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Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute

James R. Chiapetta

COMMENTS

OF MICE AND MACHINE: A PARADIGMATIC CHALLENGE TO INTERPRETATION OF THE PATENT STATUTE

I. INTRODUCTION

Biotechnology[1] is beneficially shifting the paradigms[2] by which society understands, imitates, and controls the biochemical, physiological, and pathological processes of living organisms. However, biotechnol-

1. "Biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., OTA-BA-370, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE-SPECIAL REPORT 29 (1989) [hereinafter PATENTING LIFE].

2. Paradigms provide the frameworks within which we perceive the world around us. They are not constant. As paradigms shift, society rejects its existing perception of its universe in favor of another universe that frequently is incompatible with the former. Each shift in perception raises elusive questions that challenge our notions of ethics and morality. *See, e.g.*, THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 6

ogy is also perceived as a threat to fundamental paradigms which premise society's notions of mankind's domination over the environment. One area in which our paradigms are increasingly threatened is the emerging sphere of patenting transgenic animals.[3] Indeed, the controversy embroiling animal patents reflects the continuing debate surrounding human evolutionary history.[4]

At the controversy's core is the United States Patent and Trademark Office ("PTO"). On April 7, 1987, the PTO announced that it would begin accepting applications for patents[5] on genetically altered animals.[6] Nearly one year later, the PTO granted the first animal patent to researchers at Harvard University[7] to protect a mouse that they had genetically engineered.[8]

Despite the Constitutional basis for patents[9] and the societal and economic benefits that biotechnology can provide,[10] many oppose biotechnology in general, and the patenting of animals in particular, on the basis of moral dilemma. Some inveigh against animal patenting

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(1970). Changes in perception of our known universe, and the controversy that ensues, are the characteristics that define the paradigmatic shift that is the focus of this Note.

3. Transgenic animals are created by transferring genes from an organism of one species to an organism of another species using recombinant DNA techniques. PATENTING LIFE, *supra* note 1, at 187.

4. *See* JACOB BRONOWSKI, THE ASCENT OF MAN 20-24 (1973).

> In every age there is a turning-point, a new way of seeing and asserting the coherence of the world. It is frozen in the statues of Easter Island that put a stop to time — and in the medieval clocks in Europe that once also seemed to say the last word about the heavens forever. Each culture tries to fix its visionary moment, when it was transformed by a new conception either of nature or of man. But in retrospect, what commands our attention as much are the continuities — the thoughts that run or recur from one civilization to another.

Id.

5. Patents are "a grant of a right to exclude others from the making, using or selling of an invention during a specified time." BARRON'S LAW DICTIONARY 337 (Steven H. Gifis ed., 2d ed. 1984).

6. *See* Nonnaturally Occurring Non-Human Animals Are Patentable Under § 101, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 827, at 664 (April 23, 1987).

7. Malcolm Gladwell, *Harvard Scientists Win Patent For Genetically Altered Mouse; Award Is First to Be Issued for an Animal*, WASH. POST, April 12, 1988, at A1. The patent was granted to two Harvard University scientists for development of a laboratory mouse that propagates a gene inserted from another animal which makes the mouse more likely to develop cancer. *Id.*

8. Genetic engineering or recombinant DNA ("rDNA") technology is the controlled joining of DNA from different organisms. PATENTING LIFE, *supra* note 1, at 7.

After a five year hiatus during which animal patents were not granted, the PTO issued three new animal patents in December 1992. Edmund L. Andrews, *U.S. Resumes Granting Patents on Genetically Altered Animals*, N.Y. TIMES, Feb. 3, 1993, at A1, D5. *See*, U.S. PAT. NO. 5,175,383; U.S. PAT. NO. 5,175,384; U.S. PAT. NO. 5,175,385.

9. "The Congress shall have 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. *See also infra* part III.

10. *See infra* part IV.

because it involves research on live animals;[11] others contend that the potential for risk and abuse is too great to justify the ostensible benefits of genetic engineering.[12] Although opponents argue that withholding animal patents would confine biotechnological research to acceptable limits and, thus, eradicate these problems, denial will only drive inventors to other means of protecting their research.[13] And society likely will suffer the consequences of this undesirable shift.

Encumbering the patent statute with moral values may effectively preclude patents on living organisms and it contravenes the very goals of the patent system. Moral considerations are inconsistent with prior legislation[14] and the Supreme Court's interpretation of the Congressional intent of the Patent Act.[15] But because the standards provided by prior legislation and Supreme Court decisions are hopelessly clouded, the PTO has almost no guidance in the unprecedented area of animal patents.[16] Therefore, this Comment encourages Congress to analyze the standards by which animal patents are granted and to develop appropriate means for utilizing the results.

Congress, in developing such standards, is advised to respect the Constitution's goal of stimulating inventions. Ironically, many who challenge biotechnology also look to the Constitution for support, contending that animal patents are an unconstitutional expansion of the patent system. These opponents contend that the drafters of the Constitution never conceived that a patent would be granted on living organisms.[17] While this is no doubt true, it can similarly be said that the drafters never imagined that a patent would be granted on airplanes or supercomputers. Regardless of the extent of their vision about specific inventions to which patents might be granted, the framers clearly saw

11. *See* Gladwell, *supra* note 7, at A1 (identifying organizations that have lobbied Congress to ban animal patents).

12. Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1057-58 (1988) (stating that objections to animal patenting technology include the possibility of immediate direct or indirect ecological disasters and a reduction in the gene pool).

13. *See infra* part III.B.

14. 15 U.S.C. § 3701 (1980). Known as the Stevenson-Wydler Technology Innovation Act, this law was created to improve the economic, environmental, and social well-being of the United States by encouraging the growth of technology research.

15. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 6 (1952), in finding "that Congress intended statutory subject matter to include anything under the sun that is made by man[,]" except for discoveries that are natural phenomenon that cannot be reserved to any one person). *See also infra* notes 73-82 and accompanying text.

16. *See* 35 U.S.C. § 101 (1988); *see also Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 4, 4-6 (1987) (statement of Dr. Rene Tegtmeyer, Assistant Commissioner for Patents, U.S. Patent and Trademark Office) (testifying on the PTO's authority for granting animal patents).

17. *Chakrabarty*, 447 U.S. at 318 (Brennan, J., dissenting).

and embraced the merits of stimulating research for the benefit of society through granting patents.[18] Be the object of patenting mice or machine, the constitutional patent provision must be read the same.

This Comment considers the benefits and pitfalls of animal patenting. Part II examines the context and history of the controversy surrounding animal patents. Part III compares the policies and property rights protected by the patent system with those addressed by trade secret law. Part IV provides a working definition and overview of the historical role of patent protection in biotechnological advancements.[19] Part IV analyzes the moral and economic arguments advanced by those who oppose extending biotechnological patents to genetically engineered animals and finds that the arguments fail when applied against legal, biological, and economic reality. More important, this Comment suggests that such antipathy, although professed to be in opposition to animal patents, is actually a resistance to the paradigmatic leap of human control over the living world.

II. The Transgenics Controversy

The animal patenting controversy arises in basically two paradigmatic contexts. One paradigm focuses on the ethics of granting property rights in living animals;[20] the other involves the morality of humans using genetic engineering technology to affect the living world around us.[21] Although the controversy has been staged as a challenge to the ethics of property rights in animals, the true controversy appears to reside in the challenge to human morality itself.

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18. *See infra* part III.A.2.

19. Included is a discussion of the logical extension of "old biotechnology" into "new biotechnology." Office of Technology Assessment, U.S. Cong., OTA-BA-360, New Developments in Biotechnology: U.S. Investment in Biotechnology, 3 (1988) [hereinafter U.S. Investment]. Old biotechnology refers to the use of microorganisms for brewing and baking. *Id.* New biotechnology refers to recombinant DNA technology, cell fusion, and other novel techniques. *Id.*

In addition, there is a discussion on the logical extension of patent protection from bacterial fermentation to mammalian transgenics. Transgenic animals are those that carry genes not native to that animal. Rudolph Jaenisch, *Transgenic Animals*, 240 Sci. 1468, 1468 (1988).

20. Prior to the Harvard patent, patents had been issued for nonanimal life forms. *See, e.g., Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (1985) (upholding patents on plants); Diamond v. Chakrabarty, 447 U.S. 303 (1980) (upholding patents on microorganisms).

21. *See generally* Baruch A. Brody, *An Evaluation of the Ethical Arguments Commonly Raised Against the Patenting of Transgenic Animals, in* Animal Patents: The Legal, Economic, and Social Issues 141, 145-46 (William H. Lesser ed. 1989) (defining policy concerns that include a decline in the belief in the sanction and dignity of life).

Change creates tension which induces paradigmatic shifts which, in turn, forces us to reevaluate our ethos.[22] Ownership of property rights in an animal is not new to our or any other civilized society;[23] the use of genetic engineering to create a patentable animal, however, is.[24] The tension inherent in our ability to modify the genetic composition of living animals has created a significant challenge to our fundamental ethos. Absent the intervention of science, the modification of an organism's genetic material ("DNA")[25] was historically nature's exclusive jurisdiction. Nature governed random mutation of DNA, causing living organisms to evolve into the species we know today.[26] Genetic engineering, however, shattered nature's monopoly on evolution. One author has speculated that, "humans have graduated from being subjects of evolution to being co-authors of evolution."[27] By harnessing nature's power through DNA molecule manipulation, humans have altered their role in nature.

The dilemmas that arise when humans usurp a power of nature is not new. As one commentator noted:

> Every machine is a kind of draught animal — even the nuclear reactor. It increases the surplus that man has won from nature since the beginning of agriculture. And therefore every machine re-enacts the original dilemma: does it deliver energy in response to the demand of its specific use, or is it a maverick source of energy beyond the limits of constructive use? The conflict in the scale of power goes back all the way to that formative time in human history.[28]

These same considerations apply to biotechnology. Biotechnological innovation is a powerful tool that can help us to understand and cure many evasive physiological and environmental ailments.[29] But, like

22. A quintessential paradigmatic challenge and the human response it evoked occurred when Galileo Galilei (1564-1642) challenged the Ptolemaic model of a geo-centered universe with proof of the Copernican heliocentric universe. To avoid being tortured for heresy, he signed a statement recanting his discoveries. BRONOWSKI, *supra* note 4, at 216. *See also infra* text accompanying notes 255-58.

23. For example, people have owned dogs, cats, horses, cattle, and other animal species for a variety of purposes and reasons.

24. The PTO issued the first patent on an animal in 1988 for a mouse carrying a recombinant gene making it prone to cancer. Gladwell, *supra* note 7, at A1.

25. DNA stands for deoxyribonucleic acid, an organic substance found in chromosomes located near the nucleus of cells that carries genetic instructions. ALBERT L. LEHNINGER, BIOCHEMISTRY 309 (2d ed. 1975).

