Patents for Genetically Modified Animals

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ABSTRACT: Should genetically engineered animals be patented? This issue has been one of the most contentious as lawmakers have grappled with how best to protect intellectual property. Since the 1980 case of *Diamond v. Chakrabarty*, in which the U.S. Supreme Court ruled that a living microorganism is patentable, the U.S. Patent and Trademark Office has determined that plants and nonhuman animals can be patented. These policy decisions have led to congressional debate on whether animals should be patentable subject matter. Patenting of living organisms is unique for three reasons: the invention itself is alive; the invention in some instances can reproduce itself; and the invention sometimes cannot be adequately described for patent specification purposes, leading to the need for deposit of the invention for patent purposes.

Key Words: Animals, Patents

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Introduction

Intellectual property protection—that area of the law involving patents, copyrights, trademarks, and trade secrets—is not new. Much in biotechnology, on the other hand, is relatively new. In the past 15 yr, dramatic new developments in the ability to manipulate genetic material have created heightened interest in the commercial uses of living organisms. Biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses. Although people have used organisms since the dawn of civilization to improve agriculture, animal husbandry, baking, and brewing, it is the novel uses of certain biological techniques (e.g., recombinant DNA techniques, cell fusion techniques, monoclonal antibody technology, and new bioprocesses for commercial production) that have caught the imagination of many people.

One novel result of the development of biotechnology is the creation and patenting of inventions that are themselves alive. The patenting of new life forms raises arguments in favor of and against the issuance of such patents. Most recently, public debate has centered on patenting of animals. Such debate is to be expected when an old and relatively well-settled body of law must be applied to unforeseen technologies.

The debate over whether to permit the patenting of living organisms frequently goes beyond simple questions of the appropriateness of patents per se, focusing instead on the consequences of the commercial use of patented organisms or the underlying merits of biotechnology itself. Discussion regarding the patenting of a genetically engineered organism, for example, can turn to the environmental application of the organism (e.g., the field test of a microorganism that is patented), the welfare of the organism (if it is an animal), scientific questions (e.g., whether the method of creating the organism represents a radical departure from traditional scientific or breeding methods), ethical issues (e.g., the morality of creating novel organisms or transferring genetic information between species), and economic considerations (e.g., whether the federal government should finance biotechnology-related research). One inherent difficulty in examining the patenting of living organisms is determining which arguments raised are novel and directly related to patent issues, as opposed to those questions that would exist independent of patent considerations.

This article, based on an Office of Technology Assessment (OTA) report (U.S. Congress, 1989), analyzes some of the legal, economic, ethical, religious, and practical considerations raised by the patenting of living organisms, particularly transgenic animals.

Intellectual Property

Rooted in the Constitution, intellectual property law provides a personal property interest in the work of the mind. Modern intellectual property law consists

of several areas of law: patent, copyright, trademark, trade secret, and breeders' rights.

Patents

A patent is a grant issued by the U.S. Government giving the patent owner the right to exclude all others from making, using, or selling the invention within the United States, and its territories and possessions, during the term of the patent (35 U.S.C. 154). A patent may be granted to whomever invents or discovers any new, useful, and non-obvious process, machine, manufacture, composition of matter, or any new and useful improvement of these items (35 U.S.C. 101). A patent may also be granted on any distinct and new variety of asexually reproduced plant (35 U.S.C. 161) or on any new, original, and ornamental design for an article of manufacture (35 U.S.C. 171).

The first patent act was enacted by Congress in 1790, providing protection for "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereof]." Subsequent patent statutes were enacted in 1793, 1836, 1870, and 1874, and these employed the same broad language as the 1790 Act. The Patent Act of 1952 replaced "art" with "process" as patentable subject matter (35 U.S.C. 101). The Committee Reports accompanying the 1952 Act demonstrate that Congress intended patentable subject matter to include "anything under the sun that is made by man." However, the Supreme Court has held that laws of nature, physical phenomena, and abstract ideas are not patentable. Patents have many of the attributes of personal property (35 U.S.C. 261). Property is generally viewed as a bundle of legally protected interests, including the right to possess and to use, to transfer by sale and gift, and to exclude others from possession. Patents are designed to encourage inventiveness by granting to inventors and assignees a limited property right—the right to exclude others from practicing the invention for a period of 17 yr. In return for this limited property right, the inventor is required to file a written patent application describing the invention in full, clear, concise, and exact terms, setting forth the best mode contemplated by the inventor, so as to enable any person skilled in the art of the invention to make and use it. Although a patent excludes others from making, using, or selling the invention, it does not give the patent owner any affirmative rights to do likewise. As with other forms of property, the right to make, use, or sell a patented invention may be regulated by federal, state, or local law. Patents are more difficult to obtain than other forms of intellectual property protection. All applications are examined by the United States Patent and Trademark Office (PTO), which is responsible for issuing patents if all legal requirements are met. Once obtained, the enforceability of a utility patent is maintained by the payment of periodic maintenance fees.

