PATENTING TRANSGENIC ANIMALS: WHEN THE CAT'S AWAY, THE MICE WILL PLAY

INTRODUCTION

Francis Galton, who coined the term *eugenics*,[1] said, "'What nature does blindly, slowly, and ruthlessly, man may do providently, quickly, and kindly.'"[2] Due to our intellect and technology, humans have graduated from being subjects of evolution to being co-authors of evolution.[3] During the 1970s, a series of advances in molecular biology resulted in the science of genetic engineering and the industry of modern biotechnology.[4] Recombinant DNA research, which generated the ability to create a transgenic organism by transferring genes from an organism of one species to an organism of another species, is the key to genetic engineering and the subject of intense public debate.[5] This process is virtually nonexistent in nature, with the exception of the operation of some viruses.[6]

The new science of genetic engineering confronts law as old as the Constitution when transgenic organisms are patented. The Patent and Trademark Office ("Patent Office" or "PTO") derives its authority to grant patents to inventors from the United States Constitution and patent legislation enacted by Congress.[7] In fact, the United States was the first government to promote scientific and technical progress explicitly in a constitution.[8] Historically, animals and other biological materials were denied patent

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1. Galton defined eugenics as the evolution of human traits through social selection rather than through natural selection. MONROE W. STRICKBERGER, EVOLUTION 503 (1990).

2. *Id.* Galton was the cousin of Charles Darwin, who developed the currently accepted theory of the evolution of species by natural selection. JEREMY RIFKIN, ALGENY: A NEW WORD—A NEW WORLD 229 (1983); *see* CHARLES DARWIN, THE ORIGIN OF SPECIES (W.W. Norton & Co. 1975) (1859).

3. STRICKBERGER, *supra* note 1, at 506.

4. John Golin, *Anguished Questions*, 5 DEL. LAW. 16, 16 (1986).

5. 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW 1-14 (Release #7, Mar. 1992); *see also* Golin, *supra* note 4, at 16.

6. An organism infected with a virus is not technically a transgenic organism. In the lytic cycle, the viral DNA directs the infected organism's cells to synthesize new viral DNA and proteins, resulting in new viruses. WILLIAM T. KEETON & JAMES L. GOULD, BIOLOGICAL SCIENCE 1024 (4th ed. 1986). In the lysogenic cycle, however, viral DNA may be integrated into the host's chromosomes for an indefinite number of host generations. *Id.*

7. *See infra* notes 55-56.

8. LEON R. KASS, TOWARD A MORE NATURAL SCIENCE: BIOLOGY AND HUMAN AFFAIRS 133 (1985).

protection. However, in 1980, the Supreme Court, in *Diamond v. Chakrabarty*,[9] reversed this long-standing doctrine by holding that a genetically engineered bacterium is patentable subject matter under § 101 of the Patent Act.[10] This case opened the door for the patenting of all non-plant life.[11]

In 1987, Patent Commissioner Donald J. Quigg released a statement notifying inventors that the Patent and Trademark Office would accept patent applications for animals and that claims for the animals themselves would not be rejected as products of nature.[12] Following this statement, the Patent Office determined in 1988 that the "Harvard mouse," a genetically engineered animal developed at Harvard University for cancer research, also satisfied the requirements of patent law.[13] This decision removed the last obstacle to the patenting of non-human life.[14]

Under its constitutional mandate, the patent system formulates rules to advance an agenda[15] which may not necessarily coincide with goals of the scientific community.[16] This tension is apparent in the arguments favoring and opposing the patenting of genetically engineered organisms. In fact, the extension of patent protection to living animals demands a new look at the traditional doctrines of patent law[17] and an examination of the relationship between science and public policy.[18]

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9. Diamond v. Chakrabarty, 447 U.S. 303 (1980); *see infra* part IV.A (discussing this case).

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

11. Plant life became patentable with the enactment of the Plant Patent Act of 1930, Pub. L. No. 245, 46 Stat. 376 (codified at 35 U.S.C. §§ 161-164 (1988)), and the Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321-2372 (1988)). *See infra* part IV.A, B, D (discussing this legislation).

12. *See infra* note 78 (text of statement); *see infra* notes 114-20 and accompanying text (discussing the product of nature doctrine).

13. John H. Barton, *Patenting Life*, SCI. AM., Mar. 1991, at 40.

14. *Id.* Human life is not patentable according to the 1987 PTO statement. *See infra* note 78.

15. *See generally* Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154-58 (1950) (Douglas, J., concurring).

16. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 230 (1987).

17. *Id.* at 231.

18. KASS, *supra* note 8, at 129.

This note describes the current state of patent law as it pertains to genetically engineered organisms, specifically transgenic animals. The scientific aspects of biotechnology and genetic engineering are introduced in part I. Part II provides a brief background to the patent system in the United States, and part III describes recent developments in the patenting of transgenic animals. The arguments favoring and opposing the patenting of transgenic animals are analyzed in part IV. Part V addresses the policy concerns underlying the controversy surrounding the patenting of transgenic animals, and also provides a summary and critique of legislative proposals for amending the Patent Act, in an effort to confront the legal issues and policy concerns. This note supports the position that transgenic animals are not legally patentable and that congressional action is necessary both to correct the errors made by the Supreme Court and the Patent Office and to address the underlying policy concerns raised by genetic engineering and biotechnology.

I. GENETIC ENGINEERING AND BIOTECHNOLOGY

Biotechnology is the development of products by a biological process.[19] This type of technology actually has been used by humans for over 10,000 years,[20] but modern applications of biotechnology involve the relatively new science of genetic engineering. Developments of modern biotechnology have applications in almost every industrial sector of the economy.[21] The science of genetic engineering currently can be applied to the research and development of human and animal health care, agriculture, chemicals, waste management, and energy.[22] For example, the strain of bacteria at issue in *Diamond v. Chakra-*

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19. INDUSTRIAL BIOTECHNOLOGY ASS'N, WHAT IS BIOTECHNOLOGY? iv (1989) [hereinafter WHAT IS BIOTECHNOLOGY?]. Biotechnology also has been defined as technology based on the use of other living things, 1 COOPER, *supra* note 5, at 1-1; as the manipulation of the basic substance of living matter and its modification to achieve the purposes of the manipulator, Robert L. Baechtold et al., *Property Rights in Living Matter: Is New Law Required?*, 68 DENV. U. L. REV. 141, 141 (1991); and as the use of living organisms or their components in industrial processes, Donald F. Crossan, *Agriculture and Biotechnology*, 5 DEL. LAW. 22, 22 (1986).

20. WHAT IS BIOTECHNOLOGY?, *supra* note 19, at 1. The biological activity of one-celled microorganisms plays a critical role in the fermentation and production of bread, beer, and wine. *Id.*

21. Rudolf E. Hutz, *Patent Protection for Living Organisms*, 5 DEL. LAW. 30, 30 (1986).

22. WHAT IS BIOTECHNOLOGY?, *supra* note 19, at 10.

barty can degrade several components of crude oil, and thus has potential value in oil spill remedial actions.[23]

To understand the processes of genetic engineering, it is necessary to provide a brief background on the biochemical basis of genes. Deoxyribonucleic acid ("DNA"), a complex organic molecule, provides the genetic blueprint for cellular functions and is responsible for the transfer of traits from parent to offspring.[24] Long, thread-like molecules of DNA form genes, the basic functional units of heredity.[25] Thousands of genes form chromosomes, which are found in all living organisms with the exception of viruses.[26] Genetic material, including genes, may be transferred between organisms of the same or closely related species.[27] This transfer occurs naturally by sexual reproduction.[28]

Traditional techniques of genetic engineering include mutagenesis[29] and classic selective breeding.[30] Selective breeding involves choosing organisms for particular characteristics and inducing them to mate and reproduce sexually.[31] Sexual reproduction results in the natural reassortment of parental genes. Selective breeding has been enhanced through artificial insemination,[32] but even with the enhancement of artificial insemination, selective breeding is limited to organisms that are related closely

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23. Previously, each component of crude oil was degraded by a different strain of bacteria. *Chakrabarty*, 447 U.S. at 305 n.2.

24. MARGARET MELLON, BIOTECHNOLOGY AND THE ENVIRONMENT 15 (1988); DAVID T. SUZUKI ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 1 (3d ed. 1986); KEETON & GOULD, *supra* note 6, at A33.

25. MELLON, *supra* note 24, at 16; SUZUKI ET AL., *supra* note 24, at 1.

26. SUZUKI ET AL., *supra* note 24, at 1.

27. MELLON, *supra* note 24, at 16.

28. This process also occurs naturally among bacteria by the process of conjugation. *See* KEETON & GOULD, *supra* note 6, at 730-31.

29. Mutagenesis involves the induction of changes, or mutations, in the DNA of an organism by heat, radiation, chemicals, or other known mutagens. MELLON, *supra* note 24, at 19; KEETON & GOULD, *supra* note 6, at 725-26. This technique, which is most often applied to microorganisms, causes losses, additions, or rearrangements of the genetic material, the genotype, which result in changes in the organism's traits, the phenotype. MELLON, *supra* note 24, at 19; KEETON & GOULD, *supra* note 6, at 724-25.

30. MELLON, *supra* note 24, at 17.

31. *Id.* at 20.

32. *Id.* Artificial insemination is itself a product of human technology and has been used with both animals and humans. *Id.*

enough genetically to reproduce, resulting in a limited range of possible gene combinations.[33]

Modern genetic engineering was launched by Paul Berg's creation of recombinant deoxyribonucleic acid ("rDNA") in 1972.[34] Recombinant DNA is formed by combining segments of DNA from two or more different types of organisms.[35] Modern genetic engineering involving rDNA can move DNA from any source organism into any recipient organism without the restriction of natural reproductive mechanisms.[36] The recipient organism is then considered a transgenic organism because it has a combination of DNA coding for specific genes from organisms crossing natural DNA transfer barriers, including the species barrier.[37] Indeed, researchers now can move genes not only across species lines, but across any boundaries dividing living organisms, including the most fundamental boundary, the kingdom line, which divides bacteria from higher plants and animals.[38]

Various laboratory methods have been developed for transferring genes encoded in rDNA from one organism into another.[39] These methods have been refined and are now standard laboratory procedures. As a result, there has been an extraordinary increase in the creation and use of transgenic organisms.[40]

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33. *Id.* at 17.

34. Reid G. Adler, *Introduction: Evolving and Recombinant Biotechnology Law*, 16 AIPLA Q.J. 287, 287 (1988-89). Berg received a Nobel Prize in 1980 for his monumental creation. *Id.*

35. WHAT IS BIOTECHNOLOGY?, *supra* note 19, at 6; KEETON & GOULD, *supra* note 6, at 738-40.

36. MELLON, *supra* note 24, at 17; *see* SUZUKI ET AL., *supra* note 24, at 296-329 (providing a more in-depth analysis and discussion in a chapter on manipulation of DNA).

37. MELLON, *supra* note 24, at 17.

38. DAVID SUZUKI & PETER KNUDTSON, GENETHICS: THE CLASH BETWEEN THE NEW GENETICS AND HUMAN VALUES 265 (1989).

39. *See generally* MELLON, *supra* note 24, at 20-22 (describing molecular vectors and direct transfer methods); Rudolph Jaenisch, *Transgenic Animals*, 240 SCI. 1468 (1988) (technical article describing methods of introducing genes into animals, expression of genes in transgenic animals, and application of transgenic technology); J.G. WILLIAMS & R.K. PATIENT, GENETIC ENGINEERING (1988) (technical discussion of enzymes used in genetic engineering, vectors, DNA cloning, gene analysis, and manipulation).

40. Jaenisch, *supra* note 39, at 1473.

During the next two decades, scientists expect an exponential increase in the kinds of transgenic animals created.[41]

Recombinant DNA research has already created the following transgenic animals: mice, hamsters, rats, hogs, poultry, cattle, sheep, and fish.[42] Some transgenic animals contain other animal genes, but many contain human genes. The animals containing human genes have particular commercial value in agriculture, biomedical research, and pharmaceuticals.[43] Commercialization of transgenic farm animals is expected within the next decade.[44] Production of vaccines and hormones, such as bovine somatotropin, combine pharmaceutical applications of biotechnology with animal agriculture.[45] For example, DNX Inc., a biotechnology company, used genetic engineering to create pigs that produce human hemoglobin.[46] This is one of the few times that human genes inserted into animals have actually functioned.[47] Similar experiments have failed. Federal researchers at a laboratory in Beltsville, Maryland inserted genes for human growth hormone into pigs, which crippled them with arthritis so they could not stand or walk across their pens.[48] Nevertheless, genetic engineering may be used to enhance livestock species or to create livestock capable of producing human pharmaceutical drugs in

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41. Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 137 (1991).

