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Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law

CARRIE F. WALTER*

INTRODUCTION

Biotechnology is a field that is capable of modern-day miracles. Yet it is also a field that evokes a certain "Frankenstein Factor,"[1] because those who fail to understand the benefits of biotechnology fear that tampering with natural biology will result in creatures meant only for science-fiction novels. Research in biotechnology has been met with many well-grounded moral and philosophical disagreements, and it is true that biotechnological advances have progressed at a furious pace despite the uncertain nature of the science.[2] Accompanying the debates about biotechnology itself has been a debate about whether biotechnological advances such as transgenic[3] animals and human gene sequences should be patentable.

Patents stimulate the growth of industry, and the industry of biotechnology welcomes any patent protection it receives. Due to the controversial nature of patenting "life," or products intimately associated with life, it is necessary to pursue patent protection with solid grounding in patent law that is adequately suited to biological advances. The idea of an animal patent exploded onto the scene in 1988 when the Patent and Trademark Office ("PTO") issued its first animal patent to the transgenic mouse known as the "Harvard Mouse."[4] Heated debates ensued, but no clear policy was ever articulated regarding animal patents.

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* J.D. Candidate, 1998, Indiana University School of Law-Bloomington; A.B., 1995, Duke University. Thanks to Professor Fred Cate for his helpful comments on the first draft of this Note. Special thanks to my parents, Don and Cidney Walter, my brothers, Rich and John Walter, and my fiancé, Matt Cotter, for their constant encouragement, support, and unconditional love.

1. Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1643 (1993).

2. *See Revitalizing New Product Development from Clinical Trials Through FDA Review: Hearing of the Senate Comm. on Labor and Human Resources on S. 1477*, 104th Cong. 106 (1996) [hereinafter *Revitalizing New Product Development*] (statement of David A. Kessler, Commissioner, Food and Drug Administration, Department of Health and Human Services).

3. Transgenic animals are those which have been permanently altered by introducing foreign deoxyribonucleic acid ("DNA") into a fertilized mammalian egg. *See* BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 267-68 (2d ed. 1989).

4. *See* U.S. Pat. No. 4,736,866 (Apr. 12, 1988). The mouse was developed by Philip Leder (of Harvard University) and Timothy Stewart (of Genentech). The Harvard Mouse is a genetically engineered mouse which is highly prone to breast cancer. *See* Michael B. Landau, *Multicellular Vertebrate Mammals as "Patentable Subject Matter" Under 35 U.S.C. § 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?*, 97 DICK. L. REV. 203, 213-14 (1993).

Rather, the PTO accepted transgenic animals as patentable subject matter, essentially, by default.[5]

Now applications have been filed and patents have been granted for human gene sequences,[6] and the existing law regarding animal patents does not provide a solid foundation for dealing with this new innovation. Additionally, Canada recently rejected the patent application for the very Harvard Mouse that created the controversy over animal patenting in the United States,[7] again suggesting that the debate about animal patenting is, indeed, unresolved and anything but clear-cut.

This Note focuses on the legal and social concerns that surround the patenting of transgenic animals and human gene sequences, and suggests means of dealing with these problems while still allowing such biological advances to be patentable. Part I of this Note gives an explanation and synopsis of biotechnology and its uses. Part II describes the current state of patent law and the suitability of transgenic animals and human gene sequences to the current law. Part III considers the social and ethical concerns involved in biotechnology and its patenting. Finally, Part IV discusses the limits of patents on biotechnology and weighs the costs and benefits of allowing patents on biotechnology. The economic and social benefits will eventually far outweigh the costs involved with patenting transgenic animals and human gene sequences. Eventually, it will become apparent that the root of the debate about patents for biotechnology has less to do with patent law, and more to do with fundamental concerns about the science itself. Specialized commissions such as the National Bioethics Advisory Commission ("NBAC" or "Commission") are better suited to deal with the moral and ethical problems presented by experimentation with transgenic animals and human gene sequences. The role of the PTO has been, and should remain, to decide novelty and not morality.[8] Sufficiently novel discoveries in biotechnology should receive patent protection as discoveries in all other fields do.

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5. *See* Mark O. Hatfield, *From Microbe to Man*, 1 ANIMAL L. 5 (1995).

6. *See, e.g.*, U.S. Pat. No. 5,362,623 (Nov. 8, 1994) (granting patent for gene that, apparently, causes cancer); U.S. Pat. No. 5,220,013 (June 15, 1993) (granting patent application for a DNA sequence useful in the detection of Alzheimer's disease); U.S. Pat. No. 5,169,941 (Dec. 8, 1992) (granting patent application for DNA sequence useful in diagnosing multiple sclerosis).

7. *See Appeal Filed Against Rejection of "Harvard Mouse" Application*, BNA Pat. Trademark & Copyright L. Daily (Mar. 26, 1996), *available in* WESTLAW, 3/26/96 PTD d3. The Commissioner of Patents in Canada was not ready to extend the definition of invention to include nonhuman mammals primarily because of the inability to control reproduction. *See id.*

8. *See With Science Blooming, "Tough" Patent Fight Looms for Transgenic Animals*, BIOTECH. NEWSWATCH, Mar. 1, 1993, *available in* 1993 WL 2450029 [hereinafter *Science Blooming*].

I. DNA: BACKGROUND, USES, AND TECHNIQUES

Scientists knew that a long chain-like molecule existed which encoded genetic information as far back as the 1920s;[9] however, it took over thirty years to identify DNA.[10] Once discovered, however, the field of biotechnology exploded in a very short time. James Watson and Francis Crick discovered the DNA molecule in 1952,[11] and from there spawned a fascinating new field of experimentation and research which resulted in the blindingly fast-paced world of biotechnology. Better food, healthier livestock, less expensive pharmaceuticals, and more accurate laboratory testing techniques are only a few of the examples of the ways in which biotechnology can improve our world.[12] To better understand, a little background on the history and techniques of the field is necessary.

A. A Brief History and Description of DNA

In 1952, James Watson and Francis Crick discovered that the DNA molecule was shaped like a long, twisted ladder. They described this shape as a double helix.[13] The "sides" of the double helix are composed of deoxyribose (a sugar), and the "rungs" of the double helix are composed of bases, which pair together to bring the two sides together.[14] Four bases are found in DNA: adenine (A), cytosine (C), guanine (G), and thymine (T).[15] The bases combine with the deoxyribose to form "nucleotides."[16] The double helix of DNA is formed by joining two strands of nucleotides. The bases are always found as "complementary base pairs": adenine always pairs with thymine on opposite strands, and guanine always pairs with cytosine on opposite strands.[17] Both

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9. *See* John Richards, *International Aspects of Patent Protection for Biotechnology*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 433, 434-35 (1993).

10. DNA is the building block of genetic material. It was not until the 1950s that it was generally accepted that DNA was the carrier of genetic information; however, today DNA and its role in genetic coding are absolutely fundamental to biological thought. *See* ALBERTS ET AL., *supra* note 3, at 95.

11. *See* DAVID SUZUKI & PETER KNUDTSON, GENETHICS 24 (rev. & updated ed. 1990).

12. *See generally* Diana A. Mark, *All Animals Are Equal, but Some Are Better than Others: Patenting Transgenic Animals*, 7 J. CONTEMP. HEALTH L. & POL'Y 245 (1991); Thomas Traian Moga, *Transgenic Animals as Intellectual Property (or The Patented Mouse That Roared)*, 76 J. PAT. [& TRADEMARK] OFF. SOC'Y 511 (1994); Michael E. Sellers, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing "Animal Patents"*, 47 ARK. L. REV. 269 (1994); David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417 (1991).

13. *See* SUZUKI & KNUDTSON, *supra* note 11, at 24.

14. *See* ALBERTS ET AL., *supra* note 3, at 95.

