An Agricultural Law Research Article

Ethical and Legal Issues in Patenting New Animal Life

by

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Originally published in JURIMETRICS
28 JURIMETRICS 399 (1988)

ETHICAL AND LEGAL ISSUES IN PATENTING NEW ANIMAL LIFE

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ABSTRACT

Advances in biotechnology have made the patenting of animals a subject of increased interest and controversy. The Patent and Trademark Office recently granted Harvard University researchers a patent on a genetically-engineered mouse, the first patent on a higher life form; proposed legislation is pending in Congress to delay or prohibit issuance of such patents. This article surveys the arguments for and against patenting higher life forms, concluding that methods other than patent law may be more appropriate for regulating such genetic research. The article further discusses the gaps in the current federal regulatory scheme, as well as alterations in patent law which may be needed to accommodate this new development.

INTRODUCTION

On April 7, 1987, the Commissioner of Patents and Trademarks announced that the Patent and Trademark Office (PTO) "now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter."[1] Although patent law experts and biotechnology companies greeted the decision as a welcome and logical extension of existing patent law, the action triggered a much less favorable response

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[1] *See Nonnaturally Occurring Non-Human Animals Are Patentable Under sec. 101*, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 827, at 664 (April 23, 1987). Just one year later, the PTO issued the first patent for a higher form of life. Schneider, *Patent for Mouse Issued to Harvard*, N.Y. Times, April 13, 1988, sec. 1, at 1, col. 1. *See* note 60 *infra*.

Bulgaria, Hungary, and Romania are the only other countries that currently provide some level of patent protection on animal "inventions." BIOLOGICAL APPLICATIONS PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, FEDERAL REGULATION AND ANIMAL PATENTS 5

from the media, a variety of political and religious groups, and some members of Congress. Proposed legislation was introduced in the House and Senate[2] to delay or prohibit the issuance of patents on genetically-engineered[3] invertebrate and vertebrate animals, four congressional hearings were conducted,[4] and a vocal and well-organized opposition to the new patent policy emerged.

Since the early 1980s, scientists have been creating a variety of genetically-engineered higher animal life forms in the laboratory. It took the PTO decision, however, to catalyze a full-fledged political reaction to these developments. The PTO's seemingly innocuous bureaucratic notice conveyed to concerned individuals a clear message that the moral, social, and legal issues raised by this form of biotechnology could no longer be ignored.

This article is an analysis of the ethical and legal implications of patenting novel animal life forms. In Part I, I discuss the U.S. patent system and the legal developments that paved the way for the new PTO policy. In Part II, I describe techniques for producing genetically-altered animals and potential commercial applications of the technology. Part III surveys the various ethical and policy arguments expressed against animal patenting, and the responses of patenting advocates to these arguments. In Part IV, I examine the federal regulatory system governing development and production of genetically-engineered animals. In Part V, I discuss special patent law issues raised by animal patenting. I conclude that the true conflicts over the PTO policy concern not whether higher

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(Feb. 1988) (staff paper, copy on file with this author) [hereinafter cited as FEDERAL REGULATION AND ANIMAL PATENTS]. In Japan, Australia, and several other countries, there is no explicit prohibition on animal patenting, so that animals are in theory patentable in those countries. *See* PATENTING ANIMALS, H.R. REP. DRAFT, 100th Cong., 2d Sess. 71 (1988) (draft report, copy on file with this author) [hereinafter cited as DRAFT REPORT]. The European Patent Convention governing thirteen European countries may prohibit such patenting; however, this has not been definitively established. *Id.*

[2]Senator Mark Hatfield sought to amend H.R. 1827, a supplemental appropriations bill for 1988, to prohibit use of appropriated funds for patenting genetically-engineered animals. The Senate passed the amendment, but the conference committee deleted the provision from the final legislation. FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 1. Hatfield subsequently introduced another bill to place a permanent ban on patenting genetically-altered animals. S. 2111, 100th Cong., 2d Sess. (1988).

Representative Charles Rose has introduced a bill in the House of Representatives that would place a two-year moratorium on patenting genetically-engineered animals to enable Congress to address the "profound economic, environmental, and ethical questions" raised by the issue. H.R. 3119, 100th Cong., 2d Sess. (1988). The bill is now pending in the House Judiciary Committee. FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 2.

[3]In this article, the terms genetic engineering, genetic alteration, genetic manipulation, and recombinant DNA research refer to scientific procedures involving the manipulation and recombination of an organism's genetic code. *See* Science Policy Research Division, CONGRESSIONAL RESEARCH SERVICE, PATENTING LIFE 2 (Dec. 16, 1987) (issue brief by Sarah Taylor, Order Code IB87222) (copy on file with this author) [hereinafter cited as PATENTING LIFE].

[4]The hearings were conducted in June, July, August, and November, 1987, by the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary. For additional commentary and analysis on the developments, see Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, MD. L. REV. (forthcoming).

animals should be patented, but instead address broader ethical and social issues now facing government policy-makers.

I. NOVEL ANIMAL LIFE AS PATENTABLE SUBJECT MATTER

A. Patent Law Background

The decision to issue patents on genetically-engineered animals rests on the PTO's interpretation of federal patent law, as set forth in the Constitution, the Patent Act, and judicial decisions on patentable subject matter. The Constitution empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[5] The constitutional grant reflected longstanding English patent law and colonial legislation incorporating this law.[6]

Congress enacted the first patent statute in 1790,[7] and substantially revised the law four times since then.[8] The current provision on patentable subject matter 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 therefore, subject to the conditions and requirements of this title."[9] The law's primary criteria for patentability are novelty, utility, and nonobviousness.[10] A patent application must also include a written description of the invention sufficient to enable a person

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[5]U.S. CONST. art. I, § 8, cl. 8.

[6]*See* Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1144 & nn.29-31 (1987).

[7]Act of April 10, 1790, ch. 7, 1 Stat. 109.

[8]Act of Feb. 21, 1793, ch. 11, 1 Stat. 318; Act of July 4, 1836, ch. 356, 5 Stat. 117; Act of July 8, 1870, ch. 230, 16 Stat. 198; Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified as amended at 15 U.S.C. § 1071 (1982 & Supp. II 1984), and 35 U.S.C. §§ 1-293 (1982 & Supp. II 1984)).

[9]35 U.S.C. § 101 (1982).

[10]35 U.S.C. §§ 101-03 (1982).

To meet the novelty requirement, an inventor must show that she is the first to make the invention and that it differs from prior inventions. *See* Ropski & Kline, *A Primer on Intellectual Property Rights: The Basics of Patents, Trademarks, Copyrights, Trade Secrets, and Related Rights*, 50 ALB. L. REV. 405, 409 (1986); Adler, *Biotechnology as an Intellectual Property*, 224 SCIENCE 357, 359 (1984). Courts have broadly construed the utility requirement, and an inventor need only demonstrate that the invention has a known purpose and will perform that purpose. *See* Ropski & Kline, *supra* at 409; *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. 2-3 (statement of Dr. Rene Tegtmeyer, Assistant Commissioner for Patents, U.S. Patents and Trademarks Office) [hereinafter cited as *Hearings*]. The nonobviousness standard requires an inventor to establish that, at the time the invention was made, the claimed innovation would not have been "obvious to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. The aim is to ensure that the new invention constitutes a significant technical advance beyond what already exists in the field. *See* Ropski & Kline, *supra;* Adler, *supra* at 359.

skilled in the relevant field to make and use the invention.[11] The successful patent applicant obtains the "right to exclude others from making, using, or selling" the invention for seventeen years.[12] Once the patent is granted, however, the inventor must publicly disclose the technological advance the invention represents.[13]

B. Patenting Microorganisms

A series of court decisions culminated in the PTO's conclusion that higher animal life forms could be patented. In *Diamond v. Chakrabarty*,[14] the Supreme Court held that genetically-altered bacteria were patentable subject matter. The Court relied on evidence that Congress intended section 101 of the Patent Act to be broadly construed, including a congressional report declaring that the provision encompassed "anything under the sun" made by human beings.[15] According to the Court, Congress enacted two separate statutes governing plant patents to resolve special patent law questions related to plant patenting, rather than to override the exclusion of living things from section 101 of the Patent Act.[16] For the Court, the important distinction in determining patentable subject matter was "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[17] Accordingly, a microorganism produced by "human ingenuity and research" qualified as patentable subject matter. Although the government and certain amici argued in *Chakrabarty* that patenting living organisms would present substantial risks to society and the environment, the Court dismissed this material as irrelevant to its decision and more suitable for a congressional inquiry into the appropriate national policy governing genetic engineering activities.

The *Chakrabarty* ruling clearly established that microorganisms could be

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[11] 35 U.S.C. § 112 (1982). This is referred to as the "enablement" provision.

[12] 35 U.S.C. § 154 (1982).

[13] *See* Ropski & Kline, *supra* note 10, at 412.

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

[15] *Id.* at 309, quoting S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 6 (1952).

[16] *Id.* at 310–14. These statutes are the Plant Patent Act of 1930, 35 U.S.C. §§ 161–64 (1982) and the Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321–2583 (1982). *See* OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS 239-40 (1981) (describing statutes) [hereinafter cited as APPLIED GENETICS].

[17] *Id.* at 317. The Court also noted that a negative decision on patentability would fail to prevent continued genetic engineering research. *Id.*

In a related case, *In re Bergy*, the Court of Customs and Patent Appeals held that for purposes of section 101, "the fact that micro-organisms are alive is a distinction without legal significance." *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977), *aff'd on rehearing*, 596 F.2d 952 (C.C.P.A. 1979). Bergy had created a biologically pure culture of a particular microorganism useful in producing an antibiotic. The Commissioner of Patents and Trademarks sought and was granted certiorari in both Bergy and Chakabarty, but the Bergy case was later withdrawn, probably because Chakrabarty presented a stronger case for patentable subject matter. *See* Maggs, *New Life for Patents: Chakrabarty and Rohm & Haas Co.*, 3 SUP. CT. REV. 57, 59 n.9, 70-71 (1981).

patented, but failed expressly to address the matter of higher life forms. The PTO initially responded by adopting a policy against granting patents on multicellular animals, on grounds that explicit judicial permission was needed before the agency could issue such patents.[18] Two or three claims were reportedly rejected based on this policy.[19]

C. Patenting Higher Life Forms

In re Allen[20] provided the impetus for the new policy. The applicant in *Allen* sought a patent on a method of creating polyploid oysters,[21] and on the oysters themselves. The examiner rejected the application for two reasons: (1) the polyploid oysters were "living entities controlled by laws of nature" and thus not covered by section 101; and (2) the process of creating the oysters would have been obvious to a person of ordinary skill in the area. On appeal, the PTO Board of Appeals and Interferences (Board) reversed the first determination.[22] The Board interpreted *Chakrabarty* to require that any subject matter created by human beings could be patented. As long as the polyploid oysters failed to occur naturally, they could be patented under section 101 as new manufactures or compositions of matter. The PTO Commissioner issued his notice the following week.[23]

This policy evolution is consistent with the broad principles underlying U.S. patent law. By granting inventors a limited monopoly on the patented invention, the law creates an economic incentive for inventors and their employers to bear the financial risks entailed in developing and commercializing an invention.[24] The incentive, it is hoped, will ultimately benefit the public by stimulating advancements in knowledge and technology that would otherwise be delayed or never occur.[25] The public disclosure requirement in patent law

[18] *Hearings, supra* note 10, at 160 (statement of Reid Adler, Esq.)

[19] Bishop, *U.S. to Allow Patents for Genetically Altered Animals,* Wall St. J., April 20, 1987, sec. 1, at 6, col. 1.

[20] 33 Pat. Trademark & Copyright J. (BNA) No. 826, at 638 (April 20, 1987).

[21] The oysters possessed an extra set of chromosomes that allegedly would make them edible year-round. *See* Annas, Of Monkeys, Man, and Oysters, HASTINGS CENTER REPORT, at 20, 21 Aug./Sept. 1987.

[22] *In re* Allen, 2 U.S.P.Q.2d (BNA) 1425 (P.T.O. Bd. App. & Int. 1987). The Board affirmed the denial on grounds that the oysters failed to meet the nonobviousness requirement.

[23] The PTO has created a new category to accommodate the policy, namely: "Class 800-Multicellular Living Organisms and Unmodified Parts Thereof." *See* Jones, *Patenting of Invented Animals Okd,* L.A. Times, April 18, 1987, sec. 1, at 1, 23.

Patenting attorneys registered their support for extending patent protection to animals several years ago. In 1966, the American Bar Association's Patent, Trademark and Copyright Section approved a resolution supporting "the application of all principles of the Patent System to all the agricultural arts (including . . . animal husbandry)." *See* I. COOPER, BIOTECHNOLOGY AND THE LAW § 6.02 (1987).

[24] *See Applied Genetics, supra* note 16, at 242-43; Burch, *supra* note 6, at 1147–48.