26. THE BODY MACHINE: YOUR HEALTH IN PERSPECTIVE 13 (Christian Barnard ed., 1981).

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

28. BRONOWSKI, *supra* note 4, at 79.

29. *See generally* THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 2-4 (1991) [hereinafter BIOTECHNOLOGY POLICY] (discussing examples of biotechnological innovation in medicine, agriculture, energy and the environment).

many scientific advances, biotechnology threatens potential harm at the same time it promises good. Research carries risk. Hence, within the animal patent controversy resides a dilemma: should research be stifled for fear of potential harm or fostered in an effort to reap the social benefits of technology?

This dichotomy lies at the heart of the animal patenting debate. Opponents of animal patents believe that denying patents will defeat biotechnological research on live animals.[30] It will not. The research will continue. Moreover, denial of animal patents will change the way in which the technology becomes available and is used.[31]

Our society demands biotechnology and, indeed, relies on it for survival. Without biotechnology, we are effectively prevented from devising the much needed solutions to dietary, health, environmental and other problems that plague us at record rates.[32] But balanced against these needs is immense public resistance to increasing taxes to pay for research and development.[33] Thus far, biotechnology has managed to work within relatively tight financial parameters. Biotechnology has significantly enhanced our ability to diagnose[34] and treat diseases,[35] produce food for human and animal consumption,[36] and care for the environment at a comparably small cost to the public. As societal needs increase, so will the demand for biotechnology's benefits.

Private researchers will continue to provide us with biotechnological benefits only if their investment is protected. Although patents protect private investment in biotechnological innovation, denial of patent protection on biotechnological innovations will not stifle the technology;[37] it will, however, drive inventors to use other means of intellec-

30. *See* Gladwell, *supra* note 7, at A1 (indicating the groups that are pushing for Congress to block animal patents).

31. *See infra* part V.

32. Donald S. Chisum, *Introduction*, 68 DENV. U. L. REV. 119, 119 n.1 (1991).

33. *Id.*

34. Jerry M. Adams & Suzanne Cory, *Transgenic Models of Tumor Development*, 254 SCI. 1161, 1161 (1991).

35. *See, e.g.*, Leslie Roberts, *New Targets for Human Gene Therapy*, 241 SCI. 906, 906 (1988) (describing the use of human gene therapy to treat familial hypercholesterolemia ("FH"), a disease which frequently causes death of affected persons while in their teens).

36. *See, e.g.*, Catharine M. Lemieux & Michael K. Wohlgenant, *Ex Ante Evaluation of the Economic Impact of Agricultural Biotechnology: The Case of Porcine Somatotropin*, 71 AM. J. AGRIC. ECON. ASS'N 903 (1989) (using a linear elasticity model, the authors found that use of porcine somatotropin will increase producer surplus by $250-750 million dollars and consumer surpluses between $900 million and $1.95 billion).

37. It will, however, shift the financial burden of research funding from private industry to government. For example, there have been recent legislative efforts in forming cooperatives between private industry and governmentally funded research. 15 U.S.C. § 3701 (1980).

tual property protection.[38] Trade secret law is one such alternative, but not an attractive one.[39] By its very nature, trade secret law demands keeping vital research information secret. This secrecy encourages unnecessary duplicative research, a situation successfully avoided under patent protection. Moreover, denying animal patents will likely impede regulatory efforts and may result in increased harm to animals.[40]

This Comment posits that Congress must respond to animal patenting issues. To promote societal benefits of biotechnology and to minimize risks, Congress must expressly support animal patents; only through this express support will society benefit most.

III. PROPRIETARY RIGHTS

The importance of property rights[41] in intellectual creations of inventors and artists has sparked little controversy, perhaps because such rights are founded in the Constitution. The Constitution empowers Congress to grant inventors and artists exclusive proprietary rights of a limited duration in their intellectual creations.[42] The Constitution, however, is not the sole source for these protections.

Common law also recognizes the importance of protecting property rights in inventions through the judicial doctrine of trade secret law.[43] Both patent and trade secret laws protect intellectual creations, but

38. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1032 (1989).

39. *See infra* part III.B-C.

40. Ironically, this is also a complaint of opponents to animal patents. *See infra* part V.A.3.

41. The term "property right" is a bit of a misnomer. During the evolution of patent grants, specifically in the early 1800s, some countries, France among them, recognized the grant of a patent as a proprietary right in the invention. SUBCOMMITTEE ON PATENTS, TRADEMARKS AND COPYRIGHTS, COMM. ON THE JUDICIARY, 85TH CONG., 2D SESS., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 3 (Comm. Print 1958) [hereinafter ECONOMIC REVIEW]. England regarded a patent as a grant of a royal favor and Austria insisted that the inventor was not entitled to protection but, as a matter of public policy, may be granted a privilege if it was in the public interest. *Id.*

The United States recognized this distinction early in its history when Thomas Jefferson wrote:

> Inventions then cannot, in nature, be a subject of property. Society may give an exclusive *right to the profits* arising from them, as an encouragement to man to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.

Walton Hamilton & Irene Till, *What is a Patent?*, 13 LAW & CONTEMP. PROBS. 245, 246 (1948) (citing 6 WRITINGS OF THOMAS JEFFERSON 180-81 (H.A. Washington ed., 1854)) (emphasis added).

42. U.S. CONST. art. I, § 8, cl. 8.

43. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989). *See also infra* part III.B.

they do so through different, and often inimical, means.[44] Depending on the means adopted, the inventor or artist must choose either the protection of patent or trade secret law.[45] The ramifications of that choice affect not only the inventor, but also society at large.[46] Whether an inventor or artist opts for statutory patent protection or judicially based trade secret law involves an evaluation of the rights and obligations created by each.

A. *The Patent System*

1. *Benefits of Patents*

The Framers of the Constitution granted Congress the power to promote the progress of science and the useful arts[47] which Congress effectuated through the issuance of patents.[48] Although other means were available at drafting, the Framers believed that a patent most fairly compensated the inventor's effort with minimal intrusion of free market tenets.[49]

A patent promotes development of the sciences by providing an economic incentive to inventors. When they are granted a patent, inventors obtain exclusive commercial use of their invention for seventeen years.[50] Armed with this limited monopoly, the inventor is able to recover costs incurred in inventing.[51] Society thus rewards the inventor's

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44. See Thomas G. Field Jr., *Brief Survey of Intellectual Property*, 31 IDEA J.L. & TECH. 84 (1988), for a discussion of the methods available to protect intellectual property.

45. *See* 35 U.S.C. § 101-307 (1988) (patent act); *see generally infra* notes 82-102 and accompanying text for a discussion of trade secret law.

46. *See infra* part III.

47. S. REP. No. 239, 24th Cong., 1st Sess. (1836). *See also supra* note 9.

48. *See generally* Hamilton & Till, *supra* note 41, at 246 (stating that a patent serves a public purpose for the advancement of the sciences and useful arts and it is solely for this purpose that Congress is empowered to grant a patent).

49. James Madison, generally credited as the author of the Constitutional patent clause, originally proposed the use of premiums and other provisions to reward inventors for their creations. Hamilton & Till, *supra* note 41, at 247-48. The use of patents ultimately prevailed over the use of government paid premiums because it was recognized that determining how important an invention might be at the time of invention is impossible. *Id.* at 248.

50. The standard patent term is seventeen years. 35 U.S.C. § 154 (1988). Title II of the Drug Price Competition and Patent Term Restoration Act of 1984 is one exception to this term. *Id.* § 271(e). In this act, Congress added section 156 to the Patent Act, which extended the patent term to include the time pharmaceutical manufacturers' products are delayed by the regulatory approval process. 15 U.S.C. § 156 (1988). *See also* EDMUND W. KITCH & HARVEY S. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS 853 (rev. 4th ed. 1991).

51. A patent grant only entitles the inventor to a commercial market. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY, 204 (1991) [hereinafter GLOBAL ECONOMY]. Use of the product, however, is subject to state and federal regulation. *Id.*

contribution by providing the opportunity for an economic return.[52] An invention lacking societal demand, however, will not return the costs of development.[53]

Participants in the Constitutional Convention recognized that, by creating a limited monopoly, the patent was contrary to free market tenets.[54] These patent rights, however, were expressly exempted from the general rule against monopolies,[55] which Congress justified by the greater societal benefit gained by stimulating innovation.[56] The significance of a patent's monopoly power is even more profound in modern industrial society.[57] By offering a limited monopoly, the patent system induces companies to make and perfect products for the commercial market.[58] It provides a critical economic incentive for private

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52. *See, e.g.*, Hamilton & Till, *supra* note 41, at 248. A patent merely establishes the boundaries of the inventor's exclusive rights as fixed by the invention:

> All the ways and means of securing his "reward" are left to the inventor; all the risks which attend "putting it to work" are for him to avoid. The government, in issuing the grant, guarantees to him no compensation; it assures him no right to do whatever is necessary to make his patent a commercial success.

Id.

53. A patent only provides the patentee with the right to exclude others from their market. 35 U.S.C. § 154 (1988).

54. *See generally* S. REP. NO. 239, 24th Cong., 1st Sess. (1836).

55. "It is not at this day to be doubted that the evil of the temporary monopoly is greatly overbalanced by the good the community ultimately derives from its toleration." *Id.* at 6.

Even today, debate over the societal benefits of patent protection, the suppression of inventiveness that can result when patents are blocked, and the negative economic effects created by a limited monopoly rages on. This essay does not seek to rewrite patent law. Rather, it argues in support of the tenets that justify the system's present existence. However, for incisive essays on the effects of the patent system on scientific innovation, see generally ECONOMIC REVIEW, *supra* note 41, which provides a historical review of the arguments of patent system opponents and proponents; Eisenberg, *supra* note 38, discussing the patent system's effect on basic science research; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990), which explores the effects of patent scope on fostering and inhibiting innovation); and Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977), discussing the patent system as a means toward more efficient technological expansion.

56. S. REP. NO. 239, 24th Cong., 1st Sess. 6 (1836).

57. ECONOMIC REVIEW, *supra* note 41, at 35.

58. *Id.* at 37.

> The risk attending the introduction of a new process is always great. Even when it works thoroughly well in the laboratory or model room, it may not work well in public. The man who first develops a new invention loses his whole capital if it fails. If he is immediately exposed to free competition in case of success, he can enjoy exceptional profits for a short time only. The risk of loss, under such circumstances, outweighs the possibility of gain. No man [. . .] will take the lead in a hazardous experiment when those who follow him have practically equal chance of gain and almost no chance of loss. The patent, by making the gain a permanent one, makes it safe for a capitalist to develop a new process.

Id. (citing A.T. HADLEY, ECONOMICS 133-34 (1903)).

investment in sophisticated research laboratories and in the hiring of trained professionals to develop new and necessary societal goods.[59] Rewarding the entrepreneurial spirit also creates economic security through jobs and satisfies consumer needs for new products.[60]

Although society as a whole benefits from patent protection, the true benefit of a patent system is, unfortunately, unmeasurable.[61] The factors considered in granting a patent, specifically the scope and duration of patent protection, have different stimulatory effects in different areas of manufacturing.[62] Regardless of these differences, however, it is widely accepted that the societal benefit that is gained by granting patents far outweighs the potential harm of monopolization.[63]

A patent grant is often referred to as a contractual agreement between the patentee and society. The inventor provides public disclosure[64] of the workings of a "new"[65] and "useful"[66] invention. In exchange, society grants the patentee the exclusive right to use the state's enforcement power to prohibit another from commercially using the patented invention.[67] The inventor secures a monopoly right while society receives two distinct benefits from a patent: (1) the inventor will more likely expend the costs required to make the product

59. *Id.* at 35.

