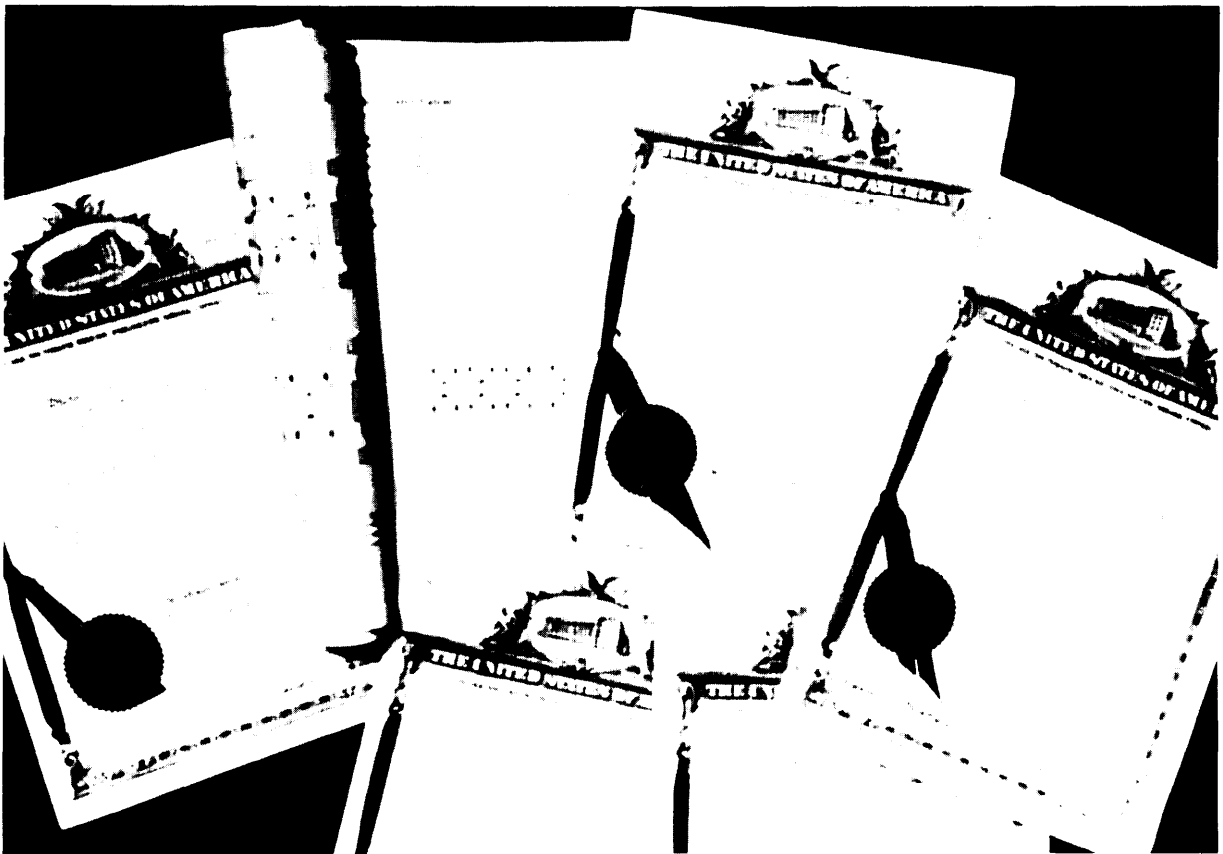


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**Part V**

# **Institutions**

# Intellectual Property Rights for Biotechnology and Computer Software



*Photo credit: Steven Bent*

## Contents

	<i>Page</i>
INTRODUCTION .....	389
INTELLECTUAL PROPERTY PROTECTION AND BIOTECHNOLOGY .....	389
Patents .....	389
Trade Secrets .....	390
The Chakrabarty Decision .....	391
INTELLECTUAL PROPERTY PROTECTION FOR PLANTS .....	391
Plant Breeders' Rights .....	391
Plant Patents v. Plant Variety Protection Certificates .....	392
Plant Patents v. Utility Patents .....	393
Plant Variety Protection Certificates. Utility Patents .....	394
Trade Secret Law .....	394
INTELLECTUAL PROPERTY PROTECTION FOR ANIMALS .....	394
Federal Regulation .....	394
Economic Considerations .....	396
Ethical Considerations .....	397
Deposit Considerations .....	397
INTERNATIONAL PROTECTION FOR PLANTS AND ANIMALS .....	398
ISSUES AND POLICY OPTIONS FOR BIOTECHNOLOGY .....	398
INTELLECTUAL PROPERTY PROTECTION AND COMPUTER SOFTWARE .....	399
Copyright .....	399
Patent .....	400
Trade Secret .....	401
INTERNATIONAL PROTECTION FOR COMPUTER SOFTWARE .....	403
ISSUES AND POLICY OPTIONS FOR COMPUTER SOFTWARE .....	403
Copyright and Patent Issues .....	403
Liability Issues .....	404
User Issues .....	404

## Boxes

<i>Box</i>	<i>Page</i>
15-A, What Can Be Patented? .....	389
15-B. International Union for the protection of New Varieties of Plants .....	393
15-C. Patent Number 4,736,866-The "Harvard Mouse" .....	395

## Tables

<i>Table</i>	<i>Page</i>
15-1. Types of Intellectual Property Protection for Plants .....	392
15-2. Member Countries of the Union for the Protection of New Varieties of Plants ... ..	393

# Intellectual Property Rights for Biotechnology and Computer Software

## INTRODUCTION

Biotechnology and advanced computer technologies have the potential to carry the productivity record of agriculture into the 21st century. Biotechnology can increase food production by lowering the costs of agricultural inputs and by contributing to the development of new high-value-added products to meet the needs of consumers and food processors. These potential products include seeds, pesticides, veterinary diagnostics and therapeutics, food additives and food processing enzymes, more nutritious foods, and crops with improved food processing qualities. Advanced computer technologies can enhance management capabilities in the agriculture and food industry. These technologies include knowledge-based systems, networks, information retrieval systems, sensors, and robotics.