[25] *See* Burch, *supra* note 6, at 1158; Adler, *supra* note 10, at 358.

also makes new knowledge available to other researchers in the field, whose own projects consequently may be hastened and enriched.[26]

In sum, the overriding goal of U.S. patent law is to further knowledge and its applications. The law incorporates an assumption that the public will ultimately benefit from technological innovations. On the other hand, the legal rights of the patent holder are limited to protect society from the risks posed by new technology. The patent grant does not authorize inventors to make, use, or sell their inventions. The inventor remains subject to any applicable regulatory or other legal restrictions on such activities.[27]

Opponents of the new PTO policy seek to exclude higher animal life forms from patentable subject matter on moral and policy grounds. But the patent law traditionally has not been applied as a means to inhibit technological developments that pose safety or other risks to society. *Chakrabarty* was a clear indicator of judicial unwillingness to restrict patentable subject matter based on the dangers a particular invention might pose. According to the Supreme Court, any such action belongs solely within the legislative sphere.

On only one occasion has Congress excluded a form of otherwise patentable subject matter from patent protection. In 1954, legislation was enacted to prohibit patenting of nuclear weapons technology.[28] In this context, Congress decided that the public would in no way benefit and indeed, would be seriously threatened, if the patent incentive and disclosure requirement were applied to technological innovations in this field. Congress preferred the possible knowledge loss resulting from its decision to restrict development of nuclear weapons technology to government-controlled programs over the dangers to national security patent availability would present.[29]

Arguments for excluding higher life forms from patentable subject matter are premised on doubts about the wisdom of applying the patent policy to another kind of technology. The dangers posed by an incentive to advance development of genetically-manipulated animals appear to some patenting opponents to be as significant as those posed by an incentive for developing nuclear weapons. The counterargument is that, unlike nuclear weapons, patented animals could confer substantial benefit on society and that this technology's risks can be adequately controlled through the regulatory system. In the next two Parts, I examine these positions in detail.

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[26]*See* Adler, *supra* note 10, at 358. There is a lack of empirical data to establish definitively that patenting does stimulate innnovation, however. *See* APPLIED GENETICS, *supra* note 16, at 242-43.

[27]*See Hearings, supra* note 10 at 14-15, 162 (statements of Rene Tegtmeyer, Assistant Commissioner for Patents, U.S. Patents and Trademarks Office, and Reid Adler, Esq.). As a result, it is possible to obtain a patent on an invention that cannot be sold. *See* DRAFT REPORT, *supra* note 1, at 62.

[28]42 U.S.C. § 2181(a) (1982).

[29]*See Hearings, supra* note 10, at 439–40 (statement of Geoffrey M. Karny, Esq.); Burch, *supra* note 6, at 1164–65.

II. THE POSITIVE VIEW: THE TECHNOLOGY AND ITS ANTICIPATED BENEFITS

A. Creating Genetically-Altered Animals

Advances in biotechnology have triggered an unprecedented partnership of biology and business, which is exemplified in the current commercial interest in genetically-engineered higher animals. The push for animal patenting is primarily attributable to two developments: scientific discoveries enabling researchers to create "transgenic"[30] and other genetically-altered higher animals, and potential commercial applications for such animals in agriculture, biomedical research, and the pharmaceutical industry.

Several techniques are now available to create transgenic animals.[31] Microinjection is the technique now appearing to hold the greatest commercial promise. In microinjection, a gene is first extracted from one organism using special bacterial enzymes capable of slicing a DNA molecule at the appropriate place.[32] Under a special microscope, purified copies of the gene are then microinjected through a glass tube into a fertilized single-cell egg of another species.[33] The egg is then surgically implanted into a female of the same species, who gestates and bears the resultant transgenic animal.[34] Because the foreign gene is added when the egg is at the single-cell stage, all the cells in the animal that develops contain the foreign gene. This includes the sperm or egg cells, so that the foreign gene may also be passed on to the transgenic animal's offspring.[35]

Human genes are used more often than those of other species to create

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[30]Transgenic animals have integrated DNA from their parents and another source, which is usually a different species. *See* Biological Applications Program, OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, TRANSGENIC ANIMALS 1 (Feb. 1988) (staff paper, copy on file with this author) [hereinafter cited as TRANSGENIC ANIMALS]. DNA (deoxyribonucleic acid) molecules contain the genetic information in an organism and determine the structure and function of the organism. OFFICE OF TECHNOLOGY ASSESSMENT, OWNERSHIP OF HUMAN TISSUES AND CELLS 157 (1987) [hereinafter cited as TISSUE AND CELL OWNERSHIP]. Genes are the specific sequences of DNA components that instruct cells to perform particular functions. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SPLICING LIFE: THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS 29 (1982) [hereinafter cited as SPLICING LIFE].

[31]*See* TRANSGENIC ANIMALS, *supra* note 30, at 1-2.

[32]*Id.* at 3. Identifying and characterizing the genes controlling the animal characteristic of interest is a complex process. *See* DRAFT REPORT, *supra* note 1, at 43.

[33]TRANSGENIC ANIMALS, *supra* note 30 at 3-4.

Besides the gene itself, researchers insert other DNA sequences that control the specific place, time, and level at which a trait will be expressed. These "genetic cassettes" are responsible for the full effect of the foreign gene. *See Hearings, supra* note 10, at 43-44 (statement of Thomas Wagner, Ohio University).

[34]*See* TRANSGENIC ANIMALS, *supra* note 30 at 4. At this point, microinjection is "tedious, labor intensive, and inefficient." *Id.* Only one or two transgenic mice are successfully produced for every one hundred fertilized mouse eggs that begin the process. *Id.* In one project using another species, only forty-three transgenic pigs were produced from over eight thousand fertilized eggs, and the success rates are even lower in cattle. *See* Schneider, *Science Debates Using Tools to Redesign Life*, N.Y. Times, June 8, 1987, sec. 1, at 1, col. 2; Bishop, *supra* note 19.

[35]*See Hearings, supra* note 10, at 43 (statement of Thomas Wagner, Ohio University).

transgenic animals. Human genes are simply the easiest to obtain, because of an independent research effort to isolate and express human genes for therapeutic and other purposes.[36] It is possible to use human genes to create transgenic animals because all mammals share a similar genetic structure and organization.[37]

For the near future, scientists expect that research on transgenic animals will involve transferring a single foreign gene or a small number of such genes into the host species.[38] Trait alteration thus will be limited in the next several years. The ability to manipulate complex traits, such as behavioral characteristics, could emerge as soon as ten years from now, however.[39] Still, only a limited amount of foreign DNA can be added to a chromosome before it becomes unstable, and at this point, the host animal's genes cannot be removed and replaced with foreign ones. As a result, most scientists now insist that transgenic animals could never be drastically different from their original species.[40]

Scientists using a second technique involving embryo fusion have created sheep-goat chimeras, christened "geeps."[41] Until this development, chimeras of two related mouse species were the sole viable mammal chimeras that had been successfully produced.[42] In contrast, sheep and goats are from distantly related species; normal sheep have 54 chromosomes and normal goats have 60.[43]

Scientists created the geeps, which contain cells of both species, using two techniques. In one, they combined individual cells from four-cell goat embryos with cells from four-cell or eight-cell sheep embryos, and enclosed the combined cells in the normal membrane that surrounds the embryo in its early stages.[44] The second approach involved wrapping cells from one species of eight-cell embryo around an eight-cell embryo of the other species.[45] The embryos created using these techniques were then implanted into sheep or goat "surrogate mothers."[46] Because the sheep-goat embryo contained cells from the mother's species, the embryo was not aborted as foreign tissue.[47]

Unlike the transgenic animals created through microinjection, chimeras created through embryo fusion will not bear genetically-identical offspring. Instead, such chimeras will produce offspring belonging to one of the chimera's

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[36]TRANSGENIC ANIMALS, *supra* note 30, at 6.

[37]*Id.* at 6–7.

[38]*Id. See also Hearings, supra* note 10, at 44 (statement of Thomas Wagner).

[39]TRANSGENIC ANIMALS, *supra* note 30, at 6.

[40]*See Hearings, supra* note 10, at 44 (statement of Thomas Wagner, Ohio University); Schneider, *supra* note 34.

[41]*See* Schneider, *Where There Can Be a Patent on Life*, N.Y. Times, Oct. 30, 1987, sec. 1, at 1, col. 3.

[42]Dixon, *Engineering Chimeras for Noah's Ark*, 10 HASTINGS CENTER REPORT, April 1984, at 10.

[43]*Id.* at 12.

[44]*Id.* at 10.

[45]*Id.*

[46]*Id.* at 11.

[47]*See* Schneider, *supra* note 41.

component natural species.[48] Although the current emphasis is on transgenic animals as potential patentable inventions, the scientific ability to create chimeras has also drawn significant attention in the patenting debate. This is because the commercial applications of embryo fusion might include human-chimpanzee hybrids that could perform simple tasks for human beings.[49]

B. Commercial Value of Transgenic Animals

In a less speculative vein, transgenic animals are presently expected to have commercial value in three primary areas: agriculture, biomedical research, and the pharmaceutical industry. In agriculture, the new techniques are viewed as a speedier and more precise means of achieving the benefits of classical animal breeding.[50] Researchers hope to create transgenic animals that are more healthy and efficient food producers than existing breeds. The need for such improvements will become more and more compelling as the expected demand for worldwide food production materializes over the coming decades.[51] Scientists have already made transgenic chickens resistant to one serious poultry virus by using a transferred gene to block the virus receptor sites, and gene transfer will be used in attempts to introduce disease resistance in other food species as well.[52] If these efforts succeed, livestock and poultry farmers could revise their current practice of giving animals antibiotics and hormones that may have negative health effects on human consumers.[53]

Researchers also anticipate creating food animals with faster growth rates,[54] reduced nutritional needs, and better-quality products. Transgenic pigs given an extra human growth hormone gene have a significantly reduced fat

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[48] *Id.* This is because the animal's individual cells belong entirely to one of its component species. It is also possible to create transgenic chimeras, however. *See* DRAFT REPORT, *supra* note 1, at 51–52.

[49] *See infra* notes 106–22 and accompanying text.

Cloning technology has also been discussed in connection with animal patenting, but this will primarily involve patents on the process, instead of on the resultant animals themselves. *See* Schneider, *Better Farm Animals Duplicated by Cloning*, N.Y. Times, Feb. 17, 1988, sec. 1, at 1, col. 3; Schneider, *New Animal Forms Will Be Patented*, N.Y. Times, April 17, 1987, sec. 1, at 1.

[50] *See* TRANSGENIC ANIMALS, *supra* note 30, at 4–6.

[51] *See Hearings supra* note 10, at 222, 468 (statements of Winston Brill, Agracetus; and Alan Smith, Integrated Genetics)

[52] *See Hearings, supra* note 10, at 46 (statement of Thomas Wagner, Ohio University); FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 6.

[53] *See Hearings, supra* note 10, at 223 (statement of Winston Brill, Agracetus).

[54] This capability was first demonstrated in 1982, when scientists described creating "supermice." These transgenic mice grew to nearly twice the normal size after the structural gene for rat growth hormone was microinjected into fertilized mouse eggs. Palmiter, Brinster, Hammer, Trumbauer, Rosenfeld, Birnberg & Evans, *Dramatic Growth of Mice That Develop from Eggs Microinjected with Metallothionein-Growth Hormore Fusion Genes* 300 NATURE 611 (1982). Similar results were obtained the following year in mice given human growth hormore genes. Palmiter, Norstedt, Gelinas, Hammer & Brinster, *Metallothionein-Human GH Fusion Genes Stimulate Growth of Mice* 222 SCIENCE 809 (1983).

content.[55] They also require much less food per unit of weight gain than normal swine, and thus could be brought to market in less time than is now required.[56] Other prospects include cows that produce more milk than normal, pigs that bear twice the usual number of piglets, and fish that grow bigger than the natural varieties.[57] One researcher foresees the development of cattle weighing more than 10,000 pounds and pigs twelve feet long and five feet high, but such ambitious predictions are rare at this point.[58]

Scientists also anticipate that transgenic animals will make several important contributions to biomedical research. It will be possible to learn a great deal about how mammalian genes and cells function by studying transgenic laboratory animals.[59] In addition, animal models are currently a fundamental tool for studying human disease and its treatment. Animal models for many human genetic conditions, infectious diseases, and cancers are currently unavailable, however, because nonhuman species are not naturally afflicted with these conditions.[60] New and highly specific animal models could be created by introducing into a laboratory animal the gene for a human genetic condition.[61]

Scientists also hope to make transgenic animals susceptible to other human illnesses.[62] HIV infection is one example. Chimpanzees are the only nonhuman species naturally susceptible to the virus, and the available supply of chimpanzees for research is extremely limited.[63] Scientists at the National Institutes of Health (NIH) recently created transgenic mice that have the AIDS virus in each of their cells and pass this trait on to their offspring.[64] From this project, scientists hope to learn more about the physiological effect of the virus and potential methods of impeding its activity.[65]

Researchers are also optimistic about the potential contributions "molecu-

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[55] *See* FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 6.

