* note 31, at 47; *Hearings*, *supra* note 12, at 520 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies); Note, *supra* note 14, at 116; Maki & Brownlee, *supra* note 68, at 26.

72. A new law has been proposed in Germany which would relax the restrictions placed on biotechnical corporations which produce non-pathogenic organisms. Pathogenic organisms cause or produce disease. TABER'S, *supra* note 4, at 1241. This change was prompted by the country's realization that its brightest and best molecular biologists are leaving for the United States. Dickson, *supra* note 70, at 1251-52.

73. *See Hearings*, *supra* note 12, at 519 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies).

74. *Id.* at 519, 523.

75. 447 U.S. 303 (1980).

76. Guaranty Trust Co. of New York v. Union Solvents Corp., 54 F.2d 400 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932).

77. 54 F.2d 400.

78. *Id.* at 410.

79. *Id.*

80. 161 F.2d 981 (7th Cir. 1947).

bacteria which aided the growth of leguminous plants.[81] The Supreme Court reversed, denying the application because the product was simply aggregated prior art.[82] The opinion did not indicate, however, that the court denied the patent because the bacteria were alive.[83]

Similarly, the court in *In Re Merat*[84] held that something occurring naturally under controlled conditions is not a manufacture of man.[85] It did not, however, address whether the subject matter's life characteristic was grounds for rejection under section 101. The question remained unanswered until 1980 when the Supreme Court reviewed *Chakrabarty* and its companion case, *In Re Bergy*,[86] and held that non-naturally occurring living organisms are patentable.[87]

In Re Bergy

Malcom Bergy applied for a patent on a process using a microorganism to produce the antibiotic lincomycin with greater efficiency. His application contained five claims. The first four related to Bergy's process, but the fifth and pivotal claim was to the microorganism itself.[88] The P.T.O. rejected the fifth claim, contending that the microorganism was a product of nature.[89] The Patent Office Board of Appeals rejected the claim also, on the grounds that living organisms were not patentable subject matter.[90] The Court of Customs and Patent Appeals (C.C.P.A.) reversed, holding that there was no legal significance to the fact the organisms were alive.[91] It reasoned that the product's use derived from the very fact that it was alive and that there was no significant difference between active chemicals classified as "dead" and organisms used for chemical reactions that occur because the organism is alive.[92] The Supreme Court vacated this judgment and consolidated the case with *Chakrabarty* for further consideration.[93]

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81. *Id.* at 986. *See also* Rosenblatt, *The Regulation of Recombinant DNA Research: The Alternative of Local Control*, 10 B.C. ENVTL. AFF. L. REV. 37, 44 (1982).

82. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130-31 (1948). The court held that each bacteria strain functioned naturally just as it would if it existed alone. *Id.* at 131. *See also* Daus, *Patents For Biotechnology*, 26 IDEA 263, 274 (1986). The discovery that these particular naturally occurring strains could be mixed together for a specific purpose was just a discovery of a natural phenomenon. Rosenblatt, *supra* note 81, at 44.

83. 333 U.S. at 129-32. *See also* Fitzgerald, *The Patentability of Living Organisms Under 35 USC section 101: Parker v. Bergy (Parker v. Chakrabarty)*, 15 NEW ENG. L. REV. 379, 395 (1980).

84. 519 F.2d 1390 (C.C.P.A. 1975).

85. *Id.* at 1393. Merat allegedly discovered a gene in chickens which produced dwarf hens. These hens, when mated to "normal" cocks, laid eggs producing normal sized chickens. Thus, the discovery reduced costs since the dwarf hens consumed less and still produced normal-sized chickens. The dwarf gene, however, is a sex-linked gene which occurs naturally. *Id.* at 1391.

86. 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978), *aff'd on rehearing sub nom.* Application of Bergy, 596 F.2d 952 (C.C.P.A. 1979).

87. *Chakrabarty*, 447 U.S. at 309-10.

88. *See* Fitzgerald, *supra* note 83, at 384-85.

89. *Id.* at 385.

90. *Id.* at 386.

91. In re Bergy, 563 F.2d at 1038; Application of Bergy, 596 F.2d at 975.

92. In re Bergy, 563 F.2d at 1038; Application of Bergy, 596 F.2d at 975.

93. *Chakrabarty*, 447 U.S. at 306. *Bergy* was eventually dismissed as moot when the plaintiff gave up his claim to the bacteria and the Supreme Court granted his motion to dismiss.

The Chakrabarty *Decision*

In 1972, Dr. Ananda M. Chakrabarty, a microbiologist employed by General Electric,[94] filed an application requesting a patent for a new, genetically engineered bacteria of the genus *Pseudomonas aeruginosa*.[95] Chakrabarty developed the bacteria by cross-breeding four different strains of oil-eating bacteria into one microorganism. Each of the four parent bacteria could digest different hydrocarbons found in crude oil.[96] Chakrabarty's bacteria contained two stable plasmids genetically transferred from the parent bacteria. The new bacteria could break down multiple components of crude oil more rapidly and efficiently than any of the four parents. Furthermore, the new bacteria's by-products — water, carbon dioxide, and bacterial protein — benefited the environment by providing nutrients for other aquatic inhabitants.[97]

The United States Patent Office (U.S.P.O.) granted the claims for producing the bacteria and for the inoculum,[98] but denied the claim to the bacterium itself on the ground that title thirty-five, section 101 of the United States Code did not to apply to living things.[99] The Board of Appeals affirmed, but the C.C.P.A. reversed, holding it was irrelevant that the organisms were alive.[100] The P.T.O. appealed to the United States Supreme Court which granted certiorari and affirmed the C.C.P.A.'s decision.[101]

The Supreme Court held that any non-naturally occurring composition of matter or manufacture produced by human invention and having a distinct character, use, and name was patentable subject matter under section 101.[102] The Court concluded that Congress intended section 101 to be construed broadly in order to encourage the introduction of new processes and products into society. The statute's terms should be construed according to their ordinary dictionary definitions,[103] and limitations and conditions not expressed by the legislature should not be read into the patent statute. Anything man-

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444 U.S. 1028 (1980). *See also* Note, *Patentability of Micro-Organisms* 14 AKRON L. REV. 341, 342 (1980).