> For the inventors in the laboratories, the modern incentive is probably preferable to the old. These men are specialists, professionals who like their work. Where society accords scientists and inventors steady income, respect, a career, and a laboratory, it is safe to assume that most prefer these emoluments, facilities, and associations to the uncertainties of isolated research and business adventure.

Id. (citing Alfred E. Kahn, *Deficiencies of American Patent Law*, 30 AM. ECON. REV. 479, 481 (1940)).

60. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974).

61. ECONOMIC REVIEW, *supra* note 41, at 79. However, there is some empirical evidence to support the notion that patents are beneficial in certain sectors. *See, e.g.*, John H. Barton, *Patenting Life*, 264 SCI. AM. 40, 40, 42 (1991) (stating that private plant breeding increased following the introduction of plant variety patenting rights in 1970). The pharmaceutical industry is one industry for which the effect of patent incentive is great. *Id.* at 41. It is reasonable that patent incentive will be equally effective in biotechnology. *Id.*

62. Merges, *supra* note 12.

63. Barton, *supra* note 61, at 1.

64. 35 U.S.C. § 112 (1988).

> 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.

65. 35 U.S.C. § 101 (1988).

66. *Id.*

67. ECONOMIC REVIEW, *supra* note 41, at 1.

available in the market place;[68] and (2) the knowledge becomes available for building incremental technological advancement.[69] Thus, a patent not only stimulates production of societally useful products, but it also mandates disclosure of the vital information that advances the solution of social problems. These benefits should not be underestimated.

In addition to satisfying the disclosure condition, an inventor must fulfill three additional statutory requirements to secure patent protection. First, the invention must be a form of technological advancement that Congress wishes to foster through patenting.[70] Second, the invention must be novel.[71] And third, the invention must be one that would not be obvious to others who are reasonably skilled in the area of technology relevant to the invention.[72] Congress has imposed these requirements to guarantee that society benefits from the novel invention while allowing the inventor to recoup the costs of developing the technology. It is only when society receives full disclosure and the inventor receives full protection that the benefits of the patent system are fully realized.

2. *Patents of Living Animals*

In 1980, the courts first considered whether "living organisms" are patentable subject matter under section 101 of the Patent Act. In *Diamond v. Chakrabarty*,[73] the Supreme Court reviewed the pertinent language of section 101 that defines patentable subject matter as "any new

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68. *Id.* at 58-59.

69. Eisenberg, *supra* note 38, at 1024.

70. The Patent Act provides:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101 (1988).

71. 35 U.S.C. § 102(a), (b) (1988); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 148 (1989) (determining the novelty necessary for a patent). Novelty, as used in patents, measures how "new" a prospective invention really is. An invention is considered "novel" when it is not known by others and has not been used before. 35 U.S.C. § 102 (1988).

72. 35 U.S.C. § 103 (1988).

> A patent may not be obtained . . . 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.

Id. This Comment focuses on subject matter propriety for patent protection; novelty and nonobviousness are thus beyond its scope.

73. 447 U.S. 303 (1980).

and useful process, machine, manufacture or composition of matter"[74] and held that living subject matter may be patented.[75]

The Court, affirming the Court of Customs and Patent Appeals ("CCPA"), specifically focused on the statutory terms "manufacture" and "composition of matter."[76] Applying standard dictionary definitions to these statutory terms, the Court determined that Congress intended the patent laws to be given "wide scope."[77] This "wide scope" meant that the patent laws are not restricted to inanimate objects;[78] they specifically encompass living organisms as well. The Court also pronounced that arguments against patentability which invoke potential hazards are properly addressed by Congress and the Executive branch, not the courts.[79] But, in the thirteen years since *Chakrabarty*, Congress has taken no action to clarify the scope of section 101 in this area. Thus, both courts and practitioners are left with only a clouded vision regarding the limits of *Chakrabarty* and the true scope of section 101.

The function of the patent system is simple: "To promote the progress of science and useful arts."[80] The boundaries of "science" and "useful arts" are vague at best. Within these boundaries, however, the vanguard of the biotechnological community is altering the genetic makeup of living organisms. Undoubtedly, potential harms are associated with these endeavors.[81] But, as indicated by the Supreme Court in *Chakrabarty*, the resolution of an invention's potential harms is not properly within the scope of the patent office. A societal issue of this magnitude is best left to the judgment of Congress.[82]

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74. 35 U.S.C. § 101 (1988).

75. *Chakrabarty*, 447 U.S. at 318.

76. *Id.* at 308. The CCPA had reversed the Patent Board of Appeals' denial of a patent for a genetically engineered bacteria. The new strain of bacteria, from the *Pseudomonas* genus, had unique degradative capabilities as a result of genetic engineering and, therefore, was useful in cleaning up oil spills. *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, 209-10 (1993).

77. *Chakrabarty*, 447 U.S. at 308. The Court went on to note that the committee reports accompanying the 1952 Patent Act revision "inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.' " *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)).

78. *Id.* at 313.

79. *Id.* at 317.

80. U.S. CONST. art. I, § 8, cl. 8.

81. Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980).

82. *Id.* at 317; *see also* Stephen A. Bent, *Issues and Prospects in the USA*, *in* ANIMAL PATENTS: THE LEGAL, ECONOMIC & SOCIAL ISSUES 5, 7 (William H. Lesser ed., 1989).

Congress delegated its authority to regulate the general issuance of patents in 1836 when it established the PTO. S. REP. NO. 239, 24th Cong., 1st Sess. (1836).

B. *Trade Secret*

In contrast to patent law protection, which was created by legislation, trade secret protection evolved through common law.[83] In 1939, section 757 of the First Restatement of Torts was created as a codification of trade secret law.[84] Although there have been attempts to impose statutory effect through adoption of the Uniform Trade Secret Act ("UTSA"),[85] trade secret protection is still found within the common law.[86]

Trade secret laws evolved from a different orientation than patent laws. Unlike patent laws, which protect inventions, trade secret laws protect consumers from unfair competition.[87] Trade secret laws protect consumers by assuring that a known product will come only from a known producer. Although they do not purport to promote inventions, trade secret laws provide protection to the inventor by preventing misappropriation of the fruits of their labor through the benefits of trade secret laws.[88]

Trade secret laws protect consumers by: (1) enforcing standards of commercial morality;[89] (2) stimulating investment into positive eco-

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It is interesting to note the role of regulatory agencies in patent issues. Historically, patents on medical products were denied because of the potential medical fraud that could arise. Merges, *supra* note 12, at 1064. However, after the development of the Food and Drug Administration ("FDA") in 1927-31, the courts, when upholding a patent, look to functional utility concerns, as opposed to clinical safety concerns that would fall within the ambit of the FDA. *Id.* This prevents the overlap of PTO and FDA jurisdictions. *Id.*

83. Edmund W. Kitch, *Intellectual Property and the Common Law*, 78 VA. L. REV. 293, 300 (1992).

84. RESTATEMENT (FIRST) OF TORTS § 757 (1939). The Second Restatement no longer incorporates this section.

85. Field, *supra* note 44, at 109. The UTSA has been adopted in whole or in part in various states. *Id.*

86. *Id.* State law occasionally overlaps patent protection, but it has been held that federal law does not preempt state trade secret law. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 165-68 (1989). The Court made clear that although federal and state laws could co-exist, state laws which acted to undermine the purpose of federal patent policy were preempted. *Id.* at 146-51.

87. Trade secret law may create "quasi-property rights" in inventors. *Id.* at 157. The focus, however, is on the protection of consumers, not the protection of producers as an incentive to product innovation. *Id.* The general concern of unfair competition is that, without some identifying feature on the product, consumers may be unable to discern the product's source, making it difficult for consumers to repurchase products of their choice. *Id.*

88. "[B]ut one may not avoid these labors [of independent research] by taking the process from the discoverer without his permission at a time when he is taking reasonable precautions to maintain its secrecy." E.I. duPont deNemours & Co. v. Christopher, 431 F.2d 1012, 1015 (5th Cir. 1970).

89. "To obtain knowledge of a process without spending the time and money to discover it independently is *improper* unless the holder voluntarily discloses it or fails to

nomic interests;[90] and (3) encouraging research and innovation.[91] As in patent law, a fundamental tension arises in attaining the goals of trade secret law. The benefit of protecting inventive efforts clashes with, and must be balanced against, the societal harm of single source pricing. However, this balance favors protecting a producer to the extent of the producer's own reasonable efforts to keep the technology secret.[92] Thus, by protecting their secrets, producers are able to keep their products distinct from the competition.

Therefore, unlike patents, which require public disclosure, trade secret law provides an incentive to inventors to keep their ideas secret.[93] Apart from any disclosure that might be obtained by commercial marketing of a product, no other disclosure is required of an inventor. In fact, in a trade secret dispute, the inventor bears the burden to prove that reasonable precautions were taken to prevent disclosure of the workings of the invention.[94] A product protected by trade secret is protected until the secret is revealed and the duration can theoretically last forever.[95]

In practice, however, it is unlikely that many products will maintain their trade secret protection forever. If an invention can be easily duplicated as the result of product inspection or reverse engineering, the product loses its trade secret protection.[96] Thus, an invention legally "discovered" before the seventeen-year patent term has expired allows society to benefit from free market competition sooner than it would under patent law. But, on the other hand, if an invention is a major advancement that is not amenable to reverse engineering, society may not receive this benefit; in fact society may suffer two harms. First, the negative effect of single-source pricing will continue longer than seventeen years of patent protection.[97] Second, without disclosure, the collateral benefit of incremental discovery beyond the invention is

take reasonable precautions to ensure its secrecy." *Id.* at 1015-16. This is the essence of commercial immorality.

90. *Id.* at 1016.

91. *Id.*

92. Metallurgical Indus., Inc. v. Fourtek, Inc., 790 F.2d 1195, 1200 (5th Cir. 1986).

93. PATENTING LIFE, *supra* note 1, at 118-19.

94. *Metallurgical Indus.*, 790 F.2d at 1200; *see also* E.I. duPont deNemours & Co. v. Christopher, 431 F.2d 1012, 1016-17 (5th Cir. 1970).

95. Field, *supra* note 44, at 112. *See, e.g.*, Manuel Schiffres & Gail Bronson, *Businesses Struggle to Keep Their Secrets*, U.S. NEWS & WORLD REP., Sept. 23, 1985, at 59 (discussing how Coca-Cola has managed to keep its recipe for Coke a secret for ninety-nine years).

96. *E.I. duPont*, 431 F.2d at 1015.

97. One commentator has noted that if secrecy for greater than seventeen years is "feasible," patents may be an unattractive alternative for an inventor. Eisenberg, *supra* note 38, at 1029.

effectively prevented.[98] As a result, society cannot realize the full benefit of the research.