[56] *See Hearings, supra* note 10, at 45 (statement of Thomas Wagner, Ohio University).

[57] *Id.* at 264 (statement of Richard Godown, Industrial Biotechnology Association); Schneider, *U.S. Farmers to Face Patent Fees for Gene Transformed Animals*, N.Y. Times, Feb. 6, 1988, at 1, col. 3; Wallis, *Should Animals Be Patented?*, TIME, May 4, 1987, at 110.

[58] *Foes of Animal Patents Predict Genetic Horrors*, Houston Post, April 21, 1987, sec. 1, at 1, col. 3.

[59] *See Hearings, supra* note 10, at 382-83 (statement of LeRoy Walters, Kennedy Institute of Ethics).

[60] *Id.* at 383–84. The first animal patent issued was for a transgenic mouse with an added cancer gene, which scientists hope will be a better animal model for studying cancer in humans. *See* Schneider, *supra* note 1.

[61] *Id. See also Hearings, supra* note 10, at 47–48 (statement of Thomas Wagner, Ohio University).

Scientists recently announced that they had produced an inherited human bone disease in transgenic mice given the defective gene. *Humanlike Defect Is Created in Mice by Using Faulty Gene*, N.Y. Times, March 18, 1988, at 8, col. 5.

[62] *Hearings, supra* note 10, at 48 (statement of Thomas Wagner, Ohio University).

[63] Altman, *Tests on Humans Near in AIDS Vaccine Hunt*, N.Y. Times, March 18, 1987, sec. 1, at 1, col. 1.

[64] Leary, *Why No Mouse Should Ever Escape AIDS Experiment*, N.Y. Times, Feb. 2, 1988, sec. 1, at 17, col. 1.

[65] *Id.* Even though the mice are kept in a highly secure facility, Jeremy Rifkin and the Foundation on Economic Trends, which he directs, have filed a lawsuit seeking to halt the research on

lar farming'' could make to the pharmaceutical industry. In this process, foreign genes for certain valuable proteins are inserted into fertilized eggs of the host species, with the aim of obtaining the protein from the resultant transgenic animal's milk.[66] In November, 1987, a team composed of NIH and private sector scientists reported developing transgenic mice whose milk contained biologically active human tissue plasminogen activator (t-PA).[67] This substance dissolves blood clots and is now used to treat heart attack victims. In China, scientists have created silkworms that produce hepatitis vaccine.[68] Other proteins valuable as drugs, veterinary biologics, and industrial enzymes are candidates for molecular farming. Some of these substances can now be produced using bacteria, but molecular farming may prove a less costly method of production.[69] Other substances are too complex to produce in mass quantities using bacteria, and molecular farming could be especially beneficial in this area.[70]

In sum, animal patenting advocates foresee significant public benefits from this form of biotechnology. According to pro-patenting representatives, the availability of patent protection will promote important biomedical and agricultural research and speed the delivery of new products to the public.[71] Indeed, industrialists claim that ''tens of billions of dollars, hundreds of thousands of jobs, and the nations's ability to compete in global agricultural markets is at stake.''[72] Moreover, they say, a two-year moratorium on issuing animal patents would seriously compromise the country's competitive position.[73] For this group, animal patenting will increase this nation's wealth and capital, preserve its research preeminence, and enhance its ability to fight human disease and hunger worldwide. In their eyes, these anticipated benefits constitute compelling justification for the new patent policy.

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grounds that it endangers the public. *See Suit Seeks to Halt Research As AIDS and Cancer Threat,* N.Y. Times, Dec. 17, 1987, sec. 1, at 15, col. 1.

[66]*See Hearings, supra* note 10, at 469 (statement of Alan Smith, Integrated Genetics).

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

[68]*See* Holzman, *Biotechnology's New Strain of Strife,* INSIGHT, Aug. 31, 1987, at 56.

[69]*See Hearings, supra* note 10, at 469 (statement of Alan Smith, Integrated Genetics).

[70]*See* Pollack, *Transforming Animals into Drug Makers,* N.Y. Times, Sept. 2, 1987, at D6, col. 5. One as yet unresolved question is whether molecular farming can yield products pure enough to meet regulatory standards. *See* Holzman, *supra* note 68, at 58.

Scottish scientists are now seeking to develop transgenic sheep that produce human proteins in their milk, with the goal of obtaining proteins valuable in treating hemophilia and emphysema. *See* Pollack, *supra.*

[71]*See* Woodruff, *Patenting of Microorganisms,* in PATENTABILITY OF MICROORGANISMS: ISSUES AND QUESTIONS 7, 11 (R.F. Acker & M. Schaechter eds. 1981) [hereinafter cited as PATENTABILITY OF MICROORGANISMS]; *Hearings, supra* note 10, at 157–58 (statement of Reid Adler, Esq.).

[72]Schneider, *Patenting Life,* N.Y. Times, April 18, 1987, sec. 1, at 6, col. 1.

[73]*See Hearings, supra* note 10, at 148–49, 265 (statements of William Duffey, Esq., and Richard Godown, Industrial Biotechnology Association). *See generally* Dibner, *Biotechnology in Europe,* 232 SCIENCE 1367 (1986). More than $3 billion was reportedly invested in biotechnology in this country in 1987, and at least four hundred companies are seeking to develop biotechnology products. *See* Schneider, *supra* note 34.

III. THE NEGATIVE VIEW: THE THREATS POSED BY ANIMAL PATENTING

A. Arguments against Animal Patenting

Opposition to the PTO's animal patenting announcement was swift and strong. There were immediate calls for the agency to rescind its policy or, alternatively, for Congress to delay or forbid animal patenting.[74] Since April, 1987, a vocal "coalition of strange bedfellows"[75] has united to express concerns in five major areas: (1) interference with the natural world; (2) devaluation of human life; (3) survival of the family farm; (4) commercialization of academic research; and (5) agriculture and laboratory animal suffering. In this part, I examine these concerns and how patenting advocates have responded in each area.

The anti-patenting arguments often conflate two distinctive positions. One is opposition to any genetic tampering with higher animal life forms; the other is opposition to applying the patent system to such technological developments. Many of the concerns about animal patenting address genetic engineering in general, not simply the patentability of genetically-engineered animals. Patenting opponents also frequently mix two types of ethical arguments against animal patenting. Part of the hostile commentary stems from the deontological argument that animal patenting is inherently wrong, because it threatens such crucial moral values as respect for God, species integrity, or the value of human life. In contrast, other anti-patenting arguments represent an instrumental view of morality. These arguments emphasize environmental, economic, and other harmful consequences animal patenting might have for society. Each of these four themes is evident in the discussion below.

B. Interference with the Natural World

Anti-patenting representatives have serious misgivings about the competence of human beings to control what has always been reliant on natural forces. The realization that researchers have achieved such a high level of knowledge about complex biological life underlies some of this concern. The recent developments in genetic engineering seem to reduce human and nonhuman life to simple molecules, diminishing the significance and mystery with

[74]A few days after the policy was issued, thirteen groups delivered a petition to the PTO requesting the policy's rescission, and in May, Senator Mark Hatfield asked the PTO to delay issuing any patents until Congress could consider the matter. The PTO agreed only to a delay until Sept. 30, 1987, and patent law experts have asserted that the PTO lacks the legal authority to refuse to issue patents. *See* Schneider, *Clash Looming on Patenting of Animals*, N.Y. Times, July 22, 1987, sec. 1, at 10, col. 1; Schneider, *supra* note 72.

[75]Holzman, *supra* note 68, at 56.

which we customarily regard ourselves and our world.[76] Patenting thus appears as the final step toward objectifying living things; now they will be "inventions," just like VCRs and computers.[77]

Religious beliefs are also shaken by the development of new animal life forms. By creating genetically-engineered animals, we are not only "playing God," we are "assuming dominion over God."[78] Several major theologians have signed a statement issued by the National Council of Churches conveying their fear that the patenting policy could erode "reverence for all life created by God."[79] On this view, the arrival of animal patenting shows that we are now driven by a completely human-centered view of life in which all resources exist for human exploitation. For this group, the new patenting policy exemplifies how the quest for profit has become the guiding force in our society, to the detriment of other important religious and cultural values.[80]

Jeremy Rifkin, a leader in the fight against animal patenting, has coined the phrase "species integrity" to convey his apprehension about creating and patenting genetically-engineered life forms. He claims that every member of a species has a "right to exist as a separate, identifiable creature."[81] According to Rifkin and his supporters, producing transgenic animals and chimeras is inherently wrong and will yield harmful consequences.[82] Rifkin and others express numerous fears regarding the potential disastrous results of meddling

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[76]*See* SPLICING LIFE, *supra* note 30, at 53-54; Fox, *Genetic Engineering and the Patenting of Life*, ANIMALS' AGENDA, Oct. 1987 at 45.

[77]*See* Wallis, *supra* note 57. *See also Hearings, supra* note 10, at 108, 486-87 (statement of Rep. Charles Rose and Jeremy Rifkin, Foundation on Economic Trends).

[78]Schneider, *supra* note 49.

[79]*See Hearings, supra* note 10, at 401 (appendix to statement of Rev. Wesley Granberg-Michaelson, National Council of Churches). In 1982, the World Council of Churches issued a report in which the *Chakrabarty* decision was criticized as seeking "to remove any distinction between living and nonliving matter," which "allows a shift in accepted ideas as to what may be done to living things." WORLD COUNCIL OF CHURCHES, MANIPULATING LIFE: ETHICAL ISSUES IN GENETIC ENGINEERING 19 (1982).

[80]*See Hearings, supra* note 10, at 397 (statement of Rev. Wesley Granberg-Michaelson, National Council of Churches); Cavalieri, *Patenting the Worm at Our Civilization's Heart*, N.Y. Times (letter, copy on file with this author).

[81]Rifkin, Letter to William Gartland, 49 Fed. Reg. 37,016 (Sept. 20, 1984).

As in other controversies over genetic engineering, Jeremy Rifkin is a central figure in the opposition to animal patenting. In this general role, he has often engendered hostility in members of the scientific community. One scientist has characterized Rifkin as a modern-day Lysenko, who could be as dangerous to U.S. science and agriculture as the Russian was to his nation. *See* Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315, 320-34 (1985). As similarities in the two men, she cites their mutual ambition and confidence, manipulation of the media to influence the public, substitution of simple ideology for complex reality, and assistance by politically powerful, scientifically ignorant accomplices. *Id.* at 323, 333-54.

[82]It is difficult to ascertain the exact rationale underlying Rifkin's objection. In response to one interviewer's question on what is wrong with violating an animal's species integrity, Rifkin replied as follows:

> Let me demonstrate by way of analogy. If some civilization were to descend onto this planet with superior genetic engineering technology and the ability to colonize the human race, and they were to inject an alien growth hormore gene into our genetic code so that all our children would grow to sexual maturity at six years of age

with the environment. Nature herself is being manipulated, they say, and history is replete with examples that we humans lack the wisdom and foresight to control our environment without damaging consequences.[83] For example, releasing the gypsy moth and kudzu vine were human errors with extremely damaging environmental effects.[84]

Another commonly raised concern is the potential loss of genetic diversity that animal patenting could produce.[85] Already, genetic stocks of agricultural animals are relatively small in number, and the worry is that patenting will exacerbate this modern trend, making our food supply even more vulnerable to lethal viruses or other potential disruptions.[86] Some wildlife preservation groups are also afraid that new forms of wild animals could drive native species to extinction.[87]

There is also strong doubt about whether we can assess adequately the magnitude and probability of the true environmental risks entailed in pursuing the animal patenting policy.[88] This has produced some dire predictions, such as the following by Michael Fox, of the Humane Society of the United States: "if the wholesale, industrialized exploitation of the animal kingdom is sanctioned, protected, and intensified, it could signify no less than the end of the natural world."[89]

> and grow twice as tall from here until eternity, what would our response to that be as a species? We would obviously think that it was a violation of our species integrity. We would say that this alien civilization had no right to engineer the genetic code of the human race and undermine our integrity as a species.

Why Jeremy Rifkin Is Saying "No" to the Age of Progress, ANIMALS' AGENDA, March, 1987, at 4, 5.

[83] *See, e.g., Hearings, supra* note 10 at 63, 108 (statement of John Hoyt, Humane Society of the United States and Rep. Charles Rose). *See also* National Council of Churches, Policy Statement, Genetic Science for Human Benefit 5 (1986) (copy on file with this author).

[84] *See Hearings, supra* note 10, at 399 (statement of Rev. Wesley Granberg-Michaelson, National Council of Churches).

[85] *See Hearings, supra* note 10 at 63, 114 (statements of John Hoyt, Humane Society of the United States and Cy Carpenter, National Farmers Union). Plant patenting has been blamed for the recent loss of genetic diversity in agricultural plants. King, *Arguments Against Patenting Modified Life Forms*, in PATENTABILITY OF MICROORGANISMS, *supra* note 71 at 36, 39.

