Volume 1, Spring Issue, 1988

CONTROLLING THE APPLICATIONS OF BIOTECHNOLOGY: A Critical Analysis of the Proposed Moratorium on Animal Patenting

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I. INTRODUCTION

> The known is finite, the unknown infinite; intellectually we stand on an islet in the midst of an illimitable ocean of inexplicability. Our business in every generation is to reclaim a little more land . . . .
>
> Thomas Henry Huxley[1]

The march of human history has produced and assimilated a host of technological marvels such as the arrowhead, plow, lateen sail, waterwheel, printing press, telescope, mass production, radio and computer.[2] Some of these inventive wonders–industrial chemistry and atomic fusion to name but two–not only have created major social change but are also imbued with the power to transform planet earth on a profound scale. The latest member of this select group of wonders may be biotechnology.[3] Since

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1. D. BOORSTIN, THE DISCOVERERS 625 (1983) (concerning C. Darwin, *Origin of Species* (1887)).

2. *See* J. BURKE, CONNECTIONS, (1978); D. BOORSTIN, *supra* note 1; M. WILSON, AMERICAN SCIENCE AND INVENTION: A PICTORIAL HISTORY (1954); J. GLEICK, CHAOS: MAKING A NEW SCIENCE (1987).

3. Biotechnology, as used in this Article, refers collectively to various genetic engineering techniques, developed during the past 20 years, which permit the controlled transfer of specific genes or groups of genes from one cell or organism to another, thereby creating cells or organisms that would not likely occur in nature or through conventional breeding practices. Recombinant DNA is the product of one of these techniques, a man-made construct which derives from *in vitro* linkage of DNA from different sources. *See* S. LURIA, S. GOULD & S. SINGER, A VIEW OF LIFE (1981). Biotechnology and genetic engineering, in the traditional sense, encompass microbial techniques dating from antiquity to bake bread and brew beer, as well as the conventional breeding of animals and the creation of industrially significant genetic microorganisms through mutagenesis and irradiation. Thus, the nomenclature "biotechnology" and "genetic engineering" may be too encompassing to define the most modern techniques. *See* Miller & Young, *Isn't It About Time We Dispensed With 'Biotechnology' and 'Genetic Engineering'?*, 5 BIO/TECH. 184 (1987).

1974 it has been possible to cause a living organism to express genetic material from outside its own species. The present debate over a proposed moratorium on the patenting of animals actually represents an inappropriate focus within the larger issue concerning control of biotechnology in general.[4]

Initially, this Article presents an historical background to the animal patenting controversy and an overview of patent law,[5] followed by a review of the present capabilities of agricultural biotechnology. The evolution of the laws that protect inventors' rights in living organisms is then discussed in the context of contemporaneous advances in biology. Moreover, the application of the patent system to these biological inventions is shown to be well supported by Congressional intention and judicial construction.

Next the Article discusses the major bases for opposing animal patenting, and shows the bases to be predicated on perceived consequences of the *applications* of this technology. Implications of biotechnology are therefore considered for the areas of animal welfare, environmental safety, preservation of biological diversity, ethical concerns over genetic alteration of living organisms, and the structure of the agricultural industry. These complex concerns, while undeniably momentous, predate animal patents and will continue to exist even if patenting is halted. In fact, each concern is shown generally to fall within the regulatory purview of existing federal agencies, policies, and laws, or to require new regulatory authority independent of the patent system.

No evidence supports the notion that a moratorium on animal patenting would eliminate the need for social and regulatory decisions concerning the impacts of biotechnology.[6] To the contrary, as discussed in this Article, a moratorium is likely to be so-

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4. The regulation of biotechnology is a detailed subject beyond the scope of this Article. For a treatment of regulation, *see generally Symposium on Biotechnology Law*, 11 RUTGERS COMPUTER & TECH. L.J. (1985); Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302 (1986) [hereinafter OSTP Framework]; Fox. *The U.S. Regulatory Patchwork*, 5 BIO/TECH. 1273 (1987); Newmark, *Discord and Harmony in Europe*, 5 BIO/TECH. 1281 (1987); Huber, *Biotechnology and the Regulation Hydra*, 90 TECH. REV. 57 (1987); Jones, *Commercialization of Gene Transfer in Food Organisms: A Science-Based Regulatory Model*, 40 FOOD DRUG COSMETIC L.J. 477 (1985).

5. The writings and Congressional testimony of many opponents of animal patenting reveal misunderstandings about the nature of the patent system, the effects of patent law and the jurisdiction of the U.S. Patent and Trademark Office (PTO). The major such misunderstandings are indicated on a topical basis *infra*.

6. Although a hope of slowing biotechnology research is advanced by most of the opponents to the patenting of living organisms, the extent to which a moratorium on patenting might affect the rate of technological development or minimize perceived risks is entirely speculative. Additionally, a moratorium may adversely affect research directed at producing human pharmaceuticals, curing human genetic diseases, improving agricultural productivity, or removing toxic wastes. OSTP Framework, *supra* note 4.

cially detrimental, by indiscriminately affecting both objectionable and unobjectionable research and slowing the acquisition of knowledge upon which future biomedical advances will depend. A patent moratorium is by no means an alternative to responsible federal regulation.[7] This Article concludes that extending the incentives of the patent system to living organism inventions is beneficial and is consonant with statutory and case law authority and broader national policies. Brief recommendations are offered for more effectively regulating the applications of biotechnology and for improving the impact of the patent system on federal policies.

II. BACKGROUND

> The grant or denial of patents on [living] organisms is not likely to put an end to genetic research or to its attendant risks. . . . Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.
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> United States Supreme Court,
> *Diamond v. Chakrabarty*[5]

Microorganisms expressing recombinant DNA were first produced in 1974.[9] In 1980, the United States Supreme Court confirmed that microorganisms *per se* were patentable in the landmark decision of *Diamond v. Chakrabarty*.[10] Both plants and animals expressing recombinant DNA were produced in 1982.[11] Plants were determined to be patentable in 1985 by the United

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7. For comments on the constitutionality and policy of using regulation to ban some forms of positive genetic engineering, *see, e.g.*, Note, *Constitutionality of Regulating Genetic Engineering*, 53 U. CHI. L. REV. 1274 (1986); Francione, *Experimentation and the Market Place Theory of the First Amendment*, 136 U. PA. L. REV. 417, 423 (1987) ("[T]he government could . . . prohibit all research involving genetic engineering so long as the purpose of the prohibition is not to suppress dissemination of information derived from such research.").

8. 447 U.S. 303, 317 (1980).

9. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-BA-218, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 4 (1984) [hereinafter OTA COMMERCIAL BIOTECH].

10. 447 U.S. 303 (1980). The Court held that living microorganisms were patentable subject matter within section 101 of the Patent Act, 35 U.S.C. §§ 1-376 (1982), which states that: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor . . . ." Plants continued to be patentable under section 161 but with relatively more limited rights granted to the patent owner. Prior to this decision, the PTO had taken the position that living organisms were excluded from patent protection under section 101. *See* Part V, *infra*.

11. 2 BIOTECH. NEWSWATCH, No. 6, at 6 (1982); Palmiter, Brinster, Hammer, Trumbauer, Rosenfeld, Birnberg & Evans, *Dramatic Growth of Mice that Develop From Eggs Microinjected with Metallothionein-Growth Hormone Fusion Genes*, 300 NATURE (LONDON) 6 (1982) [hereinafter Palmiter].

States Patent and Trademark Office (PTO).[12] These patent decisions met with great media attention but evoked relatively little public concern. In 1987, however, the Commissioner of Patents and Trademarks (the "Commissioner") extended patent protection by decree to nonhuman animals, so that "nonnaturally occurring non-human multicellular living organisms, including animals, [are now] patentable subject matter."[13] The Commissioner excluded human beings from patentability, due in part to the dictates of the Thirteenth Amendment.[14] Although 82% of Americans favor continued genetic engineering research,[15] the Commissioner's announcement was greeted with great controversy.[16]

According to the Office of Technology Assessment (OTA), American agriculture is on the threshold of a biotechnology and information technology era, in which agricultural productivity will increase phenomenally.[17] Proponents of animal patents are

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12. *Ex parte* Hibberd, 227 U.S.P.Q. 443 (PTO Bd. Pat. App. & Int. 1985) held that plants were patentable under section 101. Adoption of the *Hibberd* holding as PTO policy by the Commissioner of the PTO is at 1060 OFFICIAL GAZ. PAT. OFF. 4 (1985). The Commissioner ostensibly acts under the direction of the Secretary of Commerce. 35 U.S.C. § 6(a) (1982).

13. 1077 OFFICIAL GAZ. PAT. OFF. 24 (1987), announcement dated Apr. 7, 1987. The Commissioner's determination followed within a matter of days the decision by the PTO Board of Appeals and Interferences in *Ex parte* Allen, 2 U.S.P.Q. 2d 1425 (PTO Bd. Pat. App. & Int. 1987). *Allen* held that the particular polyploid oysters sought to be patented, created by nonrecombinant DNA techniques, were nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. § 101 and were therefore patentable subject matter. The first animal patent, U.S. Patent No. 4,736,866, issued on April 12, 1988.

14. U.S. CONST. amend. XIII, § 1. The anti-peonage laws would also preclude *enforcement* of human patents. *See* Clyatt v. U.S., 197 U.S. 207 (1905). This Article does not discuss related issues such as ownership of human organs. *See* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-BA-337, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS–SPECIAL REPORT, (1987); Wagner, *Human Tissue Research: Who Owns the Results?*, 69 J. PAT. TRADEMARK OFF. SOC'Y 329 (1987).

15. The following public opinion survey has been reported by the Office of Technology Assessment: 82% of the American public say that genetic engineering research should be continued; a majority believe the risks of genetic engineering have been greatly exaggerated; 58% believe that unjustified fears have impeded the development of valuable new drugs and therapies; 82% favor using genetically engineered organisms on a small-scale, experimental basis; 83% approve of using gene therapy to cure usually fatal genetic diseases; and 86% would be willing to have their child undergo human genetic therapy. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-BP-BA-45, NEW DEVELOPMENTS IN BIOTECHNOLOGY–BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY (1987) [hereinafter OTA PERCEPTIONS]. *But see* THE NOVO INFORMATION CENTER, THE NOVO REPORT: AMERICAN ATTITUDES AND BELIEFS ABOUT GENETIC ENGINEERING at iv (1987) ("[R]oughly four in five Americans either don't know what genetic engineering is or don't know enough about the science to understand the ethical issues involved.").

16. *See* Christian Science Monitor, Apr. 27, 1987, at 1, col. 1.

17. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-F-285, TECHNOLOGY, PUBLIC POLICY, AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE 31 (1986) [hereinafter OTA AGRICULTURE]. The aspects of this technological revolution are discussed in Part IV, *infra*. The information technology aspects of agriculture include central

enthusiastic about extending the patent incentive to the commercialization of animal biotechnology. Similarly dramatic advances in human and veterinary medicine are projected.[18] A variety of unpatented transgenic animals[19] are being used to produce human pharmaceutical compounds that would otherwise be commercially unavailable due to inadequate sources of supply or excessive costs of production. As examples of this "molecular farming," transgenic sheep produce human blood clotting factors[20] used to treat hemophiliacs, and transgenic mice produce tissue plasminogen activator (TPA)[21] used for the treatment of heart attacks.

Scientists further contemplate the development for human consumption of transgenic livestock that are leaner, more nutritious, and reach market size and weight more quickly and with a lower food input than traditional breeds of cattle and swine.[22] Transgenic cattle will also produce more milk per animal with similarly reduced food requirements.[23] Other transgenic animals will serve as experimental models for human diseases, such as hypertension and AIDS, for which no natural animal models exist.[24] The first animal patent issued on April 12, 1988

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computer systems linked to on-farm weather stations and, by radio links, to tractor and combine equipment, livestock identification and automatic feeding equipment, irrigation pumps and flow controls, livestock environment and waste monitoring controls, and crop, feed, and storage controls and processing equipment. *Id.* at 33.

18. OTA COMMERCIAL BIOTECH, *supra* note 9, at 119-57.

19. A transgenic organism has DNA from a foreign source integrated into its genetic material, *i.e.*, its chromosomes, collectively known as the organism's genome.

20. Human blood clotting Factor IX has been produced in the milk of transgenic sheep. 7 BIOTECH. NEWSWATCH, Aug. 17, 1987, at 1.

21. A transgenic mouse which produces tissue plasminogen activator (TPA) in its milk was recently announced by Integrated Genetics, Inc. and the NIH. Thompson, *From Mice, Anticlotting Drug–Rodents Altered to Produce Human Protein*, The Washington Post, Oct. 27, 1987, at A1, col. 5 [hereinafter Thompson]; Gordon, *Production of Human Tissue Plasminogen Activator in Transgenic Mouse Milk*, 5 BIO/TECH. 1183 (1987). The FDA has just approved TPA for market purposes. It is estimated that the prompt annual administration of TPA could prolong the lives of tens of thousands of Americans who would otherwise succumb to fatal heart attacks. Personal communication from Dr. Henry I. Miller, Special Assistant to the Commissioner of the Food and Drug Administration (March 14, 1988). Additionally, the world supply of Factor VIII, used for the treatment of blood clotting diseases such as hemophilia, could be produced by a herd of 100 transgenic cows. Thompson, *supra* at A12, col. 1.

22. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House of Representatives Comm. on the Judiciary*, 100th Cong., 1st Sess. 36-37, 46-49 (1988) (Testimony of Thomas E. Wagner, Professor of Molecular Biology and Director, Edison Animal Biotechnology Center, Ohio State University) [hereinafter Wagner Testimony and hearings in general, *Transgenic Hearings*].

23. OTA AGRICULTURE, *supra* note 17, at 83-85.

24. Wagner Testimony, *supra* note 22, at 47-49. Other animals used as models for studying arterial sclerosis have been bred by conventional means, but could benefit from genetic engineering. *Transgenic Hearings*, *supra* note 22, at 350-51 (Testimony of Russ Weisensel, Wisconsin Agribusiness Council) [hereinafter Weisensel Testimony].

and involves a transgenic non-human mammal, such as a mouse, that has been genetically modified to increase susceptibility to carcinogens.[25] Such animals will prove to be useful tools for research into the causes of and cures for human cancer.[26]

Opponents of animal patents argue that applying the patent system to animal technology will increase genetic research on animals. This, they collectively contend, will result in the violation of animals' rights *per se* and cause animal suffering. Additionally, they maintain that the patenting of plants and animals encourages a technology that will pose unacceptable risks to the environment, deplete the world's biological diversity,[27] induce human beings unethically to "play God," and create structural disruptions in American agriculture.[28]

As this Article goes to press, Congress is considering legislation introduced by Representative Charlie Rose (D, North Carolina) to place a two-year moratorium on the patenting of animals "changed through genetic engineering technology" in order to give Congress time to consider the ramifications of biotechnology.[29] Senator Mark Hatfield (R, Oregon) introduced a bill to ban permanently the issuance of patents on animals.[30] In the House of Representatives, the Subcommittee on Courts, Civil Liberties and the Administration of Justice, of the Committee on the Judiciary, recently held a series of hearings on the animal patenting issue (hereinafter "Transgenic Hearings").[31] Other

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25. U.S. Patent No. 4,736,866.

26. Gladwell, *Mouse Patent May Bolster Research Efforts: New Genetic Techniques Could Reduce Drug Costs*, The Washington Post, Apr. 13, 1988, at F1, Col. 2 [hereinafter Gladwell].

27. Biological diversity is officially defined as the "variety and variability among living organisms and the ecological complexes in which they occur." U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-F-330, TECHNOLOGIES TO MAINTAIN BIOLOGICAL DIVERSITY 3 (1987) [hereinafter OTA DIVERSITY]. For the purposes of this Article, "biological diversity" means the collective genetic material of a species from which desirable genetic traits may be identified and extracted or which can be altered by the insertion of foreign genetic material.

28. *See* Parts VI - X, *infra*.

29. H.R. 3119, 100th Cong., 1st Sess. (1987).

30. S. 2111, 100th Cong., 2d Sess. (1988). The moratorium proposed by this bill "is intended to give Congress the opportunity to assess the implications of animal patenting." CONG. REC. S1620, Feb. 29, 1988. Senator Hatfield previously introduced an amendment to the supplemental appropriations bill, H.R. 1827, 99th Cong., 1st Sess. to prohibit the PTO from granting patents on "vertebrate or invertebrate animals, modified, altered, or in any way changed through engineering technology, including genetic engineering" during the remainder of fiscal year 1987. 34 BNA PAT. TRADEMARK & COPYRIGHT J. 124 (1987). Although the Senate accepted the amendment and passed the bill, the animal patenting provision was deleted by the House-Senate Conference Committee. *Id.* at 277.

31. *Transgenic Hearings*, *supra* note 22. The Subcommittee's *draft* report, apparently opposed by several members, unequivocally recommended against, as both unwise and unnecessary, any prohibition or moratorium on the issuance of animal patents. *Senate Bill Seeks Animal Patenting Ban; House Panel Stalls on Issue*, 8 BIOTECH. NEWSWATCH, Apr. 4, 1988, at 6.

committee hearings are expected in 1988. The discussion in this Article focuses on the positions espoused at the Transgenic Hearings.

Opponents of animal patenting make four central but largely unsupported assumptions, later discussed on a topical basis. First, they assume that a moratorium will slow current transgenic research sufficiently to affect the rate by which regulatory issues arise. Second, they suggest that a patent moratorium will abate the existing need for policy and regulatory initiatives by Congress and the federal agencies that regulate the process and products of biotechnology, *e.g.*, the National Institutes of Health (NIH), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). Third, they assume that the applications of transgenic animal technology alone require a level of oversight which regulatory agencies cannot provide under existing or proposed statutory authority. Finally, they contend that a technological hiatus is required to allow Congress to reflect on these foregoing matters.

Patenting opponents tend to ignore or deprecate the positive aspects of biotechnology by commingling complex issues and raising extreme scenarios.[32] These parties also minimize or disregard significant domestic effects of a technology slowdown due to a ban on animal patents. The rate of increase in scientific knowledge about how genes are controlled–knowledge applicable to ongoing research on plants, animals and medicine–may diminish.[33] A ban is also likely to decrease the business incentive to develop and commercialize transgenic animals such as the patented mouse, and "molecular farming" products such as TPA and blood clotting

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32. *See generally Transgenic Hearings, supra* note 22 for the testimony of opponents to animal patenting. Alexander Morgan Capron commented, in response to a statement by church leaders calling for a ban on human genetic engineering, "The real danger is that broadside attacks that mix together many complex issues will diminish support for–or even lead to prohibitions on–those uses of genetic engineering techniques that are manifestly beneficial in treating and even curing diseases. There is no question that the new genetics offers the brightest hope for understanding and eventually controlling many debilitating and sometimes lethal conditions–from Tay-Sachs disease and sickle-cell anemia to cancer." Capron, *Don't Ban Genetic Engineering*, The Washington Post, June 16, 1983, at A29, col. 1 (editorial) (Capron was executive director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research).

33. In rejecting calls to prohibit federally funded transgenic animal research through the NIH Recombinant DNA Guidelines, the NIH Recombinant DNA Advisory Committee stated that, "Both the importance of this class of experiments in current scientific research and the long-term possibilities for treatment of human and animal disease and the development of more efficient food sources make it a moral imperative that we strongly oppose the blanket prohibition of this class of experiments." 50 Fed. Reg. 9760, 9767 (1985). *See also* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, NATIONAL INST. OF HEALTH, PUB. NO. 84-662, THE NEW HUMAN GENETICS: HOW GENE SPLICING HELPS RESEARCHERS FIGHT INHERITED DISEASE (1984).

factors.[34] Farmers denied advances in agricultural technology may actually be penalized, since biotechnology should increase their output and decrease their capital costs due to improved disease resistance in crops and livestock and to higher productivity in general.[35] Also, a ban may enhance foreign competitors' opportunities to penetrate into U.S. markets.[36] Consequently, U.S. competitiveness in foreign markets may also suffer.[37]

In the international context, the world population of five billion people is projected to double in the next sixty years.[38] Meanwhile, over twenty million people in the developing world die every year of starvation-related diseases, and an additional five hundred million people suffer from malnutrition.[39] Although many regions of the world now produce sufficient calories to feed current populations,[40] improvements in resource management, food storage facilities and distribution networks may be inade-

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34. *See* Part III, *infra*. According to industry experts, "with the guarantee of patent protection for the fruits of research and development, the number of companies doing research–and the amount of money spent on it–could skyrocket in the next few years. The result could be dramatically lower costs for producing drugs." Gladwell, *supra* note 26.

