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Patent Law: Patenting Animal Life: Another Scapegoat for Small Interest Groups

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it should have: "the ability to try all offenses committed by our service members. At the same time, however, it has charged us to responsibly apply power which has not been ours for nearly twenty years."¹²⁶ Whatever *Solorio*'s impact may be, it should be felt rapidly because both the Army¹²⁷ and the Air Force¹²⁸ have held that *Solorio* should be applied retroactively.

Conclusion

Military law strives to protect defendants' rights far more than most realize. It is not, as Justice Douglas stated, a "so-called military justice" system.¹²⁹ In addition to nonjudicial punishment, three different types of courts-martial exist whose nature and power depend primarily on the nature of the charges brought against the accused.

In June 1987, the Supreme Court overturned the landmark case of *O'Callahan v. Parker* with *Solorio v. United States*. In *O'Callahan*, the Court held that a requirement for subject-matter jurisdiction of courts-martial was that the offense be service-connected. The Court reasoned that with such a requirement, the members of the armed forces would not be deprived of the benefits of indictment by grand jury and of trial by jury.

Even with subsequent guidelines for service-connection enumerated in *Relford v. Commandant*, virtual chaos erupted in part because the exceptions engulfed the rule. Consequently, *Solorio* held that the subject-matter jurisdiction of a court-martial depends solely on the accused's status as a member of the armed forces and not on the service-connection of the offense charged. In so doing, *Solorio* properly returned the power to military courts to try all offenses committed by service members.

Gerald A. Williams

Patent Law: Patenting Animal Life: Another Scapegoat for Small Interest Groups

Misunderstanding, misinformation, and strong opinions have added yet another unwilling combatant to the arena of the quasi-legal colosseum. To the long list of battered and disputed issues such as pro-life versus abortion, creationism versus evolution, Democrats versus Supreme Court nominees, comes yet another reluctant gladiator—the patenting of animal life.

126. Morrow, *Solorio v. United States: The Death and Burial of Service-Connection Jurisdiction*, 30 A.F. L. REV. 201, 207 (1988).

127. *United States v. Starks*, 24 M.J. 857 (A.C.M.R. 1987), *petition for review granted*, 26 M.J. 83 (C.M.A. 1988).

128. *United States v. Taylor*, ACM 25834 (A.F.C.M.R. 30 June 1987).

129. 395 U.S. at 265-66.

Misunderstandings over the basis of patenting and patent laws have presented another forum for small interest groups to mount an offensive to further their moral and ethical ideals. Very recently, the Commissioner of the Patent and Trademark Office¹ issued an official statement that the Office would overrule a long-standing policy of denying United States patents for inventions on multicellular animal life.² There was an immediate outcry from "small" interest groups who vehemently opposed the new policy. They began a campaign to lobby Congress to force the Patent and Trademark Office to change its new policy on patenting of multicellular animal life.³

The proper grounds for challenging a policy decision by the Patent and Trademark Office is by challenging patent laws.⁴ The basis of awarding patents, which is rooted deep in our Constitution, is to promote the progress of science and useful arts.⁵ This is accomplished by rewarding inventors with exclusive rights in their discoveries for limited periods. Therefore, the basis of patent protection is to reward the inventor for a novel discovery that is made public and adds to the common pool of human knowledge. Small interest groups, however, have presented emotional, moral, and ethical arguments to oppose the patenting of animal life, shifting the focus of the issue away from patent law to moral and ethical views.

Three basic types of groups oppose the patenting of multicellular animal life: (1) animal welfare groups, concerned about experimentation on laboratory animals;⁶ (2) farm groups, concerned about the possible domination of animal genetic stock by a limited number of individuals;⁷ and (3) watchdog groups,

1. The Commissioner of Patents and Trademarks is also an Assistant Secretary of the Department of Commerce. 35 U.S.C. § 3(d) (1982). The present Commissioner is Donald J. Quigg.

2. The Patent and Trademark Office is a 198-year-old agency which has, until recently, been hesitant in granting patents on living matter. On April 7th, 1987, the Commissioner of Patents and Trademarks issued an official notice that recognized a growing trend in the courts to allow patents on living matter. Thus, the notice announced a new policy by the Patent and Trademark Office that applications will no longer be denied solely on the basis that the claimed invention was a living animal. See 1077 Official Gazette of the Pat. & Trademark Off. 24 (Apr. 21, 1987), for a complete transcript of the commissioner's official notice.

3. "Small" is a commonly accepted misnomer. These are really large, well-organized groups with very large interests. They include: the American Humane Society, the American Humane Association, the Fund for Animals, the American Society for the Prevention of Cruelty to Animals, the National Anti-Vivisection Society, and the Foundation on Economic Trends.

4. The Patent and Trademark Office derives its authority from 35 U.S.C. §§ 1-14 (1982) (§ 5 repealed 1972). See 35 U.S.C. § 6(a) (1982) (listing duties of the Commissioner).

