

THE MODERN INDUSTRIAL REVOLUTION: TRANSGENIC ANIMALS AND THE PATENT LAW

The recent development of transgenic animals¹ poses unique patent law questions. In 1988, the United States Patent and Trademark Office (PTO) approved the first patent for a transgenic animal.² The subsequent debate spawned by this approval pits two vital, yet distinct American industries on opposite sides: biotechnology and farming.³ To date, Congress has remained silent on the issue of animal patents.⁴ However, a 1980 Supreme Court holding approving a patent for a microorganism lends support to the PTO's decision,⁵ and may foreshadow Congress' ultimate response. In any event, Congress' reaction to the PTO decision, even if merely silent approval, will have considerable effect, as evidenced by the arguments marshalled by representatives of biotechnology and farming.⁶

The Constitution grants Congress the power to enact patent laws.⁷ Under this authority Congress enacted the Patent Act of 1952 (the Act).⁸ Section 101 of the Act directs the PTO to issue patents to "[w]hoever

1. A transgenic animal is one into which researchers introduce foreign genes while the animal is still in an embryonic stage. Jaenisch, *Transgenic Animals*, 240 SCIENCE 1468 (1988).

2. Patent No. 4,736,866. See *The Nat'l Law J.*, Aug. 15, 1988, at 3, col. 1. The patent was issued for a transgenic mouse, developed for the study of breast cancer. *Id.* The transgenic mouse is the only animal patent issued to date, though approximately 30 animal patent applications are currently pending. See also *Patents and the Constitution: Transgenic Animals: Hearings before the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice*, 100th Cong., 1st Sess. 871 (1987) (statement of the American Farm Bureau Federation, National and Environmental Resources Division) [hereinafter *Hearings*].

3. See *infra* notes 29-35 and accompanying text.

4. There have been several recent attempts to legislate in this area. In 1988, three separate bills were introduced in Congress, however, all three failed. Two of the bills proposed bans on the patentability of animals. See H.R. 3119, 100th Cong., 2d Sess. § 105 (1988) (two-year moratorium on animal patents); S. 2111, 100th Cong., 2d Sess. § 105 (1988) (complete ban on animal patents). The third bill, passed by the House, would have provided a limited exemption from infringement liability for farmers who reproduce patented animals, and declared humans beings not patentable subject matter. H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436 (daily ed. Sept. 13, 1988). The Senate did not vote on the bill before Congress adjourned, and it is uncertain whether the bill will be reintroduced in the following session.

5. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (application for bacterium upheld). See *infra* text accompanying note 14.

6. See *infra* notes 29-35 and accompanying text.

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

8. 35 U.S.C. §§ 1-293 (1982 & Supp. III 1985).

invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . ."⁹ Through the broader language of section 101 Congress sought to spur research and development that would benefit the public.¹⁰ Toward this end, Congress declared generally that any unauthorized use of a patented invention constitutes an act of infringement for which the user is liable to the patent owner.¹¹

In 1987 the PTO announced that genetically altered animals are patentable subject matter.¹² Acting under this policy, in 1988 the PTO granted a patent for a transgenic animal—a genetically altered, cancer-

9. *Id.* § 101. Section 101 is a recodification of the original patent law enacted by the first Congress in 1790. See Act of April 10, 1790, ch. 7, 1 Stat. 109-12 (1790). Subsequent enactments merely employed the identical language of the 1793 statute, which remained unchanged until 1952, when Congress substituted the word "process" for "art." See *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980).

10. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) ("The productive effort . . . fostered [by the patent laws] will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."). The underlying philosophy of the patent laws, in the words of Thomas Jefferson, is that "ingenuity should receive liberal encouragement." 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1981).

11. 35 U.S.C. § 154 (1982 & Supp. III 1985). See generally *Aro Mfg. Co. v. Convertible Top Co.*, 377 U.S. 476 (1964) (mere use of a patented invention constitutes infringement). See also *D. CHISUM, PATENTS* § 16.03[1] (1987).

12. *Nonnaturally Occurring Non-Human Animals Are Patentable Under § 101*, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 827, at 664 (Apr. 23, 1987) (The PTO "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101."). The PTO's exclusion of human beings from its expanded definition of patentable subject matter is based on its belief that the thirteenth amendment's proscription of slavery would bar such patenting.