These harms are even greater in the biotechnological community. Biotechnology, perhaps more so than any other industry, requires maximal disclosure to provide societal benefit. From an economic perspective, biotechnology is not easily reverse engineered by inspection of the product.[99] Second, disclosure permits regulators to gain increased knowledge about the respective technology thus making them better equipped to enact proper regulation. Third, disclosure provides the foundation upon which incremental discoveries are built.[100]

C. *Patents vs. Trade Secrets*

The choice between the means of intellectual property protection makes a difference in the stimulatory effect on technological advancement. Patents, on the one hand, provide broad protection from free market competition. Trade secret law, however, with its lack of disclosure, protects the inventor to the detriment of society.[101] The biotechnological industry feeds upon this disclosure; it is only through disclosure that society reaps the technology's benefit. The comparable protections furnished under trade secret law simply do not fully provide those benefits.[102]

IV. THE BIOTECHNOLOGY INDUSTRY

The biotechnology industry arose in response to society's desire to better understand and care for living organisms and their environment.[103] Basic scientific research has provided greater understanding of the functioning of living organisms, enabling human beings to con-

98. *Id.* at 1024; Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 422 (1988).

99. Reverse engineering is difficult with living animals. For example, it is difficult to determine what the differences are between a genetically engineered mouse and a normal mouse just by looking at the two, because the changes to the engineered mouse were made to its unseen genetic material. Moreover, even if newly incorporated DNA material is determinable by genetic analysis, the method of incorporation remains unknown.

100. Eisenberg, *supra* note 38, at 1024.

101. Field, *supra* note 44, at 88; Eisenberg, *supra* note 38, at 1029 (explaining in detail the benefits to society of disclosure and how trade secret law denies society those benefits).

102. *See, e.g., Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 116 (1987) (statement of A. Ann Sorenson, Assistant Director, Natural & Environmental Resources Divisions, American Farm Bureau Federation) (supporting biotechnology as a way to reduce farm costs and improve the environment).

103. *See* U.S. INVESTMENT, *supra* note 19, at 3 (describing the many different areas of biotechnology such as agricultural biotechnology).

trol, imitate, and repair the biochemical, physiological, and pathological processes of living organisms in all areas of discipline.[104] Biotechnology is the catalyst that transforms basic scientific research into practical applications.[105] It is not an isolationist industry; rather, many other industrial sectors use biotechnology as a tool to accomplish their respective needs.[106]

A. *History of Biotechnology and the Role of Patenting*

Historically, dominance over plant life and domestication of animals motivated humans to reject the nomadic ways of their ancestors.[107] Accidental and selective breeding can be regarded as the earliest forms of human genetic manipulation.[108] Genetic engineering, therefore, is consistent with the historical evolution of human intervention into the living world. In time, a patent system was created to promote innovation of useful products for society.[109] The creation of human manipulated organisms was not precluded from patent protection.[110]

The biotechnology industry as we know it today is less than twenty years old.[111] But, the history of patenting natural products can be traced to the 1800s when Louis Pasteur, one of the first biotechnology pioneers, received a patent for the process of beer fermentation in 1873.[112]

Soon after, patent protection was extended to living organisms through the 1930 Plant Protection Act ("PPA").[113] This act was created to protect the financial interests of plant breeders[114] who were concerned that reproducing asexual plant varieties could be per-

104. *See, e.g.*, Shannon Brownlee & Joanne Silberner, *The Age of Genes*, U.S. NEWS & WORLD REP., Nov. 4, 1991, at 69.

105. BIOTECHNOLOGY POLICY, *supra* note 29, at 1 n.1. Biotechnology draws for its foundation from fields such as molecular biology, structural biology, molecular genetics, immunology, cell biology, biochemical engineering, protein engineering, and traditional breeding techniques. *Id.*

106. *See* U.S. INVESTMENT, *supra* note 19, at 3.

107. BRONOWSKI, *supra* note 4, at 60.

108. *Id.* at 68.

109. *See generally* Hamilton & Till, *supra* note 41, at 245 n.1.

110. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980). *See also* PATENTING LIFE, *supra* note 1, at 31.

111. GLOBAL ECONOMY, *supra* note 51, at 3. One report distinguishes between "old" biotechnology (the use of micro-organisms for brewing and baking) and "new" biotechnology (recombinant DNA technology, cell fusion, and other novel techniques). *See* U.S. INVESTMENT, *supra* note 19, at 1.

112. *Id.* at 31. Pasteur received this patent for discovering that the process of fermentation was dependent on the enzymatic action of yeast.

113. S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930).

114. *Id.* Prior to enactment of the PPA, federally funded agricultural research stations were the source of new varieties of plants. PATENTING LIFE, *supra* note 1, at 9. Since enactment of the PPA, 6,500 plant patents have been issued by the PTO. *Id.* at 10.

formed by anyone once the process was out of the inventor's hands.[115] This protection was further enhanced in 1970, with enactment of the Plant Variety Protection Act ("PPVA"),[116] which extended breeders' protection to sexually reproducing plants.[117]

In 1985 the Patent and Trademark Office Board of Appeals further expanded patent protection ruling that, under the Patent Act, explicit provisions for patenting living organisms were not needed.[118] In *Ex parte Hibberd,*[119] the board reversed a patent examiner's denial of a patent for a maize plant that produced seeds with increased levels of amino acids.[120] The examiner asserted that, because Congress had specifically carved out protection of plant breeders' rights under the PPA and PPVA, these statutes provided the exclusive proprietary rights available.[121] Reversing, the board held that nothing in the Patent Act excluded the granting of utility patents for new varieties of plants.[122]

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115. PATENTING LIFE, *supra* note 1, at 9.

116. *Id.* at 10-11. The PPVA was enacted after the International Union for the Protection of New Varieties ("UPOV") was formed by European countries. The UPOV provided plant breeders of member nations with breeders' rights. The United States enacted the PVPA to give United States breeders rights in sexually reproduced plants that were not covered by the PPA. *Id.*

Congress's goal for enacting the PPVA was to provide an economic incentive for companies to undertake the financial risks involved in developing new plant varieties. *Id.* at 11. The PPVA is not a provision under the Patent Act, but is a separate piece of legislation that provides patent-like protection administered by the U.S. Department of Agriculture ("USDA").

117. *Id.* The PPVA provides for two exemptions from infringement. The first is a research exemption that allows other researchers to use protected plant varieties to develop new varieties. The second is a farmer exemption that allows individuals whose primary occupation is raising crops to save subsequent generations of seed for future use or to sell it to other similarly situated farmers. *Id.*

118. *Ex parte* Hibberd, 227 U.S.P.Q. 443, 444-45 (1985).

119. *Id.*

120. *Id.* at 443.

121. *Id.* at 444.

122. *Id.* As a basis for its decision, the board relied on Diamond v. Chakrabarty, 447 U.S. 303 (1980). *See supra* notes 73-79 and accompanying text. In this landmark decision, the Court reiterated the legislative intent of the Act to include as patentable "anything under the sun that is made by man," *Id.* at 309 (citing S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952).

The board noted that, as stated in *Chakrabarty,* legislative history offers two rationales for Congress's enactment of the PPA. The first was to explicitly dismiss the notion that human-altered plant life was not patentable under the Patent Act. The other was to relax the Patent Act's written description requirement (enablement § 112) to allow a plant inventor to more easily obtain a patent on a new plant variety. *Hibberd,* 227 U.S.P.Q. at 444-45.

In the eight years since *Hibberd,* Congress has done nothing to refute that interpretation. However, recent caselaw has suggested that the experimental use defense of new patents should be narrowly defined. *See* Roche Prods. v. Bolar Pharmaceutical, 733 F.2d 858, 863 (Fed. Cir. 1984) ("We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when

Chakrabarty involved patenting a genetically altered micro-organism,[123] and *Hibberd* involved a genetically altered plant.[124] It was not until 1987 that the Board of Patent Appeals addressed the patentability of a multicellular animal.[125] In *Ex parte Allen*,[126] the board rejected a patent claim for a man-made oyster.[127] However the rejection was not based on the fact that oysters are live animals. Instead, the board rejected the patent based on the obviousness provision under section 103 of the Patent Act.[128] Regarding the patentability of live animals, the board noted, that "[t]he issue . . . in determining whether the claimed subject matter is patentable under section 101 is simply whether the subject matter is made by man."[129] Thus, the *Allen* Board reaffirmed the concept that the threshold for patentability is not whether the invention is alive, but whether it has been created by man.

Shortly after *Allen* was decided, the Patent Commissioner clarified the PTO's position on patenting animals.[130] On April 7, 1987 Patent Commissioner Donald Quigg announced, in an interpretive ruling, that "nonnaturally occurring" animals were patentable subject matter.[131] One year later the first animal patent was granted to researchers at Harvard University.[132]

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that inquiry has definite, cognizable, and not insubstantial commercial purposes."). Very basically, the experimental use exception to infringement of a patent means that the use was for an academic pursuit and not for profit. *See generally* Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 Yale L.J. 2169, 2170-71 (1991).

Shortly after *Roche* was decided, Congress enacted the Drug Price Competition & Patent Term Restoration Act, which allows for such experimental use by *generic* drug manufacturers, but denies such use if it involves "commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent." *See* 35 U.S.C. § 271(e) (1988); *see also* Eisenberg, *supra* note 38, at 1023 n.25.

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

124. *Ex parte* Hibberd, 227 U.S.P.Q. at 443.

125. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (1987).

126. *Id.*

127. *Id.* at 1426.

128. *Id.*

> We agree with the examiner that in view of the express recommendation by Stanley et al., experts in the art who have successfully induced polyploidy in one species of oysters, it would have been obvious to one of ordinary skill in the art to induce polyploidy in Pacific *Crassostrea gigas* oysters.

Id. at 1427.

129. *Id.* at 1426. The Supreme Court has implied that although the Board of Patent Appeals and Interferences is merely an adjudicatory body of the PTO, its decisions are binding on the Commissioner. Brenner v. Manson, 383 U.S. 519, 523 n.6 (1966).

130. *Allen* was decided April 3, 1987. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (1987). Quigg's announcement was made on April 7, 1987.

131. "The Patent and Trademark Office now considers nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101." 1077 OFF. GAZ. PAT. OFFICE PAGE NUMBER NEEDED (1987).

132. *See* Gladwell, *supra* note 7, at A1.

Issuance of the Harvard patent in 1987 prompted Congress to consider the propriety of granting animal patents. Shortly after awarding the patent, several bills came before the House and Senate calling for a moratorium on animal patents;[133] but no bills then, or since, have been enacted.[134] Similarly, courts have provided little additional guidance in the area of animal patents. The sole challenge to animal patenting appears to have been in *Animal Legal Defense Fund v. Quigg*.[135] In *Quigg*, the Court of Appeals for the Federal Circuit denied hearing an action brought against Commissioner Quigg because the plaintiffs lacked standing to bring the suit.[136] The merits of animal patenting were never addressed. As such, neither Congress nor any federal court has explicitly addressed the animal patenting question to offer guidance in this complex, emerging legal area.

