Issue Brief

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PATENTING LIFE

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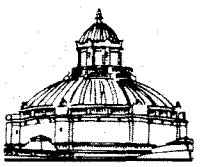

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PATENTING LIFE

SUMMARY

Advances in genetics and molecular biology have enabled scientists to genetically engineer bacteria, plants and animals, giving them unique commercial value. An important incentive for companies to develop such products is the right to commercial control, including the exclusion of others from making or selling them for a period of time. This right of exclusion is gained by patenting the product. Since patents cannot be granted for products of nature, it has been questioned whether genetically engineered products can be patented. In 1980, the Supreme Court held that genetically engineered bacteria could be patented. However, the status of higher life forms, i.e., plants and animals, under the Patent Act of 1790 is still unclear.

On Apr. 7, 1987, the U.S. Patent and Trademark Office (PTO) issued a policy finding, stating for the first time that patents could be granted for animals developed through genetic engineering. This "patenting life" decision has touched off debate on many issues, ranging from ethical and religious concerns about genetic manipulations, to farmers' ownership rights to patented animals used in agriculture. While nearly all participants in the debate agree that the PTO decision raises many thorny public policy issues, views differ on how these issues are best addressed. Some argue that the concerns should be addressed in the regulation of inventions after they are patented. Others argue animals should not be patented at all. Legislation has been introduced that would place a moratorium on patenting animals to give policymakers time to sort out and evaluate the possible ethical and economic implications. Critics of the moratorium argue that it would have a chilling effect on genetic research, which could hamper U.S. progress in a key area of international competition. The PTO has not yet granted any patents under the "patenting life" policy.

ISSUE DEFINITION

On Apr. 7, 1987, the U.S. Patent and Trademark Office (PTO) issued a policy finding (notice), stating for the first time that patents could be issued for animals and other higher life forms developed through genetic engineering. The notice explained that the 1980 Chakrabarty decision of the U.S. Supreme Court, which held that genetically engineered bacteria could be patented, also permitted patenting of higher life forms like animals. This "patenting life" decision has touched off debate on many issues, ranging from ethical and religious concerns about genetic manipulations, to farmers' ownership rights to patented animals used in agriculture. Legislation has been introduced that would place a moratorium on the PTO decision to give policymakers time to sort out and evaluate the possible ethical and economic implications. Congress had already begun to evaluate the issues related to the PTO policy, and several hearings have been held. As this consideration continues, Congress may wish to examine (1) whether a moratorium will improve or impede an evaluation of the implications, and (2) whether greater public participation is needed before a policy is implemented.

BACKGROUND AND ANALYSIS

Commercialization of Recombinant DNA

In the early 1950s, scientists Watson and Crick uncovered the genetic code inside the cells of organisms that is responsible for transmitting inherited traits from one generation to another. The chemical that makes up that code is deoxyribonucleic acid (DNA). During the 1960s and 1970s, discoveries were made in genetics, molecular biology and other disciplines that have enabled scientists to isolate single genes (the chemical code for a hereditary trait), analyze their chemical structures, make copies of the gene, and make changes in the structure of DNA. Together, these discoveries have given scientists the capability to alter some features of the genetic code of organisms, endowing them with novel traits that, in some cases, can be passed from one generation to the next. The capability to manipulate and recombine the genetic code is referred to as "recombinant DNA (rDNA) technology" or "genetic engineering."

Gradually, the potential commercial applications of genetic engineering have become evident. Cells contain sophisticated productive machinery that synthesize a range of substances, including proteins useful to the organism, according to the instructions contained in the genetic code. Genetic engineers saw the potential to harness this manufacturing capability to efficiently produce proteins for human use by altering the genetic instructions that control it. Many proteins are complex molecules that are not economically or technically feasible to make using traditional methods of chemical synthesis. Before rDNA technology, the only source of some important proteins, such as insulin used to treat diabetes, was from slaughtered cattle or hogs. For other proteins, such an animal extract would be ineffective in humans, or too costly to make it a commercially viable product.

The first commercial applications of genetic engineering have been to make proteins suitable as human drugs. For example, genetically engineered bacteria are used to produce human insulin (humulin), and human growth hormone. These drugs have been approved by the Food and Drug Administration and are already available commercially. Bacteria are also used to produce pesticides and bovine growth hormone, a drug under study for use in dairy cows. In addition, bacteria have been engineered to degrade environmental toxins (e.g., "oil-eating" bacteria). However, the commercial applications of rDNA are not limited to single-celled organisms like bacteria.