42. H.R. REP. NO. 888, 100th Cong., 2d Sess. 23 (1988) (citations omitted); *see also* Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597, 608 (1991) (research efforts have focused on transgenic mice, cattle, swine, sheep, poultry, and fish).

43. Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 407 (1988) (applications of transgenic animals, including biopharming —the production of hormones and drugs in animals and harvesting them through the milk). *See generally* INDUSTRIAL BIOTECHNOLOGY ASS'N, BIOTECHNOLOGY AT WORK: ANIMALS, PEOPLE, AND BIOTECHNOLOGY (1989) (animal research and pharmaceuticals); INDUSTRIAL BIOTECHNOLOGY ASS'N, BIOTECHNOLOGY AT WORK: AGRICULTURE AND THE NEW BIOLOGY (1987) (agricultural biotechnology).

44. *Hearings on H.R. 1556*, 101st Cong., 1st Sess. 6 (1989) (statement of Carlos J. Moorehead).

45. Kevin W. O'Connor, *Current Issues in Biotechnology*, MICPEL, Oct. 1987, at 63; *see also* John Beiswenger, Note, *Moving Beyond Risk in Assessing Technological Artifacts: The Case of Recombinant Bovine Somatotropin*, 16 VT. L. REV. 667 (1992).

46. *Another Reason Not to Ask What's in the Sausage*, 10 BIOTECH. L. REP. 363, 363-64 (Gerry J. Elman ed., 1991). At least five years of research and testing will be required to resolve safety questions before the pig-produced human hemoglobin can be marketed. *Id.*

47. *Id.* at 364.

48. Gail Vines, *Guess What's Coming to Dinner?*, NEW SCIENTIST, Nov. 14, 1992, at 14.

their milk.[49] Not all potential projects will reach fruition because any alteration of an organism's genome will be expressed differently in individuals of the same species due to natural genetic variability within populations.[50]

Scientists have little doubt that discoveries in the field of biotechnology have been beneficial,[51] but the development of transgenic animals is not without risk. Therefore, the important question becomes whether the benefits are worth the risks. Potential impacts of patenting genetically engineered animals include immediate effects on the biotechnology industry and academic research, in addition to possible long-term effects on genetic diversity, the food supply, and morality. According to a report by the Office of Technology Assessment, the real issues in this debate involve animal rights, release into the environment, and effects of large agribusiness on the farming industry.[52] The effects of patenting animals on the biotechnology industry are discussed at the end of part II. The remaining policy issues and legislation that has been proposed to address them are discussed in part V.

II. THE PATENT SYSTEM

Each year the United States issues approximately 85,000 patents.[53] A patent is a grant issued by the federal government, via the Patent and Trademark Office, which gives the patent owner the right to exclude all others from making, using, or selling the invention for seventeen years, the term of the patent.[54] The authority to grant patents is derived from the Consti-

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49. *See, e.g.*, Roger Highfield, *Block on Plan to Patent "Man-Made Cancer" Mouse*, THE DAILY TELEGRAPH (London), Mar. 15, 1989, at 8. British researchers have applied for a patent on transgenic sheep that secrete a human blood-clotting factor in their milk. *Id.*

50. Stuart Newman & Nachama Wilker, *CRG Says No to Patenting Life Forms*, 8 GENEWATCH (No. 2), July 1992, at 8.

51. Golin, *supra* note 4, at 16.

52. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE 3 (1989) [hereinafter PATENTING LIFE]. *See generally* JACK DOYLE, ALTERED HARVEST 300-21 (1985) (discussing the power of patents in the field of commercial biotechnology).

53. B.J. Spalding, *Patent Patterns in Biotech*, 9 BIO/TECH. 817, 817 (1991).

54. PATENTING LIFE, *supra* note 52, at 37. The Patent and Trademark Office is a part of the U.S. Department of Commerce. *Id.*

tution[55] and federal patent legislation.[56] Patents are designed to encourage innovation by rewarding the inventor with a monopoly for a limited time period; however, patent protection does not grant the inventor any affirmative right to use the invention.[57] Use may be regulated by federal, state, or local law,[58] or may be limited by a prior unexpired patent.

To receive a patent, the invention must meet the criteria outlined by the Patent Act.[59] These criteria include: subject matter and utility, novelty, nonobviousness, enablement, and deposit.[60] The subject matter requirement pertains to any new and useful invention or any new and useful improvement of an existing invention.[61] It may be a machine, a manufacture, or a composition of matter.[62] The novelty provision requires that the invention not be previously known or used by others in the United States and that it not have been patented or described in any publication of a foreign country.[63] The nonobviousness provision

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55. "The Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . ." U.S. CONST. art. I, § 8, cl. 8.

56. Patent Act of April 10, 1790, ch. 7, 1 Stat. 109; Act of Feb. 21, 1793, ch. 11, 1 Stat. 318; Act of July 8, 1870, ch. 230, 16 Stat. 198; Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified as amended at 15 U.S.C. § 1071 and 35 U.S.C. §§ 1-293 (1988)); Plant Patent Act of 1930, 35 U.S.C. §§ 161-164 (1988); Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321-2372 (1988).

57. PATENTING LIFE, *supra* note 52, at 37; *see* Barton, *supra* note 13, at 40. The patent system attempts to encourage innovation by providing a limited monopoly to protect the inventor from imitation. This protection encourages investment in further research and development. *Id.*

58. PATENTING LIFE, *supra* note 52, at 37.

59. 35 U.S.C. §§ 101-212 (1988).

60. *Id.* §§ 101-103, 112, 114; *see infra* part IV (discussing the Patent Act's application to transgenic organisms).

61. § 101. Inventions patentable

> 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.

Id. § 101.

62. *Id.*

63. § 102. Conditions for patentability; novelty and loss of right to patent

> A person shall be entitled to a patent unless—
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . . .

Id. § 102.

requires that the invention be sufficiently different from the prior art, which includes all prior inventions and publications, so that it would not have been obvious to a person who has ordinary skill in the field.[64] The enablement provision requires that the written description of the invention be detailed enough so that a person skilled in the field can make and use the invention.[65] The deposit requirement compels the patent applicant to provide a model of the invention or the active ingredients and specimens for inspection and experimentation if they are requested by the Commissioner via the patent examiners.[66] Therefore, patents can apply to living organisms and their genes only if they meet the essential requirements of being new, useful, and nonobvious.[67]

Patents are expected to stimulate growth and development of the biotechnology industry. According to one commentator, the genetic engineering industry would have grown regardless of the Supreme Court decision in *Diamond v. Chakrabarty*, allowing the patenting of a genetically engineered bacterium, but there is no

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64. § 103. Conditions for patentability; non-obvious subject matter

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

Id. § 103. The "person having ordinary skill in the art" is much like the reasonable person standard; it is a construct determined by the patent examiner on a case-by-case basis.

65. § 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Id. § 112.

66. § 114. Models, specimens

The Commissioner may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention.

When the invention relates to a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment.

Id. § 114.

67. Barton, *supra* note 13, at 42.

question that now it will grow much faster.[68] In fact, the recent acceleration of research in biotechnology has been attributed to the Chakrabarty patent.[69] The American biotechnology industry amassed revenues of $762 million in 1988 with export sales of $215 million.[70] These revenues were approximately double those earned in 1987 and quadruple those earned in 1986.[71] Growth of the industry is projected at forty billion dollars within the next ten years.[72] Patent protection is considered critical to stimulating innovation, growth, and competitiveness of the American biotechnology industry because patents have symbolic value in attracting the investment capital, including foreign investment, that the industry requires to survive.[73]

III. Recent Developments in Patenting of Transgenic Animals

The judicial, executive, and legislative branches of the federal government all have addressed the patenting of transgenic animals. Accordingly, the issue has been the subject of judicial and administrative decisions, proposed legislation, and scholarly literature. In *Diamond v. Chakrabarty*, the Supreme Court held, in a five-to-four decision, that a genetically engineered microorganism is patentable subject matter under § 101, as a "manufacture" or "composition of matter."[74] This holding had the practical effect of greatly expanding both subject matter patentable under § 101, and protection granted to the inventor of a new biological product.[75] Prior to the *Chakrabarty* decision, patent protection for biological materials was barred by the long-standing belief

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68. Kass, *supra* note 8, at 129.

69. Hutz, *supra* note 21, at 30.

70. Baechtold et al., *supra* note 19, at 141.

71. *Id.*

72. *Id.*

73. Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 Rutgers Computer & Tech. L.J. 1, 22 (1991). In addition, strong patent protection may be necessary to "level the playing field" between United States and foreign biotechnological concerns. *Id.*

For more information on international trade in biotechnology, see I.L. Fuller, *Intellectual Property Rights Associated with Biotechnology—An International Trade Perspective*, 16 AIPLA L.J. 529 (1988-89); Susan H. Griffen, *Exporting Biotechnology: The Pitfalls*, 16 AIPLA L.J. 542 (1988-89).

74. *Chakrabarty*, 447 U.S. at 309 (1980).

75. Hutz, *supra* note 21, at 32.

that living organisms and cells were unpatentable as products of nature.[76] Even after the decision in *Chakrabarty*, three significant legal limitations upon the patenting of living organisms remained: disclosure requirements for enablement; continuing product of nature rejections; and consistency of human life patents with constitutional rights and freedoms.[77] Despite these limitations, *Chakrabarty* opened the door for patenting of transgenic animals.

On April 7, 1987, the Commissioner of the Patent and Trademark Office, Donald J. Quigg, released a statement that the PTO will "examin[e] claims directed to multicellular living organisms, including animals."[78] The statement also included

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76. Eisenberg, *supra* note 16, at 187; *see infra* notes 114-20 and accompanying text (discussing the product of nature doctrine).

77. Peter B. Maggs, *New Life for Patents:* Chakrabarty *and* Rohm & Haas Co., 1980 SUP. CT. REV. 57, 66. Maggs considers the Supreme Court's decision in *Chakrabarty* a sharp retreat from its uniform anti-patent approach of preceding years. *Id.* at 72. In preceding opinions, the Court had suggested that the question of broadening patent scope should be left to Congress. *Id.* at 57.

78. 1077 OFFICIAL GAZETTE PAT. & TRADEMARK OFF. 24 (Apr. 21, 1987) [hereinafter Quigg Statement]. This statement, dated April 7, 1987, is signed by Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks. The complete text of the statement reads:

> Animals — Patentability
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> A decision by the Board of Patent Appeals and Interferences in *Ex parte Allen*, [2] USPQ[2d 1425] (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.
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> The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Brogdex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941).
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> A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the

the provision that a "'nonnaturally occurring manufacture or composition of matter—a product of human ingenuity' . . . will not be rejected . . . [as] nonstatutory subject matter."[79] Biotechnology companies and some patent attorneys hailed Quigg's administrative decision as a welcome and logical extension of existing patent law.[80] However, the PTO's seemingly innocuous bureaucratic notice provided the clear signal that moral, social, and legal issues concerning biotechnology could no longer be ignored.[81] According to Jeremy Rifkin, President of the Foundation on Economic Trends and perhaps the most vocal opponent of transgenic animal patents, "[i]n one regulatory stroke, the Patent Office reduced the entire animal kingdom to the lowly status of a commercial commodity, indistinguishable from electric toasters and automobiles."[82]

The 1987 PTO statement officially allowed patent applications to be filed for genetically engineered animals.[83] By 1990, more than seventy-five patent applications for multicellular living animals were pending.[84] The backlog has created an estimated seven-year delay from patent application filing date to probable patent issue date.[85] Nevertheless, the seventeen-year exclusive

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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. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter. *Id.*

79. *Id.*

80. Dresser, *supra* note 43, at 399.

81. *Id.* at 400.

82. PATENTING LIFE, *supra* note 52, at 125.

83. Quigg Statement, *supra* note 78.

84. Marsha L. Montgomery, Note, *Building a Better Mouse—and Patenting It: Altering the Patent Law to Accommodate Multicellular Organisms*, 41 CASE W. RES. L. REV. 231, 232 (1990).

