Chapter 1

Summary, Policy Issues, and Options for Congressional Action

"Last month the government granted its first patent on something that can look you in the eye. Is this small step for a mouse a giant leap backward or forward for mankind?"

The New Republic, *May* 23, 1988.

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Summary, Policy Issues, and Options for Congressional Action

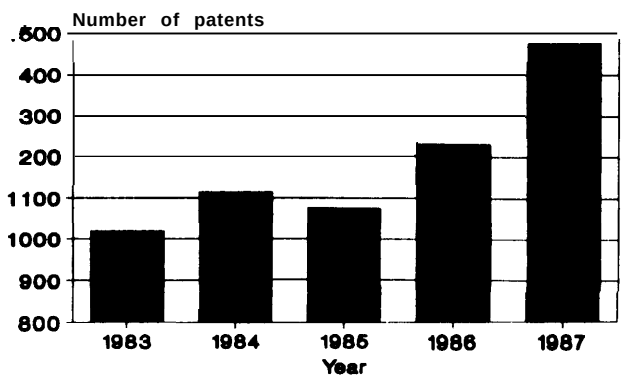
Intellectual property protection, which for purposes of this report is defined as that area of the law involving patents, copyrights, trademarks, trade secrets, and plant variety protection, is not new. The concept of patents, for example, can be traced to ancient Greece, and as developed by English common law, was defined as the grant by the sovereign to a subject under some authority, title, franchise, or property. In the United States, the concept of intellectual property rights can be found in the U.S. Constitution (Art. I; Sec. 8), which gives Congress the power "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." Subsequently, Congress enacted this Nation's first patent and copyright laws in 1790.

Much in biotechnology, on the other hand, is relatively new. In the past 15 years, dramatic new developments in the ability to select and 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 micro-organisms 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 such biological techniques (e.g., recombinant DNA techniques, cell fusion techniques, monoclinal antibody technology, and new bioprocesses for commercial production) that have caught the imagination of many people.

Patents have come to be viewed by many as vital to protecting commercial interests and intellectual property rights in biotechnology. In 1987 alone, the U.S. Patent and Trademark Office (PTO) issued 1,476 biotechnology patents, up from 1,232 in 1986 (figure 1-1). About **6,900** biotechnology patent applications were pending as of January 1988. The wide-reaching potential applications of biotechnology lie close to many of the world's major problems—malnutrition, disease, energy availability and cost, and pollution.

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 relative] y 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 micro-organism that is patented), the welfare of the

Figure I-l—Patents Issued in Biotechnology



SOURCE: "U.S. Patent and Trademark Office Issues 1,476 Biotechnology Patents in 1987," *Genetic Engineering News* 8(3):25 March 1988.

organism (if it's 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 report, the fifth in a series on new developments in biotechnology,[1] analyzes some of the legal, scientific, economic, ethical, and practical considerations raised by the patenting of micro-organisms, cells, plants, and animals. **The primary focus of this report is on subject matter patentability—what can and cannot be patented, as enacted by Congress under the patent statute and interpreted by the courts.** Other issues related to intellectual property and biotechnology, such as infringement and international harmonization, are beyond the scope of this report.

The US. **Constitution provides that** "Congress **shall have** the power. . . 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."

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 whoever invents or discovers any new, useful, and nonobvious 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, which employed the same broad language as the 1790 Act. The Patent Act of 1952 replaced "art" with "process" as patentable subject matter (35

[1]Earlier reports in the assessment of New Developments in Biotechnology are: *Ownership of Human Tissues and Cells*, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987); *Public Perceptions of Biotechnology*, OTA-BP-BA-45 (Springfield, VA: National Technical Information Services, May 1987); *Field-Testing Engineered Organisms: Genetic and Ecological Issues, OTA-BA-350* (Lancaster, PA: Technomic Publishing Co., Inc., May 1988); *U.S. Investment in Biotechnology*, OTA-BA-360 (Springfield, VA: National Technical Information Services, July 1988).

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 years. 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 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.

Copyrights

Copyrights, like patents, find their domestic roots in the Constitution, ". . . securing for limited Times to Authors. . . the exclusive right to their . . . Writings . . ." Historically, the term "writings" has been interpreted broadly. The copyright statute (17 U.S.C. 102(a)) defines a writing as that which is "fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device." Copyright protection is expressly provided for eight categories of works: literary; musical; dramatic; pantomimes and choreographic; pictorial, graphic, and sculptural; motion pictures and other audiovisual works; sound recordings; and computer programs.

A copyright does not protect an idea, but rather the expression of the idea. Copyrights also do not extend to any procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied (17 U.S.C. 102(b)). Copyright protects the writings of an author against copying, and protects the form of expression rather than the subject matter of the writing.

Trademarks

A trademark is a distinctive mark, motto, device, or emblem that a manufacturer stamps, prints, or otherwise affixes to goods, so they can be identified in the market, and their source or origin be vouched for. The law of trademarks is governed by both Federal and State law. Federal trademark law stems from the Trademark Act of 1946 (15 U.S.C. 1115-1127, popularly known as the Lanham Act), which provides for the registration of trademarks, service marks, certification marks, and collective marks. Each State has an administrative registration system that is generally parallel to but autonomous from systems in other States and from the Federal system. Prior to 1989, Federal trademark registration had a term of 20 years, which could be renewed if continuous use of the mark was shown. Under new law (Public Law 100-667), however, Federal trademark registrations have a renewable term of 10 years and a party can apply for Federal registration based on an "intent to use" the mark.

Photo credit: Gilbert Stuart's "Edgehill Portrait" of Thomas Jefferson. Jointly owned by Monticello, the Thomas Jefferson Memorial Foundation, and the National Portrait Gallery, Smithsonian Institution. Purchase funds provided by the Regents of the Smithsonian Institution, the Trustees of the Thomas Jefferson Memorial Foundation, Inc., and the Enid and Crosby Kemper Foundation.

Thomas Jefferson authored the first U.S. patent statute, enacted by Congress in 1790.
The patent law embodied his philosophy that "ingenuity should receive a liberal encouragement."

