

## Intellectual Property in Higher Life Forms: the Patent System and Controversial Technologies

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# Articles

## INTELLECTUAL PROPERTY IN HIGHER LIFE FORMS: THE PATENT SYSTEM AND CONTROVERSIAL TECHNOLOGIES

ROBERT P. MERGES\*

This article reaches four conclusions. First, animals should not be excluded from patent protection for ethical or economic reasons; both animal treatment and farm policy are and should be outside the purview of the patent system.

Second, most of the problems that will result from patentable animals will be practical, *e.g.*, detecting infringement and enforcing rights. Private contracts between patentees and their customers can be expected to solve many of these problems, and the market demand for devices to detect infringement will solve many more.

Third, current law fails to adequately address the rights of animal owners and patentees over the offspring of patented animals. Congress should consider enacting legislation paralleling the farmer's crop exemption<sup>1</sup> of the Plant Variety Protection Act of 1970,<sup>2</sup> which permits a farmer to use next-generation seed produced by a protected plant variety. The proposed legislation would allow farmers to sell or breed the offspring of patented animals without paying further royalties to the patentee.

Fourth, because of the importance of public sector agencies in agricultural research and development, Congress should consider clarifying the court-made research exemption from patent infringement.<sup>3</sup> Private rights should not hinder public research.

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1. 7 U.S.C. § 2543 (1982).

2. Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321-2582 (1982)).

3. 7 U.S.C. § 2544 (1982).

## I. INTRODUCTION

Few decisions of the Board of Patent Appeals and Interferences get much press; most could not be described as real "page-turners," and few people besides the parties involved and patent lawyers ever read them. But *Ex Parte Allen*,<sup>4</sup> decided on April 3, 1987, was different. In *Allen* the Board upheld in principle the patentability of higher life forms. Although the Pacific oyster patent in *Allen* was rejected on other grounds—the Board found it was "obvious" in light of well-known techniques in the field<sup>5</sup>—the decision set the stage for a larger debate over the future direction of animal patents. Even now, after the first animal patent has been granted,<sup>6</sup> the debate continues.

Although patent lawyers had been predicting a decision like *Allen* for some time, it was an occasion for concern and consternation in other quarters. Animal rights groups saw in it a future full of sad mutant animals twisted into unnatural forms by greedy and inconsiderate genetic engineers.<sup>7</sup> Farm groups saw the prospect of increased control by giant agri-business corporations, whose demand for royalties on patented animals would surely become yet another threat to the ever-decreasing autonomy of the small farmer.<sup>8</sup> When United States Senator Mark Hatfield entered the fray with a bill im-

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4. 2 U.S.P.Q.2d (BNA) 1425 (1987). Four days after the decision in *Allen*, the Patent Office issued a notice advising that nonnaturally occurring nonhuman multicellular organisms, including animals, are patentable under section 101 of the patent statute, 35 U.S.C. § 101 (1982). See *Notice by the Commissioner*, 1077 PAT & TRADEMARK OFF. GAZETTE 24 (Apr. 21, 1987), excerpted in 33 Pat. Trademark & Copyright J. (BNA) 664 (1987).

5. The Patent Office grants a patent when an inventor can show three things: an invention is the first of its kind, the invention is useful, and it represents a non-trivial extension of what was known. 35 U.S.C. §§ 101 (utility), 102 (novelty) & 103 (nonobviousness) (1982 & Supp. III 1985). See *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See also 1 P. ROSENBERG, PATENT LAW FUNDAMENTALS III-1 (1986). In addition, there are two types of subject matter that cannot be patented: mathematical formulas and natural laws, and unmodified products of nature. 1 P. ROSENBERG, *supra*, at § 6.02[2]. Thus there is in effect a fourth requirement—that an invention not fall into one of these categories.

6. See Schneider, *Harvard Gets Mouse Patent, A World First*, N.Y. Times, Apr. 13, 1988, at A-1, col. 5 (United States Patent 4,736,866 granted to Dr. Philip Leder of Harvard, for a transgenic mouse engineered to develop cancers not naturally occurring in mice). See also Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 Jurimetrics J. 399 (1988).

7. 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. 57 (June 11, 1987) [hereinafter *Hearings I*] (statement of John A. Hoyt, Humane Society of the United States); *The Animal Patenting Decision: Should People Own New Forms of Life?*, The Humane Soc'y News, Summer 1987, at 6 [hereinafter *Owning New Life*].

8. See *Hearings I*, *supra* note 7, at 114 (testimony of Cy Carpenter, President, Na-

posing a moratorium on animal patents, it was clear that the debate had far exceeded the usual confines of the patent community.<sup>9</sup>

The overarching question raised by the opponents of the *Allen* decision was this: Should inventors be given proprietary rights in technologies that are feared by at least some members of society? Or should we deny patents on inventions that some believe will have harmful consequences?

This article will address these questions primarily as they relate to inventions concerning higher life forms.

## II. CURRENT TECHNOLOGY

An introduction to the rudiments of the technology should aid in understanding what inventions in this field may look like. It also may help in understanding and evaluating the fears of those who oppose animal biotechnology research.

Animal biotechnology research can be divided roughly into three categories, according to the goals of the research: (1) animals that represent enhanced food sources; (2) animals that are susceptible to human diseases, to help test therapies and cures for those diseases; and (3) animals that produce human drugs and other non-food products.

### A. Enhanced Food Source Research

The invention at issue in the *Allen* decision<sup>10</sup> is an example of enhanced food source research. That case involved a patent on a method for making Pacific oysters unable to reproduce.<sup>11</sup> Scientists found that exposing newly fertilized oyster eggs to extreme water pressure disrupts the normal allocation of chromosomes during cell division, leaving the oysters with three copies of each chromosome,

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tional Farmers Union); Schneider, *Witnesses Clash on Animal Patents*, N.Y. Times, June 12, 1987, at A-21, col. 1.

9. Senator Hatfield's moratorium bill was an amendment to a supplemental appropriations bill. The amendment prohibited the Patent Office from expending funds on animal patents for the remainder of Fiscal Year (FY) 1987. See Hatfield Amendment No. 245 to H.R. 1827, 100th Cong., 1st Sess., 133 CONG. REC. S7322 (daily ed. May 28, 1987). This provision, though approved by the Senate, was later dropped from the bill. See *Briefs: Legislation, Patents*, 34 Pat. Trademark & Copyright J. (BNA) 277 (1987). It is probably no coincidence that the last patent decision that received widespread public attention was *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In this case, where the Supreme Court upheld the patentability of novel life forms, more than 70 amicus curiae briefs were filed with the Court on both sides of the issue. 447 U.S. at 316 (amicus briefs supporting reversal presented "a gruesome parade of horrors").

10. 2 U.S.P.Q.2d (BNA) 1425 (1987).

11. *Id.*

instead of the normal two (called polyploidy). This makes the oysters sterile and also eliminates their normal two-month reproductive cycle, during which they are inedible. Thus oysters treated with the new method can be harvested year-round.

This invention represents a fairly simple example of enhanced food source research. More sophisticated research involving recombinant gene techniques is also underway, and it is this research that raises most of the serious questions in the minds of critics.