85. Greenlee, *supra* note 41, at 134.

right begins with the date of issuance of the patent, not the filing date of the application.[86]

Despite the delay, the Patent and Trademark Office issued the first patent for a transgenic animal, the Harvard mouse, in 1988.[87] The patent was for a non-human mammal[88] with an inserted rDNA sequence containing an activated human cancer gene that renders the animal more susceptible to malignant tumors.[89] This transgenic animal could be used as an experimental model for human cancers because significant numbers of the transgenic mice develop a type of breast cancer within a few months.[90] DuPont, the patent licensee, currently sells "Oncomice" for $100 per mouse.[91]

Most of the debate over the PTO statement has taken place in Congress and in legal academia; however, one battle was

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86. Interview with William O. Moeser, Adjunct Professor, Vermont Law School, in South Royalton, Vt. (Feb. 1992) [hereinafter Moeser Interview].

87. U.S. Patent No. 4,736,866 (Apr. 12, 1988). Copies of patents can be obtained from the Commissioner of Patents and Trademarks, Washington, D.C. 20231. The inventors of the Harvard mouse filed for a European patent in addition to their American patent. The European Patent Office ("EPO") in Munich initially rejected the Harvard mouse patent application in 1989, but after three years of deliberation the EPO granted the inventors the first European patent for a transgenic animal. *Mouse Wins Patent as EC Law Takes Shape*, 21 CHEMISTRY & INDUS. 780 (London 1991). Animal rights groups vowed to fight the EPO decision. Roger Highfield, *Patent for Cancer Mouse Starts Row*, THE DAILY TELEGRAPH (London), Oct. 16, 1991, at 10.

Bulgaria, Hungary, and Romania also permit the patenting of animals. A. ANN SORENSEN, ANIMAL PATENTS: AGRICULTURE'S PERSPECTIVE 2 (1987). Canada does not permit patenting of plants or animals. *North American Trade Pact, Good News for Drug Firms, Not for Agriculture*, 12 BIOTECH. NEWSWATCH at 14 (Sept. 7, 1992).

88. In general, a mammal is an animal possessing the following combination of characteristics: four-chambered heart, endothermy or warm-bloodedness, insulating layer of hair or fur, differentiated teeth, behavior modifiable by experience, embryonic development in the mother's uterus, and offspring nourished by milk. KEETON & GOULD, *supra* note 6, at 1161-62.

89. *Europe Shuns Transgenic Animals*, 123 NEW SCI., July 8, 1991, at 28.

90. *Id.* As models for oncogenesis, the onset of cancer, and diseases, transgenic mice are considered to provide a better approach to laboratory study than cell cultures, the traditional test-tube studies. Jaenisch, *supra* note 39, at 1470.

91. Nigel Hawkes, *Patent Granted for Cancer Mouse*, THE TIMES (London), Oct. 15, 1991, *available in* LEXIS, Nexis Library, INTL File. Regular laboratory mice are sold for approximately $1.00 per mouse. The mice were probably given the catchy tradename Oncomice because "onco" is the prefix that generally denotes cancer. *Id.*

initiated in court.[92] In 1989, the Animal Legal Defense Fund ("ALDF") and other interest groups challenged the legality of the PTO statement signed by Commissioner Quigg.[93] In *Animal Legal Defense Fund v. Quigg*, ALDF argued that the rule was promulgated without public notice and comment, and that it was in excess of PTO's statutory authority. ALDF's main substantive argument was that neither *Chakrabarty* nor Congress expressly authorized the patenting of animals.[94] The U.S. District Court for the Northern District of California dismissed the case for lack of standing, but the district court did state that the action did not raise the question of whether any actual animal patents issued pursuant to *Ex parte Allen*[95] and *Chakrabarty* exceed the PTO's authority under § 101.[96] The court considered it an important question and acknowledged sensitivity to its possible ramifications, but the court also stated that it had no opportunity to decide the question.[97]

In 1991, ALDF appealed the district court's dismissal of the complaint. The U.S. Court of Appeals for the Federal Circuit affirmed the lower court's decision on the basis that the appellants had failed to allege facts sufficient to meet constitutional standing requirements.[98] As a result, no court has ever considered the merits of the case or the important question considered, but not decided, by the district court in *Quigg*.[99] At present, commentators are split as to whether the PTO exceeded its

92. David Burke, Note, Animal Legal Defense Fund v. Quigg: *Renewed Challenge to Animal Patents*, 59 UMKC L. REV. 409, 409 (1991).

93. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728 (N.D. Cal. 1989), *aff'd*, 932 F.2d 920 (Fed. Cir. 1991).

94. Burke, *supra* note 92, at 432.

95. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (P.T.O. Bd. Pat. App. & Int. 1987) (non-transgenic polyploid oysters properly rejected on obviousness grounds, improperly rejected on living entity grounds).

96. *Quigg*, 710 F. Supp. at 732.

97. *Id.*

98. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 939 (Fed. Cir. 1991).

99. No further appeal has been filed by ALDF or any of the other interest groups. Interview with Steven Wise, President, Animal Legal Defense Fund, in Boston, Mass. (Apr. 1993).

authority in deciding that transgenic animals are patentable subject matter.[100]

IV. LEGAL ARGUMENTS FOR AND AGAINST PATENTING OF TRANSGENIC ANIMALS

Some observers believe that biotechnology should not be forced to fit the parameters and requirements of the patent law, but neither should patent law be butchered to meet the new demands of biotechnology.[101] Many patent attorneys, however, believe there is no need to change the legal principles relating to intellectual property to accommodate biotechnology inventions.[102]

Evaluating the legal arguments for and against the patenting of transgenic animals invites the examination of the statutory guidelines for patents as they pertain to biotechnology, and other legislation addressing animals. Statutory construction must begin with the language of the statute.[103] As the majority in *Chakrabarty* noted, the words in the statute should be given their "ordinary, contemporary, common meaning."[104] Furthermore, the judiciary should not read into the statute limitations and conditions that Congress did not express.[105] Accordingly, each criterion of patentability is considered individually.

A. Subject Matter and Utility

To meet the subject matter and utility requirement under § 101 of the Patent Act, the invention can be any new and useful process, machine, manufacture, or composition of matter, or any

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100. *Compare* Elizabeth J. Hecht, Note, *Beyond* Animal Legal Defense Fund v. Quigg: *The Controversy over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1061 (1992) (PTO usurped Congress' responsibility, and thus, exceeded its statutory grant of authority) *with* Burke, *supra* note 92, at 435 (PTO decision was a logical and legal extension of existing judicial interpretations of the patent statutes).

101. *See, e.g.*, Burk, *supra* note 73, at 85.

102. *See, e.g.*, Baechtold et al., *supra* note 19, at 164; R.S. CRESPI, PATENTS: A BASIC GUIDE TO PATENTING IN BIOTECHNOLOGY (1988).

103. *Chakrabarty*, 447 U.S. at 308.

104. *Id.* (quoting Perrin v. United States, 444 U.S. 37, 42 (1979)). Chief Justice Burger wrote the opinion for the majority, which was joined by Justices Stewart, Blackmun, Rehnquist, and Stevens.

105. *Id.*

new and useful improvement thereof.[106] Generally, subject matter is the most difficult requirement for patentability. In *Chakrabarty*, the five-justice majority interpreted "manufacture" to mean "the production of articles . . . from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."[107] "Composition of matter" was defined as all compositions of two or more substances and all composite articles whether the result of chemical union or mechanical mixture of gases, fluids, powders, or solids.[108] The majority also found that the comprehensive word "any" modifying "manufacture" and "composition of matter" indicated that Congress expected the patent laws to be given broad scope.[109]

The majority in *Chakrabarty* stated that the relevant legislative history supported its broad construction of the statutory language.[110] Specifically, the majority looked to the philosophy of Thomas Jefferson, the drafter of the 1793 Patent Act, that "'ingenuity should receive . . . liberal encouragement.'"[111] In addition, the majority relied on committee reports that accompanied the 1952 recodification of the patent laws.[112] These committee reports supplied what has become the crucial language relied upon by proponents of transgenic animal patents: statutory subject matter was intended to include "'anything under the sun that is made by man.'"[113]

The majority did, however, recognize that § 101 is not limitless in its scope, even under its rather broad construc-

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106. 35 U.S.C. § 101 (1988); *see supra* note 61 (text of provision).

107. *Chakrabarty*, 447 U.S. at 308 (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931)).

108. *Id.* (quoting Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957) (citing 1 A. DELLER, WALKER ON PATENTS § 14, at 55 (1st ed. 1937))).

109. *Id.*

110. *Id.*

111. *Id.* at 308 (quoting 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871)).

112. *Id.* at 309 (citing S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)).

113. *Id.* at 309 (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)). However, this phrase could be viewed as a mere rhetorical flourish and not a legal determinant. Moeser Interview, *supra* note 86.

tion.[114] The Court acknowledged that the subject matter provision does not encompass discoveries such as laws of nature, physical phenomena, and abstract ideas.[115] For example, neither a new mineral nor a new plant found in the wild, nor Newton's law of gravity, would be patentable subject matter.[116] These discoveries are not patentable because they are considered manifestations of nature free to all people, and as such cannot be reserved exclusively to any one individual.[117] This concept provides the foundation for rejecting products of nature.

In construing the Patent Act, the majority held that the microorganism in question, a genetically engineered bacterium, "qualifies as patentable subject matter."[118] The majority asserted that the patentee, Chakrabarty, had produced "a new bacterium with markedly different characteristics from any found in nature."[119] In essence, the bacterium was not a product of nature but a product of human ingenuity.[120] Therefore, the majority found that Chakrabarty's claim satisfied the subject matter requirement as "a nonnaturally occurring manufacture or composition of matter" and could not be rejected as a previously unknown natural phenomenon.[121]

Justice Brennan, writing for the four dissenting justices, analyzed the issue differently.[122] He would have held that Congress, in enacting the patent legislation, never intended to grant monopolies on living organisms. He contended that the majority had misread the applicable legislation,[123] considering that Chief Justice Burger admitted the popular conception, even

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114. *Id.*

115. *Id.* The Court also cites Parker v. Flook, 437 U.S. 584 (1978), and Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), as support for this proposition.

116. *Id.*

117. *Funk Bros. Seed Co.*, 333 U.S. at 130.

118. *Chakrabarty*, 447 U.S. at 309.

119. *Id.* at 310.

120. *Id.* at 309.

121. *Id.*

122. *Id.* at 318 (Brennan, J., dissenting).

123. *Id.*

among advocates of agricultural patents, that living organisms were unpatentable.[124]

Similar to Chief Justice Burger, Justice Brennan cautioned the courts to be careful not to extend patent protection any further than Congress intended.[125] Courts should be cautious when Congress has not foreseen the technology or the concerns it raises, but courts should be even more cautious when asked to extend patent rights into areas Congress has foreseen and considered, but has not resolved.[126] Justice Brennan also asserted that it was the proper role of Congress, not the Supreme Court, to broaden or narrow the reach of the patent laws, especially where the invention sought to be patented raises issues of public concern.[127]

The *Chakrabarty* majority rejected petitioner Diamond's two arguments as unpersuasive.[128] Diamond first argued that the enactment of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 indicated congressional understanding that living organisms were not encompassed by the terms "manufacture" and "composition of matter."[129] The Plant Patent Act ("PPA") authorized patent protection for asexually reproduced plants.[130] The Plant Variety Protection Act ("PVPA") authorized similar protection for sexually reproduced plants.[131] Diamond also argued that microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes patent protection because genetic engineering was unforeseen when Congress enacted § 101.[132]

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124. *Chakrabarty*, 447 U.S. at 319 n.1 (Brennan, J., dissenting); *see id.* at 311-12 & n.8 (admission by majority).

125. *Id.* at 319 (Brennan, J., dissenting).

126. *Id.* at 319-20 n.2 (Brennan, J., dissenting).

127. *Id.* at 322 (Brennan, J., dissenting).

128. *Id.* at 310.

129. *Id.* at 310-11.

130. 35 U.S.C. § 161 (1988). The Plant Patent Act grants patents to the inventor of distinct and novel asexually reproduced plants. Hutz, *supra* note 21, at 30. Distinctiveness is shown by identifying a unique and visually observable characteristic, such as color, shape, size, foliage, or resistance to disease, temperature, or drought. *Id.*

131. 7 U.S.C. § 2402(a) (1988). The Plant Variety Protection Act authorizes the grant of certificates with exclusive rights for 18 years to developers of novel varieties of sexually reproduced plants. Hutz, *supra* note 21, at 30.