15. *See id.*

16. A nucleotide is the combination of a sugar and a base. *See* Richards, *supra* note 9, at 435.

17. *See* ALBERTS ET AL., *supra* note 3, at 96.

strands of the double helix contain the same information because their structures are exactly complementary to each other. Each side of the DNA, therefore, creates a "template" for making the other side.[18] This structure suggests that information transfer is accomplished by a process where the two strands of the DNA molecule separate and serve as a template for creating the partner strand.[19]

The base pairs form a sort of alphabet that spells out the codes for amino acids. Every sequence of three base pairs signifies a codon. Each codon codes for an amino acid. Different combinations of amino acids, then, "spell" out the codes for different proteins.[20] Through complicated processes known as transcription and translation, this series of codons is "read" by the DNA in order to produce the desired proteins.[21] Changing any base pair disrupts the sequence, thereby changing the code, and has the potential to create completely different proteins from those originally encoded on the original DNA. Once this initial form and function of DNA was discovered, genetics technology moved incredibly fast.

By 1956, twenty-three chromosomes[22] had been discovered. By 1966, DNA's complete genetic code had been deciphered. And by 1972, the first recombinant DNA molecule had been created in a laboratory.[23]

B. Recombinant DNA Technology

Recombinant DNA ("rDNA") technology creates new DNA sequences by joining pieces of DNA from different organisms together.[24] Bacterial enzymes known as nucleases cut specific DNA sequences, then other enzymes known as ligases allow reconnection into severed DNA strands.[25] This splicing and recombination of the DNA sequences results in totally new DNA in the host organism or cell. The host cell or organism may then express the foreign DNA by creating the desired proteins that would not have been produced had the DNA not been altered.[26] This sort of technology allows the genes responsible for the production of such proteins as insulin or human growth hormone to be introduced into bacteria or other hosts so that the new host will produce the

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18. *See id.*

19. *See id.*

20. *See id.* at 102.

21. *See* Rochelle K. Seide & Frank A. Smith, *Intellectual Property Protection and Biotechnology*, 67 N.Y. ST. B.J., May/June 1995, at 53.

22. A chromosome is a "condensed rod made up of a linear thread of DNA interwoven with protein that is the gene-bearing structure of eukaryotic cells." SUZUKI & KNUDTSON, *supra* note 11, at 340.

23. *See id.* at 26.

24. *See id.* at 348.

25. *See* Burk, *supra* note 1, at 1606-07. This technique may be used to cut and paste DNA sequences within an organism, or even from one species to another. Vectors are then used to introduce the new DNA into a host cell or species. When dealing with bacterial subjects, plasmids are used as vectors. When dealing with more complicated organisms, viruses are used as vectors. *See id.*

26. *See* Seide & Smith, *supra* note 21, at 54.

desired product.[27] It is rDNA technology which first created the need for intellectual-property protections in the field of biotechnology.[28]

The Harvard Mouse, a genetically engineered mouse designed for cancer research, was the subject of the first animal patent in the United States.[29] This mouse was created through a genetic-engineering technique known as microinjection.[30] First, purified copies of genes are injected directly into a fertilized animal egg. The egg is then surgically implanted into the mother so that she may bring it to term. Although very few of the injections result in the live birth of a transgenic animal, successful injections result in offspring which exhibit traits attributable to the inserted genes.[31] To create the Harvard Mouse, a laboratory mouse was injected with a gene known to cause cancer. The resulting transgenic mice were extremely prone to breast cancer.[32]

The Harvard Mouse serves as a valuable research tool. Because these mice are so sensitive to carcinogens, they act as detectors so that scientists can monitor both the sources of the disease and the causes. Scientists insert human genes into the mice which mutate when exposed to carcinogens. Then, when testing a carcinogenic substance, the gene mutates indicating the carcinogenic nature of the substance. With the mice more prone to the cancers, a known time frame for developing cancer is present. If the mouse develops cancer significantly sooner than the known time frame with the introduction of the carcinogen, the carcinogen may be implicated in the cause of human breast cancer.[33] This is a good example of an invaluable medical-research tool; however, biotechnology has useful applications in many fields.[34]

C. The Uses of Transgenic Animals and Human Gene Sequences

Transgenic animals and human gene sequences have enormous commercial value in agriculture, biomedical research, medicine, and the pharmaceutical industry among other fields.[35] The social impact of these forms of biotechnology is nearly limitless. In addition to providing accurate and cost-effective models for the study of human disease, transgenic animals are capable of improving food

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27. *See* Richards, *supra* note 9, at 436.

28. *See* Seide & Smith, *supra* note 21, at 53. The need arose because scientists could now create new and different organisms through the use of rDNA.

29. *See* Landau, *supra* note 4, at 213.

30. Microinjection is a technique which requires injection of purified genes into a fertilized animal egg. The animal's own enzymes, then, take care of splicing the DNA in order to incorporate the novel DNA into that of the organism. As the cell develops into a full-grown organism, the introduced DNA will have made itself part of the genetic code of each cell within the organism. *See* Malcolm Gladwell, *Building a Better Mouse to Minimize Lab Guesswork*, WASH. POST, Oct. 30, 1989, at A3.

31. *See* Sellers, *supra* note 12, at 272.

32. *See* Landau, *supra* note 4, at 214.

33. *See* Gladwell, *supra* note 30, at A3.

34. *See* Terri A. Jones, Note, *Patenting Transgenic Animals: When the Cat's Away, the Mice Will Play*, 17 VT. L. REV. 875, 877 (1993).

35. *See id.* at 880-81.

sources and disease resistance in animals. Additionally, it is possible, through transgenic technology, to engineer animals to produce pharmaceutical products in their milk or organs capable of being transplanted into humans.[36] It is true that the initial projections about the pace of biotechnological advancement were too optimistic; however, even though the innovations are proceeding more slowly than originally thought, many new and important advancements have been made.[37]

1. Health Care and Medical Research

Because transgenic animals make researching causes and possible treatments of disease easier, they have been called a "gold mine for researchers."[38] Scientists use mice, such as the Harvard Mouse, as living laboratories that remove significant amounts of the guesswork from toxicological studies.[39] Scientists remove this guesswork by "color-coding" the genes they insert into a mouse. The color shows up when a mutation occurs, thus signaling the harmful nature of a chemical.[40] Transgenic animals allow a quick check for a color change in germ cells to signal mutation, whereas currently thousands of laboratory subjects are required for similar testing.[41] These mammalian subjects are much more valuable for testing than were the previous bacterial subjects. An animal is more likely than a single-celled bacterium to exhibit the characteristics that a multicellular human would when exposed to certain chemicals.[42] Additionally, some chemicals cause mutations that are not apparent until future generations. Transgenic animals allow study on the first-generation animal as well as its subsequent generations, thereby allowing researchers to observe the effects of the genetic mutations in the transgenic animal's offspring.[43] The results of

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36. *See* Moga, *supra* note 12, at 527.

37. *See* Burk, *supra* note 1, at 1606-15.

38. Marla Cone, *The Mouse Wars Turn Furious*, L.A. TIMES, May 9, 1993, at A1.

39. *See* Manspeizer, *supra* note 12, at 426. Toxicological studies are those that distinguish between harmless and harmful chemicals. *See* Gladwell, *supra* note 30, at A3.

40. Scientists are able to insert genes into mice with characteristics that could turn a cell blue or make it glow. Scientists engineer the gene so that it will only exhibit this color characteristic if the chemical being tested will mutate the cell back to its original form. *See* Gladwell, *supra* note 30, at A3.

41. *See* Manspeizer, *supra* note 12, at 426-27.

42. *See id.* at 427. Even more guesswork is removed in cancer research because the laboratory subjects do not have to be exposed to huge doses of carcinogen to obtain results. Rather than using huge exposure to carcinogens, researchers may expose the transgenic mice to amounts of carcinogen more similar to those doses humans may be experiencing. *See Advances in Genetics Research and Technologies: Challenges for Public Policy: Hearings Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 47-48 (1996) [hereinafter *Advances in Genetics Research*] (statement of Francis Collins, M.D., Director, National Center for Human Genome Research).