[86] Six corn strains dominate U.S. agriculture, and a 1970 infection destroyed 15 percent of the corn crop. *Id.*

[87] *See Hearings, supra* note 10, at 426 (statement of Margaret Mellon, National Wildlife Federation).

[88] *See, e.g.*, Gore & Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 342 (1985). *See also Hearings, supra* note 10, at 339 (statement of Debra Schwarze, Wisconsin Family Farm Defense Fund).

An editorial in *The Economist* portrayed this concern in a humorous vein:

> August 15, 2087 was a black day for the world. That afternoon a tree fell on the fence surrounding a private genetic-engineering institute run by an eccentric trillionaire in Manaus, Brazil. Through a hole in the fence there escaped into the nearby forest six peculiar creatures. They had the bodies of snakes, the metabolism of ferns and the brains of men. It took them less than 30 years to exterminate their human creators.

Tomorrow's Animals, ECONOMIST, Aug. 15, 1987, at 11.

[89] *The Animal-Patenting Decision: Should People Own New Forms of Life?* HUMANE SOCIETY NEWS, Summer, 1987, at 6.

Animal patenting supporters have responded to each of the anti-patenting claims. First, they note that humans have "objectified" animal life for thousands of years by treating animals as property, to be bought, sold, and used to satisfy a variety of human desires.[90] They also counter the notion that human understanding and manipulation of animal genes constitutes unique, unprecedented interference with a natural or God-given plan by pointing out that countless human activities produce changes in the natural world that otherwise would never occur.[91] In addition, the profit motive for animal patenting "can be condemned only by those who categorically reject capitalism."[92] Moreover, the pro-patenting view is that no adequate religious or cultural principle has been offered to account for why animal patenting is inherently wrong; indeed, one could cite religious doctrine to support the position that humans have a "duty to employ their God-given powers to harness nature for human benefit."[93] For this group, the genuine moral and religious issues involve exercising appropriate responsibility in applying our new scientific capabilities, rather than prohibiting all such applications as intrinsically evil.[94]

The threat animal patenting poses to "species integrity" is similarly dismissed as without real substance. Scientists point out that the existing species classification system fails to reflect any objective "truth" about the biological world, rather it is simply a paradigm they have developed to help them understand the natural world.[95] The evolutionary theory underlying this classification scheme fails to incorporate any specific plan or to label any particular evolutionary change as "good" or "bad."[96] Furthermore, a close look at nature reveals that "there is no consistent or absolute rule that species are discretely bounded in any generally applicable manner."[97] Biologists note that there are numerous examples of naturally-occurring interbreeding, and in some instances genetic material commonly moves between species.[98] Patenting supporters also express doubt that scientists will ever be able to make massive enough alterations drastically to transform an animal's essential

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[90] *E.g., Yes, Patent Life,* N.Y. Times, April 21, 1987, at 26, col. 1 (editorial). *See also* Nelson, *Is It Right for Humans to Patent New Life?,* Newsday, May 14, 1987, at 97. *But see* Krimsky, *Patenting of Microorganisms and Higher Life Forms: Social and Ethical Concerns,* in PATENTABILITY OF MICROORGANISMS, *supra* note 71, at 17, 20 (arguing that ownership of animal should be distinguished from patent covering its offspring).

[91] *See, e.g.,* SPLICING LIFE, *supra* note 30, at 55.

[92] *See* National Council of Churches, *supra* note 83, at 6. *See also* Nelson, *supra* note 90 ("as long as there has been a semblance of free enterprise, people have been selling animals").

[93] SPLICING LIFE, *supra* note 30, at 56. *See also* APPLIED GENETICS, *supra* note 16, at 258-59.

[94] *Id.* at 53. *See also* PATENTING LIFE, *supra* note 3, at 7-8.

[95] *See* TRANSGENIC ANIMALS, *supra* note 30, at 7-10. The term "species" is usually defined as a group of organisms that breeds among itself and not among any other group of organisms. *See* OFFICE OF TECHNOLOGY ASSESSMENT, HUMAN GENE THERAPY—A BACKGROUND PAPER 52 (1984) [hereinafter cited as HUMAN GENE THERAPY].

[96] SPLICING LIFE, *supra* note 30, at 62-63.

[97] TRANSGENIC ANIMALS, *supra* note 30, at 8-9.

[98] *Id.* at 8; HUMAN GENE THERAPY, *supra* note 95, at 52.

structure or function.[99] Finally, patenting advocates cite a host of examples of human-initiated genetic alterations in animals achieved through traditional breeding practices. For centuries, farmers, pet-owners, and others have been genetically manipulating animals for human benefit, and the pro-patenting group contends that this activity has produced enormous gains at little cost to society.[100]

In addition, patenting supporters believe that the predictions of dire environmental consequences are unwarranted. As long as they are properly confined, new animal species will not threaten other organisms.[101] Such animals could transfer their genes to others solely by mating, which scientists note should be relatively easy to monitor and control.[102] According to patenting supporters, qualms about a potential loss of genetic diversity due to animal patenting are also misguided, for a serious situation already exists and must be dealt with independently of the patenting question.[103] Indeed, the patenting system might even help to preserve biological diversity through its enablement requirement.[104] If unforeseen environmental problems associated with patenting emerge, patenting advocates argue that they can be addressed without prohibiting patenting, through the regulatory system and other government programs.

In sum, most of the anti-patenting objections concerning interference with the environment bear on the issue of whether higher animals should ever be altered through recombinant DNA technology. Supporters of patenting claim that this is a broad national policy issue properly resolved through government regulatory channels, not through the narrow forum of patent law. Even if a decision is made to proceed very deliberately in this area, prohibiting animal patenting is neither the most direct nor the appropriate governmental means to implement such a policy. Instead, as in all areas of technological interventions, the emphasis ought to be on constructing a regulatory system that provides for adequate risk assessment and prevention as new forms of animal life are developed.[105]

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[99] TRANSGENIC ANIMALS, *supra* note 30, at 9-10. *See also Hearings, supra* note 10, at 44 (statement of Thomas Wagner, Ohio University).

[100] *See* Wallis, *supra* note 57.

[101] *See Hearings, supra* note 10, at 49 (statement of Thomas Wagner, Ohio University). *See also Tomorrow's Animals, supra* note 88, at 11-12 (easier to confine genetically-engineered animals than microorganisms).

[102] *See Hearings, supra* note 10, at 49 (statement of Thomas Wagner, Ohio University).

[103] *See Hearings, supra* note 10, at 212-13 (statement of Leo Walsh, Dean, University of Wisconsin College of Agricultural and Life Sciences) (citing as example current narrow genetic base for turkeys). *See generally* Christensen, *Genetic Ark: A Proposal to Preserve Genetic Diversity for Future Generations*, 40 STAN. L. REV. 279 (1987).

[104] *See Hearings, supra* note 10, at 169-71 (statement of Reid Adler, Esq.).

[105] *See Hearings, supra* note 10, at 143, 182, 265-74 (statements of William H. Duffey, Intellectual Property Owners, Robert Merges, Esq., and Richard Godown, Industrial Biotechnology Association).

C. Devaluation of Human Life

The second general problem patenting opponents raise involves the possibility of creating human-animal hybrids. According to the patenting policy:

> 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. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection.[106]

These statements fail to clearly exclude from the policy animal-human hybrids, as long as such creatures are defined as "non-human." Many patenting critics are alarmed by the notion that such creatures could be invented, treated as property, and used for human benefit. In their eyes, the patent policy not only objectifies nonhuman life, but implies that partially-human creatures could become commodities as well.

At this time, the quantity of human genes transferred into nonhuman species is so minimal that there should be little concern about conferring "humanity" on nonhumans.[107] But the future may be different. As one biochemist has written, "There is no scientific basis for the comforting suggestion that it will never be possible to develop procedures for transferring large blocks of genes, such as those controlling intelligence, to other species."[108] Moreover, given that scientists have already created hybrids of sheep and goats, can the possibility of creating hybrids of two closely-related species, such as chimpanzees and humans, really be dismissed as "impossibly remote"?[109]

This scenario disturbs commentators for several reasons. First, it seems to endanger the special value society gives to human life by "reduc[ing] people to a set of malleable molecules that can be interchanged with those of species that people regard as inferior."[110] Besides casting doubt on our basic assumptions

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[106]*See Nonnaturally Occurring Non-Human Animals Are Patentable Under sec. 101, supra* note 1.

[107]*See* World Council of Churches, *supra* note 79, at 28-29 (few human chromosomes and proteins inserted into nonhuman species fails to render animals sufficiently "human" to raise moral issues).

[108]Cavalieri, *Time to Question Genetic Engineering Is Now*, N.Y. Times, Oct. 30, 1984, sec. 1, at 26, col. 4 (letter).

Another scientist has presented the following scenario:

> Let's say that it's discovered that if you first put in a neurohormone, but then [a] gene, into a chimpanzee that that chimpanzee has an enormously expanded memory. Let's postulate that it's given to 25 chimpanzees and baboons as well. Further, in every case there are no harmful effects and their memory capacity and their "intelligence" is greatly increased. Would you want that gene?

Comment by W.F. Anderson, Workshop Proceedings, *Biotechnology and Agriculture: Animal and Plant Genetics*, sponsored by Institute for Theological Encounter with Science and Technology, Adamstown, Maryland (April 10-12, 1987).

[109]*See* Dixon, *supra* note 42, at 12.

[110]SPLICING LIFE, *supra* note 30, at 54. *See also* World Council of Churches, *supra* note 79, at 29-30 (essence of humanity not simply anatomical, but also spiritual).

about the unique character of the human species, the concept of human-animal hybrids seems to some observers to violate the cultural taboo against procreation between animals and humans.[111] In short, it is feared that respect for human dignity is bound to deteriorate once human-animal hybrids emerge on the scene.[112]

Additional concern centers on the moral and legal status we would confer on such hybrids. Religious and other commentators have raised several disturbing questions in this area. Should human-animal hybrids be given at least some of the rights and privileges accorded humans in our society, or should they occupy the lesser position of nonhuman animals?[113] What characteristics and capacities would be the basis of such determinations? Would it be fair or just to create a part-human "service species" designed for our exploitation?[114] Would creating such creatures constitute the practice of eugenics or, as one critic has warned, "human husbandry"?[115]

These questions are troubling in part because they force us to define what it means to "be human."[116] Answering them could challenge the validity of the current cultural assumption that human beings are absolutely superior to other species. In a similar vein, the questions compel us to examine what would be morally wrong about bestowing some human characteristics on nonhumans. Is it because the hybrid would be wrongly deprived of the opportunity to be fully human, or does the wrong lie in conferring a uniquely human capacity on a nonhuman species?[117] Finally, the questions are unsettling because, despite the PTO policy's exclusion of humans from patenting, they trigger apprehension about the "slippery slope." If we allow such manipulations on partial humans, will this ease the way to eugenic interventions on full humans, or commercialization of human embryos and fetuses?[118] Patenting critics see too many precedents in which science and technology overstepped the boundaries necessary to protect essential human values and they fear this area will be no exception.[119]

Animal patenting advocates discount the anxiety over human-animal hybrids on three grounds. First, they claim that scientists will be unable to create

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[111] *See* SPLICING LIFE, *supra* note 30, at 57.

[112] *See* PATENTING LIFE, *supra* note 3, at 7 (some believe intermingling animal and human genes raises unique issues about dignity and sanctity of human life).

[113] *See Conferring Humanity on Other Species*, N.Y. Times, Oct. 5, 1984, sec. 1, at 3, col. 1 (editorial).

[114] *See* E.J. SYLVESTER & L.C. KLOTZ, THE GENE AGE: GENETIC ENGINEERING AND THE NEXT INDUSTRIAL REVOLUTION 116 (1983).

[115] *See* Boffey, *Concern Over Genetics Prompts a New Coalition of Critics*, N.Y. Times, June 9, 1987, sec. 1, at 17, col. 1.

[116] *See* Schneider, *supra* note 34.

[117] *See* SPLICING LIFE, *supra* note 30, at 59. *See also* World Council of Churches, *supra* note 79, at 30 (intentionally creating individual with partial human attributes is "totally undesirable and the wrong use of our creative powers").

[118] *See* Annas, *supra* note 21, at 22; Boffey, *supra* note 115; National Council of Churches, *supra* note 83, at 5.

[119] *See* APPLIED GENETICS, *supra* note 16, at 250; Boffey, *supra* note 115.

such creatures in the foreseeable future.[120] As a result, they say, we have plenty of time to consider the moral issues in advance. Second, they contend that the possibility of eugenic breeding of human beings will be no more real with recombinant DNA techniques than it is with the traditional breeding techniques that have been available for years.[121] Third, they argue that the genuine ethical concerns in this area are not about the availability of patenting, but instead address the matter of whether human-animal hybrids should be created at all, and if so, how society should treat them.[122] These issues will arise whether or not patenting is available. Again, the opposition to animal patenting is misplaced, for the real questions involve the appropriate regulatory actions to take to avoid unacceptable intrusions on respect for life and other important human values.