132. *Chakrabarty*, 447 U.S. at 314.

Justice Brennan found the relevant legislative history to be the plant patent legislation. According to Justice Brennan, Congress addressed the general problems of patenting living inventions when it drafted and enacted the plant patent legislation.[133] Consequently, he accepted Diamond's first argument. Justice Brennan interpreted the plant legislation to indicate congressional understanding that § 101 does not encompass living organisms.[134] He reasoned that if "newly developed living organisms not naturally occurring" had been patentable subject matter under § 101, then new plant varieties could have been patented without the necessity of the PPA and the PVPA.[135] The majority forced itself into the untenable position of maintaining that Congress not once but three times enacted needless legislation.[136] Furthermore, Congress had chosen carefully limited language in granting patent protection for some types of living inventions while excluding others.[137] Specifically, Congress expressly excluded bacteria, fungi, and first generation hybrids from the protection of the PVPA.[138] Therefore, Brennan concluded that the majority of the Court was extending the patent system to cover living organisms even though congressional belief was to the contrary, at least at the time of enacting the PPA and the PVPA.[139]

The original framers of the Patent Act did not and could not have foreseen many later inventions and technologies. Therefore, many proponents of transgenic animal patents, including the five justice majority in *Chakrabarty*, advocate that patents on the processes and products of genetic engineering should not be prohibited merely because the framers could not have foreseen the development of modern biotechnology. Justice Brennan did not address this second argument.[140]

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133. *Id.* at 319 (Brennan, J., dissenting).

134. *Id.* at 320 (Brennan, J., dissenting).

135. *Id.*

136. Application of Bergy, 596 F.2d 952, 1000 (C.C.P.A. 1979) (Miller, J., dissenting).

137. *Chakrabarty*, 447 U.S. at 319 (Brennan, J., dissenting).

138. 7 U.S.C. § 2402(a) (1988) ("The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) . . . shall be entitled to plant variety protection . . . .").

139. *Chakrabarty*, 447 U.S. at 321-22 (Brennan, J., dissenting).

140. *Id.* at 318-22 (Brennan, J., dissenting).

Despite the rejection of the petitioner's two arguments by the majority in *Chakrabarty*, some individuals and groups have continued to argue that animals are not patentable under strict statutory interpretation. The Animal Legal Defense Fund and other interest groups have argued that animals are not patentable subject matter because they are neither "manufactures" nor "compositions of matter" within the meaning of the Patent Act.[141] The ALDF has argued that when Congress delegated authority to the PTO to determine what constitutes patentable subject matter, it did not intend to confer the authority to characterize complex living animals as compositions of matter.[142] The PTO's authority is limited solely to the patenting of "things" that are machines or manufactures,[143] even "any*thing* under the sun."[144]

Dictionary definitions of "anything" and "thing" support the conclusion that "anything under the sun," dicta in *Chakrabarty*, was not meant to apply to animals.[145] Legally, "things" comprise "the objects of dominion or property as [distinguished] from 'persons.'"[146] In addition, a "thing" is defined as "a tangible object, . . . an inanimate object . . . [an] article[], [or] device[]."[147] "Anything" refers to "any object, event, fact, . . . a thing, no matter of what kind."[148] None of these definitions refers to animals; therefore, "anything under the sun" cannot be construed to encompass animals. In addition to legal and collegiate dictionaries, animals are not referred to as either manufactures or machines in modern literature, in legal, veterinary, or medical treatises, or in common everyday language.[149]

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141. Opening Brief for Appellants at 35, Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) [hereinafter Appellant Brief, ALDF v. Quigg]. In addition, the nature of organisms is fundamentally different from inanimate chemical compositions. Application of Bergy, 596 F.2d 952, 1001 (C.C.P.A. 1979) (Miller, J., dissenting).

142. Appellant Brief, ALDF v. Quigg at 32.

143. *Id.* at 28-29.

144. *See supra* note 113 and accompanying text (emphasis added).

145. Appellant Brief, ALDF v. Quigg at 28-29.

146. BLACK'S LAW DICTIONARY 1479 (6th ed. 1990). In addition, *Black's* considers things as non-person permanent objects that are perceptible through the senses, including real and personal property. *Id.* Things personal comprise all vegetable productions, including whole plants. *Id.* This definition does not mention animals or animal products.

147. WEBSTER'S NEW WORLD DICTIONARY 1478 (2d ed. 1984).

148. *Id.* at 62.

149. Appellant Brief, ALDF v. Quigg at 29.

The majority in *Chakrabarty* found that Congress, in enacting § 101, did not distinguish between "living" and "inanimate" things.[150] According to Dr. George Pieczenik, a scientist who served as amicus curiae in the *Chakrabarty* case, the distinction between living and non-living matter has no real meaning in relation to biotechnology.[151] The distinction has no real meaning because there is no single fundamental property, law of nature, or operating principle that distinguishes living from what society considers non-living matter.[152]

Generally, life is defined by a set of characteristics, including: cellular organization, ability to derive energy from sources in the environment, response to changes in environmental conditions, and capacity to reproduce.[153] All living organisms are chemically complex and highly organized; they use energy for development and reproduction.[154] Living organisms are also "programmed" by genes that direct metabolism, development, and reproduction, and which are acted upon by evolutionary forces.[155] According to current scientific knowledge and techniques, no non-living thing possesses all of these characteristics.[156]

Legal decisions, according to Dr. Pieczenik, should not be based on a distinction that has no practical significance in the affected subject area.[157] Despite this view, Secretary of Agriculture Hyde stated, in legislative history to the Plant Patent Act of 1930, that the patent laws only cover inanimate inventions.[158] Therefore, despite the lack of practical significance that some scientists place on the living/non-living distinction, some interpretations of the patent laws have been based on the distinction between life and non-life.

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150. *Chakrabarty*, 447 U.S. at 313.

151. Amicus Brief of Dr. George Pieczenik at 3, Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) [hereinafter Pieczenik Brief].

152. *Id.*

153. *Id.*

154. KEETON & GOULD, *supra* note 6, at 2.

155. *Id.* These evolutionary forces produce generational differences in living organisms. *Id.*

156. *Id.*

157. Pieczenik Brief, *supra* note 151, at 4 n.3.

158. *Chakrabarty*, 447 U.S. at 312.

The other factor under § 101 utility is usefulness.[159] The majority in *Chakrabarty* held that the bacterium in question would be useful in the treatment of oil spills; therefore, it met the utility requirement.[160] Similarly, transgenic animals are expected to have useful applications in biomedical research, agriculture, and pharmaceuticals; therefore, they will also meet utility. For example, the Harvard mouse will be used in breast cancer research. However, usefulness may be negated by extreme dangers that would result from the invention's use. The usefulness requirement generally does not incorporate the issue of safety unless the invention is so unsafe that it is considered to have no possibility of practical use.[161]

Congress has recognized this possibility and has excluded at least one form of otherwise patentable subject matter from patent protection.[162] In 1954, Congress prohibited the patenting of nuclear weapons technology[163] because it is an extremely dangerous technology with no beneficial uses.[164] According to Robert Merges, there is a "massive gulf" between nuclear weapons and recombinant DNA gene technology.[165] Recombinant DNA, unlike nuclear weapons, is expected to have many beneficial applications, and there is only speculation about the potential negative consequences.[166] Merges argues that if Congress really intended to exclude animals from § 101 coverage, then it would have expressly stated this intent in legislation, as it had done for nuclear weapons technology.[167] Still, individuals and groups in favor of restricting the scope of § 101 argue that rDNA technology and its resultant transgenic animals are the sources of tremendous environmental hazards that are not outweighed by their

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159. *See* 35 U.S.C. § 101 (1988) ("[a]ny new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof" (emphasis added)).

160. *Chakrabarty*, 447 U.S. at 305.

161. Hutz, *supra* note 21, at 33.

162. Dresser, *supra* note 43, at 404.

163. 42 U.S.C. § 2181(a) (1988).

164. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary*, 100th Cong., 1st Sess. 181-82 (1988) [hereinafter *Transgenic Animals*] (statement of Robert P. Merges).

165. *Id.*

166. *Id.*

167. *Id.* at 192.

potential benefits.[168] In addition, the benefits of transgenic animals may be just as unknown and speculative as their risks.

B. Novelty

Another requirement for patentability is novelty. The invention must not have been known, used, or described by others in the United States or abroad.[169] The criteria for determining whether a given subject matter is "new" under § 101 are the same as the criteria for determining whether that subject matter is "novel" under § 102.[170] The patentability of an invention derived from nature is judged, at least in part, by determining the novelty of that invention as compared to the prior art, or product of nature, from which the invention was derived.[171] An unknown compound or composition of matter merely discovered from nature would be rejected as a product of nature.[172] The discovery of a product of nature, although not patentable, may lead to an invention if the proper claim language is used.[173] Proper claims can describe a physical separation of the discovered compound from its natural surroundings or its means of production and activity.[174]

A long-standing doctrine in American patent law allows a purified form of a chemical to be patented if the chemical is found in nature only in an unpurified form.[175] Similarly, an animal whose DNA and genes have been altered or engineered may also be patentable because presumably the animal exists in nature only in an unaltered form. In *Chakrabarty*, the claimed invention was capable of changing the molecular structure of a previously known and isolated product of nature by the addition of rDNA, as opposed to discovering and extracting, by physical separation, a

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168. Karl Bozicevic, *Distinguishing "Products of Nature" from Products Derived from Nature*, 69 J. PAT. & TRADEMARK OFF. SOC'Y 415, 418 (1987); *see infra* notes 266-73 and accompanying text (discussing one environmental interest group's argument on release of transgenic organisms).

169. 35 U.S.C. § 102 (1988); *see supra* note 63 (text of provision).

170. Bozicevic, *supra* note 168, at 422.

171. *Id.*

172. *Id.* at 421.

173. *Id.*

174. *Id.*

175. Barton, *supra* note 13, at 42.

product of nature.[176] Thus, the genetically engineered bacterium was considered novel because no bacterium exists in nature with the capability of degrading multiple components of crude oil.

However, natural mutations, which are routinely discovered by researchers, should not be patentable, as they constitute products of nature. In fact, mutations can be an integral part of evolution.[177] It is generally very difficult for a patent examiner to determine whether the researcher's invention actually differs from the prior art, especially when the prior art may include mutant animals with the same properties as the claimed invention.[178] It is likely that both genotype, the type and sequence of the genes, and phenotype, the physical characteristics of the organism, will be the key features used to characterize the animal and the prior art, and used to aid in determining novelty.[179]

C. Nonobviousness

The third major requirement for patentability is nonobviousness. The nonobviousness requirement assures that the invention would not have been obvious to one skilled in the field. It requires the so-called "inventive leap."[180] Nonobviousness for biological products is generally determined by applying the three criteria established in the 1966 case, *Graham v. John Deere Co.*[181] First, the scope and content of the invention and the prior art is determined by assessing the chemical, physical, and functional characteristics of both the invention and the naturally occurring material.[182] Second, the differences between the claimed invention and the naturally occurring material are ascertained.[183] Third, it is determined whether the claimed invention would have been obvious to one of ordinary skill in the

176. Bozicevic, *supra* note 168, at 423.

177. *See* STRICKBERGER, *supra* note 1, at 464.

178. There is no convenient place to search for existing mutant animals; even scientific publications are inadequate. Moeser Interview, *supra* note 86.

179. Greenlee, *supra* note 41, at 137.

180. *See generally* 35 U.S.C. § 103 (1988); *see supra* note 64 (text of provision).

181. Graham v. John Deere Co., 383 U.S. 1 (1966); *see* Bozicevic, *supra* note 168, at 423.

182. Bozicevic, *supra* note 168, at 423.

183. *Id.* at 423-24.

field using existing knowledge and techniques at the time the invention was created.[184]

At present, the Patent and Trademark Office has granted at least one patent in which a gene has been transferred from one organism into an individual of another species—the Harvard mouse.[185] However, as gene transfers become more routine laboratory practices, each specific transfer may need to be more difficult or unusual to satisfy the nonobviousness requirement.[186] This is particularly true as the level of general expertise or ordinary skill in the field of biotechnology increases.