35. OTA AGRICULTURE, *supra* note 17, at 12.

36. For example, China utilizes a swine growth hormone in large scale commercial testing situations, and U.S. farmers will need to compete with imported canned ham which is 70% fat free due to the influence of that hormone on animal growth. Wagner Testimony, *supra* note 22, at 40.

37. Some commentators feel that it is essential to provide American farmers with enhanced technology to keep them competitive. *Id. See also Transgenic Hearings*, *supra* note 22, at 320 (Testimony of Donald Haldeman, dairy farmer and President, Wisconsin Farm Bureau Foundation). Haldeman testified that he feared for the competitive position of Wisconsin farmers if animal agriculture were denied the "the newest wave of technology, as in areas of plants." *Id.* at 320-21. For example, developing countries in the past decade have been the fastest growing market for U.S. agricultural exports, accounting for 52 million metric tons of cereals and feed grains in 1983, or 50% of all such exports. Brady, *Agricultural Research and U.S. Trade*, 230 SCI. 499 (1985). Continued presence in these markets will likely require accelerated growth in overall agricultural productivity. *See* Barr, *The World Food Situation and Global Grain Prospects*, 214 SCI. 1087, 1090 (1981). Biotechnology should ultimately provide this growth. OTA COMMERCIAL BIOTECH, *supra* note 9, at 161-91; OTA AGRICULTURE, *supra* note 17, at 31-54. Future development and marketing strategies for the industrialized countries must also involve new agricultural systems and technologies adapted to the intended soils and climates. El-Ashry, *Famine: Some Additional Aspects*, 236 SCI. 1503, 1504 (1987).

38. INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT/THE WORLD BANK, WORLD DEVELOPMENT REPORT 7 (1984) [hereinafter WORLD DEVELOPMENT REPORT].

39. Press, President's Message in National Academy of Sciences, Office of Public Affairs Brochure at 3 (1984). *See also Transgenic Hearings*, *supra* note 22, at 370 (remarks of Congressman Moorhead, who agreed that in view of such "sobering realities," every reasonable incentive must be provided to those entities which conduct agricultural research and development. Congressman Moorhead noted nevertheless that the economic, ethical and other questions regarding the patenting of transgenic animals needed to be considered.).

40. *See* WORLD DEVELOPMENT REPORT, *supra* note 38, at 90-96.

quate in light of explosive population growth in many countries.[41] Thus, continuing advances in agricultural productivity through biotechnology and information technology will be necessary to keep pace with world food demand in the coming decades.[42] Even a two-year moratorium could seriously impact people deleteriously affected by delays in medical developments and food production.[43] New technologies are necessary to meet these food demands without upsetting the earth's delicate environmental balance.[44]

Finally, world-wide research and development in agricultural biotechnology will continue at an accelerating pace,[45] whether or not the United States bans animal patenting or even transgenic research. Whether to apply the patent incentive to transgenic animals may be a critical trade decision for the United States.[46]

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41. For example, the annual shortfall in rice production is projected to exceed 300 million tons by the year 2000. Swaminathan, *Biotechnology Research and Third World Agriculture*, 218 SCI. 967 (1982). Twenty-nine developing countries will be unable to feed themselves at the turn of the century. WORLD DEVELOPMENT REPORT, *supra* note 38, at 91.

42. The annual agricultural productivity increase needed to meet agricultural demand by the year 2000 can be possible only through the development and adoption of emerging technologies, *i.e.*, biotechnologies and information technologies. OTA AGRICULTURE, *supra* note 17, at 3, 84-85.

43. *Transgenic Hearings*, *supra* note 22, at 411 (Testimony of LeRoy Walters, Ph.D., Director, Center for Bioethics, Kennedy Institute of Ethics, Georgetown University) [hereinafter Walters Testimony]. "If there is an ethical dimension to the argument in favor of going ahead with patenting immediately, it would be that, if the system is disrupted and if there is a two-year moratorium, that delay is likely to delay the delivery of new medical benefits and possibly new benefits in terms of food production for the world's people." *Id.* To use the patent system to control technological risks "could seriously delay lifesaving new medicines and major agricultural breakthroughs." *Transgenic Hearings*, *supra* note 22, at 433 (Testimony of Geoffrey M. Karny, Esq.) [hereinafter Karny Testimony]. Harvard Professor Philip Leder, one of the inventors of the first patented animal, responded to critics of animal patenting, saying, "[I]t isn't right to stand by while thousands of American women die of cancer." *U.S. Patent Leaves Barnyard Gate Open*, Boston Globe, Apr. 13, 1988, at 1, col. 1.

44. Weisenel Testimony, *supra* note 24, at 350.

45. *See* YUAN, BIOTECHNOLOGY IN WESTERN EUROPE (International Trade Administration, U.S. Dept. of Commerce, 1987); Colwell, *Biotechnology Latin American Style*, 54 AM. SOC'Y. MICRO. NEWS, No. 1, at 6 (1988); McSweegan, *Biotechnology in the Soviet Union*, *Id.*; BOARD ON SCIENCE AND TECHNOLOGY FOR INTERNATIONAL DEVELOPMENT, NATIONAL RESEARCH COUNCIL, PRIORITIES IN BIOTECHNOLOGY RESEARCH FOR INTERNATIONAL DEVELOPMENT (1982) [hereinafter INTERNATIONAL DEVELOPMENT].

46. According to Robert Reich, a professor at Harvard University's Kennedy School of Government, "The U.S. continues to lead the world in new patents and Nobel laureates and other indices of inventiveness. Our real problem is that we don't get inventions from the laboratory to the workplace nearly as fast or as efficiently as our trade competitors do. These days new ideas developed in Cambridge can reach Seoul as fast as they reach Providence. The difference comes in how skillful is the work force in incorporating new ideas." Gladwell, *Foreigners Get 46.6% of U.S. Patents*, The Washington Post, Feb. 26, 1988, at F1, col. 2. *See also* OTA COMMERCIAL BIOTECH; U.S. DEPARTMENT OF COMMERCE, INTERNATIONAL TRADE ADMINISTRATION, BIOTECHNOLOGY (HIGH TECHNOLOGY INDUSTRIES: PROFILES AND OUTLOOKS) (1984); NATIONAL RESEARCH COUNCIL, INTERNATIONAL COMPETITION IN ADVANCED TECHNOLOGIES; DECISIONS FOR AMERICA (1983); De Young, *Biotechnology: Homing in on Healthcare* in *Special Report: Japan's Technology Agenda*, 5 HIGH TECH., No. 8, at 53 (1985); Sun, *The Japanese Challenge in Biotechnology*, 230 SCI. 790 (1985).

Although Japan and some European countries do not yet grant patents on plants and animals,[47] these nations have targeted biotechnology for special governmental support and funding programs.[48] Developing countries are also seeking means to enhance human health and animal productivity through biotechnology.[49]

III. OVERVIEW OF THE PATENT SYSTEM

> The patent system . . . added the fuel of interest to the fire of genius in discovery and production of new and useful things.
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> Abraham Lincoln[50]

Providing for a federal patent system was a priority of the drafters of the Constitution[51] at a time when our nation was under-industrialized. Article I, Section 8, Clause 8 of the United States Constitution authorizes Congress to enact a patent system "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[52] Traditionally, the

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47. European companies, for example, have been urging their governments to bring European patent law in line with that of the United States. *Transgenic Hearings*, *supra* note 22, at 128 (remarks of Congressman Coble). *See also infra* notes 160-61 and accompanying text.

48. For example, the government of Japan recently gave 10 awards of $2 million each to key researchers, one of whom is involved in transgenic animal studies. *Transgenic Hearings*, *supra* note 22, at 258 (Testimony of Winston J. Brill, Ph.D., Vice-President, Research and Development, Agracetus Corp.) [hereinafter Brill Testimony]. Following the stock market collapse in October 1987, U.S. biotechnology companies may have particular difficulty in raising the necessary funds and are potential takeover targets for U.S. and foreign corporations. *Biotechnology's Stock Market Blues*, 238 SCI. 1503, 1504 (1987); Klausner, *Biotech Analysts' Predictions for '88*, 6 BIO/TECH. 32 (1988).

49. *See, e.g.*, INTERNATIONAL DEVELOPMENT, *supra* note 45; Dingell, *Benefits for the Developing World*, 3 BIO/TECH. 752 (1985); Joseph, *The African Crisis: Loud and Silent Emergencies*, 3 BIO/TECH. 700 (1985); Poste, *The Pharmaceutical Industry and Health Care*, 3 BIO/TECH. 704 (1985); Goodman, *Bringing New Technology to Old World Agriculture*, 3 BIO/TECH. 708 (1985).

50. Lecture on "Discoveries, Inventions and Improvements" (Feb. 22, 1860). Lincoln was himself a patentee. U.S. Patent No. 6,469 was granted to him in 1849.

51. "The utility of this power will scarcely be questioned . . . . The public good fully coincides . . . with the claims of individuals." THE FEDERALIST NO. 43, at 271-72 (J. Madison) (C. Rossiter ed. 1961). Forman, *Two-Hundred Years of American Patent Law*, in 200 YEARS OF ENGLISH AND AMERICAN PATENT, TRADEMARK AND COPYRIGHT LAW at 21, from ABA Bicentennial Symposium 1976 (ABA 1977). Patent systems in one form or another have existed since antiquity. *See* Rich, *The Relation Between Patent Practices and the Antimonopoly Laws*, 24 J. PAT. OFF. SOC'Y 85 (1942).

52. For a more detailed overview of patent law in the genetic engineering context, *see* the masterful opinion of Judge Giles S. Rich in *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977); *see also* Adler, *Biotechnology as an Intellectual Property*, 224 SCI. 357 (1984).

patent system has not been used to control technological risks.[53] The authority to regulate the applications of biotechnology arises primarily under the "commerce" clause of Article I, Section 8, Clause 3 and the "general welfare" clause of Article I, Section 8, Clause 1. Limiting the scope of patent protection in order to control particular *uses* of biotechnology is thus rather indirect and indiscriminate regulation.

The patent system accomplishes its goals in several ways. First, it expands the technological information pool through weekly publication of newly-issued patents by the PTO. Second, and perhaps most importantly, the patent system provides potential protection as an inducement to a patent owner to risk the expenditure required to commercialize an invention.[54] Third, the system encourages competition to "invent around" or improve upon a patented invention.[55] This characteristic further advances technology by stimulating innovation.

A. Legal Aspects

A patent establishes a property right held by the grantee (*i.e.*, patentee) for a limited term of seventeen years.[56] This right is defined by at least one written claim,[57] which is analogous to the

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53. The notable exception is based on reasons of national security and concerns inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Atomic Energy Act of 1954 § 151(a), 42 U.S.C. § 2181a (1982). *See also* Karny Testimony, *supra* note 43, at 433 and 439-40. The apparent reason for this exception is that not only the products of the technology, but also the *knowledge* of the technology is a defense secret. In contradistinction, no one seriously suggests that biotechnologies should be classified.

54. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). The development of a commercial pharmaceutical costs about $100 million and takes a decade. *Transgenic Hearings*, *supra* note 22, at 136 (Testimony of William H. Duffey, General Patent Counsel, Monsanto Corp., on behalf of the Industrial Biotechnology Association and the Industrial Property Owners, Inc.) [hereinafter Duffey Testimony]. The U.S. pharmaceutical industry also operates under a variety of federal regulations within the patent system, and "is the envy of the entire developed world." *Transgenic Hearings*, *supra* note 22, at 297 (Testimony of Michael S. Ostrach, Senior Vice-President, Legal Affairs, and General Counsel, Cetus Corp.).

55. PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, TO PROMOTE THE PROGRESS OF THE USEFUL ARTS, S. DOC. NO. 5, 90th Cong., 1st Sess. at 11 (1967) [hereinafter PATENT COMMISSION]; "There are only rare instances of any situations where somebody obtains a patent on something that gives them a real monopoly in a field. What it really does when a patent is granted is stimulate others to invent around it, to improve upon it, to find a different way to do the same thing, and it spurs competition rather than restricts competition." *Transgenic Hearings*, *supra* note 22, at 27 (Testimony of Rene D. Tegtmeyer, Assistant Commissioner for Patents) [hereinafter Tegtmeyer Testimony].

56. 35 U.S.C. § 154 (1982).

57. *Id.* § 112, para. 2 (1982). Claim 1 of United States Patent No. 4,736,866 recites: "A transgenic non-human animal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or ancestor of said mammal, at an embryonic stage."

description of land in a deed. The right granted by a patent is also limited in effect: a patentee may only exclude others from making, using or selling the patented invention.[58] The patentee has only this intangible right to exclude, and has no affirmative statutory right to make, use, or sell the patented invention or an ownership interest in embodiment of a patented invention. Thus, for example, a patentee cannot sell a patented, genetically engineered pharmaceutical absent approval by the Food and Drug Administration (FDA),[59] cannot release genetically engineered microbial pesticides without a registration or experimental use permit from the EPA,[60] cannot release certain genetically engineered plants and animals defined as plant pests without permission from the USDA,[61] and cannot subject most non-farm animals to transgenic experimentation without approval by institutional review committees pursuant to federal guidelines.[62] A patentee may additionally be subject to municipal ordinance or common law, as in the case of a noisome patented invention.[63] Furthermore, the existence of a patent is no guarantee of commercial success for a product.[64]

To be patentable, the Patent Act requires that the claim(s) defining an invention must encompass subject matter that is useful,[65] novel,[66] and nonobvious.[67] The last provision disallows patent protection for those inventions that are so closely related

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58. *Id.* § 154 (1982 & Supp. 1984). The "right to exclude" may be enforced only in a federal civil action. 28 U.S.C. § 1338 (1982). A patentee may also recover damages from an infringer. 35 U.S.C. § 284 (1982).

59. The FDA regulates biotechnology on a product-by-product basis, under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982, Supp. I 1983, Supp. II 1984, Supp. III 1985 & Supp. IV 1986) and the Public Health Service Act, 42 U.S.C. § 262 (1982 & Supp. IV 1986).

60. Federal Insecticide Fungicide Rodenticide Act (FIFRA), 7 U.S.C. § 136-136y (1982, Supp. I 1983, Supp. II 1984, & Supp. III 1985); Toxic Substances Control Act (TSCA), 5 U.S.C. §§ 2901-2929 (1982). The EPA's implementing regulations for biotechnology are in OSTP Framework, *supra* note 4. *See also* Part VII, *infra.*

61. Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj (1982); Plant Quarantine Act, 7 U.S.C. §§ 151-167 (1982); Federal Noxious Weed Act, 7 U.S.C. §§ 2801-2813 (1982). The USDA's implementing regulations are at 52 Fed. Reg. 22,892 (1987) (to be codified at 7 C.F.R. § 340). *See* Part VII, *infra.*

62. 7 U.S.C. § 2143 (1982 & Supp. III 1985); Health Research Extension Act of 1985, Title IV–Animals in Research, 42 U.S.C. §§ 210 to 300c-12 (Supp. III 1985). *See* Part VI, *infra.*

63. *See, e.g.*, Patterson v. Kentucky, 97 U.S. 501 (1878); *see also* D. CHISUM, PATENTS § 16.02[1][b] at 16-8 (1987).

64. Consumer preferences, quality control, pricing and marketing are all factors which contribute to commercial success. Karny Testimony, *supra* note 43, at 439.

65. 35 U.S.C. § 101 (1982); *see also id.* § 112.

66. *Id.* § 102. Novelty does not apply to natural products in their natural form or products previously existing in the public domain. For example, a claim to a pure culture of a bacterium existing naturally in soil intermixed with hundreds of other bacteria is useful in its pure culture form to produce antibiotics, and is therefore patentable. *Ex parte* Jackson, 217 U.S.P.Q. 804 (PTO Bd. Pat. App. 1982).

67. *Id.* § 103 (1982 & Supp. II 1984).

to what was already known or existing in the public domain that attainment of the invention is within the capability of a hypothetical worker of ordinary skill in the pertinent technological field.[68] In exchange for the rights to be granted by a patent, a patent *application* must also satisfy the "enablement" provision of section 112. The "specification" (*i.e.*, application text) must contain a written description of the invention claimed and "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 . . . to make and use the same."[69]

Because even the lengthiest written description would be incapable of illustrating how to make a living organism from elemental or biochemical starting materials, a supplemental procedure for satisfying the enablement requirement was developed for patent applications claiming microorganism-related inventions.[70] An applicant for a patent may deposit a sample microorganism (or cell line, recombinant DNA, antibody, etc.) in an appropriate repository where the deposited item can be retrieved by catalogued accession number and utilized as a publicly-available "stock" reagent for making or using the invention described in the specification.[71] The PTO has proposed to accept for enablement purposes the deposit of plant seeds or plant cells that are capable of developing into a patented plant.[72]

The enablement requirement may be a difficult problem for animal inventions,[73] and therefore illustrates the continuing need for patent law to adapt to emerging technologies. The PTO has assumed, without basis, that transgenic animals will be derived from known and readily available animals and will be developed through reproducible processes. This approach conveniently eliminates the need for administrative treatment of the issue and

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68. Graham v. John Deere Co., 383 U.S. 1 (1966). This opinion judicially sanctioned a quasi-objective standard by which nonobviousness was to be determined. Prior to the Patent Act of 1952 and this decision, the standard of patentability, *i.e.*, "invention," was a highly subjective determination, unduly subject to the hindsight of trial judges. *See* NONOBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY (J. Witherspoon ed. 1980).

69. 35 U.S.C. § 112, para. 1 (1982).

70. *See* Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. PAT. TRADEMARK OFF. SOC'Y 455 (1983); Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirements*, 67 J. PAT. TRADEMARK OFF. SOC'Y 569 (1985).

71. Microorganism and DNA vector deposits, as examples, are typically preserved in viable condition by freezing in liquid nitrogen. *See In re* Lundak, 773 F.2d 1216 (Fed. Cir. 1985). An Advance Notice of Proposed Rulemaking to modify existing rules governing the deposit of biological materials for patent purposes was recently published by the PTO. 52 Fed. Reg. 34,080 (1987).

72. 52 Fed. Reg. 34,081.

73. The PTO notes, for example, that it is "presently not aware of any organization that is willing and able to undertake the responsibilities of a suitable depository for live animals." *Id.*

begs the question of enablement. As with microorganisms and plants, the original creation of a transgenic animal is often likely to be so complex or fortuitous as to deny "enablement" to a given patent application if unsupported by the deposit of an appropriate biological specimen.[74] If the PTO is unable to promulgate a more realistic technological standard for determining enablement of animal inventions, the PTO could reject animal claims for lack of enablement. Eventually Congress may need to legislate a reduced standard for enablement of animal inventions.

B. Economic Aspects

In an economic sense, patents are intended to maximize long term allocative and productive efficiencies. Social detriment occurs when output restriction, in general monopoly terms, exceeds increased industrial efficiency.[75] Any temporary "monopoly" prices[76] and inefficient resource allocations to "invent around" a patented invention are thus the trade-offs for greater long-run output. Conventional wisdom holds that in the absence of patents, inventive activity would diminish for want of incentive.[77] Furthermore, inventive activity without patent protection could be inefficiently biased toward inventions protectable by trade secrets,[78]

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74. The first animal patent complied with the enablement requirement in part by depositing plasmids bearing activated oncogene fusion genes. *See* U. S. Patent No. 4,736,866 at col. 9, lines 20-24.

75. W. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL 2-3 (1973).

76. The costs of production of patentable products do not necessarily increase. For example, Integrated Genetics, Inc., *supra* note 21, hopes to shift production of human TPA from transgenic mice to transgenic goats. Gladwell, *supra* note 26. One dose of TPA now costs $2200, largely due to the high costs of conventional protein manufacturing techniques, and 100 transgenic goats could produce the same amount of TPA as a $50 million plant the size of a football field. *Id.*

77. *See, e.g.*, remarks by Congressman Smith of Iowa that "without adequate patent protection, the commercialization of a new idea is far too costly and too risky for small firms." Floor Remarks in favor of H.R. 6933 to amend the patent law. 96 CONG. REC. 29,895-96 (1980). Referring to the issuance of the first animal patent, Don Hudson, President of Transgenic Sciences, Inc., noted, "The stakes have now been raised . . . . [T]his patent decision gives everyone much more incentive to enter the field." Gladwell, *supra* note 26.