In recombinant animal research, scientists take genes from one animal and insert them into the genetic code (DNA) of another animal, called the host.<sup>12</sup> They hope that the host animal can be induced to express the protein which the inserted gene codes for, enhancing the host animal in some way. Current research goals include making host animals bigger, leaner, and more disease-resistant.<sup>13</sup>

The most commonly used technique for introducing "foreign" genes into the host is called micro-injection. The idea is relatively simple: up to one million copies of the desired gene are injected into a newly fertilized host animal embryo. Of these, a tiny portion is taken into the nucleus and, if all goes well, several will integrate into the host's DNA. With luck, at least one copy will be expressed, producing the desired protein (*e.g.*, growth hormone, disease antibodies), and will pass to the next generation when the host animal mates.<sup>14</sup>

Scientists pioneered this technique on relatively simple animals, such as flies, toads and mice.<sup>15</sup> Now private firms and universities are spearheading the effort to apply micro-injection to commercially important animals, such as cows, pigs, and fish.<sup>16</sup> Recombinant

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12. See Office of Technology Assessment, *Transgenic Animals 1-5* (Feb. 1988) (unpublished staff paper of the Office of Technology Assessment Biological Applications Program, on file with the author) [hereinafter OTA Staff Paper].

13. *Id.* at 6.

14. *Id.* at 4.

15. See Brinster, *Factors Affecting the Efficiency of Introducing Foreign DNA into Mice by Microinjecting Eggs*, 82 PROC. NAT'L ACAD. SCI. U.S. AM. 4438 (1985); Etkin & Balcells, *Transformed Xenopus Embryos as a Transient Expression System to Analyze Gene Expression at the Midblastula Transition*, 108 DEVELOPMENTAL BIOLOGY 173 (1985) (toads); Spradling & Rubin, *The Effect of Chromosomal Position on the Expression of the Drosophila Xanthine Dehydrogenase Gene*, 34 CELL 47 (1983) (flies). Scientists have also used techniques other than micro-injection. For example, a virus that usually infects pigs has been used to carry new genes into mice. Elbrecht, DeMayo, Tsai & O'Malley, *Episomal Maintenance of a Bovine Papilloma Virus Vector in Transgenic Mice*, 7 MOLECULAR & CELLULAR BIOLOGY 1276 (1987).

16. See J. Marx, *Cloning Sheep and Cattle Embryos*, 239 SCI. 463 (1988); *Animal Biotech Update*, 8 BIOENGINEERING NEWS 1 (25 Aug.-1 Sept. 1987) (cattle breeding research);

techniques are attracting attention because of their advantages over conventional breeding practices. It is possible, for example, to produce a new animal line carrying a desired trait much faster, because the trait can be isolated and quickly introduced into a large number of host animals. This also allows breeders much greater specificity; they can unlink desired traits from undesirable ones much more easily using these techniques.<sup>17</sup>

### B. *Animal Models*

Much of the food and drugs we use is tested on animals to make sure it is safe and, in the case of drugs, effective. Not all human diseases are shared by animals, however, so some therapies and drugs are difficult to test before they are given to humans. To solve this problem, some scientists are attempting to engineer human susceptibilities into animals that would not normally have them. One example of this line of research is the recombinant mouse described in the first animal patent, issued to Dr. Philip Leder of Harvard.<sup>18</sup> This patent describes a technique for correcting a new strain of mice whose genomes include a cancer-causing gene from other species; the mice therefore can be used to study forms of cancer that do not naturally occur in them, such as human cancers. Another example of animal model research is the attempt to make laboratory mice or rats susceptible to infection with the AIDS virus.<sup>19</sup> Animal rights groups often object to this type of research; proponents cite the toll in human lives that would be taken by direct human testing of experimental drugs. Indeed, studies consistently point to the essential role of animal models in modern biomedical research.<sup>20</sup>

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Graff, *Countless Copies of Choice Cattle*, N.Y. Times, Nov. 8, 1987, at F-19, col. 1 (same); Maclean, Penman & Zhu, *Introduction of Novel Genes into Fish*, 5 *BIO/TECHNOLOGY* 257 (1987) (introduction of novel vertebrate genes into various fish species and preliminary evidence for expression of those genes and transmission to next generation).

17. See OTA Staff Paper, *supra* note 12, at 4-5.

18. See Schneider, *supra* note 6. Note that this patent actually describes and claims a general technique for introducing foreign animal susceptibilities into a range of host animals, including, but not limited to, mice.

19. See *Hearings I*, *supra* note 7, at 48 (statement of Dr. Thomas E. Wagner, Ph.D., Director, Edison Animal Biotechnology Center, Ohio State University).

20. See HEALTH BENEFITS OF ANIMAL RESEARCH (W. Gay ed. 1985) (study by the Foundation for Biomedical Research); Barnes, *Benefits of Animals in Research Described in New Publication*, 232 *SCI.* 310 (1986) (quoting Dr. Gay: "Recently, animal rights groups have declared the use of animals in research to be exploitation and have placed a high priority on its elimination . . . [This] would herald the end of biomedical research as we know it.").

### C. *Animals as Product Factories*

A small number of scientists are attempting to get laboratory animals to produce certain commercially useful products not normally made in those animals. One example is the tissue plasminogen activator-producing mouse.<sup>21</sup> Scientists inserted the human gene coding for the protein known as tissue plasminogen activator (tPA)—a blood clot dissolver with remarkable effectiveness in heart attack victims, in whose hearts dangerous clots often form—into female lab mice.<sup>22</sup> The mice secreted the tPA in their milk.<sup>23</sup>

## III. CONCERNS ABOUT THE TECHNOLOGIES

There are four fears voiced by the critics of this technology: (1) immediate ecological disasters; (2) indirect ecological dangers; (3) reduction in the gene pool of the world; and (4) ethical dilemmas. The text that follows elaborates on these concerns, and the next section considers whether the patent system can address them.

### A. *Deliberate Release and Immediate Ecological Disasters*

The first concern is that recombinant or transgenic animals will somehow escape confinement, infect other organisms, and cause an ecological disaster. This was one of the fears that prompted the Foundation on Economic Trends, led by anti-biotechnology advocate Jeremy Rifkin, to file suit, requesting the United States Department of Agriculture to file an environmental impact statement covering department-sponsored research on animal biotechnology.<sup>24</sup>

Although the case was dismissed on other grounds,<sup>25</sup> it is difficult to see how recombinant animals pose a direct threat to the ecological balance. Such animals usually are kept in captivity, and in any event, they can mate only with animals of the same species. Rapid and widespread transmission of genetic material across species boundaries seems highly unlikely.

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21. Gordon, Lee, Vitale, Smith, Westphal & Hennighausen, *Production of Human Tissue Plasminogen Activator in Transgenic Mouse Milk*, 5 *BIO/TECHNOLOGY* 1183 (1987).

22. *Id.* at 1184.

23. *Id.*

24. *Foundation on Economic Trends v. Lyng*, 817 F.2d 882 (D.C. Cir. 1987).

25. *Id.* at 885-86 (affirming dismissal of action because the Department of Agriculture's animal productivity research did not constitute a unified program for purposes of the National Environmental Policy Act, 42 U.S.C. §§ 4331-4361 (1982)).

### B. *Indirect Ecological Dangers*

The second objection is that transgenic animals could have a deleterious effect on ecological balance over the long run. Under one scenario, transgenic animals, bred to be superior, overcome natural population limitations and wreak havoc by sheer numbers. Under another, animals are bred to thrive in heretofore barren areas, leading to a long-term change in the ecological landscape of those areas.<sup>26</sup>

These are more serious worries. Ecology is a young science, and ecosystems are amazingly complex. Although farmers have been breeding animals for centuries with seemingly few known catastrophic effects, the possibility exists that accelerated breeding on a large scale could lead to some unforeseen disaster. Section IV discusses whether the patent system is an appropriate place to address these concerns.