D. The Social Contract of Disclosure

Disclosure of the invention to the public is considered the quid pro quo from the inventor in return for the exclusive patent right from the government.[187] Disclosure embodies the requirements of description, enablement, and deposit under § 112 and § 114.[188] An invention must be adequately described in the patent application such that a person skilled in the field is enabled to make and use the invention.[189] In some cases, the patent examiner may require deposit of a model, specimen, or ingredients either at the Patent Office or a public depository.[190] The Animal Legal Defense Fund argues that because it is so difficult for a patent claimant to specify adequately an animal invention to meet the description and enablement requirements, Congress must not have intended animals to be patentable subject matter.[191]

Biological material, including animals, may not be reproducible from a written description.[192] In addition, the complexity of living organisms makes it difficult for patent examiners to

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184. *Id.* at 424.
185. Barton, *supra* note 13, at 40.
186. *Id.*
187. Bozicevic, *supra* note 168, at 420 & n.33.
188. 35 U.S.C. §§ 112, 114 (1988); *see supra* notes 65, 66 (text of provisions).
189. *Id.* § 112.
190. *Id.* § 114.
191. Appellant Brief, ALDF v. Quigg at 33-34.
192. Hutz, *supra* note 21, at 33.

determine novelty, nonobviousness, and enablement.[193] The difficulty arises because living organisms express different characteristics in different environments, and because both scientists and patent examiners have incomplete knowledge of biophysical and biochemical reactions.[194] As a result, it is often not possible to provide a sufficiently detailed, reproducible written description for a living organism.[195] If such inventions cannot be reproduced from the patent application, then those inventions fail the enablement requirement of § 112.

However, as scientific knowledge of genes and the mechanisms by which they work increases, § 112 may no longer pose a significant problem for inventors of transgenic animals. According to Dr. George Pieczenik, molecules of DNA are generally definable and enumerable chemical compounds.[196] In addition, compositions of matter, such as recombinant DNA, arguably remain chemically definable whether they exist inanimate in a test tube or function within a living cell.[197] Furthermore, living cells are identifiable and describable entities that can be distinguished by a combination of physical, chemical, and functional criteria.[198] Although these arguments were drafted to support the patenting of genetically engineered bacteria, they can be applied to animals also.

Critics of animal patents disagree with Dr. Pieczenik. According to the Council for Responsible Genetics, "the idea that a transgenic animal is an invention, e.g. a product of human ingenuity with definable and reproducible novel qualities, is based on an extreme oversimplification of the relation of genes to traits."[199] Each gene product can affect many traits and each trait in interest may be the result of many gene products.[200]

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193. OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS 246 (1981).

194. *Id.* at 246-47.

195. Gary M. Hoffman & Geoffrey M. Karny, *Can Justice Keep Pace with Science*, WASH. POST, Apr. 10, 1988, at B3.

196. Pieczenik Brief, *supra* note 151, at 8.

197. *Id.* at 9.

198. *Id.* at 12.

199. Newman & Wilker, *supra* note 50, at 8.

200. *Id.*

Subsequently enacted plant patent legislation used the same broad language as the Patent Act.[201] However, the plant patent legislation addressed the specific disclosure problems of patenting living organisms.[202] Plant patent applications were unable to meet the description and enablement requirements of § 112; as a result, separate requirements were enacted to allow patents on plants.[203] The description required in a plant patent application was reduced from "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use"[204] the invention to only "as complete as is reasonably possible."[205] Enablement is likewise not required if a specimen of the plant in question is kept at a public depository.[206] By analogy, Congress must enact separate legislation to authorize the PTO to grant transgenic animal patents and to address the similar description and enablement problems of transgenic animals.

Both the PPA and the PVPA were drafted to deal specifically with the problems of living plants; the Patent Act, on the other hand, was not designed to address the problems of living organisms, especially genetically engineered animals.[207] If living organisms were included under § 101, then it would have been unnecessary to enact legislation covering plants.[208] One response to this argument is that Congress did not express any intention that the PPA and the PVPA be the exclusive means of patent protection for plants. Accordingly, Congress believed the PPA was necessary to overcome the belief that plants were products of nature.[209] In summary, Congress intended to pro-

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201. *Chakrabarty*, 447 U.S. at 309.

202. *Id.* at 319 (Brennan, J., dissenting).

203. Appellant Brief, ALDF v. Quigg at 34.

204. 35 U.S.C. § 112 (1988); *see supra* note 65 (text of provision).

205. *Id.* § 162 ("No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible. The claim in the specification shall be in formal terms to the plant shown and described.").

206. Hutz, *supra* note 21, at 30. Despite the reduction of description and enablement obstacles, the PTO grants less than 100 plant patents per year. *Id.*

207. *Id.* at 32.

208. Nancy J. Linck, *Patentable Subject Matter Under Section 101—Are Plants Included?*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 489, 499 (1985).

209. *Id.* at 501.

vide alternative protection under the PPA to applicants unable to provide an enabling description for their plants.[210]

The arguments that the plant patent legislation was necessary to authorize the Patent Office to grant patents for plants and to address the enablement and description problems have been weakened by recent activity in the field of plant patents. To extend protection to identical subject matter under all three statutes—Patent Act, Plant Patent Act, Plant Variety Protection Act—would allow duplicative patents.[211] However, the Supreme Court has held that, when two statutes address the same subject, both must be given effect unless there is such a "positive repugnancy" that the statutes cannot coexist.[212] Applying this rule in *Ex parte Hibberd*,[213] the PTO's Board of Patent Appeals and Interferences held that the PPA and the PVPA do not restrict the scope of patentable subject matter under § 101.[214] Therefore, § 101 also covers plant material that is otherwise protectable under the plant patent provisions or the Plant Variety Protection Act.[215] The *Hibberd* case involved maize plants that were not altered with recombinant DNA technology.[216]

In an effort to address the description and enablement problems raised by inventions in the field of biotechnology, the PTO has outlined deposit requirements.[217] The Rules of Practice in Patent Cases now contain a section on Biotechnology Invention Disclosures.[218] At this time, transgenic animals may be covered by the definition of biological material, "material that is capable of self-replication either directly or indirectly."[219]

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210. *Id.* at 503.

211. *Id.* at 499.

212. United States v. Borden Co., 308 U.S. 188, 198-99 (1939).

213. *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. of Pat. & Int. 1985).

214. *Id.* at 445-46. The Board decision was based on language in *Chakrabarty* that neither the Plant Patent Act nor the Plant Variety Protection Act preempts § 101 of the general Patent Act. Reid G. Adler, *Can Patents Coexist with Breeder's Rights?*, 2 INT'L REV. INDUS. PROP. & COPYRIGHT L. 195, 202 (1986).

215. *Hibberd*, 227 U.S.P.Q. at 443.

216. Adler, *supra* note 214, at 202.

217. Hutz, *supra* note 21, at 33. The requirements are found in § 608.1(p)C of the Manual of Patent Examining Procedures. *Id.*

218. 37 C.F.R. §§ 1.801-.809 (1991).

219. *Id.* § 1.801.

However, transgenic animals are not expressly referred to in the provision.[220] Deposit is required only when access to such material is necessary to satisfy the statutory requirements for patentability under § 112.[221]

The following criteria must be met to comply with the statutory description requirement: deposit of the biological material or organism in a depository that can assure at least thirty-year storage,[222] access to the material by patent examiners while the application is pending, and ready accessibility to the public once the patent is granted.[223] These requirements may be adequate for bacteria or recombinant DNA sequences, but they are not adequate for multicellular animals. It is both impractical and prohibitively expensive to maintain depositories for transgenic animals unless deposit is limited to storage of frozen embryos.[224] Even if deposit were limited to embryos, significant technical problems concerning viability and reproducibility would remain.[225] Currently, no depositories are willing to accept animals for deposit due to prohibitive maintenance costs, possible adverse publicity, and impracticality of keeping samples alive for lengthy time periods.[226] In the case of the Harvard mouse, only the recombinant DNA was deposited.[227]

E. The Animal Difference

In summary, the decision in *Diamond v. Chakrabarty* resulted in the leap from the patenting of inanimate inventions to the patenting of genetically engineered living microorganisms. The biotechnology industry and the Patent Office accepted this leap

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220. Examples of biological material are "bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds." *Id.*

221. *Id.* § 1.802.

222. For example, the American Type Culture Collection, located in Rockville, Maryland, is a non-profit organization that has provided a patent depository service for organisms and other biological materials for more than 40 years.

223. Hutz, *supra* note 21, at 33.

224. O'Connor, *supra* note 42, at 616; Hoffman & Karny, *supra* note 195. An embryo is "[a] plant or animal in an early stage of development; generally still contained within the seed, egg, or uterus." KEETON & GOULD, *supra* note 6, at A33.

225. O'Connor, *supra* note 42, at 615; Hoffman & Karny, *supra* note 195, at 20.

226. O'Connor, *supra* note 42, at 615; Montgomery, *supra* note 84, at 249.

227. O'Connor, *supra* note 42, at 615.

and leaped again from the patenting of genetically engineered bacteria and newly developed varieties of plants to the patenting of transgenic animals. Even accepting that patenting of genetically engineered microorganisms and plants is legally permissible, there are nevertheless significant differences between multicellular animals and microorganisms and plants.

The differences between animals, plants, and microorganisms have been recognized in both science and law. Scientists classify animals, plants, and microorganisms in three different taxonomic kingdoms.[228] In addition, society in general has recognized these differences. Humans consider animals as different from plants and microorganisms, and clearly different from chemicals and inanimate inventions. Biochemically, physiologically, and behaviorally, animals are very different from microorganisms.[229] Unlike microorganisms, multicellular animals, especially mammals, are closely related to humans and, thus, share our ability to feel pleasure and pain.[230] In fact, ninety-nine percent of human DNA is identical to the DNA of chimpanzees and gorillas.[231]

As a result of this recognition, animals, unlike plants and microorganisms, have benefited from legislation and common law designed to promote their welfare.[232] For example, all fifty states have enacted some type of anti-cruelty statute designed to protect animals.[233] These statutes require civil and criminal

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228. Taxonomy is the branch of science that classifies organisms on the basis of their evolutionary relationships. KEETON & GOULD, *supra* note 6, at A44. Organisms are taxonomically classified in a hierarchy from kingdom to species based on degree of relationship among the organisms. *Id.* at 918. For example, organisms classified in the same species are closely enough related to reproduce; whereas, organisms in different kingdoms share very little in common. Kingdom Monera consists of the bacteria; Kingdom Plantae the plants; and Kingdom Animalia the animals. *Id.* at A1-A6.

229. Appellant Brief, ALDF v. Quigg at 29-30.

230. *Id.* at 30.

231. SUZUKI & KNUDTSON, *supra* note 38, at 322. The line between humans and other animals will become increasingly blurred as human genes are inserted into animals. Hugo A. Delevie, *Animal Patenting: Probing the Limits of US Patent Law*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 492, 498 (1992).

232. Appellant Brief, ALDF v. Quigg at 29-31.

233. Richard F. McCarthy & Richard E. Bennett, *Statutory Protection for Farm Animals*, 3 PACE ENVTL. L. REV. 229, 238 (1986); *see also* 4 AM. JUR. 2D *Animals* §§ 129-151 (1962) (explaining the liability for injuries to animals).

penalties to be imposed for improper treatment of animals.[234] Other federal legislation addresses animal welfare in transportation, slaughter, and experimentation.[235] In addition, the Endangered Species Act, Marine Mammal Protection Act, and international treaties were drafted for the protection of wildlife and its habitat.[236] Although some plants are covered by the Endangered Species Act, no such legislation has been enacted to protect microorganisms, possibly because microorganisms are considered more like inanimate chemical compounds than animals.[237]

V. POLICY CONCERNS AND PROPOSED LEGISLATION

Patenting of transgenic animals will affect scientific research, farmers, animal welfare, and the environment. In addition to these tangible effects, transgenic animal patents also raise moral concerns. Congress and scholars have struggled to address these issues in proposed legislation and commentary. To date, members of Congress and other interested parties have developed three basic approaches to resolving the legal issues and policy concerns.

First, Congress could overturn PTO policy, as expressed in Commissioner Quigg's statement, and ban and revoke transgenic animal patents. This option would resolve the legal debate raised by *Chakrabarty* and the Harvard mouse patent, but may do little to resolve the underlying policy issues surrounding genetic engineering and biotechnology. Although this approach is supported by Jeremy Rifkin and others who would like to stop genetic engineering altogether, it has been referred to in only one

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234. Jae H. Kim, Note, *Patent Law: Patenting Animal Life: Another Scapegoat for Small Interest Groups*, 42 OKLA. L. REV. 131, 143 (1989).