78. *See* Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 190-95 (discussing trade secrecy's ineffective protection in competitive research fields). "If we resort or allow parties to resort to trade secrecy and encourage that instead of the patenting, we will slow down the development. Some part of it will still occur, some of it will not. If high investments and low profit margins are involved and there is a risk you can reverse engineer, the development may not ever reach the marketplace. Where it does, it is going to be masked in secrecy." Tegtmeyer Testimony, *supra* note 55, at 310. Additionally, because of the economics of developing improved breeding stocks, trade secrecy will "keep the individual farmer completely out of the game." Wagner Testimony, *supra* note 22, at 98.

thereby depriving society of technological information and further wasting resource allocation in efforts to penetrate commercial secrecy.[79]

Some commentators conclude that the patent system exerts a strong positive influence on innovation.[80] Although rigorous scientific data to prove the favorable impact of the patent system are limited,[81] economists generally agree that the available evidence does not support termination of the patent system.[82] For example, a recent empirical study supports the role of the patent system in inducing industry to invest in developing new technology.[83] According to the companies surveyed, the three most important reasons for filing a patent application were: (1) securing a technological advantage over competitors; (2) securing important foreign markets through long-term patent protection in those countries; and (3) protecting new investments necessary to market an invention.[84]

Most researchers feel that the patenting process is more conducive to the sharing of information between scientists than is trade secrecy. *Transgenic Hearings*, *supra* note 22, at 209 (Testimony of Dean Leo Walsh, Dean of the College of Agriculture, Life Science, University of Wisconsin at Madison) [hereinafter Walsh Testimony]. Lipsey, *Protecting Trade Secrets in Biotechnology* (pts. 1-2), 2 TRADE SECRET L. REV. 21, 41 (1986); Kiley, *Trade Secrets and Biotechnology* in PROTECTING TRADE SECRETS 413 (1981); and Whale, *Trade Secrets and Biogenetic Engineering* in PROTECTING TRADE SECRETS 405 (1981).

79. R. POSNER, ECONOMIC ANALYSIS OF LAW 2d at 53 (1977).

80. PATENT COMMISSION, *supra* note 55; Troller, *Industrial Property, Catalyst and Stabilizer of International Economic Cooperation*, 26 IND. PROP. 444 (1987); Jucker, *Drug Innovation and Patents* 10 AM. PAT. LAW ASS'N Q.J. 81 (1982); Rabinow, *Are Patents Needed*, 18 IDEA, No. 3, at 19 (1976); Udell, *To Promote The Progress of Science and Useful Arts: Public Law and Technological Innovation*, 22 IDEA 285 (1977). The Plant Variety Protection Act of 1970 is also believed to have dramatically increased at least the number of private soybean breeding programs. *Transgenic Hearings*, *supra* note 22, at 293-94 (Testimony of Richard D. Godown, President, Industrial Biotechnology Association) [hereinafter Godown Testimony]. *See* Part VIII, *supra*.

81. *See, e.g.*, Marquir, *An Economic Analysis of the Patentability of Chemical Compounds*, 63 J. PAT. OFF. SOC'Y 3 (1981); Panel Discussion, *The Value of Patents and Other Legally Protected Commercial Rights*, 53 ANTITRUST L.J. 535 (1985).

82. *See, e.g.*, Machlup, *An Economic Review of the Patent System*, STUDY NO. 15 IN THE STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 85th Cong., 2nd Sess. (1958); Mansfield, *Patents, Innovation, and U.S. Technology Policy*, 10 AM. PAT. L.A.Q.J. 35 (1982). More comprehensive research on these points would undoubtedly be helpful.

83. Oppenlander, *The Influence of the Patent System on Readiness of Industry to Invest–An Empirical Analysis*, 25 IND. PROP. 494 (1986). The analysis of motivation for filing patent applications was based on a study jointly instituted and completed in 1985 by the European Patent Office, the Commission of the European Communities and the Ifo Institute for Economic Research in Munich, Federal Republic of Germany.

84. *Id.* Interest in filing patent applications for biotechnological products is high, with over 6,000 applications presently pending. Weiss, *Technology and Law: How Do You Patent a New Elephant?*, The Washington Post, Sept. 20, 1987, at C3, col. 1. The volume of patent applications has created a 4.5-year pendency for patent applications in the biotechnology field. Crawford, *Patent Claim Buildup Haunts Biotechnology*, 239 SCI. 723 (1988). This patent backlog is considered serious enough to warrant Congressional hearings. *Hearings Before the Sub-*

Because much of the present commercial development of biotechnology is performed by small start-up ventures, companies may depend heavily on patent protection to justify the major research and development investments necessary to undertake difficult technological challenges.[85] Agricultural research, development and marketing, and private sector involvement have increased since more limited types of plant protection became available.[86] Still, innovation also responds to commercial exigencies–such as uniform maturation dates, resistance to bruising during handling and transportation, and mechanized harvesters' need for crops of uniform height–as well as a myriad of other factors. Thus an absolute correlation between patents and agricultural innovation is obscured.[87]

Primarily the farmers critical of animal patents question the need for increased agricultural productivity in light of our country's 200 years of tremendous agricultural advances.[88] Specifically, they maintain that at a time when farmers are paid

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comm. on Regulation and Business Opportunities of the House Comm. on Small Business, 100th Cong., 2d Sess. (Mar. 29, 1988) [hereinafter *Patent Backlog Hearings*]. Yet, the "patent approval process can shape–or warp–the future of an entire fledgling industry" since "patents are the financial and legal backbone of any biotech firm." *Id.* (Statement of Subcomm. Chair, Ron Wyden (D, Oregon)).

85. Brill Testimony, *supra* note 48, at 224; Karny Testimony, *supra* note 43, at 454-55. "Patent protection is the lifeblood of the pharmaceutical and biotechnology industries," according to Steven Holtzman, CEO of Embryogen Corp. Gladwell, *supra* note 26. There is evidence that increases in stock prices of biotech companies reflect issuances of patents. *Patent Backlog Hearings*, *supra* note 84 (Testimony of Linda I. Miller, First Vice President, Paine Webber, Inc.). Senator Patrick Leahy (D, Vermont) has further stated that international patent protection is necessary to protect inventors and entrepreneurs. 4 INT. TRADE REP. 1407 (1987). *See also* NATIONAL RESEARCH COUNCIL, INTERNATIONAL COMPETITION IN ADVANCED TECHNOLOGY: DECISIONS FOR AMERICA 39 (1983); OTA COMMERCIAL BIOTECH, *supra* note 9, at 16-17.

86. *See* Evenson, *Intellectual Property Rights and Agribusiness Research and Development: Implications for the Public Agricultural Research System*, 65 AM. J. AGR. ECON. A. 967 (1983) [hereinafter Evenson], who found a sharp acceleration in private plant breeding programs after enactment of the PVPA. *See also* HOUSE COMMITTEE ON AGRICULTURE, PLANT VARIETY PROTECTION ACT AMENDMENTS [TO ACCOMPANY H.R. 999], H.R. Rep. No. 1115, 96th Cong., 2d Sess. 4-5 (1980); Murphy, *Plant Breeders' Rights in the United Kingdom*, 1 EUR. IND. PROP. REV. 236, 240 (1978).

87. Adler, *Can Patents Coexist with Breeders' Rights? Developments in U.S. and International Biotechnology Law*, 17 INT. REV. IND. PROP. COPYRIGHT L. 195, 220-21 (1986) [hereinafter Adler Patents].

88. *Transgenic Hearings*, *supra* note 22, at 69, 82-83 (Testimony of Jack Doyle, Director, Agricultural Resources Project, Environmental Policy Institute) [hereinafter Doyle Testimony]; *Transgenic Hearings*, *supra* note 22, unprinted letter submitted for the record (Statement of Charles L. Frazier, Director, Washington Office, National Farmers Organization) [hereinafter Frazier Testimony]; *Transgenic Hearings*, *supra* note 22, at 115 (Testimony of Cy Carpenter, President, National Farmers Union on Behalf of National Farm Organization, American Agricultural Movement, Coalition to Save the Family Farm, and League of Rural Voters) [hereinafter Carpenter Testimony].

by the federal government not to produce milk[89] and not to plant certain crops[90] because of overproduction, there is no need for transgenic animals and plants that are even more productive.[91] This insular view may be a reaction against demographic changes in the agricultural sector that will occur regardless of the animal patent outcome.[92] The anti-patent position somewhat conflicts with OTA's assessment of the need for continuing biotechnological development[93] and with recognition of the patent system's role in developing and commercializing technology.

Critics further contend that sufficient economic incentive exists without animal patents for agricultural biotechnology companies to form or to continue doing business.[94] They also speculate that transgenic animals would be more cheaply available to farmers and with greater competition in the absence of patents.[95] Yet, an inventor has control of an unpatented animal only during the time before the animal reproduces, while patents grant a monopoly for 17 years.[96] The absence of patent protection reduces the time available in which to recover the financial investment, and raises initial product prices. Thus, companies will exist only if the market can bear this increased price.[97]

IV. OVERVIEW OF CURRENT PLANT AND ANIMAL GENETIC TECHNOLOGY

> The world's many paths diverge, in both reality and imagination. . . . But it may happen that some of our fellow mammals will one day be our partners.
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> David Brin, *Startide Rising*[98]

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89. The federal government funds 63% of the dairy buyout program which has a total cost of $1.8 billion and attempts to cut milk production by 8.7%. The use of bovine growth hormone injected into cows to increase milk production promises to increase total milk production by 10-40%. *Transgenic Hearings*, *supra* note 22, at 330 (Testimony of Debra Schwarze, Esq., The Wisconsin Family Farm Defense Fund, Inc.) [hereinafter Schwarze Testimony]. The impacts of hormones and transgenic technology are discussed in Part X, *infra*.

90. OTA AGRICULTURE, *supra* note 17, at 115.

91. Carpenter Testimony, *supra* note 88, at 115.

92. *See* Part X, *infra*.

93. OTA AGRICULTURE, *supra* note 17, at 12.

94. Doyle Testimony, *supra* note 88, at 12-13 (over 100 livestock biotechnology companies were formed before the PTO's decision to patent animals).

95. *Transgenic Hearings*, *supra* note 22, at 311 (Testimony of Stewart Huber, President, Farmers Union Milk Marketing Cooperative) [hereinafter Huber Testimony].

96. *See infra* note 157 and accompanying text.

97. *Id.*

98. D. BRIN, STARTIDE RISING 461-62 (1983).

Although genetic manipulation of plants, animals and microbes has served human purposes for thousands of years,[99] modern biotechnology will have a tremendous impact upon agricultural productivity.[100] Emerging scientific developments will create a biotechnology and information technology era for crops and livestock as significant as the preceding eras of farm mechanization (1930-1950) and agricultural chemistry (1950-1970).[101] The costs and benefits of agricultural biotechnology, considered in isolation, are highly favorable. Animal-related capital costs to farmers will decrease and farm productivity will increase.[102] Enhanced disease resistance and reduced feed, pesticide and fertilizer inputs will provide the American agricultural sector with a "decided advantage over competing nations."[103]

Understanding this technology is essential for effective regulation, because misunderstanding and emotional reaction cloud discussions of patenting, as well as those of health, safety and other regulatory concerns.[104] Genetic engineering is expected to overcome the randomness of heritability associated with conventional plant and animal breeding.[105] Thus, a genetic engineer will be able to predict, much more accurately than could a breeder, the genetic traits of a transgenic plant or animal. Changes in crops and livestock could therefore be accomplished more expeditiously through genetic engineering than through conventional techniques for producing transgenic organisms, *i.e.*, selective breeding.[106] (Present technology, however, permits only the addition of a gene at a new site, not the replacement of a defective gene.[107])

Nevertheless, biotechnological developments will ultimately depend upon conventional breeding techniques to reliably establish new traits in marketable varieties of plants and animals.[108]

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99. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *Transgenic Animals* at 5 (Staff Paper 1988) [hereinafter OTA ANIMALS]. In fact, many feel that the new biotechnologies are not a radical departure from historical practices. *Id.*

100. *See, e.g.*, OTA AGRICULTURE, *supra* note 17; OTA COMMERCIAL BIOTECH, *supra* note 9; Brill, *Genetic Engineering Applied to Agriculture: Opportunities and Concerns*, 68 AM. J. AGRIC. ECON. 1081 (1986) [hereinafter Brill Agriculture].

101. OTA AGRICULTURE, *supra* note 17, at 31.

102. *Id.* at 12. Information technology cost increases may more than offset the biotechnology savings, however. *Id.*

103. Wagner Testimony, *supra* note 22, at 46; *See* Brill Testimony, *supra* note 48, at 223.

104. Brill Testimony, *supra* note 48, at 218.

105. Additionally, the technology which allows the establishment of a desired trait in a transgenic animal line in as little as one generation, rather than the many generations of selective breeding required by conventional breeding, also allows scientists to avoid the simultaneous transfer of unwanted genetic material. OTA ANIMALS, *supra* note 99, at 5.

106. *Id.* at 4.

107. Roizman, *Molecular and Genetic Engineering: The Principles, the Power and the Promise*, 239 SCI., Feb. 12, 1988, at G110 (pt. II).

108. Reid, *Biotechnology and Breeding Team Up in Agriculture*, 5 BIO/TECH. 899 (1987).

Due in part to this technical interdependence, it is projected that varieties of plants improved by gene transfer will be commercially available in 7 to 10 years.[109] For animals, the low efficiency of present techniques in producing transgenic eggs, genetically stable transgenic embryos, and viable or fertile transgenic animals[110] limits the application of gene transfer technology.[111] Still, varieties of transgenic animals of substantial economic importance or research utility are expected to be marketed within 5 to 10 years.[112]

One of the ultimate goals for the application of biotechnology to plant agriculture is the modification of crops to yield more nutritious seed and fruit. Some plant research seeks to develop virus tolerance,[113] pest resistance,[114] and herbicide tolerance.[115] Chemical control of plant pests worldwide is estimated to cost over $3 billion annually.[116] Other research seeks to modify plants to survive in harsh environments and to carry out nitrogen fixation.[117] Through genetic engineering, future agriculture should be

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109. OTA AGRICULTURE, *supra* note 17, at 47; Krieger, *Plant Biotechnology Experts Assess Hopes for Long and Short Term*, 62 CHEM. ENG NEWS, No. 44, at 16 (1984); Vidaver, *Plant-Associated Agricultural Applications of Genetically Engineered Microorganisms. Projections and Constraints*, 8 RECOMBINANT DNA TECH. BULL. 97 (1985).

110. For example, of 2,860 DNA-injected sheep eggs, only 0.6% gave rise to transgenic lambs. Newmark, *Protein Production in Transgenic Animals*, 5 BIO/TECH. 874 (1987). The success rate has improved to about 1.5% in the most recent experiments. *Id.*

111. Renard & Babinet, *Genetic Engineering in Farm Animals: The Lessons from the Genetic Mouse Model*, 27 THERIOGENOLOGY 181 (1987).

112. OTA ANIMALS, *supra* note 99, at 2. The most widely held view is that it may be as much as ten years, or longer, before commercial herds or flocks of transgenic livestock are produced. *Id.* at 6. The technically more difficult manipulation of traits mediated by more than one gene will require a 10 to 30 year time span. *Id.* at 6.

113. Abel, Nelson, DeHoffmann, Rogers, Fraley & Beachy, *Delay of Disease Development in Transgenic Plants that Express the Tobacco Mosaic Virus Coat Protein Gene*, 232 SCI. 738 (1986).

114. *See, e.g.*, *Harnessing Alfalfa's Defenses*, 5 BIO/TECH. 1006 (1987), which discusses the creation of a DNA library from an alfalfa species in order to identify the gene which encodes a phytoalexin (toxin) that kills fungus; Haggin, *Monsanto Uses Genetic Engineering To Solve Agricultural Problems*, 66 CHEM. & ENG. NEWS, Feb. 15, 1988, at 28.

115. Shah, Horsh, Klee, Kishore, Winter, Turner, Hironaka, Sanders, Gasser, Axkent, Siegel, Rogers & Fraley, *Engineering Herbicide Tolerance in Plants*, 233 SCI. 478 (1986).

116. Fischhoff, Bowdish, Perlak, Marrone, McCormick, Niedermeyer, Dean, Kusano-Kretzmer, Mayer, Rochester, Rogers & Fraley, *Insect Tolerant Transgenic Tomato Plants*, 5 BIO/TECH. 807 (1987). This Article describes the insertion into tomato plants of the gene for an insecticidal protein from a bacterial species which specifically kills lepidopteran insect pests (*i.e.*, the larvae of moths and butterflies). The transgenic plants and their progeny are tolerant, *i.e.*, resistant, to these pests. Over $400 million annually is spent in the United States to control lepidopteran pests alone. *Id.*

117. OTA AGRICULTURE, *supra* note 17, at 44-62. Nitrogen fixation occurs through the action of bacteria that associate symbiotically with the roots of certain plants such as legumes and grasses. It may be possible to insert the bacterial gene encoding the enzyme responsible for nitrogen fixation into the genome of a plant, thereby freeing the plant of the need for external chemical fertilization. Timm, *Identifying and Improving Nitrogen-Fixers*, 5 BIO/TECH. 1015 (1987). In Brazil, for example, sugarcane growers currently spend over $250 million annually on nitrogen fertilizers. *Id.*

safer and more efficient.[118]

Because the patenting debate centers primarily on animals, the remainder of this Part focuses on animal biotechnology. At present, animal genetic engineering techniques include three major procedures: embryo transfer, monoclonal antibody production, and microinjection coupled with recombinant DNA techniques.[119] Collectively, these procedures have significant implications for animal reproduction, regulation of growth and development, animal nutrition, and control of diseases and pests.[120] Embryo transfer, for example, will fundamentally change the livestock breeding process by allowing implantation of genetically superior frozen embryos. Monoclonal antibodies used for diagnosis and passive immunization will greatly enhance the health of animals with respect to current diseases.[121]

Our present technological capability allows a genetic engineer to add one gene, or at most a few foreign genes, to an organism and to have that genetic construct survive.[122] Typically, foreign genes are microinjected into fertilized eggs.[123] The limited genetic material that may be added will not replace or remove native genes. Thus, specific genes may augment an animal's genome, but the "essence of the basic animal remains fixed."[124] Because an organism's tens of thousands of genes "are finely tuned with respect to each other," it is difficult to add even a single gene without disrupting this balance.[125] Using present technology, transgenic animals will differ genetically only slightly from their natural counterparts.[126] Insights into gene regulation revealed by research may allow more extensive genetic manipulation in the future.[127]

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118. Brill Testimony, *supra* note 48, at 223.

119. OTA AGRICULTURE, *supra* note 17, at 33-43. The goal of these procedures, as understood by the OTA, is to increase the efficiency of production so that fewer animals and less labor will be required to produce the necessary animal products. *Id.* at 38. Additional goals involve, for example, improving aspects of human nutrition by the creation of leaner meat products.

120. *Id.* at 34, Table 2.1.

121. *Id.* at 35-36.

122. Brill Testimony, *supra* note 48, at 223.

123. *See* Wagner Testimony, *supra* note 22, at 35; Hammer, Pursel, Rexroad, Wall, Bolt, Ebert, Palmiter & Brinster, *Production of Transgenic Rabbits, Sheep and Pigs by Microinjection*, 315 NATURE (LONDON) 680 (1985). Microinjection is presently the method most likely to lead to practical applications in mammals. OTA ANIMALS, *supra* note 99, at 2.

124. Wagner Testimony, *supra* note 22, at 35, 44.

125. Brill Testimony, *supra* note 48, at 222.

126. Wagner Testimony, *supra* note 22, at 44. In fact, centuries of selective breeding have altered domestic animals far more than the next several decades of transgenic modifications are expected to alter them. OTA ANIMALS, *supra* note 99, at 10.

127. At some point in time, regardless of patenting, technology will advance to the stage that other technology policy choices, presently inchoate, will need to be made. The current discussion over how to control biotechnology should be a useful paradigm.