B. Biotechnology Today

The growing reach of biotechnology affects many disciplines, including food production, energy production, and environmental cleanup.[137] Biotechnology's greatest benefit, however, has accrued to the health care industry.[138] These benefits are realized through genetic

133. The announcement by then Commissioner Quigg led to a number of bills in the House and Senate proposing a moratorium on animal patents. None were passed. *See* Hugo A. Delevie, *Animal Patenting: Probing the Limits of U.S. Patent Laws*, 74 J. PAT. & TRADEMARK OFF. SOC'Y. 493, 499 n.39-40 (1992). Congress has not provided any further statutory guidance in this area.

134. It appears, however, that the PTO acted under a self-imposed moratorium for five years because no new animal patents had been granted between 1987 and 1992. Andrews, *supra* note 8, at A1. The hiatus ended in December 1992 with the issuance of patents for transgenic mice to three different organizations. U.S. PAT. NO. 5,175,383; U.S. PAT. NO. 5,175,384; U.S. PAT. NO. 5,175,385.

135. 710 F. Supp. 728, 729 (N.D. Cal. 1989).

136. *Id.*, *certifying questions to* 900 F.2d 195, 195 (9th Cir. 1990), *aff'd*, 932 F.2d 920, 922 (Fed. Cir. 1991). The plaintiffs comprised individual farmers or animal husbanders and various non-profit groups "championing" the rights of animals. 710 F. Supp. at 729. The district court granted the defendant's motion to dismiss the case for failure to state a claim. *Id.* Plaintiffs then appealed the dismissal to the Ninth Circuit. 900 F.2d at 196. In turn, the Ninth Circuit referred the case to the Federal Circuit which has exclusive appellate jurisdiction for cases arising under 28 U.S.C. § 1338. *Id.*

137. BIOTECHNOLOGY POLICY, *supra* note 29, at 3; *see also* GLOBAL ECONOMY, *supra* note 51, at 3.

138. GLOBAL ECONOMY, *supra* note 51, at 45. "In 1988, [Office of Technology Assessment] found that human health care was the focus of research for most companies, whether large or small. Agriculture and chemicals were the focus of far fewer firms, and environmental applications of biotechnology were even less well represented." *Id.*

therapy,[139] pharmaceutical production,[140] and understanding disease mechanisms.[141]

The area of health care most significantly affected by biotechnology is the treatment of genetic diseases, from the common cold to cancer.[142] Genetic engineering has already produced a vaccine that successfully prevents viral poultry disease.[143] Looking forward, extrinsic genetic material may soon be used to treat diseases such as cystic fibrosis.[144]

More recent genetic engineering advances demonstrate even more dramatically the life-saving capacity of biotechnology in health care. In 1990, for example, the FDA approved the first clinical trial for human gene therapy.[145] One result of that study may have saved the life of a young girl suffering from adenosine deaminase deficiency ("ADA").[146] Researchers used genetic engineering technology to insert the gene for ADA into deficient cells taken out of her body.[147] The cells containing the newly incorporated gene were then reinserted into her body, allowing her to live a healthier life. Prior to this technology, such a disease had no chance of being treated.

Biotechnology has also enhanced the pharmaceutical industry. Drug manufacturers can now develop complex therapeutic drugs previously not capable of being produced in laboratories.[148] Another ad-

139. *See, e.g.*, Brownlee & Silberner, *supra*, note 104, at 69 (discussing the treatment of genetic disorders).

140. *See, e.g.*, BIOTECHNOLOGY POLICY, *supra* note 29, at 3 (discussing production of insulin).

141. *See, e.g.*, GLOBAL ECONOMY, *supra* note 51, at 73. *See also infra* notes 156-58 and accompanying text.

142. The common cold is believed to be caused by a virus which, by definition, is a packet of genetic material that invades the host's body. TABER'S CYCLOPEDIC MEDICAL DICTIONARY V-28 (13th ed. 1977). The genetic link of some cancers is well known. *Id.* at C-9. Because genetic material forms the basis of these diseases, they have colloquially been included under the general heading of genetic diseases.

143. Malcolm Gladwell, *USDA's Chicken Feat: A Resistant New Breed*, WASH. POST, Aug. 11, 1988, at E3. Scientists inserted genes into one day old chick embryos which blocked the effect of the avian leukosis virus; this virus was estimated to cost U.S. egg producers between $50 and $100 million annually. *Id.*

144. In 1989, scientists discovered the gene that codes for cystic fibrosis, and have since been able to determine the structure of the protein involved. The gene has not yet been inserted into affected humans, but it has been successfully inserted into transgenic mice that are secreting an enzyme into their milk. Although these mice may be able to provide humans with this enzyme, direct insertion of the gene into affected humans would provide a more lasting effect. Joanne Silberner, *Following the Blueprint of a Deadly Inherited Disease*, U.S. NEWS & WORLD REP., Nov. 4, 1991, at 73.

145. Brownlee & Silberner, *supra* note 104, at 69.

146. *Id.* ADA is an inherited disorder that destroys the body's immune cells; its effect is similar to that caused by Acquired Immunity Deficiency Syndrome ("AIDS"). *Id.*

147. *Id.*

148. Erythropoietin, a drug used to treat anemia caused by bone marrow suppression, is one example of a drug that is now being produced by genetically engineered

vantage of biotechnology is its ability to cost effectively produce predictable amounts of essential natural products that are inherently scarce and difficult to extract.[149] Insulin,[150] for example, has been traditionally collected by isolating it from the pancreas of pigs and cattle at slaughter houses.[151] As a result of genetic engineering, however, large quantities of highly pure human insulin are produced through genetic manipulation of bacterial organisms.[152] Although genetically altered microbial agents continue to be a viable producer of new drug products, biotechnology is rapidly expanding into new frontiers. New technologies will soon produce larger quantities of new drugs that can be secreted into the milk of domestic animal species.[153]

A third area in which biotechnology has enhanced human health care is through the production of animal disease models.[154] The patented Harvard mouse,[155] for example, has a higher than average propensity to develop cancer thus enabling researchers to increase the sensitivity of detection of carcinogens and maximize the validity of such studies.[156] Other animal models are being developed to study such human diseases as neurofibromatosis[157] and hypertension.[158]

In addition to its direct impact on health care, biotechnology indirectly affects human health through the production of more wholesome food products. The benefits of this technology were recently

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microorganisms. The drug is essentially composed of a collection of protein molecules that were too large to be created through traditional commercial synthesis. Margaret Fischl et al., *Recombinant Human Erythropoietin for Patients with ADS Treated with Zidovudine*, 322 NEW ENG. J. MED. 1488, 1492 (1990).

149. BIOTECHNOLOGY POLICY, *supra* note 29, at 3.

150. Insulin is used to regulate blood sugar imbalances which occur in diabetes.

151. BIOTECHNOLOGY POLICY, *supra* note 29, at 3.

152. During the 1980s it was discovered that by inserting human gene coding for insulin into microorganisms, a purer and more specific human form of insulin could be produced. This technique is used for insulin production today. *Id.*

153. At this writing, three independent research groups are experimenting with goat, sheep, and cattle that will secrete quantities of large complex human proteins in their milk. Anne Simon Moffat, *Transgenic Animals May Be Down on the Pharm*, 254 SCI. 35, 35 (1991). These proteins include clotting factors to treat hemophilia; erythropoietin to stimulate bone marrow production suppressed due to AIDS or cancer; and alpha-1 antitrypsin (AAR), which may alleviate emphysema and other degenerative lung diseases. *Id.*

154. Jaenisch, *supra* note 19, at 1468.

155. U.S. PAT. NO. 4,736,866.

156. *Id.*

157. Steven H. Hinrichs et al., *A Transgenic Mouse Model for Human Neurofibromatosis*, 237 SCI. 1340, 1340 (1987). Neurofibromatosis is an autosomal dominant disease that can cause severe cosmetic deformity. *See* MEDICAL GENETICS: PRINCIPLES AND PRACTICE 173 (James J. Nora & F. Clarke Fraser eds., 1981).

158. S. Kimura et al., *High Blood Pressure in Transgenic Mice Carrying the Rat Angiotensinogen Gene*, 11 EMBO. J. 821, 821 (1992). Hypertension refers to the elevation of systolic or diastolic blood pressure. THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, ch. 26, at 390-403 (R. Berkow ed., 15th ed. 1987).

recognized by a National Academy of Sciences ("NAS") committee[159] in a report proposing that, in order for Americans to achieve the American Heart Institute reduced fat intake goals, leaner farm animals are essential. The committee went on to suggest genetic engineering as the source of the long term solution.[160]

Although it is capable of resolving a variety of enigmatic social issues, biotechnology is not an end in and of itself. Not only must the products of biotechnology be applied once developed, there must be an initial incentive to even perform the research. Biotechnology research requires a substantial financial outlay and the private industry will only make these investments if they receive some form of protection, usually through patents. Without this protection, the flow of competitively priced goods will likely be inhibited.

Patent protection is particularly important to a start-up high technology companies.[161] The inability to obtain a patent can severely limit the investment incentive needed to finance the development of new products and processes, and in these companies there are often significant investment requirements with restricted available funds.[162] Absent some form of certainty with regard to protection of intellectual property rights, investment in research will undoubtedly be cur-

159. A three year study funded by the USDA found that thirty-six percent of Americans' diet comes from fat. The American Heart Association, however, suggests an intake of not more than thirty percent fat. Most dietary fat comes from animal food products. Although one solution to healthier diets is trimming excess fat from meats at slaughter, the "real solution lies in the production of leaner animals . . . [c]hanges in their diet, breeding, and genetic engineering will all help to produce less fatty meat." Marjorie Sun, *Designing Food by Engineered Animals*, 240 SCI. 136, 136 (1988).

160. *Id.* The report also acknowledged that federal policies must change. For instance, the USDA meat grading system continues to reward cattlemen for producing fatter animals. *Id.*

Biotechnology has been applied to ensure a more constant food supply, not only by increasing the efficiency of food production but also by making farmers less vulnerable to seasonal effects. *See, e.g.*, Lemieux & Wohlgenant, *supra* note 36, at 903. The technology is helping to reduce the adverse environmental effects of agricultural practices. Council Report, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1429 (1991) (indicating that by 1995, genetically engineered plants will successfully resist insects, viruses, frost, and temperature changes).

For example, a natural product called brassinolide is being used as a plant growth stimulator. When sprayed on plants impaired by adverse growing conditions, this product will cause them to recover the growth and development that was retarded. N. Bhushan Mandava, *Plant Growth-Promoting Brassino-Steroids*, 39 ANN. REV. PLANT PHYSIOL. & PLANT MOL. BIOL. 23 (1988).