### C. *Depleted Gene Pool*

This objection to biotechnology is related to the concern about long-term ecological effects. Scientists are aware of many examples of populations that have been completely eradicated because of susceptibility to disease or other organic attacks.<sup>27</sup> All such events are regrettable; we are all lessened by the death of any species. But those that result from overreliance on a particular species are particularly heinous—they might have been avoided. The fear is that reliance on particular strains of engineered “super” animals would be dangerous because of the loss of the natural diversity of a “wild” (*i.e.*, nonengineered) population. This is especially true of animals developed with the micro-injection cloning technique described above. To the extent that such genetically identical animals displace naturally diverse animals, they introduce the risk that all might die when exposed to a novel disease or pest if the original parent cell did not include a gene conferring resistance to the new threat. Without genetic engineering, probably only some would die.

Experience with plants has shown that this can indeed be a problem.<sup>28</sup> But at least some commentators believe that since intellectual property rights have been granted for new sexually repro-

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26. See, e.g., *Audubon Wants Biotech Study*, 8 *BIOENGINEERING NEWS* 1 (16 Nov. 1987) (describing Audubon Society call for major study on possibility that biotechnology research could lead to irreversible damage, such as destruction of arid climate ecologies).

27. Dutch elm disease is one example.

28. See S. WITT, *BRIEFBOOK: BIOTECHNOLOGY AND GENETIC DIVERSITY* 67 (1985) (California Agricultural Lands Project Briefbook No. 2) (the term “genetic diversity”



ducing plants, the variety of new strains has actually *increased*.<sup>29</sup> And even before biotechnology research, efforts were under way to create "seed banks" to preserve the genetic diversity of various crops.<sup>30</sup> This, together with the prospect of breeding in diversity for traits other than the engineered one, could alleviate the threat of overreliance on a small number of strains.

#### D. Ethical Objections

There are two basic ethical objections to patenting animals developed through biotechnology research: concerns with "owning life" and the notion of "species integrity."

The first concern is reflected in a number of our legal and social practices. Slavery—owning a human being—is banned under the Constitution,<sup>31</sup> and the United States Patent Office has declared that the slavery provision bars patents on improved humans.<sup>32</sup> Likewise, Western legal systems have never permitted free trade in such body parts as kidneys,<sup>33</sup> although there is a large market for artificial body parts and medical devices.

Those who object to biotechnology consider intellectual property rights tantamount to ownership and exclusive claims to small components of living systems to be tantamount to owning life itself.<sup>34</sup> Firms in the industry, and their patent lawyers, disagree. They point out that this is an old practice; many patents have been granted for the use of micro-organisms in fermentation and antibi-

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became popular during the 1970 Southern Corn Leaf Blight epidemic, said to highlight dangers of breeding plants from narrow genetic base).

29. See Evenson, *Intellectual Property Rights and Agribusiness Research and Development: Implications for the Public Agricultural Research System*, 65 AM. J. AGRIC. ECON. 967 (1983).

30. See, e.g., *Germplasm News*, 8 BIOENGINEERING NEWS 4 (25 Aug.-1 Sept. 1987) (description of National Small Grains Germplasm Research Facility, which stores samples of wheat, oats, rice, and barley). See also *Hawaii Plant Gene Repository*, 8 BIOENGINEERING NEWS 4 (16 Nov. 1987) (describing the opening of the Plant Germplasm Repository for Tropical Fruit and Nut Crops, to store and maintain strains of, e.g., papaya, breadfruit, macadamia nuts, pineapple).

31. U.S. CONST. amend. XIII (prohibiting slavery).

32. See *Notice by the Commissioner*, *supra* note 4 (stating that nonnaturally-occurring and—because of the thirteenth amendment, *nonhuman*—multicellular organisms are patentable).

33. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS* at 75-76 (1987) (citing the National Organ Transplant Act, 42 U.S.C. § 273 (Supp. IV 1986)).

34. See *Owning New Life*, *supra* note 7; Lang, *Plant Breeders' Rights Bill: There is a Great Moral Dilemma Posed by the Private Ownership of New Life Forms*, 32 CANADIAN LABOUR 15 (1987).

otic production, for example.<sup>35</sup> More importantly, they stress the benefits of applied biomedical research carried out with the promise of patent protection—new drugs, better plants, even human gene therapy for now-incurable diseases.<sup>36</sup> Finally, they emphasize the limited nature of a patent, which grants a seventeen-year right to exclude others only from the specific novel element of the invention it describes.<sup>37</sup>

Underlying the debate is a philosophical tension that has been present since Darwin's time. Many biologists tend to view living organisms as very complex chemical systems, different from nonliving systems primarily in the degree of organization.<sup>38</sup> To them, and to patent lawyers familiar with patents on new chemical compounds, patents on the modified genetic codes of life forms are a logical extension of current practice. They present no new problems. But for those who harbor reservations about biotechnology, this is the source of the problem; they believe that life has special properties that are beyond the realm of science.<sup>39</sup> To them, owning life is a form of secular sacrilege—it violates their fundamental sense of the

35. Louis Pasteur, for example, patented a number of yeast-related inventions. See Frederico, *Louis Pasteur's Patents*, 86 SCI. 327 (1937), reprinted in 19 J. PAT. OFF. SOC'Y 966 (1937); *Pasteur's Patents*, 20 J. PAT. OFF. SOC'Y 642 (1938). See also *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2d Cir. 1908) (patent for original bacteria-using septic tank).

36. See *Hearings I*, supra note 7, at 47-49 (statement of Dr. Thomas E. Wagner, Ph.D., Director, Edison Animal Biotechnology Center, Ohio State University).

37. 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. 156 (July 22, 1987) [hereinafter *Hearings II*] (statement of Reid Adler of the intellectual property law firm of Finnegan, Henderson, Farabow, Garrett & Dunner).

38. See, e.g., I J. WATSON, N. HOPKINS, J. ROBERTS, J. STEITZ & A. WEINER, *MOLECULAR BIOLOGY OF THE GENE* 28 (4th ed. 1987) ("[The] almost mystical ideas [of biologists who believed in a vital life force distinguishing living from nonliving things] never led to meaningful experiments and, in their vague form, could never be tested. Progress was made instead only by biologically oriented chemists and physicists patiently attempting to devise new ways of solving the structures of more and more complex biological molecules."). See also F. JACOB, *THE POSSIBLE AND THE ACTUAL* 45 (1982) (describing, in the course of a lecture on evolution and biotechnology, the religiously inspired but unfounded fears of non-scientists over "tinkering" with living things).

39. 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. 396 (Nov. 5, 1987) (statement of Rev. Wesley Granberg-Michaelson, National Council of Churches of Christ in the United States); R. Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399 (1988). The general term for this conflict in world views, coined by C.P. Snow in his famous Rede Lecture of 1959, is the problem of the "two cultures." See C.P. SNOW, *THE TWO CULTURES AND OTHER ESSAYS* (1960). The problem Snow identified has persisted, and in fact may be worsening. See T. Pynchon, *Is it O.K. to Be a Luddite?*, N.Y. Times, Oct. 28, 1987, § 7 (Book Review), at 1.

proper order of things.<sup>40</sup> In addition, they believe it smacks of hubris, because we are, after all, only one of many species on the earth.<sup>41</sup>

The second major ethical objection to patents on higher life forms centers on the concept of species integrity. Proponents of this concept believe that species should not be crossed—that each species has a right to have its genetic composition left alone.<sup>42</sup> In this view, transgenic animals should be banned, because producing them violates the integrity of both the host and the donor species.