43. *See* Gladwell, *supra* note 30, at A3.

studies with transgenic animals are quicker, less expensive, and more realistic than previous methods.[44]

Transgenic animals improve the quality of disease study in many cases; but in other cases, transgenic animals are the only way to study disease. Some substances which are harmful to humans do not appear as harmful in animal subjects.[45] By inserting human genes into the animals, serious human ailments may be studied without the use of any human subjects.[46] Currently transgenic-animal disease models exist for AIDS,[47] sickle cell anemia, Down's syndrome, hepatitis B, Alzheimer's disease, high cholesterol,[48] and various cancers.[49] Beyond simply creating disease models, scientists hope transgenic animals will be the source of donor organs in the future.[50]

Researchers have already successfully transplanted human organ tissue into mice,[51] and researchers hope that the use of "near human" organs such as livers, kidneys, or hearts of animals will be used in the future for those in need of transplants.[52] By developing transgenic animals that create human proteins, scientists expect they will be able to create animal organs that the human body will not reject after transplantation.[53]

Finally, by developing transgenic animals as disease models, pharmaceutical companies have a more economic and realistic way to test their products. By creating the animals to be prone to certain ailments, pharmaceutical companies may test the effectiveness of vaccines and drugs.[54] The pharmaceutical industry

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44. *See Advances in Genetics Research*, *supra* note 42, at 47-48. Because of the more realistic nature of the testing performed on transgenic animals, researchers should be able to gain a better understanding of the molecular and cellular levels of disease. This, in turn, should improve the ability to study intervention and protection techniques in the environment to limit human exposure. *See id.*

45. A frequently cited example of this is the extensive animal testing which took place with thalidomide before it was administered to pregnant women. The harmful effects to human fetuses was not apparent in the animal testing. *See* Manspeizer, *supra* note 12, at 425-26.

46. *See* Malcolm Gladwell, *Mouse Patent May Bolster Research Efforts*, WASH. POST, Apr. 13, 1988, at F1.

47. The Ohio Mouse is used for testing AIDS. *See Genetically Engineered Mouse Mighty Big with Ohio U. Creators*, PLAIN DEALER (Cleveland), Jan. 13, 1993, at 2G [hereinafter *Genetically Engineered Mouse*].

48. *See* Burk, *supra* note 1, at 1634 & n.283.

49. *See Transgenic Animals: Production and Use as Experimental Models for Human Diseases*, LIFE SCI. & BIOTECH. UPDATE, Jan. 1, 1996, *available in* 1996 WL 2088895; *see also supra* text accompanying notes 29-32.

50. *See* Moga, *supra* note 12, at 536.

51. *See Anticancer Applies for Transplanted Animal Patent*, BIOTECH PAT. NEWS, Oct. 1, 1991, *available in* 1991 WL 2730943.

52. *See* Moga, *supra* note 12, at 536.

53. *See Departments of Labor, Health and Human Servs., Educ., and Related Agencies Appropriations for 1997: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 104th Cong. 218 (1996) (statement of Claude Lenfant, M.D., Director, National Heart, Lung, and Blood Institute).

54. *See* Elisabeth T. Jozwiak, Comment, *Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries*, 14 NW. J. INT'L L. & BUS. 620, 623 (1994).

does not just utilize transgenic animals for research. Transgenic animals will be very helpful in the actual production of pharmaceuticals as well.

2. Pharmaceutical Industry

The pharmaceutical industry uses both transgenic animals and human gene sequences in order to help aid people with such ailments as genetic disorders, hormone deficiencies, and enzyme deficiencies.[55] By altering the DNA of some animals, it is possible to create animals who secrete beneficial proteins in their milk.[56] For example, a transgenic goat was created which produces in its milk a drug used in the treatment of cystic fibrosis.[57] A transgenic sheep also exists which is able to produce up to five ounces a day of a protein used to treat emphysema.[58] Insulin, human growth hormone, and drugs for the treatment of heart attack and stroke victims are all possible candidates for production in the milk of transgenic animals.[59]

Animals have been used as "factories" for producing such proteins as human growth hormone and insulin for a long time; however, the animals (usually pigs and sheep) were previously sacrificed in order to obtain the protein. With transgenic technology, it will no longer be necessary to slaughter the animals in order to produce the proteins necessary for various pharmaceuticals.[60] Additionally, mass production of the proteins will be much easier and far more cost effective.[61] Because transgenic animals produce therapeutic proteins far more economically than common methods do, some estimate the current cost to consumers of such proteins will be reduced by as much as 100 times.[62] Finally, the quality of the drugs produced with transgenic animals and gene sequences may be much higher than drugs produced synthetically.[63] People expect similar rewards for the use of transgenic animals in agriculture.

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55. *See* Mark, *supra* note 12, at 251.

56. *See Transgenic Animal-Based Protein Products Move Toward Clinical Trials*, GENETIC ENGINEERING NEWS, May 1, 1996, at 37, *available in* 1996 WL 9121156.

57. *See Transgenic "Pharming" Drugs in Clinical Trials*, 14 NATURE BIOTECH. 1205 (1996).

58. *See Gene-Altered Animals Producing Disease-Fighting Human Protein*, CHI. TRIB., Aug. 27, 1991, § 1, at 8. Five ounces is nearly a one-year supply for an emphysema patient. *See id.*

59. *See* Mark, *supra* note 12, at 250.

60. *See* Moga, *supra* note 12, at 531.

61. For example, for one particular protein, a transgenic lamb was able to produce 18 times the concentration than is usually found in human serum. If a herd is produced from this transgenic animal, mass production of the protein would be quite possible and far less expensive. *See id.* at 534-35.

62. *See* Manspeizer, *supra* note 12, at 427; *see also* Vicki Brower, *PPL Floats IPO as Companies Consider Transgenic Switch*, 14 NATURE BIOTECH. 692 (1996). Some of the possible drugs for this method currently cost as much as $2200 per dose. *See* Gladwell, *supra* note 46, at F1.

63. *See* Moga, *supra* note 12, at 532-34.

3. Food and Agriculture

Creating transgenic animals for agriculture may lower costs to farmers by creating animals that are better able to resist disease, have increased growth performance, and have better reproductive traits. This benefit is two-fold as it creates lower costs to the farmers and increases quality for the consumer.[64] Researchers have been successful in creating larger and leaner fish, rabbits, and sheep through transgenic technology.[65] Additionally, the technology should improve the production of cow milk.[66]

The concept of "engineering" animals to be better sources of food is not new. Traditionally this has been accomplished through selective breeding. The introduction of transgenic animals will improve the quality of animals within one generation rather than through the long, multigenerational process of selective breeding.[67] Additionally, the problems traditionally associated with selective breeding will be avoided.[68] These transgenic animals will reduce costs for farmers and provide many health benefits for consumers.[69]

II. PATENT LAW: PURPOSES, ORIGINS, AND THE SUITABILITY OF BIOTECHNOLOGY TO PATENT PROTECTION

It is obvious that biotechnological advances have many uses that will benefit public health and wellness. The research required to create these advances, however, is very expensive to undertake.[70] Patent protection is one means by which people with the genius to make technological advances are rewarded for their willingness to undertake risky and expensive research, development, and manufacture. The patents allow these people to receive benefits from their work, but more importantly, the patents encourage further research and development.[71] If it is desirable to encourage further research in the field of biotechnology, patent protection is both desirable and necessary.

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64. *See* Sellers, *supra* note 12, at 271.

65. *See* Moga, *supra* note 12, at 530.

66. *See id.* at 527.

67. *See* Burk, *supra* note 1, at 1635.