161. Mandava, *supra* note 160, at 212.

162. *Id.*; *Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 220 (1987) (statement of Winston J. Brill, Ph.D., Vice President, Research and Development, Agracetus Corp.) (testifying that his company, Agricetus, depended on patent protection to "justify major investments in biotechnology").

tailed.[163] Biotechnological industries are further burdened when the government restricts the use of newly invented products. Industries involving food and drugs must comply with stringent regulation not encountered by other industries.[164] The rigorous safety studies imposed on food and drugs are costly, thus increasing the initial cost of commercializing a product.[165] These same concerns—protecting investment and the need for large initial cash outlays to accommodate regulatory constraints—plague inventors seeking patents on animals.[166]

IV. Analysis of Animal Patenting Issues

The animal patenting debate is far from over. On the contrary, it has scarcely begun. From the 1987 pronouncement of then Commissioner of Patents Donald Quigg that nonnaturally occurring animals were patentable[167] and the grant of the first animal patent in 1988, the debate has continued to intensify.[168]

Many of those who oppose animal patenting question whether the benefits of the technology are worth the risks,[169] but until the technology is developed, the question must remain unanswered. Without practical biotechnology research, the risks are mere speculation.[170] The arguments that most frequently arise in opposition to animal patents likewise are based on speculative harms that involve morality and economics. These arguments focus on: "(1) interference with the natural world; (2) devaluation of human life; (3) survival of the family farm; (4) commercialization of academic research; and (5) agriculture and laboratory animal suffering."[171] Unfortunately, when the debate over animal patents is confined to theoretical issues of morality and economics, core issues such as the purpose of the patent system and the role of regulation get overlooked.

Morality is a dubious standard upon which to deny patent protection. Courts that considered early patent cases, however, withheld pat-

163. Many see intellectual property protection as a "paramount" consideration of national competitiveness in biotechnology. Global Economy, *supra* note 51, at 203.

164. U.S. Investment, *supra* note 19, at 11.

165. *Id.*

166. *See supra* part III.A.

167. Brody, *supra* note 21, at 141.

168. *See* Patenting Life, *supra* note 1, at 12.

169. *See, e.g.*, John B. Attanasio, *The Genetic Revolution: What Lawyers Don't Know*, 63 N.Y.U. L. Rev. 662, 714 (1988) (stating caution is essential when encountering such a multifaceted area as biotechnology that may well produce untold benefits).

170. *See, e.g.*, Jones, *supra* note 27, at 909; Merges, *supra* note 12, at 1059; Patenting Life, *supra* note 1, at 17.

171. Dresser, *supra* note 98, at 410; *see also* Patenting Life, *supra* note 1, at 18; Brody, *supra* note 21, at 142-50 (discussing similar concerns).

ents when they perceived an immoral purpose or utility.[172] In these cases, denial was justified as an effort to preclude (1) inventions that served no purpose other than to defy a readily identifiable norm; or (2) inventions that could only be used for fraudulent purposes.

Gambling devices are examples of inventions whose sole purposes were considered a contravention of readily identifiable norms. In the early nineteenth century, patents were frequently denied on gambling devices because gambling was believed to be "morally wrong."[173] By the 1970s this trend reversed,[174] partly because gambling was no longer a "major moral issue" and partly because courts found that the moral-worth test was an indeterminate standard.[175] "Miracle cures" in medicine exemplify inventions that were deemed to be used for fraudulent purposes.[176] Patents on dubious medical treatments were systematically denied before the FDA was established to regulate medical drugs and devices.[177]

In the foregoing examples, patents were denied on products whose utility was limited to immoral or fraudulent purposes. In the case of animal patents, however, the patentable invention arguably offers a beneficial use.[178] Thus, concern that societal benefit might be outweighed by the ostensible immorality of human dominance should be immaterial for PTO purposes. The proper venue for consideration of moral issues of biotechnology is within the regulatory agency entrusted with the product's oversight, not the PTO.[179]

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172. *See generally* Merges, *supra* note 12, at 1062.

173. *Id.* at 1063.

174. *Id.*

175. *Id. See, e.g.*, Griswold v. Connecticut, 381 U.S. 479, 480 (1965) (holding that Connecticut statutes were unconstitutional which imposed criminal sanctions for providing contraceptive devices). Thus birth control devices, once considered illegal, are now recognized as socially useful to prevent population explosion. With regard to this transition, one commentator notes: "[I]n determining 'utility' based on public mores, the courts should apply a test which will not penalize an inventor who may be prescient enough to be anticipating basic needs of a society changed by forces yet unrecognized by the general public." R. CHOATE, CASES AND MATERIALS ON PATENT LAW 76 (3d ed. 1987).

176. Merges, *supra* note 12, at 1064.

177. *Id.* Creation of the FDA, the agency entrusted to regulate food and drugs, allowed courts to consider only functional utility of an invention. Appropriately, clinical safety is now left to the regulators. Merges, *supra* note 12, at 1064.

178. For example, a genetically engineered pig that could produce human hemoglobin would, arguably, be a major benefit to the chronic blood shortages throughout the world. *See* Andrews, *supra* note 8, at D5 (indicating that DNX Corporation is pursuing human hemoglobin production in pigs).

179. *Id.* at 1068. *See, e.g., In re* Application of Anthony, 414 F.2d 1383, 1398-99 (C.C.P.A. 1969) (finding that although the antidepressant drug for which a patent was requested was suspended by the FDA for safety reasons, that was immaterial to grant of the patent).

Each of the above-mentioned concerns will be individually addressed in terms of their relevance to the purpose of the patent system, the reality of biological systems and the fallibility of human premonition. Moreover, the perceived cause and effect relationship between biotechnological patents and other events will be evaluated.

A. *The Morality of Animal Patenting Issues*

1. *Animal Patents Will Cause a Loss of Species Integrity*

The first moral issue that arises in the context of animal patents is the concern that animal patents will cause a loss of species integrity. The fallacy in this concern, however, is the assumption that species are separate and distinct.[180] They are not. A species ability to survive is dependent on a diverse and dynamic gene pool.[181] Unlike classic selective breeding, genetic engineering may allow selection of a single genetic attribute without loss of overall genetic diversity.[182]

Similarly, the perception that genetic engineering will result in a loss of species integrity is fallacious and fails to comport with biological reality. The distinct lines that divide species are not an inviolate law of nature. In fact, the very classification of distinct species is a man-made contrivance.[183] From the initial publication of *The Origin of Species*[184] in 1859, to the current day, variation within species has been recognized as fundamental to nature.[185] Species, by their very essence, exist within a continuum of constant transition.[186] The taxonomic classification system that categorizes species into distinct groups is only a framework—a scientific paradigm—that allows biologists to better understand our world.[187] It is not a definition of the living world. Moreover, scientific evidence suggests that interspecies breeding is more frequent than once thought.[188] This interspecies breeding serves as a natural method to introduce new genetic material into a species when

180. Recombinant DNA Research; Proposed Actions Under Guidelines, 49 Fed. Reg. 37,016 (1984). An excerpt from this letter states: "The crossing of species borders and the incorporation of genetic traits from one species directly into the germ line of another species represents a fundamental assault on the principle of species integrity and violates the right of every species to exist as a separate, identifiable creature." *Id.* at 37,017.

181. *See, e.g.*, THE WONDERS OF LIFE ON EARTH 47 (Life & Lincoln Barnett eds., 1960).

182. PATENTING LIFE, *supra* note 1, at 13-14.

183. *See generally* PHILIP APPLEMAN, DARWIN 98 (1970).

184. CHARLES DARWIN, THE ORIGIN OF SPECIES (1859).

185. APPLEMAN, *supra* note 183, at 98.

186. PATENTING LIFE, *supra* note 1, at 14.

187. Dresser, *supra* note 98, at 413.

188. Peter R. Grant & B. Rosemary Grant, *Hybridization of Bird Species*, 256 SCI. 193-94 (1992).

environmental conditions require the option of adaptation or extinction.[189]

Biotechnology provides for the creation of animals with new genetic attributes in a more controlled manner.[190] It also provides for repair of faulty attributes. Unlike traditional breeding methods, which also allow the selection of specific attributes, transgenic animals may possess genetic traits not typically found in the species.[191] It is this ability to expand an animal's genetic make-up by introducing genetic material from an unrelated species that causes the most concern.[192]

Ironically, advocates of "species integrity" are not equally vocal about the harmful effect of narrowing the gene pool through natural, controlled breeding.[193] Classic selective breeding produces proven detrimental results through uncontrolled selection for more than one trait at a time. Problems have arisen, for example, in Arabian horses when breeding for a desired "look" and "type" of animal inadvertently introduced an hereditary immune disease that strips afflicted horses of their immune system, resulting in an effect similar to the AIDS virus.[194] An estimated twenty-six percent of the Arabian horse population carries this gene and essentially all animals afflicted with this recessive gene die by six months of age.[195] This unintended breeding result is only one of many debilitating diseases that afflict domestic animals exposed to human selective intervention.[196] Genetic engineering, on the other hand, potentially avoids these problems by allowing expression of a single desirable trait without concomitant selection of others.[197]

Opposition to animal patents based on concern over loss of "species integrity" fails to recognize the scope of the problem. In the natural world, species diversity provides the best chance for survival. Genetic engineering allows an alternative means to attain the desired results of classical breeding while minimizing the potential for narrowing the

189. *Id.* at 197.

190. *See generally* Ina Hoeschele, *Potential Gain from Insertion of Major Genes into Dairy Cattle*, 73 J. DAIRY SCI. 2601, 2603 (1990). To date, there are two common methods for insertion of genes from one specie into another: pronuclear injection("PI") and retroviral ("RV") vectors. The former technique is used in mammals, the latter more frequently in birds.

191. Jones, *supra* note 27, at 875.

192. PATENTING LIFE, *supra* note 1, at 97.

193. Boyce Rensberger, *A Rescue Mission for Dying Breeds: U.N. Program Targets Indiginous Farm Animals*, WASH. POST, Feb. 3, 1992, at A3 (discussing the absence of protest over the extinction of many domesticated animals from controlled breeding).

194. Roger M. Genetzky et al., *Combined Immunodeficiency in an Arabian Filly*, 7 THE COMPENDIUM ON CONTINUING EDUCATION S319 (1985).

195. *Id.*

196. *See, e.g.*, Gary Wilkes, *Dogs Have Quirks That Don't Show On Pedigree*, STAR TRIB. (Mpls.), July 6, 1993, at 7E (identifying Dalmatian dog breeding that selects for appearance only, but also carries the gene for nerve deafness, a common Dalmatian disorder).

197. *See* PATENTING LIFE, *supra* note 1, at 97.

gene pool. The significant difference between the two is that genetic engineering does so within a more controlled environment. Therefore, concern for species integrity will not be served by denial of animal patents. Effective regulation of both traditional and recombinant gene selection is necessary, but it must be evenly applied.

2. *Animal Patents Will Lead to the Devaluation of Human Life*

Patent opponents also fear the possibility of creating human-animal hybrids which, they contend, is intrinsically immoral.[198] As a result of our ability to transfer genes of one mammal into another, some fear that animals will be created with enough human genes to be "partially-human" creatures.[199] At the core of this concern is the issue of defining what it means to be human, a concept we have always taken for granted.[200] The definition may challenge the validity of our cultural assumption that humans are superior beings.[201]

Opponents disregard the fact that the rationale and incentive for biotechnological innovation has been recognition of the value of human life. Both humans and animals suffering from previously incurable diseases now have hope for new therapies and even cures.[202] It is because of the high esteem afforded life that we must allow the benefits of our skill and knowledge to enhance the human condition; we cannot let it be stifled by some irrational notion of what "human" really means. Despite fears of harm posed by patenting biotechnology, society continues to demonstrate a need for new treatment methods. The answer, therefore, is not suppression, but regulation.