94. General Electric was the assignee of Dr. Chakrabarty's patent application. *Chakrabarty*, 447 U.S. at 305.

95. Smith, *The Promise of Abundant Life: Patenting a Magnificent Obsession*, 8 J. CONTEMP. L. 85, 92 (1982).

96. Biologically controlling oil spills presently requires using a mixture of bacteria each of which are capable of degrading only one component of crude oil. The process is not very efficient since only a small portion of the bacteria actually survive to decompose the oil spill and the bacteria that do endure can only degrade one oil component. *Chakrabarty*, 447 U.S. at 305 n.2.

97. *See* Smith, *supra* note 95, at 92.

98. An inoculum is a substance, generally a serum, microorganism, or viral organism, which is introduced into the host by inoculation. TABER'S, *supra* note 4, at 850.

99. Rosenblatt, *supra* note 81, at 40-41.

100. *Id.* at 41.

101. *Chakrabarty*, 447 U.S. at 306-07, 318. The language most often cited as the Court's specific holding is: "anything under the sun that is made by man" is patentable subject matter. *Id.* at 309.

102. *Id.* at 303.

103. *Id.* at 308.

made is patentable subject matter[104] except naturally occurring physical phenomena, abstract ideas, and the laws of nature.[105]

In reaching this decision, the Court rejected both of the government's arguments. The government first asserted that the 1930 Plant Patent Act[106] and the 1970 Plant Variety Protective Act[107] excluded bacteria as patentable subject matter. After reviewing the House and Senate committee reports, the Court determined Congress had distinguished between products of nature and man-made inventions, and not between living and inanimate things, and that nothing in the legislative history supported a contrary conclusion.[108]

The government also claimed that living matter can not be patented until Congress expressly authorizes such protection. The majority rejected this argument, deeming it irrelevant whether Congress anticipated genetic engineering when it drafted the patent statute. In fact, the Court noted that requiring anticipation would undermine Congress's intent to reward ingenuity.[109] Additionally, the Court stated that Congress can amend section 101 to exclude living organisms as patentable subject matter if that is its intention.[110]

After Chakrabarty: *Ex Parte Allen*

Although *Chakrabarty*'s rule was expansive, the Board of Patent Appeals did not expressly include animals in that rule until 1987.[111] Relying upon *Chakrabarty*, the Board in *Ex parte Allen* held that the polyploid oysters in question, which could be eaten year round instead of only nine months,[112] were patentable subject matter if they existed by man's intervention and did not occur naturally.[113] The P.T.O. subsequently issued a formal memo announcing that it now included as patentable subject matter any multicellular organisms that occur non-naturally.[114] It recognized that *Chakrabarty*'s broad interpretation of the patent statute was controlling, but the P.T.O. specifically disallowed any claims made regarding human beings.[115]

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104. *Id.* at 309.
105. *Id.*
106. 35 U.S.C.A. § 161 (West 1930).
107. 7 U.S.C.A. § 2402(a) (West 1970).
108. *Chakrabarty*, 447 U.S. at 313.
109. *Id.* at 316.
110. *Id.* at 318.
111. Ex Parte Allen, 2 U.S.P.Q.2d 1425 (1987).
112. *See* Maki & Brownlee, *supra* note 68, at 25.
113. Ex Parte Allen, 2 U.S.P.Q.2d at 1427.
114. Westerhoff & Morrison, *Patent Applications Will Be Entertained for New Organisms: In a Decision with Important Implications for Genetic Engineering, the Government Has Given a Broad Reading to the Patentability of New Animal Life Forms Created by Science*, Legal Times, June 15, 1987, at 16.
115. *Id.* at 16-17. This policy against human patents is based on the United States Constitution. To grant a patent on a person is to grant limited but exclusive rights to that person, and the thirteenth amendment expressly forbids slavery and involuntary servitude. Neither slavery nor involuntary servitude may exist within the United States' jurisdiction except as a post-conviction sanction. U.S. CONST. amend. XIII, § 1.

ISSUES RAISED BY THE *CHAKRABARTY* DECISION

Although biotechnology promises tremendous societal advancements,[116] there is increasing criticism from philosophers, animal right activists, farmers, and environmentalists that the technology's dangers overshadow its potential benefits. Biotechnical corporations and many scientists challenge these arguments. The major issues are public safety, impact on the ecology, economic effect on small farmers, ethical considerations, and the welfare of laboratory animals.

Public Safety

Opponents of animal patents are concerned that the interspecies transfer of genetic material will result in the creation of dangerous organisms. For example, an organism resistant to the human immune system could be created and accidently released into the environment with potentially catastrophic consequences.[117] Animal patent advocates argue, however, that a recent National Academy of Sciences (NAS) report[118] concluded that there is no evidence of any unique hazards involved with the transfer of genetic material between unrelated species.[119] The NAS reported that the risks associated with introducing genetically engineered organisms into the environment are similar to those associated with organisms modified by some other process, such as traditional breeding practices.[120] The report indicated that assessing risks associated with the introduction of transgenic organisms is to be based upon the nature of the organism introduced and the environment into which it is to be released, and not upon the method which produced the organism.[121]

Patent opponents also argue that animal patents will create a loss of genetic diversity. They believe that transgenic animals and plants, including the world's food supplies, will become increasingly vulnerable to epidemics and disease as we rely more heavily upon transgenic food products.[122] There are many known examples of populations that are now extinct due to susceptibility to organic attacks and disease.[123] Advocates reply that animal patents are irrelevant to diminishing species genetic diversity.[124] In fact, they argue it is in

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116. Products already developed through biotechnology techniques include human growth hormone, gamma interferon (used to treat cancer), erythropoietin (used to treat anemia), Factor VIII C (used to treat hemophilia), and bacteria that make potatoes and strawberries frost resistant. Schaffer, *supra* note 55, at 24.

117. *See* Note, *supra* note 14, at 119.

118. *See* INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987). *See also Hearings*, *supra* note 12, at 441-42 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

119. *Hearings*, *supra* note 12, at 442-43 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

120. *Id.*

121. *Id.*

122. *See* Dresser, *supra* note 50, at 412.