Trade Secrets

Trade secret protection is governed by State law, and extends to information used in a trade or business that is maintained secret by its owner and provides a competitive business advantage over those not having the information. A plan, process, tool, mechanism, chemical compound, customer list, and formula are all examples of information that can be maintained as trade secrets. Affirmative steps must be taken by an employer to keep information secret (e.g., by limiting access or by contract), so that the secret is disclosed in confidence only to those having a reasonable need to know (e.g., employees). Once the information becomes publicly known, it loses its status as a trade secret.

U.S. trade secret law has been fashioned to promote two beneficial ends. It encourages commercial morality and fair-dealing, and it encourages research and innovation. It does not, however, promote disclosure, which is one of the end results of a patent.

Plant Variety Protection

Plant variety protection provides patent-like protection for breeders of certain sexually reproduced plants. Like patents, plant variety protection is governed by Federal statute (see subsequent discussion on Plant Variety Protection Act). However, the plant variety protection statute is administered by the U.S. Department of Agriculture (USDA), not PTO.

PATENTING OF MICRO-ORGANISMS 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, while 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 micro-organism 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 micro-organisms (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, 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. 101. 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 invention was thought to have significant value for cleaning up oil spills.

Chakrabarty's claims to the bacteria were rejected by PTO on two grounds:

- micro-organisms are "products of nature;" and
- as living things, micro-organisms are not patentable subject matter under 35 U.S.C. 101.[2]

Following two levels of appeals, the case was heard by the U.S. Supreme Court, which in a 5-4 ruling, held that **a live, human-made micro-organism 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 micro-organism 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 micro-organisms 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 Congress and the executive branch for regulation or control, not to the judiciary.

Post-Chakrabarty Events and Trends

The *Chakrabarty* decision and subsequent actions by Congress and the executive branch provided great economic stimulus to patenting of micro-organisms 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 98-620) encourage 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,

[2]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.

alpha interferon, factor VIII, and use of dual monoclinal antibody sandwich immunoassay 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 of 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 **PTO** to process biotechnology applications in a timely manner. The number of these applications has severely challenged the process and examination capabilities of PTO. In March 1988, 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 months lapse, on average, before examination of a biotechnology application initiates, and an average of 27 months 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.

INTELLECTUAL PROPERTY PROTECTION AND PLANTS

To date, plants are the sole life form for which Congress has expressly permitted intellectual property protection. Federal statutory protection of ownership rights in new plants has existed for almost 60 years. Today, two Federal statutes, a decision by PTO Board of Appeals, and recognized trade secret law provide a variety of protection for inventions that constitute plant life.

Plant Patent Act of 1930

Prior to 1930, plant breeding and research depended primarily on federally funded agricultural experiment stations and the limited endeavors of amateur breeders to develop new disease-resistant, cold-tolerant, or medicinal varieties. Financial incentives for private sector breeders were inadequate, since the breeders' sole financial reimbursement was through high sales prices of comparatively few reproductions during the first 2 or 3 years after the variety's initial availability. Once a variety left a breeders' hands, it could be reproduced in unlimited quantity by anyone.

In 1930, Congress enacted the Plant Patent Act (PPA) to extend patent protection to new and distinct asexually propagated varieties other than tuberpropagated plants. The **PPA was the first and remains the only law passed by Congress specifically providing patent protection for living matter.**

Photo credit: U.S. Patent and Trademark Office

Design, plant patent 641, rose plant.

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Plant Variety Protection Act of 1970

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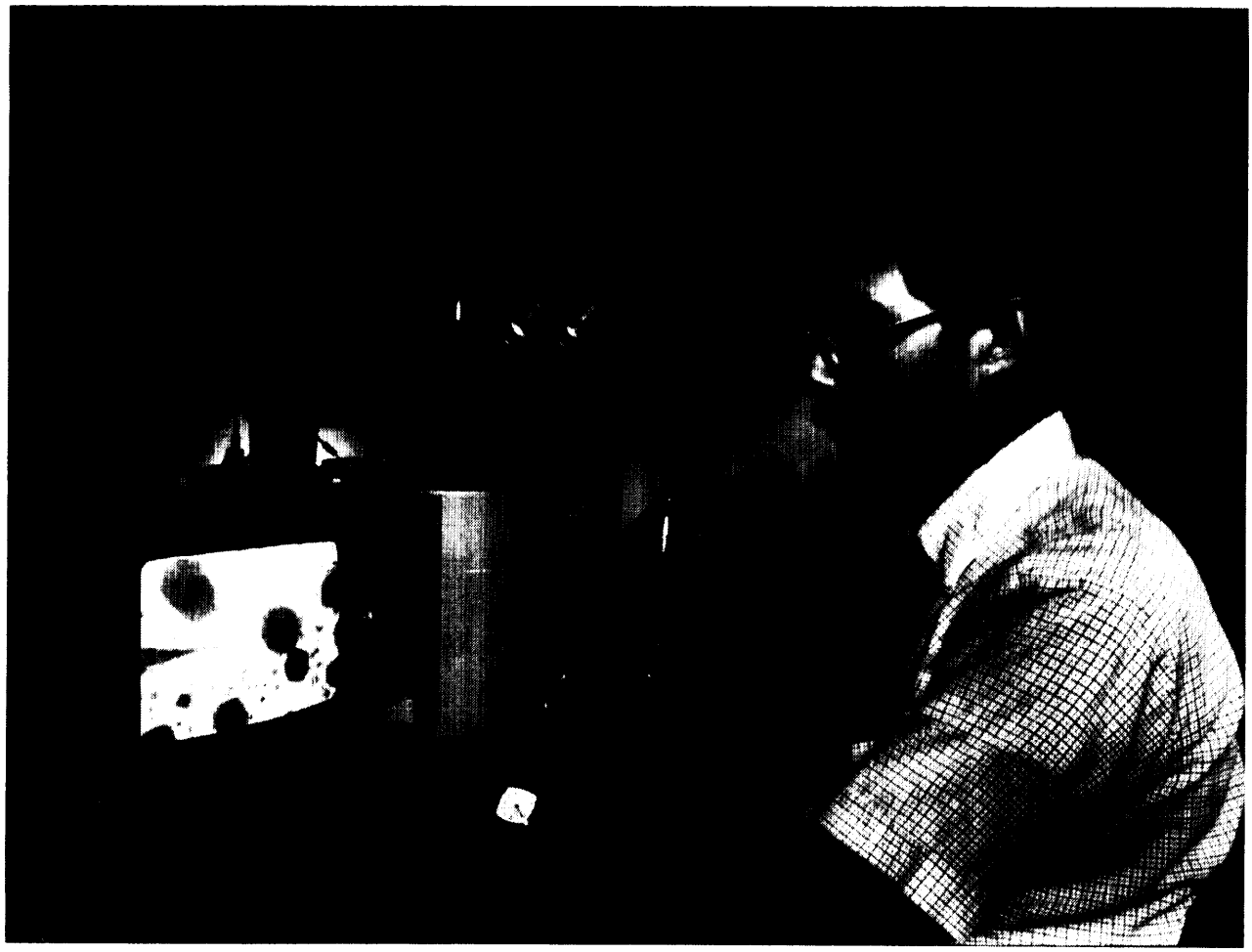