235. McCarthy & Bennett, *supra* note 233, at 236. The Live Stock Transportation Act, also known as the Twenty-Eight Hour Act, prohibits the transportation of animals for longer than 28 hours without unloading into pens for rest, water, and food. Live Stock Transportation Act, 45 U.S.C. §§ 71-74 (1988). The Humane Slaughter Act declares that the use of humane methods in slaughtering livestock prevents needless suffering. Humane Slaughter Act, Pub. L. No. 85-765, 72 Stat. 862, *amended by* Humane Methods of Slaughter Act of 1978, Pub. L. No. 95-455, 92 Stat. 1009 (codified at 7 U.S.C. §§ 1901-1906 (1988)). The Animal Welfare Act addresses registration and licensing of research facilities that engage in animal experimentation. Animal Welfare Act, 7 U.S.C. §§ 2131-2157 (1988).

236. Endangered Species Act, 16 U.S.C. §§ 1531-1544 (1988); Marine Mammal Protection Act, 16 U.S.C. §§ 1361-1407 (1988). *See generally* M.J. Bowman, *The Protection of Animals Under International Law*, 4 CONN. J. INT'L L. 487 (1989) (international wildlife protection treaties).

237. Linck, *supra* note 208, at 499.

piece of proposed legislation.[238] It is also possible that the court system could resolve the legal issues itself, if a party before the court could satisfy constitutional and statutory standing requirements to challenge the PTO policy or a transgenic animal patent.

Second, Congress could enact a moratorium on the granting of transgenic animal patents. A moratorium would allow Congress and the public time to consider the policy issues and to decide whether the benefits of patents are worth the risks. Moratoria have been proposed in virtually every legislative session since the PTO granted the Harvard mouse patent in 1987.[239] A moratorium approach would be especially appropriate because the federal government has failed to conduct a broad-scale inquiry into potential long-term social and environmental consequences of manipulating animal life, including the creation of human-animal hybrids.[240] Furthermore, the foundations for the federal biotechnology regulatory structure are laws not originally intended for regulating genetically engineered organisms and other products of biotechnology.[241] At least one commentator has concluded that the federal regulatory structure is an incomplete plan that is full of gaps, conflicts, and ambiguities.[242] A moratorium would not only allow consideration of the effects of genetic engineering and patenting, but would also allow an adequate regulatory scheme to be set in place.

Third, Congress could adopt the PTO policy and expressly allow for transgenic animal patents. Congress could also create

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238. A supplemental appropriations bill, H.R. 1827, was amended by Senator Hatfield to prohibit the use by the Patent and Trademark Office of appropriated funds for the patenting of genetically engineered or altered animals. Dresser, *supra* note 43, at 400 n.2; *see also* 133 CONG. REC. 13,914-15 (1987) (accompanying remarks by Sen. Hatfield). The amendment was passed by the Senate but was not adopted during conference committee debate. O'Connor, *supra* note 45, at 75.

239. This approach is also advocated by some interest groups overseas. The Green Group in the European Parliament pushed for a moratorium on patent legislation until the end of 1992 so that a committee could study the ethical, social, and ecological implications of patenting transgenic animals. Suzanne Perry, *Decision to Grant Patent on "Harvard Mouse" Won't Stop EC Debate*, THE REUTER LIBR. REP., Oct. 16, 1991, *available in* LEXIS, Nexis Library, INTL File.

240. Dresser, *supra* note 43, at 430.

241. *See generally* Gregory A. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491 (1987).

242. *Id.* at 528.

statutory adjustments to address patent application problems and problems that may result from the patents. This approach would modify the general patent law by creating farmer, researcher, and disclosure requirement exemptions patterned on the plant patent legislation. Bills adopting this compromise approach also have been introduced each year since 1987.[243]

This section first discusses the general implications of patenting transgenic animals and the moratorium approach. Then, the specific problems and the compromise approach are considered.

A. General Implications

The availability of patent protection has significant effects on the biotechnology industry. Patent lawyers consider patent protection important in the biotechnology industry because product research is expensive, but imitation, once the product is developed, is relatively easy.[244] The limited monopoly provided by the patent allows the developer of the product to recover her investment by preventing imitation and its resulting competition. The availability of patent protection is also likely to encourage innovation in biotechnology.[245] However, if patent protection were unavailable for transgenic animals, innovation would still occur because inventors could receive patents for the processes by which transgenic animals are created. In addition, even Rene Tegtmeyer, Assistant Commissioner for Patents, asserted in a congressional hearing that the availability of patent protection may accelerate genetic research, but its absence would not deter research.[246]

The commercialization of basic research discoveries in biotechnology and the availability of patent protection, however, have generated concern in the scientific community about the

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243. *See infra* notes 326-34 and accompanying text.

244. Barton, *supra* note 13, at 40. Patent protection is also important in the pharmaceutical industry for the same reasons. *Id.*

245. *Id.* at 41-42.

246. *Transgenic Animals*, *supra* note 164, at 17 (statement of Rene D. Tegtmeyer).

impact of patent law on the behavior of research scientists.[247] New ideas are most likely to be developed where scientific information and research materials are exchanged freely.[248] The patent system, however, tends to slow the exchange of information and materials because inventors delay publication of their research in scientific journals until after a patent application is filed.[249] Because publications are a portion of the prior art, publishing scientific results more than one year before filing the patent application would cause the invention to fail the novelty requirement.[250] Disclosure as required under the patenting process can delay disclosure to the scientific community by as much as two years.[251] The availability of patent protection, as a result, may adversely affect the behavior of researchers.

With respect to the environment, animals, and industry, the lack of federal regulation is troubling. According to Rebecca Dresser, the federal regulatory system does not adequately respond to the objections to animal patents.[252] Agencies such as the National Institutes of Health and the U.S. Department of Agriculture have conflicting roles as both promoters and financial supporters and as regulators of recombinant DNA research.[253] These conflicting roles raise questions about their ability to exercise appropriate oversight.[254] In addition, federal agencies have overlapping jurisdiction in some areas and explicit federal authority to regulate is lacking in other areas.[255] These other

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247. Eisenberg, *supra* note 16, at 230. Patent protection also raises the issue of whether the recipients of federal funding for research should also receive exclusive patent rights for the products they develop from that research. *See, e.g.*, David E. Korn, Note, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191 (1987).

248. Barton, *supra* note 13, at 40.

249. *Id.*

250. *Id.*

251. Eisenberg, *supra* note 16, at 207. Proponents of transgenic animal patents counter this statement with speculation that scientists would protect their inventions by trade secrecy, in the absence of patent protection, which would result in an indefinite delay of disclosure. Barton, *supra* note 13, at 40. *See generally* Korn, *supra* note 247.

252. Dresser, *supra* note 43, at 430.

253. *Id.*

254. *Id.*

255. *Id.*

areas include non-federally funded rDNA research and the environmental release of genetically engineered animals.[256]

Genetically engineered animals may also change the nature of the agricultural industry and, as a result, alter our food supply. The addition of genes for fecundity[257] into embryos could lead to increased reproduction in livestock.[258] These engineered embryos could assist biotechnology corporations in outcompeting already economically stressed family farms.[259] Although genetic engineering may help farmers create better breeds of livestock, it may also decrease the genetic diversity of the breeds. Decreased genetic diversity, in turn, may make livestock more susceptible to disease and less able to adapt to changing environmental conditions. In addition, the rapid exchange of genes between unrelated species may have unpredictable results and cause increased suffering in animals.[260]

The release of genetically engineered organisms is probably the most troubling of all biotechnology issues. During the early 1970s, some scientists began to express concern about the possible hazards of manipulating gene segments.[261] These hazards may affect the transgenic animal created. Transgenic animals, in turn, may affect genetic diversity of a given population with resulting effects on the environment. It is uncertain what effects a changed genotype will have on a phenotype and ecological stability. Two scientific commentators advise that "[u]ntil we have a better understanding of the extent of genetic exchange between distantly

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256. *Id.*

257. Fecundity is an ecological concept based on the number of offspring produced during a given period of time, as opposed to fertility, which is the physiological concept indicating an organism is capable of reproducing. CHARLES J. KREBS, ECOLOGY: THE EXPERIMENTAL ANALYSIS OF DISTRIBUTION AND ABUNDANCE 167 (3d ed. 1985).

258. Crossan, *supra* note 19, at 23.

259. This issue has been addressed in proposed legislation in the context of a farmer's infringement exemption. *See infra* part V.B.

260. PATENTING LIFE, *supra* note 52, at 133. The Animal Welfare Act of 1985 may provide a safeguard against some animal suffering, but its regulations do not apply to rodents or livestock, the majority of transgenic animals created. *Id.* However, the U.S. District Court for the District of Columbia found the USDA's interpretation of the Animal Welfare Act, excluding birds, rats, and mice, arbitrary and capricious, and it ordered reconsideration of ALDF's rulemaking petition to include these animals in its regulations. Animal Legal Defense Fund v. Madigan, 781 F. Supp. 797, 806 (D.D.C. 1992).

261. SUZUKI ET AL., *supra* note 24, at 327.

related species in nature, we ought to consider evolutionary 'boundaries'—areas of relatively limited genetic exchange—as at least provisional warning signs of potential danger zones for the casual transfer of recombinant genes between species."[262]

There seems to be little, if any, consensus on the environmental effects caused by transgenic animals. According to a 1987 report by the National Academy of Sciences ("NAS"), there is no evidence that unique hazards exist in the use of recombinant DNA techniques or in the movement of genes between unrelated organisms.[263] NAS considers the risks of introducing transgenic organisms into the environment to be the same as the risks encountered in introducing unmodified organisms or organisms modified by methods other than genetic engineering into the environment.[264] Therefore, NAS asserts that risk assessment should be based upon the nature of the organism and the environment rather than based upon the fact that it is a transgenic organism developed by genetic engineering.[265]

The National Wildlife Federation ("NWF"), on the other hand, is especially concerned with the possible long-term implications transgenic organisms—animals, plants, and microorganisms—may have on wildlife in the United States.[266] Many potentially patentable animals include those intended for release into the wild—such as transgenic fish, mussels, oysters, and clams—and those which may have contact with wild animals and their habitats—transgenic farm and laboratory animals.[267] Genetic engineering may cause long-term adverse consequences on the gene pools of both wild and domestic animals.[268] As a result, transgenic animals could potentially outcompete natural species, which may result in the extinction of natural species. Further-

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262. SUZUKI & KNUDTSON, *supra* note 38, at 265.

263. NATIONAL ACADEMY OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES 22 (1987).

264. *Id.*

265. *Id.* This would be an example of product-based regulation as opposed to process-based regulation.

266. *Transgenic Animals*, *supra* note 164, at 420 (statement of Dr. Margaret Mellon).

267. *Id.* at 421 (statement of Dr. Margaret Mellon).

268. *Id.* at 3 (statement of Mr. Synar). A gene pool is the aggregate of all the genes of all individuals in a population. KEETON & GOULD, *supra* note 6, at A35.

more, effects on the offspring of transgenic animals and future generations are still unknown.

NWF opposes patenting of transgenic animals primarily because there is little regulatory legislation addressing biotechnology and no single agency in control of the release of genetically engineered organisms into the environment.[269] Existing statutes either do not cover animals or are limited to a particular kind or use of an animal.[270] NWF advocates that researchers should not have the "carrot" of patents until the "stick" of regulation is established.[271] In other words, legal responsibility for releases into the environment, whether planned or accidental, should be considered and addressed by researchers and regulators,[272] prior to the granting of patents for transgenic organisms. NWF believes that the federal government's variety of ad hoc research and regulatory policies is not sufficient; a uniform policy addressing transgenic research and use is needed.[273] Until such policy is in place, interest groups will continue to challenge patent protection for transgenic animals.

In addition to legal arguments, many opponents of transgenic animal patents also rely on moral arguments.[274] For example, genetic engineering itself violates species integrity.[275] The species integrity argument has been attributed to Jeremy Rifkin and various religious organizations, including the National Council of Churches, the Synagogue Council of America, and the United States Catholic Conference.[276] In response to this argu-

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269. *Transgenic Animals*, *supra* note 164, at 421 (statement of Dr. Margaret Mellon).