Current studies with transgenic laboratory animals, particularly transgenic swine, have shown that these animals exhibit a "remarkable" decrease in the quantity of feed required for a unit of weight gain, thereby arriving at market weight earlier than would otherwise be possible.[128] In fact, preliminary studies suggest that the required feed costs might be decreased by as much as 25-30%; when feed costs are coupled with decreased production time, profit margins could be increased several fold.[129]

Disease is estimated to prevent most livestock operations from achieving even 75% of possible feed utilization efficiency.[130] Large confinement rearing systems, as used for commercial production of poultry and swine, accelerate disease transmission. Diseases become a major factor in reducing production efficiencies and profit margin.[131] Accordingly, a primary target for animal genetic engineering is the identification and incorporation of disease resistance genes into livestock species. This is a key research goal for lesser developed countries.[132]

The potential benefits of biotechnology to animal welfare and to poultry farmers were illustrated by studies at the USDA Poultry Research Laboratory at Michigan State University. The protein product of a transferred gene blocked virus receptor sites, thereby making chickens resistant to deadly disease.[133] These proteins are not dangerous to humans or other non-target organisms,[134] unlike dietary antibiotics and hormones (such as DES), which may cause harm to humans who consume treated animals.[135]

Transgenic mice already represent a powerful tool for research on the immune system, genetic diseases, viral diseases, and mechanisms of embryonic development.[136] For example, human genes may be transferred into various animals in order to obtain knowledge of human physiology.[137] Because only humans and

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128. Wagner Testimony, *supra* note 22, at 45.

129. *Id.*

130. *Id.*

131. *Id.* at 45-46.

132. Baltimore, *Priorities in Biotechnology* in INTERNATIONAL DEVELOPMENT, *supra* note 45. For example, The Peoples Republic of China and India have sophisticated agricultural genetic engineering laboratories, as do many other countries. Brill Testimony, *supra* note 48, at 222.

133. Wagner Testimony, *supra* note 22, at 46.

134. Brill Testimony, *supra* note 41, at 223.

135. *Id.*

136. Camper, *Research Applications of Transgenic Mice*, 5 BIOTECHNIQUES 638 (1987).

137. Besides the compelling need to understand human genetics, transgenic animals carrying human genes will also be produced for reasons of convenience. Most mammalian genes are cross-functional in other mammalian species, and human genes of interest are often more readily available. OTA ANIMALS, *supra* note 99, at 6-7. Some critics of animal patenting find objectionable the transfer of human genes to animals, apparently on ethical grounds. *See, e.g., Transgenic Hearings*, *supra* note 22, at 111 (comments of Congressman Rose); Part IX, *infra*.

chimpanzees have a cellular receptor for the AIDS virus, introducing the gene for this receptor into mice may produce an animal model for the study of this disease and for the screening of drugs before they are tested in humans.[138] This type of basic research is expected to contribute to major advances in plant and animal technology as well as in human and animal medicine.[139]

V. COEVOLUTION OF GENETICS AND THE APPLICATION OF THE PATENT SYSTEM TO LIVING ORGANISMS

> [D]iscovery of new plants . . . will revolutionize agriculture as inventions in steam, electricity, and chemistry have revolutionized those fields and advanced our civilization.
>
> U.S. Congress[140]

Microorganisms have been applied for millennia to industrial purposes such as baking and fermentation.[141] Plants and animals have been domesticated and bred for human use even longer. Humankind's ability to knowingly manipulate genetic material, though, is of much more recent origin. Both the science of genetics and modern agricultural breeding techniques stem in large part from the work of an eastern European monk, Gregor Mendel, whose pea plant research was reported in 1865.[142] Mendel concluded that characteristics varying from individual to individual within a species were transmitted as distinct, inherited traits.[143] DNA was discovered in 1869,[144] but was not identified as an agent of heredity until 1944.[145] Discovery of the DNA structure by Watson and Crick in 1953[146] led to an understanding of, and an ability

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138. Wagner Testimony, *supra* note 22, at 37.

139. *See* Walters Testimony, *supra* note 43, at 372 (stating that a type of human disease has been cured in mice through genetic transfer). Dr. Walters chaired the Working Group on Human Genetic Therapy of the NIH Recombinant DNA Advisory Committee. His testimony concerned the promise of human genetic therapy. *Id.* at 369-92.

140. H.R. REP. NO. 1129, 71st Cong., 2d Sess. 2 (1930).

141. Demain, *Industrial Microbiology*, 214 SCI. 987 (1981).

142. Mendel's work remained obscure until after his death, when it was initially rediscovered about 1900. *See generally* K. ARMS & P. CAMP, BIOLOGY 192-95. (1979).

143. *Id.*

144. This discovery was made by Miescher. A. LEHNINGER, BIOCHEMISTRY: THE MOLECULAR BASIS OF CELL STRUCTURE AND FUNCTION 859 (2d ed. 1975) [hereinafter LEHNINGER].

145. Avery, Macleod & McCarty, *Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types*, 79 J. EXPT'L MED. 37 (1944).

146. Watson & Crick, *A Structure for Deoxyribonucleic Acid*, 171 NATURE (LONDON) 737 (1953); Watson & Crick, *Genetic Implications of the Structure of Deoxyribonucleic Acid*, 171 NATURE (LONDON) 964 (1953). *See also* J. WATSON, THE DOUBLE HELIX (1968) for a personal account of this discovery. *See generally* B. LEWIN, GENE EXPRESSION (vol. 1) (1974) [hereinafter LEWIN].

to manipulate, the DNA genetic code.[147]

A. Developments Prior to Discovery of the Genetic Code

Developments in the law with respect to protecting rights of invention in living organisms has paralleled technological developments in biology, with progressively decreasing lag times. The Convention of Paris for the Protection of Industrial Property (which the United States joined in 1883)[148] defined industrial property[149] to extend "not only to the products of industry in the strict sense but also to agricultural products (wines, grain, fruit, cattle, etc.), and mineral products which are put into trade."[150] Subsequent revisions to the Convention of Paris, and various European statutes and court decisions, addressed the need for protection of agricultural advances and the propriety of the patent system.[151] No uniform practice was apparent, however.

By 1906, some members of Congress felt it desirable for United States agriculture, which had entered into a scientific industrial phase, to receive the same benefits from the patent system as did industry.[152] Two obstacles were perceived. First, plant varieties were thought to be unpatentable as products of nature,[153] notwithstanding the time, expense and application of human intellect required to produce a novel plant variety. Second, plant inventions were thought not to be capable of description in writing, so that an inventor could not comply with the fundamental *quid pro quo* of enabling workers to make the invention for which patent protection was sought.[154] To circumvent these perceived limitations, Congress ultimately enacted the Plant Patent Act of 1930,[155] (hereinafter the "Plant Patent Provisions") by which Con-

147. *See* LEWIN, *supra* note 146; LEHNINGER, *supra* note 144.

148. Convention of Paris for the Protection of Industrial Property, March 20, 1883 [hereinafter Paris Convention].

149. Industrial property is the counterpart term outside of the United States for "intellectual property," which includes the property rights in patents, trademarks, copyrights, and semiconductor chip registrations, among others.

150. Paris Convention, *supra* note 148, at para. 2.

151. *See* S. BENT, R. SCHWAAB, D. CONLIN & D. JEFFREY, INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 40-80 (1987) [hereinafter BENT].

152. *See, e.g.*, H.R. No. 18851, 59th Cong., 1st Sess. (1906) entitled "A bill to amend the laws of the United States relating to patents in the interest of the originators of horticultural products." Similar legislation was introduced in 1907, 1908 and 1910. Other legislation to protect both plants and animals was proposed but not enacted.

153. Based upon an 1889 decision by the Commissioner of Patents. *Ex parte* Latimer, 1889 Dec. Comm. Pat. 123 (1889).

154. *See generally* Rossman, *Plant Patents* 13 J. PAT. OFF. SOC'Y 7 (1931); Magnuson, *A Short Discussion on Various Aspects of Plant Patents.* 30 J. PAT. OFF. SOC'Y 493 (1948). In 1930, even *differentiation* between new plant varieties based only on a written description was thought to be impossible. *Hearings on H.R. 11372 before the House Comm. on Patents*, 71st Cong., 2d Sess. 4, 7 (1930) (Memorandum of Patent Commissioner Robertson).

155. Presently codified at 35 U.S.C. §§ 161-164 (1982).

gress expressly extended the patent system to the plant agricultural sector:

> No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of fruit or other plant to mankind.
>
> This Bill is intended not only to correct such discrimination, but [also to stimulate] invention . . . .[156]

The foregoing reasoning is equally valid for today's agricultural sector, which is poised on the brink of a new era of productivity driven in turn by the research and development efforts of science and industry. As Congress noted in 1930:

> Today, the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all. The originator's only hope of financial reimbursement is through high prices for the comparatively few reproductions that he may dispose of during the first two or three years. After that time, depending upon the speed with which the plant may be asexually reproduced, the breeder loses all control of his discovery. Under the bill the originator will have control of his discovery during a period of 17 years, the same term as industrial patent. If the new variety is successful, the breeder or discoverer can expect an adequate financial reward. . . . It is hoped that the bill will afford a sound basis for investing capital in plant breeding and consequently stimulate plant development through private funds.[157]

The same federal interest–but with greater direct federal involvement–in stimulating private enterprise applies today,[158] as do

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156. H.R. REP. NO. 1129, 71st Cong., 2d Sess. 2 (1930).

157. *Id.* at 1-2; S. REP. NO. 315, 71st Cong., 2d Sess. 1-2 (1930).

158. Federal Technology Transfer Act of 1986, 15 U.S.C. §§ 3701-3714 (Supp. IV 1986). This Act is intended to promote technology transfer from the federal government to the private sector by authorizing federal laboratories to enter into cooperative research agreements with industry and by other means. "Patenting definitely contributes to technology transfer and utilization of research results." Speech by Dr. Philip S. Chen, Jr., Associate Director for Intra-Mural Affairs, NIH, at the American Council on Science and Health Media Education Conference on Biotechnology, in New York City (Apr. 12, 1988).

the concerns recognized in 1930 of making new technology widely available at lower initial market prices.

The Plant Patent Provisions modified existing patent law by designating asexually reproduced plants[159] as patentable.[160] The right granted by a section 161 plant patent (the provisions are now codified at sections 161-64 of the Patent Act) is "the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced."[161] A section 161 plant patent need not comply with the stringent "enablement" requirements of 35 U.S.C. § 112,[162] because the "claim" is extremely limited, being restricted to the plant that is "shown and described" by photograph appended to the patent.[163]

The Plant Patent Provisions are silent as to the possibility that the identical subject matter could be patented under section 101 of the Patent Act because, as discussed above, it was thought that section 101 could not apply to plants because plants are products of nature and because section 112 enablement requirements could not be met.[164] Sexually-reproduced seed plants were excluded from the Plant Patent Provisions because it also was believed that plants could not be stably reproduced by seed for commercial purposes.[165] Therefore, protection against unauthorized sexual reproduction of plants was not considered important.[166] By court decision in 1940, bacteria were excluded from protection under the Plant Patent Provisions because bacteria were not plants as contemplated by Congress.[167]

Between 1940 and 1950 various European countries had adopted differing approaches to protecting plant-related inventions.[168] For example, Czechoslovakia (1921), Holland (1946), and

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159. Asexual reproduction occurs by grafting, budding, cuttings, layering and division.

160. 35 U.S.C. § 161 (1982).

161. *Id.* § 163.

162. *Id.* § 162.

163. *Id.* An example of a section 161 plant patent claim: "A new and distinct variety of chrysanthemum plant, substantially as herein shown and described, characterized by its very large, bright yellow blooms, its excellent production of well formed flowers, flowering with a very even eleven-week response and producing very few culls." Pan-American Plant Co. v. Matsui, 198 U.S.P.Q. 462, 464 (N.D. Cal. 1977).

164. Similar enablement considerations for animal inventions may require Congressional revision of section 112. *See supra* note 67 and accompanying text.

165. S. REP. NO. 315 at 5; H.R. REP. NO. 1129 at 6. Some commentators have suggested that an additional reason for excluding sexually-reproduced plants may have been the fears of scientists and farmers that such inclusion might have inhibited the free exchange of germplasm (*i.e.*, genetic material). Ruttan, *Changing Role of Public and Private Sectors in Agricultural Research*, 216 SCI. 23, 25 (1982).

166. S. REP. NO. 315, at 3; H.R. REP. NO. 1129, at 4.

167. *In re* Arzberger, 112 F.2d 834 (C.C.P.A. 1940).

168. *See* Matthey, *Les Brevets de Végétaux* 13-25 (Université Lausanne 1954) [hereinafter Matthey]. *See generally* S. Beier & J. Straus, *Patents in a Time of Rapid Scientific and Technological Change: Inventions in Biotechnology (part one)* in BIOTECHNOLOGY AND PATENT PROTECTION: AN INTERNATIONAL REVIEW (S. Beier, R. Crespi & J. Straus ed. 1985); Straus,

Austria (1946) enacted plant breeders' protection laws or plant variety registration systems; France (1922) and Germany (1934) enacted breeders' rights laws but also issued patents on plants; other countries, such as Italy (1951), issued patents for plants without adopting a special breeders' rights law; and Sweden, Hungary and Japan have also issued plant patents.[169]

The United States patent law was recodified and revised in part by the Patent Act of 1952[170] without significantly changing the Plant Patent Provisions of 1930. Contemporaneously, the desirability of an international accord to protect plant inventions was being debated by Western European nations.[171] Ultimately an international conference was convened, resulting in the creation of the Union for the Protection of New Varieties of Plants and the adoption of the International Convention for the Protection of New Varieties of Plants[172] (referred to by their French acronym as "UPOV" and the "UPOV Convention"). The UPOV Convention became effective in 1968.[173]

Also in the late 1950s and early 1960s, European nations were negotiating a treaty that culminated in the establishment of a European patent system.[174] Because of the difficulties in reconciling the varied national protection schemes for plants,[175] the resulting Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions (1963) permitted contracting nations "to refrain if they chose, from granting patents on plant or animal varieties or essentially biological

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Industrial Property Protection of Biotechnological Inventions 60-62 (World Intellectual Property Organization Working Paper WIPO BIG/281, 1985) [hereinafter Straus]; BENT, *supra* note 151, at 40-80.

169. Matthey, *supra* note 168, at 13-25; Straus, *supra* note 168, at 61.

170. 35 U.S.C. §§ 1-376 (1982).

171. *See, e.g.*, Reports Prepared on the Question of Protecting New Plant Varieties, Section 7 in the Annuaire de L'Association Internationale pour la Protection de la Propriété Industrielle, Congrès de Vienne 2 Juin - 7 Juin, 1952 at 1,373 (1954).

172. Oct. 23, 1978, T.I.A.S. 10199 [hereinafter UPOV Convention]; *see also* 20 INDUS. PROP. 24, 25 (1981).

173. *See* UPOV Actes des Conférences in Internationales Pour la Protection des Obtentions Végétales 1957-61, 1972 (WIPO, Geneva, 1974) (selected history of the UPOV Convention). The substantive requirements of this breeders' rights protection scheme are discussed in Byrne, *The Agritechnical Criteria in Plant Breeders' Rights Law*, 22 INDUS. PROP. 293 (1983). *See also* Williams, *Protection of Plant Varieties and Parts as Intellectual Property*, 225 SCI. 18 (1984) [hereinafter Williams].

174. For an international analysis of patent law unification developments in the agricultural field, *see* COMMITTEE OF EXPERTS ON BIOTECHNOLOGICAL INVENTIONS AND INDUSTRIAL PROPERTY, WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Industrial Property Protection of Biotechnological Inventions*, Nov. 5, 1985; BENT, *supra* note 151, at 62-70.

175. *See* Adler Patents, *supra* note 79, at 211-12; BENT, *supra* note 151, at 62-70.

processes for the production of plants or animals."[176]

During the unification process, a committee of experts on patents recommended that European patent harmonization efforts defer to the UPOV for the development of a separate convention relating to plant varieties. Efforts to incorporate patent protection for living organisms into the European Patent Convention of 1973 were abandoned in the interest of expediency in achieving a harmonized regional patent accord.[177] European national patent laws, revised since 1973, exclude living organisms from patentability in an apparent effort to harmonize with the European Patent Convention, although it never decided the issue.[178] Current trends in European patent law, however, reflect a desire to expand existing protection to plants and animals,[179] reportedly to conform to trends in the United States.[180]

B. Developments Between Discovery of the Genetic Code and the Advent of Recombinant DNA Technology

On the technical front, the complete genetic code was determined in the 1960s,[181] thereby providing the Rosetta stone for biotechnology. At the same time the commercial importance of sexually-reproduced (seed) plants became appreciated. Congress and the President then began to contemplate providing statutory protection for the breeders of sexually-reproduced plants.

The President's Commission on the Patent System

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176. Article 2(b). Article 53(b) of the European Patent Convention of 1973 excludes living subject matter except as created by "microbiological processes," a phrase originally thought to include microorganisms and cells but to exclude plants and animals. This exclusion provided the least common denominator for varied national practices, and reflected the contemporary trend for the signatory nations to have enacted UPOV-type plant protection schemes.

177. Straus, *supra* note 168, at 63 & n.251-53. It is thought that genetically engineered plants and animals might nevertheless be patentable under the European Patent Convention Art. 53(b) if created by or as products of the "microbiological processes" mentioned in Art. 53(b) of the European Patent Convention. *See* 4 BIOTECH. L. REP. 307 (perspective on European patent situation regarding biotechnology, item BLR 434) (1985); *See also* Teschemacher, *The Practice of European Patent Office Regarding Grant of Patents for Biotechnological Inventions*, 19 INT. REV. IND. PROP. COPYRIGHT L. 18, 20-22 (1988).

178. *See* Adler Patents, *supra* note 79, at 210-12. *See also* J. CURRY, THE PATENTABILITY OF GENETICALLY ENGINEERED PLANTS AND ANIMALS IN THE U.S. AND EUROPE: A COMPARATIVE STUDY 21-22 (Intell. Prop. Publish. Ltd., London 1987); BENT, *supra* note 151, at 62-70.

179. *See* Ciba-Geigy, T49/83 (EPO Technical Board of Appeals); *Perspective on European Patent Situation Regarding Biotechnology*, 4 BIOTECH. L. REP. 307 (1985). *See also* BENT, *supra* note 151, at 154-61.

180. Duffey Testimony, *supra* note 54, at 136-137. Duffey was reporting on proceedings of a recent meeting of a group of biotechnology patent experts of the World Intellectual Property Organization.

181. *See* LEWIN, *supra* note 146, at 33-37.

(hereinafter the "Patent Commission") issued a report in 1966 that favored protection for plant inventions, but recommended that all plant protection be deleted from the Patent Act and instead be provided for by an alternative protection scheme.[182] The Patent Commission acknowledged the benefit of breeders' efforts, but concluded that patent applications for section 161 plant patents could not be examined appropriately for compliance with the novelty, utility and nonobviousness criteria of the Patent Act.[183] This viewpoint echoed the conventional wisdom of the time that no living organism could satisfy patent requirements.

Ultimately, a bill to expand section 161 was proposed in 1968. The bill was not adopted due to a perceived "significant difference of opinion" over the propriety and feasibility of extending the patent system to seed-reproduced plants as opposed to enacting an alternative mechanism to stimulate private development efforts.[184] The UPOV Convention had been negotiated by this time, although the United States would not join it for over a decade. A major dissatisfaction with widening the scope of section 161 centered on the distinction between sexually and asexually-reproduced plants. Sexually-reproduced plants are not genetically or phenotypically (*i.e.*, in appearance) identical from generation to generation. Asexually-reproduced plants, however, are genetically identical because they are reproduced from pieces of the parent stock. Thus, an additional objection to expanding section 161 may have been that the protection offered by section 161 for plants "shown and described" by a photograph would be rather limited.[185]

After the concerned trade associations and other interested parties reached agreement on proposed legislation, the Plant Variety Protection Act of 1970[186] (the "PVPA") was enacted to extend patent-like protection to sexually-reproduced plants.[187] The PVPA authorizes the issuance to plant breeders of variety certificates[188] which are analogous to the patents issued to inventors. Although applications for section 161 plant patents benefit from a relaxed enablement standard, those claims must still satisfy the novelty and nonobviousness requirements of the Patent Act.

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182. PATENT COMMISSION, *supra* note 55, at 20-21.

183. *Id.* at 20.

184. An historical overview of these circumstances is provided by the remarks of Senator C. McClellan introducing a bill on patent law revision, S. 3892. 114 CONG. REC. 23,492 (1968). *See also* S. REP. NO. 1246, 91st Cong., 2d Sess. 2-3 (1970). Comm. on the Judiciary, Report to Accompany S. 3070 (The Plant Variety Protection Act Bill).

185. *See* Adler Patents, *supra* note 87, at 204-05 for a discussion of the scope of protection provided by a section 161 plant patent.

186. 7 U.S.C. § 2321-2583 (1982).

187. S. REP. NO. 1138, 91st Cong., 2d Sess. (1970), Senate Agriculture and Forestry Comm. Report to Accompany S. 3070.

188. 7 U.S.C. § 2482 (1982).