Thus far, biotechnology research and development (R&D) has focused on those crops and traits that are easiest to manipulate, particularly single-gene traits in certain vegetable crops. As technical roadblocks are lifted, however, R&D likely will lead to a wide range of agricultural products. Likewise, computer software R&D and further advances in networks, sensors, and robotics will spawn numerous computer-related technologies for food and agricultural use. A critical incentive for R&D efforts in biotechnology and information technology is adequate intellectual property protection for these emerging processes and products.

Intellectual property law, which protects works of the mind as personal property, is of increasing importance to those who create new products and processes using biotechnology and computers. Intellectual property involves several areas of the law: patent, copyright, trademark, trade secret, and plant variety protection. All affect emerging high-technology industries and can help bring important technological information and products into commerce. This chapter examines intellectual property rights for inventions created through the use of biotechnology (with particular focus on plants and animals) and computer-related technologies.

## INTELLECTUAL PROPERTY PROTECTION AND BIOTECHNOLOGY

**Intellectual** property protection encompasses several areas of statutory and common law: patent, copyright, trademark, trade secret, and plant variety protection; other laws discourage unfair competition. Patents, trade secrets, and plant variety protection are particularly important to biotechnology.

### *Patents*

United States patent law has its roots in the Constitution, which gives Congress broad powers 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” (article 1, section 8). The first patent act was enacted by Congress in 1790 and, though amended several times, still allows broad scope as to what can be patented. (See box 15-A).

A patent is a grant issued by the U.S. Government that gives the patent owner the right to exclude all others from making, using, or selling the invention within the United States, its territories, and possessions during the term of the patent (35 U.S. C. 154). There are three types of patents. The most common type is the utility patent. To qualify for utility patent protection in the United States, an invention must meet several requirements:

### **Box 15-A—What Can Be Patented?**

One section of the U.S. patent law, 35 U.S.C. 101, defines what constitutes a patentable invention:

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

This section of the patent code has changed little since it was first enacted in 1790, and its broad language has made possible the issuance of more than 5 million patents.

SOURCE: Office of Technology Assessment, 1992.



The U.S. 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."

- it must be a process, machine, manufacture, or composition of matter (35 U.S.C. 101);
- it must be new, useful, and not obvious (35 U.S.C. 101-103); and
- it must be disclosed in sufficient detail to enable a person skilled in the same or the most clearly related area of technology to construct and operate it (35 U.S.C. 112).

A second category, patents for plants, includes cultivated sports, mutants, hybrids, and newly found seedlings. A third category, patents for designs, is not relevant to biotechnology-related inventions.

Patents serve two important policy objectives:

- by rewarding successful efforts, a patent provides inventors and their backers with incentive to risk time and money in R&D; and
- by requiring disclosure of the manner and process of making an invention, a patent encourages public disclosure of otherwise secret information, so that others are able to use it.

Although a patent gives the inventor the right to exclude others from making, using, or selling the invention for 17 years, it does not grant the inventor any affirmative right to make or use an invention. Commercial use of a patented invention, just like other products, can be regulated by Federal, State, or local law.

Once obtained, a patent has a term of 17 years, assuming that maintenance fees are paid (35 U.S. C. 154). One exception to the 17-year term is relevant to bio-

technology: patents on a human drug product, medical device, food, or color additive that have undergone regulatory review prior to FDA approval for commercial marketing or use may be eligible for an extension of up to 5 years, if certain conditions are satisfied (35 U.S.C. 156).

Recent revisions in Federal patent policy have encouraged increased patent activity from federally funded researchers. Prior to 1980, 26 separate patent policies promulgated by various government agencies existed for such research (9). Recognizing that a uniform patent policy would encourage cooperative relationships and commercialization of government-funded inventions, Congress passed the Patent and Trademark Amendments of 1980 (P. L. 96-517) and amendments in 1984 (P. L. 98-260). The law allows nonprofit institutions (including universities) and small businesses to retain title to patents arising out of federally funded research, with the Federal agency retaining a nonexclusive, worldwide license. Universities are required to share royalties with the inventor and to use any net income for research and education (35 U.S.C. 202).

The law, which gave statutory preference to small businesses and nonprofit organizations, was extended by executive order to larger businesses in 1983 (6). The Technology Transfer Act of 1986 (P. L. 99-502) granted Federal authority to form consortia with private concerns. Executive order 12591, issued in 1987, further encouraged technology transfer programs, including the transfer of patent rights to government grantees.

### Trade Secrets

Trade secrets extend protection to information used in one's trade or business, that is maintained in secret by its owner, and provides a competitive business advantage over those not having the information. A plan, process, tool, mechanism, recipe, chemical compound, customer list, or formula all are examples of information that can be maintained as trade secrets.

Unlike patents (which are governed exclusively by Federal law), trade secrets are the subject of State law. Trade secret law promotes not only commercial morality and fair dealing, but also research and innovation. Unlike patent law, however, trade secret law discourages rather than encourages public disclosure of technical information.

Trade secret rights require that a trade secret be disclosed in confidence only to those having a reasonable need to know (e. g., employees). Measures must be taken

by the owner of the trade secret to prevent disclosure of the trade secret to the public or to competitors (e.g., expressly identifying the information as a trade secret and prohibiting its disclosure).

### ***The Chakrabarty Decision***

During the 1980s, two events in the United States shaped the application of intellectual property law to biotechnology. First, the Supreme Court was called on to determine whether a living organism could be patented. Second, Congress and the executive branch took actions making it easier for federally funded inventions to become commercialized. These actions ignited a flood of biotechnology patent activity. By 1989, an examining unit specifically for biotechnology was established at the Patent and Trademark Office (PTO).