Scientists have a hard time with this argument. They point out that man has been systematically altering species for millennia, through practices such as cattle breeding, selective crop breeding, and hybridization.<sup>43</sup> Moreover, the animals currently used as transgenic hosts are themselves the product of human intervention. As the Office of Technology Assessment reports:

[T]he domestic animals that are now the subjects of transgenic research, and are likely to be for the foreseeable future, are already the products of centuries, and in many cases millennia, of human manipulation. Whatever integrity they may once have had as biological units has already been far more altered by human intervention than transgenic manipulations are likely to lead to even within the next several decades.<sup>44</sup>

In addition to these objections, a young but growing group of philosophers has begun to fashion a much more general critique of our society's use of animals. Their criticisms are directed at the entire range of animal-related activities—from eating meat to animal

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40. To others, it represents yet another example of the denial of animals' basic rights. One animal rights defender has even coined the phrase "speciesist" to describe someone who makes a distinction between species on "irrelevant" bases. P. SINGER, *ANIMAL LIBERATION: A NEW ETHICS FOR OUR TREATMENT OF ANIMALS* 7 (1975).

41. See, e.g., Kass, *Patenting Life*, 63 J. PAT. OFF. SOC'Y 571, 599 (1981) (discussing hubris inherent in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), holding that bacterial life form is patentable). Scientists sense a much greater degree of hubris in the scenarios of animal patent opponents. Such "achievements" as hybrid human-monkeys and two-headed cats are a long way from being possible with the techniques known today. Cf. *What Price Mighty Mouse*, *The Atlantic Monthly*, May 23, 1988, at 7, 8 ("What scientists are actually doing is taking a very mundane, single human gene and inserting it in a very mundane organism. . . . So far, none of the bacteria have sprouted ears or started carrying briefcases, and we don't expect them to any time soon.").

42. See generally J. RIFKIN, *ALGENY* (1984).

43. See, e.g., OTA Staff Paper, *supra* note 12, at 11 (species integrity argument has "no known foundation in biology"); *Hearings II*, *supra* note 37, at 117, 120 (statement of Dr. A. Ann Sorenson, American Farm Bureau Federation).

44. OTA Staff Paper, *supra* note 12, at 11.

research.<sup>45</sup> On this view animal patenting is only the newest invasion of animals' inherent rights. While this is not the place (and I am not the person) to mount a full critique of these positions, it seems important to make several basic points.

Animal rightists argue that animals have a consciousness that is qualitatively similar to that of humans.<sup>46</sup> From this, they proceed to the notion that animals have a distinct form of autonomy, similar to but less developed than full human autonomy.<sup>47</sup> Thus animals are deprived of this important feature—autonomy—when confined, experimented on, or eaten. The conclusion, with some modifications,<sup>48</sup> is that animals possess minimum inherent rights which must be respected. One problem with this line of reasoning stems from its opening assumption that human and animal consciousness is qualitatively similar. There is no reason to take this assumption as true. If language is a proper criterion on which to judge consciousness, for example, the assumption obviously fails. If Regan were criticized for equating admittedly less-developed animal autonomy with full-blown human autonomy, on what basis could he respond? We have come too far in our understanding of the contingent and socially mediated nature of categories and distinctions to accept at face value an argument about inherent qualitative similarity. That is to say, scholars may choose to accept a certain distinction, but if they choose otherwise, they will not be ignoring a qualitative similarity, they will simply be defining it out of existence.

More importantly, even accepting for the sake of argument the qualitative similarity between human and animal consciousness, animals and humans still can be distinguished without doing wrong or being evil. This is because animal rightists' arguments are, at heart, arguments about consistency, logic, or coherence, not about ineluc-

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45. See, e.g., T. REGAN, *THE CASE FOR ANIMAL RIGHTS* (1983); B. BOLLIN, *ANIMAL RIGHTS AND HUMAN MORALITY* (1981); Regan, *An Examination and Defense of One Argument Concerning Animal Rights*, 22 *INQUIRY* 189 (1979). See also Dresser, *Respecting and Protecting Nonhuman Animals: Regan's The Case for Animal Rights*, 1984 *AM. BAR FOUND. RES. J.* 831 (reviewing Regan's book and related literature); Nozick, *About Mammals and People*, *N.Y. Times*, Nov. 27, 1983, § 7 (Book Review), at 11 (reviewing Regan's book and discussing issues it raises).

46. T. REGAN, *supra* note 45, at 28.

47. *Id.* at 84-86.

48. Although he rejects utilitarianism, for instance, Regan recognizes that even an individual rights-based conception of ethics would allow four human survivors in a rowboat to kill and eat a fifth, or to throw overboard even a million dogs, because the magnitude of harm to each individual in each case would be greater if the fifth human survivor were not eaten or if the dogs were not thrown overboard. *Id.* at 324-25.

table right and wrong.<sup>49</sup> And, as Arthur Leff has written, "[I]llogic, irrationality, and incoherence are not *evil*, unless one declares them so, presumably in the normal fashion, by assertion. . . . Briefly, intellectual coherence is intellectual coherence; it becomes something else—right, good, noble—only if so stipulated."<sup>50</sup> The choice about how to treat animals, like the choice about whether to accept consistency as the key criterion of our ethical system, is in the end society's to make. Society is not compelled by the presence of consciousness or any other attribute to act in any particular way at all.

#### IV. CAN THE PATENT SYSTEM ADDRESS THESE CONCERNS?

Whether or not the ethical and other concerns of biotechnology opponents have merit, for reasons outlined below, the patent office is not the proper place to address these concerns.

##### A. *History as a Guide: Patents for "Immoral" Inventions*

What the opponents of biotechnology seek—to deny patents for subject matter they consider immoral—is not unknown in the history of patent law. From the early nineteenth century until mid-way through this century, courts often were willing to withhold patents on inventions they considered immoral. These inventions fell chiefly into two classes: (1) inventions used to defraud buyers, and (2) machines used for gambling. Moral worth proved to be a difficult test of patentability—a fact which should give pause to those anxious to revive it.

The concept of immoral subject matter is thought to have originated in dictum from a Joseph Story opinion.<sup>51</sup> The question before the court was whether the patent at issue described an inven-

49. Regan, for example, ultimately bases his animal ethics on a sort of modified intuitionism. He says moral intuitions are a good guide to action, so long as they reflect "considered beliefs." T. REGAN, *supra* note 45, at 121-49. Considered beliefs, of course, are the necessary "filter" a philosopher must construct to counter the possibility that intuitions will lead to racial prejudice and other reprehensible things. Only intuitions that measure up to the criteria of a considered belief are said to be "valid." *Id.* at 136-40. Thus even intuition is not always an accurate source of moral guidance; it too must be measured against Regan's plausible but by no means objectively grounded criteria. It is consistency with this criteria, and not conformance to an unquestionable standard of right and wrong, that is the ultimate test of a moral judgment.