5. U.S. CONST. art. I, § 8, cl. 8.

6. The animal welfare organizations are listed in note 3, *supra*. For example, the American Humane Society argues that animal patenting will result in a monopoly of genetic stock by owners of animal patents resulting in destruction of genetic diversity. *Patent & Trademark Office: Non-naturally Occurring Non-Human Animals Are Patentable Under § 101*, 33 Pat., Trademark & Copyright J. (BNA) 664 (1986).

7. For example, Cy Carpenter of the National Farmer's Union suggests that allowing patents on animal life will ultimately benefit only major corporations. Carpenter points to "seed patenting," a reference to the Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982), which gives the Department of Agriculture authority to give exclusive rights for newly discovered seeds. However, these statutes have nothing to do with patenting. Seed patenting is alleged to have caused the acquisition of 120 formerly independent seed companies by five major corporations

who are simply opposed to genetic research.⁸

The most vociferous opposition has come from the third category, headed by Jeremy Rifkin, president of the Foundation on Economic Trends.⁹ He has spearheaded a coalition of groups, including several animal welfare organizations, and petitioned the Patent and Trademark Office to reverse its newly adopted policy.¹⁰ The petition apparently did not make a dramatic impression upon the Patent and Trademark Office because a patent was subsequently issued on a genetically engineered mouse.¹¹

The strong opinions voiced by these various opponents to animal patenting range from a fear of increased suffering and pain for laboratory mice to a fear of "the end of the natural world."¹² Perhaps the end of the world does not really hinge on whether further patents are issued on animal life, but Congress was sufficiently impressed by the lobbying efforts of the opposition groups to hold several subcommittee hearings on the subject.¹³ Two drastic bills were introduced in Congress. The first suggested cutting off animal patent funds from the Patent and Trademark Office budget. The second proposed placing a moratorium on the Patent and Trademark Office's issuance of any patents on animal life for two years.¹⁴

that now control farm-seed distribution in the United States. 35 Pat., Trademark & Copyright J. (BNA) 322 (July 30, 1987).

8. Unlike humane societies and farmers, watchdog groups have a broader base of interests and often serve as a mouthpiece for other small interest groups. See *infra* notes 9 and 10.

9. The Foundation on Economic Trends is a Washington, D.C.-based organization with a president, Jeremy Rifkin, and a staff of two. The purpose of this organization is to disseminate selective views to the public on issues such as genetic engineering, religion, and economics. For example, Jeremy Rifkin stated that the new Patent and Trademark Office policy "is the first step towards a brave new world where all animals may be re-classified and reduced to the level of chemical composition." 35 Pat., Trademark & Copyright J. (BNA) 29 (Nov. 12, 1987).

10. Jeremy Rifkin is the spokesman for the petitioners who include all the organizations mentioned in note 3, *supra*.

11. United States Patent No. 4,736,866 is issued to Harvard College, Cambridge, Mass. Harvard is the assignee of the two inventors Philip Leder and Timothy Stewart. See also *infra* note 32 and accompanying text.

12. John Hoyt, president of the American Humane Society, issued a statement which predicted that the Patent and Trademark Office's new policy would increase animal experimentation and result in abnormal birth in some cases. The Humane Society feels that such exploitation of the animal kingdom will result in the end of the natural world. Mr. Rifkin, as the petitioners' spokesman, asserts the issue is really one of morals and ethics. *Patent & Trademark Office: Nonnaturally Occurring Non-Human Animals Are Patentable Under § 101*, 33 Pat., Trademark & Copyright J. (BNA) 664 (Apr. 23, 1986).

13. The House Subcommittee on Courts, Civil Liberties and the Administration of Justice held four hearings in 1987. See *infra* note 28. The subcommittee's chairman is Rep. Robert W. Kastenmeier. Also on the subcommittee is Rep. Mike Synar.

14. Senator Mark O. Hatfield proposed amendment No. 245 to supplemental appropriations legislation (H.R. 1827) in an attempt to cut off funds that the Patent and Trademark Office would use to process applications on animal patents. The Hatfield amendment was passed in the Senate, but a joint House-Senate conference committee struck the amendment from the records. 133 CONG. REC. H5,654 (daily ed. June 27, 1987).

Rep. Charles Rose introduced H.R. 3119 on August 5, 1987. 100th Cong., 1st Sess. (1987). The bill called for the addition of a new section to title 35 of the United States Code (35 U.S.C. § 105). The new section would impose a two-year moratorium on the Patent and Trademark

A more reasonable bill, introduced by Representative Robert W. Kastenmeier, proposes modification of the patent statutes.¹⁵ Kastenmeier's bill suggests merely amending the patent statutes to limit ownership rights of animal patent owners instead of cutting funds from the Patent and Trademark Office or banning animal patent applications all together.

The purpose of this note is to review the most recent events leading to this controversy and to clarify the misunderstandings concerning patent law and the patenting of animal life. Furthermore, an effort will be made to correct some of the misinformation about patents on animal life that has become evident in the media and elsewhere because of this controversy. Hopefully, the issue patenting of multicellular animal life will not be subject to media hype and public slogan chanting and can be resolved where it belongs—in the context of our laws.