Scientists are also experimenting with the genetic codes of plants and higher animals. They are exploring ways to make plants pesticide and disease resistant. They are also exploring ways to alter the genetic code of animals to produce animals more suitable for certain human uses. For example, the gene for human growth hormone was inserted into the genetic code of a hog in an experimental effort to produce a hog with leaner meat. Work is underway to manipulate the genetic code of certain laboratory animals so that they respond to drugs or other chemicals in a way more similar to humans, making them more useful in human health research.

rDNA technology is still in its infancy. Scientists know enough about relatively few genes to manipulate and transfer them. Also, scientists are currently able to transfer successfully only one gene at a time, and can delete or disable other genes present in the DNA. Multiple gene insertions into DNA are not anticipated for 20 or more years. In addition, little is known about the characteristics that will result from a particular gene manipulation (predictive genetics). The limited scientific capabilities concerning rDNA restrict the types of genetic changes that are possible for the foreseeable future. Significant scientific hurdles must be overcome to improve these capabilities.

An important incentive for companies to conduct research and develop products involving rDNA, is the right to exclude others from making or selling products they invent for a period of time. This right of exclusion is gained by patenting products.

What is a Patent?

A U.S. patent is a form of property ownership granted by the Federal Government to an inventor which gives the inventor, for a stated period of time, the exclusive right to make, use, and sell an invention or discovery. The "right to exclude" must be distinguished from a right to use or sell a product commercially. Many products, including drugs, food additives and pesticides must be licensed (approved or registered) before they can be marketed. A patent does not confer a right to sell.

Article I, section 8, of the Constitution gives Congress the power to "Promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Under this authority, Congress has enacted patent statutes that vest the U.S. Patent and Trademark Office

(PTO) with authority to grant patents, and that define the characteristics of a patentable discovery or invention. More detailed criteria for patent qualification are found in the precedential value of the PTO's past patent decisions, and in court decisions in patent cases.

There are three "patent" statutes: the Patent Act of 1790 (has been amended several times since 1790), which applies to a range of subject matter [35 U.S.C. 100 et seq.]; and two statutes that provide patent-like protection for certain plants, the Plant Protection Act of 1930 (PPA) [35 U.S.C. 161, et seq.] and the Plant Variety Protection Act (PVPA) [7 U.S.C. 2321, et seq.]. This report focuses on the Patent Act of 1790 (Patent Act), the subject of the PTO decision.

The criteria that must be satisfied under the Patent Act for an inventor to be entitled to a patent included the requirement that the invention qualify as "patentable subject matter" [35 U.S.C. 101]:

> Section 101. Inventions Patentable
> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Patentable subject matter is required to be a "novel," "non-obvious" [35 U.S.C. 102-103], and "useful" [35 U.S.C. 101] "process," " machine," "manufacture," or "composition of matter" [35 U.S.C. 101]. It also must not be "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon" [Atomic Energy Act, 42 U.S.C. 2181]. These criteria traditionally precluded the patenting of products of nature. (See Chakrabarty decision, below.)

Patenting Living Organisms

Some of the organisms developed using recombinant DNA technology have appeared to have commercial potential, and inventors have sought patents on them. However, until the 1980 Chakrabarty decision, the PTO would not grant patents for such inventions, deeming them to be "products of nature," and, thus, not patentable subject matter.

Patenting Microorganisms: The Chakrabarty Decision

In its 1980 landmark decision, Diamond v. Chakrabarty, 447 U.S. 303 (1980), the Supreme Court held that a bacterium that had been genetically engineered to degrade crude oil could be patented. The bacterium was believed to be valuable in cleaning up oil spills. The Supreme Court affirmed the decision of the Court of Customs and Patent Appeals (CCPA), reversing the decision of the PTO. The PTO had rejected the patent claim for the bacterium itself, allowing only "process" patent claims for the method of producing the bacteria, and for the mixture (i.e., straw and bacteria) used to introduce the bacteria into an oil spill on water.

The rationale of the Supreme Court in allowing the bacterium to be patented was that Congress intended that the patent laws should be given wide scope, as evidenced by the use of such expansive terms describing patentable subject matter as "manufacture" and "composition of matter." The Court also cited the legislative history of the law which indicated that section 101 should be construed liberally. The clause embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragement." The Court ruled that Congress did not intend to exclude living things from patentability. The Court cited as evidence of congressional intent, the Plant Protection Act and Plant Variety Protection Act, the statutes enacted specifically to provide patent-like protection for plants. Instead, the relevant distinction was deemed not that between living and inanimate things, but that between "products of nature, and human-made inventions." The oil-eating bacterium was not considered a natural phenomenon, but a product of human ingenuity, that qualified as a manufacture or composition of matter. Further, the Court found no bar to patentability in the fact that genetic technology was unforeseen when the patent law was enacted.