D. Survival of the Family Farm

The third major target of the anti-patenting efforts is the policy's projected economic effect, particularly on U.S. agriculture. Some say patenting threatens the very survival of the family farm.[123] Many farmers are deeply disturbed at the idea of paying licensing fees and royalties to the biotechnology companies that obtain patents on genetically-engineered animals.[124] They fear that higher costs and increased productivity will force more family farmers out of business, depriving them of their livelihood and destroying the cultural and community values traditionally so important in American agriculture.[125]

Farmers are also worried that patenting will allow a relatively small number of large corporations to gain control of the market for genetically-engineered animals.[126] The current trend toward large firms controlling the livestock business will be exacerbated, they charge, with negative effects on both farmers and consumers.[127] According to Representative Charles Rose,

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[120]*See, e.g.*, SPLICING LIFE, *supra* note 30, at 59–60; Davis, *How Real Are the Dangers of Recombinant DNA Technology?*, in PATENTABILITY OF MICROORGANISMS, *supra* note 71, at 12, 15.

[121]Davis, *supra* note 120, at 15.

[122]*See* Godown, *Give Genetic Inventions Patents*, N.Y. Times, Aug. 8, 1987, sec. 1, at 14, col. 4 (letter); Monmaney, *Should Man Make Beast?* NEWSWEEK, May 4, 1987, at 64.

[123]Farms supplying the primary income to an individual or family usually are classified in the moderate category of gross annual sales. *See* OFFICE OF TECHNOLOGY ASSESSMENT, TECHNOLOGY, PUBLIC POLICY, AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE 3, 19-23 (1985) [hereinafter cited as TECHNOLOGY AND AGRICULTURE]. Small farms typically fail to produce significant income and are operated for recreaction or by people living in poverty. *Id.* at 20.

[124]*See Hearings, supra* note 10, at 108 (statement of Rep. Charles Rose). *See infra* notes 244-50 and accompanying text on the question of whether farmers should be partially exempt from such payments.

[125]*See Hearings, supra* note 10, at 337–38, 486 (statements of Debra Schwarze, Wisconsin Family Farm Defense Fund and Jeremy Rifkin, Foundation on Economic Trends). *See also* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 25-26 (family farm associated with maintaining basic American values and family as institution).

[126]*See, e.g.*, Hearings, *supra* note 10, at 84–90 (statement of Jack Doyle, Environmental Policy Institute).

[127]*Id.*

who introduced the bill calling for a moratorium on animal patenting, the PTO policy "places major chemical, biotechnological and pharmaceutical companies in the position to virtually take over animal husbandry in America."[128] Already, fewer than twenty companies control the poultry industry and have created a system in which individual farmers raise chickens on contract for the companies.[129] To many farmers, this "tenant farming" constitutes an unacceptable loss of independence and autonomy for the individual farmer.[130]

Farmers also cite the seed industry as a disturbing precedent in this regard. Corporate acquisitions of seed companies rose dramatically after the Plant Variety Protection Act was passed in 1970.[131] Seed prices have also risen sharply since that time, and some economists attribute this to the availability of patents.[132] Patenting critics are afraid the same process will occur in the food animal industry, with farmers and consumers bearing the resultant burdens.

Farm groups are also dubious about the true need for animal patenting as a means of increasing agricultural production. Before the patenting policy was issued, over 100 livestock biotechnology companies already existed, and numerous advancements have occurred in the absence of animal patenting.[133] In addition, many believe the major problem in U.S. agriculture is overproduction, not underproduction.[134] Efforts to increase milk production in cows, for example, seem unjustifed in light of the existing surplus in the dairy industry.[135] In 1986, the federal government spent $1.8 billion on a dairy buy-out program in which it purchased dairy cows for slaughter in an effort to cut production by 8.7 percent.[136] Farm groups fear innovations such as patented animals will simply worsen the situation, at a high cost to farmers and taxpayers.

But even farmers are not completely unified in their opposition to the patenting policy. In contrast to organizations advocating on behalf of family farmers, the American Farm Bureau Federation generally favors animal patenting.[137] Its representatives predict that patenting will yield healthier and cheaper animals and create new agricultural markets in areas such as molecular farming.[138] They believe the changes will help U.S. agriculture maintain its economic strength and competitive position in world markets.[139]

Other patenting supporters claim that the move toward large corporate

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[128] *Id.* at 108 (statement of Rep. Charles Rose).

[129] TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 24.

[130] *See* Schneider, *Witnesses Clash Over Patenting New Animal Life*, N.Y. Times, June 12, 1987, sec. 1, at 12, col. 3.

[131] *See Hearings, supra* note 10, at 77-80, 115 (statements of Jack Doyle, Environmental Policy Institute; and Cy Carpenter, National Farmers Union).

[132] *Id.* at 80 (statement of Jack Doyle, Environmental Policy Institute).

[133] *Id.* at 82-84 (statement of Jack Doyle, Environmental Policy Institute).

[134] *Id.* at 115 (statement of Cy Carpenter, National Farmers Union).

[135] *See* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 3, 53-61.

[136] *See Hearings, supra* note 10, at 337 (statement of Debra Schwarze, Wisconsin Family Farm Defense Fund).

[137] *Id.* at 121 (statement of Ann Sorenson, American Farm Bureau Federation).

[138] *Id.* at 118-19.

[139] *Id.* at 118.

control over agriculture will persist whether or not patenting is available.[140] Thus, those dissatisfied with this development are again seeking change in the wrong forum. Others have asserted that patenting could actually help family farmers by reducing the food and drug costs of raising their animals or increasing the value of their commodities (such as might occur with low-calorie beef).[141] This group claims that the market will keep the fees patent holders charge below the advantage the farmer gains in productivity.[142] In this vein, they also note that economists disagree on the genuine effects of patenting on the seed industry, with some analysts attributing the current situation to factors other than patenting.[143]

Finally, patenting advocates argue that any government decision to limit corporate control over the food animal industry should be implemented through the antitrust, tax, or agricultural policy laws, not the patent law.[144] They contend that prohibiting animal patenting would be an ineffective method to limit corporate control, because corporations could still find ways of controlling access to genetically-engineered animals through trade secret protection or patents on the processes or genes used in creating the novel animals.[145] If the government wants to avoid any negative impact of animal patents on the family farm, the appropriate approach is to create mechanisms to enable all farmers to gain access to this new technological development through agricultural extension services and special subsidies.[146]

E. Commercialization of Academic Research

Patenting opponents perceive a fourth threat in the policy's incentives for increased commercialization of academic research. They point to the rapid increase in industrial support of other types of biotechnology research in academia and predict that this will be replicated if patents become available on higher life forms.[147] Three concerns predominate. One is that patenting will

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[140] *Id.* at 119. *See also* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 19-32 (describing changes in economic structure of U.S. agriculture).

[141] *See Hearings, supra* note 10, at 264 (statement of Richard Godown, Industrial Biotechnology Association).

[142] *Id.* at 3, 62-63 (statement of Nicholas Seay, Esq.).

[143] *See* Holzman, *supra* note 68, at 57. *See also* APPLIED GENETICS, *supra* note 16 at 154-60 (no conclusive evidence that plant patenting has contributed to increased concentration in plant breeding industry or loss of genetic diversity in crops).

[144] *See Hearings, supra* note 10, at 119 (statement of Ann Sorenson, American Farm Bureau Federation). *See also* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 28-31 (describing public policies that could be altered to influence structure of agriculture sector).

[145] *See infra* notes 161-165 and accompanying text.

[146] *See, e.g., Hearings, supra* note 10, at 364 (statement of Nicholas Seay, Esq.). *See also* TECHNOLOGY AND AGRICULTURE 3, 65-74 (presenting suggestions for increasing availability of new technology to small and moderate-sized farms).

[147] Industry funds now comprise between 16 and 24 percent of all funds available for biotechnology research. Blumenthal, Gluck, Louis, Stoto & Wise, *University-Industry Research Relationships in Biotechnology: Implications for the University* 232 SCIENCE 1361 (1986). A recent

create a need for secrecy among academic researchers who have traditionally exchanged their research materials and findings quite freely.[148] It is feared that scientific progress will be hindered and research benefits delayed as a result of this secrecy.[149] Another worry is that financial incentives will lead academic researchers to shift their work to commercially lucrative areas, away from the basic research[150] that has proven so crucial to the advancement of knowledge.[151] A related issue is whether commercial involvement will cause faculty researchers to neglect their institutional responsibilities, or will compromise their "objectivity" as evaluators of public policy questions.[152] Third is the concern that scientists and their corporate employers will reap substantial monetary rewards by building on knowledge that was generated through tax-supported research. It seems unfair that certain individuals will disproportionately benefit from these public investments.[153]

Animal patenting supporters counter these points with several arguments. They note that patents have been available for many years in other biotechnology areas, and potential detrimental effects on academic research have proven largely unfounded.[154] Furthermore, they contend that for U.S. science and technology to maintain its competitive position, industry research support will be a much-needed supplement to declining government funding.[155] They dis-

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survey also showed that university-industry research relationships produced more than four times as many patent applications per industry dollar invested than was produced by other company-sponsored research. Blumenthal, Gluck, Louis & Wise, *Industrial Support of University Research in Biotechnology*, 231 SCIENCE 242 (1986). Such research relationships range from infrequent consulting arrangements between companies and faculty members, to arrangements in which faculty members hold large portions of stock in biotechnology companies. *See* TISSUE AND CELL OWNERSHIP, *supra* note 30, at 61–62.

[148]*See* World Council of Churches, *supra* note 79, at 19; APPLIED GENETICS, *supra* note 16, at 248–49.

[149]*See, e.g., Hearings, supra* note 10, at 63–64 (statement of John Hoyt, Humane Society of the United States). *See also* SPLICING LIFE, *supra* note 30, at 75–78 (discussing general concerns raised by industry involvement in biotechnology).

[150]Basic research entails the pursuit of knowledge without concern for its potential practical or commercial application. *See* Korn, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191, 201–02.

[151]*See* SPLICING LIFE, *supra* note 30; Korn, *supra* note 150, at 201–03.

[152]*See* Korn, *supra* note 150, at 203-04.

[153]*See* King, *supra* note 86, at 37; World Council of Churches, *supra* note 79, at 19; Goldworth, *The Moral Limit to Private Profit in Entrepreneurial Science*, HASTINGS CENTER REPORT, JUNE 1987, at 8.

Questions have also arisen about the possible implications for agricultural research and land grant universities that enter into relationships with commercial entities or directly seek patent or other property rights in their employees' inventions. *See* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 71. Again, there is concern that access to information will be restricted and individuals will reap unfair profits from work largely subsidized by the taxpayers. *Id.*

[154]*See* Sims, *Business-Campus Ventures Grow*, N.Y. Times, Dec. 14, 1987, sec. 2, at 25, col. 3 (describing acceptable compromise agreements worked out between universities and private companies). *But see* Krimsky, *Call It Exploitation*, N.Y. Times, Oct. 27, 1987, at 22, col. 4 (letter) (university's independence and integrity threatened by ties with industry, particularly in rapidly commercialized field of genetics).

[155]*See* D. NELKIN, SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS RESEARCH? 16–18 (1984); Korn, *supra* note 150, at 192.

agree that researchers' priorities will be substantially altered by commercial sponsorship; indeed, a recent study showed that faculty members receiving industry funds tended to publish more, patent more, earn more money, and spend the same amount of time on teaching and administration as those without such funds.[156]

Patenting advocates also insist that the possibility that researchers and their industry supporters will be unfairly rewarded for work based on government-sponsored research should be evaluated in light of the likelihood that numerous public benefits would never be developed if financial rewards such as licensing fees and royalties were unavailable.[157] Before 1980, the government marketed only 4 percent of its patented inventions.[158] To address this situation, Congress acted affirmatively to promote patenting of inventions developed in federally-funded projects by passing the 1980 Patent and Trademark Act Amendments.[159] The law now enables nonprofit institutions and small businesses to obtain patents on such inventions, subject to certain conditions designed to benefit the public as well. For example, the federal funding agency retains a nonexclusive, worldwide license to use the invention, and universities must use their share of the royalties in research, development, and education.[160]

Animal patenting supporters also dispute the view that patenting will encourage secrecy in academic research. Instead, they claim that patenting will constrain the free exchange of information much less than the primary legal alternative that enables inventors to protect their financial interests in inventions. This is trade secret law, which is designed to prevent the unlawful obtaining of an inventor's proprietary information.[161] Its exact parameters are a function of state law, but it generally allows the secret-holder to obtain damages if information is stolen or disclosed contrary to an employee's contractual agreement or other legal duty of confidentiality.[162] A company's choice between relying on patent or trade secret law to protect its inventions ordinarily depends on several variables, but if patenting is completely unavailable, inventors of new animal life forms will be forced to resort to trade secrecy whenever possible.[163] As a result, inventions will be kept secret for an indefinite time, whereas patenting law would require their disclosure as soon as the patent was

[156]*See* Blumenthal, Gluck, Louis, Stoto & Wise, *supra* note 147.