Recent Developments in the Law of Animal Patents

In 1980 the United States Supreme Court upheld the granting of a patent on a genetically engineered live bacterium. In the landmark decision of *Diamond v. Chakrabarty*,¹⁶ the Court held that the statutory definition of the subject matter of patents was broad enough to include man-made organisms. Although the patent statutes did not expressly provide for live animals, the Supreme Court held that genetically manufactured organisms could be "inventions" deserving patent protection if two conditions were met: (1) that the living invention did not otherwise exist in nature; and (2) that the living invention demonstrate some utility to humans.¹⁷

Surprisingly, the reaction to this decision was unlike the righteous indignation that is presently being expressed about the Patent and Trademark Office's new policy. The decision concerned only tiny bacteria that cleaned up messy oil spills.¹⁸ The possession of such microscopic animals by corporate entities did not outrage the animal welfare organizations because the benefits to the environment were obvious.

In stark contrast, the notice issued by the Commissioner of the Patent and Trademark Office, announcing the new policy on patenting multicellular organisms, met strong opposition.¹⁹ The Commissioner's official notice was a response to a patent application on a man-made oyster.²⁰ The oyster patent

Office from granting animal patents. The bill further proposed a retroactive revocation of animal patents already granted. This proposed legislation did not survive the House Subcommittee on Courts, Civil Liberties and the Administration of Justice. *Legislation: Bill on Animal Patenting is Approved by House Panel*, 36 Pat., Trademark & Copyright J. (BNA) 271, 272 (July 14, 1988).

15. Rep. Kastenmeier introduced H.R. 4970, 100th Cong., 1st Sess. (1987). The bill proposes additions to sections 101, 112, and 271 of title 35 of the United States Code to accommodate animal patents into the patent statutes. 35 U.S.C. §§ 1-376 (1982). See 134 CONG. REC. E2235 (daily ed. June 30, 1988) (statement of Rep. Kastenmeier).

16. 447 U.S. 303 (1980).

17. *Id.* at 310.

18. The patent application in dispute covered claims for genetically engineered bacteria designed to consume oil spills. *Id.* at 305.

19. See *supra* note 2.

20. *In re Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (Bd. of Pat. App. & Int. 1987).

did not issue because the oyster invention was determined to be “obvious” when compared to prior art and not novel enough by patent law standards.²¹ The decision gave no indication that the rejection of the application was based on fears of exploitation of oysters by man.

The Patent and Trademark Office’s Board of Patent Appeals and Interferences stated that, in its opinion, if there had been no other patent law objections, the man-made oyster could be patentable.²² The Commissioner issued the official notice to avoid confusion between the holding and the opinion and to clearly state the position of the Patent and Trademark Office.²³

Opposition to the Commissioner’s official notice by the animal welfare groups came in the form of a petition calling for an immediate reversal of the new policy.²⁴ The petitioners threatened to ask Congress to overrule the Patent and Trademark Office if the Commissioner did not rescind the new policy.

The Commissioner did not yield, and, accordingly, the petitioners took their grievances to the United States Congress. The first legislative response was a proposal in the Senate, by Senator Hatfield, to amend legislation providing funds to the Patent and Trademark Office.²⁵ The Hatfield amendment called for a bar on Patent and Trademark Office funds specifically designated for expenses associated with granting patents on genetically engineered animals.²⁶ This proposed amendment was subsequently struck from the records after Congress decided that a more sensible approach was to schedule hearings on the controversy.²⁷

The House Subcommittee on Courts, Civil Liberties, and the Administration of Justice began hearings on June 11th, 1987.²⁸ During those hearings, interested parties from all segments of society, including agriculture, academia, industry, and, of course, small interest groups, gave testimony regarding the patenting of higher life forms.²⁹

21. 35 U.S.C. § 103 (1982) states:

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.

The *Allen* court reasoned that it was obvious to a genetic engineer (one skilled in the art) to induce genetic changes in oysters with processes well known in the genetic engineering industry (prior art). Thus, in compliance with 35 U.S.C. § 103 (1982), the patent application was denied. *In re Allen*, 2 U.S.P.Q. 2d (BNA) 1425, 1427 (Bd. of Pat. App. & Int. 1987).

22. The Patent and Trademark Office’s Board of Patent Appeals and Interferences is a quasi-judicial appeals board within the Patent and Trademark Office. 35 U.S.C. § 7 (Supp. IV 1986). The members are designated by the Commissioner from the examining staff of the Patent and Trademark Office. *Id.* The Commissioner is also a member of this board. *Id.*

23. See *supra* note 2.

24. See *supra* note 10 and accompanying text.

25. See *supra* note 14 (Senate amendment No. 245 to H.R. 1827).

26. *Id.*

27. See *supra* note 14 (the Hatfield amendment).

28. The hearings were conducted on June 11, July 22, and November 4, 1987 in Washington, D.C., and August 21, 1987 at Madison, Wis.