123. Dutch elm disease is an example. *See* Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1057 n.27 (1988).

124. For example, the corn leaf blight of the 1970's occurred in the absence of animal patents. Even the genetic base for turkeys is currently too narrow, and this has happened with-

the genetic researcher's interest to maintain genetic diversity to improve existing breeds.[125] Genetic diversity is of critical importance whether or not animal patent protection is available.[126]

Ecological Issues

Opponents fear that transgenic species bred to survive in desolate areas will dramatically alter the natural ecological landscape.[127] Advocates insist, however, that transgenic species will actually preserve the ecology. Native species can be altered to survive acid rain and resist pollution, thus maintaining the surrounding environment.[128] Furthermore, they argue, the appropriate regulatory agencies can forestall the introduction of truly dangerous organisms into the environment and prohibit the commercial exploitation of animals presenting an ecological hazard.[129]

Opponents also contend that if biotechnology introduces superior transgenic animals into the environment they will overtake the native populations[130] and drive them into extinction.[131] Advocates, however, insist there is very little chance of any ecological disasters resulting from genetically altered animals.[132] The majority of transgenic animals, they argue, are kept in captivity. Even if they should escape, many can mate only within their own species.[133] Those animals capable of mating with the native population can only pass their transgene to offspring if it is contained in their germ line.[134] Thus, rampant and extensive transfer of genetic material among species is unlikely.[135] Advocates further argue that denying animal patents altogether would be overrestrictive, because not all transgenic animals are dangerous. Moreover, denying animal patents would be an ineffective means of control, because the

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out the influence of animal patents. *Hearings*, *supra* note 12, at 212 (statement of Leo Walsh, Dean, College of Agriculture and Life Sciences, University of Wisconsin-Madison).

125. *Id.* at 883 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation, National and Environmental Resources Division). *See also* PATENT REFORM ACT, *supra* note 31, at 11.

126. *Hearings*, *supra* note 12, at 212 (statement of Leo Walsh, Dean, College of Agriculture and Life Sciences, University of Wisconsin-Madison) ("Genetic diversity is a quality we must strive for with or without patent law.").

127. *See, e.g.*, Merges, *supra* note 123, at 1057.

128. *Hearings*, *supra* note 12, at 428 (statement of Margaret Mellon, Director, Biotechnology Project of the National Wildlife Federation) ("[S]triped bass [can be] engineered to survive acid rain pulses [and] crabs engineered to resist pollution. . . .").

129. *Id.* at 525 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies).

130. Merges, *supra* note 123, at 1057.

131. Dresser, *supra* note 50, at 412; Merges, *supra* note 123, at 1057; *Hearings*, *supra* note 12, at 426 (statement of Margaret Mellon, Director, Biotechnology Project of the National Wildlife Federation).

132. *See Hearings*, *supra* note 12, at 441 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

133. *See* Merges, *supra* note 123, at 1056.

134. A gene which is part of the germ line participates in reproduction. If a transgene is not within the germ line, it will not be passed to the parent's offspring. TABER'S, *supra* note 4, at 850.

135. *See* Merges, *supra* note 123, at 1056.

unavailability of patents would slow but not halt the commercial development of transgenic animals.[136]

Small Farmers

The overwhelming concern of small farmers is that they will be forced out of business. They fear that larger farms, which can afford to invest in the agriculturally geared biotechnical corporations or pay the licensing fees and royalties to use transgenic animals, will reap all the benefits of this technology.[137] Advocates predict, however, that the advantages gained from animal patents will completely overshadow any licensing or royalty cost. Small farmers argue, however, that agricultural corporations will monopolize the industry and corporate demands for royalties will tremendously increase farming costs. The increased costs will ultimately bankrupt small farmers or force them into tenant farming, depriving them of their autonomy.[138] They argue, for example, that less than twenty corporations dominate the poultry industry and a system of poultry tenant farming now exists in which individual farmers contract to raise chickens for a large corporation.[139] Small farmers fear that integrating transgenic animals will accelerate the expansion of contract farming.

Patent advocates do not agree that developing transgenic animals signals the demise of small farmers. They contend that small farmers will not purchase transgenic animals unless the animals are sufficiently superior to warrant the premium the farmers will pay.[140] Advocates further claim that farmers have lived with patents for decades. The farmers' machinery, tools, fertilizers, veterinary pharmaceuticals and vaccines, and animal feeds are usually patented. He is no more a tenant of those patent holders than he will be of animal patent holders.[141] Advocates also assert that small farmers are using the wrong forum to limit corporate control because prohibiting animal patents would be an ineffective control against agricultural monopolies.[142] The proper forums are state and federal legislatures, which can regulate agricultural policies, taxes, and corporations.[143]

Patent advocates also insist that small farmers will actually experience a reduced cost by using transgenic animals, which have lower drug and food costs and a greater market value.[144] Transgenic pigs, for example, which express a gene for Bovine Growth Hormone (BGH), characteristically experience a

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136. *See Hearings*, *supra* note 12, at 525-26 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies).

137. Schaffer, *supra* note 55, at 24.

138. Dresser, *supra* note 50, at 417-18; Merges, *supra* note 123, at 1052.

139. Dresser, *supra* note 50, at 418. Without such a contract, the small farmer is powerless to deliver a market-ready bird to the public. *See Hearings*, *supra* note 12, at 115 (statement of Cy Carpenter, President, National Farmers Union).

140. *See Hearings*, *supra* note 12, at 521 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies).

141. *Id.* at 523-24 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies).

142. *See* Dresser, *supra* note 50, at 418-19.

143. *Id.* at 419.

144. *Id.* at 407.

significant weight gain and have a reduced fat content.[145] Other transgenic prospects include pigs that may bear twice as many piglets as normal pigs.[146] Biotechnology can potentially produce low calorie beef cattle,[147] dairy cows capable of producing more milk than typical breeds,[148] fish that grow larger than native species,[149] and bacteria that make potatoes and strawberries resistant to frost.[150]

Additionally, advocates argue that farmers can soon revise their practice of giving antibiotics to food species[151] because transgenic animals have a greater resistance to many diseases commonly infecting farm animals.[152] The small farmer will thus avoid the added expense of vaccinating their animals and the cost of raising food animals will decrease. Moreover, the value of animal food products will dramatically increase because they will not contain the potentially harmful antibiotics. These advantages will outweigh any additional cost the farmer might experience in order to obtain the use of patented transgenic animals.[153] The availability of animal patents will also encourage the development of superior food animals, thus making cheaper and healthier animal products available to the public. This in turn will strengthen the nation's economic and competitive position in global markets.[154]

Small farmers disagree, arguing that these predictions are misleading. While transgenic pigs do weigh more and contain less fat, they also have significantly higher incidence of kidney disease, dermatitis,[155] arthritis,[156] cardiomegaly,[157] and gastric ulcers.[158] Food products from these unhealthy animals might not be better for human consumption than animals treated with

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145. *See* Pursel, Pinkert, Miller, Bolt, Campbell, Palmiter, Brinster & Hammer, *Genetic Engineering of Livestock*, 244 SCIENCE 1281 (1989) [hereinafter *Engineering of Livestock*].