The development of rDNA technology in the 1970s led to debate regarding what constitutes a patentable invention. Although patents on biotechnological processes had been issued since the 1800's, PTO did not permit patents on living products created by the technology on the grounds that such matter were "products of nature" and not statutory subject matter as defined by 35 U.S.C. 101 (see box 15-A). Although proposed patent claims to living organisms were rejected by PTO, patent protection had been 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) (8).

The issue of whether a genetically engineered organism itself could be patented was addressed by the Supreme Court in 1980, in *Diamond v. Chakrabarty* (2). In this case, the patent applicant had developed a genetically engineered, but not recombinant, bacterium capable of breaking down multiple components of crude oil. Because no naturally occurring bacterium possessed this property, Chakrabarty's bacterium was thought to have significant value for the cleanup of oil spills.

Chakrabarty filed a patent application with 36 claims. Process claims for the method of producing the bacteria were allowed by the PTO; but claims for the bacterium, itself, were rejected on two grounds: 1) microorganisms are "products of nature," and 2) as living things, microorganisms are not patentable subject matter under 35 U.S.C. 101. The case was eventually heard by the Supreme Court; the justices, in a 5-4 ruling, held that a live, human-made microorganism is patentable subject matter under section 101 as a "manufacture" or "composition of matter."

The *Chakrabarty* decision provided a judicial framework for subsequent PTO decisions to issue patents under 35 U.S.C. 101 for plants and nonhuman animals. The decision also provided great stimulus for the economic development of biotechnology processes and products in the 1980s.

## **INTELLECTUAL PROPERTY PROTECTION FOR PLANTS**

### ***Plant Breeders' Rights***

No intellectual property rights relevant to new plant varieties existed prior to 1930. Plant breeding and research were conducted primarily by federally funded agricultural experiment stations and, to a limited extent, by amateur breeders. Private breeders had few financial incentives—their 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 the plant left a breeders' hands, it could be reproduced in unlimited quantity by anyone.

Proprietary protection specifically for plant varieties has evolved in the United States over the last 60 years and now is based on several statutes, a Federal decision, and recognized trade secret and contract law. (See table 15-1.) Although in the United States an exclusive right to an invention is as old as the Constitution, until the late 1920s the sentiment was largely held that plant varieties were not patentable under the general patent statute. In deciding to expressly provide intellectual property protection for asexually reproduced plants, Congress concluded that the work of the breeder was an aid to nature and thus the resulting plant was a patentable invention.

Two Federal statutes specifically confer ownership rights to new plant varieties: the Plant Patent Act (PPA) of 1930 (35 U.S.C. 161-164) and the Plant Variety Protection Act (PVPA) of 1970 (7 U.S.C. 2321 *et seq.*). The PPA extended patent protection to most new and distinct asexually propagated varieties. It was the first, and to date, only law passed by Congress specifically providing patent protection for living matter. Since then, more than 6,500 plant patents have been issued by PTO covering flowering plants, ornamental and fruit trees, nut trees, grapes, and vegetable crops. Plant patents cannot be obtained for seeds, tubers, biotechnology processes, recombinant DNA (rDNA), or genes (5). On average, more than 225 plant patents are issued each year (10).

Table 15-1—Types of Intellectual Property Protection for Plants

Type	Citation	Subject matter
Plant patent .....	35 U.S.C. 161-164	Asexually reproduced varieties
Plant variety protection certificate, ... ..	7 U.S.C. 2321 <i>et seq.</i>	<b>Sexually reproduced varieties</b>
Utility patent .....	735 U.S.C. 101 <i>et seq.</i>	<b>Process, machine, manufacture, composition of matter</b>
Trade secret .....	State law	<b>Information used in trade or business that is kept secret</b>

SOURCE: Office of Technology Assessment, 1992

Commercial and international developments between 1930 and 1970 encouraged the United States to consider protecting sexually reproduced plants as well. Plant breeders had developed new sexually reproducing plants that could replicate “true-to-type” but that could not be patented under the PPA. In 1961, several European countries formed the International Union for the Protection of New Varieties of Plants (UPOV) to protect breeders’ rights. (See box 15-B. ) At the time, U.S. breeders had no law protecting their inventions, other than the PPO for asexually reproduced plants.

The PVPA was enacted by Congress in 1970 to provide patent-like protection for certain types of new, sexually reproduced plant species. It is mainly of interest to breeders and farmers of sexually reproduced varieties of crops such as: wheat, alfalfa, soybeans, cotton, corn, lettuce, soybeans, and watermelon (1).

Although PVPA is not a patent statute, the protection it provides to breeders of new plant varieties is similar in concept to patent protection. The act is administered by the U.S. Department of Agriculture (USDA). Upon application to USDA and examination by this agency, a plant variety protection certificate may be issued on any novel variety of sexually reproduced plant—other than fungi, bacteria, or a first-generation hybrid. The novel variety must have distinctiveness, uniformity, and stability. Amendments in 1980 (P. L. 96-574) added protection for six vegetable crops and extended coverage to 18 years so the PVPA would be consistent with UPOV provisions.

Under PVPA, the breeder can exclude others from selling, offering for sale, or reproducing (sexually or asexually) the variety; producing a hybrid from the variety; and importing or exporting the protected variety.

PVPA contains two important exclusions to this protection:

- **A research exemption** that precludes a breeder from excluding others from using the protected variety to develop new varieties; and
- **a farmers’ exemption that allows an individual whose primary occupation is growing crops for sale, for other than reproductive purposes, to use protected seed on his or her farm or to sell it to people whose primary occupation, also, is growing crops.**

From 1970 through 1988, 2,783 applications for plant variety protection certificates were filed with the USDA for some 100 different crops. By December 31, 1988, 2,133 certificates had been issued and 274 applications were pending. Another 376 applications had been abandoned, withdrawn, declared ineligible, or denied ( 10).