68. *See, e.g., Milk Implicated in Triggering Diabetes*, Agence France-Presse, Feb. 27, 1997, *available in* 1997 WL 2066974 (describing how selective breeding of cows in order to create protein-rich milk has resulted in milk that may trigger diabetes in people); Auberon Waugh, *The Sad History of the Bulldog*, SUNDAY TELEGRAPH (London), Mar. 9, 1997, Comment Section, at 35, *available in* LEXIS, World Library, Telegr File (describing how selective breeding of the bulldog has resulted in a head so large that caesarean section is necessary for birth).

69. *See* David R. Purnell, *International Implications of New Agricultural Biotechnology*, 25 U. MEM. L. REV. 1189, 1191-92 (1995).

70. *See* David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 DENV. U. L. REV. 173, 190 (1991).

71. *See id.*

A. The Origins of Patent Law in Biotechnology

U.S. patent law is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution.[72] Title 35 of the *United States Code* codified the Patent Act of 1952. Rooted in each of these documents are the basic tenets of patent law: novelty,[73] utility,[74] and nonobviousness.[75] Title 35 U.S.C. § 101 states, "[w]hoever 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

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72. Congress shall have the power "[t]o 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.

73. *See* 35 U.S.C. § 102 (1994):

> Conditions for patentability; novelty and loss of right to patent:
> A person shall be entitled to a patent unless—
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
> (c) he has abandoned the invention, or
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representative or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
> (f) he did not himself invent the subject matter sought to be patented, or
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

74. *See id.* § 101.

75. *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 89 (1995). Nonobviousness is discussed in 35 U.S.C. § 103:

> 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.

of this title."[76] Much biotechnology falls beneath the "composition of matter" portion of § 101. However, for many years, judicial doctrine limited "composition of matter" to exclude products of nature from patentable subject matter.[77]

The products-of-nature doctrine prevents patents from being issued to discoveries that do not require any invention.[78] For many years, the products-of-nature doctrine acted as a bar to patents pertaining to living matter. Once the products-of-nature doctrine was purportedly overturned by the landmark case, *Diamond v. Chakrabarty*,[79] opponents used the Plant Patent Act of 1930[80] and the Plant Variety Protection Act of 1970[81] to block animal patents. These opponents stated that only those organisms which fall under the protection of one of those acts should be afforded patent protection.[82]

In 1980, the Supreme Court decided *Diamond v. Chakrabarty*[83] which addressed the patentability of a bacterium capable of breaking down crude oil. *Chakrabarty* set the stage for animal patenting. Ananda M. Chakrabarty created a genetically engineered bacterium capable of breaking down multiple components of crude oil. Mr. Chakrabarty contended that, because of this property, his bacterium possessed a trait not found in naturally occurring bacteria, and, therefore, sought patent protection.[84] The PTO denied Mr. Chakrabarty's patent application on the grounds that the microorganisms are products of nature and, as living things, per se nonpatentable.[85] Mr. Chakrabarty then appealed his claim all the way to the Supreme Court. The Court decided that the language of 35 U.S.C. § 101 was sufficiently broad to encompass the living microorganism, thus signaling the expansion of patent law to living matter. The Court invited Congress to address the issue and exclude living organisms not

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76. 35 U.S.C. § 101.

77. *See* Scalise & Nugent, *supra* note 75, at 89-90.

78. *See id.* at 90. For example, if you were to discover a new variety of plant, and then were to realize it could be used for medicinal purposes in its natural form, you would not be able to obtain a patent. Although it would be indisputable that your discovery is both new and useful, there is no element of invention. *See id.*

79. 447 U.S. 303 (1980).

80. Pub. L. No. 71-245, 46 Stat. 376 (current version at 35 U.S.C. §§ 161-164). The Act states, that "[a]ny person . . . who has invented or discovered and asexually reproduced any distinct and new variety of plant . . . may . . . obtain a patent." *Id.* sec. 1, § 4886 (current version at 35 U.S.C. § 161). The Plant Patent Act was passed so that agriculture could reap the benefits of the patent system as well as industry. *See* Scalise & Nugent, *supra* note 75, at 91.

81. Pub. L. No. 91-577, 84 Stat. 1542 (current version at 7 U.S.C. §§ 2321-2582 (1994 & Supp. II 1996)). The Plant Variety Protection Act extended patent protection to some sexually reproduced plants, provided they satisfy the requirement that they differ in some way from all prior varieties. *See id.* sec. 42 (current version at 7 U.S.C. § 2402). This act also gave two important exemptions from the patent protections. Researchers and farmers were allowed to reproduce the plants naturally without paying royalties. *See* Scalise & Nugent, *supra* note 75, at 94-95.

82. *See* Scalise & Nugent, *supra* note 75, at 95.

83. 447 U.S. 303.

84. *See id.* at 305.

85. *See id.* at 306.

contemplated by the Plant Patent Act or the Plant Variety Protection Act from patent law,[86] however, Congress failed to accept this invitation.

Although *Chakrabarty* did not give a full invitation to patent all life forms, the case certainly opened the door for animal patenting. In 1987, *Ex parte Allen*[87] tested the strength of the *Chakrabarty* decision for the first time. *Ex parte Allen* challenged the rejection of a patent for genetically engineered oysters. The PTO rejected the patent on the grounds that it was naturally occurring subject matter and obvious.[88] Allen appealed the PTO's rejection to the Board of Patent Appeals and Interferences, but the board ultimately rejected his application on the grounds of obviousness. Although Allen's patent application was denied, the board rejected the claim that the oysters were naturally occurring subject matter and consequently left open the possibility of patenting a living organism.[89] On April 7, 1987, immediately following the decision in *Ex parte Allen*, the PTO issued a statement reflecting the policy for which *Ex parte Allen* stood. The PTO stated:

> 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 [sic].
>
> 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 [sic]. 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 . . . .
>
> 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 [sic].[90]

This statement made the first animal patent inevitable, and one year later, on April 12, 1988, the PTO issued a patent for the Harvard Mouse.[91]

B. Suitability of Genetic Engineering to Patent Law

By granting patent protection to the Harvard Mouse, the PTO lifted the final obstacle in the fight for animal patents. However, sensitivity to political pressures has affected the number of patents and the willingness of the PTO to

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86. *See id.* at 318. The Court stated it was trying to interpret the intention of Congress by allowing a broad reading of the patent statutes; however, the Court invited Congress to "amend § 101 so as to exclude from patent protection organisms produced by genetic engineering." *Id.* For a complete discussion of *Diamond v. Chakrabarty* and its legacy, see Scalise & Nugent, *supra* note 75, at 95-101.

87. 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Interferences 1987).

88. *See id.* at 1426.

89. *See id.* at 1427.

90. Patent and Trademark Office Notice: Animals–Patentability, 1077 Official Gazette U.S. Pat. & Trademark Off. 8 (Apr. 21, 1987).

91. *See* U.S. Pat. No. 4,736,866 (Apr. 12, 1988).

actually grant animal patents.[92] Although the number of animal patents has increased, the problem remains that there are still few guidelines and many unanswered questions. In addition to transgenic animals, scientists wish to patent human gene sequences and human embryos.[93] It is, therefore, important that there be a solid foundation in the law of animal patents. A court has yet to decide whether the PTO exceeded its authority by issuing its statement that they would grant animal patents.[94] Currently, biomedical advances that satisfy the criteria of novelty, utility, and nonobviousness may receive patent protection.

1. 35 U.S.C. § 102: The Novelty Requirement

Because animals and gene sequences exist naturally, some argue that it is impossible for such living matter to be novel.[95] This argument fails to recognize the many ways in which biotechnology alters naturally existing organisms so they differ dramatically from naturally occurring organisms. Additionally, after the Supreme Court's decision in *Chakrabarty*,[96] it became apparent that nonnaturally occurring organisms that have been "man-made" or "man-altered" satisfy the novelty requirement.[97] When a transgenic animal is created, it is a product of human ingenuity, and it qualifies as patentable under the standard of novelty.[98] By issuing its rule contemplating animals as patentable subject matter, the PTO strengthened the position stated in *Chakrabarty*.