146. Dresser, *supra* note 50, at 407-08.

147. *Id.* at 419.

148. *Id.* at 408.

149. *Id.*

150. Schaffer, *supra* note 55, at 24.

151. Antibiotics currently administered to food species are potentially harmful to human health. Dresser, *supra* note 50, at 407.

152. For example, chickens have been produced which are resistant to a serious poultry disease. *Id.* at 407. *See also Hearings*, *supra* note 12, at 46 (statement of Thomas Wagner, Director, Edison Animal Biotechnology Center, Ohio University). It is hard to imagine that transgenic animals that are resistant to disease are not in the small farmers' best interest. *See* PATENT REFORM ACT, *supra* note 31, at 66.

153. *See* Schaffer, *supra* note 55, at 24; *Hearings*, *supra* note 12, at 46 (statement of Thomas Wagner, Director, Edison Animal Biotechnology Center, Ohio State University), 882 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation, National and Environmental Resources Division).

154. *See* Dresser, *supra* note 50, at 418. Although the United States is leading the biotechnical industry overall, it follows Great Britain and Ireland with respect to animal biotechnology. *Hearings*, *supra* note 12, at 882 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation, National and Environmental Resources Division).

155. Dermatitis is an inflammation of the skin characterized by redness, itching, and skin lesions. TABER'S, *supra* note 4, at 442.

156. Arthritis is an inflammation of joints and is characterized by pain, swelling, and sometimes, structural changes of the joint itself. *Id.* at 134.

157. Cardiomegaly is an increase in the size of the heart. *Id.* at 271.

158. A gastric ulcer is an open sore on or a lesion of the stomach and is commonly accompanied by pain, nausea, vomiting, anorexia, and diarrhea. *Id.* at 1796, 1254. *See also Engineering of Livestock*, *supra* note 145, at 1281.

antibiotics. Advocates disagree, arguing that the transgenic pig's negative side effects can be reduced through better control of the expressed BGH gene.[159] Furthermore, unwanted characteristics result from traditional breeding practices as well as from genetic engineering. For example, some dog breeds exhibit higher incidence of kidney disorders, respiratory problems, and various other disabilities.[160]

Small farmers are concerned that animal patents will increase production, arguing that the nation's problem is overproduction, not underproduction.[161] This food products surplus will reduce small farmers' profits and force many into bankruptcy. Animal patent advocates respond that if overproduction became a problem, the government could then regulate transgenic animal production in the same manner as traditional food species.

Transgenic animals certainly will impact the agricultural industry.[162] It is unclear, however, how extensive that impact will be and whether it will be detrimental to the farming community. An accurate assessment is simply impossible until researchers conduct multigenerational studies. It is important to realize, however, that successful farmers continually implement new technologies in order to compete, and genetic engineering offers a strong market advantage to those who will implement transgenic animals.[163]

Fundamental Changes In The Relationship Of Man And Animals

The Commercialization of Animals

Opponents of animal patents maintain that permitting man to own an entire species grossly exploits life for the sole purpose of satisfying human wants and needs.[164] They insist that owning more of nature than is required for one's own livelihood is difficult to justify,[165] and that it is unethical for man to exercise responsibility over an entire species. Opponents claim granting animal

159. *See Engineering of Livestock*, *supra* note 145, at 1281.

160. *See Hearings*, *supra* note 12, at 470 (statement of Dr. Alan E. Smith, Vice President and Scientific Director, Integrated Genetics Inc.).

161. *See generally* Dresser, *supra* note 50, at 418 ("Efforts to increase milk production in cows, for example, seems unjustified in light of the existing surplus in the dairy industry."); *Hearings*, *supra* note 12, at 228 (statement of Winston Brill) ("Dairy farmers are going out of business because they cannot obtain sufficiently high prices for milk to cover costs and receive reasonable profits. With higher milk production predicted through application of genetic engineering, the future looks even more bleak for many farmers."). *But see* PATENT REFORM ACT, *supra* note 31, at 12, 14 ([Animal] patent[s] [are] necessary to provide an incentive for agricultural research and development needed to alleviate predicted world-wide food shortages. . . . Mankind will experience a tremendous increase in need for production over the next forty years. . . .").

162. A recent survey of agriculture by the United States Congress, Office of Technology Assessment (O.T.A.) projected a decline in the number of farms in the United States. The factors influencing this decline are: capital factors, associated economies of scale, technology, and specialization. It is difficult to speculate what the consequences of any one variable will be. *See* PATENT REFORM ACT, *supra* note 31, at 65.

163. *Id.*

164. Kass, *Patenting Life*, 63 J. PAT. OFF. SOC'Y. 571, 597 (1981). Opponents also argue that genetic engineering is the final step toward objectifying all life and that the actual degree of risk involved has not been fully considered. *See* Dresser, *supra* note 50, at 410-11.

165. *See* Kass, *supra* note 164, at 597. This argument, however, misses the entire point of patents which is to make knowledge available to the public.

patents is granting monopolies on life and oversteps man's place in nature. They insist that animal patents show intolerable arrogance toward life and a materialistic approach toward nature.[166] Advocates respond that man should use nature to better his existence and by genetically altering animals to provide for his needs more efficiently and more effectively, man is simply improving his environment to the best of his ability.

Opponents also question the morality of reducing animals to commercial commodities.[167] Advertising, however, is one of the most effective methods for making products available to corporations engaged in genetic engineering, and exchanging this information will facilitate research. Furthermore, animals have been recognized as commercial commodities for centuries; they are bought and sold on the open market every day.[168] Advocates also note that animals bred and slaughtered for their meat and fur have been recognized as property for centuries, and protesting their use as commercial objects is hypocritical.[169]

Animal Welfare

Perhaps the most sensitive issue surrounding animal patenting is the potential for increased animal suffering. Opponents claim that animal patents will lead to excessive and possibly unnecessary research and experimentation, resulting in a dramatic increase in animal suffering.[170] They assert that genetically engineered animals will be abnormal at birth and that generations of their offspring will endure untold agony[171] until scientists perfect techniques for treating their deformity.[172] This barrage of animal experimentation unleashes the potential for unjustified and uncontrollable suffering.[173]

166. *See Hearings, supra* note 12, at 64-66 (statement of John Hoyt, President, Humane Society of the United States).