However, the PVPA further relaxes the breeders' burden. For example, varieties protectable under the PVPA must be *novel* (*i.e.*, distinct, uniform and stably reproducible)[189] but need *not* be nonobvious, as required by the Patent Act. Following enactment of the PVPA, plant breeders enjoyed the option of applying for a variety certificate or, when the nonobviousness standard could be met, a section 161 patent.[190] However, the *scope* of protection under the PVPA also differs from patent protection under section 161. A variety certificate protects against unauthorized selling, reproducing, importing or exporting but does not preclude the use of a protected variety for development of other varieties.[191]

Although analysis of whether a hierarchal protection scheme paralleling that of plants should be enacted for microorganisms and animals is beyond the scope of this Article,[192] note that uncertainty inherent in the plant protection scheme has created doubts regarding the viability of this dual protection approach.[193]

C. Developments After the Advent of Recombinant DNA Technology

By 1970, a restriction enzyme capable of cutting DNA was isolated and, in 1972, a DNA ligase, an enzyme capable of joining DNA fragments, was first used to produce recombinant DNA molecules.[194] In 1973, foreign DNA fragments were inserted into a cell via a plasmid,[195] and in 1974, the first gene from a foreign species was expressed in bacteria.[196] Microorganisms *per se* were still considered unpatentable, although microorganism-related inventions such as antibiotics or other metabolic products were

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189. *Id.* § 2401(a).

190. Plant breeders may also apply for a section 101 plant patent.

191. 7 U.S.C. §§ 2541, 2544 (1982). For a comparison of the various protection modes for plant inventions, *see* Adler Patents, *supra* note 87, at 204-07, and Williams, *supra* note 158.

192. A "Living Organisms Variety Protection Act" may be effective for this purpose, if warranted. Adler Patents, *supra* note 87, at 226.

193. Adler Patents, *supra* note 87, at 214; Straus, *The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint*, 18 INT'L REV. INDUS. PROP. & COPYRIGHT L. 723, 727-30 (1987).

194. OTA COMMERCIAL BIOTECH, *supra* note 9, at 4, Fig. 1.

195. A plasmid is a small circular non-chromosomal DNA found in bacteria which often carries the genes for traits such as antibiotic resistance, and which has been used industrially to introduce recombinant DNA into an organism for replication and expression of desired cellular products.

196. Expression refers to the production of functional protein from the inserted gene. For an interesting account of the early years of recombinant DNA technology, *see* J. WATSON & J. TOOZE, THE DNA STORY. A DOCUMENTARY HISTORY OF GENETIC CLONING (1981) [hereinafter WATSON]; S. KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY (1982) [hereinafter KRIMSKY].

patentable.[197] Concurrently, Dr. Chakrabarty's patent application, claiming protection for a bacterium modified to digest petroleum, was working its way from the PTO to the Supreme Court.[198]

As early as the 1950s, it had become evident that other scientists with access to the necessary cell cultures could reproduce microorganism-related inventions from patent specifications. The deposit practice was approved by the Court of Customs and Patent Appeals in 1970.[199] To facilitate the patent process for these inventions, the United States in 1978 joined the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure[200] (hereinafter the "Budapest Treaty"). This treaty established uniform international procedures and criteria for repositories of biological material.

In 1980, the United States acceded to the UPOV Convention[201] and subsequently amended the PVPA,[202] although discussions of recombinant DNA technology apparently did not enter the process. Also in 1980, the Supreme Court decided *Diamond v. Chakrabarty*,[203] holding that a living microorganism was encompassed by the categories of patentable subject matter set forth in section 101 of the Patent Act.[204] This decision came ten years after the German Federal Civil Supreme Court's holding in 1969 that *animals* could be patented if the process for their production could be repeated,[205] and Hungary's legislation in 1969 providing that animals could be patented if they were "distinguishable, novel, homogeneous and stable."[206] The Canadian Patent Appeal Board followed after *Chakrabarty*, stating in 1982 that living organisms

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197. *See In re* Marcy, 499 F.2d 1289 (C.C.P.A. 1974).

198. *See, e.g., The Pros and Cons on the Patentability of Microorganisms Per Se*, 7 AM. PAT. L.A.Q.J. 172-174 (1979).

199. *In re* Argoudelis, 434 F.2d 1390, 1393 n.5 (C.C.P.A. 1970).

200. Aug. 19, 1980, 32 U.S.T. 1241, T.I.A.S. No. 9768; 17 INDUS. PROP. 192, 193 (1978).

201. UPOV Convention, *supra* note 172.

202. Pub. L. No. 96-574, 94 Stat. 3350 (1980).

203. 447 U.S. 303 (1980). *Chakrabarty* was a 5-4 decision. For a thoughtful analysis of the societal interests affected by this decision, see Kass, *Patenting Life*, 63 J. PAT. OFF. SOC'Y 571 (1981). *See also* Watson, *The Patentability of Living Organisms*, 20 AM. BUS. L.J. 93 (1982); Halluin, *Patenting the Results of Genetic Engineering Research: An Overview* in BANBURY REP. 10, *Patenting of Life Forms* (1982); Mandel, *The Animal Patent Controversy*, 13 NEW MATTER, No. 1, at 3 (1988).

204. *Chakrabarty*, 447 U.S. at 309.

205. Rote Taube (Red Dove), 1 INT'S REV. INDUS. PROP. & COPYRIGHT L. 136 (1970) (patent rejected because no certainty that breeding method can be repeated, and because animal high on evolutionary scale and has complex hereditary characteristics).

206. Hungarian Patent Law at Art. 71 (1969). *See* Szentpeteri, *Patenting Inventions in the Field of Biotechnology in Hungary*, 1 PAT. WORLD, No. 5, at 24 (1987).

could be patented.[207] Higher life forms also would be patentable in Australia.[208]

Congress in 1980 had not contemplated the patent-related aspects of modern genetic engineering technology. In its *Chakrabarty* opinion, however, the Supreme Court noted that Congress had plainly contemplated that the patent laws would be given "wide scope" by wording 35 U.S.C. § 101 with such "expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any.' "[209] The Supreme Court rejected arguments that enactment of the Plant Patent Provisions and the PVPA evidenced a Congressional understanding that section 101 excluded living things. Rather, the Court noted that the original impetus for the plant-specific acts was the then-conventional wisdom that plant inventions could not satisfy the requirements of the patent law. The Court in *Chakrabarty* held that the broad Congressional goals sought to be achieved by the Patent Act required a broad construction of section 101. Thus, the Supreme Court concluded that Congress intended statutory subject matter to "include anything under the sun that is made by man."[210]

By statutory definition, all patentable inventions must be novel and nonobvious.[211] There is no indication that Congress intended the Commissioner to determine that some technological inventions were nevertheless unpatentable due to the degree of their novelty or possible social impact. In fact, as long as the other requirements were satisfied, an applicant was "*entitled* to a patent" if the invention was novel.[212] Recognizing these circumstances, the *Chakrabarty* opinion concluded that the broad language of section 101 was selected precisely because such inventions were often unforeseeable.[213]

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207. *In re* Abitibi Co., 62 C.P.R.2d 81, 90 (1982), *in dicta*. Subsequently, the Canadian Commissioner of Patents decided that claims to a variety soybean plant were unpatentable, distinguishing *Abitibi* as limited to microorganisms. The Federal Appeals Court affirmed the Commissioner, but on the narrower basis that plants produced by conventional breeding techniques were unpatentable. Pioneer Hi-Bred Ltd. v. Commissioner of Patents, 14 C.P.R.3d 491 (1987). By implication, genetically engineered plants and animals should be patentable in Canada.

208. Tegtmeyer Testimony, *supra* note 55, at 33.

209. *Chakrabarty*, 447 U.S. at 308.

210. *Id.* at 309, *citing* S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952). The Supreme Court noted that Congress defines the limits of patentability and that Congress was free to amend section 101 to "exclude from patent protection organisms produced by genetic engineering." 447 U.S. at 318.

211. 35 U.S.C. §§ 102, 103.

212. *Id.* § 102 (emphasis added).

213. *Chakrabarty*, 447 U.S. at 316. The Supreme Court reasoned that, "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. . . . [T]he inventions most benefiting mankind are those that 'push back the frontiers of chemistry, physics, and the like.' " *Id.*

By the early 1980's, developments in biological technology were accelerating. The first human recombinant DNA pharmaceutical (insulin) was approved in 1982 by the FDA.[214] A foreign gene was first expressed by a transgenic plant in 1982,[215] and a transgenic mouse expressing a rat growth hormone gene was also reported in that year.[216]

Notwithstanding the intention of Congress (stated as early as 1930) that plant inventions should receive the same benefits from the patent system as mechanical inventions,[217] as well as the broad import of the *Chakarbarty* decision, the PTO adopted a conservative approach to patentability of living organisms under section 101. Although the Supreme Court held that the Plant Patent Provisions and the PVPA did not implicitly preclude the patentability of microorganisms under section 101, the PTO determined that section 101 patents for plant inventions had been preempted by these plant-specific statutes. The Commissioner expressly awaited judicial approval before issuance of section 101 plant patents.[218] Quasi-judicial authorization was granted by the PTO Board of Appeals and Interferences (the "PTO Board") in *Ex parte Hibberd*,[219] a section 101 patent application involving modified maize plants.[220] The PTO Board, relying largely on the *Chakrabarty* opinion, flatly rejected the Commissioner's narrow construction of section 101.

Despite *Chakrabarty* and *Hibberd*, the Commissioner continued to refuse patent applications on animal inventions until the PTO Board decided *Ex parte Allen*, which ruled that polyploid (*i.e.*, containing multiple sets of chromosomes) oysters were patentable subject matter.[221] Several days later, on April 7, 1987, the Commissioner announced that animals thereafter could be patented.[222]

As genetic research developed over the past century, Congressional efforts followed to enfranchise agricultural technology

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214. OTA COMMERCIAL BIOTECH, *supra* note 9, at 4, Fig. 1.

215. 2 BIOTECH. NEWSWATCH, No. 6, at 6 (1982).

216. Palmiter, *supra* note 11, at 611.

217. *See supra* note 156 and accompanying text.

218. The unenlightened PTO policy was sharply criticized. *See* Adler, *Biotechnology Development and Transfer: Recommendations for an Integrated Policy*, 11 RUTGERS COMPUTER & TECH. L.J. 469, 478-481 (1985) [hereinafter Adler Biotechnology].

219. 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985).

220. Claim 249 of the patent application is representative: "A maize plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germinating into a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight." *Id.* at 443.

221. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Int. 1987).

222. 1077 OFFICIAL GAZ. PAT. OFF. 24 (1987). *See also supra* note 13.

through patent or analogous protection schemes. Enactment of the Plant Patent Provisions and the PVPA was motivated by the then-contemporary understanding that agricultural technology could not accommodate the patent system's novelty and enablement requirements. The march of technology has since made that accommodation possible. Thus, the United States' accession to the UPOV Convention and the Budapest Treaty evidenced an awareness by Congress of advances in agricultural and biological sciences as well as legislative initiative to extend the benefits of the patent system to such developments. Extension of patent protection to animal inventions is consistent with the statutory construction noted in *Chakrabarty* and the expressed intention of Congress to stimulate agricultural innovation.

Except for the argument that the act of patenting living organisms is unethical, the rationales advanced by opponents of plant and animal patents are not patent law issues *per se*. These opposing views are discussed in the following sections.

VI. ANIMAL WELFARE

> The greatness of a nation and its moral progress can be judged by the way its animals are treated.
> Mahatma Gandhi[223]

Animals are the major source of nutritional protein in the United States and have an important role in research. This part reviews the need for commercial applications of biotechnology in agriculture and the statutory framework for animal research regulation. The arguments against animal patenting are analyzed in light of the foregoing realities.

The United States food animal industry comprises a large proportion of the American diet: food animals provide 70% of the protein, 35% of the energy, 80% of the calcium, 60% of the phosphorus, and significant proportions of vitamins and minerals consumed by Americans.[224] The OTA found that the increased world food demand by the year 2000 could be met only through the development and adoption of new agricultural biotechnologies and information technologies.[225] Although the unnecessary use of animals in research is disfavored, Congress considers animal research to be instrumental in education and in the pursuit of cures and treatments for injuries and diseases afflicting both humans

223. *Quoted in* Bennon, *Research Guide for Animal Welfare and Animal Rights*, 4 LEGAL REFERENCE SERVICES Q., No. 3, at 3 (1984).

224. OTA AGRICULTURE, *supra* note 17, at 39.

225. *Id.* at 3.

and animals.[226] As such, Congress favors faster, less expensive, and more accurate non-animal testing methods.[227]

Traditionally, animal welfare legislation has been compartmentalized. Agricultural livestock practices (transportation, sale and slaughter) were least controlled.[228] Pets and research animals were to be accorded "humane" treatment, as determined by the Secretary of Agriculture, for various purposes including transportation, housing, sale and exhibitions.[229] The Secretary, however, was expressly denied authorization to intervene in the design or implementation of actual experiments, except for essentially analgesic concerns.[230] Thus, particular uses of experimental animals were exclusively determined by the research facility.[231]

Recently, federal policy and Congressional intentions to protect research animals have undergone a significant change.[232] The impetus for change was in part a response to a widely-publicized 1983 animal cruelty case involving federally funded research.[233] Since 1985, the Secretary has been required to oversee

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226. Food Security Act of 1985, § 1751(1), Pub. L. No. 99-198, 99 Stat. 1354,1645 (1985).

227. *Id.* § 1751(2). Congress found that the minimization or elimination of unnecessary animal experimentation can result in more productive use of federal funds and that limiting animal experimentation was important to meet the public concerns about laboratory animal care. *Id.*

228. *See, e.g.*, 7 U.S.C. §§ 1901-04, 2142-43 (1982).

229. Animal Welfare Act of 1966, 7 U.S.C. § 2131 (1982), Pub. L. 89-544, 80 Stat. 350 (1966) (subsequently amended).

230. Animal Welfare Act of 1970, 7 U.S.C. § 2143(a) (1982), Pub. L. 91-579, 84 Stat. 1560, 1563 (1970) (subsequently amended).

231. S. REP. NO. 1281, 89th Cong., 2d Sess. (1966) *reprinted in* 1966 U.S. CODE CONG. & ADMIN. NEWS 2635, 2637.

232. State law, however, appears to have lagged. Although state statutes exist which attempt to prevent cruelty to animals, it is difficult for private citizens and animal welfare organizations to intervene in state courts. This creates a situation which frustrates both animal welfare advocates and animal welfare policy goals. While animals do not benefit from the legal protection accorded fetuses, women, and blacks, an emerging public consensus finds increased attention to animal welfare appropriate and necessary. Congress and the federal agencies have recognized that consensus. Commentators on animal rights, however, suggest that more public attention to animal rights and more private enforcement efforts would reduce animal suffering and contribute to the substitution of non-animal alternatives where possible. *See, e.g.*, Comment, *Creating a Private Cause of Action Against Abusive Animal Research*, 134 U. PA. L. REV. 399 (1986); Thomas, *Antinomy: The Use, Rights and Regulation of Laboratory Animals*, 13 PEPPERDINE L. REV. 723 (1986); Bennon, *Research Guide for Animal Welfare and Animal Rights*, 4 LEGAL REFERENCE SERVICES Q., No. 3, at 3 (1984); Dresser, *Research on Animals: Values, Politics, and Regulatory Reform*, 58 S. CAL. L. REV. 1147 (1985).

233. E. Taub, the chief of a private research lab, was arrested in 1981 for violating a Maryland provision that makes cruelty to animals a criminal misdemeanor. Seventeen monkeys were alleged to have been treated cruelly because of insufficient food and water, inadequate veterinary care, and unsanitary conditions. Taub was ultimately convicted on one count of cruelty to animals. However, on appeal this conviction was reversed on the ground that the Maryland Code did not apply to an institution conducting medical research pursuant to a federal program. Taub v. State, 296 Md. 439, 463 A.2d 819 (Md. 1983). After the interven-

the establishment of animal welfare committees at all research facilities using certain non-farm animals[234] and to promulgate guidelines for reducing pain and distress in these research animals.[235] The National Institutes of Health (NIH) were required to promulgate similar guidelines for NIH researchers and grantees.[236] According to the OTA, public opinion does not find direct genetic manipulation of plants and animals, however, to be morally wrong.[237]

Against this cultural and legislative backdrop, the Humane Society of the United States (the "Humane Society") believes the patenting of animals conceptually "reflects human arrogance toward other living creatures that is contrary to the concept of the inherent sanctity of every unique being and the recognition of the ecological and spiritual interconnectedness of all life."[238] The Humane Society assumes that patent protection for animal inventions will lead to a "dramatic increase in the suffering of animals resulting from agricultural, biomedical and other in-

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tion in state court of animal welfare organizations and removal to federal court, the organizations' suit for designation as the guardians of the monkeys was dismissed due to lack of standing because "preservation and encouragement of civilized and humane treatment of animals" was insufficient grounds under the Animal Welfare Act. International Primate Protection League v. Institute for Behavioral Research, Inc., 799 F.2d 934, 938 (4th Cir. 1986).

234. 7 U.S.C. § 2143 (Supp. IV 1986), as amended by the Food Security Act of 1985, *supra* note 226. Farm animals are not subject to the secretary's regulatory authority over research. 7 U.S.C. § 2132(f) (1982).

235. The USDA's proposed research rule was published in March, 1987, 52 Fed. Reg. 10,292 (1987), and generated over 8,000 comments, many sharply critical of the logistics of compliance. Holden, *Animal Regulations: So Far, So Good*, 238 SCI. 880, 881 (1987).

236. Health Research Extension Act of 1985, Title IV–Animals in Research, 42 U.S.C. §§ 201 to 300c-12 (Supp. III 1985). The Secretary of Health and Human Services, through the director of the National Institutes of Health (NIH), has promulgated guidelines for the care and use of laboratory animals. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, "Guide for the Care and Use of Laboratory Animals" (NIH Pub. No. 86-23 1985). This policy was based upon the principles developed by the federal Interagency Research Animal Committee. These guidelines require, *inter alia*, that the minimum number of animals required to obtain valid results be utilized and that procedures involving animals be designed and performed with due consideration to human and animal health, the advancement of knowledge, and the good of society. A significant statutory provision to ensure compliance is the requirement for an animal care committee at each entity that conducts biomedical and behavioral research with federal funds. 42 U.S.C. § 289d(b). *See also* Office for Protection from Research Risks (OPRR), National Institutes of Health, *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (September 1986).

237. Of those surveyed, 68% found this to be not morally wrong and 24% objected on moral grounds. A similar percentage, 26%, found the creation of hybrid plants and animals through conventional crossbreeding to be morally wrong. OTA PERCEPTIONS, *supra* note 15, at 58-59.

238. *Transgenic Hearings*, *supra* note 22, at 64-65 (Testimony of John A. Hoyt, President of the Humane Society of the United States) [hereinafter Hoyt Testimony]. *See also* Position Statement of the Humane Society of the United States: The Patenting of Animals (1987) [hereinafter *Humane Society Statement*]. The ethical component of this position is discussed in Part IX, *infra*.

dustrial research."[239] Moreover, these advocates contend that the "wholesale industrialized exploitation of the animal kingdom will be sanctioned, protected and intensified,"[240] despite the high existing level of agricultural industrialization and the projected need for continuing industrialization to satisfy world food demands noted above.

The Humane Society in part predicates its fears of animal mistreatment on the uncertain outcome of individual transgenic research experiments.[241] Overall, however, transgenic research promises dramatic medical breakthroughs, major advances in knowledge about gene regulation, and potential reductions in animal suffering through genetic protection from common livestock diseases.[242] Based on the experimental results of transgenic research obtained to date, animal health and welfare should improve and the numbers of animals required for agricultural purposes should decrease.[243] The Humane Society offers no compelling basis for allowing short-term distress to deny imminent benefits to agriculture and livestock. In any event, Congress broadly decided animal research policy questions in 1985, well into the transgenic era, in favor of continued animal experimentation.[244]

The Humane Society also fears that patenting will stimulate transgenic research, producing new health problems and causing generations of animals to suffer from congenital abnormalities.[245] The basis for such allegations appears to be the results of initial transgenic swine research by the USDA in which animals having arthritis-like disorders and shortened life spans resulted from the insertion of foreign growth hormone genes.[246] No scientific ration-

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239. Hoyt Testimony, *supra* note 238, at 62-63.

240. *Humane Society Statement*, *supra* note 238.