The Supreme Court decision in *Diamond v. Chakrabarty* (2), coupled with a 1985 ruling of the PTO Board of Appeals (3), affords individuals the additional option of seeking a utility patent (35 U.S.C. 101 ) to protect a novel plant variety. In 1985, the PTO Board of Appeals and Interferences ruled, in *Ex parte Hibberd* (3) that a corn plant containing an increased level of tryptophan, an amino acid, was patentable subject matter under 35 U.S.C. 101. To summarize, federally credentialed protection of plants encompasses three forms: plant patents, plant variety protection certificates, and utility patents. Recognized trade secret law provides further protection for inventions that constitute plant life. Each of these four methods of protection differs from the others in some respects, as described below.

### ***Plant Patents v. Plant Variety Protection Certificates***

PPA provides rights, through plant patents, to plant breeders who discover or develop new distinct plant varieties and propagate them by asexual reproduction. In contrast, Plant Variety Protection Certificate (PVPC) holders under PVPA are granted protection for discovering or developing new, uniform, stable, and distinctive

**Box 15-B—International Union for the Protection of New Varieties of Plants**

With the development of plant sciences came the realization that the rights of plant breeders were entirely overlooked in many countries. The patent laws of many countries, for example, specifically excluded the patenting of any type of lifeform. An international conference in 1957 led to the drafting of the International Union for the Protection of New Varieties of Plants (UPOV); it was signed by several nations in 1961 and entered into force in 1968. Currently, 19 nations are members of UPOV (see table 15-2).

**Table 16-2-Member Countries of the Union for the Protection of New Varieties of Plants**

Australia	The Netherlands
Belgium	New Zealand
Denmark	Poland
France	South Africa
Germany	Spain
Hungary	Sweden
Ireland	Switzerland
Israel	United Kingdom
Italy	United States
Japan	

SOURCE: Office of Technology Assessment 1992.

The International Union for the Protection of New Varieties of Plants was designed “to recognize and to ensure the breeder of a new plant variety. . . the right to a special title of protection or of a patent.” The goal was to provide a model for the adoption of breeders’ rights statutes in individual countries and to assure reciprocity between countries in the convention.

To obtain protection in each member country, it is currently necessary to file a separate application in each country. There is no central filing system, nor is international protection available by filing in only one member country. While both sexually and asexually reproduced plants can be protected, the UPOV convention requires that each protected variety have a specific, unique name for registration purposes. In all member nations except the United States, new varieties are subject to official inspection establishing that conditions for protection are satisfied.

The UPOV convention presently is under consideration for revision. A recent diplomatic conference, held in March 1991, may lead to revision of Article 2, which currently does not allow both patent and breeders’ rights for the same botanical species or genus (14).

SOURCE: Office of Technology Assessment, 1992.

plant varieties that are propagated by sexual reproduction. Protection under PPA and PVPA complement each other in providing protection for all new varieties of plants—asexually reproduced by plant patents and sexually reproduced by PVPCs.

***Plant Patents v. Utility Patents***

Utility patents provide protection for plants, including asexually reproduced plants such as those included within PPA, as well as plant parts (e.g., flowers, fruits, and nuts) and hybrids, which are excluded from PPA. Also, seeds and plants with defined physical traits can be protected through utility patents. Utility patents for plants, when the requirements can be satisfied, offer broader coverage than would be available for the same plant under PPA.

Advantages of obtaining a utility patent for an asexually reproduced plant are many. A plant patent is limited to a single claim; a utility patent need not be so limited. Perhaps the most significant advantage of the utility patent is that it provides broad protection for inventions that can affect more than a single variety and can cover plant parts including flowers, nuts, fruits, and cuttings that do not asexually reproduce a plant. Further, no requirement exists for utility patents that an infringing plant be reproduced asexually from the patented plant, hence sexual reproduction of the protected variety is also covered.

One disadvantage of utility patents is that the description requirement is more stringent than it is for a plant patent. To satisfy this requirement for utility patents,



placing the plant or seed on deposit may be necessary (depending on whether or not the production of the plant can be redescribed by words alone).

### ***Plant Variety Protection Certificates v. Utility Patents***

Compared to PVPCs, several aspects of utility patent coverage for sexually reproduced plants appear advantageous to plant breeders. A utility patent is not limited to the specific variety described; it can protect the specific variety, as well as other varieties having the same traits and functional properties. Hybrids are specifically excluded from plant variety protection but are fully protectable by utility patents. Extensive scope of coverage is another significant advantage of utility patents over PVPCs. Utility patents can protect the plant, seed, plant parts, genes, plants having a specific physical trait, and processes for developing new varieties and hybrids.

Another key difference is that utility patent statutes do not provide for a farmer's exemption. Consequently, if anyone other than the patent owner makes, uses, or sells the seed for reproductive purposes, it is an infringement of the utility patent, subject to judicial enforcement. Utility patents also do not allow research exemptions (i. e., it is an infringement of the utility patent to use the patented plant or variety in developing a new variety or hybrid). Finally, compulsory licensing cannot be mandated by any Federal agency for a utility patent. In compulsory licensing under PVPA, the Secretary of Agriculture directs the PVPC holder to grant a license to a third party if the Secretary determines that such a license is in the public interest. The owner receives a reasonable royalty but has no option and must grant the license.

An advantage of PVPCs over utility patents is that the latter have stringent description requirements that may necessitate the deposit of the plant or seed, such that it is publicly available when the utility patent issues. The present Plant Variety Protection Office (PVPO) policy is not to make most deposited seed available to the general public. One other advantage of PVPCs is that protection is afforded to the new variety before the issuance of the certificate ( 10).