167. The June 16, 1989 issue of *Science* contained two advertisements offering animals for sale. One promoted DuPont's OncoMouse. It extolled the value of the transgenic mouse which is able to undergo predictable carcinogenesis (the act of producing cancer) and claimed it is a shorter path to a cure for cancer. 244 SCIENCE 1267 (1989). The other ad, sponsored by BAbCO, asked potential customers to send for a catalog containing laboratory animals sold on the basis of their genetic content. *Id.* at 1322.

168. *See Hearings, supra* note 12, at 525 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies) ("It is a bit late to say that animals are not objects of commerce, and a bit hypocritical to object to patenting animals while tolerating the traditional exploitation of animals, [sic] by mankind.").

169. *See Hearings, supra* note 12, at 525 (statement of Iver Cooper, Patent Counsel, Association of Biotechnical Companies). Sentiment for animals, however, appears to be growing in this country.

170. *See generally Hearings, supra* note 12, at 59 (statement of John Hoyt, President, Humane Society of the United States) ("[Animal patents unleash] the potential for uncontrollable and unjustified animal suffering"), 496 (statement of Father Roger Scheckel, Chairman, Rural Life Committee).

171. *Id.* at 63 (statement of John Hoyt, President, Humane Society of the United States) ("such experiments and their consequences will be cloaked in secrecy and deliberately hidden from the eyes of the public").

172. *Id.*

173. *Id.* at 59.

Opponents maintain that scientists should not ignore the suffering they create;[174] they, too, must maintain a proper regard for life.

Advocates respond that it is doubtful scientists could ever make the massive alterations required to change an animal's essential function or structure.[175] Moreover, humans engage in countless activities producing changes in nature,[176] including traditional breeding practices that have produced genetically specific animals for centuries.[177]

Opponents maintain that patents will encourage a competitive atmosphere rather than a collaborative one, resulting in unnecessary research duplication and increased animal experimentation.[178] At least theoretically, however, scientists will be more inclined to publish research details if the patent statute protects their efforts and this will in turn reduce unnecessary experiments. Furthermore, Congress could draft legislation limiting animal experimentation to critically important research requiring that the information be unobtainable by other means.[179] Commissioners who are knowledgeable in animal psychology and health could inspect research corporations engaged in animal experimentation to assure compliance with the federal legislation;[180] thus minimizing animal suffering.

Human-Animal Hybrids

The most serious dilemma animal patent opponents raise is the very real possibility of creating human-animal hybrids.[181] The current patenting policy[182] fails to exclude such hybrids as non-patentable subject matter as long as they are described as non-human.[183] Whatever their technical definition might be, the issue is how to view these hybrids. In other words, to what extent should society accord human-animal hybrids privileges and rights? Patent opponents argue that it would be unethical and immoral to create a hybrid service species designed purely for exploitative purposes.[184] They feel we must

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174. *See* Passmore, *Philosophical Aspects of Experimenting with Life*, 17 AUSTL. J. FORENSIC MED. 103, 108 (1985).

175. *See* Dresser, *supra* note 50, at 413-14.

176. *Id.* at 413.

177. *Id.* at 414. The miniature pony is an example of breeding for specific physical characteristics.

178. *Id.* at 64 (statement of John Hoyt, President, Humane Society of the United States).

179. *See* Passmore, *supra* note 174, at 108.

180. *See* Holden, *Cambridge To Oversee Animal Research*, 244 SCIENCE 1253 (1989).

181. Cavalieri, *Time To Question Genetic Engineering Is Now*, N.Y. Times, Oct. 30, 1984, at 26. A sheep-goat hybrid has already been created. The possibility of a hybrid being produced from two closely related species, such as humans and chimpanzees, is quite real. *See generally* Dresser, *supra* note 50, at 415.

182.

> A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under U.S.C. 101 [sic]. The grant of a limited, but exclusive right in a human being is prohibited by the Constitution.
>
> Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection.

Dresser, *supra* note 50, at 415.

183. *Id.*

184. *Id.* at 416.

first define what it means to be human;[185] then, any animals exhibiting a human trait which has been exaggerated or is more discernible than what naturally occurs in the species, should be unpatentable.[186] Whenever this ethical exception is triggered, the burden should rest upon the inventor to prove his invention does not violate it.[187]

Advocates discount these arguments on three grounds. First, there is time to consider the ethics of producing such creatures because scientists will be unable to create animals with noticeably human traits in the near future.[188] Second, the possibility of breeding humans by eugenics[189] is no more likely than with traditional breeding practices.[190] Third, the ethical concerns associated with human-animal hybrids do not relate to animal patents, but to whether such hybrids should be created at all and, if so, what their place is in society.[191] These questions will exist even in the absence of animal patents. Furthermore, the antagonism felt toward animal patents is misplaced. The real issues are solved by regulatory procedures, not by altering the patent act, and in a more appropriate forum than Congress.

TOWARD A SOLUTION

The objections against animal patents are actually objections to the technology itself. The answer does not lie in denying animal patents or in reforming the patent statute, but in administrative guidelines and oversight coupled with appropriate judicial review.

Congressional Reforms Are Not the Answer

In 1988, the Subcommittee on Courts, Civil Liberties, and the Administration of Justice (Subcommittee) conducted a four-day hearing[192] after which it rejected a bill proposing a two-year moratorium on the issuance of animal patents.[193] On March 22, 1989, Representative Kastenmeier (D-WI)

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185. *Id.* at 416; Note, *supra* note 14, at 122.
186. *See* Note, *supra* note 14, at 122.
187. *Id.*
188. Dresser, *supra* note 50, at 416-17.
189. Eugenics is the "study of hereditary improvement by genetic control." AMERICAN HERITAGE DICTIONARY, *supra* note 19, at 168.
190. Dresser, *supra* note 50, at 416-17.
191. *Id.* at 417.
192. The hearings reviewed a moratorium's potential impact on biotechnical research, considered the adequacy of the current regulatory framework, evaluated the potentially negative repercussions of a moratorium on this nation's competitiveness in light of animal patent availability in other countries, and considered the risks of setting a bad precedent by reforming the patent statute to address concerns, such as moral and ethical issues, which are normally left to state and federal regulations. *See generally Hearings*, *supra* note 12.
193. Representative Rose (D-NC) introduced H.R. 3119 and argued that Congress needed the time to adequately review the issues raised by the practice of animal patenting. PATENT REFORM ACT, *supra* note 31, at 3, 11. The Subcommittee also found that: the patent statute "is designed to be expansive in terms of the types of inventions which are patentable. . . . The availability of patent protection for biologically derived inventions has been the catalyst for the current biotechnology industry . . . [and that] . . . meaningful patent protection for animals is the major factor in obtaining venture and development capital." It also noted that "[t]he existing research on transgenic animals is designed to benefit both humans and animals . . . [and that most] . . . of the arguments against patenting animals are, in reality, arguments against the existence of the research in the first place. The patent law is not the place to exercise judgments

introduced another bill urging patent reform in the area of transgenic animals.[194] This bill is still in the House. This maneuvering represents two possibilities: reforming the patent statute or the abandoning animal patents altogether. Both propositions have serious consequences.