[157]*See Hearings, supra* note 10, at 120 (statement of Ann Sorenson, American Farm Bureau Federation). *See generally* Lomasky, *Public Money, Private Gain, Profit for All,* HASTINGS CENTER REPORT, JUNE 1987, at 5.

[158]D. NELKIN, *supra* note 155, at 14.

[159]35 U.S.C. §§ 200-212 (1982).

[160]*See generally* TISSUE AND CELL OWNERSHIP, *supra* note 30, at 50; APPLIED GENETICS, *supra* note 16, at 250-51.

[161]*See generally* Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research,* 97 YALE L.J. 177, 190-95 (1987); Korn, *supra* note 150, at 209, 218-19; Adler, *supra* note 10, at 361. *But see* DRAFT REPORT, *supra* note 1, at 79, (arguing that trade secret law is less desirable than patent protection for genetically-altered animals).

[162]*See* TISSUE AND CELL OWNERSHIP, *supra* note 30, at 78; APPLIED GENETICS, *supra* note 16, at 237-38.

[163]*See* APPLIED GENETICS, *supra* note 16, at 24-46.

granted.[164] In sum, according to patenting supporters, although patenting may produce a short-term lag in communication, the overall effect will be to expand the exchange of knowledge.[165]

Pro-patenting commentators also point out that "pure" academic research is governed by its own rewards, and researchers often keep their discoveries secret until they are published in the appropriate scientific journals.[166] In addition, they contend that academic institutions can avoid undesirable restrictions on information dissemination through their contractual negotiations with commercial sponsors.[167] Last, patenting supporters concede that unwanted costs of the increased industrial involvement in academic research could become evident over time. Institutions and the government can minimize this possibility, however, by closely monitoring developments in this area and intervening if biotechnology research becomes overly constrained by its commercial sponsors.[168]

F. Animal Suffering

The welfare of the transgenic and other novel animals that will be candidates for patenting is the final major focus of the animal patenting controversy. Animal rights and welfare groups argue that the experiments needed to develop the "custom-designed" creatures industrialists envision are destined to produce numerous animals with painful and distressing anomalies.[169] This phenomenon is exemplified in the transgenic pigs given human growth hormone genes: the pigs have disabling arthritis and crossed eyes, and die prematurely.[170] In addition, animal protection groups predict that new types of abnormalities will occur in the genetically-altered animals, and veterinarians initially will be unable to provide adequate treatment for these conditions.[171] This group

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[164]*See* Korn, *supra* note 150, at 230–31. In the patenting system, information dissemination is delayed while the patent application is processed, which can take years. *See* Schneider, *Biotechnology Advances Make Life Hard for Patent Office*, N.Y. Times, April 17, 1988, sec. 4, at 1, col. 1 (average time to process biotechnology patent applications is thirty-two months).

[165]*See* D. NELKIN, *supra* note 155, at 15–16.

[166]*See* Zindler, *Genetic Engineering and Patenting*, in PATENTABILITY OF MICROORGANISMS, *supra* note 71, at 4-5; Korn, *supra* note 150, at 205–08.

[167]*See, e.g.*, Blumenthal, Gluck, Louis, Stoto & Wise, *supra* note 147, at 1366.

[168]*See id.* at 1365–66. *See also* Eisenberg, *supra* note 161 (concluding that patent law system will need some adjustment to conform with scientific norms); Goldworth, *supra* note 153, at 9–10 (suggesting that government assess high tax on commercial products developed using publicly-funded research and create incentives to encourage development of products that will benefit public). *See also infra* notes 251–55 and accompanying text (discussing research exemption from patent payments).

[169]*See, e.g.*, HUMANE SOCIETY NEWS, *supra* note 89, at 6.

[170]*See* PATENTING LIFE, *supra* note 3, at 6; Schneider, *supra* note 34.

[171]*See Hearings*, *supra* note 10, at 62–63 (statement of John Hoyt, Humane Society of the United States).

is also afraid that patenting will further encourage the intensive farming methods that already confer extreme suffering and deprivation on farm animals.[172]

Patenting opponents also object to the likely effects of animal patenting on laboratory animal welfare. The emergence of molecular farming and new animal models for human disease will enhance the demand for laboratory animals, to the detriment of current efforts to reduce scientific reliance on animal studies.[173] According to patenting critics, the availability of patenting makes genetic manipulation of farm and laboratory animals more likely, especially in the large-scale commercial facilities most likely to neglect animal welfare.[174]

Those in favor of animal patenting contend that it fails to raise any novel animal welfare problems. The reality is that our society routinely compromises the interests of nonhuman animals to obtain a variety of benefits for human beings.[175] Patenting supporters claim that every harmful aspect of animal patenting is present in existing agricultural and scientific practices. For instance, turkeys bred through traditional methods have breasts so large that they cannot mate, and veal calves spend their lives confined in stalls so small they can barely move.[176] Some patenting advocates have argued that animals will be better off with patenting, because it will encourage use of new genetic techniques that reduce the incidence of the unplanned negative results frequently occurring in traditional breeding. They also predict that patenting will help animals by eventually yielding a "more suitable animal for the stress of the livestock production system."[177] Finally, patenting advocates point out that their opponents who focus on animal welfare represent only the small portion of society dissatisfied with traditional human attitudes and practices involving nonhuman animals.[178]

Given the current social consensus that it is appropriate for humans to use animals for human benefits, patenting supporters say it is unfair to single out animal patenting for criticism. As one congressional witness testified, "When compared with the ethical issues involved in our breeding, buying, selling, confining, eating, and performing research on animals, the ethical questions

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[172] *Patenting: The Newest Form of Animal Exploitation*, ANIMAL LEGAL DEFENSE FUND NEWSLETTER, Oct. 1987, at 1.

[173] *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, ALTERNATIVES TO ANIMAL USE IN RESEARCH, TESTING, AND EDUCATION (1986) [hereinafter cited as ALTERNATIVES TO ANIMALS]; Dresser, "Assessing Harm and Justification in Animal Research: Federal Policy Opens the Laboratory Door," RUTGERS L. REV. (forthcoming).

[174] *See Moratorium Proposed on Animal Patenting*, MAINSTREAM, Fall 1987, at 27.

[175] *See generally* P. SINGER, ANIMAL LIBERATION: A NEW ETHICS FOR OUR TREATMENT OF ANIMALS (1975).

[176] *See* ANIMAL WELFARE INSTITUTE, FACTORY FARMING: THE EXPERIMENT THAT FAILED 35-41 (1987); J. MASON & P. SINGER, ANIMAL FACTORIES 13-14 (1980); PATENTING LIFE, *supra* note 3, at 7.

[177] *Hearings*, *supra* note 10, at 47 (statement of Thomas Wagner, Ohio University).

[178] *Id.* at 533-34 (statement of Richard Godown, Industrial Biotechnology Association). *See also* Boffey, *supra* note 115 (quoting ethicist John Fletcher's comment that concerns of animal rights organizations are out-of-step with dominant societal views).

surrounding animal patents seem relatively less important.''[179] Once more, patenting supporters echo their refrain: the degree of protection the government wants to confer on farm and laboratory animals is a broad policy issue that should be addressed comprehensively through the regulatory system.[180] Accordingly, patented animals should simply be governed by the same ethical and legal standards for humane care and use that apply to other animals used in agriculture and research. Prohibiting animal patenting would be an inefficient and ineffective approach to protecting animal welfare.

In summary, many of the fears expressed about animal patenting fail to apply to patenting alone; instead, they bear on the broader issue of whether scientists should be permitted to manipulate higher animal life at all. Moreover, the concerns that do apply specifically to the patenting of genetically-manipulated animals are equally relevant to existing practices in other areas of biotechnology research and development, modern U.S. agriculture, and non-human animal use. The debate over animal patenting thus represents a conflict over the appropriate resolution of these broader issues, and the genuine disagreement appears to concern the substantive values to be represented in U.S. policy governing such issues. In Part IV, I examine the current federal policy relevant to these areas.

IV. THE RELEVANT FEDERAL POLICIES

A. NIH Guidelines

Congress and a variety of administrative agencies have traditionally assumed the role of assessing and minimizing the risks posed by new technologies.[181] In these settings, ethical and safety issues ideally are resolved through a process that gives affected groups, including the public, an opportunity to comment on such issues. The development and sale of patented animals would be

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[179] *Hearings, supra note* 10 at 389 (statement of LeRoy Walters, Kennedy Institute of Ethics).

[180] *Id.* at 265–74 (statement of Richard Godown, Industrial Biotechnology Association).

A 1986 public survey commissioned by the Office of Technology Assessment of the U.S. Congress found that 68 percent of the respondents felt no moral opposition to creating hybrid plants and animals through genetic engineering. OFFICE OF TECHNOLOGY ASSESSMENT, PUBLIC PERCEPTIONS OF BIOTECHNOLOGY—A BACKGROUND PAPER 3-4, 57-58 (1987). Although 24 percent of the respondents expressed the belief that such practices are morally wrong, about the same proportion was similarly opposed to classical methods of crossbreeding and cross-fertilization. *Id.* at 58–59. Respondents opposed to genetic manipulation cited the following reasons for their position: objections to interfering with nature (35 percent); religious beliefs (31 percent); risk of unforeseen consequences (8 percent); objections to research on animals (4 percent); fears that "monsters" will be created (2 percent); and concern that humans will be subjected to the techniques (2 percent). *Id.* at 58.

[181] Federal regulation of biotechnology is an evolving process. Since 1984, government officials have been seeking to coordinate various regulatory functions among the agencies authorized to oversee biotechnology activities. *See* Jaffe, *Inadequacies in the Federal Regulation of Biotech-*

subject to the requirements of several oversight bodies. These requirements address containment of genetically-altered animals, safety of products obtained from such animals, and standards for humane care and use of agricultural and laboratory animals.[182]

The National Institutes of Health (NIH) has developed guildelines governing laboratory containment and experimental practices in recombinant DNA (rDNA) research. Institutions receiving NIH support for rDNA research must comply with these guidelines, or risk loss of such funds.[183] Institutions must assemble an Institutional Biosafety Committee, which must review all rDNA research conducted at the institution, and carry out several other oversight responsibilities.[184] The committee must include a community representative and members qualified to assess the health and environmental risks posed by rDNA research proposals.[185] At the federal level, the Director of NIH (Director) is charged with coordinating and implementing oversight. The NIH Recombinant DNA Advisory Committee (RAC) advises the Director on technical issues, including possible hazards posed by specific research proposals.[186] The RAC meets two or three times each year to consider changes in the NIH guidelines and any experiments that raise serious safety questions.[187]

The initital version of the NIH guidelines, issued in 1976, was relatively

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nology, 11 HARV. ENVTL. L. REV. 491, 522-27 (1987). From Oct. 1985 through Oct. 1987, a sub-Cabinet level advisory body, the Biological Science Coordinating Committee (BSCC), was charged to manage federal regulation of biotechnology. *See* Fox, *The U.S. Regulatory Patchwork*, 5 BIO/TECHNOLOGY 1273, 1274 (1987). In Dec. 1987, a new committee on life sciences was formed under the Federal Coordinating Council of Science, Engineering and Technology, which is housed in the President's Office of Science and Technology Policy. *See* Palca, *Changing Features Sighted on the Biotechnology Horizon*, 330 NATURE 512 (1987). The new committee will share with the BSCC oversight of federal regulatory activities. *Id.* In spite of the government's efforts in this area, the federal regulatory system is often criticized as an inadequate patchwork in need of further revision. *See, e.g.*, Jaffe, *supra* at 528-47; Gore & Evans, *supra* note 88, at 348-51.

[182]On Dec. 11, 1987, the Office of Technology Assessment conducted a workshop on the potential uses and regulation of genetically-altered animals. At the meeting, representatives of federal agencies responsible for regulating animals and animal products or involved in animal use in research, testing or product development discussed their anticipated use and regulation of patented animals. *See* FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1.

[183]*See* APPLIED GENETICS, *supra* note 16, at 212.

[184]*Id.* at 214.

[185]*Id. See also* U.S. Dep't of Health & Human Services, Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,962-63 (1986).

[186]APPLIED GENETICS, *supra* note 16, at 213. *See also* 51 Fed. Reg. 16,963-64 (1986). The RAC includes experts in molecular biology, environmental sciences, and other scientific fields, as well as experts in law, public policy, ethics, and public and environmental health. *See id.* at 16,964.

[187]*See Hearings*, *supra* note 10, at 268-69 (statement of Richard Godown, Industrial Biotechnology Association).