Fears that introduction of human genes into the germ line (the genetic material passed on to offspring) of animals will blur the distinction between human and nonhuman are, at least for the foreseeable future, exaggerated. As one scholar stated:

It is important . . . to understand that the best that a genetic engineer can do is to add one gene, or at most, a couple, foreign genes to an organism and have that organism survive and be important. An organism's tens of thousands of genes are finely tuned with respect to each other. And it takes a very clever molecular biologist to add even a single gene in a way so that this fine tuning will not be significantly interrupted. So, one cannot take genes from a chicken and add them to a cow's chromosome and get a cow that lays eggs. Monster animals or weeds that get out of control will not result from this technology.

Hearings, supra note 2, at 218 (statement of Winston J. Brill, Ph.D., Agracetus Corp.). See also *Karny, Regulation of the Environmental Applications of Biotechnology*, ENVTL. L. 1, 2 (1987), reprinted in *Hearings, supra* note 2, at 923-24 ("As work [with genetic transfer] went forward, it became clear that the initial fears about the possible risks were greatly overstated . . . [T]here was no evidence of any harm to human or animal health or the environment from [genetic engineering].").

sensitive mouse developed for the study of breast cancer.¹³ While the PTO decision to grant animal patents is not expressly authorized by the Patent Act, the decision is consistent with the Supreme Court's broad interpretation of section 101 in *Diamond v. Chakrabarty*.¹⁴ In *Chakrabarty* a sharply divided Court held that a genetically altered, oil-eating bacterium was a patentable "composition of matter" within the meaning of section 101.¹⁵ In sweeping terms, the Court declared that section 101 encompasses "anything under the sun that is made by man."¹⁶

The PTO's decision to issue an animal patent raises the question of whether an inventor will enjoy legal protection for his transgenic animal creations. Acts constituting patent infringement are somewhat more complicated when the patented invention is a living organism.¹⁷ As noted above, generally any unauthorized use of a patented invention constitutes an actionable act of infringement.¹⁸ Clearly, the unauthorized sale of a patented animal would constitute such an infringement.¹⁹ Moreover, under the Plant Patent Act of 1930²⁰ and the Plant Variety Protection Act of 1970,²¹ both asexual and sexual reproduction of pat-

13. See *supra* note 2. See also *The Nat'l Law J.*, Aug. 15, 1988, at 3, col. 1; 332 *NATURE* 668 (1988).

14. 447 U.S. 303 (1980).

15. *Id.* at 305, 318 (5-4 majority).

16. *Id.* at 309. See also *In re Allen*, 2 U.S.P.Q.2d (BNA) 1425 (1987). In *Allen* the PTO affirmed a patent examiner's rejection of an application to patent a polyploid oyster because § 103 of the Act requires that the invention not be "obvious." However, the PTO relying on *Chakrabarty*, rejected the argument that the oysters were unpatentable because they were living entities. *Id.* at 1427.

The language of § 101 does not suggest a distinction between microorganisms and higher animal forms; if the former are "composition of matter" within the meaning of the statute, it follows that the latter are patentable as well. Further, the Court's broad interpretation of § 101 in *Chakrabarty* undoubtedly encompasses the patentability of animals. In order for the Court to treat bacteria and mice differently, the Court would have to divine from the phrase "composition of matter" a distinction between higher and lower life forms that is simply not there. *Chakrabarty*, 447 U.S. at 315.

17. There are several unique problems involved in obtaining a patent on living organisms. See, e.g., Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 *FORDHAM L. REV.* 592 (1984) (discussing the problems of how an applicant deposits a patented microorganism with the PTO).

18. See *supra* note 11 and accompanying text.

19. D. CHISUM, *supra* note 11, § 16.03[1]; E. LIPSCOMB III, *WALKER ON PATENTS* § 22:1 (1987) ("[A] single sale [of a patented invention] is sufficient to constitute a trespass on the patentee's patent property and an infringement of his patent").

20. 35 U.S.C. §§ 2321-2364 (1982).