Reforming the Patent Statute

The bills introduced in the House in March of 1989[195] propose amending the patent statute to include two rDNA regulatory measures.[196] Reforming the patent statute, however, is not the answer because patenting and regulating animals are two entirely separate issues. The goals of the patent statute and the goals of statutory regulation are not the same.

The government implemented the patent system to encourage technological advancement for the benefit of society. Patents reward inventors' persistence, creativity, and efforts by granting them the exclusive right to their invention for a limited time.[197] Patents also induce the inventor to publicly disclose his invention, enabling society to benefit immediately from the information.[198] Congress did not design the patent system to regulate inventions or assess their risks. The patent system should remain ethically neutral, amoral, and above any manipulation seeking to control the impact of biotechnology on society.[199]

Regulation is designed to monitor research processes and supervise the introduction of patented inventions into society.[200] It balances a product's risks against its utility and public benefit, and prohibits people from marketing an invention whose risks overwhelm its benefits.[201] It would be inappropriate to transform the patent statute's refined mandates into a conflicting mass of moralizing edicts.

Congress enacted the patent statute to determine an invention's originality, not its morality. Administrative regulations should address public safety and health issues. Furthermore, Congress lacks rapid flexibility and is inadequately equipped to address the highly technical issues animal patents present.

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about scientific activities." Finally, the Subcommittee found that although the existing biotechnology regulations needed "some marginal changes," they were for the most part sufficient. *Id.* at 69-70.

194. *See generally* PATENT REFORM ACT, *supra* note 31. Representative Kastenmeier (D-WI) introduced H.R. 1556 and also H.R. 1557, the Transgenic Animal Regulatory Reform Act. Both bills derived from previous bills that he introduced. H.R. 4970, 4971, 100th Cong., 2d Sess. (1988). Although the House passed both of these bills on September 13, 1988, the Senate did not consider them. As it stands today, H.R. 1556 primarily concerns a patent's scope regarding transgenic farm animals and proposes creating two exceptions to patent infringement penalties. The first would prevent criminalization of patented transgenic farm animal reproductions and the second would provide for scientists' use of patented animals without the patent owner's permission, but only for the purpose of conducting research. *See* H.R. 1556, 101st CONG., 2d Sess., 135 CONG. REC. 830 (1989) (statement of Rep. Kastenmeier).

195. *See supra* note 189.

196. *See* PATENT REFORM ACT, *supra* note 31, at 2-3.

197. *See Hearings*, *supra* note 12, at 437-38 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

198. *Id.* at 439 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

199. *Id. See also* PATENT REFORM ACT, *supra* note 31, at 16.

200. *See Hearings*, *supra* note 12, at 439 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).

The relevant federal agencies[202] are better prepared to respond quickly and effectively to this rapidly advancing industry.[203]

Abandoning Animal Patents

Even if Congress forbade all animal patents, biotechnical corporations arguably could turn to copyrighting. Under title seventeen of the United States Code, an original work of authorship fixed in a tangible medium of expression from which the subject matter can be reproduced, perceived, or otherwise communicated, either directly or by the assistance of a machine or device, qualifies for a copyright.[204] A "work of authorship" includes pictorial, graphic, and literary works. Moreover, "tangible medium of expression" is interpreted to include computer programs.[205] Transgenic animals and the method of their creation qualify as copyrightable subject matter if adequately described and explained, a task which has been dramatically simplified with the advent of computer technology. The copyright protection extends to the real and written rDNA molecule.[206] Furthermore, copyright protection commences immediately after the invention is fixed in a tangible medium,[207] whereas considerable delays can occur between filing for a patent and receiving it.

Copyright protection, however, is more intrusive upon society's interests than patents because copyrights last for a much longer time. A copyright owner exclusively controls the reproduction of his invention for the life of the author plus fifty years after his death.[208] Patents, on the other hand, protect the owner's rights for only seventeen years.[209] Thus, a copyright excludes the public from an invention's benefit for a much longer time, which would undoubtedly delay further biotechnical advances.[210]

Administrative Regulation of Biotechnology

Administrative regulation is the best solution for controlling biotechnology because the relevant agencies[211] are capable of efficiently regulating rDNA. The Office of Science and Technology Policy (O.S.T.P.) published a *Federal*

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201. *Id.*
202. These agencies include the United States Department of Agriculture (USDA), the Public Health Service (PHS), the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).
203. *See* PATENT REFORM ACT, *supra* note 31, at 15-16.
204. 17 U.S.C.A. § 102 (West 1976).
205. *Id.*
206. *See* Smith, *supra* note 1, at 1108.
207. *Id.*
208. 17 U.S.C.A. §§106, 302 (West 1976).
209. The patent can be renewed. Once the patent expires, however, the public can access and use the invention as it sees fit. *Hearings*, *supra* note 12, at 438 (statement of Geoffrey Karny, Lawyer, Dickstein, Shapiro, and Morin).
210. Corporations might also prefer patent protection for their transgenic animals because the patent right of exclusion is superior to that of the copyright. For example, assume Company Alpha is granted a copyright for a product it developed called "transmouse." If Company Beta creates "transmouseII," a product identical in every respect to "transmouse," Company Beta can also obtain a copyright for its product if it can show independent development of the resources and knowledge of Company Alpha because the test for copyrightability is originality, not novelty, of the creation. If Company Alpha patented "transmouse," Company Beta is then denied a patent for "transmouseII" because it is not a novel product.
211. *See supra* note 189.

Register notice[212] stating that the existing regulatory framework can sufficiently manage biotechnology[213] and no new legislation is necessary.[214] The notice announced the creation of a new "umbrella" agency, the Biotechnology Science Coordinating Committee (BSCC),[215] and defined which agencies would regulate various biotechnical products.[216] Five primary administrative agencies will regulate research animals, genetic research procedures, and the products of genetic research: USDA, PHS, NIH, EPA, and FDA.