241. Hoyt Testimony, *supra* note 238, at 62-63 ("[T]he outcome of many genetic experiments cannot be predicted in relation to the animals' health and welfare or in relation to [the experiments'] long-term social, economic, and environmental impact.").

242. Godown Testimony, *supra* note 80, at 263.

243. *See* Part IV, *supra* and Part X, *infra*.

244. *See supra* notes 226 and 234-36 and accompanying text.

245. Hoyt Testimony, *supra* note 238, at 62-63. The Humane Society further contends that veterinary medicine will be unable to keep up with these "problems" and that preventive treatment will be impossible because such speculative problems are unknown by definition until they occur. *Humane Society Statement*, *supra* note 238.

246. Fox, *Genetic Engineering: Nature's Cornucopia or Pandora's Box?*, THE ANIMALS' AGENDA, Mar. 1987, at 10 ("Some of the pigs carrying the human gene are apparently abnormal, lethargic, and prone to arthritis." One researcher has predicted "the development of cattle weighing over 10,000 pounds, pigs twelve feet long and five feet high."). Even assuming the existence of a causal relationship between patenting and the motivation for the USDA or others to pursue transgenic research, there is no evidence that transgenic research is inherently pathological or that fewer swine would not ultimately be needed for research or consumption if current research and patenting continue.

ale, however, is offered for the belief that genetic manipulation is necessarily harmful to an animal's welfare. In one instance in contradistinction to the Humane Society's speculations, the research team which created the TPA-producing transgenic mice has observed no deleterious effects on the animals' health.[247]

Furthermore, all patented and prescription drugs have side effects, as do experimental pharmaceuticals used in toxicity studies in animals. No showing has been made that transgenic research is of such qualitative difference with respect to producing adverse side effects as to justify an attempt to slow transgenic animal biotechnology indiscriminately through a patent moratorium. Assuming that transgenic research will continue, slowing such research will only postpone the experience needed to make such a judgment.

Congress has been advised through the Transgenic Hearings that conventional breeding of agricultural animals can be considered to be equally or more "harmful" to animals than is production of new strains through genetic engineering. Traditional techniques yield unwanted progeny with a range of undesirable traits, such as reproductive deficiencies or structural unsoundness.[248] This occurs because conventional breeders must take the "good with the bad."[249] Genetic engineering research will make possible more precise, and perhaps more humane, genetic changes in animals.[250] "A major benefit of this technology" will be the ability "to breed animals for good, general, healthy, sound characteristics, and then impart [to them] a single gene" for a desired agricultural trait.[251] Furthermore, when contrasted with the animal welfare aspects of breeding, buying, selling, owning, domesticating, eating, and performing research on animals, the patenting of animals seems relatively benign.[252]

Because animals were not patentable until April 7, 1987 and since the first animal patent issued April 12, 1988, the existence

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247. *Transgenic Hearings*, *supra* note 22, at 463 (Testimony of Dr. Alan E. Smith, Vice-President and Scientific Director, Integrated Genetics, Inc.) [hereinafter Smith Testimony].

248. Wagner Testimony, *supra* note 22, at 46.

249. *Id.* at 46-47. Unlike conventional breeding, which randomly combines the genes of two mated animals, genetic engineering technology (specifically recombinant DNA) can be used to isolate and transfer one particular gene, thereby decreasing the numbers of progeny which lack the desired trait. This practice should at least reduce the number of experimental animals unmodified for an intended characteristic.

250. *See* Meeting Notice, 50 Fed. Reg. 9764-67 (1985)(Dr. Landy of the NIH Recombinant DNA Advisory Committee discussing animal germline gene transfers as producing the "desirable without the undesirable.").

251. Wagner Testimony, *supra* note 22, at 37.

252. Walters Testimony, *supra* note 43, at 389. Animal welfare groups do object to confinement rearing and many other commercial agricultural practices. *See* Hoyt Testimony, *supra* note 238, at 98-99. The mistreatment of animals in the larger, non-genetic engineering sense was expressly not addressed in the House Transgenic Hearings. *Transgenic Hearings*, *supra* note 22, at 99 (remarks of Congressman Kastenmeier).

of patents cannot be the cause of transgenic animals. The animal welfare opponents of animal patenting have not adequately justified taking the risk that vital biomedical and agricultural developments will be delayed if a moratorium is enacted. Nor has it been proved that the regulatory agencies or Congress requires a moratorium on transgenic technology in order to reconsider animal research policies reflected in the 1985 legislation.

VII. ENVIRONMENTAL RISKS

> Mounting concerns about environmental degradation, together with the pressing problems of ensuring adequate food and health care for a rapidly expanding global population, provide a compelling rationale for the accelerated study and development of biological organisms for use in agriculture, health care, and biosphere management. The committee concludes that R-DNA techniques constitute a powerful and safe new means for the modification of organisms.
>
> Committee on the
> Introduction of Genetically
> Engineered Organisms into
> the Environment[253]

If "biotechnology" or "genetic engineering" is defined so as to encompass conventional plant and animal breeding as well as conventional microbial mutation and selection techniques, then genetically engineered plants,[254] animals,[255] and microorganisms[256] can be said to have long been utilized in the environ-

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253. Committee on the Introduction of Genetically Engineered Organisms into the Environment, Report prepared for the Council of the National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* 6 (1987) [hereinafter *NAS Environment*]. This report has been criticized as a rather brief treatment of the topic. *See, Transgenic Hearings, supra* note 22, at 461 (Testimony of Margaret Mellon, Director of the Biotechnology Project, National Wildlife Federation) [hereinafter Mellon Testimony]. Other commentators find the report to be more satisfactory. *See, e.g.*, Young & Miller, *The NAS Report on Deliberate Release: Toppling the Tower of Bio-Babble*, 5 BIO/TECH. 1010 (1987).

254. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. OTA-HR-132, IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS 137 (1981) [hereinafter OTA GENETICS]. Since the beginning of the 20th century, breeders have helped increase the productivity of many important plants for food, feed, fiber and pharmaceuticals by cultivating varieties to fit specific environments and production practices.

255. *Id.* at 168-71.

256. *Id.* at 117-20. In mining, for example, microorganisms have been used for the following purposes: (1) to extract 10-15% of the total annual copper production; (2) to recover uranium through underground solution mining (a practice considered to be less environmentally damaging than traditional digging); (3) to extract sulfur-containing compounds from coal so that coal can be burned with less release of environmentally-damaging sulfuric acid; and (4) to recover oil. *Id.*

ment outside of containment systems. Agriculture and other sectors have benefitted from these environmental uses of living organisms.

In order to capture the benefit of genetically engineered organisms, some must be tested outside of the laboratory and introduced or released into the environment.[257] Some parties contend that the environmental introduction of organisms that are genetically engineered by recombinant DNA or other modern techniques,[258] represents an unacceptable risk of harm to the environment.[259] A recent report prepared for the National Academy of Sciences (NAS),[260] however, studied the planned introduction into the environment of organisms genetically engineered by recombinant DNA techniques. Here, the authors concluded that there was "adequate knowledge of the relevant scientific principles, as well as sufficient experience with [recombinant DNA] engineered organisms, to guide the safe and prudent use of such organisms outside research laboratories."[261]

A key finding of the NAS Committee was that the ecological risks associated with the introduction of genetically engineered organisms, produced by any technique, were the same as those associated with the introduction of any new, but genetically unmodified, organism into a given ecosystem.[262] Thus, the NAS maintained that the possibility of environmental harm from genetically engineered organisms was extremely unlikely be-

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257. *NAS Environment*, *supra* note 253, at 8.

258. Earlier in the biotechnology era, this concern formed the basis for the 1975 International Asilomar Conference that recommended a temporary moratorium on recombinant DNA research until experimental bacteria could be developed which would not survive outside of research laboratories. *See* Watson, *supra* note 196; Krimsky, *supra* note 196. *See also* McChesney & Adler, *Biotechnology Released From the Lab: The Environmental Regulatory Framework*, 13 ENVT'L. L. REP. 10366 (1983); *Environmental Implications of Genetic Engineering, Hearings before the Subcomm. on Investigations and Oversight, of the Subcomm. on Science, Research and Technology, of the House Comm. on Science and Technology*, 98th Cong., 1st Sess. (1983). After appropriate containment practices had been developed, the moratorium, then supervised by the National Institutes of Health Recombinant DNA Advisory Committee, was lifted subject to prescribed laboratory procedures.

259. *See, e.g.*, Sharples, *Spread of Organisms with Novel Genotypes: Thoughts From an Ecological Perspective*, 6 REC. DNA TECH. BULL 43 (1983); Mellon Testimony, *supra* note 253, at 419-32. Of particular concern are the possibilities that deliberately-released organisms genetically-modified by recombinant DNA and other modern techniques might unpredictably be as harmful to the environment as imported, non-native (but not genetically engineered) organisms such as the gypsy moth, starling, Japanese beetle, and Kudzu vine, which have caused environmental catastrophes. On the other hand, new species introductions can be valuable, in that virtually all of the commercially-significant crops grown today in the United States are non-native species; NATIONAL ACADEMY OF SCIENCES, GENETIC VULNERABILITY OF MAJOR CROPS (1972); OTA GENETICS, *supra* note 254, at 139-40. The same is true of most pets and ornamental plants. *NAS Environment*, *supra* note 253, at 18.

260. *NAS Environment*, *supra* note 253.

261. *Id.* at 6.

262. *Id.* at 22-23.

cause these organisms "resemble the parent organism in their reproductive and growth characteristics, and are often at a disadvantage with respect to their parents in their ability to survive and to reproduce."[263] As discussed above, most transgenic modifications will have a minute overall impact on an organism's genome.[264] Thus, organisms modified through recombinant DNA techniques are not wholly "novel" organisms but rather are like a breeder's new flower variety, in terms of environmental risk.[265] The NAS study stressed that some risks nevertheless will remain associated with the introduction of certain organisms and that, "[t]herefore, society's task must be to classify and manage the risks appropriately."[266]

Recognizing this uncertainty or risk, some opponents of animal patenting contend that patents will accelerate the development of genetically engineered organisms and, because science cannot yet guarantee the safety of all such organisms once released, Congress must apply a brake to genetic research via a patent moratorium.[267] Two general classes of transgenic animals are identified as posing environmental risk. The first consists of farm and laboratory animals, which exist in synthetic, confined ecosystems;[268] the second is composed of animals to be released into the wild, such as fish and shellfish used in aquaculture.[269] What appears to be the more serious concern, is the uncertainty about potential harm to wildlife caused by the introduction of genetically engineered animals that might displace inhabitants of a natural ecosystem.[270] Other opponents of animal patenting contend that patentability of living organisms will skew corporate strategies away from releasing naturally occurring, perhaps less hazardous, products and toward products which are genetically engineered and patentable.[271]

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263. *Id.* at 14. *See also* Karny Testimony, *supra* note 43, at 442-43.

264. *See supra* notes 122-26 and accompanying text.

265. *NAS Environment*, *supra* note 253, at 14.

266. *Id.* at 18. The NAS recommended that key biological and ecological parameters must be evaluated to minimize the risk to ecosystems. These parameters include the biological properties and the source and target environments of the organism, as well as the scale and frequency of such introductions. *Id.* at 7. It appears that additional basic ecological research must be conducted on the survivability of modified organisms. *See, e.g.*, Regal, *Models of Genetically Engineered Organisms and Their Ecological Impact*, 10 RECOMB. DNA TECH. BULL. 67, 81-82 (1987).

267. *See, e.g.*, Mellon Testimony, *supra* note 253, at 419-20; Doyle Testimony, *supra* note 88, at 70-71.

268. *See, e.g.*, Wagner Testimony, *supra* note 22, at 50.

269. *See, e.g.*, Mellon Testimony, *supra* note 253, at 420.

270. *See id.*; *see also* Wagner Testimony *supra* note 22, at 38.

271. Doyle Testimony, *supra* note 88, at 70-71, 92. However, some transgenic research will minimize the use of environmentally harmful pesticides. For example, Calgene Corp. has genetically engineered plants to resist treatment with a "soft" herbicide, glyphosate, which does not persist in the environment but biodegrades into carbon dioxide and water. Godown Testimony, *supra* note 80, at 533.

Given the historic introduction into the environment of agricultural organisms altered through conventional genetic techniques, and given the perceived remoteness of environmental risk and the benefits expected from the agricultural and environmental uses of genetically engineered organisms,[272] many proponents of animal patents fear an unwarranted level of federal regulation.[273] For example, the NAS urged that "paralyzing overregulation" be avoided in favor of developing valid scientific considerations that must underlie an effort to categorize risks.[274] To the extent that regulation reflects the political climate, it is significant that a majority of the public would approve the environmental use of a genetically engineered organism having no direct risk to humans when the risk of losing some local species of plants or fish was as great as 1 in 1,000.[275]

Two key questions are thus presented. First, is the existing statutory and regulatory authority adequate to manage the environmental risks? Second, can the environmental risks be regulated under existing or proposed environmental laws so as to preclude the need for a broad patent or research moratorium on all transgenic animals? At present, federal regulation of environmental release of organisms is divided essentially between the USDA, primarily for plant pests, and the EPA, primarily for microorganisms.[276] The USDA requires a permit for interstate transport, or for release into the environment, of a genetically engineered organism[277] listed as a plant pest[278] or, arguably, an animal pest.[279] The EPA controls the environmental testing of

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272. *See generally* OTA GENETICS, *supra* note 254.

273. *See, e.g.*, Karny Testimony, *supra* note 43, at 453-55; Brill Agriculture, *supra* note 100, at 1087.

274. *NAS Environment*, *supra* note 253, at 12. The NAS also warned against the other extreme of "inattention to significant potential hazards." *Id.*

275. OTA PERCEPTIONS, *supra* note 15, at 64. A larger majority (74%) would approve such an environmental use at a risk to local species of 1 in a million. *Id.* Over 70% would approve the environmental use of genetically engineered organisms to produce disease-resistant crops, bacteria to clean oilspills, and frost-resistant crops. *Id.* at 65.

276. *See* OSTP FRAMEWORK, *supra* note 4.

277. 7 C.F.R. § 340 (1987). Genetic engineering is defined by the USDA as the modification of organisms by recombinant DNA techniques. *Id.* § 340.1. The USDA regulations are promulgated pursuant to the Plant Quarantine Act and the Federal Plant Pest Act, *supra* note 61.

278. 7 C.F.R. § 340.2 (1987). Unclassified organisms are also regulated. *Id.* Plant pests are defined to include insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any similar organisms which can directly or indirectly injure or cause disease or damage plants. *Id.* § 330.100(h)(1). The agricultural pest market may be the leading contender for transgenic research. More than one-third of all U.S. crops (worth about $50 billion) are lost to pests each year. Pimentel, *Down on the Farm: Genetic Engineering Meets Ecology*, 90 TECH. REV. 24 (1987). Genetic engineering could reduce the annual cost of pesticides by as much as $500 million. *Id.*

279. *See* Virus-Serum-Toxin Act, 21 U.S.C. § 151-158 (1982 & Supp. III 1985).

microbial pesticides and the environmental release of many microorganisms.[280] The NIH also regulates the environmental release of organisms modified through recombinant DNA techniques,[281] but defers to other agencies in situations of jurisdictional overlap.[282] Each of the foregoing regulatory agencies requires a demonstration that appropriate, scientifically-justifiable containment procedures have been adopted for regulated releases.

No agency has claimed statutory jurisdiction, for example, over the release of transgenic fish or shellfish into waterways or over the possible escape of transgenic research animals or livestock into the wild.[283] Thus, some opponents of animal patenting contend that the regulatory control of biotechnology lacks an adequate statutory basis to address the environmental issues raised by transgenic animals.[284] Accordingly, it is argued that no justification can exist to stimulate technology through patenting absent at least a linkage with new legislation to provide broader regulatory authority.[285] In response to environmental concerns, Senator Baucus (D, Montana) has recently proposed an amendment to the Toxic Substances Control Act[286] that would expand the EPA's regulatory jurisdiction to "novel or exotic organisms" and provide stiff civil penalties and criminal sanctions for unpermitted releases.[287] Such legislation could fill gaps in the present environmental protection laws.[288]

The management of environmental risk through the planned introduction of such organisms is a subject that patenting opponents admit will require federal oversight regardless of

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280. EPA's rules were promulgated pursuant to FIFRA and TSCA, *supra* note 60.

281. *See NIH Guidelines for Research Involving Recombinant DNA Molecules*, 51 Fed. Reg. 16,958, 16,961 at Section III-B-4 (1986) [hereinafter *NIH Guidelines*]. These Guidelines apply only to scientists and institutions receiving NIH funding. *Id.* § I-C, at 16,959. Industry has followed these guidelines on a voluntary basis since their inception in 1976. *See* Karny Testimony, *supra* note 43, at 445.

282. *See NIH Guidelines*, *supra* note 281 (as amended at 52 Fed. Reg. 31,848 at Section IA (1987)).

283. *See* Mellon Testimony, *supra* note 253, at 421.

284. *Id.* Because transgenic research will continue regardless of a moratorium, environmental legislation and regulation is needed to address the risks of inevitable research. *Id.*

285. *Id.* at 421-22.

286. TSCA, *supra* note 60.

287. *Senator Seeks Drastic Penalties for Releasing Novel or Exotic Organisms*, 8 BIOTECH. NEWSWATCH, Mar. 21, 1988, at 3. Such legislation is in part a response to recent release incidents reported in the press. *See, e.g., NIH Probe Exonerates Elm-Disease Scientist of Violating r-DNA Rules*, 8 BIOTECH. NEWSWATCH, Jan. 18, 1988, at 8.

288. New legislation might also address preemption issues, since some states' own agricultural agencies must issue permits notwithstanding EPA approval. *See, e.g., EPA Gives Go-Ahead to Field-Test r-DNA Nitrogen-Fixing Bacterium*, 8 BIOTECH. NEWSWATCH, Mar. 21, 1988, at 1; Gladwell, *Towns Restricting Tests of Altered Organisms: New Laws Reflect Worries Regarding the Effects of Outdoor Tests on Environment*, The Washington Post, Mar. 20, 1988, at H1, col.1.

whether a moratorium on animal patents is enacted.[289] To the extent that the release of genetically engineered organisms into the environment requires federal regulation, the issue can apparently be dealt with by the agencies responsible for that regulation, such as the EPA and the USDA. Congressional oversight appears to be necessary in order to establish a broader statutory base for regulation. If the concerns of the environmentalists are sufficient to justify a moratorium on releases, then an express federal moratorium on the release of transgenic organisms would be indicated–not an indirect regulation of the rate of research which may also slow the production of transgenic animals, such as those claimed in the first animal patent, that are intended for biomedical research rather than for environmental dissemination.

VIII. PRESERVATION OF BIOLOGICAL DIVERSITY

> The Congress further finds that the extinction of animal and plant species is an irreparable loss with potentially serious environmental and economic consequences for developing and developed countries alike.
>
> The International Environmental Protection Act of 1983[290]

Opponents of animal patenting argue that plant patenting triggered corporate consolidation in the plant agricultural industry and that such consolidation directly resulted in lowered diversity of commercial agricultural products.[291] They contend that the patenting of animals will similarly cause a reduction of the genetic diversity in commercial animals.[292] While decreased diversity is admittedly a serious concern, the link between patent or PVPA protection and decreased agricultural diversity is not convincing. For example, a five-fold increase in the number of companies undertaking soybean research and a ten-fold increase in the number of soybean breeders occurred after enactment of the PVPA.[293]

The concern over genetic diversity in commercial agriculture is acute, since world agricultural production relies primarily on

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289. Mellon Testimony, *supra* note 253, at 421.

290. 22 U.S.C. § 2151(q) (Supp. I 1983).

291. Doyle Testimony, *supra* note 88, at 77-80 and 94-95; Mooney, *The Law of the Seed, Another Development in Plant Genetic Resources*, 1-2 DEVELOPMENT DIALOGUE 1 (1983) [hereinafter Mooney]; J. DOYLE, ALTERED HARVEST (1985).

292. Doyle Testimony, *supra* note 88, at 89.

293. Duffey Testimony, *supra* note 54, at 138.

eight domesticated plants to provide most of the protein and calories consumed by humans and by agriculturally important animals.[294] The United States is particularly at risk because it is a gene-poor nation.[295] The ancestors of many crops arrived literally in the pockets of immigrants.[296] Moreover, current United States agricultural crops have been further bred to a high degree of genetic uniformity from the originally narrow base of genetic variability.[297] Such genetic uniformity increases the risk of pandemic disease or pest infestation because genetic uniformity means common susceptibility.[298] In order to obtain genetically diverse breeding stock, the United States must either become dependent on those countries, predominantly in the Third World, that have undeveloped areas of untapped germplasm or create diversity through genetic engineering, or both.[299]

The critics of animal patents have recognized, however, a recent and "considerable consolidation throughout livestock agribusiness."[300] This consolidation occurred prior to the PTO's April 7, 1987 announcement that animals were patentable subject matter. The acknowledged, preexisting trend toward concentration in the livestock industry suggests causal factors in corporate acquisitions other than, or at least in addition to, the possibility of intellectual property protection.