50. Leff, *Memorandum* (Book Review), 29 STAN. L. REV. 879, 881 (1977). See also Leff, *Unspeakable Ethics, Unnatural Law*, 1979 DUKE L.J. 1229 (concluding that without an unquestioned generator or unquestionable judgments, e.g., a God, there is no such thing as an unchallengeable evaluative system, and thus no way to prove one ethical system, e.g., one based on logic or consistency, superior to any other).

51. *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568).

tion that was useful—utility, along with novelty, was the test for patentability at the time.<sup>52</sup> Judge Story rejected the defendant's contention that the plaintiff's patent was invalid for want of utility; he went on to say that "the law will not allow the plaintiff to recover, if the invention be of mischievous or injurious tendency."<sup>53</sup> As examples, he cited patents to "poison people, or to promote debauchery, or to facilitate private assassination."<sup>54</sup>

This doctrine was invoked often in the late nineteenth century to deny patents on gambling devices.<sup>55</sup> Interestingly, it was a successful bar to patentability even where inventions appeared to be useful for things other than gambling.<sup>56</sup> Patents were struck down on this basis well into the twentieth century,<sup>57</sup> and even as late as 1941, in a pinball machine patent case, the Seventh Circuit was careful to note the distinction between playing pinball and gambling.<sup>58</sup> By the 1970s, however, the courts were regularly upholding patents on gambling devices—both because gambling was no longer seen as a major moral issue, and because courts had become more wary of denying patents on the basis of an indeterminate moral standard.<sup>59</sup>

The fight against immoral inventions was not limited to patents for gambling devices. Another line of cases denied patents for inventions that could be used only to defraud. In one leading case, the Second Circuit invalidated a patent on a process for artificially producing spots on domestic tobacco, finding that the sole use for the process was to make domestic tobacco resemble fine grades of

52. *Id.* at 1019. See also Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUP. CT. REV. 293, 303-15 (describing the history of tests of patentability).

53. 15 F. Cas. at 1019.

54. *Id.*

55. See, e.g., *Reliance Novelty Corp. v. Dworzek*, 80 F. 902, 904 (N.D. Cal. 1897) (patent on design for slot machine cover struck down for lack of utility). See generally 1 D. CHISUM, PATENTS, § 4.03[1] (1977, rev. 1988) (general description of the doctrine and its history).

56. See, e.g., *Schultz v. Holtz*, 82 F. 448, 449 (N.D. Cal. 1897) (patent on coin return device for coin-operated machines denied because it had application to slot machines); *National Automatic Device Corp. v. Lloyd*, 40 F. 89, 90 (N.D. Ill. 1889) (patent on toy horse race course denied on evidence that toy course was used in bars for betting purposes).

57. See, e.g., *Meyer v. Buckley Mfg. Co.*, 15 F. Supp. 640, 641 (N.D. Ill. 1936) (patent denied on "game of chance" vending machine, where user inserted coin and tried to manipulate miniature steam shovel to scoop up a toy). But see *Fuller v. Berger*, 120 F. 274, 281 (7th Cir. 1903) (reversing denial of patent for mechanism to detect bogus coins, due to use in slot machines).

58. *Chicago Patent v. Genco, Inc.*, 124 F.2d 725, 728 (7th Cir. 1941) (upholding patent on pinball machine). But cf. *Meyer*, 15 F. Supp. at 641.

59. See, e.g., *Ex parte Murphy*, 200 U.S.P.Q. (BNA) 801, 803 (1977) (upholding claim for "one-armed bandit").

imported tobacco.<sup>60</sup> This was in keeping with other cases holding that patents could be granted only for devices having no fraudulent uses.<sup>61</sup>

Cases on medicinal products make up a special class of "fraudulent use" cases. Beginning in the nineteenth century, courts were wary of placing the government's imprimatur on medicines and devices hawked to an unsuspecting public in the free-wheeling days before the establishment of an effective Food and Drug Administration (FDA).<sup>62</sup> The result was a higher standard of utility for health-related inventions, vestiges of which still can be seen in patent cases and patent office practices.<sup>63</sup>

Now that a powerful FDA has far-reaching powers to regulate drugs and medical devices, however, courts are increasingly willing to focus on functional utility rather than clinical safety when medical patents are at issue.<sup>64</sup> The rationale for this more limited role is to avoid duplication of effort. As one court stated, "[T]o require the Patent Office to make an affirmative finding as to the safety of a drug for human use would work a serious overlapping of the respective jurisdictions of the Patent Office and the FDA."<sup>65</sup>

What conclusions can be drawn from the attempts of the courts to enforce moral norms by denying patents? First, as in the case of gambling devices, moral norms—or at least the courts' perceptions of them—change over time. One leading patent casebook implies that changes in moral norms are at least in part a function of the very thing patents are supposed to bring about—new technologies:

Birth control devices, in a period of thirty to forty years,

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60. *Rickard v. Du Bon*, 103 F. 868, 873 (2d Cir. 1900).

61. *See, e.g., Klein v. Russell*, 86 U.S. (19 Wall.) 433, 468 (1873) (affirming trial court jury instruction on utility which stated that inventions with no honest uses were unpatentable). *See also In re Corbin*, 6 F. Cas. 538, 542 (C.C.D.C. 1857) (No. 3,224) (upholding grant of patent on artificial honey).

62. *See, e.g., Mahler v. Animarium Co.*, 111 F. 530, 537 (8th Cir. 1901) (patent denied for medical device using electricity to cure diseases). Indeed, firms often used their patents as a selling tool, thus giving "patent medicines" a bad name. *See E. KITCH & H. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS* 808 (3d ed. 1986).

63. 1 D. CHISUM, *supra* note 55, at § 4.04[2]; Brand, *Utility in a Pharmaceutical Patent*, 39 *FOOD DRUG COSM. L.J.* 480 (1984). *See generally* Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 *TEX. L. REV.* 1139 (1987).

64. This has been the trend for some time. *See, e.g., In re Anthony*, 414 F.2d 1383, 1400 (C.C.P.A. 1969) (refusing to invalidate patent for anti-depressant drug Monase, despite FDA's suspension of drug because of acute side-effects); *In re Hartop*, 311 F.2d 249, 260 (C.C.P.A. 1962) (rejecting argument that patent for thiobarbituric acid was invalid for lack of utility due to potential for dangerous side effects).

65. *Carter-Wallace, Inc. v. Riverton Laboratories, Inc.*, 433 F.2d 1034, 1039 n.7 (2d Cir. 1970).

have come from a position of illegality to a position where they are welcomed by some as a means of curbing a population explosion. Thus, in 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.<sup>66</sup>

A second conclusion is that even in those cases where moral norms have been invoked to deny patents, the inventions at issue posed a direct threat to a readily identifiable norm—a marked contrast to the case of biotechnology inventions. Gambling, for example, was considered bad in itself; gambling devices were used directly to perform an immoral act. Bogus medicines were the same—they were themselves the instruments of fraud. Biotechnology, at least at this state, arguably presents a different situation. If the norm is species integrity or natural species barriers, today's recombinant researchers are no more culpable than the myriad natural mechanisms for the transfer of genetic material—viruses, for instance.<sup>67</sup>

But even conceding that biotechnology is analogous to gambling or selling fake medicines, another problem remains: what are the limits of the immorality test? How far into the future can the patent challenger look for the immoral effects of an invention, and what consensus version of morality can the courts rely on?