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except for asexually reproduced plants covered by PPA.

The Plant Variety Protection Act (PVPA) was enacted by Congress in 1970 to encourage the development of new, sexually reproduced plants by providing an economic incentive for companies to undertake the costs and risks inherent in producing new varieties and hybrids. Although PVPA is not formally part of the patent act and is not administered by PTO, the protection it provides to breeders of new plant varieties is comparable to patent protection. Upon application to, and examination by USDA, a plant variety certificate may issue on any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrid). Amendments in 1980 added protection for six vegetable crops, and extended coverage to 18 years so PVPA would be consistent with UPOV provisions.

PVPA includes two important exclusions to a certificate holder's protection:

. research exemption that precludes a breeder from excluding others from using the protected variety to develop new varieties; and
. farmer's exemption that allows individuals whose primary occupation is growing crops for sale, for other than reproductive purposes, to save protected seed for use on their farm or for sale to people whose primary occupation also is growing crops.

From 1970 through 1988, 2,783 applications for plant variety protection certificates were filed at USDA for some 100 different crops. By December 31, 1988, 2,133 certificates had been issued and 274 applications were pending. Another 376 applications have been abandoned, withdrawn, declared ineligible, or denied.

Utility Patents for Plants

Although *Diamond v. Chakrabarty* held that living things, namely micro-organisms, were patentable, the specific issue of whether utility patents could be issued for plants was not addressed by the Supreme Court. Subsequently, in 1985, PTO's Board of Patent Appeals and Interferences ruled in Ex *parte Hibberd* that a corn plant containing an increased level of tryptophan, an amino acid, was patentable subject matter under 35 U.S.C. 101.

Since the *Hibberd* ruling, utility patents have been granted on plants, even though protection was already available under PPA or PVPA. There are no statutory exemptions from infringement for a plant utility patent—in contrast to PVPA, the holder of a plant utility patent can exclude others from using the patented variety to develop new varieties.

Comparison of Different Forms of Plant Intellectual Property Protection

Utility patents, when the requirements can be satisfied, generally offer broader protection for the same plant than would be available under PPA or PVPA (tables 1-1 and 1-2). Although trade secret protection is available, plants are by nature ill-suited to such protection since they often cannot be confined to an enclosed space, and some plants are easily reproduced and grown.

An OTA survey of universities, nurseries, seed companies, and biotechnology firms found an array of opinions on intellectual property protection of plants, especially regarding utility patents. Many respondents viewed utility patents as beneficial and necessary to provide adequate protection for new varieties. Some seed companies, however, expressed concern about utility patents, including: restriction of germplasm, industry concentration, and domination of the industry by large conglomerates.

From a practical perspective, it is unclear that any single approach to protecting plant intellectual property will be the most productive. Accordingly, present strategies involve multiple approaches based on several factors, including crop type, farmer's exemption under PVPA,

Table I-l-Comparison, Utility Patents and Plant Patents

[Statute]	
Utility patents (35 U.S.C. 101)	Plant patents (35 U.S.C. 161)
No **limit on number of claims**	**Limited to** single claim
Can cover plant parts (e.g., flowers, fruits, nuts)	May not cover plant parts
Can cover sexually reproduced varieties	Cannot cover sexually reproduced varieties
Stringent disclosure required	Less stringent disclosure required
Fees for patent filing and maintenance higher than fees for plant patents	Fees for patent filing and maintenance lower than fees for utility patents

SOURCE: **Office of Technology** Assessment, 1989.

Table 1-2-Comparison, Utility Patents and Plant Variety Protection Certificates

[Statute]	
Utility patents (35 U.s.c 101)	Plant variety protection certificates (7 U.S.C. 2321)
Not limited to a single variety	Limited to a specific variety
Extensive scope of protection (e.g., plant, seeds, plant parts, genes, specific traits, processes)	Limited to a specific variety
Can cover asexually reproduced varieties	Cannot cover asexually reproduced varieties
No farmer's exemption	Farmer's exemption
No research exemption	Research exemption
Protection commences when patent issues	Protection commences when certificate is filed.

SOURCE: Office of Technology Assessment, 1989.

litigation, licenses, research exemption under PVPA, and deposit.

PATENTING OF ANIMALS

In April 1987, the Board of Patent Appeals and Interferences ruled that polyploid oysters were patentable subject matter. Subsequently, 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.

Photo credit: John Kuhtik, ©DISCOVER PUBLICATIONS

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 E.I. du Pont de Nemours & 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." In November 1988, du Pont announced its intention to begin sales of the patented "oncomouse" in early 1989. 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 or from 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. (see table 1-3). **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 years). Beyond mice, the major research efforts involving transgenic modifications focus on cattle, swine, goats, 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:

- 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.**
- 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.**
- With 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 closely 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 years) because of greater technical difficulty and the current lack of understanding of how such traits are controlled by genes.