Although the PTO and other interested parties raised policy issues regarding the desirability and implications of genetic technology, the Court ruled that it was the Court's role to determine what the law is, but the role of the Congress to define the limits of patentability. The Court expressly refused to weigh the potential hazards of the technology saying, "[w]hatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts."

Patenting Higher Life Forms

Although the Supreme Court gave a broad interpretation to section 101 in the Chakrabarty decision, which permitted microorganisms to be patented, some observers have questioned whether the decision applied also to higher life forms. Two recent cases suggest that higher life forms may be patentable subject matter. In Ex parte Hibberd, 227 USPQ 443 (Bd. App. & Inf. 1985) the Board of Patent Appeals and Interferences (Board) held that man-made plants are patentable subject matter under section 101, even though Congress had enacted the PVPA and PPA (above), statutes that created separate forms of protection for "man-made" plants.

In a more recent case, Ex parte Allen, 2 USPQ 2d 1425 (Bd. App. & Int. Apr. 3, 1987), the Board reviewed a PTO decision that a method of inducing polyploidy (sterility) in oysters, and the resulting oysters, were not patentable. The PTO had rejected the patent claim because: (1) the polyploidy was "controlled by the laws of nature and not a manufacture by man that is patentable," and (2) because the method was "obvious" (not novel) to one of ordinary skill. The Board agreed with the PTO that the oyster should not be patented because it was obvious, but reversed the PTO's other ground for rejection. The Board reasoned that under the Chakrabarty decision, an invention could be patented if it was made by man, and the fact that a method of making the invention was controlled by nature was irrelevant.

Based on the Allen decision, and the body of law that had developed from the Chakrabarty decision, the U.S. Patent Office announced a new policy regarding higher life forms. On Apr. 7, 1987, the Assistant Secretary and Commissioner of PTO issued a notice stating that the "Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101." [1077 Official Gazette for Patents 24, Apr. 21. 1987.] The notice excluded patent claims that would include within its scope a human being, stating that such a property interest in a person would be unconstitutional. This notice has been referred to as the "patenting life" or "animal patent" decision.

At least 15 "animal patent" claims are estimated to be pending before PTO. The details of these claims are not public information.

Public Policy Issues Related to Patenting Life

The "patenting life" decision has touched off debate on many issues, ranging from ethical concerns about genetic manipulations, to such economic issues as farmers' ownership rights to patented animals used in agriculture. While nearly all participants in the debate agree that the PTO decision raises many thorny public policy issues, views differ on how these issues are best addressed. Some argue that the concerns should be addressed in the regulation of inventions after they are patented. Others argue higher life forms should not be patented at all.

Ethics

Some observers believe that the PTO decision encourages applications of genetic engineering that pose significant ethical problems. For example, a coalition of animal welfare, religious and other groups, coordinated by the Foundation on Economic Trends, is calling for a moratorium on the PTO decision while these issues are considered.

The ethical concerns that have been raised revolve around the development of so-called "transgenic animals," i.e., animals resulting from the addition of genes from another species. Animal welfare advocates argue that such gene transfers across species boundaries will cause unacceptable suffering to animals subjected to such experimentation. They argue that because the outcome of transgenic experiments is currently unpredictable, animals produced will be abnormal at birth, and likely to develop novel ailments that veterinary medicine will be unable to prevent. A frequently cited example of the problems they anticipate is some of the early transgenic animal work conducted by scientists with the Department of Agriculture (USDA). JSDA scientists have been trying to produce a hog with leaner meat by inserting the human growth hormone gene into a hog's genetic material (DNA). Many of the experimental transgenic hogs have died. However, although one surviving hog did develop lean meat, it also grew excess hair and had structural deformities that produced a bigger snout, and caused difficulty in walking.