29. *Id.*

Meanwhile, on August 5th, 1987, Representative Charles Rose introduced a bill that proposed the addition of a new section to title 35 of the United States Code.³⁰ The proposal called for a statutory two-year moratorium on the issuance of patents on vertebrate and invertebrate animals. Representative Rose pointed out that a two-year moratorium would allow for a study into the possible economic and environmental effects that could result from the issuance of such patents. Furthermore, the bill proposed a retroactive revocation of patents on such animals already issued. This proposed legislation was voted down by the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice.³¹

As the hearings and proposals in Congress progressed, the Patent and Trademark Office issued United States Patent No. 4,736,866, on April 12th, 1988, for a transgenic mouse.³² This unique mouse was genetically engineered to be particularly susceptible to cancer. Agents suspected of causing cancer could easily be tested on this mouse to determine carcinogenic potential.³³

Animal rights groups have been relatively silent about the mouse patent because it clearly has the potential of reducing the number of mice inevitably destroyed during cancer experimentation. However, as the Patent and Trademark Office presently reviews numerous applications on animal inventions, the various opponents continue to present their arguments, anxiously awaiting Congress' decision on further proposed legislation.

A compromise bill, introduced by Representative Robert Kastenmeier, was approved by the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice on July 13th, 1988.³⁴ This proposed legislation, titled "Transgenic Animal Patent Reform Act," introduces amendments to existing

30. See *supra* note 14, discussing H.R. 3119, 100 Cong., 1st Sess. (1987) (proposed addition of 35 U.S.C. § 105).

31. The House Subcommittee on Courts, Civil Liberties and the Administration of Justice, on a vote of 8-6, struck down this bill. *Legislation: Bill on Animal Patenting is Approved by House Panel*, 36 Pat., Trademark & Copyright J. (BNA) 272 (July 14, 1988).

32. U.S. Patent No. 4,736,866 is actually a patent that claims a transgenic nonhuman mammal whose body and reproductive cells contain a DNA sequence making this mammal easily susceptible to cancer. The patent is commonly referred to as the "mouse" patent, but the claims are broad enough to support an elephant with similar oncogenic cells.

33. Medical experts state that the mouse patent would allow for a more efficient biological system in which to test new cancer therapies. This animal invention could be easily induced with the same type of malignancy often found in human cancer patients. Before introducing a newly proposed therapy into a human patient, it could be used on the patented mouse to determine the beneficial or detrimental effects without risk to human life. Schneider, *Patent for Mouse Issued to Harvard*, N.Y. Times, Apr. 13, 1988, at 1, 13.

Furthermore, these animals can serve as "cancer detectives" because they will develop tumors at a rapid rate when exposed to even small amounts of cancer-causing chemicals. *Patent & Trademark Office: Patent & Trademark Office Issues First Animal Patent*, 35 Pat., Trademark & Copyright J. (BNA) 508 (Apr. 14, 1988).

34. *Legislation: Bill on Animal Patenting is Approved by House Panel*, 36 Pat., Trademark & Copyright J. (BNA) 271, 272 (July 14, 1988). See also Farmers Exemption Bill, 134 CONG. REC. E2235 (daily ed. June 30, 1988) (statement of Rep. Kastenmeier).

sections of the patent statutes³⁵ that would set statutory limitations on animal patents.³⁶

The first proposal calls for an addition to section 101 of title 35 of the United States Code, which defines patentable subject matter.³⁷ The phrase "except that human beings are not patentable subject matter" is to be added to the end of section 101. This is consistent with the Commissioner's official notice and would be a codification of the nonhuman restriction on patented living organisms.³⁸

The second proposal is the addition of two subsections to section 271 of title 35, which defines acts of patent infringement.³⁹ One proposed subsection would allow the infringement of animal patents by nonprofit bioresearch organizations.⁴⁰ This subsection allows noncommercial researchers to make or use, but not sell, patented animals.⁴¹

Another proposed addition to section 271 provides for an exemption for single-family farmers who breed animals and who earn less than \$500,000 per year.⁴² A farmer within this category would not infringe an animal patent even if he breeds, uses, or sells patented animals. Furthermore, the proposed subsection also exempts from patent infringement any farmer, regardless of earnings, who is not engaged in farming for the sale of reproduced animals.⁴³

This subsection is a response to concerns expressed by American farmers over the effects of animal patenting on agriculture. Jeremy Rifkin, speaking on behalf of the American farmer, fears a domination of American agriculture by the biotechnical and chemical industries who, he anticipates, will eventually own all animal patents.⁴⁴ This, he argues, would have a detrimental economic impact on the individual farmer having to pay expensive patent royalties.⁴⁵

This is an incorrect view. The American farmer is not the stereotypical pastoral fool or country bumpkin of trite cliché. Today's farmer is a sophisticated user of all available agricultural science. This is what makes him the leader of world food production. Additionally, he has access to centuries of breeding techniques by heritage. The modern farmer will have a choice

35. 35 U.S.C. § 1-376 (1982).

36. See H.R. 4970, *Transgenic Animal Patent Reform Act*, 36 Pat., Trademark & Copyright J. (BNA) 283 (July 14, 1988).

37. 35 U.S.C. § 101 (1982), states: "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."