Species Barriers and Species Integrity

Some concern has been raised over negative impacts transgenic animals might have on their own species, based on the assertion that transfer-

Table 1-3-Advantages of Mice for Research in Gene Transplantation

. A warm blooded mammal with many similarities to humans in genetics and physiology.
. Small organism, easy to maintain in the laboratory, can be raised in substantial numbers easily and quickly, at modest expense.
• Compared to other mammals, genetics and physiology very well known.
. Available in a variety of different, well characterized, genetically consistent lines for use in different types of studies.

SOURCE: Office of Technology Assessment, 1989.

ring genes between species transgresses natural barriers between species, and thus violates their "integrity" or identity.

Modem biologists generally think of species as reproductive communities or populations. They are distinguished by their collective manifestation of ranges of variation with respect to many different characteristics or qualities simultaneously. The parameters that limit these ranges of variation are fluid and variable themselves: different species may have substantially different genetic population structures, and a given species may look significantly different in one part of its range than it does in another while still demonstrably belonging to the same gene pool or reproductive community. Although research into the nature of species continues to be vigorous, marked by much discussion and disagreement among specialists, general agreement among biologists exists on at least one point: **nature makes it clear that there is no universal or absolute rule that all species are discretely bounded in any generally consistent manner.**

The issue of species integrity is more complex and subtle than that of species barriers. If a species can be thought of as having integrity as a biological unit, that integrity must, because of the nature of species, be rooted in the identity of the genetic material carried by the species. Precisely how a species might be defined genetically is not yet apparent.

Any genetic definition of species, grounded in the perception of a species as a dynamic population, rather than a unit, cannot be simple; it must be statistical and complex. Therefore, **to violate the "integrity" of a species it is not sufficient to find a particular gene, once widespread throughout the species, now entirely replaced by a different gene.** Such changes occur repeatedly throughout the evolutionary history of a lineage and are described as microevolutionary. These changes are usually insufficient to alter a species in any fundamental way or to threaten any perceived genetic integrity.

If it is possible to challenge the integrity of a species, it would have to be by changing or disrupting something fundamental in its genetic architecture, organization, or function. Mammals like mice, cattle, or humans may contain from 50,000 to 100,000 or more genes. Whatever it is in the organization and coordination of activity between these genes that is fundamental to their identity as species, it is not likely to be disrupted by the simple insertion or manipulation of the small number of genes (fewer than 20) that transgenic animal research will involve for the foreseeable future.

The right of a species to exist as a separate, identifiable creature has no known foundation in biology. Species exist in nature as reproductive communities, not as separate creatures. The history of systematic and taxonomy (the disciplines of naming and describing species) demonstrates that species' existence has often been independent of scientists' shifting understanding or abilities to discern this existence. Furthermore, most of the domestic animals that are now the subjects of transgenic research (with the possible exception of some fish), and are likely to be for the foreseeable future, are already the products of centuries, and in many cases millennia, of human manipulation.

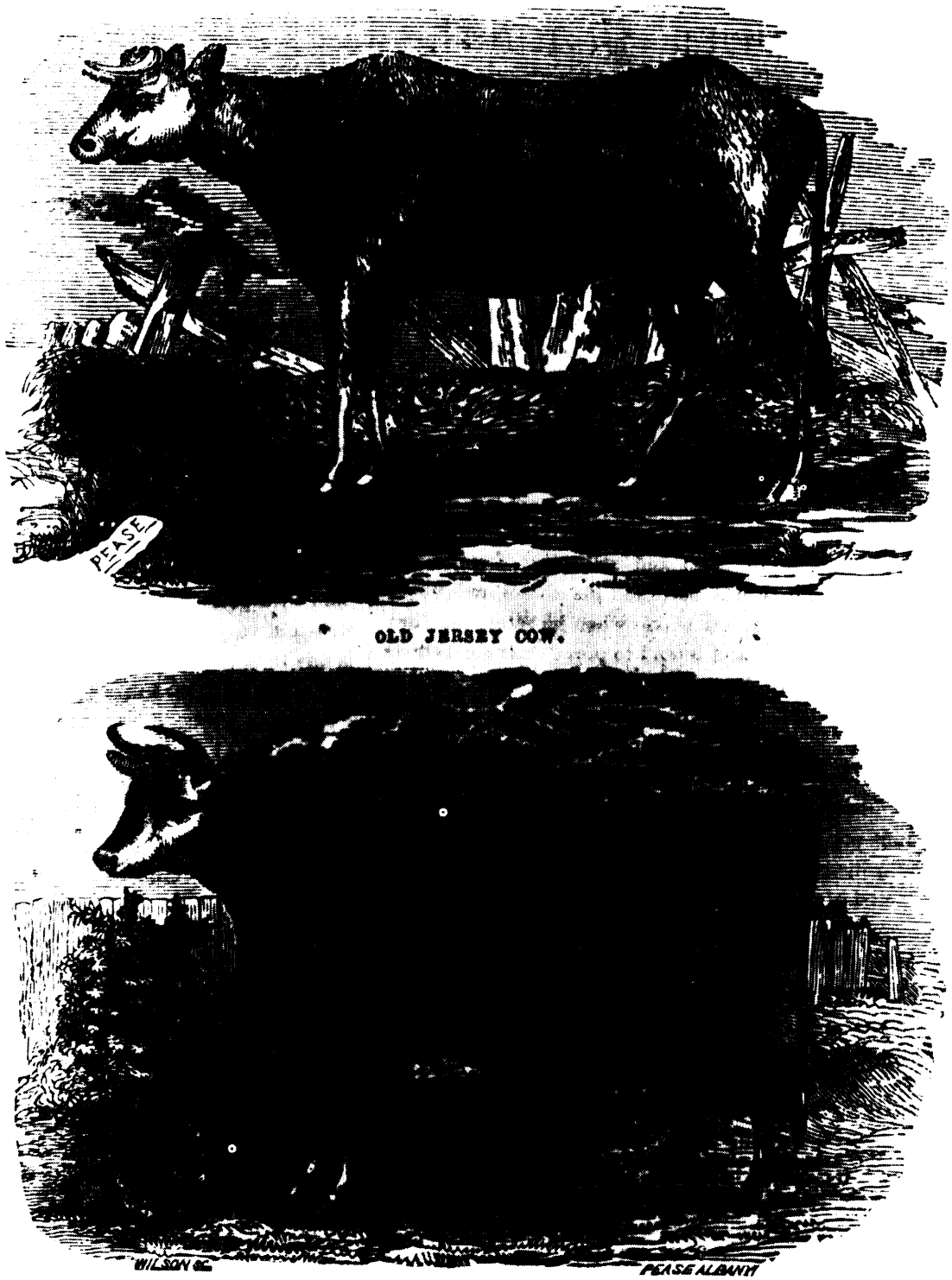

Photo credit: Library of Congress

Line drawing, early 1900s, Old Jersey Cow and Improved Jersey Cow.