270. *Id.* at 429 (statement of Dr. Margaret Mellon) (referring to Coordinated Framework for Regulation of Biotechnology (1986)).

271. Telephone Interview with Dr. Margaret Mellon, Director, National Wildlife Federation's Biotechnology Project (Sept. 1991).

272. Crossan, *supra* note 19, at 23. In addition to liability for planned and accidental releases of transgenic organisms, there also may be substantial liability for the products of biotechnology. *See, e.g.*, Joyce Brinton, *Biotechnology Licensing: Issues from the University Perspective*, 16 AIPLA Q.J. 479 (1988-89); Stephen R. Permut, *Biotechnology Law: Public Protection or Stifled Progress?*, 5 DEL. LAW. 26 (1986).

273. H.R. REP. NO. 888, *supra* note 42, at 28.

274. An extensive discussion of the moral arguments against the patenting of transgenic organisms is beyond the scope of this note. *See generally* Dresser, *supra* note 43; SUZUKI & KNUDTSON, *supra* note 38.

275. H.R. REP. NO. 888, *supra* note 42, at 60.

276. *Id.*

ment, the Office of Technology Assessment has asserted that "[t]here is no consistent or absolute rule that species are discretely bounded in any generally applicable manner."[277] Moreover, according to a presidential commission's report on ethical issues in medical research, species barriers were not an issue when tangelos were produced by hybridizing tangerines and grapefruits or when mules were produced by mating asses with horses.[278]

The analogy is also made that genetic engineering will affect species no more than has occurred with traditional selective breeding.[279] But genetic engineering is fundamentally different from selective breeding because in selective breeding each gene has coevolved with every other gene in the organism. This results in incremental changes generally at a rate on par with changes in the organism's environment.[280] Nevertheless, because scientists lack knowledge about the extent of natural genetic exchange or the effects one organism's genes will have in another organism, the species integrity issue deserves consideration and study. In addition to violating species integrity, genetic engineering spurred by the availability of patents may increase animal suffering.[281] The Office of Technology Assessment has admitted that the potential uses of patented products or techniques may cause animal suffering, but that it is not an adequate reason to deny patent protection.[282] Furthermore, production of new life forms simply for profit is morally offensive,[283] and patents involving human genes are inappropriate.[284]

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277. *Id.* (citing OFFICE OF TECHNOLOGY ASSESSMENT, TRANSGENIC ANIMALS 8-9 (1988) (footnote omitted)).

278. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SPLICING LIFE: A REPORT ON THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS 57 (1982). This commission was appointed in 1982 by President Carter at the urging of religious organizations. H.R. REP. NO. 888, *supra* note 42, at 60.

279. H.R. REP. NO. 888, *supra* note 42, at 61 (citing OFFICE OF TECHNOLOGY ASSESSMENT, TRANSGENIC ANIMALS 10 (1988)).

280. Newman & Wilker, *supra* note 50, at 9.

281. *Id.* at 61-62.

282. *Id.* at 62.

283. *Id.*; Newman & Wilker, *supra* note 50, at 9 (animals are inappropriate for patenting).

284. H.R. REP. NO. 888, *supra* note 42, at 63.

Theologians have attacked PTO policy, as found in the statement by Commissioner Quigg, because it equates "heaven-made creatures" with manufactured goods of the market place.[285] In addition, theologians also consider the policy a giant step down the slippery slope leading to the patenting of genetically altered humans and society's full assumption of god-like powers.[286] Genetic engineering also threatens to erode humanity's respect for the individuality and value of all forms of life.[287]

Furthermore, the use of human genes and characteristics in other animals raises the ethical dilemma of creating semi-human creatures.[288] Hybrids of humans and chimpanzees could perform simple tasks for humans,[289] and may have applications in medical research. At this time, however, most research has been limited to inserting one or a few human genes into bacteria or farm and laboratory animals. It has been argued that the transfer of a single human gene does not give the animal human characteristics.[290] The question of how many genes make an organism human is a difficult question to answer, especially since the DNA in humans and chimpanzees and gorillas is so similar.[291]

Equally difficult is the issue of whether patent ownership of human genes inserted into animals violates the constitutional mandates of the Thirteenth Amendment. Commissioner Quigg attempted to address this issue in advising inventors to incorporate the non-human limitation in their patent application claims.[292] Another troubling issue has resulted from the resurgence of fetal tissue research. "There is nothing in the present statutes, however, to prevent the patenting and sale of genetically modified human embryos for research and therapeutic

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285. GEORGE P. SMITH II, THE NEW BIOLOGY: LAW, ETHICS, AND BIOTECHNOLOGY 7 (1989).

286. *Id.*

287. *Beware the 'New Creationism,'* CHRISTIAN SCI. MONITOR, June 3, 1988, at 15.

288. 133 CONG. REC. 13,915 (1987).

289. Dresser, *supra* note 43, at 407. Chinese scientists have undertaken artificial insemination experiments in an effort to cross a human with a chimpanzee. KASS, *supra* note 8, at 150.

290. H.R. REP. NO. 888, *supra* note 42, at 63.

291. *See supra* note 231 and accompanying text.

292. Quigg Statement, *supra* note 78, at 24.

purposes. This is a development [that the Council for Responsible Genetics] would strongly oppose."[293]

One interesting response to applied technology patents was developed by Chet Fleming. He received a patent for a discorporation device that is used to keep a severed head alive.[294] Concerned about the potential misuse of discorporation experiments occurring in a few research laboratories, he wanted to encourage society to consider the potential impacts of discorporation and to debate openly its social, legal, and moral consequences.[295] Although Fleming did not plan to prevent the research for the term of his patent, he did require approval of at least two scientific review panels at the institution conducting the research as a part of his licensing agreements.[296] Fleming's action was not entirely effective. Not long after the patent was granted, the PTO decided to re-examine the patent application.[297] During May 1991, the U.S. Court of Appeals for the Federal Circuit declared the patent invalid for failing the nonobviousness requirement.[298]

It is possible that interest groups and concerned citizens could adopt Fleming's approach. They could receive patents for transgenic animals and, in effect, ban or restrict transgenic animal creation and use. However, this private regulation could be no more than a temporary solution since all patent rights for the animal would expire after seventeen years. At that time, both the transgenic animal and the techniques used to create the animal would be open to the public. In addition, because infringement is so difficult to detect, it is likely that private citizens would have great difficulty enforcing their prohibitions or restrictions. After *Animal Legal Defense Fund v. Quigg*,[299] it appears that only holders of animal patents and their licensees

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293. Newman & Wilker, *supra* note 50, at 9.

294. U.S. Patent No. 4,666,425: Device for Perfusing an Animal Head (1987). *See generally* CHET FLEMING, IF WE CAN KEEP A SEVERED HEAD ALIVE . . . : DISCORPORATION AND U.S. PATENT 4,666,425 (1987).

295. FLEMING, *supra* note 294, at xxvi-xxx.

296. *Id.* at xxviii.

297. Victoria Slind-Flor, *Patents Pending?: Lawyers, Inventors Battle over New Technologies*, NAT'L L.J., June 8, 1992, at 40.

298. *In re* Dis Corp., 937 F.2d 623 (Fed. Cir. 1991).

299. Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).

would be likely to have standing to challenge other such patents.[300]

According to Robert Kambic, the patent system is not the proper forum in which to debate genetic engineering.[301] He feels the injection of ethics and morality into the legal process of patent determination will cause uncertainty in the business and scientific communities and will result in economic losses.[302] "When it acts on animal patent applications, the Patent Office is in effect making public policy decisions with no public input. In a field with as far-reaching implications as genetic engineering, that should not be allowed to happen . . . ."[303]

Congress is the proper forum to debate the issues of genetic engineering and biotechnology, including patentable subject matter as mandated by the Constitution. The first moratorium bill, to allow time for this debate, was introduced in the House of Representatives in 1987 in response to the Harvard mouse patent.[304] This bill would have placed a two-year moratorium on patenting animals and would have revoked previously granted animal patents, including the Harvard mouse patent.[305] Charlie Rose, a sponsor of the bill, advised Commissioner Quigg that the Patent Office had been given no clear signal from Congress that unrestricted patenting of animals would be acceptable public policy.[306] Quigg seemed unconcerned as he responded that there

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300. Hecht, *supra* note 100, at 1059.

301. Robert B. Kambic, Note, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URB. L.J. 441, 464 (1988).

302. *Id.*

303. PATENTING LIFE, *supra* note 52, at 32.

304. H.R. 3119, 100th Cong., 1st Sess., 133 CONG. REC. 22,588 (1987).

305. *Id.* The revocation of an existing patent may raise a takings challenge. However, Congress when revoking patents for nuclear weapons inventions expressly provided that just compensation would be paid. *See* 42 U.S.C. § 2181(a) (1988) ("Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor.").

306. Letter from Charles Rose to Donald Quigg (Apr. 12, 1988), *reprinted in* Defendant Exhibit #1 at 42, Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728 (N.D. Cal. 1989).

is no public policy exemption in the patent laws.[307] Rose's moratorium bill was subsequently defeated in committee.[308]

In 1988, Senator Hatfield urged rescission of the PTO policy and introduced a bill virtually identical to the Rose bill.[309] In 1989, Representative Ben Cardin of Maryland introduced another moratorium bill.[310] This moratorium would have been in effect until the establishment of a proper regulatory review and approval process, that would take into consideration environmental, health, safety, and biomedical ethical standards.[311] In 1990, Senator Hatfield introduced another bill proposing a five-year moratorium on the patenting of transgenic animals.[312] Hatfield's 1991 moratorium bill covered patents on animals developed by traditional breeding as well as those developed by genetic engineering.[313] On April 28, 1992, Representative Cardin introduced a bill proposing a five-year moratorium essentially identical to Hatfield's 1991 bill.[314] A moratorium would be the best option at this time, especially in light of the lack of adequate regulation. Unfortunately, moratorium bills lack the political backing necessary to get them through the committee and subcommittee stages; furthermore, they are strongly opposed by the biotechnology industry.

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307. Letter from Donald Quigg to Charles Rose (Apr. 19, 1988), *reprinted in* Defendant Exhibit #1 at 43, Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728 (N.D. Cal. 1989).

308. 134 CONG. REC. 23,565 (1988).

309. S. 2111, 100th Cong., 2d Sess., 134 CONG. REC. 2676 (1988).

310. H.R. 3247, 101st Cong., 2d Sess. (1989).

311. Diana A. Mark, Comment, *All Animals Are Equal, but Some Are Better than Others: Patenting Transgenic Animals*, 7 J. CONTEMP. HEALTH L. & POL'Y 245, 266-67 (1991).

312. S. 2169, 101st Cong., 2d Sess., 136 CONG. REC. S1610-12 (daily ed. Feb. 26, 1990). This bill was supported by the following organizations: American Humane Association, Humane Society of the United States, Friends of Animals, Animal Welfare Institute, Humane Farming Association, National Wildlife Federation, National Farmers Union, The Foundation on Economic Trends, and others. 134 CONG. REC. S1612 (daily ed. Feb 26 1990); *see* S. REP. NO. 17, 102d Cong., 1st Sess. (1991).

313. S. 654, 102d Cong., 1st Sess. (1991); H.R. 1417, 102d Cong., 1st Sess. (1991); *see also Congress Considers "Boucher" Again*, 10 BIOTECH. L. REP. 549, 549-50 (1991); S. 1291, 102d Cong., 1st Sess. (1991); 137 CONG. REC. S7817 (daily ed. June 13, 1991) (five-year moratorium).

314. H.R. 4989, 102d Cong., 2d Sess. (1992); 138 CONG. REC. H2712 (daily ed. Apr. 28, 1992); *see also* 138 CONG. REC. E1117-19 (daily ed. Apr. 28, 1992) (accompanying remarks of Rep. Cardin). Senator Hatfield withdrew a similar bill to amend H.R. 2507, the NIH reauthorization bill, that would have prohibited the PTO from issuing animal patents for at least three years. 138 CONG. REC. S4723-24 (daily ed. Apr. 2, 1992).