The case for novelty in human gene sequences is slightly different. Instead of patenting new animals with genetic material different from that which is found in nature, scientists seek to patent human gene sequences that certainly occur naturally. Currently, the policy seems to be to treat human gene sequences like naturally occurring substances and chemicals.[99] Genes may be patented if they

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92. *See Disclosure Duty and Cost Concerns Dominate "PTO Day" Discussions*, BNA Pat. Trademark & Copyright L. Daily (Jan. 10, 1992), *available in* WESTLAW, 1/10/92 PTD.

93. Questions abound about the patentability of human embryos because of the age-old debate about whether an embryo is "human." *See* Burk, *supra* note 1, at 1656.

94. *See* Jones, *supra* note 34, at 888; *see also* Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) (failing to reach the actual issue of animal patenting because the PTO's rule is exempt from the notice-and-comment rule and because those bringing suit did not have standing to seek the desired declaration).

95. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (holding that a mixed bag of different bacteria, each with a certain function, does not satisfy the novelty requirement because no new bacteria was created, and each of the bacteria was functioning as nature originally provided).

96. Diamond v. Chakrabarty, 447 U.S. 303 (1980); *see supra* Part II.A.

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

98. *See id.*

99. Naturally occurring substances and chemicals may be patented if they are extracted, isolated, and purified. Additionally, the substances must have some greater value than previously existed in the natural form. *See* Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 988-90 (1996). *See generally* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958) (upholding a patent for a vitamin B concentrate which had been extracted from its natural form and purified); Parke-Davis & Co. v. H.K. Mulford & Co., 196 F. 496 (2d Cir. 1912) (upholding a patent for adrenaline isolated from animal suprarenal glands).

are in an isolated and purified form, but not if they are simply in the form in which the scientist discovered the sequence.[100] Gene sequences contain a great deal of extraneous information because they are comprised of sections which code for proteins as well as sections that do not. When scientists clone sequences, they isolate only the protein-coding portions, thus isolating and purifying the gene sequence.[101] Applying these standards of novelty, it is appropriate that isolated and purified gene sequences be awarded patent protection in accordance with the novelty standard.

2. 35 U.S.C. § 101: The Utility Requirement

Transgenic animals and human gene sequences are clearly useful. As previously discussed, biotechnology utilizes transgenic animals and human gene sequences to develop disease models, pharmaceuticals, and improved food products.[102] Some claim, however, that the standard of utility has been elevated for biotechnological innovations. In most technologies, the utility standard is considered de minimis. However, because many of the innovations in biotechnology seem "unbelievable," patents have sometimes been refused for lack of utility.[103] Fortunately, guidelines that do not require human clinical trials to be performed before an innovation is accepted as useful have squelched this trend somewhat. The guidelines, additionally, now require the PTO examiner to clearly assert why an innovation is rejected for lack of utility.[104]

Because scientists generally create transgenic animals with a specific use in mind, the utility requirement does not pose a significant roadblock to patent protection. Gene sequences are more difficult, however, because once sequences are discovered and purified, it is often known that they produce human protein, but not what the actual function of the protein is.[105] In these cases, the patent applicants try to show that the gene sequences function as different types of markers, probes, and primers for various genetic research.[106] If the applicants are capable of showing that their sequence can be utilized for one of these purposes, they will have satisfied the utility requirement under 35 U.S.C § 101.[107]

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100. *See* Erramouspe, *supra* note 99, at 988.

101. *See id.* at 991.

102. *See supra* Part I.C.

103. *See* Seide & Smith, *supra* note 21, at 55.

104. *See* PTO Examination Guidelines on Utility Requirement, 50 Pat. Trademark & Copyright J. (BNA) 295, 304-05 (July 20, 1995); *see also In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995) (holding human testing of pharmaceuticals not necessary to satisfy the utility requirement).

105. *See* Christopher A. Michaels, *Biotechnology and the Requirement for Utility in Patent Law*, 76 J. PAT. [& TRADEMARK] OFF. SOC'Y 247, 258 (1994).

106. These three uses involve segments of cloned DNA. Markers are used to identify individual human chromosomes, probes are used in genetic screening, and primers are used for genetic fingerprinting. *See id.* at 259.

107. *See id.*

3. 35 U.S.C. § 103: The Nonobviousness Requirement

A 1995 amendment to 35 U.S.C. § 103 somewhat revamped the nonobviousness requirement in order to incorporate biotechnology.[108] The basic tenets have remained the same, however. In order to ascertain the obviousness of an invention, the invention must be viewed in light of other inventions in the prior art. If the new invention is one which could be easily accomplished by one with skill in the prior art, the invention will not be granted a patent.[109] Obviousness has been a sticky subject in the realm of biotechnology because scientists use similar techniques to isolate different gene sequences, even though the gene sequence may be new.[110]

The Federal Circuit decision of *In re Deuel*[111] dealt directly with the obviousness requirement for biotechnology. The court seemed to relax the obviousness standard by stating that "[a] general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene

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108. *See* 35 U.S.C.A. § 103(b) (West Supp. 1997).

> (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—
>
> (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and
>
> (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.
>
> (2) A patent issued on a process under paragraph (1)—
>
> (A) shall also contain the claims to the composition of matter used in or made by that process, or
>
> (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.
>
> (3) For purposes of paragraph (1), the term "biotechnological process" means—
>
> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—
>
> (i) express an exogenous nucleotide sequence,
>
> (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
>
> (iii) express a specific physiological characteristic not naturally associated with said organism;
>
> (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
>
> (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

Id.

109. *See* Graham v. John Deere Co., 383 U.S. 1 (1966).

110. *See* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 736 (1990).

111. 51 F.3d 1552 (Fed. Cir. 1995).

that is subsequently obtained as a result of that search. More is needed and it is not found here."[112] This decision allowed patents to be granted for DNA molecules even if the method for finding the DNA was obvious[113] and seemed inconsistent with previous understanding of the nonobviousness requirement.[114] The 1995 amendment to 35 U.S.C. § 103, however, seems to require that both the process and the molecule be nonobvious to satisfy the nonobviousness requirement.

Clearly, many biotechnology advances are capable of satisfying the requirements for patentability. From a purely legal standpoint, innovations in biotechnology are as capable as those in any other field of being useful, novel, and nonobvious. Patents are legally appropriate. The crux of the patent debate, however, has never really been the ability of biotechnology to satisfy the requirements. The debate has centered primarily on whether we *should* reject patents for biotechnology for social reasons, regardless of their novelty, utility, and nonobviousness.

III. SOCIAL CONSIDERATIONS: DISCIPLINARY CONCERNS IN PATENTING BIOTECHNOLOGY

Legally, many transgenic animals and gene sequences satisfy the standards for patent protection. The more difficult question is whether patent applications for transgenic animals and gene sequences should be denied for moral and ethical reasons.[115] Many, however, argue that morality is not one of the criteria on which the PTO issues patent protection.[116] It is undisputed that biotechnology is capable of remarkable benefits to society. The advances in biotechnology and the PTO's willingness to grant patent protection to the creators of transgenic animals, however, have spurred fear and controversy in economic, environmental, and ethical spheres of thought.[117] The President himself, in fact, has stated that "'[t]he breathtaking advances in science and technology demand that we always

112. *Id.* at 1558. The court justified its decision by basing it on the decision in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), which held "obvious to try" did not make an invention "obvious." If an invention was "obvious to try" but satisfied three other criteria, it would satisfy the nonobviousness requirement. The three indicia are: 1) there must be no expectation of success, 2) there must be no indication in the prior art disclosing what was necessary to vary in order to reach the desired result, and 3) there must be only general guidance in the prior art. *See* Eisenberg, *supra* note 110, at 732.

113. *See* Seide & Smith, *supra* note 21, at 57.

114. *See* Philippe Ducor, *The Federal Circuit and* In re Deuel*: Does § 103 Apply to Naturally Occurring DNA?*, 77 J. PAT. [& TRADEMARK] OFF. SOC'Y 871, 898 (1995).