### ***Trade Secret Law***

While patents and protection certificates have been applied successfully to plants, they are ill-suited to trade secret protection. Plants often cannot be easily confined to an enclosed space, thus making them susceptible to theft by outsiders. Some plants are easily grown from

only a portion of the parent or, if the plant is an inbred, from a seed—if someone obtains inbred seeds, plants from those seeds can be easily reproduced. Theft of secret plant varieties jeopardizes producers' potential compensation for their investment of creative effort, time, and dollars. Nevertheless, some inventors within the agricultural and horticultural industries successfully employ trade secret protection by not releasing the parents of hybrids that they sell.

## **INTELLECTUAL PROPERTY PROTECTION FOR ANIMALS**

in April 1987, the Board of Patent Appeals and interferences ruled that it would henceforth consider non-naturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter under general patent law. This statement initiated broad debate and the introduction of legislation concerning the patenting of animals. The first—and, to date, only—animal patent was issued in April 1988 to Harvard University for mammals genetically engineered to contain a cancer-causing gene (see box 15-C). Exclusive license to practice the patent went to duPont Co., which was the major sponsor of the research. The patented mouse was genetically engineered to be unusually susceptible to cancer, thus facilitating the testing of carcinogens and of cancer therapies. Specifically, the patent covers

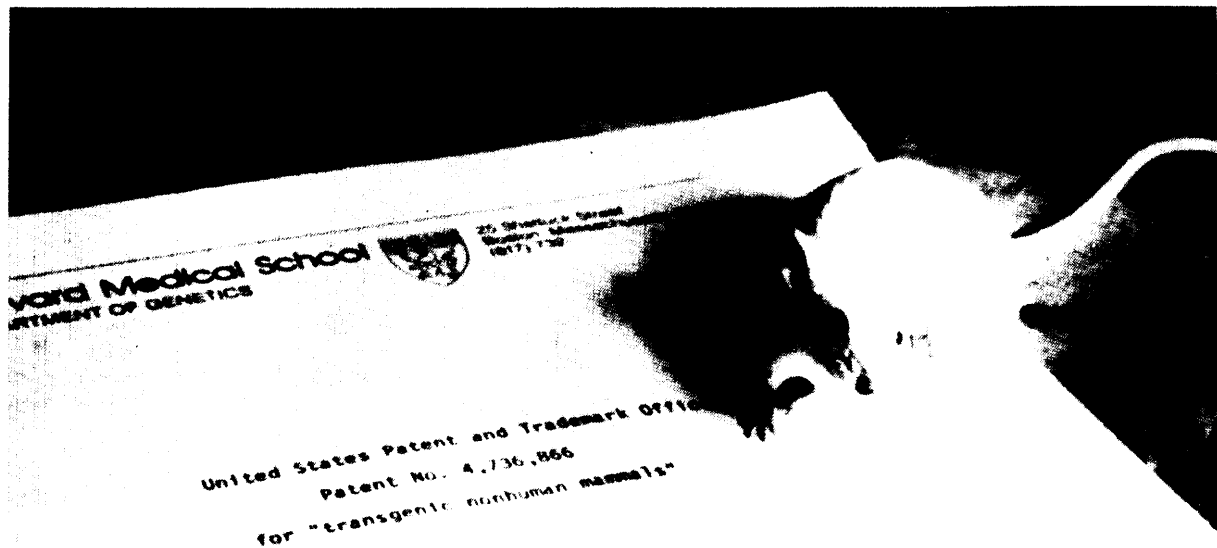
*... a transgenic nonhuman eukaryotic animal (preferably a rodent **such as a mouse**) whose germ cells and somatic cells contain an activated **oncogene sequence introduced into the animal . . . which increases the probability of the development of neoplasms (particular] y malignant tumors ) in the animal.***

The 1987 PTO policy and the 1988 issuance of the first patent on a transgenic animal spurred public debate on scientific, regulatory, economic, and ethical issues.

### ***Federal Regulation***

Several Federal 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 proj-

**Box 15-C—Patent Number 4,736,866-The ‘Harvard Mouse’**



*Photo credit: Ira Wyman/Sigma*

On April 12, 1988, the U.S. Patent Office issued the first patent of a living animal to Harvard Professor Philip Leder and Timothy A. Stewart of San Francisco, California. The patent was assigned to the President and Fellows of Harvard College. The patent claims “a transgenic nonhuman eukaryotic animal (preferably a rodent, such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence.” The claim cited a mouse into which had been inserted a gene that causes an increased propensity for the mouse to develop cancerous tumors. Such mice can be used to test materials suspected of being carcinogens. These tests “can be extremely sensitive” and “will permit suspect materials to be tested in much smaller amounts . . . used in current animal carcinogenicity studies.” The patent points out that this “will minimize one source of criticism of current (testing) methods, that their validity is questionable because the amounts of the tested material used is greatly in excess of amounts to which humans are likely to be exposed.”

Such transgenic mice “can also be used as tester animals for materials. . . thought to confer protection against the development of “cancerous tumors (e.g., antioxidants such as beta-carotene or Vitamin E).

The precise language of the patent described several similar lines of laboratory mice that had been engineered by the insertion of an activated oncogene sequence, specifically, the mouse “myc” **myelocytomatosis) gene under control of a promoter or regulatory gene sequence derived from the** mouse mammary tumor virus (MMTV LTR). Gene fusions of the myc and MMTV LTR genes were created and inserted into fertilized one-cell mouse eggs via microinjection. The treated eggs were then implanted in receptive female mice and the offspring were raised, used to establish laboratory populations, and then analyzed for incorporation and expression of the inserted genes.

**The actual patent coverage is broad, embracing virtually any species of “transgenic nonhuman mammal** all of whose germ cells **and somatic cells contain a recombinant activated oncogene sequence introduced into** said mammal, or an ancestor of said mammal, at an embryonic stage.”