Some religious groups also oppose animal patenting; some believe it may undermine human reverence for all life as a creation of God by fostering economic pressures to view animal life as an industrial product invented and manufactured by humans; others urge that care be taken to guard against "abuse." While some religious bodies support genetic engineering that brings such benefits to society as disease treatment and an expanded food supply, they are very concerned that animal life may be treated as commercial property. A particular concern has been raised about transgenic animals produced by inserting human genes into the DNA of animals. Some believe that intermingling human and animal genes poses unique moral, ethical, and theological questions regarding the sanctity and dignity of human life. At the heart of the ethical concerns of the animal welfare and religious groups appears to be a belief that the commercial potential of genetic engineering is unique and significantly different from that of traditional animal breeding techniques. However, these concerns are not shared by all ethicists. Some believe that rDNA presents no unique ethical problems as long as transgenic animals are humanely cared for.

Some advocates of the PTO decision, including biotechnology companies specializing in agricultural applications of genetic engineering, counter the concerns expressed by some ethicists by emphasizing the similarities between genetic engineering and traditional breeding. They argue that while rDNA technology offers unique capabilities, the ethical issues it raises are not unique. In contrast to traditional breeding practices that involve the transfer of thousands of genes, rDNA allows targeted tinkering with only one or a handful of genes that control the characteristic of interest. It is argued that desired changes may be achieved ultimately with less animal experimentation. Some advocates also question the characterization of religious groups that individual genes are "human" and "animal." At the molecular level, all genes are chemicals made up of "base-pairs." The chemical language of inheritance expressed through genes is the same throughout the known plant and animal world. Thus, some observers suggest that "human-ness" or "animal-ness" can be found only in the cumulative effects of thousands of genes, not in single genes.

In addition, some advocates admit that while the technology can produce animals with undesirable characteristics, so also can traditional breeding practices. A frequently cited example is commercial turkeys which have been bred to have such large breasts that some cannot mate.

Advocates of the PTO decision also argue that there are ethical implications of not pursuing rDNA applications in agriculture. Some suggest that rDNA offers a chance to better combat such human problems as world hunger by developing plants and animals that can survive in arid or other stressful environments. Some suggest that rDNA technology could be used to better protect the environment, by engineering pest resistant plants that can grow with reduced need for agricultural chemicals.

In addition, some argue that rDNA technology will improve animal welfare. For example, in modern intensive agriculture, animals are given a variety of drugs (e.g., antibiotics and hormones) to prevent disease and enhance growth. Some advocates suggest that genetic engineering offers the potential to alter the animal itself, so that it is better suited for

the environment it already occupies, without the aid of drugs. They point to rDNA research which is directed at improving the disease resistance of animals. They point out that agricultural animals have historically served an economic purpose and have occupied a unique and closed "ecological niche." For this reason, some consider new ethical problems to be limited to bioengineering wild animals or animals capable of mingling and mating with wild animals with unpredictable results.

Those that support rDNA applications in agriculture argue that the ability to obtain a patent on higher life forms is an essential incentive for innovation in this area. For this reason, they argue that if policymakers wish to influence the direction of rDNA research or manage consequences of rDNA commercialization, laws other than patent law should be used.

Economic Issues

Agriculture Industry

There appears to be consensus among scientific and farm organizations that biotechnology has the potential to revolutionize agriculture. Patent policy is viewed on all sides as a key determinant of the rate and direction of agricultural biotechnology development. However, there are divergent views on whether the ultimate effect of the PTO "patenting life" policy will be good or bad for agriculture.

Representatives of the biotechnology industry and of some farm organizations (e.g., the American Farm Bureau Federation) believe that biotechnology offers a new opportunity to address many serious problems in agriculture, such as reducing farming costs and adverse environmental effects, and expanding the uses of farm products. They argue that because of these expected benefits, the United States cannot afford to stifle innovation by denying patent protection to inventors of novel animals and plants, particularly when U.S. competitors are pursuing such work.

Other farm organizations (e.g., the National Farmers Union) believe that sufficient improvement in farm production and efficiency through improved plant and animal breeds has been attained historically without the ability to gain a patent. They appear unconvinced that patenting is now required to encourage further innovation. These interests view patenting as a policy which would "open Pandora's box," producing tremendous dislocations in the economic power structure in agriculture.

The concerns of many critics of the PTO decision are founded on what they consider to have been the deleterious effects of the PPA and PVPA (noted above) on the seed industry and on plant breeding. Critics note that significant economic concentration occurred in these industries after the enactment of those Acts. The increasing concentration has occurred as chemical and pharmaceutical companies have acquired seed businesses. Critics believe that the increased financial incentive to develop new plant breeds provided by the patent-like protection of the Acts, drew large companies to the seed industry. Some consider these mergers to be especially significant as rDNA technology advances, because the resulting

conglomerate firms possess both the technical expertise for gene manipulations in the chemical and pharmaceutical divisions, and the plant genetics and breeding expertise of the seed divisions. In addition, these firms own the seeds themselves, the marketable "packages" of rDNA technology. In an era of biotechnology, some see the mergers as "vertical integration" in the seed industry. The critics warn that similar effects are likely to develop in the animal breeding industry under the recent PTO decision.