Regulating Research Animals

Several agencies monitor animal welfare, including animal care, housing, and minimizing stress and pain. The USDA regulates research animal facilities. Its Animal and Plant Health and Inspection Service (APHIS) regularly inspects transgenic animal housing facilities. APHIS also reviews proposed animal research projects to ensure that the pain and distress animals may experience is the absolute minimum necessary to obtain the desired knowledge.[217]

Within the PHS, a Policy on Humane Care and Use of Laboratory Animals regulates the welfare of animals used in research, as well as in agriculture. The Animal Welfare Act (AWA) mandates inspection of animal research activities substantially affecting interstate or foreign commerce.[218]

The NIH, an agency of the United States Department of Health and Human Services, closely controls rDNA through the Recombinant DNA Advisory Committee (RAC). The NIH's purview includes regulating the welfare of laboratory animals used by federally funded institutes through the

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212. 49 Fed. Reg. 50,856 (1984). The notice, entitled "Coordinated Framework for the Regulation of Biotechnology," was published with the cooperation of the EPA, FDA, USDA, and the NIH. *See* PATENT REFORM ACT, *supra* note 31, at 55. *See also* Bonk, *FDA Regulation of Biotechnology*, 43 FOOD DRUG COSM. L.J. 67, 69 (1988). The notice was updated in 1986. 51 Fed. Reg. 23,302 (1986).

213. Inherently embraced within the term "biotechnology" are transgenic animals which are patentable subject matter.

214. *See* Bonk, *supra* note 212, at 69. *See also* Mahinka & Sanzo, *Biotechnology Litigation and Federal Regulation: Status and Implications*, 42 FOOD DRUG COSM. L.J. 500, 501 (1987). Although the USDA and the FDA both consider their existing regulatory framework sufficient to control biotechnology, all of the agencies recognize that additional regulation might be needed in some circumstances because various rDNA products might pose unique risks. Furthermore, a congressional subcommittee concluded that the existing regulatory framework, as discussed in part above, is sufficient for biotechnology. The subcommittee also determined that each of the three goals of biotechnology, producing pharmaceutical proteins, creating animal models to study human diseases, and improving farm livestock, are legitimate and traditional goals within our culture and that the objections raised to animal patents ignore these goals. *See also* PATENT REFORM ACT, *supra* note 31, at 7, 62.

215. The BSCC consists of several senior officials from the EPA, FDA, NIH, USDA, and the Occupational Safety and Health Administration (OSHA). The BSCC will primarily adopt consistent definitions of the transgenic organisms subject to review and coordinate the above listed federal agencies involved in biotechnology regulation. A detailed explanation of the role of the BSCC is described in 51 Fed. Reg. at 23,306. *See also* Bonk, *supra* note 212, at 70; PATENT REFORM ACT, *supra* note 31, at 55.

216. For a complete list of the agencies involved in regulating biotechnology and the products for which they are responsible, see Bonk, *supra* note 212, at 70-72.

217. Dresser, *supra* note 50, at 427.

218. *Id.* at 428.

NIH *Guide for the Care and Use of Laboratory Animals*.[219] Together, the USDA, the PHS, and the NIH adequately address the issues surrounding research animal care, housing, and use, and establish standards regulating the distress and pain imposed upon laboratory animals.

Regulating Research Procedures

Congress subjects federally funded research institutions to more stringent regulations than privately funded institutes. The NIH, the primary federal sponsor of biotechnology, first issued its *Guidelines For Research Involving Recombinant DNA Molecules*[220] (Guidelines) on June 23, 1976. The guidelines were produced after extensive public and scientific discussions related to rDNA research safety. Their purpose is to assess and minimize the risks associated with rDNA experimentation[221] and they apply to institutions funded in whole or in part by either the NIH or the National Science Foundation (NSF).[222] Although the guidelines do not govern the final products of rDNA research, they do regulate the specific techniques for the handling, construction, and containment of rDNA organisms.[223] Recently the USDA proposed its own guidelines to direct government-sponsored research of transgenic animal research, including containment issues.[224] These guidelines would require funding applicants to provide information on the nature of any transgenic animal which will potentially be released into the environment.[225] Additionally, the guidelines would govern the housing of research animals, as well as the transport, containment, and disposal of transgenic animals. For animals without modified germ lines, however, the regulations would be less restrictive.[226]

The greatest disadvantage of the NIH regulations and the proposed USDA regulations is their limited authority. Privately funded institutions are not subject to the NIH or USDA guidelines. The agencies do, however, urge

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219. A majority of states and localities have their own animal cruelty statutes regulating research animals. *See* PATENT REFORM ACT, *supra* note 31, at 57.

220. The guidelines have been updated many times since 1976 in response to the rapid developments being made in rDNA research. The most current version of the Guidelines can be found at 51 Fed. Reg. 16,958 (1986).

221. NATIONAL INSTITUTES OF HEALTH, RECOMBINANT DNA RESEARCH DOCUMENTS RELATING TO "NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES" 469 (1986) (Pub. No. 86-2865).

222. *Id.* at 478. The NIH Guidelines apply whether or not the particular experiment submitted for approval is directly funded by the NIH. The test is whether the institution receives federal support for any rDNA research. *See generally* PATENT REFORM ACT, *supra* note 31, at 56; Bonk, *supra* note 212, at 72.

223. *See* PATENT REFORM ACT, *supra* note 31, at 56. The guidelines also mandate that each institute involved in rDNA research creates an International Biosafety Committee (IBC). The IBC is notified prior to the initiation of any rDNA experiment and it evaluates the risks posed by that research to the environment and the public's health. The agency is made up of community representatives and other individuals qualified to assess any potential risks. Dresser, *supra* note 50, at 425. The IBC also functions to ensure that the institute implements the guidelines. PATENT REFORM ACT, *supra* note 31, at 56. In addition to creating an IBC, each institute must appoint a Biological Safety Officer (BSO). The BSO ensures that institutions follow laboratory standards, report any problems to the IBC, and develop an emergency plan in the event of a lab accident. 51 Fed. Reg. 16,958 (1986).

224. Dresser, *supra* note 50, at 426.

225. *Id.* at 426-27.