115. *See* Barbara Looney, Note, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement*, 26 LAW & POL'Y INT'L BUS. 231, 271-72 (1994).

116. *See* James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 178 (1994).

117. *See* Sellers, *supra* note 12, at 283.

keep our ethical watch light burning.'"[118] Others state, however, that although the arguments advanced by biotechnology-patenting opponents seem emotionally and politically compelling, they rest on a poor logical framework.[119] Patenting proponents state that morality and ethics are not properly debated in the area of patent law, but rather these are issues that Congress should address while discussing appropriate regulations for biotechnology research as a whole.[120]

A. Agricultural Concerns

Although transgenic animals have much to offer to the productivity and quality of farm animals,[121] small family farmers fear allowing patents on transgenic animals will push them out of the market. The same increased productivity that sounds so economically desirable sounds like financial ruin to small family farms. Because genetically created animals will likely be expensive, small farmers fear that a small number of large corporations will be able to corner the market on genetically engineered animals, thereby depriving the small family farms of their livelihood.[122] Additionally, the farmers are concerned that the initial acquisition price of genetically altered animals, and the subsequent royalties, will increase rather than decrease the costs for farmers and consumers.[123]

This position is fairly weak, however, because the transgenic farm animals will be stronger and more disease resistant, and should balance the cost of the initial investment.[124] Proponents of animal patents additionally point out that the patent protection for the transgenic animals may actually help the farmers. This argument suggests that without PTO-issued protection, the owners of the transgenic animals will license their animals selectively, resulting in a small concentration of significantly advantaged, commercialized farming.[125] The position of the small farmers weakens further when it is considered that the main interest in transgenic animals is currently in medical research. Transgenic farm animals are certainly possible; however, the inception of large numbers of such animals in the near future is considered unlikely.[126]

Finally, not all farmers object to the idea of patented farm animals. The American Farm Bureau Federation ("AFBF"), which consists of 3.7 million

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118. Ruth Faden, *The Advisory Committee on Human Radiation Experiments: Reflections on a Presidential Commission*, HASTINGS CTR. REP., Sept.-Oct. 1996, at 5, 9 (alteration added) (quoting President Clinton).

119. *See* Burk, *supra* note 1, at 1639.

120. *See* Jones, *supra* note 34, at 915.

121. *See supra* Part I.C.3.

122. *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 417 (1988).

123. *See* Sellers, *supra* note 12, at 285.

124. *See* Jozwiak, *supra* note 54, at 628.

125. *See* Sellers, *supra* note 12, at 286.

126. *See id.* at 285.

member families, strongly supports the patenting of transgenic farm animals.[127] In fact, the AFBF did not support the Transgenic Animal Patent Reform Act of 1989 because it allowed too much of a farmers' exemption, and would have allowed unfair competition between the patent holders and those farmers allowed to reproduce the farm animals without paying royalties.[128]

Although the Transgenic Animal Patent Reform Act did not pass the Senate,[129] this sort of legislation is the appropriate response to the concerns of small farmers. The PTO is not the appropriate body to weigh the effects of patented subject matter on particular markets. The PTO's job is to decide novelty, utility, and nonobviousness. Carefully drafted legislation, with additions to those suggested by the AFBF,[130] will better serve the concerns of small family farmers while allowing biomedical advances to continue to progress.

B. Environmental Concerns

Some environmental groups are concerned with the fact that we do not have clear ideas of what could happen if these transgenic organisms were set free in the environment. The National Wildlife Foundation ("NWF") opposes patenting for transgenic animals because of the lack of legislation in the area concerning their release into the wild.[131] Although rejecting patent applications for transgenic animals does not mean the creation and release of such animals is prohibited, the NWF fears that allowing patents will cause a greater number of transgenic animals to be created, thus increasing the risk to the environment.[132]

There is really nothing known about the long-term effects of releasing transgenic animals into the environment. However, some environmentalists speculate that such a release might be real and possibly harmful to human and environmental health.[133] This argument fails to acknowledge, however, that the

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127. *See Transgenic Animal Patent Reform Act of 1989: Hearings on H.R. 1556 Before the Subcomm. on Courts, Intellectual Property, and the Admin. of Justice of the House Comm. on the Judiciary*, 101st Cong. 33 (1989) [hereinafter *Patent Reform Act Hearings*] (statement of Donald Haldeman, President, Wisconsin Farm Bureau Federation, on behalf of the AFBF).

128. *See id.* at 35. The proposed farmers' exemption would have allowed *any* occupational farmer to reproduce transgenic animals through breeding for any purposes. *See id.* at 36. The AFBF feared this exemption would reduce the incentive to develop transgenic animals in the future. The AFBF suggested language that would better restrict the uses of those animals reproduced through breeding to farming uses and sale for nonreproductive uses. *See id.* at 35-36.

129. *See* Moga, *supra* note 12, at 519.

130. *See supra* note 128.

131. *See Patent Reform Act Hearings*, *supra* note 127, at 226-27 (statement of Margaret Mellon, Director, National Biotechnology Center, NWF).

132. *See id.*

133. *See The Evaluation of Federal Programs in Agricultural Research, Educ., and Extension: Hearings Before the Subcomm. on Resource Conservation, Research, and Forestry of the House Comm. on Agric.*, 104th Cong. 250 (1996) (statement of Margaret Mellon, Union of Concerned Scientists). Some of the arguments postulated by environmentalists claim that transgenic animals in the wild will cause a loss of species integrity. This argument, however, makes the incorrect assumption that all species are completely distinct. Rather, transgenic animals may be better for species integrity than traditional selective breeding because scientists

release of "naturally" occurring organisms into new environments is also detrimental to environmental health.[134] Although the uncertain nature of the environmental effects is certainly a plausible argument for regulating the release of transgenic animals into the wild, the argument has little to do with patenting, and should not be a substantial roadblock to the patenting of transgenic animals.

The availability of patents for biotechnology should not be used as an environmental-regulation mechanism. Nuclear weapons are the *only* example of inventions that have been denied patent protection for the safety of the public.[135] The only possible function of the atomic bomb is to kill. Biotechnology is capable of so many public benefits that it should not be stifled by denying it patent protection. The concerns of the NWF and other environmentalists are valid, however, which is why the EPA should review the appropriateness of biotechnology practice. If necessary, regulations regarding the creation and release of transgenic animals could be easily created. Requiring the PTO to decide the possible environmental consequences of furthering biotechnology research again takes the PTO out of its role of deciding novelty, utility, and nonobviousness.

C. Animal-Rights Concerns

Concerns about the cruel treatment of animals are quite prevalent in discussions about transgenic animals. It is true that many of the animals engineered to help in human-disease research are bred to suffer from such diseases as AIDS, sickle cell anemia, cystic fibrosis, and cancer.[136] Although it is unpleasant to consider the experimental conditions that these transgenic research animals must endure, denying patent protection will not ease their suffering. Animals have been research subjects for a very long time, and humans have benefitted immeasurably from their use.[137]

It is quite possible that transgenic animals will actually limit the amount of animal suffering endured by research subjects and animals in general. For instance, using transgenic animals requires the use of fewer animals because the animals are created for the particular study purpose and are more responsive to the experimentation.[138] Similarly, fewer research animals (such as mice) are needed for each experiment because they have been engineered to be healthier, and are less likely to die of causes other than the research.[139] Additionally, the whole point of transgenics in agriculture is not to create freakish chimeras but

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can retain overall genetic diversity, only singling out a desirable genetic trait. *See* Chiapetta, *supra* note 116, at 179.

134. For example, gypsy moths were intentionally introduced into this country and now they are responsible for the destruction of acres of forest. *See* Sellers, *supra* note 12, at 290.