B. Specific Problems

The specific problems of transgenic animal patents involve researchers, farmers, and disclosure. According to John Barton, Director of Stanford University's Law and High Technology Program, the progress of science would be served best if all academic and commercial laboratories were free to experiment with patented organisms.[315] He believes this freedom would increase incentives for follow-up research.[316] He further advocates that a monopolistic right on transgenic organisms and their offspring is stricter than necessary to promote innovation in biotechnology.[317] Without an exemption for research and experimentation, researchers may be prohibited expressly from use of the transgenic animal or practically by high royalties.

Acts constituting patent infringement are more complicated for living organisms than they are for inanimate inventions.[318] In addition, it is not clear whether patent claims for transgenic animals encompass the animals' offspring, or even if they ever should.[319] Under the property rule of increase, the offspring of animals belong to the owner of the mother.[320] However, under patent law, breeding or reproducing a patented animal generally would be considered unauthorized copying of the invention, or an infringement of the patent right.[321] A special exemption allowing free reproduction of patented animals is urged, despite the long history in the patent field of repugnance for compulsory licenses.[322] In the context of plants, this progeny infringement problem was settled by the plant patent acts.[323] Under the plant patent legislation, a farmer can replant seeds harvested from a protected variety.[324] However, the problem is unlikely

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315. Barton, *supra* note 13, at 43.

316. *Id.*

317. *Id.* at 45.

318. Robert L. King, Note, *The Modern Industrial Revolution: Transgenic Animals and the Patent Law*, 67 WASH. U. L.Q. 653, 655 (1989).

319. Barton, *supra* note 13, at 43.

320. JESSE DUKEMINIER & JAMES E. KRIER, PROPERTY 127-28 (2d ed. 1988).

321. Barton, *supra* note 13, at 43; King, *supra* note 318, at 656.

322. Baechtold et al., *supra* note 19, at 144.

323. Barton, *supra* note 13, at 43.

324. *Id.*

to be settled for long because some inventors are now protecting seeds under the Patent Act.[325]

Several commentators have proposed animal variety protection legislation based on the plant patent statutes.[326] After much debate in Congress, an infringement exception for researchers and family farmers was incorporated into the Transgenic Animal Patent Reform Act.[327] This bill was introduced in 1988 and reintroduced in 1989 by Representative Kastenmeier.[328] In addition to infringement exemptions, the bill also addressed depository requirements and codified part of the PTO policy

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325. *Id.*

326. *See, e.g.*, Paul T. Clark, *Animal Invention Protection*, 16 AIPLA Q.J. 442, 452-53 (1988-89); John M. Czarnetzky, Note, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327 (1988).

327. H.R. 4970, 100th Cong., 2d Sess. § 2 (1988).

328. H.R. 4970, 100th Cong., 2d Sess. (1988), *reintroduced as* H.R. 1556, 101st Cong., 1st Sess. (1989). The full text of the bill reads:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transgenic Animal Patent Reform Act."

SEC. 2. INFRINGEMENT OF PATENT.

Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(g)(1) It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.

"(2) Notwithstanding the provisions of paragraph (1), it shall be an act of infringement for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal.

"(3) For purposes of paragraphs (1) and (2)—

"(A) the term 'transgenic farm animal' means farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal; and

"(B) the term 'farm animal' means any animal used or intended for use as food or fiber."

SEC. 3. SPECIFICATION OF PATENT APPLICATION.

Section 112 of title 35, United States Code, is amended by adding at the end the following new paragraph:

"With respect to an invention involving biological material, the Commissioner may accept a deposit of biological material to satisfy any requirement of this section if made accessible under such conditions as the Commissioner may require."

SEC. 4. PATENTABILITY OF HUMAN BEINGS.

Section 101 of title 35, United States Code, is amended by adding before the period at the end a comma and the following: "except that human beings are not patentable subject matter."

H.R. REP. No. 888, 100th Cong., 2d Sess. 2 (1988).

statement concerning patenting of human beings.[329] The infringement exemption for farmers was patterned on the Plant Variety Protection Act's crop exemption provision.[330] The crop exemption was founded on the historical right of tenant farmers to reserve seed for the next year's crop,[331] which may not be as relevant in the context of transgenic animals.

In considering the Transgenic Animal Patent Reform Act, the House Committee on the Judiciary rejected an amendment by Representative Morrison that would have placed a two-year moratorium on issuance of patents for genetically altered animals.[332] Reasons for the rejection included: possible negative impacts of patent moratorium on biomedical research; possible negative repercussions on United States competitiveness due to availability of patent protection in other countries; possible bad precedent for patent law in denying patents based on moral, ethical, or regulatory concerns; and, ironically, that the amendment would have left too much discretion to the Commissioner of the Patent and Trademark Office.[333] The fact that Kastenmeier introduced the Transgenic Animal Regulatory Reform Act[334] to accompany the Transgenic Animal Patent Reform Act suggests that he wanted to keep the regulatory and patent issues separate.

One commentator considers congressional inability to reach consensus on the patenting issue and express approval of PTO action in some proposed bills a suggestion that Congress has acquiesced in PTO's interpretation of the patent legislation.[335] This commentator also asserts that neither the courts nor the PTO should become the political battleground for special interest groups seeking to advance their personal agendas; Congress alone is the proper forum for such debate.[336] Although a moratorium may be a better approach, compromise legislation would provide

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329. *Id.*

330. 7 U.S.C. § 2543 (1988). *See generally* Baechtold et al., *supra* note 19, at 162.

331. Baechtold et al., *supra* note 19, at 164.

332. H.R. REP. NO. 888, *supra* note 42, at 3 (bill also provides for a shorter moratorium period in the event federal regulatory legislation is passed).

333. *Id.*

334. H.R. 4971, 100th Cong., 2d Sess. (1988), *reintroduced as* H.R. 1557, 101st Cong., 1st Sess. (1989).

335. Burke, *supra* note 92, at 437.

336. *Id.*

more certainty in the field of biotechnology patents and would have a significantly better chance of being enacted.

CONCLUSION

While Congress has been "away," failing to regulate genetic engineering adequately, biotechnology companies and research scientists have been pushing the frontiers of science and patent law in an effort to stimulate their industry and enhance their profit margins. Legally, transgenic animals are not patentable subject matter. The Supreme Court in *Chakrabarty* incorrectly interpreted the patent legislation, including the plant patent acts, to allow genetically engineered bacteria to meet patentability as "manufactures" or "compositions of matter." This decision was extraordinary. The dissent in *Chakrabarty* discerned congressional intent that living organisms not be patentable as products of nature, and expressly excluding bacteria from the coverage of the Plant Variety Protection Act. Following the *Chakrabarty* decision, the Patent Office extended patent protection to transgenic animals, despite the legal and scientific distinctions between animals and microorganisms.

In addition to the legal errors, not everyone is convinced that an ailing American economy is an adequate reason to extend the protection of our patent system to transgenic animals. According to medical ethicist Leon Kass, "[t]here is something obviously and immediately disquieting about the human ownership of an entire living species, even one brought into being wth [sic] the partial aid of art."[337] This is especially true when so many of the policy concerns of genetic engineering have been left unresolved. If nothing else, transgenic animal patents should spur society to re-examine the social contract of patents and to determine whether the benefits of applied science are worth the risk of opening Pandora's box. This note agrees with the Council for Responsible Genetics that transgenic animal patents are "bad science, bad for science, bad for agriculture and ultimately detrimental to productive interactions between ourselves and with nature."[338]

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337. KASS, *supra* note 8, at 150.

338. Newman & Wilker, *supra* note 50, at 9.

In weighing the policy concerns of genetic engineering and the legal arguments favoring and opposing patenting of transgenic animals, Congress has three basic options. First, Congress can maintain the status quo both by allowing the Patent and Trademark Office to continue granting patents on virtually all forms of genetically engineered life, and by allowing the courts to uphold or reject challenges to the patents. Second, Congress can pass a moratorium on the granting of transgenic animal patents to provide time for the American public, as well as all three branches of the federal government, to weigh the benefits and risks of animal patents, including moral and social concerns. Third, Congress could draft legislation outlining its specific intent with regard to the problems of biotechnology patents. Whatever Congress decides about patenting transgenic animals, genetic engineering and biotechnology will remain controversial long into the next century.

POSTSCRIPT

On December 29, 1992, the Patent and Trademark Office ended a four and one-half year hiatus in the granting of patents for transgenic animals by issuing three new animal patents. The PTO granted a patent to Harvard researcher Dr. Philip Leder for another transgenic mouse.[339] This mouse is genetically engineered so that the males develop benign prostatic hypertrophy, or enlargement of the prostate gland.[340] A patent was also granted to Paulus J.A. Krimpenfort and Antonius J.M. Berns of Genpharm International for a mouse genetically engineered to lack a functional immune system.[341] Lack of immunity allows bone marrow and tissue transplants, including human tissue, without rejection; thus, the Genpharm mouse will be useful in studying AIDS and human cancers.[342] The third patent was granted to

339. U.S. Patent No. 5,175,383 (Dec. 29, 1992). Copies of patents can be obtained from the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

340. Robert Cooke, *3 Designer Mice Patented: Regulatory Logjam Broken*, NEWSDAY, Dec. 30, 1992, at 6. Prostate enlargement is a health problem common in human males age 50 or older. *Id.*

341. U.S. Patent No. 5,175,384 (Dec. 29, 1992). Copies of patents can be obtained from the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

342. Cooke, *supra* note 340, at 6. The GenPharm mouse will also be useful in organ transplantation studies. Richard Saltus, *Harvard Wins Gene-Altered Rodent Patents*, BOSTON GLOBE, Dec. 30, 1992, at 57, 59.

Thomas E. Wagner and Xiao-Zhuo Chen of the University of Ohio for a transgenic mouse containing the human interferon gene, which makes it more resistant to viral infections than normal, unaltered mice.[343] Both the Harvard mouse and the Ohio mouse were developed by microinjection of a human gene into mouse embryos.[344] Tests have demonstrated that the Ohio mice continually produce low levels of human interferon and that the human gene has been consistently passed on to offspring for fifteen generations.[345]

Nearly two hundred applications for patents of mice, fish, pigs, goats, and other animals are already on file.[346] Eighty percent of pending applications are for transgenic animals to be used in medical research and twenty percent for agricultural uses.[347] According to Dr. Margaret Mellon, Director of the National Wildlife Federation's National Biotechnology Policy Center, the PTO is "on the brink of issuing a cascade" of animal patents.[348] She also reiterated that animal patents should not be granted until an adequate regulatory system to address environmental risks is established.[349]

Although the European Patent Office also had granted a patent for the original Harvard mouse in 1991, the European Parliament recently passed an amendment barring the issuance of further animal patents.[350] The issuance of three additional animal patents by the U.S. Patent and Trademark Office does not indicate that legal, social, and ethical issues have been resolved.[351] Legislatures and courts in both the United States and the European Community must decide the following questions:

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343. U.S. Patent No. 5,175,385 (Dec. 29, 1992). Copies of patents can be obtained from the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

344. *Virus-Resistant Mouse to Receive a Patent*, N.Y. TIMES, Dec. 28, 1992, at D2.

345. *Id.*

346. Cooke, *supra* note 340, at 19. In June 1992, over 160 applications for animal patents were pending before the PTO. David Goldman et al., *Moratorium on Animal Patenting*, 4 J. PROPRIETARY RTS. (No. 6) 32 (1992).

347. Goldman et al., *supra* note 346, at 32.

348. Cooke, *supra* note 340, at 19.

349. *Id.*

350. Saltus, *supra* note 342, at 57.

351. Robert C. Cowen, *US Patents Issued for Two Transgenic Mice*, CHRISTIAN SCI. MONITOR, Dec. 30, 1992, at 9.

> Should [the patents] include the techniques used to produce a novel animal—effectively locking up a whole research field—or should they cover only the animal itself? Should farmers who buy transgenic animals have the right to breed them and sell their offspring? Or should the patentholder own the progeny? *Should patents be granted on animal life forms at all?*[352]

In addition, serious consideration must be given to the "ultimate limits of patent protection."[353] Therefore, congressional action is imperative and a moratorium on the further issuance of animal patents should be enacted immediately. Otherwise, the patenting of transgenic animals may become the usual course of business and bring with it a host of legal, environmental, health, and social problems we are not yet equipped to solve or resolve.

Terri A. Jones

352. *Id.* (emphasis added).

353. John S. Hudson, *Biotechnology Patents After the "Harvard Mouse": Did Congress Really Intend* Everything Under the Sun *to Include Shiny Eyes, Soft Fur and Pink Feet?*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 510, 511 (1992).