Patenting of Microorganisms and Cells

Patents on biotechnological processes date from the early days of the United States. Louis Pasteur received a patent for a process of fermenting beer. Acetic acid fermentation and other food patents date from the early 1800s, and therapeutic patents in biotechnology were issued as early as 1895.

The development of recombinant DNA technology (rDNA), the controlled joining of DNA from different organisms, has resulted in greatly increased understanding of the genetic and molecular basis of life. Following the first successful directed insertion of recombinant DNA into a host microorganism in 1973, scientific researchers began to recognize the potential for directing the cellular machinery to develop new and improved products and processes in a wide variety of industrial sectors. Many of these products were microorganisms (microscopic living entities) or cells (the smallest component of life capable of carrying on all essential life processes). With the development of recombinant DNA technology, the potential of patenting the living organism resulting from the technology arose.

Prior to 1980, the PTO would not grant patents for such inventions, deeming them to be "products of nature" and not statutory subject matter as defined by 35 U.S.C. 1012. Although patent applications were rejected if directed to living organisms per se, patent protection was granted for many compositions containing living things (e.g., sterility test devices containing living microbial spores, food yeast compositions, vaccines containing attenuated bacteria, milky spore insecticides, and various dairy products). In the absence of congressional action, it took a catalytic court decision to clarify the issue of patentability of living subject matter.

The Chakrabarty Case

The Supreme Court's single foray into biotechnology occurred in 1980 with its ruling in the patent law case of *Diamond v. Chakrabarty*. Chakrabarty had developed a genetically modified bacterium capable of breaking down multiple components of crude oil. Because this property was not possessed by any naturally occurring bacteria. Chakrabarty's invention was thought to have significant value for cleaning up oil spills.

Chakrabarty's claims to the bacteria were rejected by the PTO on two grounds: microorganisms are "products of nature" and, as living things, microorganisms are not patentable subject matter under 35 U.S.C. section 101.

Following two levels of appeals, the case was heard by the U.S. Supreme Court, which, in a five to four ruling, held that a live, human-made microorganism is patentable subject matter under section 101 as a "manufacture" or "composition of matter." The court

reached several conclusions in analyzing whether the bacteria could be considered patentable subject matter within the meaning of the statute: The plain meaning of the statutory language indicated Congress' intent that the patent laws be given wide scope. The terms "manufacture" and "composition of matter" are broad terms, modified by the expansive term "any." The legislative history of the patent statute supported a broad construction that Congress intended patent protection to include "anything under the sun made by man."

Although laws of nature, physical phenomena, and abstract ideas are not patentable, Chakrabarty's microorganism was a product of human ingenuity having a distinct name, character, and use. The passage of the 1930 Plant Patent Act (affording patent protection for certain asexually reproduced plants) and the 1970 Plant Variety Protection Act (providing protection for certain sexually reproduced plants) does not evidence congressional understanding that the terms "manufacture" or "composition of matter" do not include living things. The fact that genetic technology was unforeseen when Congress enacted section 101 does not require the conclusion that microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. Arguments against patentability based on potential hazards that may be generated by genetic research should be addressed to the Congress and the Executive for regulation or control, not to the Judiciary.

Events and Trends After Chakrabarty

The *Chakrabarty* decision provided great economic stimulus to patenting of microorganisms and cells, which in turn provided stimulus to the growth of the biotechnology industry in the 1980s. In addition to the *Chakrabarty* decision, revisions in federal patent policy promoted increased patenting of inventions in general, including living organisms and related processes. The Patent and Trademark Amendments of 1980 (Public Law 96-517), as amended in 1984 (Public Law 98-260) encourages the patenting and commercialization of government-funded inventions by permitting small businesses and nonprofit organizations to retain ownership of inventions developed in the course of federally funded research.