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 5 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 Institutes of Health is currently the largest user of such animals for biomedical research projects. USDA has conducted research on the genetics of animals for many years. 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. 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 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

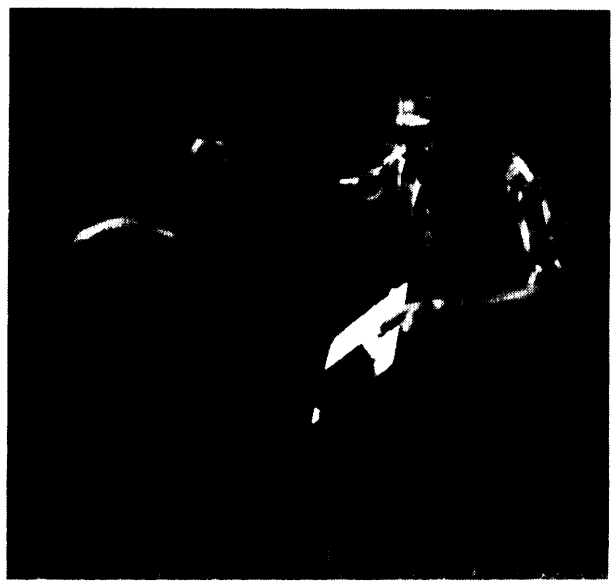

Photo credit: Agricultural Research Service

USDA animal physiologist Dr. Vernon Pursel examines a pig born with a bovine growth hormone gene inserted in the embryo. Scientists hope to produce leaner and faster growing pigs using less feed. To date, these animals have been lethargic and have had health problems. As part of a long term research effort, USDA hopes current studies will lead to better understanding of how growth hormone works and how to better control it.

large-scale commercial production of such livestock and poultry is unlikely in the near future (5 to 10 years).

The largest economic sectors likely to be influenced by animal patents are the different markets for agricultural livestock and some sectors of the pharmaceutical industry. The principal agricultural markets involve poultry, dairy, and red meat. These markets are organized quite differently, and 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 much more diffuse. Different economic forces are important in markets as well: Federal price supports are of major importance in the dairy market, while 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 where 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 arguments have been used to support and oppose the concept of animal patenting (see table 1-4).

Many arguments relating to the consequences of animal patenting are difficult to evaluate since 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, since 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 with those persons holding opposing and often strongly held beliefs.

Table 14-Arguments For and Against Patenting Transgenic Animals

Arguments for patenting transgenic animals:
• Patent law regulates inventiveness, not commercial uses of inventions
• Patenting promotes useful consequences, such as new products and research into solutions of problems.
. Patenting is necessary if the Nation's biotechnology industry is to be able to compete internationally.
. If patenting is not permitted, inventors will resort to trade secret protection, which could hinder the sharing of useful information.
• Patenting rewards innovation and entrepreneurship.
Arguments against patenting animals:
• Patenting raises metaphysical and theological concerns (e.g., promotes a materialistic conception of life, raises issues of the sanctity of human worth, violates species integrity).
• Patenting will lead to increased animal suffering and inappropriate human control over animal life.
• Other countries do not permit the patenting of animals, leading to potential adverse economic implications for the Third World.
. Patenting promotes environmentally unsound policies.
. Patenting produces excessive burdens on American agriculture (increased costs to consumers, concentration in production of animals, payment of royalties for succeeding generations of animals).

SOURCE: Office of Technology Assessment, 1989.

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
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, PTO began recommending that patent applications for inventions involving micro-organisms should include the deposit of the pertinent micro-organism with a culture collection. Although not a formal requirement, patent examiners advised applicants that in cases where words alone were not sufficient to describe the invention adequately, a deposit was advisable.

Currently, patent applications for inventions involving micro-organisms, plasmids, vectors, cells, plant tissues, seeds, and other biological materials that are not generally available or reproducible without undue experimentation by persons skilled in the pertinent field are often supported by a deposit in a recognized patent depository.

Biotechnology presents a unique administrative issue in that it is the only art known where words alone may be incapable of describing an invention sufficiently to enable one skilled in the art to make and use it in a reproducible manner. 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 requi
employed in many cases to meet the requirement that a patent provide enablement or the best mode of practicing an invention.

PTO first published guidelines on the deposit of micro-organisms in 1971. In 1977, establishment of the Budapest Treaty required contracting states that allow or require the deposit of micro-organisms as part of their patent procedure to recognize the deposit of a micro-organism 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

Figure 1-2-Figures, Mousetrap and Mouse Patents

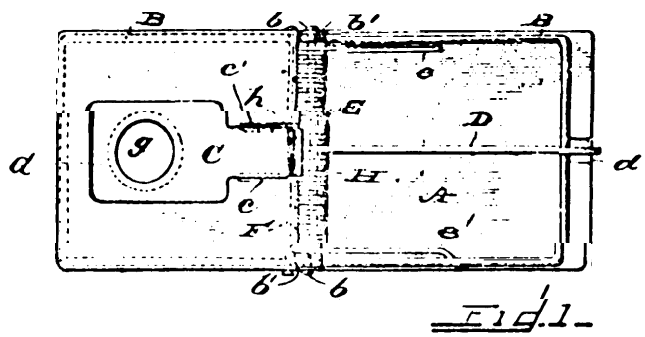

Fig. 1

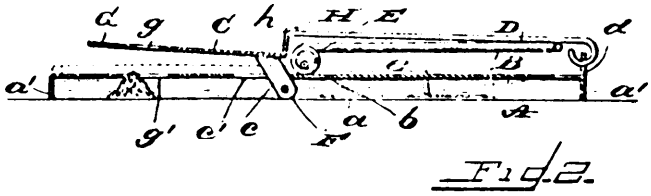

Fig. 2

Above--Two figures were submitted for U.S. Patent No. 661,068, the mousetrap, which was issued in 1900. The invention is "a trap of simple construction which can be manufactured inexpensively" in which "the bait cannot be removed without releasing the engaging jaw."