135. *See* Robert S. Wasowski, *The Evolution of Patentable Compositions of Matter: The United States Patent Office Accepts Genetically Altered Animals as Patentable Subject Matter Under 35 U.S.C. § 101*, 2 ADMIN. L.J. 309, 327 (1988).

136. *See* Cone, *supra* note 38, at A1.

137. *See* Jozwiak, *supra* note 54, at 628.

138. *See id.*

139. *See Genetically Engineered Mouse*, *supra* note 47, at 2G.

rather to create healthier animals.[140] Patenting these transgenic animals may limit the necessary amount of animal suffering. Because patents serve as economic incentives, transgenic animals that do not improve market value will not be economically desirable and will not be produced.[141]

It is indisputable that some animals suffer with transgenic research; however, animals may suffer even more with traditional animal research. It seems that it is not the patenting of the transgenic animals that is bothersome to animal-rights activists, but rather the actual science and the transgenic research.[142] Denying patents for transgenic animals will not stop transgenic-animal research. Those truly concerned with animal rights in transgenic research should be asking Congress to regulate the types of research performed, and not the patent protection extended.[143] Legislation already exists that limits animal research, and transgenic research is not among the varieties limited.[144] Opponents to transgenic animal research may be better served by lobbying to have this legislation expanded rather than opposing the patentability of all transgenic animals and stifling biotechnological advance. If the treatment of animals has no bearing on the novelty, utility, or nonobviousness of an invention, the PTO is not in a position to make its decision based on the treatment of animals.

D. Moral and Religious Concerns

Similar to the debate about animal rights, those opposed to patenting biotechnology based on moral or religious concerns seem to be much more opposed to the existence of the science, rather than the existence of patents for the discoveries. The general concern is that research in biotechnology is "playing God" and undermining the "sanctity of life" as God created it.[145] This position loses sight of the fact that biotechnological research is performed to help the human condition rather than harm it. These arguments, however compelling, are not aimed at the patent process, but rather at the research itself.[146]

It is usually not the issuance of patents that evokes the moral dilemma, but rather misconceptions about biotechnology.[147] However, some feel that the sanctity of life is not well served by allowing the creation of transgenic animals. The argument then suggests that patenting animal life exacerbates the problem. One commentator suggested that the PTO turned animals into commercial

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140. For example, a chicken has been engineered to resist a common ailment: the avian leukemia virus. *See* Chiapetta, *supra* note 116, at 183.

141. *See id.*

142. *See* Mark, *supra* note 12, at 253-54.

143. *See* Landau, *supra* note 4, at 221.

144. *See* Mark, *supra* note 12, at 254.

145. *See id.* at 257; *see also* Purnell, *supra* note 69, at 1193 (noting the risks involved in the creation or alteration of new and existing life forms).

146. *See* Jozwiak, *supra* note 54, at 629.

147. *See* Burk, *supra* note 1, at 1643; *see also* Chiapetta, *supra* note 116, at 189 (suggesting that the arguments against animal patents are more compelling when made against the technology which the patents protect).

commodities, and likened them to "electric toasters and automobiles."[148] If the role of the PTO is to act as a regulator of the societal impact of technologies, then it is possible that it should make these considerations when deciding whether to grant a patent to an applicant. The role of the PTO should not be to act as a regulator of societal impact, however, and the requirements for successfully obtaining a patent should remain solely in novelty, utility, and nonobviousness.

IV. RESOLUTIONS: LIMITS, LAWS, AND THE ULTIMATE BENEFIT OF BIOTECHNOLOGY PATENTING

Until 1995, the U.S. carried the dubious distinction of being one of the few industrialized nations without a commission to examine bioethics.[149] Finally, the NBAC was formed on October 3, 1995.[150] In forming this Commission, President Clinton has required that one high priority is to review the appropriateness and implications of human gene patenting.[151] Although President Clinton instructed the Commission to address human gene patenting as one of its first issues,[152] to date no discussion has commenced. This leaves us to grapple with the still uncertain state of "animal patent law" to determine the appropriateness of granting patents for human gene sequences.

A. Suggested Limits

Transgenic animals and human gene sequences, as well as other biotechnology, may be patented under our current system of patent law. The parameters for these patents remain unknown, however, because no clear dialogue and resolution have taken place in Congress.[153] It is inappropriate for the PTO to make far-reaching ethical decisions simply by granting or rejecting a patent application based on existing statutes. However, it is also inappropriate for the PTO to step outside of its role of deciding patents based on novelty, utility, and nonobviousness.[154] Many concerns possessed by biotechnology-patenting opponents are more appropriately addressed by agencies and legislation separate from the PTO because the problem lies not with biotechnology patenting, but with biotechnology.[155] There are some concerns, however, aimed directly at

148. Jones, *supra* note 34, at 886.

149. *See* Hatfield, *supra* note 5, at 7.

150. *See* Exec. Order 12,975, 3 C.F.R. 409 (1996); *supra* text accompanying note 8.

151. *See* Exec. Order 12,975, 3 C.F.R. 409; *see also Morning Edition: New Federal Bioethics Commission Convenes Today* (NPR radio broadcast, Oct. 4, 1996) (transcript available in 1996 WL 12730100) (noting that President Clinton created the NBAC to first consider the safeguards of human experimentation and genetic patenting).

152. *See* Exec. Order 12,975, § 1, 3 C.F.R. at 409-10.

153. *See* 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); *see also* Hatfield, *supra* note 5, at 6 (noting that consideration of genetic alteration has not taken place).

154. *See* Hatfield, *supra* note 5, at 6.

155. *See supra* Part III (discussing the concerns of biotechnology).

biotechnology patenting, and in the absence of congressional guidance, the PTO may make its decisions based on novelty, utility, and nonobviousness, and perhaps issue patents for subject matter Congress would prefer it did not for social or ethical reasons. A safeguard in addition to agency regulation and legislation is therefore necessary.

Creation of the NBAC is an important first step in evaluating the consequences and importance of patents on biotechnology. The NBAC should evaluate the different possible approaches for Congress to take concerning biotechnology patents and consider the long-term consequences of each. It is far more appropriate for the NBAC to make these moral, ethical, and societal decisions regarding the long-term effect of biotechnology patents than for the PTO to make them. It is important for the NBAC to acknowledge a position on animal patenting as well as human gene patenting so the debate may finally come to rest on solid principles, rather than "allow such issues to be decided by default in a vacuum of leadership."[156]

Suggestions for the limitations of biotechnology and biotechnology patents range from fines and jail time for misuse of the technology to accepting the status quo.[157] One commentator has suggested that the PTO weigh the costs and benefits of each biotechnology patent application in addition to the three current patent criteria. If too many negative social implications could possibly arise from the issuance of the patent, it would be denied.[158] This would essentially add a fourth criterion to the patent laws for biotechnology: social implication. Perhaps this is the ideal rule from a social standpoint; however, the practical implementation of such a rule would be nearly impossible, and the PTO is not the appropriate body to make such decisions.

A more practical approach would be for the NBAC to identify and separate categories of biotechnology research (rather than individual applications) that are appropriate (from a social standpoint) for patents from those that are not. Such categories could include transgenic research animals, transgenic farm animals, transgenic animals for the production of pharmaceuticals, isolated human gene sequences with known utility, and human gene sequences with unknown utility. Isolating separate categories of biotechnology will allow more independent evaluation of the social implications at stake and thoughtful decisions regarding the patentability of more narrow categories than limiting the discussion to the issue of biotechnology patenting as a whole. A categorical approach will prove far more workable than individual evaluation of the long-term implications of granting each biotechnology patent application. The NBAC should then present these categories to Congress for adoption under Title 35. Creating categories and offering suggestions as to the appropriateness of patent protection for each

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156. Hatfield, *supra* note 5, at 5.

157. *See* Jones, *supra* note 34, at 904-05; *see also* Richard Kevin Zepfel, Note, *Stopping a "Gruesome Parade of Horribles": Criminal Sanctions to Deter Corporate Misuse of Recombinant DNA Technology*, 59 S. CAL. L. REV. 641, 658 (1986) (noting that some commentators have suggested collecting fines from the "white-collar criminal" genetic-engineering corporations).