Critics of the PTO patenting life decision fear increased concentration and vertical integration in agriculture for several reasons. They believe that it ultimately will lessen the genetic diversity of plants and animals in the marketplace, and therefore in use. This fact, they argue, presents a danger of reducing the germplasm resources, i.e., the pool of genetic material that is available for breeding for a given plant or animal. Reduced germplasm resources means that there are reduced supplies of diverse genes for a species that may be used in further plant or animal breeding. A genetically diverse supply of germplasm is important for maintaining long-term improvements in plant and animal breeds. Genetic diversity in the varieties of plants and animals in use is also considered an important protection against widespread disease epidemics in plants or animals that are susceptible to the same diseases because of a common genetic make-up.

Another concern is that if large companies hold patent rights to plants or animals, farmers may be permitted only to license them from the patentee, not own them. Some critics envision a future where the ownership rights of agricultural products are held by large corporate entities and where farmers only lease rights to them. Some critics have termed this scenario a "new form of tenant farming." Some have suggested that the PTO decision may provide an apropos time for Congress to take a step back and evaluate whether any "patents" should be granted for life forms -- even under the PPA and PVPA.

The concerns of some critics of the PTO decision are the result of intense study of changes that occurred in the seed industry following the enactment of PPA and PVPA. In fact, there is substantial documentation that the seed industry became more concentrated after the plant patent statutes were enacted. However, there is disagreement concerning the causes of the concentration, what role, if any, patenting played in the development, and whether the consequences are harmful to U.S. agriculture. Similarly, there is little factual evidence that enables one to predict with accuracy what will be the implications of the PTO decision, and whether the effects will benefit or harm agriculture.

Advocates of the PTO decision counter the concerns of critics with several arguments. First, advocates emphasize the agricultural benefits of rDNA technology, such as more rapidly developing improved breeds. They argue that the ability to patent an improved breed is a necessary incentive for companies to invest in genetically improved animal breeds. Next, they question the premises of the critics that the plant patent statutes are a model for the effects to be anticipated from the PTO decision, or that the plant patent statutes are a cause of economic concentration in the seed industry, or any other effects being ascribed to

them. They argue that the implications of higher life form patenting are uncertain, and that predictions the critics make are speculative at best.

In general, advocates of the PTO decision appear to acknowledge that the decision presents some significant policy issues. However, they believe that most problems the technology creates should be dealt with by contract between the patent holder and licensee, or under the body of law intended to deal with problems of that sort. To do otherwise, it is argued, would threaten progress in rDNA technology and potentially deprive society of its benefits. Furthermore, advocates argue that the technology is still at an infant stage, and it will be many years before it will yield significant benefits, or influence the economy in an important way. Therefore, it is argued, there will be time to evaluate the issues as they arise. For example, advocates argue that if the seed or animal breeding industry appears to be getting too economically concentrated, the antitrust laws should be used to prevent mergers and stop anticompetitive practices. If products are being developed that are unsafe for human or animal health, they should be regulated under food and drug or environmental laws.

This philosophy is consistent with the case-by-case problem solving approach that has been used to develop the "RAC Guidelines" (Recombinant DNA Committee Guidelines) that control research practices concerning federally funded rDNA research. The concept of regulating biotechnology under already existing law is in keeping with that of the Federal Coordinated Framework for Regulation of Biotechnology, the umbrella policy that guides the regulation of products produced by biotechnology. It is also consistent with the recommendations of the World Intellectual Property Organization (WIPO), that advised that no special patent policies be developed for biotechnology innovations.

Advocates of the PTO decision are concerned that attempting to regulate rDNA technology and its implications through the patent law will have a chilling effect on research and development of rDNA and technology in general. They argue that patent policy should be "morally neutral," and that any attempt to guide the direction of innovation would depart from traditional patent policy, which has separated concerns of the moral or economic value of an innovation from questions of patentability. However, one such departure may already be presented in the Atomic Energy Act (42 U.S.C. 2181, section 151), which precludes granting a patent on an invention that is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. While the policy was enacted to protect national defense and promote peaceful uses of nuclear materials, it has been viewed as implying a moral position, i.e., that the property rights in such a powerful technology should not be held in private hands.