38. See *infra* note 72 and accompanying text.

39. 35 U.S.C. § 271 (1982).

40. *Transgenic Animal Patent Reform Act*, 36 Pat., Trademark & Copyright J. (BNA) 283 (July 14, 1988).

41. *Id.*

42. *Id.*

43. *Id.*

44. 35 Pat., Trademark & Copyright J. (BNA) 29 (Nov. 12, 1987).

45. Jack Doyle, director of the Agricultural Resources Project of the Environmental Policy Institute, testified to this effect at the first hearing of the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice, June 11, 1987. 100th Cong., 1st Sess. (1987).

between traditional breeding techniques or paying for the use of an animal patent.⁴⁶ The farmer will not be forced to enter into a patent license agreement. The matter will be one of simple economics; if it is cheaper to breed a patented animal, the farmer will do so.

Ann Sorensen, spokesperson for the American Farm Bureau Federation, testified in the congressional hearings that genetic technology would be able to achieve in one gestational period rapid genetic improvements that would take decades through classical breeding techniques.⁴⁷ She predicts that genetic engineering will actually reduce farm expenditures by increasing disease tolerance and growth performance.

Furthermore, the proposed bill would create exceptions for a farmer's infringement of genetically altered animals. If the bill were to be passed in its present form, single-family farmers would be free to breed patented animals without paying royalties.⁴⁸

Therefore, the legislation introduced by Representative Kastenmeier addresses the economic fears expressed by the agricultural sector. The proposed legislation also allows nonprofit research organizations to compete with large corporations that could easily buy out the incentives for noncommercial research.⁴⁹ However, because none of these new proposals directly address genetic research or animal experimentation, opponents to animal patents continue their lobby efforts.

A New Administrative Policy on Animal Patents

Relative to its 198-year-old history, the Patent and Trademark Office has

46. The argument that patented animals will compete with traditionally bred animals is also speculative. Purebred varieites, such as cows with high milk yield, have already been isolated. It would be a simple matter to obtain these cows to start a dairy farm.

If an application for a "supercow" that could produce three times the milk of a conventional cow were to be filed, it would probably be rejected because it would have to overcome two difficult barriers. First, the Commissioner has required that such patents be on nonnaturally occurring animals. See *infra* note 70 and accompanying text. The specific gene sequence for a "supercow" for high milk yield probably already exists in nature. A researcher would be required to isolate the location of the gene sequence in the cow genome for high milk yield. If such a cow already exists in nature the proposed patent would fail the nonnaturally occurring limitation.

The second barrier is the "obviousness" test in 35 U.S.C. § 103 (1982). See *supra* note 21. In order to obtain a patent on a supercow, the applicant would have to show that it would not have been obvious to one skilled in the science of genetic engineering to isolate such a DNA sequence.

47. Dr. A. Ann Sorenson testified on behalf of the American Farm Bureau Federation at the second subcommittee hearing, July 22, 1987. See *supra* note 28. The American Farm Bureau Federation consists of forty-eight state farm bureaus and the Farm Bureau of Puerto Rico. The federation is based in Park Ridge, Ill., with a staff of 102. Its 3,297,224 members are all individual family farmers. The main goal of the federation is economic and social advancement of its members through education and information. 34 Pat., Trademark & Copyright J. (BNA) 322 (July 30, 1987).

48. See *supra* note 42 and accompanying text.

49. Farmers Exemption Bill, by Rep. Kastenmeier, discussing the proposed additions to 35 U.S.C. § 271 (1982). 134 CONG. REC. E2235 (daily ed. June 30, 1988) (statement of Rep. Kastenmeier).

only recently considered granting patents on living matter. In 1930, Congress added the Plant Patent sections to title 35 of the United States Code. These sections allowed the Patent and Trademark Office to issue patents on asexually produced plants that existed only in a cultivated state.⁵⁰ These new sections were unique in that they, unlike other parts of the patent statutes, specifically provided for patents on living plants. Because of these specific provisions, the Patent and Trademark Office was reluctant to grant patents on living forms other than asexually reproduced plants.

In 1977 the Court of Customs and Patent Appeals in *In re Bergy*⁵¹ held that a patent claim could not be rejected merely because it referred to living organisms. The two requirements for allowing patent claims on living matter were outlined as follows: (1) that the living matter does not presently exist in, is not found in, and is not a product of nature;⁵² and (2) that the live matter claimed serve some utility.⁵³ Accordingly, the *Bergy* court found that a claim to a living, pure culture of microorganisms was patentable because: (1) pure cultures of the strain could not be found in nature and could only be isolated under carefully controlled laboratory conditions; and (2) the culture could produce a specific, useful human antibiotic.⁵⁴

The invention in the *Bergy* patent application was to a process of isolating an antibiotic, and only one claim referred to living organisms as a part of the overall process.⁵⁵ Three years later, the United States Supreme Court in *Diamond v. Chakrabarty*⁵⁶ went one step further. The Court held that living microorganisms were patentable subject matter, under section 101 of title 35, as a separate and distinct invention. Unlike the invention in *Bergy*, which referred to a living culture of fungus as only part of an overall process, the application in *Chakrabarty* claimed a living organism as the entire invention.