These policies, which gave statutory preference to small businesses and nonprofit organizations, were extended to larger businesses by executive order in 1983. The Technology Transfer Act of 1986 (Public Law 99-502) granted federal authority to form consortia with private concerns. An executive order issued in 1987 further encouraged technology transfer programs, including the transfer of patent rights to government grantees. Increased patenting of biotechnology inventions has led to litigation, primarily related to patent infringement issues. Already, patent battles are being fought over interleukin-2, tissue plasminogen activator, human growth hormone, alpha interferon, factor VIII, and use of dual monoclonal antibody sandwich immonoassays in diagnostic test kits. It is likely that patent litigation relating to biotechnology will increase given the complex web of partially overlapping patent claims, the high-value products, the problem of prior publication, and the fact that many companies are pursuing the same products.

One negative trend arising from the increase in patent applications is the inability of the PTO to process biotechnology applications in a timely manner. The number of these applications has severely challenged the process and examination capabilities of the PTO. In March 1988, the PTO reorganized its biotechnology effort into a separate patent examining group. As of July 1988, 5,850 biotechnology applications had not yet been acted on. Currently, approximately 15 mo lapse, on average, before examination of a biotechnology application is initiated, and an average of 27 mo passes before the examination process is completed by grant of the patent or abandonment of the application. Turnover among patent examiners, lured to the private sector by higher pay, is cited as a significant reason for the delay in reviewing patents.

Patenting of Animals

In April 1987, the Board of Patent Appeals and Interferences ruled that polyploid oysters were patentable subject matter. Subsequently, the PTO announced that it would henceforth consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter under general patent law. This statement initiated broad debate and the introduction of legislation concerning the patenting of animals. The first animal patent was issued in April 1988 to Harvard University for mammals genetically engineered to contain a cancer-causing gene (U.S. 4,736,866). Exclusive license to practice the patent went to duPont Co., which was the major sponsor of the research. The patented mouse was genetically engineered to be unusually susceptible to cancer, thus facilitating the testing of carcinogens and of cancer therapies. Specifically, the patent covers "a transgenic nonhuman eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . . which increases the probability of the development of neoplasms (particularly malignant tumors) in the animal." The 1987 PTO policy and the 1988 issuance of the first patent on a transgenic animal spurred public debate on scientific, regulatory, economic, and ethical issues.

Producing Transgenic Animals

Most potentially patentable animals are likely to be transgenic animals produced via recombinant DNA techniques or genetic engineering. Transgenic animals are those whose DNA, or hereditary material, has been augmented by adding DNA from a source other than parental germplasm, usually from different animals, including humans.

Laboratories around the world are conducting research that involves inserting genes from vertebrates (including humans, mammals, or other higher organisms) into bacteria, yeast, insect viruses, or mammalian cells in culture. A variety of techniques, most developed from early bacterial research, can now be used to insert genes from one animal into another. These techniques are known by a number of exotic names: microinjection, cell fusion, electroporation, retroviral transformation, and others. Of the currently available scientific techniques, microinjection is the method most commonly used and most likely to lead to practical applications in mammals in the near future. Other methods of gene insertion may become more widely used in the future as techniques are refined and improved. If protocols for human gene therapy now being developed in animal models or laboratory cultures of mammalian cells prove successful and broadly adaptable to other mammals, other gene insertion techniques could supplant microinjection.

Although the number of laboratories working with transgenic animals remains small (no more than a few hundred, worldwide), and researchers with the required skill and experience are not common, the number of research programs using these techniques has grown steadily in recent years. For reasons of convenience, much research involving transgenic mammals continues to be done using mice, although programs using several larger mammals have made significant progress. It is anticipated that some animals of research utility or substantial economic importance will become more common as subjects of transgenic modifications in the near future (within 5 to 10 yr). Beyond mice, the major research efforts involving transgenic modifications focus on cattle, swine, sheep, poultry, and fish.