In 1985, citing many of the same objections he has raised against animal patenting, Jeremy Rifkin asked the Director of the NIH to prohibit "any experimentation involving the transfer of a genetic trait from any human being into the germ line of another mammalian species" and "any experimentation involving the transfer of any [other] mammalian species into the germ line of a human being." *See* 50 Fed. Reg. 9760-01 (1985). He also proposed prohibiting all cross-species gene transfers, including those not involving human beings. *Id.* The RAC considered the proposals and its recommendation against approving the request was accepted by the NIH Director. *Id.*

strict and prohibited several types of experiments.[188] As rDNA research proved less dangerous than was first anticipated, the guidelines were relaxed.[189] Currently, the guidelines govern rDNA research on whole animals and prescribe the methods and equipment to be used at four different containment levels, depending on the dangers involved.[190]

The biggest drawback to this system is its limited coverage. Institutions that fail to receive NIH funds for rDNA research need not comply with the guidelines.[191] Although industry and other funding entities have thus far voluntarily participated in the NIH program, there is no guarantee that this will continue.[192] Another major criticism is that the guidelines are designed to provide health and environmental protection, but they neglect other ethical issues, such as the threat rDNA research could pose to respect for human life.[193] Last, there are questions about the system's ability to ensure compliance even among those institutions clearly subject to the guidelines.[194]

B. USDA Supervision

Government-sponsored research on genetically-altered livestock and other food animals is typically funded by the USDA. The agency recently proposed guidelines to govern research on and containment of genetically-altered animals.[195] The provisions will apply to all federally-funded agricultural biotechnology research.[196] They are patterned after the NIH guidelines, and have the same general shortcomings. The proposed guidelines demand that funding applicants submit data on the nature of any genetically-altered animal that will

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[188]*See* APPLIED GENETICS, *supra* note 16, at 212. For a detailed description of the events leading to implementation of the NIH oversight system, *see* Swazey, Sorenson & Wong, *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Controversy*, 51 S. CAL. L. REV. 1019 (1978).

[189]*See* Jaffe, *supra* note 181, at 499.

[190]51 Fed. Reg. 16,961, 16,972-77 (1986).

In Aug. 1987, the RAC recommended to the NIH Director certain changes to relax and simplify plant and animal containment requirements. 52 Fed. Reg. 29,800 (1987). The Director is currently considering these recommendations. *See Hearings, supra* note 10, at 446 (statement of Geoffrey Karny, Esq.).

[191]*See* Gore & Owens, *supra* note 88, at 344-45.

[192]*See* Jaffe, *supra* note 181, at 534-35.

[193]*See* APPLIED GENETICS, *supra* note 16, at 217 (broader questions of where DNA technology might lead and whether it should be done at all not formally considered).

[194]*See* Schneider, *Panel in Montana Suggests Gene Scientist Be Rebuked*, N.Y. Times, Sept. 3, 1987, at 10, col. 1 (describing violations of NIH Guidelines by scientist at Montana State University conducting research on genetically-altered bacteria).

[195]The proposed regulations were promulgated under the statutory authority of the National Agricultural Research, Extension, and Teaching Policy Act Amendment of 1985, 7 U.S.C. §§ 3101-3336 (Supp. III 1985), which directs the Secretary of Agriculture to establish "appropriate controls with respect to the development and use of the application of biotechnology to agriculture." *Id.* § 3121 (12).

[196]Projects governed by the guidelines or regulations of another federal agency are exempt from the USDA guidelines. 51 Fed. Reg. 23,369 (1986).

be released into the environment, and the plan for housing such animals.[197] With the goal of preventing unintended transmission of rDNA, the USDA provisions also set containment, transport, and disposal standards for genetically-engineered "nonmicroscopic animals," which vary according to whether or not the germ line has been modified.[198] Again, voluntary compliance by industry and other nonfederally-funded research entities is encouraged, but not mandatory.[199]

Other federal statutes extend the USDA's authority to regulate environmental release of genetically-altered animals produced in commercial and other private settings.[200] These include laws governing veterinary biological products,[201] interstate movement of plant pests, and animal quarantine.[202] The USDA's official position is that the agency's existing regulatory framework is adequate to oversee the development and production of genetically-altered organisms, and that it will seek additional statutory authority if the agency is found to lack jurisdiction over any such organism.[203]

The safety of products prepared using genetically-altered animals will be monitored by the USDA and the Food and Drug Administration (FDA). The USDA's Food Safety and Inspection Service (FSIS) inspects livestock, poultry, and their food products to ensure they are safe, wholesome, and unadulterated.[204] Other inspection categories cover additional food animal species, but the FSIS has indicated that new regulations may be needed to provide the agency with adequate authority to inspect genetically-engineered animals and their offspring.[205] The FDA is authorized to assure the safety and efficacy of food products for human consumption, human and veterinary drugs, and biological products for human use.[206] Current law would apply to any substance produced in transgenic animals.[207] This would include the products of molecular farming, as well as transgenic animal products intended as food. The agency could also require special labeling for such products.[208]

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[197] *Id.* at 23,374.

[198] *Id.* at 23,384-85. *See* APPLIED GENETICS, *supra* note 16, at 12-13, 15-16 for a description of the relevant funding policies of the National Science Foundation and other federal agencies.

[199] 51 Fed. Reg. 23,369 (1986).

[200] *See* Jaffe, *supra* note 181, at 503-06; FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 8.

[201] The term encompasses "all viruses, serums, toxins, and analogous products of natural or synthetic origin . . . intended for use in the diagnosis, treatment or prevention of diseases in animals." 9 C.F.R. § 101.2 (w) (1986).

[202] *See* Jaffe, *supra* note 181, at 503-06; *Hearings, supra* note 10, at 446-50 (statement of Geoffrey Karny, Esq.).

[203] *See* Jaffe, *supra* note 181, at 501, 503: *Hearings, supra* note 10, at 446-50 (statement of Geoffrey Karny, Esq.).

[204] *See* FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 8-9; *Hearings, supra* note 10, at 272-73 (statement of Richard Godown, Industrial Biotechnology Association).

[205] *See* FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 9.

[206] *See* Jaffe, *supra* note 181, at 517; FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 10 (describing relevant statutory authority).

[207] FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 10.

[208] *Id.*

C. Animal Welfare

The USDA and the Public Health Service (PHS) are primarily responsible for the welfare of animals used in agriculture and research. At present, the USDA is charged with implementing the two federal laws concerning humane treatment of livestock animals. The Twenty-Eight Hour Law[209] regulates conditions for livestock in shipment, and the Humane Slaughter Act[210] requires that livestock be slaughtered by specific methods deemed humane. At this time, however, there are no U.S. statutes or regulations governing conditions of confinement and other aspects of agricultural animal care.[211] The lack of government attention to farm animal welfare is a major concern of animal protection groups, and is partially responsible for their opposition to animal patenting.[212]

In relative terms, federal oversight of laboratory animal welfare is comprehensive and demanding. The Animal Welfare Act (AWA)[213] governs all research activities in or substantially affecting interstate or foreign commerce. It sets standards for transportation, sale, handling, care, and treatment of several laboratory animal species.[214] The law and its implementing regulations are administered by the USDA's Animal and Plant Health Inspection Service (APHIS), and oversight committees at the individual research facilities.[215] APHIS officials and institutional committee members regularly inspect animal housing facilities, and the committees review proposed animal research projects to ensure that the pain and distress entailed is the minimum necessary to obtain the desired scientific knowledge.[216]

The PHS Policy on Humane Care and Use of Laboratory Animals governs research funded or conducted by the five agencies constituting the primary federal sponsors of biomedical research.[217] The policy and the NIH Guide for the Care and Use of Laboratory Animals[218] together address most aspects of laboratory animal housing, care, and use, and set standards similar to those in the AWA governing the pain and distress imposed on animal research subjects. The PHS policy applies to all vertebrate animals and is administered primarily

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[209]45 U.S.C. §§ 71-74 (1982).

[210]7 U.S.C. §§ 1901-1906 (1982).

[211]Some state anticruelty laws require that animals be provided appropriate food, water, and shelter, but these laws have not been applied to challenge intensive farming practices. *See* ANIMAL WELFARE INSTITUTE, ANIMALS AND THEIR LEGAL RIGHTS 16-18, 73 (3d ed. 1978); McCarthy & Bennett, *Statutory Protection for Farm Animals*, 3 PACE ENVTL. L. REV. 229, 240-55 (1986).

[212]*See, e.g., Patenting: The Newest Form of Animal Exploitation, supra* note 172.

[213]7 U.S.C. §§ 2131-57 (1982 & Supp. III 1985).

[214]The statute and its implementing regulations fail to cover rats, mice, birds and farm animals used in research. 7 U.S.C. § 2132(g) (1982); 9 C.F.R. § 1.1 (n) (1986).

[215]*See generally* Dresser, *supra* note 173; Dresser, *Research on Animals: Values, Politics, and Regulatory Reform*, 58 S. CAL. L. REV. 1147 (1985).

[216]7 U.S.C. § 2143(b)(3). The institutional committees must include at least one veterinarian and a community member "intended to provide representation for general community interests in the proper care and treatment of animals." 7 U.S.C. § 2143(b)(1)(B)(iii).

[217]PUBLIC HEALTH SERVICE, POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS (rev. ed. 1986) (copy on file with author) [hereinafter cited as PHS POLICY].

[218]U.S. Dept. of Health and Human Services, NIH Pub. No. 85-23 (rev. ed. 1985).

by Institutional Animal Care and Use Committees, through research protocol review and facility inspection.[219] Institutions must file annual reports to the PHS, and are subject to site visits by the agency at any time.[220] Failure to comply with the policy could jeopardize an institution's federal research funds.[221]

Critics of the federal policy on laboratory animal welfare perceive several flaws in the system. The AWA fails to cover rats and mice, which comprise 85 percent of the laboratory animals used annually in the U.S. Similarly, the law fails to apply to farm animals used in research.[222] Thus, commercial entities and other nonfederally-funded research facilities that conduct research solely on these species are not subject to any federal constraints. This suggests that a substantial amount of private-sector research involving patented animals would be exempt from federal oversight.[223] In addition, animal rights and welfare groups question the stringency with which institutional oversight committees fulfill their responsibilities, given that the committees are primarily composed of institutional employees.[224] Finally, critics frequently attack the federal policy's substantive standards, which allow researchers to inflict any level of pain and distress on animals to satisfy a project's scientific aims.[225] Thus, as long as a researcher can demonstrate acceptable scientific justification, the federal animal welfare policy will allow any genetic alteration to be performed on an animal, no matter how painful and distressing the effects might be.

D. Farm Policy

U.S. farm policy is another general area implicated in the debate over animal patenting. Farm policy is controlled by Congress and is usually implemented by the USDA. The most common federal interventions include commodity programs, tax policies, and credit policies.[226] The central but unresolved political question in this area is whether and, if so, to what extent the government ought to adopt policies that perpetuate a wide dispersion of ag-

[219]PHS POLICY, *supra* note 217, at III. A., IV. B., C. The Committee must include at least one veterinarian, nonscientist, and one community member. *Id.* at IV. A. 3.

[220]*Id.* at IV. A., F., V. C.

[221]*Id.* at IV. A.

[222]*See* ALTERNATIVES TO ANIMALS, *supra* note 173, at 64.

[223]State anticruelty laws generally exempt or fail to address laboratory animal use, but a few such statutes do extend to research animals. *See id.* at 305-23.

[224]*See* Hutchinson, *The Role of Lay Members on Animal Care Committees*, NEW PATHS, Fall, 1986, at 5 (Fall 1986).

[225]*See* Dresser, *supra* note 173.

The U.S. Department of Interior's Fish and Wildlife Service has several regulatory provisions aimed at protecting the genetic integrity, biological diversity, and natural habitat of wild animals. *See* FEDERAL REGULATION AND ANIMAL PATENTS, *supra* note 1, at 17. Representatives of the agency have stated that the Fish and Wildlife Service probably lacks the authority to regulate transgenic animals, except in cases in which genetically-altered animals threaten a species covered by the Endangered Species Act. *Id. See also Hearings, supra* note 10, at 429 (statement of Margaret Mellon, National Wildlife Federation) (federal regulatory system now inadequate to address wildlife concerns).

[226]*See* TECHNOLOGY AND AGRICULTURE, *supra* note 123, at 29-31.

ricultural land ownership.[227] This goal traditionally has been viewed as important in preserving certain cultural values associated with farming in this nation.[228] But many government officials now believe that agriculture should be treated no differently than any other business, and are opposed to policies that disproportionately benefit owners of small- and medium-sized farms.[229] The farming community's opposition to animal patenting is simply one facet of their struggle to resist this trend.[230]

E. Gaps in Federal Regulation

In summary, the federal regulatory system reveals an incomplete response to the objections to animal patenting. The existing regulatory framework indicates that government officials are cognizant of certain anti-patenting fears, but it also evinces several general shortcomings. For example, agencies such as the NIH and the USDA have conflicting roles as promoters and financial supporters of the very research they are assigned to regulate, which raises questions about their ability to exercise appropriate oversight.[231] Agencies also appear to have overlapping jurisdiction in some areas, while in others, including nonfederally-funded rDNA research and environmental release of certain genetically-altered animals, explicit federal authority to regulate is lacking.[232]

Furthermore, concerns about particular environmental, health, and animal welfare effects of animal patenting are only partially addressed by the existing regulatory system. In some areas, modifications in agency policy and existing statutes would be required if patenting opponents convinced federal officials that their concerns merited further government action. Other concerns relevant to animal patenting have received little or no federal attention. Farm animal welfare has never been a particularly compelling issue for federal officials, and Congress has done nothing to discourage the intensive farming methods that will be applied in raising patented animals for food and other products. In addition, except for the 1980 Patent and Trademark Act Amendments, the federal government has made no effort to regulate commercial-academic research relationships. Similarly, the government has failed to conduct a broad-scale inquiry into the potential long-term social and environmental consequences of manipulating higher animal life, including the possible effects of

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[227] *See id.* at 25-26.