The opposition to patenting living microorganisms in *Chakrabarty* came from the Patent and Trademark Office.⁵⁷ Sidney A. Diamond, who was the Commissioner of Patents and Trademarks at the time, argued that Congress had specifically enacted the Plant Patent Act, and it was up to Congress to specifically legislate new sections to the patent statutes before patents on other types of living matter should be allowed. Diamond reasoned that all other patentable subject matter was inanimate and plants were the only specific living inventions that were patentable.⁵⁸

50. 35 U.S.C. §§ 161-164 (1982).

51. 563 F.2d 1031 (C.C.P.A. 1977).

52. *Id.* at 1035.

53. *Id.* at 1038.

54. *Id.* at 1035.

55. *Id.* at 1032.

56. 447 U.S. 303 (1980).

57. The Patent and Trademark Office initially rejected a microbiologist's patent application because the invention claimed living matter. 447 U.S. 303 (1980). The Patent and Trademark Office Board of Appeals affirmed the rejection. *Id.* The Court of Customs and Patent Appeals reversed. *Id.* On certiorari, the United States Supreme Court affirmed the Court of Customs and Patent Appeals' ruling. *Id.*

58. 447 U.S. at 310-11.

Chief Justice Burger, author of the majority opinion, set this argument aside by pointing out that the key factor in determining patentability of living subject matter was whether it was found free in nature. An invention, inanimate or living, was unpatentable if it was found free in nature, or prior art, readily available to anyone.⁵⁹ An invention was patentable if it was a result of discovery and ingenuity through research and development.⁶⁰

The decision in *Chakrabarty* was limited to allowing patents on single-celled living organisms. In 1987, in *In re Allen*,⁶¹ the Patent and Trademark Office Board of Patent Appeals and Interferences held that multicellular, living oysters were patentable subject matter. Although the invention was rejected for other reasons, the opinion revealed the Patent and Trademark Office's position on patents for multicellular animals.⁶² Before this opinion, as demonstrated by former Commissioner Diamond's opposition in *Chakrabarty*, the Patent and Trademark Office appeared reluctant to allow patents on any living matter. This opinion not only reversed that attitude but seemed to enlarge the scope of animal patenting beyond *Chakrabarty*.

Because the decision and dictum in *Allen* could potentially be confusing, and in light of the growing trend for courts to allow patents on living matter, the Commissioner of Patents and Trademarks issued an official notice in 1987.⁶³ The notice announced the new policy that applications will no longer be denied solely on the basis that the claimed invention is a living animal.⁶⁴

The Legal Basis of Patenting Life Forms

Title 35, section 101, of the United States Code outlines patentable subject matter as follows: "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."⁶⁵ In *Chakrabarty*,⁶⁶ the United States Supreme Court interpreted the section 101 terms "manufacture" and "composition of matter" to include live, human-made organisms. The Court cited the legislative intent behind section 101,⁶⁷ which was that the intended patentable subject matter included "anything under the sun that is made by man."⁶⁸ The Court quoted Thomas Jefferson, author of the first patent act in 1793, who said, "ingenuity should receive a liberal encouragement."⁶⁹ Article I,

59. "Prior art" is knowledge that is well known in a particular industry or skilled trade. The term usually refers to a printed publication and includes prior issued patents. See note 21, *supra*.

60. 447 U.S. at 313.

61. 2 U.S.P.Q. 2d (BNA) 1425, 1427 (Bd. of Pat. App. & Int. 1987).

62. *Id.*

63. See 1077 Official Gazette of the Pat. & Trademark Off. 24 (Apr. 21, 1987).

64. *Id.*

65. 35 U.S.C. § 101 (1982).

66. 447 U.S. 303 (1980).

67. S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 6 (1952).

68. *Diamond v. Chakrabarty*, 447 U.S. at 309.

69. *Id.* at 308-09.

section 8, clause 8 of the United States Constitution states that the purpose of granting patents is to promote progress in science and useful arts by granting exclusive rights to the inventor of a discovery.

The basis of patent protection is to reward the inventor for a novel discovery that is made public and adds to the common pool of human knowledge. The legal basis for granting patents on animal life is, thus, to reward the inventor for discovering a man-made animal that serves a useful function for humans.

The Commissioner of the Patent and Trademark Office gave clear limits to the subject matter of patentable animal life in the recent official notice.⁷⁰ The limitations are that the patentable invention be (1) nonnaturally occurring and (2) nonhuman. The first limitation is consistent with other patent law principles, which recognize that naturally occurring phenomena are in the public domain and should not be reserved for an individual to exclude others from using.⁷¹ The second limitation is simply a constitutional one, that no human should own another.

Commissioner Quigg's official notice states: "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."⁷² However, inventions of human cells and human molecular byproducts have already been patented prior to the official notice.⁷³ From these conflicting factors, a logical conclusion is that claims to an entire human being will not be allowed. But the possibility remains that parts of a human body, up to the limit of an entire body, may be patented.