Producing transgenic animals by microinjection, although tedious, labor-intensive, and inefficient (only a small fraction of injected eggs develop into transgenic animals), compares favorably in at least three respects with traditional breeding techniques. First, the rapidity with which a specific gene can be inserted into a desired host means that the time it takes to establish a line of animals carrying the desired trait is much reduced. Second, the specific gene of interest can be transferred with great confidence, if not efficiency, and if proper purification protocols are followed, without any accompanying, unwanted genetic material. Third, with the proper preparation, genes from almost any organism can be inserted into the desired host, whether it is a mouse or some other animal. Historically, genetic material exchanged by classical hybridization (crossbreeding) could only be transferred between related species or different strains within a species.

If there is a fundamental difference arising from the new techniques, it is that breeders have greatly augmented ability to move genes between organisms that are not close genetic relatives (e.g., human and mouse, or human and bacterium). Most transgenic animal research in the near future will likely focus on traits involving a single gene. Manipulation of complex traits influenced by more than one gene, however, such as the amount of growth possible on a limited food regimen, or behavioral characteristics, will develop more slowly (perhaps within 10 to 30 yr) because of greater technical difficulty and the current lack of understanding of how such traits are controlled by genes.

Federal Regulation and Animal Patents

To gain an understanding of the potential use and regulation of genetically altered animals that might be patented, OTA asked selected federal agencies the following questions: How are genetically altered animals currently used in research, product development, and mission-oriented activities conducted or funded by your agency? What are the potential uses of such animals during the next five years? How does (or would) your agency regulate such animal use? What statutes, regulations, guidelines, or policy statements are relevant?

Several agencies currently use transgenic animals. The National Institute of Health is currently the largest user of such animals for biomedical research projects. The USDA has conducted research on the genetics of animals for many years. The USDA's Agricultural Research Service reported projects involving the use of growth hormone in sheep and swine, and chickens engineered by recombinant DNA technology to be resistant to avian leukosis virus. The USDA's Cooperative Research Service is in the early stages of supporting extramural research projects involving genetically engineered animals. The National Science Foundation (NSF) currently funds research involving transgenic animals in a range of experiments, all involving laboratory animals. With the use of transgenic animals becoming central to whole lines of investigation, NSF expects that work with such animals will increase. The Agency for International Development (AID) funds research involving conventional and transgenic animals at international research centers that are only partially funded by the United States. Accordingly, AID has minimal control over such research activities. Several federal agencies regulate the experimental use or commercial development of genetically altered

animals. Because current statutes regulate various uses and protections for animals, no single federal policy governs all uses of genetically altered animals. In the absence of a single policy, federal agencies will rely on existing statutes, regulations, and guidelines to regulate transgenic animal research and product development. Current federally funded research efforts could lead to patents on animals. The patentability of an animal, however, does not affect the manner in which the animal would be regulated by any federal agency.

Economic Considerations

Economic considerations will influence the order in which different transgenic animals are produced for commerce. Transgenic animals used for biomedical research are likely to be developed first, primarily due to extensive research in this area. Transgenic agricultural animals are also likely to be produced, although large-scale commercial production of such livestock and poultry is unlikely in the near future (5 to 10 yr). The largest economic sectors likely to be influenced by animal patents are the different markets for agricultural livestock, and possibly some sectors of the pharmaceutical industry. The principal agricultural markets involve poultry, dairy, and red meat. These markets are organized quite differently, and they are subject to different degrees of economic concentration. Poultry is most concentrated (though still diffuse by the standards of other industries, such as automobiles), and the dairy and red meat sectors are much more diffuse. Different economic forces are important in markets as well: federal price supports are of major importance in the dairy market, whereas the market for poultry is more open and competitive. It is difficult to predict the manifold consequences of any particular approach to protecting intellectual property, especially across so wide a range of economic activity as that spanned by patentable animals. This range embraces diverse sectors of the agricultural livestock markets, pharmaceutical and other chemical production, as well as academic research or industrial testing. The economics of patenting and the effect on inventors and consumers will be determined by the potential use of the animal, its market, its reproduction rate, and its relative value. The existence of animal patents and the degree to which they are employed in the different markets may introduce some new economic relationships. It is not now clear that these are likely to have any substantially adverse effects on the major markets or existing market forces. The same types of pressures that have driven economic choices in the past are likely to continue to dictate them in the future. If an innovation increases costs (e.g., if a patented animal costs more than the unpatented alternative) it is unlikely to be adopted unless it commensurately increases outputs or product values. It therefore seems that although cost savings can be anticipated to follow from animal patenting in some areas (e.g., pharmaceutical production or drug testing), innovations attributable to patented animals are likely to advance more slowly in low-margin operations such as raising beef cattle. In some cases, efficient alternatives to protection of intellectual property via patents are feasible. Trade secrets or contractual arrangements might serve well in cases in which the animals involved have a high intrinsic value and are limited in number (e.g., animals used for pharmaceutical production). When faced with the complexity of the markets for pork or beef production, however, such alternatives are clearly less practical, although the same complexity complicates any scheme for enforcement or royalty collection associated with patenting animals per se.