Two areas where some patent law experts believe special exemptions from the PTO decision may be desirable concern researchers and farmers. These experts have suggested that to facilitate research, scientists should be allowed to use patented animals or plants without entering a licensing agreement with the patent-holder.

Another exemption that has been offered would allow farmers to breed patented animals without paying license fees for the offspring. The patent-holder could preserve the value of its patent by, for example, selling only patented animals of one sex. Cross-breeding a patented animal with an unpatented one not possessing the desired characteristic would dilute the characteristic in successive generations ("genetic drift"). The principle of genetic drift is considered by some as a natural method of enforcing patent rights. Farmers would, therefore, need to license additional patented animals to develop and maintain a herd with the desired characteristic.

These possible exemptions are similar to those provided under the PVPA for plants having patent-like protection. However, there is controversy over whether the PVPA exemptions have been effective.

International Competitiveness

The question of how biotechnology should be regulated has long been debated. The recent uncompetitive position of U.S. companies concerning such electronic products as certain semiconductors and video cassette recorders has raised concerns about the ability of the United States to compete effectively in the international high technology marketplace. These concerns have been heightened by the growing U.S. trade deficit. Because the United States is a world leader in biotechnology, it is generally considered to be well-positioned to commercialize and to capture international markets. There is concern that overzealous regulation might squander the scientific lead the United States currently has over foreign competition, giving the competition an opportunity to gain a foothold in international markets.

Critics of the PTO patenting life policy argue that there is little danger that foreign competition will benefit if higher life form patents are barred in the United States because only the United States and a handful of Eastern block nations allow such patents. On the other hand, advocates of the decision argue that the U.S. patent policy is widely regarded as the most progressive in the world, and that international biotechnology competitors are likely to recognize higher life form patents as rDNA technology advances in those countries. They argue that the U.S. Patent Policy is a competitive advantage that should be preserved.

Points for Further Consideration

As the Congress examines the appropriateness of the PTO decision and whether a moratorium on animal patenting should be enacted, it may wish to consider related ethical and economic issues. In addition, Congress may wish to evaluate the appropriate role of public participation in this area. Relevant questions include:

Do the implications of "patenting life" merit public participation in the formulation of a policy on the issue? Is it sufficient that the public be included as the PTO decision is fleshed-out on a case-by-case basis as issues emerge in the coming years? Is a moratorium on animal patenting necessary for issues to be explored adequately? Will a

moratorium necessarily improve the exploration of ethical and economic issues? Is it possible to effectively analyze the implications before experience is gained through implementation of the policy? Will a moratorium have a chilling effect on research and innovation that falls outside its scope?

LEGISLATION

H.R. 3119 (Rose)

Amends the patent laws to prohibit for 2 years the patenting of vertebrate and invertebrate animals altered through genetic engineering technology. Revokes previously granted patents for such animals. Introduced Aug. 13, 1987; referred to Committee on the Judiciary. Referred to Subcommittee on Courts, Civil Liberties, and the Administration of Justice.

CONGRESSIONAL HEARINGS, REPORTS, AND DOCUMENTS

U.S. Congress. House. Committee on the Judiciary. Subcommittee on Courts, Civil Liberties, and the Administration of Justice. Patents and the Constitution. Hearing, 100th Congress, 1st session. June 11, July 22, Aug. 21, and Nov. 5, 1987. (not yet printed)

CHRONOLOGY

11/05/87 --- The House Judiciary Committee held a field hearing on Patents and the Constitution.

09/09/87 --- The PTO proposed a rule that sets forth rules regarding the deposit of sample material which is a condition of patenting certain biological materials. [52 FR 34080]

08/02/87 --- The House Judiciary Committee held a field hearing in Madison, Wisconsin, on Patents and the Constitution.

08/13/87 --- Representative Rose introduced H.R. 3119, a bill that would impose a 2-year moratorium on patenting vertebrate and invertebrate animals.

06/11/87 --- The House Judiciary Committee held hearings on patents and the Constitution.

04/07/87 --- The Patent and Trademark Office announced that it considered higher life forms, e.g., animals, to be patentable subject matter. The decision was based in part on Ex parte Allen, a case decided Apr. 3, 1987, that involved a patent claim for oysters.

06/16/80 --- The U.S. Supreme Court decided that rDNA microorganisms could be patented.

1973 --- The first successful gene insertion into DNA using rDNA techniques.

1953 --- Watson and Crick discover the double-helix structure of DNA.

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