[228] *Id. See also* Reynolds, *Jewish Groups Examine Farm Crisis*, N.Y. Times, Feb. 29, 1988, at 8, col. 1 (describing need to protect threatened values).

[229] *See* Schneider, *Agency Plans Aid on $7 Billion Debt Owed By Farmers*, N.Y. Times, March 2, 1988, at 1, col. 3 (describing opposition to keeping "inefficient" farmers in business).

[230] *See* Schneider, *Washington Loosens Grip on Indebted Farms*, N.Y. Times, March 6, 1988, at 5, col. 3 (noting activist groups' role in debate over farm policy).

[231] *See* Jaffe, *supra* note 181, at 529.

[232] *See id.* at 531-32. *See also* Fox, *supra* note 181, at 531-32; Schneider, *Morass of Gene Regulations Leads to Dismay on All Sides*, N.Y. Times, Sept. 29, 1987, at 15, col. 1. *See also* DRAFT REPORT, *supra* note 1, at 79-21-25 (suggesting revisions in regulations governing genetically-altered animals).

creating human-animal hybrids.[233] Finally, sharp disagreement exists regarding the appropriate federal response to the declining family farm.

The opposition to animal patenting can thus be traced to gaps in the existing regulatory structure and to conflicts over the substantive values currently given priority in various government policies. The vehemence of the anti-patenting reaction is also partially attributable to the government's failure to devote the time and attention necessary to analyze and respond comprehensively to the ethical issues raised by the scientific ability to genetically alter higher animal life, the decline of the family farm, the commercialization of academic research, and the humane care of agricultural and laboratory animals.

V. PATENT LAW ISSUES

A. Enablement

Even if Congress decides against overruling the PTO decision that higher animal life forms are patentable subject matter, it could still enact legislation to modify certain patent law rules that would otherwise be especially burdensome to patent applicants, farmers, and researchers. If Congress fails to take such action, these matters will probably come before the courts or the PTO for resolution. Decision-makers addressing these matters will face some of the same policy issues raised in the broader debate over patentability of higher animals.

Three modifications in the patent law have been proposed to accommodate certain features of the new form of patentable subject matter. The first concerns the enablement provision in section 112 of the Patent Act, which requires patent applicants to include a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same. . .".[234] This description is disclosed as part of the patent law goal of advancing knowledge. With living material, however, it can be difficult to meet the statutory demands without providing access to the material itself. Congress enacted the special plant patent laws partially to address this problem.[235] These laws permit inventors to fulfill the enablement requirement with a disclosure that is "as complete as rea-

[233] Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1341 (1986) (until now, government entities considering genetic research have glimpsed "only intermittently" larger philosophical issues). These questions could be addressed by the Biomedical Ethics Board of the U.S. Congress, which was established in 1985 to consider such issues. *See* Wallis, *supra* note 57.

[234] 35 U.S.C. § 112 (1982).

[235] *See* Diamond v. Chakrabarty, 447 U.S. 303, at 312.

sonably possible.''[236] A 1970 decision by the Court of Customs and Patent Appeals permitted patent applicants to fulfill the enablement requirement for inventions involving microorganisms and simple life forms by depositing the life form in a public repository.[237] The U.S. has signed the Budapest Treaty on the International Recognition of Microorganisms, which specifies standards governing deposit, culture maintenance, and distribution for patent purposes.[238]

A similar requirement for patents on multicellular organisms could be more difficult to implement, however. If whole animals must be deposited, "the logistics, maintenance, and distribution costs involved may be prohibitive.''[239] For example, to ensure continued access, animals would have to be housed in the depository, and replaced in the event of death or illness.[240] Procedures governing their study and distribution would have to be devised as well. Some have suggested that the enablement requirement for patented animals might be satisfied by maintaining a repository of the animals' fertilized eggs or embryos.[241] But another commentator has noted that this method could create difficulties in evaluating infringement claims if the animal required a long gestation and maturation period.[242] This would depend on whether infringement could be detected simply by comparing the genetic content of the egg or embryo with that of the animals at issue. (Molecular biological techniques are currently available to indicate the presence of a patented gene or gene sequence in an animal.[243]) To address this area of uncertainty, one congressional witness has urged the PTO to publish for public comment potential standards and procedures for addressing the enablement requirement for patents on higher animal life forms.[243a]

B. Problems of Exclusion

The remaining patent law issues concern whether certain exemptions should be created to limit the patentee's rights to exclude others from making and using the invention. One exemption is proposed to resolve problems related to an unusual characteristic of living inventions: their ability to reproduce themselves. The Commissioner of Patents and Trademarks has written that under present patent law, a patent owner would be entitled to royalties for the offspring of patentable animals, and that unauthorized reproduction could con-

[236] 35 U.S.C. § 162 (1982).
[237] *See* Maggs, *supra* note 17, at 67-68.
[238] *See id.*
[239] Adler, *supra* note 10, at 360.
[240] *See* Maggs, *supra* note 17, at 69-70.
[241] *See, e.g.*, Cooper, *supra* note 23, at § 6.03.
[242] *See* Adler, *supra* note 10, at 360.
[243] *See Hearings, supra* note 10, at 184 (statement of Robert Merges, Esq.).
[243a] *Hearings, supra* note 10, at 166 (statement of Reid Adler, Esq.) The Draft Report of the Subcommittee on Courts, Civil Liberties, and the Administration of Justice concluded that Congress should authorize the establishment of a certified depository for the germ plasm of genetically-altered animals. DRAFT REPORT, *supra* note 1, at 79-18.

stitute patent infringement.[244] It is feared, however, that such a rule could create significant impediments for farmers.

A proposed "Farmer's Exemption" would excuse farmers from infringement liability and royalty payments for offspring of the patented animals they purchase.[245] This exemption could parallel the "Farmer's Crop Exemption" in the Plant Variety Protection Act of 1970, which allows farmers to use or sell to other farmers seeds produced by the patented plants they purchase.[246] The exemption is designed mainly to accommodate the farmer's interest in avoiding high costs and extensive recordkeeping.[247] The claim is that a farmer's exemption would not significantly affect the market for patented animals, because the phenomenon of "genetic drift" would limit the number of offspring possessing the patented trait.[248] But others have questioned the effect of such an exemption on the patent incentive system.[249] This group believes that the problems associated with self-reproducing animals could be adequately controlled through the market system, in which patent holders and farmers could negotiate contracts and licensing agreements that included mutually satisfactory terms governing these problems.[250]

The second proposed exemption concerns research performed using patented animals. To encourage scientific progress, courts have formulated a doctrine allowing individuals to use a patented article or process in research without compensating the patent holder, as long as there is "no intended commercial use of the patented article."[251] The "Research Exemption" fails to encompass research aimed at commercial application, however.[252]

There is concern that the existing Research Exemption is too narrow to accommodate publicly-supported agricultural and other applied research on patented animals.[253] If publicly-supported researchers must pay licensing fees and royalties on the patented animals they use in research, their efforts to improve such animals might be hindered, and important public benefits delayed

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[244]*See* Schneider, *U.S. Farmers to Face Patent Fees for Gene-Transformed Animals*, N.Y. Times, Feb. 6, 1988, at 1, col. 1.

[245]*See Hearings, supra* note 10, at 185-89, 213 (statements of Robert Merges, Esq., and Leo Walsh, Dean, University of Wisconsin College of Agriculture and Life Sciences).

[246]*See* 7 U.S.C. § 2543 (1982).

[247]*See Hearings, supra* note 10, at 120–21, 188 (statements of Ann Sorenson, American Farm Bureau Federation and Robert Merges, Esq.).

[248]*Id.* at 186 (statement of Robert Merges, Esq.).

[249]The exemption could make the cost of patented animals abnormally high, because of the resultant lost sales of offspring. *See Hearings, supra* note 10, at 303-04 (statement of Michael Ostrach, Esq.).

[250]*Id.* at 168 (statement of Reid Adler, Esq.). In its Draft Report, the staff of the Congressional Subcommittee supported the creation of a "small farmer exemption," on grounds that the social benefits would outweigh the costs. DRAFT REPORT, *supra* note 1, at 79-20.

[251]Pfizer, Inc. v. Int'l Rectifier Corp., 217 U.S.P.Q. 157, 161 (C.D. Cal. 1982). The federal courts have not unanimously adopted the exemption, and for those that have, the precise boundaries of permissible research remain unclear. *See* Eisenberg, *supra* note 161, at 219-26; *Hearings, supra* note 10, at 167, 190 (statements of Reid Adler, Esq., and Robert Merges, Esq.).

[252]*See id.*

[253]*See id.*

or lost. One suggestion is for Congress to enact an exemption that duplicates a provision in the Plant Variety Protection Act. The provision exempts all "bona fide" research uses from infringement.[254] This exemption, it is claimed, has not unduly decreased the patent incentive; instead it has stimulated development of new plant varieties in both public and private research sectors, thus advancing the nation's overall agricultural productivity.[255]

These proposed modifications in the patent law present policy issues that require decision-makers to balance the social goals of the patent system against competing social goals, such as the enhancement of agricultural production and avoidance of undue burdens on farmers. Congress and other policy-makers confronting these issues thus face some of the same ethical, economic, and social questions raised in the broader debate over patentability of higher animal life forms. Once again, the rules governing patenting of higher animals will reflect positions on more general issues confronting contemporary U.S. policy-makers.

CONCLUSION

The animal patenting controversy is really a battle over other policy issues. To its opponents, animal patenting symbolizes a variety of unwanted social developments. The anti-patenting coalition has seized upon the new PTO policy as a vehicle for presenting their objections to these more general trends. Yet patenting supporters have adequately demonstrated that novel forms of animal life offer benefits to society. Like most new technology, however, this scientific capability could also have negative effects on our environment and culture.

The genuine challenge is thus to minimize the technology's negative effects while maximizing its positive contributions. Prohibiting animal patenting would be an overinclusive government response because it would discourage the efforts of inventors and industry to develop the technology's beneficial applications. At the same time, a patent prohibition would be underinclusive in that it would fail to prevent creation of genetically-manipulated animals in the laboratory, and probably fail to prevent commercialization of such animals, given the alternative strategies biotechnology companies could pursue to protect their financial interests in the animals.

The animal patenting controversy could still have a significant outcome, however. The inquiry into animal patenting could force members of Congress

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[254] 7 U.S.C. § 2544 (1982).

[255] *See Hearings, supra* note 10, at 191, 212 (statements of Robert Merges, Esq., and Leo Walsh, Dean, University of Wisconsin College of Agriculture and Life Sciences).

The policy issue again is whether such an exception would decrease too drastically the patent incentive. *See* Eisenberg, *supra* note 161, at 224; *Hearings, supra* note 10, at 195 (statement of William Duffey, Esq.). The subcommittee's Draft Report recommended that Congress revise the Patent Act to include a general research exemption, applicable to all patented inventions. DRAFT REPORT, *supra* note 1, at 77.

and other government officials to examine in detail the adequacy of the existing statutes and regulations governing recombinant DNA research and its applications. The debate over animal patenting could also spur officials to create a process for scrutinizing closely such matters as the appropriate boundaries between human and nonhuman organisms and articulating more clearly the meaning of respect for human and nonhuman life in light of these contemporary scientific developments. It could compel officials to formulate more definite policies on preservation of the family farm and commercialization of academic research as well. Last, the animal patenting controversy could lead Congress and the appropriate federal agencies to adopt standards and procedures for analyzing and resolving the new problems and issues that will undoubtedly emerge with further development of this technology. Thus, for all its conceptual flaws and misplaced criticism, the argument against animal patenting could prove to be immensely valuable in encouraging government decision-makers to confront several crucial policy choices now facing this nation.[256]

[256]As this article goes to press, the legislative future of animal patenting is unclear. On Mar. 30, 1988, the House Subcommittee on Courts, Civil Liberties and the Administration of Justice voted against accepting its staff's draft report, which concluded that animal patenting should be permitted, with certain modifications. Schneider, *House Panel Rebuffs Staff on Animal Patents*, N.Y. Times, March 31, 1988, sec. 1, at 7, col. 2.