Ethical Considerations

A number of ethical issues have been raised in regards to patenting animals. Many of these arguments focus on the consequences that could occur subsequent to the patenting of animals. Other arguments focus on religious, philosophical, spiritual, or metaphysical grounds. These issues have been used to support and oppose the concept of animal patenting. Many arguments relating to the consequences of animal patenting are difficult to evaluate because they are speculative, relying on factual assertions that have yet to occur or be proven. Arguments based largely on theological, philosophical, spiritual, or metaphysical considerations are likewise difficult to resolve, because they usually require the assumption of certain presuppositions that may not be shared by other persons. Thus, such arguments are not likely to be reconciled among those persons holding opposing, and often strong, beliefs. Most arguments that have been raised both for and against the patenting of animals concern issues that would be materially unchanged whether patents are permitted or not. Most arguments center on issues that existed prior to the current patenting debate (e.g., animal rights, the effect of high technology on American agriculture, the distribution of wealth, international competitiveness, the release of novel organisms into the environment). It is unclear that patenting per se would substantially redirect the way society uses or relates to animals. Many concerns about the consequences of patenting can be addressed by appropriate regulations or statutes, rather than by amendments to patent law. Other arguments, particularly those of theological, philosophical, spiritual, or metaphysical origin, need to be debated more fully and articulated more clearly.

Deposit Considerations

In 1949, the PTO began recommending that patent applications for inventions involving microorganisms should include the deposit of the pertinent microor-

ganism with a culture collection. Although not a formal requirement, patent examiners advised applicants that in cases in which words alone were not sufficient to describe the invention adequately, a deposit was advisable. Currently, patent applications for inventions involving microorganisms, plasmids, vectors, cells, plant tissues, seeds, and other biological materials that are not generally available to or reproducible without undue experimentation by persons skilled in the pertinent field are often supported by a deposit in a recognized patent depository. Whether or not a deposit is necessary is a decision made on a case-by-case basis. The decision generally takes into account the reproducibility of the invention based on a written description alone, the level of skill in the art, the teachings of the prior art, and the availability of the starting materials. Although not automatically required, a deposit is employed in many cases to meet the requirement that a patent provide enablement or the best mode of practicing an invention. The PTO first published guidelines on the deposit of microorganisms in 1971. In 1977, establishment of the Budapest Treaty required contracting states that allow or require the deposit of microorganisms as part of their patent procedure to recognize the deposit of a microorganism with any International Depositary Authority. In 1985, the Court of Appeals for the Federal Circuit held that the enablement provision of the patent statute did not require a deposit in a recognized depository by the filing date of the patent application, but only before the issuance of the patent. The PTO published rules for deposit of biological materials for patent purposes. These rules assist the inventor and the depository in defining the position of the PTO on deposits. A culture depository accepts, maintains, and distributes cultures of microorganisms, viruses, cells, or other genetic-type material. The deposit of seeds and plant tissue culture has become established practice. A depository may be public or private, nonprofit or for profit. The main function of a public culture depository is the preservation and distribution of reference cultures that serve as standards for users in the scientific and educational communities. The new patentable status of animals raises the possibility that the PTO will encourage or require the deposit of animal forms to support certain patent applications. To date, no animal has been deposited with a depository. In the case of the first animal patent granted (U.S. 4,736,866), the deposit requirement was satisfied not by deposit of a mouse or other animal, but by deposit of the cancer-causing genes intended for transfer into an animal. DNA plasmids bearing those genes were deposited. In the patent, the inventors describe detailed instructions for inserting those genes into mouse embryos to produce transgenic mice. The patenting of animals could cause problems for a depository if deposit of the animal is required. Currently no depository is willing to accept the deposit of animals for several reasons. The cost of facilities and expertise that might be needed to maintain animals would be prohibitive. A depository maintaining animals for patent purposes might be subject to adverse publicity. If it were necessary to maintain the animal, a depository might need to grow another sample to prove the replication of the animal. After growth of the animal, disposal might not be acceptable, and, therefore, maintenance of progeny would be necessary. How would a depository make samples of the animal available? Grow more animals? Maintenance of many kinds of animals for the current required period of 30 yr would not be practical or possible, because their life spans are shorter than 30 yr.