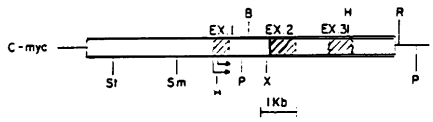

FIG 1

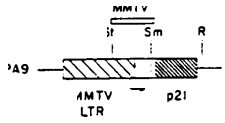

FIG 2

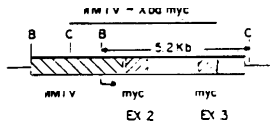

FIG 3

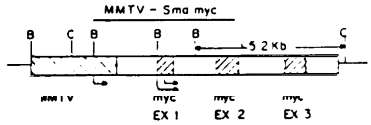

FIG 4

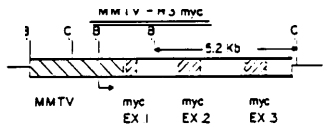

FIG 5

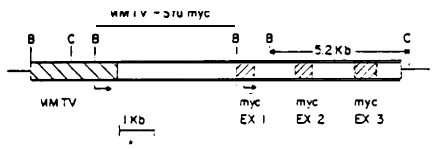

FIG 6

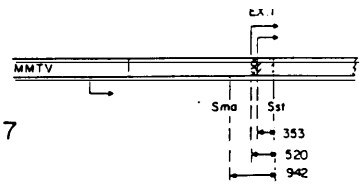

FIG 7

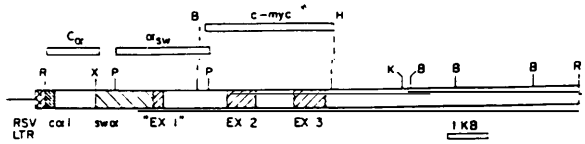

FIG 8

Right column—Eight figures were submitted for U.S. Patent No. 4,736,866, "Transgenic Non-Human Mammals," which was issued in 1988. The invention "features a transgenic non-human eukaryotic animal (preferably a rodent such as a mouse) whose germ, cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage." The eight figures represent plasmids, activated oncogene fusions, and a probe.

SOURCE Office of Technology Assessment, 1989; adapted from U.S. Patents 661,068 (1900) and 4,736,866 (1988)

Photo credit: U.S. Department of Agriculture

Cloned strawberry plants in a growth chamber.

deposit in a recognized depository by the filing date of the patent application, but only before the issuance of the patent. In 1988, PTO published proposed rules for deposit of biological materials for patent purposes (see app. C). These rules, if adopted formally by PTO, will assist the inventor and the depository in defining the position of PTO on deposits.

A culture depository accepts, maintains, and distributes cultures of micro-organisms, viruses, cells, or other genetic-type material. The deposit of seeds and plant tissue culture has become established practice. A depository maybe public or private; nonprofit or for profit. The main function of a public culture depository is preservation and distribution of reference cultures that serve as standards for users in the scientific and educational communities (table 1-5).

The new patentable status of animals raises the possibility that PTO will encourage or require 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 the following 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 animal types for the current required period of 30 years would not be practical or possible, as their life spans are shorter than 30 years.

The deposit of animal embryos may not present the same difficulties as long as the

Table 1-5-Fees, Deposit for Patent Purposes

Fee, **30 years of maintenance and viability testing on a culture deposited** for patent Purposes:	
American Type Culture Collection Rockville, MD	$670
In Vitro International, Inc. Linthicum, MD	$610
Northern Regional Research Laboratory Peoria. IL	$500

SOURCE: Office of Technology Assessment, 1988.

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 MICRO-ORGANISMS, 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.

International Agreements and Laws of Other Countries

Several international treaties and agreements are relevant to biological inventions (table 1-6). 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 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, 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 which are in the genetically fixed form of a plant variety, i.e., a specific variety such as the rose "Peace" or the wheat cultivar "Chinese Spring." Thus, 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 EPO, which in early 1988 granted a patent on a technique for increasing protein content of forage crops such as alfalfa and for plants produced with the aid of that technique. This

Table l-6-international Agreements and Biotechnology Patents

Agreement	Entered into force	Number of signatories
Paris Union Convention	July 7, **1884**	**97**
Budapest Treaty	**Aug. 19, 1980**	**22**
Patent Cooperation Treaty . .	Jan. 24, 1978	40
European Patent Convention	Oct. 7, 1977	13
Union for the Protection of New Varieties of Plants . . .	Aug. 10, 1968	17

SOURCE: Office of Technology Assessment, 1989.

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. In October 1988, the European Communities Council published a proposed directive recommending that plants and animals that are not in the genetically fixed and stable form of a variety be patentable subject matter. The proposed directive will be debated by European Community nations as part of the program for the completion of the internal European market in 1992.

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 micro-organisms, as are various forms of patents and breeder's certificates for plant life. 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, although at least 9 such patent applications have been filed in Europe (see box l-A). 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 this study. They are:

- patenting of animals,
- intellectual property protection for plants, and
- . enablement of patents involving biological material.

Associated with each policy area are options that Congress might consider, ranging from taking no action to making major changes. Some of the options involve direct legislative action. Others are oriented to the actions of the executive branch that involve congressional oversight or direction. The order in which the issues and options are presented should not imply their priority. The options provided for each issue are not, for the most part, mutually exclusive: adopting one does not necessarily disqualify others in the same category or within another category. However, changes in one area could have repercussions in others.

ISSUE 1: Should the patenting of animals be permitted by the Federal Government?