21. 35 U.S.C. §§ 2321-2583 (1982).

ented plants without authorization constitutes an infringement.²² Similarly, under the Act, a patent owner may exclude others from making the patented invention and from reconstructing a depleted patented product.²³ By analogy, it seems apparent that an unauthorized reproduction of a patented animal through breeding would constitute infringement.²⁴

Yet, even should liability attach to the unauthorized breeding of patented animals, courts may apply a judge-made exemption from liability which they have used in the past. This exemption applies when the unauthorized use of a patented invention is purely one of research or experimentation and lacks any commercial purpose.²⁵ However, most recent decisions considering this "experimental purpose" exception construe it narrowly.²⁶ In fact, the experimental purpose exception has rarely been the basis of a successful defense against an alleged patent infringement.²⁷ Whether the courts will revive the experimental purpose doctrine to exempt from liability the laboratory use of patented animals is uncertain.²⁸

As a precursor to possible legislative debate on the issue of animal patents, it is worth considering the reactions of two key American industries to the PTO's approval of animal patents. The biotechnology industry has made a strong case against a per se ban on animal patents. The industry argues that banning animal patents would force researchers to resort to trade secrecy to protect their inventions. This reaction, contend the researchers, would inevitably obstruct the free flow of information necessary to maintain the United States' competitive edge in medical re-

22. 35 U.S.C. § 2483(a) (1982).

23. D. CHISUM, *supra* note 11, § 16.03[3] (1987).

24. The PTO has taken the position that "unauthorized acts of reproduction . . . [of patented animals] would seem to be an infringement." Letter from Patent Office Commissioner, Donald J. Quigg to Senator Dennis DeConcini, Chairman of the Senate Subcommittee on Patents, Copyrights and Trademarks, *reprinted in Hearings, supra* note 2, at 576-80.

25. D. CHISUM, *supra* note 11, § 16.03[1].

26. *Pfizer, Inc. v. Int'l Rectifier Corp.*, 217 U.S.P.Q. 157, 161 (C.D. Cal. 1982) ("[T]he underlying rule of permissible experimental use demands that there must be no intended commercial use of the patented article, none whatsoever, if the exception is to be recognized at all."); *Douglas v. United States*, 181 U.S.P.Q. 170, 176 (Ct. Cl. 1974) ("the defense of experimental use has been only sparingly applied"); *Bee, Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957) (maintaining that the "experimental use" doctrine should be completely abolished). *But cf. Hantman, Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617 (1985) (discussing necessity of the "experimental use" doctrine).

27. D. CHISUM, *supra* note 11, § 16.03[1].

28. Resolution of this question may depend upon Congress. See *supra* note 4 for discussion of recent Congressional attempts to legislate in this area.

search.²⁹ Patent protection for transgenic animals is beneficial under this view because it promotes industrywide disclosure of important research developments while simultaneously protecting researchers' proprietary interests in their work.³⁰

In stark contrast to the biotechnology industry, the farming industry is opposed to the approval of animal patents because of the potentially ruinous economic effects such patents might have on livestock farming.³¹

29. Adler, *Biotechnology as an Intellectual Property*, 224 *SCIENCE* 357, 361-62, reprinted in *Hearings*, *supra* note 2, at 650, 655-56.

30. *Id.* The importance of encouraging such research is evident merely from the nature of the inventions themselves. Genetic engineering has delivered bacteria that can produce human insulin and promises cows that produce human insulin and secrete it in their milk. Brill, *Genetic Engineering Applied to Agriculture: Opportunities and Concerns*, 68 *AM. J. AGRIC. ECON.* 1081, 1083 (1986), reprinted in *Hearings*, *supra* note 2, at 226-32.

Furthermore, transgenic animal research has made AIDS research possible. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 *YALE L.J.* 177 (1987).

In the future, genetic engineering will likely create larger and more rapidly developing animals. Brill, *supra* note 30, at 1082. It further promises greater insight into the genetics of cancer and mammalian development. Jaenisch, *supra* note 1, at 1468.

31. See *Hearings*, *supra* note 2, at 306-12 (statement of Farmer Union Milk Marketing Cooperative and Wisconsin Farmers Union). Farmer opposition to animal patenting, however, is by no means unanimous. *Id.* at 116-35 (statement of the American Farm Bureau Federation).

Also in opposition to arguments made by the biotechnology industry, animal rights organizations and some religious leaders argue vehemently against the issuance of animal patents. Animal rights activists fear that patent holders will mistreat animals and that animal patenting will somehow cloud the ownership of wild animals. *Id.* at 63-64 (statement of John A. Hoyt, President of the Humane Society of the United States). Mr. Hoyt expressed concern that animal patenting will create new health problems and will diminish genetic diversity within a species. *Id.* The Humane Society also fears that animal patents will cause economic concentration of the livestock industry. See *infra* note 36 and accompanying text (discussion of a farmer's exemption from infringement liability).