In contrast to the argument that patenting decreases plant and animal varieties, the House Committee on Agriculture found that three times more wheat, three times more soybean, and six times more cotton varieties were developed during the 10-year period after enactment of the PVPA as compared to the same time period prior to its enactment.[301] This finding indicates that plant protec-

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294. OTA COMMERCIAL BIOTECH, *supra* note 9, at 172.

295. OTA GENETICS, *supra* note 254, at 154-58.

296. *See* Burley & Courrier, *A Genetic Cornucopia*, The Washington Post, Nov. 22, 1984, at A27, col. 1.

> One day each year our forebears praised Nature from whom all blessings and most profits flow. Appropriately, they feasted. But had the pilgrims stuck strictly to native fare, their fish, meat and fowl would have been accompanied primarily by pecans, cranberries, Jerusalem artichokes and sunflower seeds.
>
> In 17th century America, indigenous vegetables were scarce, and today most of what we eat comes from seeds immigrants first brought from Mexico (corn), Peru via Great Britain (potatoes and tomatoes), Portugal (onions), Cyprus (cauliflower), the Netherlands (carrots), France (peas), Germany (cabbage), Italy (broccoli and zucchini) and dozens of other countries. Even autumn's icon, the pumpkin, was probably imported from Latin America.

Id.

297. OTA COMMERCIAL BIOTECH, *supra* note 9, at 172.

298. NATIONAL ACADEMY OF SCIENCES, GENETIC VULNERABILITY OF MAJOR CROPS (1972). *See* Adler Biotechnology, *supra* note 218, at 471-78.

299. *See* OTA GENETICS, *supra* note 254, at 154-62.

300. Doyle Testimony, *supra* note 88, at 84.

301. H.R. REP. NO. 1115, 96th Cong., 2nd Sess. 4 (1980) (House Committee on Agriculture Report to Accompany H.R. 999). *See* Adler Patents, *supra* note 79, at 220-21.

tion may stimulate crop diversity notwithstanding ongoing industry consolidation. Other investigators have also reported a sharp increase in the number of new plant varieties since enactment of the PVPA.[302] Thus, the existence of causal connections between patent protection, industrial consolidation, and crop uniformity are far from established.[303]

In reality, multiple factors are at work in the narrowing of the agricultural genetic base. For example, mechanized harvesting and processing require uniform maturation, size, and shape within crops.[304] Similar processing factors are already influencing livestock production.[305] A factor that may further limit commercial germplasm diversity is reflected in the ongoing research to make various plants genetically resistant to certain herbicides and pesticides and therefore preferred.[306] This practice would presumably continue in the absence of plant patents.[307] Finally, although patents could affect breeders' access to plant and animal germplasm by raising the commercial value of this germplasm,[308] this enhanced value may stimulate the collection and preservation of germplasm with ultimate public access through the marketplace.[309]

In summary, the opponents of plant and animal patenting cannot prove that a moratorium on animal patents will diminish corporate consolidation already occurring in the livestock industry. They have not shown the existence of a causal link between patents and corporate consolidation or between patents and the narrowing of commercial genetic diversity. Nor do they refute evidence that patenting increases diversity. Genetic engineering may be used to overcome the deficiencies of our narrow agricultural genetic base through addition of individual genes from

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302. Evenson, *supra* note 86; *Transgenic Hearings*, *supra* note 22, at 535 (Testimony of David R. Lambert, Director of Government Relations, American Seed Trade Association).

303. *See* OTA GENETICS, *supra* note 254, at 157.

304. *Id.*; Martin & Olmstead, *The Agricultural Mechanization Controversy*, 227 SCI. 601 (1985).

305. OTA AGRICULTURE, *supra* note 17, at 38-39.

306. Some companies avoid detrimental environmental consequences by developing plants resistant to "soft" herbicides. Such herbicides readily biodegrade in the environment to carbon dioxide and water rather than to toxic chemical species. Godown Testimony, *supra* note 80, at 533-34.

307. A patented plant resistent to a herbicide cannot be used to control sales of the chemical. A patent cannot be used to suppress competition of an unpatented article. *See, e.g.*, Morton Salt Co. v. G.S. Suppiger, Co., 314 U.S. 488 (1942), *reh'g denied* 315 U.S. 826 (1942).

308. *See, e.g.*, Hilts, *Battles Sprout Over World Seed Supplies*, The Washington Post, Nov. 4, 1985, at A3, col. 1. This privatization threat has been widely condemned. *See, e.g.*, Mooney, *supra* note 291.

309. Lesser, *Patenting Seed in the United States of America: What to Expect*, 25 IND. PROP. 360, 366 (1986).

foreign plants.[310] Advances in transgenic technology may play a vital role in preventing or treating agricultural diseases or pests. Indeed, it would be foolhardy to allow a patent moratorium to slow the acquisition through research of transgenic agricultural knowledge because of a coincidental trend toward corporate consolidation.

IX. THE ETHICS OF ANIMAL PATENTING

> It appears to me that in Ethics, as in all other philosophical studies, the difficulties and disagreements, of which history is full, are mainly due to a very simple cause: namely to the attempt to answer questions, without first discovering precisely *what* question it is which you desire to answer.
>
> George Edward Moore[311]

The Humane Society believes that animal patenting "violates the basic ethical precepts of civilized society."[312] The President of the Humane Society testified before Congress that "the patenting of animals reflects a human arrogance toward other living creatures that is contrary to the concept of the inherent sanctity of every unique being and the recognition of the ecological and spiritual interconnectedness of all life."[313] Public opinion, by an almost three-to-one ratio overall, aligns with an opposite view–that the creation of hybrid plants and animals through direct manipulation of DNA is not morally wrong.[314] Although not dispositive of what is or is not ethical, public opinion is a significant factor guiding Congress in its ethical decisions.

In the arguments against animal patenting, no real distinction has been made between patenting and the technology to be patented. Indeed, objections to patenting are typically com-

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310. *See* Part IV, *supra*. Although genetic engineering may be used to increase the world's stock of genetic resources, on the other hand, "the great promise of biotechnology may never be realized if genetic resources, the essential raw material for this technology, continue to disappear." Christensen, *Genetic Ark: A Proposal to Preserve Genetic Diversity for Future Generations*, 40 STAN. L. REV. 279, 320 (1987).

311. J. BARTLETT, BARTLETT'S FAMILIAR QUOTATIONS, (E. Beck ed., 14th ed. 1968).

312. Hoyt Testimony, *supra* note 238, at 59.

313. *Id.* at 64.

314. Sixty-eight percent (and 81% of college graduates) had no moral qualms while 24% (and 13% of college graduates) felt that genetic manipulation was morally wrong. OTA PERCEPTIONS, *supra* note 15, at 58. A comparable number, 26%, felt that the creation of hybrid plants and animals through conventional breeding techniques also was morally wrong. *Id.* at 59. Courts tend to rely on the ethics of Congress, examining only whether the statute grants patent protection to an invention and, if so, assuming Congress felt it was for the public good. Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1149-51 (1987).

mingled with concerns about the impacts of the underlying technology. In this context, transgenic research has been described in somewhat pejorative terms, such as "tinkering" or "manipulation" instead of "modification" or "improvement."[315] (For example, it was argued that "[s]uch genetic tinkering and alteration, including human/animal gene-splicing, raises troubling moral and legal questions."[316] Also, this view has been described as a reactive fear that "takes the form of anger at the thought of 'tinkering' with human beings or human nature."[317])

The National Council of Churches, while not opposed to genetic engineering *per se*, believes that the "[r]everence for all life created by God may be eroded by subtle economic pressures to view animal life as if it were an industrial product invented and manufactured by humans."[318] Moreover, the Council fears that the "rapid pace of this technology is outstripping society's capacity for considered moral judgment."[319] Thus, the patenting of animals to some may seem a symbolic step in the advance of biotechnology from which retreat is unlikely.[320] The Humane Society, in fact, fears that this step will not stop at non-human animals. It sees the first animal patent to represent the elimination of all ethical and social constraints against the genetic alteration of human beings.[321] No justification for this fear is advanced. The strict regulations and procedures governing human experimentation are promulgated and administered separately from the research aspects of animal experimentation.[322] Furthermore, the public ap-

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315. Fletcher, *Ethics and Recombinant DNA Research*, 51 S. CAL. L. REV. 1131 (1978). Fletcher noted that: "[T]he use of the word 'tinkering' in this context illustrates how language is more important in ethical discourse than in scientific discourse because of the role played by semantics. In common usage, certain words carry a negative connotation. The literature of biomedical ethics is filled with pejorative words such as 'tinkering' rather than 'modifying,' 'engineering' rather than 'construction,' 'manipulation' rather than 'control,' 'gadgetry' rather than 'technology,' and 'potential horrors' rather than 'risks.' These are examples of wordcraft; they are logomachies used to slant discussion." *Id.* at 1131 n.2.

316. Information Statement of the Coalition Against the Patenting of Animals (1987). This Coalition was spearheaded by the Humane Society of the United States and the Foundation on Economic Trends.

317. Fletcher, *Ethics and Recombinant DNA Research*, 51 S. CAL. L. REV. 1131 (1978).

318. *Transgenic Hearings*, *supra* note 22, at 399 (Testimony of Minister Wesley Granberg-Michaelson on behalf of the National Council of Churches) [hereinafter Granberg-Michaelson Testimony]; *id.* at 351 (Testimony of Bishop Schumacher).

319. Granberg-Michaelson Testimony, *supra* note 318, at 398. Similarly, others fear that by permitting animal patenting we "may lose our reverence for life and diminish our own humanity." *Transgenic Hearings*, *supra* note 22, at 407 (Testimony of Rabbi Michael Berenbaum, Scholar-in-Residence, Religious Action Center of Reform Judaism). *See also Transgenic Hearings*, *supra* note 22, at 408-19 (discussion among the clergy in response to questions from Congressmen Kastenmeier, Moorhead and Berman).

320. "Patenting new animal life forms is like crossing the Rubicon. It is a decision with potentially momentous consequences, not easily undone." *Id.* at 399.

321. Hoyt Testimony, *supra* note 238, at 65.

322. National Research Act, 42 U.S.C. § 289 (1982).

parently does not share the Humane Society's fears, as polls show that approximately 86% of Americans would be at least somewhat willing to have their own child undergo genetic therapy to correct a usually fatal genetic disease.[323]

The opponents of animal patents urge, at minimum, a temporary patent moratorium to enable contemplation not of the legal basis for animal patents, but of the indirect consequences of patenting, *i.e.*, the medical and industrial applications of biotechnology. Little attempt to balance the benefits and risks of genetic engineering or of patenting is made, apparently on the ground that too many fundamental questions exist regarding control of the technology (*i.e.*, who will utilize transgenic techniques, for whom, why, and under whose supervision).[324] However, in view of the importance of transgenic experiments in scientific research, the treatment of human and animal diseases, and the development of more efficient food sources, the NIH Recombinant DNA Advisory Committee considered it to be a *moral imperative* to oppose the blanket prohibition of transgenic research.[325] As stated previously, a patent moratorium may exact a high price from those deprived of medical advances or expanded food supplies if technology is delayed.[326]

Animal genetic engineering has been criticized because it allows exchanges of genes between unrelated species, a phenomenon not observed in nature or in conventional breeding practices.[327] However, LeRoy Walters, a noted bioethicist, finds the notion that genetic boundaries between species are inviolable is based on an "implausible philosophy of nature" which "ignores evolutionary theory and the findings of twentieth-century biology,"[328] that species in nature do not exist as separate creatures.[329]

Since the work of Charles Darwin,[330] species are no longer thought of as unitary groups of types of organisms.[331] The contemporary understanding is that species are reproductive communities or populations "distinguished by their collective manifestation of ranges of variation with respect to many dif-

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323. OTA PERCEPTIONS, *supra* note 15, at 75-77. Also, 78% of the public surveyed would be at least somewhat willing to undergo genetic therapy to correct a gene that would likely lead to a serious or fatal genetic disease later in life. *Id.*

324. Granberg-Michaelson Testimony at 318.

325. 50 Fed. Reg. 9760, 9767 (1985).

326. Walters Testimony, *supra* note 43, at 411.

327. Hoyt Testimony, *supra* note 238, at 62.

328. Walters Testimony, *supra* note 43, at 388. Walters was responding to an allegation of Jeremy Rifkin, Letter to William Gartland, 49 Fed. Reg. 37,016 (1984).

329. OTA ANIMALS, *supra* note 99, at 10 ("The right of a species to exist as a separate, identifiable creature has no known foundation in biology because species in nature exist as reproductive communities, not as separate creatures.").

330. C. DARWIN, ON THE ORIGIN OF SPECIES (1859).

331. OTA ANIMALS, *supra* note 99, at 7.

ferent characteristics or qualities at the same time."[332] As the parameters which define these variations are themselves variable, there is no absolute rule that species are bounded by a discrete genetic profile.[333] To violate "species integrity," to the extent that it exists, would require a genetic disruption so extreme that the reproductive community could no longer exchange genetic information, a feat beyond the ability of current techniques.[334]

LeRoy Walters reasons that a legitimate ethical distinction can and should be made between transgenic research and patenting, unless patenting will necessarily or almost certainly lead to inhumane treatment of animals, which has not been shown.[335] He also believes that unless the "venerable" systems of patent and copyright law are found to produce serious harm to human or animal welfare, they "should be preserved intact as an ethically-appropriate way of acknowledging the initiative and creativity of authors and inventors."[336]

Several other commentators also object to addressing ethical questions within the context of patentable subject matter. "The patent system is certainly the wrong place to regulate matters of ethical, social or moral concern."[337] Such concerns are susceptible to much more precise and direct regulatory intervention if needed.[338] Thus, these commentators favor an approach that would avoid the indiscriminate slowing of those applications of biotechnology which do not present ethical concerns or which, on balance, are highly favorable. The patenting of animals is considered by many to be a relatively benign ownership practice given the existing agricultural and research industries' utilization of animals.[339] More broadly, the patenting of living organisms is further considered to be morally justified at least on utilitarian grounds.[340] Other commentators simply see no need to reflect on the ethics *per se* of animal patenting because the underlying technology is not unethical.[341] In fact, since the environments of agricultural animals have been drastically altered from their natural ecosystems, some suggest we are further obligated to alter their genes to match the agricultural settings.[342] The

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332. *Id.* at 8.
333. *Id.* at 8.
334. *Id.* at 10.
335. Walters Testimony, *supra* note 43, at 388.
336. *Id.* at 389.
337. Duffey Testimony, *supra* note 54, at 147; Smith Testimony, *supra* note 247, at 464.
338. *See, e.g., supra* notes 52-56 and accompanying text.
339. Walters Testimony, *supra* note 43, at 389.
340. Holtzman, *Patenting Certain Forms of Life: A Moral Justification*, 9 THE HASTINGS CENTER REP., June, 1979, at 10.
341. *See* Part VI, *supra.*
342. Wagner Testimony, *supra* note 43, at 38, 50.

sanctity of life and the ethics of research and breeding programs furthermore are considered by many to have been thoroughly reviewed by Congress.[343]

In summary, those who oppose the patenting of animals on ethical grounds have not demonstrated that application of the patent system is harmful to society or to animals. It is also noteworthy that public opinion is not opposed to the genetic engineering of plants and animals. Should the twenty-first century bring new technological capacity to transfer large gene complexes or multiple genetically based traits across species lines, at that time "[o]ne hopes," as Walters notes, "that timely, calm, and systematic discussion of these technical possibilities will lead to a social consensus on reasonable ethical limits to human curiosity and ingenuity."[344]

X. AGRICULTURAL DEMOGRAPHICS

> When tillage begins, other arts follow. The farmers therefore are the founders of human civilization.
>
> Daniel Webster[345]

This Part describes the trends in farm demographics and technology utilization in the agricultural sector. The dairy subsector, which is expected to initially feel the most dramatic effects of biotechnology and information technology,[346] is discussed by way of example.

The Jeffersonian ideal of the independent, autonomous farmer had disappeared from United States agriculture decades before the advent of modern genetic engineering. The reasons discussed below for the transition to large consolidated farm enterprises are complex. One million farms, one out of two now in existence, are projected to disappear by the year 2000.[347] The continuing decline of small and moderate size farms raises the complex issue of whether the preservation of unique social, cultural, and traditional values associated with family farming requires federal intervention.[348]

From a peak of about 6.8 million in 1935, the total number of farms in this country has declined to approximately 2.2 million.[349] Post-World War II mechanization and utilization of fuel, fertilizer

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343. *See, e.g.*, Smith Testimony, *supra* note 247, at 464, 466.
344. Walters Testimony, *supra* note 43, at 390.
345. J. BARTLETT, BARTLETT'S FAMILIAR QUOTATIONS (E. Beck ed., 14th ed. 1968).
346. OTA AGRICULTURE, *supra* note 17, at 84.
347. *Id.* at 96.
348. *Id.* at 117.
349. *Id.* at 91.

and other chemicals increased by fifteen-fold the pre-war dollar value of farm capital per worker.[350] Productivity more than doubled between 1930 and 1980 due to this chemical investment as well as to new technologies involving hybrid seeds, improved livestock feeding, and disease prevention.[351] During the period from 1969 to 1982, the majority market share shifted from the combined incomes of small, part-time, and moderate size farms to that of the combined shares of the large and very large farms. Very large farms, with greater capacity to control costs of production, increased their share of net farm income from 36% in 1969 to 64% in 1982.[352]

If present trends in market share and consolidation continue, the total number of farms will decline to about 1.2 million by the year 2000.[353] The numbers of small, part-time, and moderate size farms will decrease between 30% to 60%, while the numbers of large farms will increase, and very large farms will double in number to about 50,000.[354] The very large farms will probably produce 75% of all farm products, and the remaining small farms will likely disappear to the extent that their operators rely upon farm income.[355] Specific geographic regions and market subsectors (cash grains, cotton, fruit and tree nut, vegetables and melons, dairy, poultry, cattle and calf, and pork) will experience variations on this demographic pattern.[356]

The causes of these structural changes are complex. Three major determinants are: (1) technological–involving capital requirements, specialization and economies of size; (2) institutional–relating to costs of inputs and prices for products as well as research and extension services; and (3) economic and political–involving commodity support programs, tax policy, international trade, agricultural credit, and consumer preferences.[357]

Livestock, which may be most affected by transgenic technology, represents our largest agricultural sector with respect to sales and geographic scope.[358] Much of the livestock supply is

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350. *Id.*
351. *Id.*
352. *Id.* at 93.
353. *Id.* at 96.
354. *Id.* at 96.
355. *Id.* at 97.
356. *Id.* at 97-105.
357. *Id.* at 112-17. The consumer preference factor is reflected, for example, in the increased health concerns about over-consumption of animal products. *Transgenic Hearings*, *supra* note 22, at 122 (Testimony of Dr. A. Ann Sorensen, Assistant Director, Natural and Environmental Resources Division, American Farm Bureau) [hereinafter Sorensen Testimony].
358. William Lesser, Associate Professor of Marketing, Department of Agricultural Economics, Cornell University, Presentation entitled "Applying Animal Patents in Agriculture" at the Symposium on the Protection of Biotechnological Inventions in Ithaca, New York, June 4-5, 1987 [hereinafter Lesser Presentation].

produced by large, specialized farms.[359] The diversity of producers, and the varied breeding practices and marketing patterns of livestock subsectors (*e.g.*, dairy, beef cattle, or hogs) may give rise to difficult patent enforcement logistics and may result in complex licensing practices for patented animals.[360] These hurdles should not prove insurmountable if the economic advantage of acquiring such animals makes the necessary business mechanics worthwhile.[361] Additionally, questions of infringement have been raised.[362] These questions are discussed in Part XI.