Option 1.1: *Take no action.*

Since April 1987, PTO has considered nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter. Congress could take no action if it determines that the present PTO policy is adequate for such inventions. If Congress takes no action, patent claims for animals will be reviewed by PTO, and such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter. Claims directed to or including a human being will not be considered to be patentable subject matter under 35 U.S.C. 101 on the grounds that a limited but exclusive property right in a human

Box l-A—Patenting of Animals: Nine Applications for European Patents

Under U.S. law, the contents and status of a patent application are maintained in confidence by the Patent and Trademark Office (35 U.S.C. 122). Such is not the case with patent applications filed in Europe, which are published 18 months after their original filing date. At least nine applications claiming animals have been filed with the European Patent Office (EPO), and each has also been filed with the U.S. Patent and Trademark Office. Of the nine applications, six are from U.S. inventors, and one (from Harvard College) has received a U.S. patent.

The applications generally cover methods for creating transgenic animals, methods for producing animals that express biological substances, and the final product of both methods (i.e., the animals). The nine applications have priority dates ranging from June 1984 (Harvard College) to April 1987. A summary of the nine applications:

- *Method for transferring organic or inorganic substances to egg cells or somatic cells of animals and compositions for use #herein.* A method for transferring organic or inorganic substances to egg cells or somatic cells of animals by combining sperm of the respective type, optionally modified by chemical or physical means, with vesicles or granulae containing the desired organic or inorganic substances and subsequently contacting the loaded sperm with egg cells or somatic cells under intracorporal or extracorporal conditions. The invention also includes animals produced by the method. Applicant: Transgene (Bad Soden, West Germany).
- *Peptide production.* A method that involves incorporating a DNA sequence coding for a peptide into the gene of a mammal (such as a sheep) coding for a milk whey protein so that the DNA sequence is expressed in the mammary gland of the adult female mammal. The substance may be a protein such as a blood coagulation factor. Applicant: Pharmaceutical Proteins Ltd. (Cambridge, Great Britain).
- *Transgenic animals.* A method for creating new breeds of animals that involves: 1) obtaining a recently fertilized ovum; 2) isolating a gene sample of a characterizing hormone homologous with the ovum; 3) introducing the gene sample into the male pronucleus of the ovum prior to fusion with the female pronucleus to form a single cell embryo; and 4) subsequently implanting the ovum into a suitably prepared female animal. Applicant: Luminus PTY Ltd. (Adelaide, Australia).
- Expression *of heterologous proteins by transgenic lactating mammals.* Mammals capable of expressing recombinant proteins by lactation are produced by micro-injection of recombinant DNAs that contain novel expression systems into fertilized ova. Applicant: Immunex (Seattle, WA).
- *Method for producing transgenic animals.* A method for producing a transgenic eukaryotic animal having an increased probability of developing neoplasms by introducing an activated oncogene sequence. The animal may be used in testing a material suspected of being carcinogenic or of conferring protection against carcinogens. Applicant: President and Fellows of Harvard College (Cambridge, MA).
- Transgenic mammal containing *heterologous* gene. A process for producing a transgenic mammal, especially a mouse that contains and expresses a heterologous gene, especially the human insulin gene. The mice are useful for studies of pharmacological and drug reactions. Applicant: The General Hospital Corp. (Boston, MA).
- *Transgenic animals secreting desired proteins into milk.* Animals expressing proteins useful in the treatment, prevention, or diagnosis of human disease (e.g., t-PA and hepatitis B **surface** antigen). Applicant: Integrated Genetics, Inc. (Framingham, MA).
- *DNA sequences to target proteins to the mammary gland for efficient secretion.* A method of targeting specific genes to the mammary gland which results in the efficient synthesis and secretion of biologically important molecules. Further, a transgenic mammal having the ability to reproduce itself and being suitable for the secretion of biologically active agents into its milk. Applicant: Baylor College of Medicine (Houston, TX).
- *Procedure for transplanting a donor bovine* embryo into *a recipient ovocyte, and bovine embryo created by this procedure. The* invention concerns a procedure to transplant bovine donor nuclei from an embryo into enucleated recipient oocytes. Applicant: N.L. First, F. Barnes, R.S. Rather, and J.M. Robl (Madison, WI).

The European Patent Office's view on patenting living material is based strictly on the provisions of the European Patent Convention, which permit patenting of certain life forms if they are novel, inventive, and industrially applicable, if the invention is not contrary to public order, and does not cover plant or animal varieties per se. According to EPO, "the use to which certain inventions are put must be the subject of other legislation, apart from patent law," thereby balancing "the inventor's rightful claim to recognition and economic reward" with "the public's legitimate right to be protected. . . from any possible dangers to which technology may expose it."

SOURCE: Office of Technology Assessment, 1989; adapted from "Patenting of Life Forms," European Patent Office, 1988.

being is prohibited by the Thirteenth Amendment to the U.S. Constitution.

Option 1.2: *Enact a moratorium on the issuance of animal patents.*

Congress could enact a moratorium on the issuance of animal patents. The duration of such a moratorium-based either on time or on fulfillment of particular conditions-could be specifically mandated by Congress. A moratorium would allow further opportunity for public debate on the economic, ethical, and public policy issues of patenting animals and could be used to gather information from Federal agencies regarding the regulation and use of such animals. Enactment of a moratorium, however, would be the first time Congress has so acted to limit subject matter patentability. Such action could serve as a precedent for future moratoriums to limit the kinds of inventions that could be patented. A moratorium could decrease research and investment in the production of new inventions that are animals.

Option 1.3: *Enact an animal variety protection statute modeled after the Plant Variety Protection Act.*

Congress could enact a statute providing animal breeders with rights similar to those enjoyed by plant breeders under the Plant Variety Protection Act. A combination of selected elements found in the plant variety protection statute (e.g., USDA registration, a farmer's exemption, a research exemption, an 18-year term of protection) could be used to address specific concerns raised by animal patenting. Such a statute, however, would raise many of the same issues found in the legislative history of the Plant Variety Protection Act (e.g., industry concentration, genetic diversity, effects of exemptions, mandatory deposit). If enacted without congressional examination of utility patent protection, such a statute could provide inventors with an additional statutory safeguard for intellectual property protection of animal inventions; conversely, issues raised by patenting could remain unresolved.