SOURCE: U.S. Patent and Trademark Office, U.S. Patent No. 4,736,666 (1966).

ects involving genetically engineered animals. The National Science Foundation (NSF) currently funds research involving transgenic animals in a range of laboratory experiments. 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 only partial control over such research activities. Several Federal agencies regulate the experimental use or commercial development of genetically altered animals. Because current statutes regulate various uses and protections for animals, no single Federal policy governs all uses of genetically altered animals. In the absence of a single policy, Federal agencies will rely on existing statutes, regulations, and guidelines to regulate transgenic animal research and product development. Current federally funded research efforts could lead to patents on animals. The patentability of an animal, however, does not affect the manner in which the animal would be regulated by any Federal agency.

### *Economic Considerations*

Economic considerations will influence the order in which different transgenic animals are produced for commerce. Transgenic animals used for biomedical research are likely to be developed first, primarily due to extensive research in this area. Transgenic agricultural animals are also likely to be produced, although large-scale commercial production of such livestock and poultry is unlikely in the near future (5 to 10 years). The largest economic sectors likely to be influenced by animal patents are the different markets for agricultural livestock, and possibly some sectors of the pharmaceutical industry.

The principal agricultural markets involve poultry, dairy, and red meat. These markets are organized quite differently, and they are subject to different degrees of economic concentration. Poultry is the most concentrated (though still diffuse by the standards of other industries, such as automobiles) and the dairy and red meat sectors are more diffuse. Different economic forces are important in these three 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 may make use of patentable animals. In addition to the diverse sectors of the agricultural livestock markets, and pharma-



*Photo credit: Kevin O'Connor*

The economics of patenting, such as for these transgenic pigs, will be determined by the potential use of the animal, its market, reproduction rate, and relative value.

ceutical and other chemical production, there are academic research or industrial testing activities to consider.

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 output 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. However, the same complexity must be accommodated

by 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 human health or environmental consequences that could occur subsequent to the patenting of animals. Other arguments focus on religious, philosophical, spiritual, or metaphysical grounds. These grounds have been used by different parties to support and oppose the concept of animal patenting. Many arguments relating to the consequences of animal patenting are difficult to evaluate since they are speculative, relying on hypothetical scenarios or on as yet unproven assertions. Arguments based largely on theological, philosophical, spiritual, or metaphysical considerations are likewise difficult to resolve, since these may not be acceptable or relevant to other persons holding opposing beliefs. Most arguments that have been raised 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 substantially would redirect the way society uses or relates to animals. Many concerns about the consequences of patenting can be addressed by appropriate regulations or statutes, rather than by amendments to patent law. Other arguments, particularly those of theological, philosophical, spiritual, or metaphysical origin, need to be debated more fully and articulated more clearly.

### ***Deposit Considerations***

In 1949, the PTO began recommending that patent applications for inventions involving microorganisms should include the deposit of the pertinent microorganism in a culture depository. A culture depository accepts, maintains, and distributes cultures of microorganisms, viruses, cells, or other genetic-type material. The deposit of seeds and plant tissue culture has become established practice. A depository may be public or private, nonprofit or for profit. The main function of a public culture depository is the preservation and distribution of reference cultures that serve as standards for users in the scientific and educational communities.

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 microorganisms, plasmids, vectors, cells, plant tissues, seeds, and other biological materials that are not generally available or reproducible are often supported by a deposit in a recognized patent depository. A deposit is employed in many cases to meet the requirement that a patent provide 'enablement' or the best mode of practicing an invention.

The PTO first published guidelines on the deposit of microorganisms in 1971. In 1977, establishment of the Budapest Treaty required contracting States that allow or require the deposit of microorganisms as part of their patent procedure to recognize the deposit of a microorganism with any International Depository Authority. In 1985, the Court of Appeals for the Federal Circuit held that the enablement provision of the patent statute did not require a deposit in a recognized depository by the filing date of the patent application, but only before the issuance of the patent. In 1988, the PTO published proposed rules for deposit of biological materials for patent purposes. These rules, if adopted formally by the PTO, will assist the inventor and the depository in defining the position of the PTO on deposits.

The new patentable status of animals raises the possibility that the PTO will encourage or require the deposit of animal forms to support certain patent applications. To date, no animal has been deposited with a depository. In the case of the first animal patent granted (U.S. 4,736,866), the deposit requirement was satisfied not by deposit of a mouse or other animal, but by deposit of the DNA plasmids bearing the cancer-causing genes intended for transfer into an animal. In the patent, the inventors provide detailed instructions for inserting those genes into mouse embryos to produce transgenic mice.

The patenting of animals could be problematic if deposit of the animal is required. Currently no depository is willing to accept the deposit of animals because the cost of facilities and expertise 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. It is not clear how a depository would make samples of an animal available or how it would create more animals. Maintenance of many kinds of short-lived animals for the current required period of 30 years would not be possible.

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

## INTERNATIONAL PROTECTION FOR PLANTS AND ANIMALS

Intellectual property protection of microorganisms, plants, animals, and biological processes is of increasing concern to the world community. International patentability is one element of the current debate in the United States regarding the scope of patentable matter. For example, those who favor patenting of animals point out other countries that either permit or do not expressly exclude the possibility of such patents. Opponents of patenting of animals can point to other nations that expressly exclude or have yet to issue patents on animals.

Several international treaties and agreements relevant to biological inventions seek to harmonize various procedural and substantive elements of international patent practice. However, the patenting of animals is not the subject of any existing treaty. Of the existing agreements, the European Patent Convention (EPC) is most relevant to the substantive issue of patenting plants and animals. Article 52(1) of the EPC defines patentable subject matter as inventions that are susceptible to industrial application, are new, and involve an inventive step. This definition is extraordinarily general. Rather than providing a precise, positive definition of patentable subject matter, the EPC instead narrows this broad definition by explicitly specifying negative restrictions. 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), article 53(b) of the EPC prohibits only the patenting of plants that 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 protection for a plant that has had a gene inserted (e.g., corn having gene X), if it is not a specific plant variety (e.g., corn inbred A having gene X). Similarly, a process for transforming a plant to insert a desired gene would

be patentable because human intervention played a greater role in the final result than biological forces. This viewpoint has been adopted by the Swiss Patent Office as well as by the European Patent Office, which in early 1988 granted a patent on a technique for increasing the protein content of forage crops such as alfalfa and for the plants produced with the aid of the technique. This decision arguably opens the door for plant and animal patenting in Europe, subject to the specific treatment of European patents on a country-by-country basis.