For example, historians and sociologists have long noted the profound social changes that accompanied the invention of the automobile. Some of these changes had unquestionable moral dimensions, such as the impact of automobiles on the incidence of premarital sex. Assuming these changes could have been foreseen, immoral use might have been raised as a reason not to enforce the patent.<sup>68</sup> A host of other technologies, *e.g.*, cattle prods (sometimes

66. R. CHOATE, *CASES AND MATERIALS ON PATENT LAW* 76 (3d ed. 1987).

67. *See, e.g.*, G. TORTORA, B. FUNKE & C. CASE, *MICROBIOLOGY: AN INTRODUCTION* 339-76 (1986) (chapter on viruses); I. J. WATSON, *supra* note 38, at 205-08 (description of "transduction," a process whereby viral particles carry bacterial genes from one organism to another). *See generally* L. THOMAS, *Organelles as Organisms*, in *THE LIVES OF A CELL* 69 (1974) (speculating on the basis of research findings that many sub-cellular components such as mitochondria were separate organisms that integrated themselves into our cells early in our evolution, implying that man is actually a composite of many "sub-species").

68. *See* *Columbia Motor Car Co. v. C.A. Duerr & Co.*, 184 F. 893 (2d Cir. 1911). This case concerned the famous "Selden Patent," United States Patent No. 549,160, granted in 1895, a broad patent encompassing essentially the early automobile. The court found that the patent challengers (including Ford Motors) had not infringed the



used in torture) and abortion-inducing drugs (safer than procedures, but considered immoral by some), can be thought of in this vein.

Even under the traditional immoral use doctrine, however, courts sometimes held that an invention was patentable so long as it had some nonimmoral applications.<sup>69</sup> Thus some classes of biotechnology-related inventions still might be patentable under a sort of moral balancing test—those that prevented degenerative childhood muscular dystrophy, for example. In these cases the norm concerning species integrity presumably would bow to a broader humanitarian sense of morality.

### B. *Inventions Involving Nuclear Energy*

The opposition to biotechnology research often carries the faint echoes of the antinuclear movement. Because some of the moral claims are the same—particularly those directed at society's duty to future generations—it might be instructive to see how the patent system treats nuclear energy and nuclear weaponry patents.

In general, patents are granted in this field the same as in any other. The only exception is for civilian inventions that may have military applications. In this case, the patent application is reviewed by the Department of Defense to see if there are any weapons-related uses for the invention.<sup>70</sup> If there are only defense applications, the Defense Department can obtain all rights to the invention, but it must compensate the inventor.<sup>71</sup> If there are civilian as well as military applications, the inventor must surrender rights to the military uses.<sup>72</sup> This is interpreted narrowly; the Court of Customs and Patent Appeals held in 1980 that this provision only applies if an invention has absolutely no function other than as an atomic

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patent by making its own model automobiles—a decision reversing, at the end of the patent's life, a long string of victories for Selden. 184 F. at 915.

69. *See supra*, note 61.

70. This is done in accordance with the Invention Secrecy Act of 1951, Pub. L. No. 82-256, 66 Stat. 1 (codified as amended at 35 U.S.C. §§ 181-188 (1982)). Under this Act, whose predecessors date from 1917, the Patent Office is instructed to review all patent applications for military content. 35 U.S.C. § 181 (1982). The Atomic Energy Act of 1954, carrying over certain prior provisions of law, prohibited the patenting of nuclear inventions with only military applications. Atomic Energy Act of 1954, ch. 1073, § 1, 68 Stat. 943 (codified as amended at 42 U.S.C. § 2181 (1982)). The Act also gives the government an exclusive license to the military applications of any nuclear invention having both military and civilian applications. 42 U.S.C. § 2183(b) (1982).

71. 42 U.S.C. § 2187 (1982).

72. *Id.* § 2181(b).

weapon.<sup>73</sup>

National security concerns, rather than moral considerations, are at the heart of these provisions.<sup>74</sup> Thus the patent system constrains nuclear energy-related inventions in a number of ways, but it does so to keep information out of the hands of those who would misuse them. The goal is not to place a disincentive in the path of development, but rather to keep developments out of the hands of those who would misuse them. The law does not enact a moral norm; instead, it enforces the military norm of secrecy.

There are obviously great differences between nuclear weapons and recombinant gene technology. The former has no beneficial uses; the latter has many. It would have been grotesque if a nuclear physicist had argued in 1946 that the government should give incentives for the private development and sale of nuclear weapons. Yet in the first hearing on animal patents, Dr. Thomas Wagner, a prominent molecular biologist noted for his research on gene transfers in animals, spoke for the overwhelming majority of his colleagues when he advocated patent protection for new inventions pertaining to animal traits on the grounds that there are and will be many benefits from such research.<sup>75</sup>

By contrast, there are known, severe dangers, as well as a complete absence of benefits, in the case of nuclear weapons. Thus, even if one chooses to view the provisions of the Atomic Energy Act as a kind of moral objection to patenting nuclear weapons, these weapons still would constitute a rare, limiting case—a technology we do not want to encourage.

### C. *Inventions and Moral Judgments: Summary*

Based on the preceding sections several conclusions can be made. First, patent protection for a new technology normally should not be denied on the basis of speculation about potential negative consequences, such as those suggested by opponents of animal patents.<sup>76</sup> The patent system normally is not the proper

73. *In re Brueckner*, 623 F.2d 184, 187 (C.C.P.A. 1980).

74. See, e.g., legislative history of the Invention Secrecy Act of 1951, *supra* note 70; S. REP. NO. 1001, 82d Cong., 1st Sess. (1951); H.R. REP. NO. 1028, 82d Cong., 1st Sess. (1951). See also *Halpern v. United States*, 258 F.2d 36, 38 (2d Cir. 1958) (fundamental purpose of the Invention Secrecy Act was to continue in peacetime the authority to prevent dissemination of information contained in patent applications whenever that information would endanger national security).

75. *Hearings I*, *supra* note 7, at 39.

76. In fact, it can be argued that even in the regulatory context, new technologies normally should not be prohibited on the basis of speculative fears over their impact.

place to conduct technology assessment. Its purpose is much simpler—"to promote the progress of science and useful arts," according to the Constitution.<sup>77</sup>

Second, patents on animals should not be excluded because of arguments about their potential social consequences. Those problems, if they eventually arise, should be dealt with outside the patent law. The FDA, for example, now handles questions about the safety and efficacy of drugs; the considerable regulatory structure that has grown up around biotechnology is the proper place to address concerns about potential deleterious effects of animal patents.

#### V. PRACTICAL IMPACT OF ANIMAL PATENTS

At least in the short term, the problems engendered by animal patents are likely to be less earth-shattering than the ones identified so far. Most of these problems will stem from the fact that animals are *self-reproducing*. Unlike other patented technologies, humans will not have to intervene for a patented animal to be "copied."

The self-reproducing feature of animals will have one of two effects, depending on the normal function of the animal and the goal of the people involved in its reproduction. Under current law, if the purchaser or licensee of a patented animal intentionally breeds it, or tries to copy its patented features in the laboratory, with the goal of attempting to maintain and reproduce the patented trait, the purchaser probably will be liable for patent infringement. But if the animal is simply permitted to mate with other, nonpatented animals under normal pen or cage conditions, the law is unclear as to whether liability will attach. This gap in current law—and the uncertainty it creates—provides the rationale for the farmer's exemption discussed in the next section.