Although the technology that would allow transfer of large blocks of human genes into animals is not presently within our grasp, consider, arguendo, that human-animal hybrids are ready for patenting. How should the risks be evaluated? One technique is to compare the potential harms of biotechnology with known risks of other harmful technologies. One commentator has compared the issuance of animal patents with the issuance of patents on nuclear technology.[203] Nuclear technology patents are granted in the same way as are patents in other technologies,[204] but they are reviewed and regulated by the Department of Defense.[205]

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198. Dresser, *supra* note 98, at 415.

199. *Id.* Some observers fear that this capability will reduce "people to a set of malleable molecules that can be interchanged with those of species that people regard as inferior." *Id.*

200. *Id.* at 415-16.

201. *Id.*

202. *See* Roberts, *supra* note 35, at 906 (discussing research that suggests many diseases that originate in the liver may be candidates for gene therapy).

203. Merges, *supra* note 12, at 1066-67.

204. *Id.* at 1066.

205. *Id.*

Through regulation, the goal of the patent system in the nuclear area becomes clear: It is not to stifle development of the technology, but rather to keep the technology out of the hands of those with harmful intent.[206] Comparison of genetic engineering with nuclear technology also elucidates the potential ills that biotechnology might foist upon society. As one commentator noted, "The nuclear saga teaches society harsh lessons about the need for caution in encountering powerful new technologies."[207] This caution underscores the need for regulation to control harmful proliferation. Thus, prophylaxis against a genetic parade of horribles requires a realistic approach to regulation, not blanket inhibition of the technology.

Patent law history offers many examples of technologies that are capable of both good and evil.[208] The fact that harm may arise from misuse of an invention is not sufficient grounds to deny a patent. On the contrary, it is a valid reason to strengthen regulatory mechanisms. It is intellectually facile to sit back and ponder potential evils of technology, but these armchair inquiries must be balanced against real life successes. A true vision of morality looks at both sides of the issue.

3. Animal Patenting Will Cause Increased Animal Suffering

Many opponents to animal patenting also fear that the research required by these patents will lead to increased animal suffering. These concerns have been raised both at Congressional hearings[209] and by plaintiffs in the courts.[210] However, in neither instance was it shown that animal patents are more likely than not to lead to increased animal suffering. In *Animal Legal Defense Fund v. Quigg*, the court noted that these were regulatory issues and, as such, already addressed by federal statute.[211] Some animal suffering concerns may in fact be better prevented by permitting animal patenting.

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206. *Id.* at 1067.

207. Attanasio, *supra* note 169, at 683.

208. *See, e.g.*, Merges, *supra* note 12, at 1062 (discussing inventions that are neither good or evil in and of themselves and suggesting that their use determines their moral character).

209. *See Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 62-63 (1987) (statement of John Hoyt, Humane Society of the United States) (testifying about concerns that animal patents will increase animal suffering).

210. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925 (Fed. Cir. 1991). Plaintiffs asserted that they were harmed as a result of the Commissioner's statement, because their efforts to prevent injury to farm and laboratory animals would be frustrated. *Id.*

211. The court stated, "[F]or increased experimentation to lead to increased cruelty, appellants would have to allege that the existing animal cruelty laws are insufficient or that the issuance of 'animal' patents would 'encourage' researchers to disobey these laws." *Id.* at 937.

A frequently cited example of the harmful effects of genetic engineering has been the incorporation of the bovine growth hormone gene into pigs.[212] This gene promotes an increased lean to fat ratio that produces a more wholesome meat product.[213] Animals expressing the gene, however, have correlated increases in health and fertility problems.[214] Transgenic offspring that expressed the gene were found to be lethargic, arthritic, and to have an increased vulnerability to stress,[215] thus reducing their market value. As discussed earlier, the function of the patent system is to provide economic incentive for innovative activity, not to produce economic idiots.[216] Products with little market value will either stimulate additional research to perfect, or at least improve, the product, or inhibit release of the product into the marketplace.[217]

Unfortunately, transgenics success stories are less frequently mentioned. Consider, for example, the genetically engineered transgenic chicken that resists avian leukemia virus.[218] The incorporated gene not only results in healthier birds but it saves the industry an estimated $50 to $100 million per year.[219]

Similar to these claims involving farm animals, the argument that animal patents may cause increased suffering of nonfood producing animals is likewise questionable.[220] This argument erroneously presumes that nongenetically engineered laboratory animals are not used in laboratory research. We have long allowed, and even condoned, a limited amount of animal suffering for the benefit of society at large. Opponents of animal patents ignore the counterargument that creation of animals with specific desirable traits will likely decrease the overall number of animals suffering by decreasing the amount of animals needed to constitute a statistically significant research population.[221] But, as in the case of the "Harvard Mouse," the fact that a single mouse now has an increased chance of cancer is in itself a more

212. *See generally* Dresser, *supra* note 98, at 422; Hoeschele, *supra* note 190, at 2613; Jones, *supra* note 27, at 880; PATENTING LIFE, *supra* note 1, at 106; Pursel et al., *Genetic Engineering of Livestock*, 244 SCI. 1281, 1282 (1989).

213. Pursel, *supra* note 212, at 1282.

214. *Id.* at 1284.

215. *Id.* However, these same symptoms, to a somewhat lesser degree, are widespread in the general swine population as a result of traditional breeding methods. *Id.* at 1285.

216. *See supra* part III.A.

217. *See supra* part III.A.1. Animals with the pathological conditions of the pigs constitute a high commercial risk and negate the potential for economic gain by marketing in the agricultural industry. Hoeschele, *supra* note 190, at 2613.

218. Gladwell, *supra* note 7, at E3.

219. *Id.*

220. PATENTING LIFE, *supra* note 1, at 134-35.

221. *Id.*

fundamental moral question.[222] This concern is real and is subsumed by the essential issue of sacrificing animal life for human life.

Whether it is morally correct to sacrifice an animal life for a human life is an issue that transcends the context of animal patenting. As stated by one Congressional witness, "When compared with the ethical issues involved in our breeding, buying, selling, confining, eating, and performing research on animals, the ethical questions surrounding animal patents seem relatively less important."[223] Nonetheless, these are important issues and society must ultimately decide how to regulate the humane treatment of animals. Denial of animal patents, however, is not part of the solution. Whether animal suffering should be permitted and whether animals should be patented are completely different issues.

4. *Animal Patenting Will Cause Commercialization of Academic Research*

Another argument in the morality-based attack claims that animal patents will lead to increased commercialization of academic research.[224] This line of argument predicts: (1) impeded scientific progress as the result of the secrecy of pending patent[225] technology;[226] (2) attrition of basic research as the result of financial incentives inducing academic researchers into commercially profitable areas;[227] and (3) financial windfalls to corporations that build on knowledge generated through tax-supported research.[228] Although these events likely will occur, this eventuality is not the result of animal patenting, but of market economics and express Congressional intention.

These changes in academic research will occur for several reasons. First, new products generated by biotechnology create markets that did not previously exist. With each new market comes new commercial opportunities, which is precisely the tenet on which the free market

222. *Id.*

223. Dresser, *supra* note 98, at 423-24.

224. *Id.* at 419; Eisenberg, *supra* note 38, at 1018.

225. Although patents encourage disclosure, the Patent Act precludes patenting any invention known or published more than one year prior to the inventor's invention date, or known or published more than one year prior to the applicant's date of filing for a patent. 35 U.S.C. § 102(a), (b) (1993). Hence, an inventor may—and should—refrain from disclosing an invention until after publicly filing the patent application. Once filed, a patent application typically takes about eighteen months to be granted, at which time disclosure is then made available to the public. PATENT & TRADEMARK OFFICE, DEPARTMENT OF COMMERCE, ANNUAL REPORT vii (1992).

226. *See, e.g.*, Eisenberg, *supra* note 38, at 1017 (stating that the idea that patents will "promote scientific progress is counter-intuitive to many observers of research science"); Dresser, *supra* note 98, at 419-20 ("patenting will create a need for secrecy among academic researchers").

227. Dresser, *supra* note 98, at 421.

228. *Id.* at 420.

system rests. Changes in academic research may also occur because the federal government has expressly legislated to foster these changes.[229] That is, after all, why we elect our representative officials—to legislate in ways that will benefit society.

Although these effects may occur, patents themselves are not wholly to blame. For example, animal patents do not contribute to increased secrecy in technological advancement; they are merely a means to maintain proprietary rights in a commodity for which a societal need, as reflected by a commercial market, has arisen. In fact, without the subsequent protection of a patent, researchers would have an incentive to keep major discoveries secret until the discoveries could be commercialized as is required under trade secret law. Therefore, animal patents arose from the same factors that provoked an increase in secrecy: the creation of a commercial market that reflects societal needs.

Once a commercial market for a product is established, there arises an incentive to maintain proprietary rights as long as possible to maximize economic benefit.[230] Hence, the transfer of knowledge is not impeded by the patent system, but by the desire to control the economic value in a product by protecting proprietary rights. Thus, only by eliminating the societal need for biotechnology will the market dissipate so that inventors will no longer have a reason to protect their intellectual products. As long as the market endures, biotechnology will continue, but without patent protections it will continue in secret. It is possible, therefore, that denying animal patents may only exacerbate the consequences of secrecy in academic research.

Moreover, it is unreasonable to blame animal patenting for effects intended by express Congressional enactment. The Stevenson-Wydler Technology Innovation Act of 1980,[231] the Bayh-Dole Act of 1980,[232] and the Federal Technology Transfer Act of 1986[233] were specifically enacted to promote national competitiveness.[234] The Stevenson-Wydler Act was enacted to promote commercialization of inventions from federally funded research.[235] The Bayh-Dole established uniformity in

229. *See generally* 15 U.S.C. § 3701 (1980); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785.

230. *See, e.g.*, Gautam Naik, *Cellular Phone Rates Spark Static from Users*, WALL ST. J., May 5, 1994, at B1. Explaining the cellular phone industry's failure to lower consumer prices in light of the industry's decreasing costs, an industry representative noted, "Cellular firms clearly have room to lower prices. But they know they have competition coming. So you get your margins while you can." *Id.*

231. 15 U.S.C. § 3701 (1980).

232. 35 U.S.C. §§ 200-210.

233. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended in scattered sections of 15 U.S.C.).