Differences do exist between nations regarding intellectual property protection of biotechnological inventions, including the issue of what constitutes patentable subject matter. Patent protection is widely available for microorganisms, as are various forms of patents and breeders' certificates for plant life. Analysis of the laws of other nations indicate that patent protection on animals is permissible or theoretically possible in a number of nations. Any projection of the number of nations permitting animal patents must be speculative in the absence of additional activity in this area. To date, only the United States has announced a policy permitting patents on animal life forms and issued a patent on an animal invented through biotechnological techniques. It is likely that other nations will issue such patents in the future. The Japanese patent office, for example, recently issued an internal notice announcing its intention to grant patents on nonhuman animals if they meet the requirements of their patent law.

## ISSUES AND POLICY OPTIONS FOR BIOTECHNOLOGY

Intellectual property is one of the most important assets for a company attempting to commercialize biotechnology-related processes and products. Patents often are used by start-up companies to lure crucial financing and to gain access to new markets. Patent protection has played a major role in the development of biotechnology-based pharmaceuticals. Patents and other forms of intellectual property (plant breeders' rights, trademarks) are similarly important to the commercial development of a range of agricultural products.

Under United States law, patents may be issued for any new, useful, unobvious process, machine, manufacture, composition of matter, or new and useful improvement of these items. Under this broad umbrella, U.S. law has permitted the patenting of micro-organisms, plants, and nonhuman animals. The patenting of nonhuman animals has led to legislative debate regarding whether such patents should be granted. Options for congressional action—including discussion on issues such as deposit con-

siderations and exemptions from infringement for certain classes of users—were presented in an earlier OTA report (*New Developments in Biotechnology: Patenting Life*) and are incorporated here by reference ( 10).

In terms of the breadth of patentable items, U.S. patent law is the most inventor-friendly statute in the world; it is unique in that it makes no exceptions to patentability found in the statutes of many other countries (e.g., animal and plant varieties, public order or morality, products such as pharmaceuticals, and foods). If Congress takes no action regarding patentable subject matter, broad protection for inventions created by biotechnology will continue. Laws created by Congress to regulate interstate commerce would be relied on to govern the development, approval, sale, and use of such inventions. Congress could, either through moratorium or prohibition, specifically bar patents from issuing for nonhuman animals or human beings. Such action would clarify congressional intent regarding the limits of subject matter protection, but it would also create a precedent of using patent law, rather than laws regulating commerce, to discourage certain types of inventions.

To date, only one patent on an animal has been issued. Since this occurred ( 1988), no further patents have been issued, and the backlog of such patent applications now numbers over 160. Since the status of specific patent applications is, by law, confidential, there is no way to ascertain when, or if, the PTO will issue subsequent animal patents; and further, if issued, whether such patents will have agricultural applications. Congress could, through its oversight powers, ask PTO to explain the present status of such patent applications.

The need to harmonize U.S. patent law with the laws of other nations is likely to come to Congress' attention as a result of several ongoing efforts: the General Agreement on Tariffs and Trade (GATT), the World Intellectual Property Organization (WIPO), amendments to the Union for the Protection of New Varieties of Plants (UPOV), and other bilateral and multilateral trade discussions. It is too early to predict specific options arising from each of these forums. In all cases, the goal of harmonization should be the creation of consistent laws addressing substantive and procedural issues in patent practice.

## INTELLECTUAL PROPERTY PROTECTION AND COMPUTER SOFTWARE

As with biotechnology, the merging of intellectual property law and computer software represents the join-

ing of old law with new technology. Computer software can be protected under copyright, patent or trade secret law, or some combination of these. This section briefly reviews these forms of protection for computer software and discusses some issue areas for agricultural software use.

### Copyright

The current copyright law is enacted in the Copyright Act of 1976, as amended. A 1980 amendment made explicit provisions for computer programs as (literary) works of authorship (P. L. 96-5 17). Copyright protects "original works of authorship" from unauthorized uses including reproduction (copying), making derivative works (adaptation), public distribution, public performance, and display. Generally, the term copyright for new works is the life of the author plus 50 years, or 75 years for works made for hire (e. g., by an employee of a firm).

Copyright has been the form of software protection favored by most nations and will be the most widely used for agricultural software. Obtaining a copyright is easy, inexpensive, and quick compared to the requirements for a patent. And since a copyright is administered under Federal law, unlike trade secret protection, it is uniform in all the states. The duration of copyright protection is very long, compared to the expected economic or technical lifetimes of computer programs.

The doctrine of fair use is one of several statutory limitations on copyright holders' exclusive rights. Under this doctrine, certain unauthorized uses, such as copying for the purposes of teaching, scholarship, or research, may be considered "fair use," not copyright infringements. Whether an instance of copying is a fair use instead of an infringement is determined by the courts.

Another statutory limitation on the rights of software copyright holders is contained in the 1980 amendment. It states that it is not an infringement for the owner of a copy of a computer program to make or authorize the making of a copy or adaptation of that computer program provided that such new copy or adaptation is created as an essential step in utilizing the program or that it is for archival purposes only and that all archival copies are destroyed in the event that continued possession of the computer program should cease to be rightful. This limitation clarifies the right of a user who legitimately owns a software product to make "backup" copies of the software to protect against damage or loss, to load the software onto the hard disk of a computer for easier or more efficient use, and to make any necessary adaptations to make the program usable on a computer. It does not



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Agricultural Research Service*

There is disagreement over what features of a computer program are copyrightable. The distinction between idea and expression can be difficult to determine.

permit, for example, the making and distributing multiple copies for school or office use.