Regardless of the existence of transgenic animals or animal patents, the dairy industry, for example, faces profound changes caused both by preexisting industry trends in consolidation and by economic factors, which exert strong pressure to increase the size of herds.[363] Based in part on economies of scale, the larger dairies are more profitable than smaller dairies,[364] and more capital-intensive operations are also relatively more profitable.[365] New technologies, such as biotechnologies and information management technologies, provide greater financial opportunities for large rather than small dairies.[366]

Also irrespective of transgenic animal research, existing *bacterial* recombinant DNA technology will exert a profound influence on milk productivity and profitability. Recently, the availability of bacterially-expressed bovine growth hormone has led to an increase in milk production and a decrease in production cost.[367] Based on such productivity aids, as well as emerging

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359. *Id.* at 2. (Only 35% of livestock farms report annual sales exceeding $10,000).

360. *Id.* at 2-11.

361. Biotechnology portends no change in the legal and economic issues related to the licensing of inventions. Schlicher, *Some Thoughts on the Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, 69 J. PAT. TRADEMARK OFF. SOC'Y 263 (1987). Appropriate licensing practices for patented animals will be worked out by the parties involved. *Transgenic Hearings*, *supra* note 22, at 173 (Testimony of Robert P. Merges, Julius Silver Fellow in Law, Science & Technology, Columbia University Law School) [hereinafter Merges Testimony]. *See* Stern, *Shrink-Wrap License of Mass Marketed Software: Enforceable Contract or Whistling in the Dark?*, 11 RUTGERS COMPUTER & TECH. L. REV. 51 (1985), for an analysis of shrink-wrap licensing of computer software, a market transaction analogous to animal patents in the sense that new licensing procedures are developed in the market place to accommodate emerging technologies.

362. *See, e.g.*, Sorensen Testimony, *supra* note 357, at 123-24. Although it was suggested that the PTO address such questions, matters of infringement are beyond the jurisdiction of that agency. *In re* Hogan and Banks, 559 F.2d 606 (1977).

363. OTA AGRICULTURE, *supra* note 17, at 194.

364. *Id.* at 193.

365. Sinclair, *Dairy Farms That Don't Need Pastures: High Output of Family-Run Milk Factories in California Inspires Awe, Draws Resentment*, The Washington Post, Mar. 28, 1988, at A4, col. 1.

366. OTA AGRICULTURE, *supra* note 17, at 202.

367. The OTA estimates that by the year 2000, the average milk production per cow will double from about 12,000 lbs per year to about 24,000. *Id.* at 189.

nutrition and information management technologies, it has been estimated that 30% fewer cows will be needed by the year 2000.[368] The economic effects of these developments most heavily will impact the smaller size farms, which may then be placed at an even greater competitive disadvantage.[369]

This dairy market outlook convinces some dairy farmers that animal patenting should be proscribed until Congress and society have thoroughly considered the social consequences of agricultural biotechnologies.[370] Like other opponents of animal patents, some dairy farmers also raise specific policy concerns with respect to transgenic agriculture, such as the questionable safety of consuming transgenic livestock[371] and the existence of a chronic commercial surplus of milk in the United States, due in part to the federal milk price support programs.[372]

The National Farmers Union, for example, uses a "look before we leap" justification for supporting a moratorium on the issuance of animal patents.[373] The National Farmers Union is also broadly concerned with the impact of animal patenting on traditional animal breeding and on shrinkage of the gene pool. The Union points to a potential competitive disadvantage if farmers in the United States are forced to pay royalties to patent owners when overseas farmers do not face similar premiums in countries where animal patenting is not allowed.[374] Notwithstanding the existing concentration in livestock agribusiness, the National Farm Organization also opposes animal patents on the ground that benefits from new technologies would flow to only a few individuals and businesses, leading to monopolistic pricing of the food supply.[375]

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368. *Id.* at 189.

369. *Id.* at 232.

370. Schwarze Testimony, *supra* note 89, at 340.

371. Transgenic meats from animals having the genes of different species (*e.g.*, the beefalo and the cattlo) have been produced by non-recombinant DNA techniques and are already on the market. Meat food products for human consumption are inspected by USDA to ensure that they are wholesome, unadulterated, and properly labeled. The Federal Meat Inspection Act, 21 U.S.C. § 601; Poultry Products Inspection Act, 21 U.S.C. § 451. The USDA anticipates that meat from transgenic animals would be substantially the same as meat from non-transgenic animals and would therefore be subject to the same inspection procedures. *See* Karny Testimony, *supra* note 43, at 449.

372. Schwartz Testimony, *supra* note 89, at 337-338. The payment of milk price supports is a policy question which the OTA has suggested that Congress review as part of a broad review of federal farm policy. In 1983, for example, the overproduction of milk cost the taxpayers about $2.6 billion. OTA AGRICULTURE, *supra* note 17, at 189. Isolated surpluses in particular subsectors of various nations' agricultural industries do not solve the world's projected food shortfalls either quantitatively or logistically, given difficulties in transportion and storage of commodities such as milk. *Id.* at 189-202.

373. Carpenter Testimony, *supra* note 88, at 114.

374. *Id.* at 115. However, the actual competitive advantages or disadvantages for U.S. producers who sell overseas is entirely speculative, particularly in that it does not account for any cost savings that genetically engineered animals will provide to U.S. farmers.

375. Frazier Testimony, *supra* note 88.

As is the case with advances in other technologies, most developments in animal genetic engineering are likely to be incremental. Therefore increases in economic values and costs of transgenic animals are likely to be incremental and not revolutionary.[376] Because preexisting public domain varieties of plants and animals will remain available without premium, the added expenditure by farmers for transgenic animals will be justified under patent economic theory only when the increased profitability of such animals justifies their acquisition costs.[377]

The American Farm Bureau Federation (representing 3.5 million member families) favors animal patenting and looks forward to major improvement of animal breeds.[378] Furthermore, the Farm Bureau supports genetic research and the commercialization of new agricultural products.[379] The Wisconsin Farm Unity Alliance noted that some small family farms may fail if they are unable to afford the new technologies. The Alliance also suggested that many farmers may lose their farms if their breeding stocks' value is eroded by newer, patented animals.[380] However, the Farm Bureau noted that policy should not be used in an attempt to prevent these displacements.[381] "Instead of trying to keep U.S. agriculture technologically behind to give some hypothetical, and in any case, temporary relief to agriculture, we should attack this problem through other means."[382] Given the international context of United States agriculture, there is "nothing we could do that would drive our family farms out of business more quickly, than if we denied them the research advances needed to produce the most modern, efficiency-enhancing, input-sparing technologies possible."[383]

A major OTA study on agricultural policy[384] presented a thorough analysis of the complex factors and trends which are altering the structure of the United States agriculture industry. The OTA report considered and proposed a series of policy adjustments that, if adopted by Congress, would lend transitional support to farms of various size classes. OTA proposals include price

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376. Seay Testimony, *supra* note 193, at 362-63.

377. *See* Part IIIB, *supra*; Godown Testimony, *supra* note 80, at 259-60.

378. Sorensen Testimony, *supra* note 357, at 118. Sorensen testified that her group is the largest general farm organization in the United States. *Id.*

379. *Id.* at 116.

380. *Transgenic Hearings*, *supra* note 22, at 322, 327 (Testimony of Thomas Saunders, dairy farmer, and member of the Wisconsin Farm Unity Alliance) [hereinafter Saunders Testimony].

381. Sorenson Testimony, *supra* note 357, at 119.

382. *Id.*

383. Walsh Testimony, *supra* note 78, at 210.

384. OTA AGRICULTURE, *supra* note 17.

supports, direct payments to farmers, expanded farm extension services, loans, credits, and retraining in nonfarm occupations.[385]

The OTA report discussed patents, largely in the context of inventions financed by publicly-funded land grant university research and extension programs.[386] Without analyzing the policies and economic bases underlying the patent law and the PVPA, the OTA report summarized concerns that the benefits of publicly-funded research would become unavailable to farmers, because of involvement of the private sector in commercial development, and unavailable to the patent system. Due to a dearth of economic analysis, the OTA report lacks a sufficient basis for its conclusions that steps should be taken to prevent "monopoly rents" (*i.e.*, patents) from stifling the discovery and dissemination of new knowledge through the land-grant university agricultural research system.[387] While the agricultural extension services of the land-grant university and state agricultural programs are widely regarded as successful, the federal policy has been to transfer patent rights from the public sector to the private sector where they may be more readily commercialized.[388]

In summary, the agricultural opponents of animal patents make no showing that a patent moratorium will slow the continued progress of agricultural biotechnology. No adequate basis has been laid for contending that a patent moratorium will ease the present need for social policy treatment of structural demographics in the agricultural sector. Additionally, because modern farm technologies include several new components (*e.g.*, artificial insemination and artificial embryonation, animal growth hormones, and information monitoring and management systems) the contribution of transgenic animals to the overall picture has not yet been identified. In view of the complex technological, economic, climatic, and political aspects of agriculture, no causal relationship has currently been identified between the patenting of animals and the present need for agricultural policy analysis. Consequently, no basis for an indiscriminate slowdown of transgenic technology has been demonstrated.

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385. *Id.* at 285-94 (Ch. 13, *Implications and Policy Options for Agriculture*). The benefits of agricultural biotechnology may be lost if displaced farmers turn to welfare for want of retraining or job placement assistance. Pimental, *supra* note 278, at 30.

386. OTA AGRICULTURE, *supra* note 17, at 272-76.

387. *See id.* at 293 (OTA report conclusions). The OTA also warns of the stifling effect of overregulation. *Id.* Some researchers, however, "have never seen patents having an adverse effect on land grant research in the past." Sorensen Testimony, *supra* note 357, at 129.

388. *See, e.g.*, the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3701-3714 (Supp. IV 1986), and its legislative history at 1980 U.S. Code & Administrative News at 4892. Biotechnology research is expensive, and land-grant institutions no longer have the necessary funding. Accordingly, researchers are turning to private corporations for support. Access by scientists to various biotechnological processes is important and, given the funding realities of biotechnology research, can be achieved only through patents, not through trade secret protection. Sorensen Testimony, *supra* note 357, at 129.

XI. CONCLUSIONS AND RECOMMENDATIONS

Soon after the advent of modern genetics and the industrialization of agriculture, Congress extended the incentives of the patent system to the agricultural sector in order to place it on an equal footing with traditional industry. The Congressional intent behind the patent law, as interpreted by the Supreme Court in *Diamond v. Chakrabarty*,[389] was to establish a patent system broadly encompassing all inventions. There is no evidence that Congress intended the patent system to exclude categories of inventions such as transgenic animals. Except in the case of atomic weapons, where the knowledge of technology threatens national security, patent law has not been used to control technological risk.[390]

The concerns of the animal patenting opponents largely involve consequences associated with the uses of genetically engineered organisms. A moratorium on patenting is sought as a means of slowing transgenic research, thereby *indirectly* reducing the hazards associated with genetically engineered organisms and providing to Congress and federal agencies additional time to decide how to control biotechnology. Concerns about the applications of transgenic research will continue to exist regardless of patenting. Such concerns are much more reasonably addressed by existing agencies having appropriate experience and sufficient regulatory jurisdiction (*e.g.*, the EPA and the USDA for environmental risks, and the USDA and the NIH for animal research).

In 1985, Congress determined that research on animals is necessary for gathering knowledge and learning how better to treat human and animal disease. At present, animal experimentation is regulated for humane purposes by federal law under NIH and USDA regulations. Environmental dissemination of microorganisms and plant pests is regulated by EPA and USDA permitting requirements, intended to assure safe utilization of transgenic organisms and to gather sufficient data about the environmental fate of those organisms to guide future releases. Weaknesses in the statutory scheme of protection should be addressed through legislation enforced by these agencies.

The narrowing of genetic diversity through corporate consolidation or other means does not appear to be caused by the existence of plant or animal patents. To conclude otherwise would be to ignore two hundred years of innovation stimulated by the

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389. 447 U.S. 303 (1980).

390. *See supra* note 53 and accompanying text. In this way, the patent system differs from some other areas of the law, such as Internal Revenue Service regulations, which may be implemented to further social policy goals, *e.g.*, discrimination.

patent system, to invite the use of trade secrecy rather than patents for industrial protection, and to ignore the funding and marketing realities of commercial biotechnology firms. Transgenic technology will likely be both necessary and instrumental in avoiding the undesirable consequences of the narrow crop base in the United States.

Transgenic agricultural techniques may revolutionize the production of crops and livestock, decrease farmers' capital costs, and enhance the international competitiveness of the United States agricultural sector. Plants capable of resisting pests and carrying out nitrogen fixation will reduce requirements for fertilizers and pesticides. The demographic changes sweeping the domestic agricultural sector are largely inevitable and are caused by a multitude of factors. Transgenic animals, which are not projected to have a wide presence in commercial marketing for a decade, perhaps represent the least important of these factors.

If sufficient evidence exists to justify a slowdown in any particular application of transgenic research, such as the possible planned introduction of transgenic wildlife, then the necessary and appropriate Congressional or federal response should be specifically targeted to that application. To attempt broader control through a patent moratorium would raise significant problems. A moratorium may inhibit the acquisition of scientific knowledge that would help regulators better understand and control the problems associated with specific uses. Additionally, a moratorium would have a negative impact on commercialization of transgenic research in other areas and deny the world the benefits of new pharmaceuticals and higher agricultural productivities.

The projected geometric expansion of the world's population and accompanying anticipated food shortfalls, coupled with the expected benefits to humankind from agricultural biotechnology, make a compelling argument for applying every reasonable incentive, including that of the patent system, to these technologies. On balance, the risk of inadequate food supplies for future populations appears to outweigh the risk of environmental harm, given the existing and proposed regulatory structure for control of biotechnology.

Application of the patent incentive to transgenic technology is both imperative and wise. This conclusion, however, should not detract from the necessary attention to animal welfare, environmental protection, preservation of biological diversity, and agricultural farm demographics, all of which require an enhanced level of awareness and concern at the highest policy-making levels.

The following recommendations are offered in an effort to more effectively regulate the impacts of the new biotechnologies:

1. No moratorium or prohibition on animal patenting should be enacted.
2. Environmental legislation, such as that proposed by Senator Baucus, should be enacted to provide a clear and sufficiently broad statutory authority for federal regulation of both novel (*i.e.*, invented) and exotic (*i.e.*, imported or transplanted) organisms of all kinds.
3. The animal welfare provisions under which the USDA will promulgate humane research standards should be amended to include farm animals used for research purposes.

The patent system represents a powerful engine for commercializing the results of research, an ability which the United States has been criticized as lacking relative to some of its major trading partners. The patent system can and should be finely tuned in a manner that advances other policy goals as well, without compromising its fundamental mission. In that regard, the following recommendations are offered:

(1) To the extent that the patenting of living organisms might hamper the free exchange of germplasm materials between researchers,[391] it has been proposed that the United States create a Library of Germplasm Resources, analogous to the Library of Congress, that would act as a repository for cells, seeds, germplasm, propagated material or other biological samples required by the PVPA or relied upon for enablement purposes under section 112 of the Patent Act.[392] The Patent Act authorizes the Commissioner of the PTO to require applicants to furnish specimens,[393] and this provision is equally applicable to section 101 patents and section 161 plant patents.[394] The PVPA also requires that 2500 seeds accompany any application for a Certificate of Protection from the USDA.[395] Existing federal germplasm repositories such as the National Seed Storage Laboratory should be incorporated into the proposed National Germplasm

391. Doyle Testimony, *supra* note 88, at 82.
392. Adler Biotechnology, *supra* note 218, at 494-95.
393. 35 U.S.C. § 114, para. 2 (1982).
394. *Id.* § 161, para. 2.
395. 7 U.S.C. § 2321 (1982).

Library.[396] In this way, the United States can harness the patent system to produce and make available germplasm research materials. The international network of gene banks[397] might be accessed on a "lending library" basis in order to facilitate access by United States researchers to foreign germplasm.

Under existing procedures, a biological deposit made to "enable" a United States Patent application is freely available to the public once a patent issues. This creates a possibility that a competitor of the patentee may obtain a sample that is, in effect, a miniature factory that can be transplanted to countries in which patent protection is unavailable to the patentee. The World International Property Organization (WIPO) has proposed that access to deposited materials be conditionally restricted, with a requestor agreeing not to share the material with third parties, not to export the material to countries in which the patentee does not have a patent or a pending application, and not to use the material for other than experimental purposes.[398] The PTO has solicited comments on this scheme[399] which might serve the purpose of minimizing piracy of biotechnological inventions.[400] The scheme would, however, severely limit the exchange of biological diversity with the germplasm-rich developing countries that lack comprehensive patent systems. A more effective way to counteract piracy while benefitting from internationally-shared germplasm resources may be to encourage the broader adoption of invention protection systems. On balance, the availability of foreign germplasm may outweigh the "head start" which deposited materials might afford to competitors and countries sufficiently industrialized to exploit the material.

(2) It has also been proposed that Congress enact a research exemption into the Patent Act[401] similar to that which exists

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396. It has also been suggested that "universities and other public institutions should cooperate in establishing and maintaining gene banks, which will preserve reservoirs of genetic diversity." Walsh Testimony, *supra* note 78, at 209.

397. *See* Plucknett, Smith, Williams & Anishetty, *Gene Banks and the World's Food*, Princeton University Press (1987).

398. COMMITTEE OF EXPERTS ON BIOTECHNOLOGICAL INVENTIONS AND INDUSTRIAL PROPERTY, *Industrial Property Protection of Biotechnological Inventions* (WIPO BIOT/CE/III/2/1987).

399. 52 Fed. Reg. 34,091 (1987).

400. The United States is presently negotiating this point with its trading partners through the General Agreement on Tariffs and Trade. *See* U.S. INTERNATIONAL TRADE COMMISSION, REPORT TO U.S. TRADE REPRESENTATIVE, INVESTIGATION NUMBER 332-245, FOREIGN PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE EFFECT ON U.S. INDUSTRY AND TRADE; *U.S. Firms Lose Billions Annually to Foreign Piracy, ITC Intellectual Property Study Finds*, 5 INT'L TRADE REP. (BNA) 290 (1988).

401. Walsh Testimony, *supra* note 78, at 209; Merges Testimony, *supra* note 361, at 179.

under the PVPA.[402] The Patent Act research exemption that was judicially created[403] lacks explicit boundaries and is narrowly limited to research involving a patented article having no intended commercial use.[404] The United States Court of Appeals for the Federal Circuit recently held that the experimental use doctrine did not exculpate an infringer's limited use of a patented drug for the testing and investigation required to obtain FDA marketing approval, when such use occurred during the last six months of the term of the patent in question.[405] Though the appellate court's decision was reversed by Congressional action on other grounds, a relevant portion of the Federal Circuit's holding survives. Thus, the infringer's "unlicensed experiments conducted with a view to adaption of the patented invention to the experimenter's business" may be an actionable infringement if the infringer's use was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[406]

Outside of the federal drug area, the boundary between permissible research and impermissible infringement is not clear under the Federal Circuit's "amusement, idle curiosity, or philosophical inquiry" standard. Although excused for a plant under the PVPA, the experimental breeding (*i.e.*, making) of a patented animal in order to understand or to add improved traits (*i.e.*, using) for the purpose of long-range commercial application (*i.e.*, selling) does not fall within the experimental use doctrine under the Patent Act. Because of this uncertainty, Congress should consider enacting an express research exemption for the Patent Act.

(3) In order to ameliorate the apparently inevitable consolidation and marketing trends in the agricultural sector, Congress should consider excluding from infringement the reproduction through conventional breeding of a patented transgenic plant or animal for certain farmers.[407] This exclusion would be analogous

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402. The use and reproduction of the protected variety for bonafide research purposes is expressly a non-infringing use. 7 U.S.C. § 2544 (1982).

403. *See, e.g.*, Dugan v. Lear Avia, Inc., 55 F. Supp. 223 (S.D.N.Y. 1944), *aff'd*, 156 F.2d 29 (2d Cir. 1946); Chesterfield v. United States, 159 F. Supp. 371 (Ct. Cl. 1958).

404. Pfizer, Inc. v. International Rectifier Corp., 217 U.S.P.Q. 157, 161 (C.D. Cal. 1982).

405. Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress overruled *Roche Products* to legislatively excuse from infringement the uses of a patented pharmaceutical reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs.

406. *Roche Products*, 733 F.2d at 863.

407. *See* Walsh Testimony, *supra* note 78, at 209.

to the exemption for farmers under the PVPA.[408] By the year 2000, 75% of the United States agricultural market will be supplied by large and very large farms. Since larger farms have a competitive advantage in adopting new technologies, the exemption might be limited to small and moderate size farms according to the differentiation scheme adopted by the OTA.[409]

408. 7 U.S.C. § 2543.
409. *See* OTA AGRICULTURE, *supra* note 17, at 8-9.