Option 1.4: *Enact a statute amending the patent law to address the patenting of animals.*

Congress could amend the patent statute to address specific issues raised by the patenting of animals. Such action would indicate congressional intent that patenting of animals is permitted and could address unresolved issues such as exceptions from infringement, patent specification, or selected limitations on subject matter patentability.

One provision that has already proven contentious is an exception from infringement for persons whose occupation is farming. Too narrow an exception could result in extensive and costly compliance that would outweigh intended benefits. On the other hand, too broad an exception could deprive inventors of rewards for certain animal inventions or stifle research and development in animal agriculture.

During the 100th Congress, on September 13, 1988, the House of Representatives passed the Transgenic Patent Animal Reform Act (House Rule 4970). The bill implicitly acknowledged the patentability of nonhuman animals and provided for an exemption from liability for farmers who reproduce patented animals. The bill was not brought to a vote in the Senate.

Option 1.5: *Enact a statute explicitly providing for patents on animals.*

Congress has the authority to expand or restrict the kinds of inventions that are patentable. Currently, 35 U.S.C. 101 permits patents on any new and useful process, machine, manufacture, or composition of matter. Patent protection has also been explicitly extended to plants (35 U.S.C. 161) and designs (35 U.S.C. 171). By amending the patent statute to include patents on animals, Congress would erase any doubt regarding whether animals are intended to be patentable subject matter. Such a statute could also include any limitations or exceptions

to subject matter patentability on animals, deposit, or infringement. Such action, however, is presently unnecessary if Congress' sole intent is to permit the patenting of animals, and could be interpreted by future court action as limiting the patentability of certain kinds of inventions in the absence of explicit congressional action.

Option 1.6: *Enact a statute prohibiting the issuance of patents on animals.*

Congress could amend 35 U.S.C. 101 to explicitly prohibit the issuance of patents on animals. Such action would bar the patenting of animals per se, while still permitting the patenting of processes that produce novel animals. A prohibition could result in a redirection of investment in medical and agricultural research. This could slow the invention of new and useful animals that could be used for production of food, pharmaceuticals, and medical research tools. A prohibition could also serve as a precedent for limiting the patentability of technologies that are currently unimagined or to regulate subject matter that is perceived to be immoral or inadequately regulated.

ISSUE 2: Is the current statutory framework of intellectual property protection for plants appropriate?

Option 2.1: *Take no action.*

There are four principal means for inventors to protect plants—plant patents, Plant Variety Protection Certificates, utility patents, and trade secrets. The first two are forms of plant protection expressly permitted by Congress through legislation: the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. Thousands of plants are protected by the four mechanisms.

Absent congressional action, inventors will continue to seek protection for plant intellectual property by balancing the factors inherent in each of the four approaches. Inventors employ a strategy that balances crop type, farmer's exemption under PVPA, litigation, licenses, research exemption under PVPA, deposit considerations, and other factors. Inventors use no single approach to protecting plant intellectual property, as the different forms of plant protection each have unique advantages and disadvantages. The present system provides inventors much flexibility.

With regard to germplasm, inventors will likely continue to seek protection through the avenue they deem most appropriate or advantageous. Germplasm exchange would continue on an ad hoc basis. Some parties claim that intellectual property protection for plants interferes with exchange of germplasm.

Option 2.2: *Direct the Secretary of Agriculture to report on the effect of the farmer's crop/seed exemption under the Plant Variety Protection Act of 1970.*

In passing the Plant Variety Protection Act of 1970, Congress permitted farmers to save protected seed for subsequent crop production on their farms without being considered as infringing upon the Plant Variety Protection Certificate holder. Farmer-saved seed is a common practice for crops such as wheat, cotton, and soybeans. Complaints about abuses of the farmer's exemption, notably from seed companies, have been lodged with the U.S. Department of Agriculture, which enforces the PVPA. USDA may be moving toward a clarification of the limits of the farmer's exemption.

Congress could direct the Secretary of Agriculture to collect information and report on the practical impact of the farmer's exemption. Of particular interest **would be** the degree to which property rights of PVPC holders are compromised by the farmer's exemption and the dimensions of the economic benefit reaped by farmers exercising their rights under PVPA.

Option 2.3: *Direct the Secretary of Agriculture to report on the impact that plant protection has on germplasm exchange.*

Congress could direct the Secretary of Agriculture to report on the impact that proprietary interests in plants had on germplasm exchange. To date, any information on the issue is anecdotal. Because all interested parties agree that free exchange of germplasm is necessary to continue progress in agricultural research and development and in plant biotechnology, a comprehensive analysis examining trends in plant protection and germplasm exchange could reveal that a problem exists, that no problem exists, or could direct attention to potential problems.

ISSUE 3: Is the current system of patent enablement adequate **for biological material?**

Option 3.1: *Take no action.*

Congress could take no action if it determines 35 U.S.C. 112 in its present form adequately addresses patent specification requirements for biological inventions. Currently, a deposit of living material is sometimes required in order to meet the requirement that the invention be described in such terms as to enable any person skilled in the art to make and use the invention in the best mode contemplated. Deposit is currently considered on a case-by-case basis for patent applications involving biological material. Under this course of action, it is unlikely that whole animals will be deposited, since transgenic animals will be derived from known and readily available animals and developed using known reproducible processes. The courts would likely be called upon to interpret the validity of PTO policies regarding deposit and disputes of fact and law arising from the current, broad statutory language.

Option 3.2: *Enact a statute providing PTO Commissioner with the authority to set conditions for the deposit of biological material.*

If Congress determines that PTO requires additional authority to regulate the deposit of materials, it could amend 35 U.S.C. 112 to expressly provide such authority. Such action would provide PTO with the express authority and flexibility to maintain an enablement policy that expressly addresses biological material, and could lessen the need for court interpretation of deposit requirements under Section 112. Such action, however, could lead to required deposit of every living organism for which a patent is sought. This would set a separate and unequal specification standard for inventions that are biological in nature and could be unduly burdensome for the inventor, deposit facility, or both.