To understand the law as it relates to intentional reproduction of the patented feature, consider the example of a research laboratory which buys or licenses a patented rat. Suppose the rat has been engineered so that it contains a defective human gene which causes

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The opposite scenario—the dangers of holding a new technology back—also should be weighed in the balance. See H. KAHN, W. BROWN, & L. MARTEL, *THE NEXT 200 YEARS* 167-73 (1976). See generally J. Krier & C. Gillette, *The Un-Easy Case for Technological Optimism*, 84 MICH. L. REV. 405 (1985) (reviewing implications of technological optimism in a democratic system, and expressing fear that our reliance on technological fixes poses grave dangers given the combination of possibly rapid, irreversible disasters from modern technologies and the lack of advance planning inherent in our crisis-oriented democracy).

77. U.S. CONST. art. I, § 8, cl. 8.

a common disease in humans. The patentee sells the rat to laboratories who want to test the effectiveness of drugs against the disease.<sup>78</sup> To avoid paying more royalties, the owners of the research laboratory could mate the rat with one of their own and hope that half of the offspring exhibit the patented feature. The patentee would argue that the laboratory was infringing its patent.

A line of Supreme Court cases provides the authority for this argument. Under these cases the Court has held that while the purchaser or licensee of a patented product may use or resell the product, or even replace worn-out components, the entire product may not be reconstructed when its useful life is over.<sup>79</sup> Thus so long as the patentee could prove that the infringer *intentionally* mated the patented animal, with the goal of reproducing the patented trait, infringement probably would be established.<sup>80</sup>

As a practical matter, it would not be difficult for the patentee to prove infringement. Molecular biologists have devised a number of techniques for determining the presence of a specific gene or sequence. Patentees no doubt would find it worth their while to apply these techniques to the development of simple tests that would indicate the presence of the patented gene or sequence in offspring of the animal.

In addition, license agreements can be expected to resolve many potentially troublesome issues. Such issues as the right of the patentee to test for infringing offspring, and the right to prohibit the resale of patented animals for breeding purposes, can be expected to be solved in this manner. In other areas where intellectual property rights involve difficult problems of infringement and enforcement, such as in the licensing of computer software, the parties involved have demonstrated a high degree of creativity in drafting contractual solutions to these problems.

In sum where a customer tries to perpetuate a patented trait, infringement is clear. Moreover, the existence of sound law in this area will provide a solid framework within which parties to license

78. This is not far-fetched; the Leder patent, *supra* note 6, could be used as the basis of a lab supply business where patented, engineered mice are sold to the public.

79. See, e.g., *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961); *Cotton-Tie Co. v. Simmons*, 106 U.S. 89, 95 (1882); *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340, 350 (1868).

80. Unintentional mating outside the breeder's control, however, might be a different story. The intent to reproduce the trait would best reveal itself if, for example, the purchaser of the patented animal began to sell the offspring of the animal containing the trait. Such an obvious attempt to set up a business competing with the patentee's would clearly establish infringement.

agreements may bargain over the details of enforcement and the like. But what about incidental or unintentional reproduction as a result of normal breeding activities? The rules here are far less clear, making a farmer's exemption a logical solution.

*A. Necessity for a Limited Livestock Farmer's Exemption*

As mentioned above, unintentional copying of the patented trait via routine reproduction presents an ambiguous situation under existing law. In reality, this copying will probably not be of much concern to companies in the business of supplying research animals, because those animals are easy to keep separate. It is likely to be a real problem, however, with farmers.

Farmers will want to use patented animals (and their descendants) for normal breeding with the other animals on their own farms. For reasons outlined below, this is a problem area where private, contractual solutions are unlikely to be effective. Thus there exists a need for a limited livestock farmer's exemption from infringement liability.

The exemption would closely parallel the provisions of the farmer's crop exemption of the Plant Variety Protection Act of 1970,<sup>81</sup> which reads as follows:

[I]t shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale [to another farmer without use of a middleman].<sup>82</sup>

The Plant Variety Protection Act (PVPA) protects sexually reproduced varieties of plants; it is the only intellectual property statute in American law that has ever dealt with the question of self-reproducing subject matter.<sup>83</sup> Equally important, it was drafted with a sensitivity to the practical problems of farmers who have to cope with intellectual property rights over their primary source of livelihood. The PVPA therefore provides an excellent starting place to look for solutions to the practical problems farmers will be faced with in the area of animal patents.

Such an exemption would not destroy the market for a paten-

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81. Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321-2582 (1982)).

82. Pub. L. No. 91-577, § 121, 84 Stat. 1555 (codified at 7 U.S.C. § 2543 (1982)).

83. The Plant Patent Act of 1930 applies only to asexually reproduced plants. See Plant Patent Act of 1930, 46 Stat. 376 (codified at 35 U.S.C. §§ 161-164 (1982)).

tee's invention, because of a phenomenon known as "genetic drift." Even in the first generation of offspring from a patented animal (assuming it was not mated with another that possessed the patented trait), only a maximum of sixty percent of the offspring, and quite likely a much smaller percentage, would possess the patented trait.<sup>84</sup> As a consequence, farmers who wanted the advantages of a patented animal would soon have to buy or license a new one, even with an exemption for on-farm breeding. Thus the exemption would not undercut in any serious way the financial incentives for patentees to engage in research and development of new animals.

A similar situation prevails with respect to seeds protected by the PVPA. The farmer's crop exemption has not severely undermined the efficacy of the PVPA, because farmers typically have to buy new seeds after two or three years. Again, genetic drift is the reason.<sup>85</sup> In addition, there is some evidence that seed companies have taken the exemption into account, and have adjusted the prices of the protected seed to reflect a two- or three-year useful life.<sup>86</sup>

In any event, the farmer's exemption in the PVPA has not reduced the effectiveness of that statute, which is generally credited with inspiring a very substantial increase in the number of productive new plant varieties developed in the United States.<sup>87</sup> And it has helped to ensure that farmers will reap the benefits of new varieties without excessive and burdensome involvement in the enforcement

84.

Approximate Heritability Rates for Selected  
Characteristics in Livestock and Poultry

Characteristic	— Percentage —			
	Dairy Cattle	Beef Cattle	Hogs	Poultry
Number born	—	5	10	—
Birth weight	60	40	5	—
Weight at weaning	—	25	10	—
Mature weight	60	—	—	50
Milk production	25	—	—	—
Egg production	—	—	—	35
Feed efficiency	—	40	30	—
Percent lean meat	—	40	35	—

Source: D. ACKERS, ANIMAL SCIENCE AND INDUSTRY, Table 18-1 (3d ed. 1983).

85. See W. LESSER & R. MASSON, AN ECONOMIC ANALYSIS OF THE PLANT VARIETY PROTECTION ACT 123 (1985).

86. See W. Lesser, Applying Animal Patents in Agriculture, at 9 (June 4 & 5, 1987) (unpublished paper presented at the Symposium on the Protection of Biotechnological Inventions, Ithaca, N.Y.; on file with author).