226. *Id.*

private institutions to adopt those guidelines voluntarily and, according to the General Accounting Office, the degree and nature of private compliance with the NIH Guidelines is greater than that of the public sector.[227]

Regulating Products of Biotechnology

Currently, transgenic animal research is primarily focused on three goals: creating animal models for studying human disease, improving plants and breeds of farm animals, and producing protein pharmaceuticals for human and veterinary use.[228] Any product intended for commercial purposes is subject to federal regulations. The relevant administrative agencies (the FDA, the EPA, and the USDA) are already in place and have experience with rDNA research.

The FDA regulates human food and drugs, veterinary drugs and their use in food animals, and biologicals.[229] Officially the FDA does not view biotechnology differently than any other technology that generates products coming within its regulations. The agency asserts that the important issue is the final product's intended use and not the type of technology producing that product.[230] The EPA presently governs rDNA research through its Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[231] and its Toxic Substances Control Act (TSCA).[232] FIFRA permits the EPA to regulate pesticides and microorganisms, including transgenic varieties. TSCA includes under its authority the regulation of transgenic animals and microorganisms.[233]

The USDA monitors animals treated with veterinary drugs when the animals are intended for human consumption.[234] The USDA also governs the release of transgenic animals into the environment, the interstate transport of plant pests, and animal quarantine provisions.[235] The USDA's Food Safety and Inspection Service (FSIS) regulates transgenic poultry and livestock, including their respective food products, to ensure they are safe for human consumption.[236] The USDA also supervises the safety and integrity of human and veterinary drugs and biological products intended for human use. The USDA can require special labeling for transgenic products within its authority.[237]

The Role Of The Judiciary

The judiciary provides recourse when governing agencies fail to administer effectively. For example, in 1978 the NIH lifted its prohibition on the

227. PATENT REFORM ACT, *supra* note 31, at 58.
228. *Id.* at 20, 62.
229. *Id.* at 58. Biologicals is a "[g]eneral term applied to medicinal compounds that are prepared from living organisms and their products." It includes antigens, vaccines, antitoxins, and serums. TABER'S, *supra* note 4, at 199.
230. *See* Mahinka & Sanzo, *supra* note 214, at 504. *See also* PATENT REFORM ACT, *supra* note 31, at 73; Pape, *Regulation of New Technologies: Is Biotechnology Unique?*, 44 FOOD DRUG COSM. L.J. 173, 177 (1989).
231. 7 U.S.C. §§ 136-136y (1982).
232. 15 U.S.C. §§ 2601-2654 (1982).
233. PATENT REFORM ACT, *supra* note 31, at 59.
234. *Id.* at 58.
235. One of the goals of the USDA is to prevent the unintended transmission of rDNA. Dresser, *supra* note 50, at 427.
236. *Id.*

deliberate release of rDNA organisms into the environment and decided to evaluate any proposed release on a case-by-case basis. In 1983, it approved a field test of *Pseudomonas syringe*.[238] A small public interest group, the Foundation on Economic Trends (F.E.T.), challenged the decision on the grounds that the NIH had violated the Administrative Procedure Act (APA)[239] and the National Environmental Policy Act (NEPA).[240] The district court enjoined the NIH from conducting the particularized deliberate release experiment and from approving any other release experiments.[241] Stating that the NIH had failed to adequately consider the environmental impact, the Court of Appeals for the District of Columbia affirmed.[242]

The F.E.T. has challenged other administrative decisions pertaining to the regulation of biotechnology. In 1985, the EPA granted a permit to Advanced Genetic Sciences, Inc. allowing it to field test ice-minus bacteria on strawberry plants.[243] The F.E.T. challenged the proposed test alleging that the EPA had violated the APA and the NEPA. Due to local opposition, the EPA suspended the permit and the F.E.T. dismissed its complaint on the condition the suspension was continued. It challenged the EPA again after a similar field test proposed by the University of California was approved. The university agreed to suspend the experiment pending further investigation regarding the test's potential environmental effects.[244] These challenges to the EPA's decisions regarding recombinant DNA illustrate the potential use of local and state laws in regulating biotechnology's development. The judiciary can thus provide an adequate check upon this new technology.

CONCLUSION

The benefits biotechnology promises our society are a compelling justification for permitting animal patents. The availability of animal patents will encourage rDNA research by granting the inventor and his investors the exclusive rights to their products. Biotechnology is no more intrusive upon a species' genetic integrity than traditional breeding practices.[245] It is merely a more efficient, effective, and precise method for producing desired traits. Animal patents will increase our nation's capital and wealth, enhance our ability to combat worldwide hunger and disease, and preserve the United States' research preeminence.[246]

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237. *Id.*

238. *Pseudomonas syringe* is a transgenic bacteria that delays frost formation on beans, potatoes, and tomatoes. Mahinka & Sanzo, *supra* note 214, at 507.

239. 5 U.S.C. §§ 702, 706 (1982). Enacted in 1946, the APA governs the practice and proceeding of federal administrative agencies. BLACK'S LAW DICTIONARY 43 (5th ed. 1979).

240. 42 U.S.C. §§ 4321-4370a (1982). NEPA sets forth national environmental goals and policy. It requires federal agencies to include an environmental impact statement with each legislative program or recommendation affecting the environment.

241. Foundation on Economic Trends v. Heckler, 587 F. Supp. 753 (D.D.C. 1984).

242. Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985). *See also* Mahinka & Sanzo, *supra* note 214, at 506-07.

243. The EPA granted the permit under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Mahinka & Sanzo, *supra* note 214, at 508.

244. *Id.*

245. *See* PATENT REFORM ACT, *supra* note 31, at 61.

246. *See* Dresser, *supra* note 50, at 409.

Additionally, Congress and the relevant federal agencies have concluded that existing regulatory framework can safely and effectively regulate biotechnology. Any novel risks posed by rDNA research are addressed more rapidly by changing administrative regulations. Recent cases have shown that the judiciary provides an adequate check on the administrative agencies governing this area. Furthermore, the objections raised toward animal patents are misplaced. Since transgenic animals will exist even in the absence of animal patents, a decision to prohibit such patents will not alleviate the concerns surrounding transgenic animals. Other, more appropriate, forums can address concerns regarding the possible dangers transgenic animals present.

Properly regulated biotechnology offers virtually unlimited opportunities to improve society's general health, environment, and economy. Although there are potential risks associated with this technology, there is no evidence suggesting the risks are greater than those associated with other technologies. Unless biotechnology is encouraged, opportunities for advancement in medicine and agriculture will be lost.