The Commissioner's limitations closely follow the boundaries of animal patenting already provided in *Chakrabarty*.⁷⁴ Furthermore, the limitation against patenting human beings is an additional safeguard added by the Commissioner and supported by the Constitution. Opponents to patenting higher life forms have not addressed these limitations and merely point to the possibility that genetic research may increase as a result of granting patents on animal life. Nevertheless, as Chief Justice Burger pointed out in *Chakrabarty*, the grant or denial of patents will not increase or diminish genetic research.⁷⁵

70. See *supra* note 2.

71. *Parker v. Flook*, 437 U.S. 584 (1978); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931).

72. See 1077 Official Gazette of the Pat. & Trademark Off. 24 (Apr. 21, 1987).

73. See *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985) (patent claims directed to new human cell lines that were a result of fusing hybridomas and lymphoid cells); *Monoclonal Antibodies, Inc. v. Hybritech, Inc.*, 107 S. Ct. 1606 (patent claims directed to immune assay using human monoclonal antibodies); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 678 F. Supp. 1429 (N.D. Cal. 1988) (patent claims directed to human blood-clotting factor).

74. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

75. *Id.* at 317. Chief Justice Burger stated that genetic research had been expanding despite the uncertainty that patent protection could be obtained for recombinant DNA inventions. The impetus for the growth of genetic research has been the desire to explore the unknown by probing scientific minds, and has not been dependent on whether the legislature or the judiciary might grant an inventor a special property right in his new discoveries.

Arguments Against Genetic Research and Animal Patenting

Animal welfare activists and antigenetic research groups make the most basic arguments against animal patents. The basic argument is a moral and ethical one.⁷⁶ The general premise is that owning patents on animals created in a laboratory is wrong. The problem with this argument is that it is a repackaged argument against genetic research in general. It totally ignores the basis of patent laws and forces argument over the propriety of genetic engineering in relation to patents. This is entirely out of context with the purposes of our patenting system.

The patent statutes grant exclusive rights to inventors for novel, useful, and unobvious inventions.⁷⁷ The standards provided by those statutes are that the claims to the invention fit requirements of grammatical form and style. Furthermore, the statutory standards require sufficient disclosure so that any person, skilled in the art to which the invention relates, could make and use the disclosed invention.⁷⁸ Nowhere in the statutory scheme is there a requirement that the inventions meet moral and ethical standards.

The animal rights coalition argues that granting animal patents will result in a restructuring of the animal kingdom and the eventual demise of the natural world.⁷⁹ Arguments such as this demonstrate basic scientific misunderstandings. The animal kingdom is a scientific categorization system designed to classify major groups of living organisms. Scientists will not be forced to remake a classification system merely because patents are issued on animal life. Of course, the innuendo in such an argument is that animal life will somehow be adulterated and deformed from the state it presently enjoys.

The "great catastrophe" argument, which predicts the end of the natural world, evokes strong emotions. But the world as we know it will not end because patents are granted on animal life forms. Case law and the Patent and Trademark Office's new policy make it clear that the line will be drawn on living inventions that are: (1) nonnaturally occurring—leaving the natural world as it is; (2) nonhuman—no entity will be allowed a patent on a man, woman, or child; and (3) nongratuitous—useless patents on living inventions that have no utility will not be allowed.⁸⁰

The patenting system is an improper forum to argue issues against genetic research. Administrative agencies specifically designated to oversee the many facets of genetic engineering of animals already exist. The National Institute of Health is authorized by Congress to issue strict regulations and guidelines on animal genetic research.⁸¹ The Food Safety and Inspection Service of the

76. See *supra* note 12 (John Hoyt, president of the American Humane Society).

77. 35 U.S.C. § 101, 103 (1982).

78. *Id.* § 112, ¶ 1.

79. See *supra* note 9 (statement by Jeremy Rifkin of the Foundation on Economic Trends). See also *supra* note 12 (statement by John Hoyt of the American Humane Society).

80. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977); *In re Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (Bd. of Pat. App. & Int. 1987). See text accompanying notes 65-75, *supra*.

81. N.I.H. Guidelines for Research Involving Recombinant DNA: 41 Fed. Reg. 27,902 (1976), Guidelines on NIH-supported research on recombinant DNA molecules; 43 Fed. Reg. 60,080

Department of Agriculture also has definite regulations on the use of recombinant DNA experimentation on animals that are reproduced for human consumption.⁸² The Animal and Plant Health Inspection Service is another federal agency empowered to regulate experiments involving animals.⁸³ This area is also subject to state and local control. For example, state and local laws impose criminal penalties for cruelty to animals.⁸⁴ Furthermore, state civil statutes regulate animal experimentations as an additional protection for animal welfare.⁸⁵

Thus, animal experimentation and genetic research are controlled by regulatory agencies and courts enforcing animal experimentation laws. Researchers conduct animal experiments under strict regulations, well aware of civil and criminal penalties for improper treatment of animals. Likewise, DNA-RNA genetic manipulations must follow very definite and strict guidelines.⁸⁶

Grievances against improper use of laboratory animals or violations of genetic research regulations are most effective when addressed to such agencies and courts. These administrative agencies and judicial tribunals are better able to set standards because they have the technical expertise and, more important, the congressional authority to do so. Furthermore, they have the power to prevent abuses with the deterrent effect of imposing sanctions should the standards be violated. Animal experimentation and genetic research are valuable contributors to the quality of human life. They will continue regardless of whether living matter is patentable. Therefore, the patent system is not the proper forum in which to file protests against genetic research and animal experimentation.