The deposit of animal embryos may not present the same difficulties as long as the embryos can be successfully frozen and recovered. To date, at least 13 species of animal embryos (cattle, mice, rats, rabbits, hamsters, sheep, goats, horses, cats, antelopes, and three species of nonhuman primates) have been successfully frozen and recovered.

International Protection for Microorganisms, Plants, and Animals

Intellectual property protection of microorganisms, plants, animals, and biological processes is of increasing concern to the world community. Subject matter patentability is an important consideration facing an inventor who wants to patent living matter in a foreign country. In addition, international subject matter patentability is one element of the current debate in the United States regarding the scope of patentable subject matter. For example, those who favor patenting of animals point out that other countries either permit or do not expressly exclude the possibility of such patents. Opponents of patenting of animals conclude that other nations expressly exclude or have yet to issue patents on animals. Several international treaties and agreements are relevant to biological inventions. These agreements are efforts by member countries to harmonize various procedural and substantive elements of international patent practice. The patenting of animals is not the subject of any existing treaty. Of the existing agreements, the European Patent Convention (EPC) is most relevant to the substantive issue of patenting plants and animals. Article 52(1) of the EPC defines patentable subject matter as inventions, which are susceptible to industrial application, which are new, and which involve an inventive step. This definition is extraordinarily general and broad. Rather than providing a precise, positive definition of patentable subject matter, the EPC instead takes the approach of narrowing this broad definition by explicitly specifying negative restrictions thereto. One such exclusion is Article 53(b), which stipulates that European patents will not be issued for plant or animal varieties and

essentially biological processes for the production of plants and animals (with the exception of microbiological processes or the products thereof). Although plant varieties are specifically excluded, there is no general exclusion for plants. According to the Technical Board of Appeal of the European Patent Office (EPO), EPC Article 53(b) prohibits only the patenting of plants that are in the genetically fixed form of a plant variety (i.e., specific variety, such as the rose 'Peace' or the wheat cultivar 'Chinese Spring'). Thus, the EPO will grant utility patent (generic) protection for plants, for example, where a gene has been inserted into a plant (e.g., corn having gene X) but is not fixed in a single plant variety (e.g., corn inbred A having gene X). Similarly, a process for transforming a plant to insert a desired gene would be patentable because human intervention played a greater role in the final result than biological forces. This viewpoint has been adopted by the Swiss Patent Office as well as by the European Patent Office, which in early 1988 granted a patent on a technique for increasing the protein content of forage crops such as alfalfa and for the plants produced with the aid of the technique. This decision arguably opens the door for plant and animal patenting in Europe, subject to the specific treatment of European patents on a country-by-country basis. Differences exist between nations regarding intellectual property protection of biotechnological inventions, including the issue of what constitutes patentable subject matter. Patent protection is widely available for microorganisms, as are various forms of patents and breeders' certificates for plant life. Analysis of the laws of other nations indicates that patent protection on animals is permissible or theoretically possible in a number of nations. Any projection of the number of nations permitting animal patents must be considered speculative in the absence of patent prosecution in this area. To date, only the United States has both announced a policy permitting patents on animal life forms and issued a patent on an animal invented through biotechnological techniques. It is likely that other nations will issue such patents in the future. The Japanese patent office, for example, recently issued an internal notice announcing its intention to grant patents on nonhuman animals if they meet the requirements of their patent law.

Policy Issues and Options for Congressional Action

Three policy issues relevant to patenting of living organisms were identified during the course of the OTA study. Of these, the issue of whether the patenting of animals should be permitted by the federal government has garnered the most debate. Four options were provided to the Congress by OTA: take no action; enact a moratorium on the issuance of animal patents; enact an animal variety protection statute modeled after the Plant Variety Protection Act; enact a statute amending the patent law to address the patenting of animals.

To date, no law has been passed by both houses of Congress on this issue. However, as patents are issued, Congress may well return to the public policy ramifications resulting from animal patenting.

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