158. *See generally* Paul B. Thompson, *Conceptions of Property and the Biotechnology Debate*, 45 BIOSCIENCE 275 (1995).

category would give the PTO some guidance so that the PTO may continue to decide "novelty" rather than "morality."[159] There is some guidance existing in the Constitution, current precedent, and formerly proposed legislation to aid in the creation of such guidelines.

B. Helpful Guidance for a Clear Standard

The issues of patenting humans, the breadth of biotechnology patents, and infringement exemptions for certain classes of people are all valid concerns dealing directly with biotechnology patent law, and these are concerns that must all be addressed in order to give guidance to the PTO. The issue that generally garners the most hysterical reactions when discussing biotechnology and patenting is the possibility of patenting a "human" or an animal such as a chimpanzee that has been engineered to be "partially human" in order to perform menial human tasks.[160] Although the likelihood of such an invention is slim, and although most of the concern stems from the existence of such a creature rather than its patentability, under current patent laws such a creature might be able to satisfy the criteria for a patent. The PTO maintains its position that it will not issue a patent for a human;[161] however, scientists currently combine human gene sequences with mice to create transgenic animals that have been patented. This raises a fundamental question: How much human genetic material must be inserted into another organism to make it human enough to prohibit patenting? The NBAC must address this question in order to create workable guidelines.

Some argue that the Thirteenth Amendment restricts patenting transgenic humans.[162] This argument is faulty because the Thirteenth Amendment does not prohibit patenting of transgenic animals with some human genetic component; rather, it prohibits the use of a human for servitude.[163] Taking cues from the Thirteenth Amendment, however, the PTO may easily institute a policy to reject patent applications for anything remotely resembling a transgenic human. Contemplating transgenic humans is probably the most extreme issue the NBAC and PTO would have to address. More imminent issues involve the breadth of animal patents and the economic concerns of farmers and researchers who would be using, and necessarily reproducing, transgenic animals.

The initial patent granted for the Harvard Mouse was quite broad. Under the Harvard Mouse patent, the creation of any animal with a susceptibility to cancer due to the prescribed method could possibly infringe upon the patent.[164] Since the PTO issued the Harvard Mouse patent, subsequent successful animal patents

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159. *See Science Blooming*, *supra* note 8.

160. *See* Dresser, *supra* note 122, at 407.

161. *See supra* note 8 and accompanying text.

162. "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." U.S. CONST. amend. XIII, § 1.

163. *See* Burk, *supra* note 1, at 1647-48.

164. *See* Landau, *supra* note 4, at 215.

have been far more limited in scope.[165] This trend should continue to be followed in order to encourage more participation in biotechnology. By allowing specific, limited-scope patents, no one process or technique will overtake the industry, and research will not be stifled.

Finally, as discussed previously, Congress should seriously consider the possibility of limited farmers' and researchers' exemptions from patent infringement. A farmers' exemption was proposed in the Transgenic Animal Patent Reform Act of 1989.[166] The proposed legislation would have allowed farmers to breed transgenic animals without having to pay royalties for their offspring. This proposal was passed in the House of Representatives, but failed in the Senate.[167] Some objectors to the proposed legislation felt the exemptions were too broad and should have been limited only to those farmers who used the animals for sale in nonreproductive roles. Though the Transgenic Animal Patent Reform Act failed, a more narrowly drafted form of this legislation is a good means of remedying the concerns of small family farmers. The NBAC should weigh the merits of such an exemption, and consider the benefits of a similar exemption for those using transgenic animals for research purposes.[168]

C. The Benefits Prevail

Denying patents for biotechnology will result in the inhibition of competitively priced goods and a reduced initial incentive to engage in biotechnological studies.[169] Patent protection gives companies reasons to expand their research in genetics, and ensures that such research will continue.[170] Allowing patents on biotechnology will encourage investment in studies valuable in the quest to combat disease and improve the quality of food.[171] Such an incentive is necessary because biotechnology is a high-risk, high-cost form of research. Patent protection will create the kinds of economic incentives necessary for people to engage in this research and, ultimately, drastically improve public health.[172]

Harm from the misuse of technology should not be grounds for denial of patent protection, but it should be a good reason for better regulation of the trade and patent practice used in biotechnology.[173] Issuing patents may actually allow better visibility of biotechnology because patents will encourage disclosure of

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165. *See* Moga, *supra* note 12, at 520-21. Other animals which have received patents include both rabbit and mouse models for AIDS testing. These patents are limited to the specific animals and the specific methods, thus limiting significantly the scope of the patents. *See id.*

166. *See Patent Reform Act Hearings*, *supra* note 127.

167. *See* Moga, *supra* note 12, at 519.

168. *See* Eisenberg, *supra* note 110, at 743. "An experimental use exemption from infringement liability could prevent patents from burdening the progress of research science while still preserving incentives for private investment in research and development in biotechnology." *Id.*

169. *See* Chiapetta, *supra* note 116, at 160, 176.

170. *See* Scalise & Nugent, *supra* note 75, at 97.

171. *See* Jozwiak, *supra* note 54, at 624.

172. *See* Beier & Benson, *supra* note 70, at 190.

173. *See* Chiapetta, *supra* note 116, at 182.

advances.[174] If secrecy becomes unnecessary, then protection of the public good will be enhanced by keeping tabs on what is going on in this world[175] of "uncertain science and explosive growth."[176]

Clearly aspects of biotechnology are present that require careful consideration before issuing patents. Although, on their faces, biotechnology inventions may satisfy the existing patent laws, moral, ethical, and social implications also exist which require thoughtful consideration. In the end, however, the benefits of issuing patents for biotechnology will outweigh the costs.

CONCLUSION

The economic and social benefits of patenting transgenic animals and gene sequences far outweigh the possible social costs. Biotechnology holds the key to finding cures for many of our most serious and baffling diseases, improving the quality of our food, and making our pharmaceuticals more cost-effective to produce. Most of the concern with biotechnology patents is not directed at patent law, but rather at the technology itself. The PTO is, therefore, not the appropriate agency to make decisions about the appropriateness of biotechnology research. Additionally, denial of patent protection is not an appropriate or effective means of conduct control. Instead, agencies with expertise in the areas of concern[177] and legislation specifically tailored to deal with the areas of concern[178] should be employed to ameliorate these problems.

Moreover, denying animal patents will not defeat biotechnology research, it will just suppress it. Because biotechnology is a discipline which will serve to improve the human condition, the answer should be to allow biotechnology to flourish through the granting of patents.[179] As an additional safeguard to agency evaluation and legislation, guidelines for biotechnology patents should be formed with social implications in mind.

Congress, with the guidance of the NBAC, should certainly evaluate the social and moral concerns of biotechnological patenting. A careful review of the potential problems will reveal that the majority of biotechnology advance is appropriate under the current patent laws, and in terms of the societal benefit such advance will create. By creating standards that address the fears of patent opposers, however, those who have "the genius to make a significant

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174. *See* Jozwiak, *supra* note 54, at 624.

175. *See* Moga, *supra* note 12, at 518.

176. *Revitalizing New Product Development*, *supra* note 2, at 106 (statement of David A. Kessler, Commissioner, Food and Drug Administration, Department of Health and Human Services).

177. For example, the EPA may deal with the concerns of environmentalists to create guidelines to deal specifically with the release of transgenic animals into the wild. *See supra* Part III.B.

178. For example, legislation similar to the Transgenic Animal Patent Reform Act. *See supra* Part III.A.

179. *See, e.g.*, Chiapetta, *supra* note 116, at 181 (noting the societal need for the regulation, not suppression, of biotechnology patenting).

[biotechnological] advance" will be able to reap the benefits of patent protection that they deserve.[180]

180. Beier & Benson, *supra* note 70, at 183.