Furthermore, a patent grant is not an absolute exclusionary right. The grant of a patent is not an incontestable right backed by limitless legal sanctions.⁸⁷ Even after the grant of a patent, the owner is still subject to nonpatent laws.⁸⁸

(1978), Department of Health, Education & Welfare, National Institute of Health's Guidelines on recombinant DNA research in the United States; 43 Fed. Reg. 60,108 (1978), Department of Health, Education & Welfare, Revised National Institute of Health's Guidelines on research involving recombinant DNA.

82. U.S.D.A., Food Safety and Inspection Services' Standards of Identity or Composition of Meats for Human Consumption, 9 C.F.R. § 319 (1988). See also 43 Fed. Reg. 60,134 (1978), Department of Health, Education & Welfare, Food and Drug Administration regulations which follow NIH guidelines on recombinant DNA research. See *supra* note 81.

83. *Legislation: House Panel Holds Third Hearing on Animal Patents*, 34 Pat., Trademark & Copyright J. (BNA) 460 (Sept. 3, 1987).

84. 21 OKLA. STAT. § 1685 (1981) (defines the crime of cruelty to animals). 21 OKLA. STAT. § 1681 (1981) (defines a broad range of other crimes involving injury to animals).

85. For example, 4 OKLA. STAT. §§ 391-402 (1981) (civil statutes regulating the use of animals in scientific experiments); 4 OKLA. STAT. §§ 501-508 (1981) (regulating proper disposal of animals); 2 OKLA. STAT. § 2-19 (1981) (analytic laboratories that conduct animal experiments); 2 OKLA. STAT. § 6-183 (1981) (regulating inspection of slaughtered animals for meat).

86. 49 Fed. Reg. 46,266 (1984), Department of Health and Human Services, National Institute of Health Guidelines for DNA molecular research.

87. The basic legal rights granted to a patent owner are exclusive property rights. Enforcement of these rights are limited to civil actions for infringement of a patent. 35 U.S.C. § 281 (1982).

88. Patents have the attributes of personal property. 35 U.S.C. § 261 (1982). Thus a patent owner's legal protection is limited to property law principles of the specific exclusionary rights

A United States patent only provides the right to exclude others from making, using, or selling the invention disclosed in a patent. A patent does not shield an owner from acts performed by him that are prohibited by other laws.⁸⁹

Genetic research dates back to the eighteenth century. DNA and RNA manipulation on animal chromosomes began decades before anyone even considered applying for patents on living matter. Out of necessity, genetic research will continue regardless of Congress' decision on the proposed legislation. Opponents fear that allowing animal patents will encourage the growth of genetic engineering.⁹⁰ This may be true in light of the enormous investments that must initially be made to begin genetic research and development. The possibility of obtaining patents will make such initial investments a little less risky. However, because the possibility of a patent may encourage an industry to expand is no argument against the patent system.

Conclusion

At the turn of the century, an Episcopalian clergyman was overheard commenting on the wonders that existed in the 1900s. He marveled at the flushable commode, the steam locomotive, the telephone, and canned food. He truly believed that man had reached his zenith, that science should progress no further. This man was Bishop Wright, whose sons later invented the airplane (United States Patent No. 821,393). Many in our society fear the unknown future and oppose change. Such is the situation with the opposition to patenting animal life.

The cold laboratories of genetic research have stirred the latent apprehensions of laymen and have given rise to subjective imagery of the deformed creations of Dr. Frankenstein. The opposition fears the doctor is now asking for patents on his horrible creations. Antigenetic engineering groups have decided to storm the Patent and Trademark Office to tear down the gruesome laboratories and burn the horrible monsters. This is the crux of the problem. The Patent and Trademark Office issues patents; it neither conducts experiments nor creates monsters.

The fears expressed by opponents to genetic research are maintained without a firm basis. The apprehensions are childlike fears of the dark. As to the potential horrors that are anticipated by opponents of animal patents, Chief Justice Burger summed up the opposition in *Diamond v. Chakrabarty* by quoting Hamlet: "to bear those ills we have than fly to others that we know not of."⁹¹

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granted by the patent statutes. 35 U.S.C. §§ 1-376 (1982). Therefore, the owner of a patent remains subject to all other laws.

89. 35 U.S.C. § 154 (1982).

90. Opponents have not presented any concrete evidence on the nexus between the grant of animal patents and the predicted increase in genetic research. The only evidence is opinion testimony to that effect.

91. *Diamond v. Chakrabarty*, 447 U.S. at 316 (quoting W. Shakespeare).