87. See W. LESSER & R. MASSON, *supra* note 85; Evenson, *supra* note 29.

of seed companies' proprietary rights.<sup>88</sup>

Thus there is little danger that a farmer's exemption would severely reduce the incentive effect of patent protection for animals. This would be especially true if the exemption were explicitly limited to true farmers, *i.e.*, as in the PVPA exemption those "whose primary farming occupation is the [raising] of [animals] for sale for other than reproductive purposes."<sup>89</sup>

While only minimally reducing the incentive effect of patent protection, such an exemption would help farmers in a number of ways. First, it would ensure that they will not be saddled with burdensome recordkeeping and patent enforcement duties. Although the burden of establishing infringement is normally upon the patentee, patent licensing agreements might require farmers to keep records to avoid infringement liability. An exemption would remove this burden. This would be especially important to the United States beef cattle industry, because beef cattle reproduce freely on the open plain, making recordkeeping of specific matings virtually impossible.<sup>90</sup> Even outside the beef cattle industry, recordkeeping by small farmers raising dairy cows and hogs would be onerous.

Second, a farmer's exemption would reduce uncertainty. Under present law, it is simply not clear whether a farmer who allowed a patented animal to breed would be infringing the patent.<sup>91</sup> A farmer's exemption would make clear that a farmer would have no liability for infringement in these circumstances—so long as the farmer was not breeding a patented animal just to reproduce the patented trait or to sell offspring for breeding purposes.

Third, a statutory farmer's exemption would prevent patentees from using the threat of patent infringement to extract major concessions from farmers negotiating license agreements. In the absence of an exemption, for example, the parties might bargain for a license containing two clauses: (1) a provision stating that royalties are to be paid for the first and second generation of the patented animal but not for the third generation and beyond—*i.e.*, a contractual version of the exemption; and (2) a provision restricting the farmer's right to resell the animal, or requiring the farmer to

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88. See Lesser, *Patenting Seeds in the United States of America: What to Expect*, 25 *INDUS. PROP.* 360, 364 (Sept. 1986).

89. 7 U.S.C. § 2543 (1982).

90. See W. Lesser, *supra* note 86, at 8.

91. Recall that the old Supreme Court cases prohibited reconstruction of a patented product, but of course said nothing about products that "reconstruct" themselves without human intervention. See cases cited *supra* note 79.

purchase unpatented ancillary products (*e.g.*, special feeds or hormones) which the patentee claims are necessary to make the animal's patented trait more effective. In such a situation, the farmer would not be able to challenge the restrictive clause (number two above) as a violation of the antitrust laws, for fear that if the license agreement were declared invalid, the farmer would no longer be protected by the first clause. Farmers might easily fear that if a court invalidates the entire agreement, third generation (and beyond) animals that would have been exempt from royalty payments under the licensing agreement might be found to infringe the patent; as a result, they would be unlikely to challenge restrictive clauses in the agreement.

### B. *Research Exemption*

The only other change in current law that Congress might consider is exemption from liability for research uses of a patented animal. Actually, this is but one aspect of a larger problem—the scope of the general research exemption in patent law. This exemption is not part of the patent statute; it was created by courts in a line of cases whose continuing validity is open to question.<sup>92</sup> The basic rule—though by no means unequivocally accepted—is that a patentee will not be allowed to prevent experimentation using a patented product or process for bona fide research activities designed to further scientific knowledge.

While this entire area of patent law could stand some clear-sighted legislation, clarity is especially important for animal research. This is because of the large amount of research that is conducted by public agencies in the agricultural sector—especially the United States Agricultural Research Service and the state agricultural experiment stations. With the heavy involvement of the public sector in mind, Congress exempted research uses from infringement under the Plant Variety Protection Act.<sup>93</sup> Congress should consider doing the same for animal research.

One of the few clear rules that emerges from the sketchy contours of the research exemption doctrine in the courts is this: research aimed at commercialization does not fall under the exemption, and so constitutes infringement.<sup>94</sup> Public research

92. See, *e.g.*, 4 D. CHISUM, *supra* note 55, at § 16.03[1].

93. See 7 U.S.C. § 2544 (1982).

94. See 4 D. CHISUM, *supra* note 55, at § 16.03[1]. Note that under this principle, if a patentee sells his or her patented product primarily to research scientists, an infringer cannot sell copies of the product without infringing. In this sense, the exemption does



agencies in agriculture are not involved in basic research. Their mission, which they perform admirably, is to supply farmers with new tools for increased productivity. They are involved in dissemination, not just research.<sup>95</sup> Thus there is a likelihood that their activities will not qualify for the exemption, and therefore their research will be restricted by patents on animals. Patents therefore will prevent public researchers (in the absence of licenses) from investigating ways to improve the patented animals that are developed in the private sector.

Experience in seed research proves why this might be detrimental. Although in 1957 the private sector supplied ninety-five percent of the hybrid corn varieties used on American farms, today roughly eighty percent of the hybrid varieties in use came from public research agencies.<sup>96</sup> This is the type of interaction between public and private sectors that would be fostered by a research exemption for patented animals. With the public and private sectors both working actively on state-of-the-art animal research, farmers would be the clear winners.

Although a research exemption no doubt will raise concerns in the private sector, which will see it as a threat to the incentive structure of the patent system, these concerns have no foundation. In the field of seed research, spending by the private sector—and the number of new varieties introduced—have risen sharply since the passage of the PVPA in 1970.<sup>97</sup> Clearly the research exemption will not substantially harm the private sector; why did seed researchers invest in new varieties after passage of the PVPA if the exemption had significantly diluted the incentive effect of the Act? All a research exemption will do is help farmers.

## VI. CONCLUSION

Patents for animals have no proven harmful consequences, but offer many benefits. There is no reason to invoke the nuclear analogy *at this stage of the debate*, and thereby prevent this new technology from claiming its rightful place in the American system of intellec-

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not apply to a market, *i.e.*, all researchers, but instead to an activity, *i.e.*, researching a patented product with an eye toward understanding it or (arguably) improving it.

95. See Evenson, *Agriculture*, in GOVERNMENT AND TECHNICAL PROGRESS: A CROSS-INDUSTRY ANALYSIS 233 (1982). See also Fox, *Patents Encroaching on Research Freedom*, 224 Sci. 1080 (1984) (anecdotal evidence that biotechnology patents may have slowed down certain lines of research). See generally Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

96. Evenson, *supra* note 95, at 265.

97. See Evenson, *supra* note 29, at 971.

tual property. There are, however, sound reasons to consider two limited exemptions from patent infringement liability: a farmer's livestock exemption and a research exemption.

The first exemption is important because it will keep farmers from becoming "patent police" on their own farms. The second exemption would be beneficial because of the important interplay between public and private sector research in the agricultural industry. Both are sound, hard-headed ways for Congress to provide sensible "farm aid" to those who will bear some of the costs of the new era of animal research, while still recognizing the importance of intellectual property rights in encouraging agricultural innovation.

No one should think that allowing patents on higher life forms has put an end to the debate over biotechnology, however. There is still much to learn about the powerful new discoveries driving this technology. Opponents of *Ex Parte Allen*<sup>98</sup> will proceed on other fronts and, in some of these fights, they will deserve support. Policies that lead to the devastation of the earth or drastic reductions in genetic diversity should be opposed, and if this requires limitations on the applications of biotechnology, so be it.

But avenues of scientific research must not be closed off in fear of what we will find out. Technology is neither inherently good nor inherently bad—it just is, until it is applied in a specific context. Patents on new technology should be granted, reserving the right to regulate specific applications. This is the only sensible course.

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98. 2 U.S.P.Q.2d (BNA) 1425 (1987).