234. *Bill Mandates Contractor Ownership of IP Rights from Federal R&D Pacts*, 46 PAT. TRADEMARK & COPYRIGHT J., (BNA) 507 (Oct. 14, 1993). [hereinafter MANDATE]

235. 35 U.S.C. §§ 200-210.

patenting inventions resulting from federally-funded research, and encouraged commercialization of these inventions.[236] The Federal Technology Transfer Act established a process for cooperative research and development agreements between government-controlled laboratories and private sector industry.[237] Both the Stevenson-Wydler Act and the Federal Technology Transfer Act were enacted to increase joint research between federally funded laboratories and private sector industry and to promote the transfer of federally supported scientific research into the commercial marketplace.[238]

Academic research is indeed commercialized, but not as the result of animal patents. Commercialization occurs because there is a societal demand for the product and because Congress has specifically legislated for it. Therefore, by denying animal patents based on these perceived ills, we shift the attention from the true sources of stifled research—the free market and lack of proper regulation.

B. The Economics of Animal Patents

Concern with the economics of animal patenting have been raised by both sides. Opponents contend that animal patents will bring about the economic demise of the family farm.[239] Proponents contend that the denial of animal patents will bring about the demise of a biotechnology industry.[240] In reality, neither argument is relevant to the PTO's purpose in issuing patents.

The PTO does not determine patentability based on the economic value of an invention.[241] It has been well recognized, since the Constitution was drafted, that the economic value of an invention is indeterminable at the time the patent is initially granted.[242] In fact, the ability to predict *any* economic worth, much less the ultimate worth, is almost impossible at the time of patent.[243] An invention's economic worth is

236. H. REP. NO. 1307, pt. 1, 96th Cong., 1st Sess. 3 (1980).

237. MANDATE, *supra* note 235 at 507.

238. Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified as amended in scattered sections of 15 U.S.C.); BIOTECHNOLOGY POLICY, *supra* note 29, at 6.

239. Dresser, *supra* note 98, at 417.

240. *See Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 117, 118 (1987) (statement of A. Ann Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation) (testifying in favor of animal patents as necessary to international competition).

241. *See, e.g., In re* Kirk, 376 F.2d 936, 963 (C.C.P.A. 1967) (stating that patentability has nothing to do with commercial value).

242. Hamilton & Till, *supra* note 41, at 247-48. And there has been no reason since to question this premise.

243. Consider, for example, the French military commander who said in 1911, "Airplanes are interesting toys but have no military value." Dick Youngblood, *Ideas for New Products Stretch the Imagination*, STAR TRIB. (Mpls.), Nov. 1, 1992, at 2D. In the 1920s,

determined by the free market, not by the patent system.[244] If society determines that an invention has no use, there is no economic market value,[245] and the invention will be limited by its own inherent worthlessness.[246]

The economics of patenting is fundamental to the patent system, but it plays no role in determining whether a patent should be granted. The societal benefit for patent-stimulated advancement was aptly noted in 1948 by one commentator who stated that "the useful arts stand at the very center of the economy."[247] Unfortunately, the issues of patents and economics have been obfuscated in the animal patenting debate. Instead of considering patents in terms of their economic benefits to society, the debate has been staged in the context of the economic effects of animal patents in two major industries: the United States farm industry and the biotechnology industry.

Most animal patent opponents that raise economic concerns represent the agriculture sector[248] and contend that continued animal patenting will lead to the demise of the family farm.[249] This argument is based on two major premises: (1) animal patenting will lead to higher priced animals that will be available only to corporate farmers, putting the family farmer at an economic disadvantage; and (2) animal patent-

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one of the movie industry's Warner brothers said of "talkie" movies, "Who wants to hear an actor talk?" *Id.* IBM Chairman Thomas Watson predicted in 1943 "a [total] world market for about five computers." *Id.* Most significant, however, is the 1899 prognostication by the then director of the PTO who announced that "[e]verything that can be invented has been invented." *Id.* Based on our track record, now would seem an inappropriate time to start asking the patent office to make the economic determination of an invention a criteria for patentability.

244. Eisenberg, *supra* note 38, at 1028.

245. *Id.*

246. *Id.*

247. Hamilton & Till, *supra* note 41, at 259.

248. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 923 n.3 (Fed. Cir. 1991). In contrast, the economic concerns of medical and laboratory animal interests strongly favor patenting. *See, e.g., Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 37 (1987) (statement by Dr. Thomas Wagner, Edison Animal Biotechnology Center, Ohio University, Athens, Ohio) (testifying that medical and pharmaceutical research will greatly benefit from transgenic animal production).

Interestingly, many farm organizations including the American Farm Bureau Federation, which claims approximately 80% of American farmers as members, have gone on record in support of granting animal patents. A. Ann Sorenson, *Perspectives of Farmers, in* ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES 117, 124 (William H. Lesser ed., 1989).

249. *Animal Legal Defense Fund*, 932 F.2d at 932; *see also Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 117, 119 (1987) (statement of Dr. A. Ann Sorenson, Assistant Director, Natural & Environmental Resources Divisions, American Farm Bureau Federation) (testifying that Patent Office policy should not be used in an attempt to prevent the displacement of family farms).

ing will produce animals with increased production efficiency, reducing the number of farmers needed.[250] Assuming, arguendo, that both premises are true, they are nonetheless irrelevant to the animal patent issue and contrary to common logic.

The patent system exists to bring new products and ideas to the market by offering economic incentives to inventors.[251] Obviously, a predictable result of the patent system is that new technology will foreclose the need for antiquated technology.[252] Although it is unfortunate that increasing farming efficiency will drive more farmers out of business, other new technologies in farming have already had the effect of causing fewer and larger farms.[253] Animal patents are not unique in that regard.[254] Making a sector of industry more efficient is the constitutional purpose of the patent system. Denial of patents for this reason would completely contravene the constitutional purpose of the patent system.

On the other hand, biotechnology experts argue that without the security of patents, their industry will flounder. This, too, is not relevant to the PTO. What is relevant is whether biotechnology is constitutionally intended to be promoted through patent protection. It is. This contention is supported by both Congress and the Supreme Court.[255]

Economic considerations affect animal patenting in only a very limited way. The appropriateness of animal patents does not rely on the economic value of the invention. Even opponents to animal patenting admit to this view. The significance of economics is limited to whether an invention may possibly benefit society which, at the time of patenting, is rarely known. Thus, it is important to deflect attention from speculative, economic concerns and toward the heart of the issue: whether we want the technology produced in animal patenting to be part of the current world within which we live.

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250. *American Legal Defense Fund*, 932 F.2d at 932; *see also Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 350, 350 (1987) (statement of Russ Weisensel, Wisconsin Agribusiness Council) (testifying that the corporate farms feared today are the same as those feared in the 1930s: the farms that market the top bloodlines for livestock available to the small farmer); LESSER, *supra* note 21, at 83 ("Whenever productivity improvement has come about as the result of previous new technologies the effect has been fewer and larger farms.").

251. *See supra* text accompanying notes 50-60.

252. Eisenberg, *supra* note 38, at 1038.

253. LESSER, *supra* note 21, at 83.

254. The "warped logic" of denying biotechnological advancements that would improve farming efficiency should likewise be extended to outlaw plows, tractors, and fertilizers. Malcolm S. Forbes, *Ignorance Triumphs*, FORBES, May 28, 1990, at 19.

255. *See supra* part IV.A. and notes 231-36 and accompanying text.

C. *The Paradigmatic Reality*

Evaluating the arguments against animal patents leads to one indisputable conclusion: animal patents are not the cause of the perceived ills, thus denying animal patents will not eliminate them. The more compelling concerns lie within the technology which the patent protects. Opposition to biotechnology does not stem from the known immense benefit it will bring but from the specter of possible havoc that might result if humans use the technology for mischievous purposes.

Biotechnology has shifted the paradigm within which humans exist. Those who challenge animal patents are struggling against the paradigmatic shift. Their arguments reinforce the notion that society favors familiar paradigms.[256] But, human evolution demonstrates that paradigms serve a valuable function only until they become obsolete.[257]

Attempts to suppress paradigmatic challenges that cause a reevaluation of human positioning are as old as the species itself. For example, in 1633, Galileo Galilei was suppressed by the Catholic Church for his heretical view that the sun, not the earth, was the center of the universe.[258] To avoid the rack, Galileo recanted his findings.[259] After rising from kneeling before his inquisitors he is rumored to have muttered "*E pur, si muove*" — "Even so, it does move."[260] Three hundred fifty nine years later, in 1992, the Catholic Church admitted error in condemning Galileo.[261] It is time to realize that even with suppression of animal patents, biotechnology too, will move.

Human evolution advanced through our dominance over the animal kingdom.[262] Harnessing animal power through domestication was a first step to becoming a social being.[263] Now, we are taking the next inevitable step. Genetic engineering is an inescapable extension of human domination over the environment. Because it renders as obsolete our old, familiar paradigms, many are rallying to fight the change. Such opposition, however, is not new; it occurs whenever our paradigms shift.

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256. *See* KUHN, *supra* note 2, at 10-51.

257. *Id.*

258. *Id.* at 211.

259. *Id.* at 216.

260. *Pope Ready to Admit Church's Error in Condemning Galileo*, STAR TRIB. (Mpls.), Oct. 31, 1992, at 11A.

261. *Id.*

262. BRONOWSKI, *supra* note 4, at 79-80.

> The horse had begun by drawing wheeled carts, like the ox - but rather grander, drawing chariots in the processions of kings. And then, somewhere around 2000 BC, men discovered how to ride it. The idea must have been as startling in its day as the invention of the flying machine.

Id.

263. *Id.* at 60.

VI. CONCLUSION

The patent system was established to stimulate innovation for the benefit of society. Society benefits when its needs are fulfilled; biotechnology fulfills a vital societal need. But the patent system was not designed to regulate the inventions it promotes. Denial of animal patents will not suppress speculative harm, though it may hinder the development of regulatory measures that would reduce the threat of harm. The most responsible way to minimize harm and maximize benefits is through regulation based on complete disclosure. Indeed, this is what the patent system was designed to do.

The purpose of the patent system as envisioned by the Constitution is quite simple. It is not to judge, it is not to regulate, it is not to speculate; it is to stimulate society to innovate for its own benefit. To require the patent system to make moral or economic judgments before issuing a patent entrusts the key to society's technological future to this one gatekeeper. Technological advancement is too important to our survival to be limited to the discretion of one governmental office; society as a whole should judge the moral or economic worth of a technological advancement.

The grant of a patent on a living mammal symbolizes the power of biotechnology. As a result of genetic engineering, humans are able to produce animals that are sufficiently unique to be considered patentable. Hence, through means previously unimaginable, humans have created new animal life. In essence, we have acquired a power that requires us to expand the paradigm within which we view ourselves in relation to the rest of the living world. We fear this; expanding the scope of the paradigm in terms of human preeminence forces us to consider our own fallibility.

Acknowledging our fallibility can be positive. It helps to perpetuate our survival and secures us in our role in the universe. However, it cuts both ways. Although we may cause harm by tampering with powerful technologies, we may provoke equal harm if, in our ignorance, we fail to recognize the full potential of its benefits. Thus, there is only one viable option: not to suppress technology, but to stimulate it. Society needs this technology. At the same time, society needs strong regulation to prevent harm from misuse. Open disclosure of emerging new technologies must be shared with the public and this is exactly what the patent system was designed to do. Whether the consequence of research be mice or machine, the patent system must remain the same.

James R. Chiapetta, D.V.M.