Religious leaders argue that the patenting of animals poses serious nonsecular issues: "The gift of life from God, [in] all its forms and species, should not be regarded solely as if it were a chemical product subject to genetic alteration and patentable for economic benefit." *Hearings*, *supra* note 2, at 401 (statement of religious leaders against animal patenting).

The foregoing arguments against permitting animals to be patented, however, do not survive closer scrutiny. The animal rights activists offered no evidence in recent hearings to support their allegations that patent owners will mistreat genetically altered animals merely because they are patentable. See generally *Hearings*, *supra* note 2. Furthermore, it simply does not follow that patented animals will be mistreated with any greater frequency than other animals. Similarly, fears that animal patenting will "cloud the ownership of wild animals" miss the mark because animal patents are granted for genetically altered animals, not for wildlife. *In re Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (1987) (patent for a genetically unaltered "polyploid oyster" denied for reasons of obviousness). See *supra* note 16 for a discussion of *Allen*. As a result, it seems apparent that wild animals cannot be patented because they fail to meet the statutory requirements of novelty, utility, and nonobviousness. See 35 U.S.C. §§ 101-103 and 112 (1982). The objections of religious leaders, though lofty in their

Under the PTO's 1987 policy,³² if a farmer breeds and raises patented livestock, the law would require him to pay a royalty fee for each offspring produced.³³ Quite expectedly, many small farmers fear they will be unable to afford such royalties and, therefore, will be unable to market genetically altered livestock. As a result, they will face the prospect of competing in the markets against genetically superior animals³⁴—animals that produce larger and higher quality yields.³⁵

The scientific community recognized this problem and is exhorting Congress to provide a patent infringement exemption for farmers as a means of quelling farm opposition to animal patents.³⁶ Under such an exemption, farmers would be able to breed and produce patented livestock without paying a royalty fee. Granting this exemption would also allow the PTO to gain much needed experience with animal patents.³⁷

The importance of transgenic animals to scientific and medical research is indisputable. Quite simply, patents provide the proper incentive to encourage open scientific discussion of genetic engineering. It is im-

praise of the gift of life, amount to nothing more than an emotional conclusion that animals should not be patented.

Animal rights activists argued to the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice: "Animal patenting violates the basic ethical precepts of civilized society and unleashes the potential for uncontrollable and unjustified animal suffering If patenting of animals is permitted, there will surely be a dramatic increase in the suffering of animals resulting from agricultural, biomedical, and other industrial research." *Hearings, supra* note 2, at 62-63 (statement of John A. Hoyt, President of the Humane Society of the United States). Such concerns, however, while relevant to regulating genetic engineering, are of little help in determining whether the products of legal genetic engineering should be patentable.

32. See *supra* notes 12-13 and accompanying text.

33. See *supra* notes 20-22 and accompanying text.

34. *Hearings, supra* note 2, at 306-12 (statement of Farmers Union Milk Marketing Cooperative and Wisconsin Farmers Union).

35. Other farmers oppose animal patenting aside from the issue of patent infringement because they fear the almost certain increased yields resulting from the use of patented animals will only add to the already glutted farm markets. *Id.* "The patenting of animals would almost guarantee additional milk production at a time when we are already in surplus Animal patenting is hardly an answer to this Wisconsin dairy farmer's prayers." *Id.* at 312. See also *id.* at 115 (statement of Cy Carpenter, National Farmers Union).

36. McCormick, *Animal Patents*, 6 BIOTECHNOLOGY 623 (1988) ("If the biotech community is to convert farmers from powerful opponents into powerful allies, it must accept the realities of the farm market and tailor its notions of proprietorship to fit.")

37. A bill passed by the House would have provided: "[i]t shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding . . ." H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436 (daily ed. Sept. 13, 1988). Subsequently, this bill died in Senate committee; Congress adjourned before the Senate voted on its provisions.

portant to recognize that a per se ban on animal patents will seriously handicap the U.S. biotechnology industry. However, it is also noteworthy that unbridled issuance of animal patents may adversely affect the U.S. farm industry. Absent deliberate congressional review of the issue of transgenic animal patents, it seems prudent to continue issuing animal patents to genetic engineers, while simultaneously calling on Congress to grant on an interim basis a limited exemption from liability for breeding patented farm animals.

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