Copyright does not confer rights over ideas—only the expression of an idea is protected, not the underlying idea itself. This could be considered a disadvantage by the software developer because the copyright will not preclude a competitor from creating a new work embodying the same idea, so long as the competitor does not incorporate copyrighted expression from the first program into the second program. For software, copyright may also allow reverse engineering practices. This means that one team of software developers studies the code of a copyrighted program to extract the underlying ideas. A second team then creates a new program, based on

the first team's functional specifications. The extent to which these are protectable expressions, as opposed to uncopyrightable ideas, is the focus of recent court cases.

Considerable disagreement exists over what features of a computer program are copyrightable. The distinction between idea and expression can be quite difficult to determine, even for some traditional literary works like books and plays. For software, which is intrinsically functional, idea and expression are closely interwoven. It is difficult to separate which elements of a program are the expression and which are the underlying idea. There is substantial disagreement among legal scholars and among software developers and computer scientists as to whether copyright should protect only against literal or near-literal copying or should also protect a program's structure, sequence, and organization and user interfaces as well. For example, some argue that a program's "look and feel" (e.g., computer program screen displays) should not be protected by copyright;<sup>1</sup> instead protection for "look and feel" is better suited by a patent. Others are critical of the patent protection for computer programs (11).

### *Patent*

As discussed earlier, a patent protects an invention including the expression of an underlying idea, from copying and from independent creation for a period of 17 years. It protects against literal infringement (making, using, or selling the claimed invention) and also against infringement by equivalent inventions, whether or not the infringing inventor had prior knowledge of the patented invention. The subject matter of a patent is limited to a process, machine, article of manufacture, or composition of matter that is novel, nonobvious, and useful, or to new and useful improvements to these classes of patentable subject matter. However, the following generally cannot be patented: ideas, scientific principles, phenomena of nature, and mental processes. For a knowledge-based system, obviously it may be difficult to patent the knowledge in the system if it is common knowledge associated with the profession (4). Patents probably will be of little value to applications of advanced computer technologies, although they should be of value to a basic computer scientist who develops domain-independent tools (e.g., inference engines).

The requirements for a patentable invention are relatively stringent; patents do not reward hard work per se.

<sup>1</sup>Courts have addressed copyright issues in disputes relating to computer program screen displays, distinguishing **copyrightable expression from unprotected elements** in the text, menu hierarchies, command structure, key sequences, and other aspects of a program's "interface" with the user (12).

The patent requirements for novelty and nonobviousness are more difficult to satisfy than the “originality” criterion of copyright. (All “original” software is eligible for copyright, as with any other work of authorship, and copyright inheres in a work as soon as it is created. ) Although patents are being granted for software-related inventions, only a small fraction of these inventions is likely to contain a computer process meeting the tests of novelty and nonobviousness.

An advantage of patent protection for the discoverer of a software-related invention is that the patent will protect all the claims for the invention as a whole. In contrast, many of the processes underlying a software invention would likely not be protectable under copyright because they would be considered part of the unprotected “idea. A single computer program may consist of a number of patentable processes and algorithms. At the same time, the claimed invention might be executed by a number of copyrighted programs. Depending on how carefully claims are constructed, the computational logic and processes and even the algorithm itself can be patent protected.

The availability of patent protection for software-related inventions was unclear until the early 1980s. During the 1980s patents were issued for software-related inventions such as linear-programming algorithms, spell-checking routines, and logic-ordering operations for spreadsheet programs.

Some patent lawsuits concerning software-related inventions and controversies concerning patents for algorithms became highly visible in the late 1980s. These lawsuits have focused concerns over the appropriateness of patent protection for software-related inventions and algorithms. Some argue that patents on computer-program processes do not encourage technological progress and point to the practical problems of administering the patent system for software-related inventions.

One such problem is the incomplete “prior art” available to patent examiners in evaluating patent applications for processes involving computers, especially those involving software and algorithms.<sup>2</sup> The published literature does not completely represent developments in the fields of software and computer science. In many cases, important prior art exists only in product form and is not described in print form such as articles in technical or scientific journals. Another problem is the lack of special

classifications or cross-references to issued patents. As a result, it is virtually impossible to find, let alone count or profile, all software-related patents. Thus, patent examiners have no effective way of searching and studying such patents.

Another problem is the long time lag between patent application and issuance, compared to quick-moving software life cycles. Patents under examination are not disclosed, so a competitor may put considerable effort into developing a program that unknowingly duplicates computer processes for which one or more patents are pending. Finally, the process of obtaining a patent is expensive and lengthy, compared to copyright or trade secret protection. Although turnaround time in the Patent and Trademark Office (PTO) is decreasing, a patent still may take years to issue in an industry where products have short economic lifetimes (11).

### *Trade Secret*

Trade secret protection, provided under individual State laws, protects against use or willful disclosure of trade secrets by others, but does not penalize independent discovery. Unlike copyright or patent, there is no limitation on its duration. Trade secret has been the most-used form of protection for mainframe and minicomputer software. Its main advantages are that it protects a program’s underlying ideas, logic, and structure, not just expression as in copyright. Trade secret avoids formalities of registration or application and lengthy waits for protection. Enforcement is straightforward and injunctions or compensatory relief is available for those who can prove misappropriation of trade secrets.

Trade secret protection, however, does not protect against independent creation, reverse engineering, or accidental disclosure of the secret. For software protection it is relatively weak and is best used in conjunction with a copyright or patent (7). It can also be costly or impossible to maintain secrecy. Finally, the lack of uniformity in State laws can be frustrating.

If software is protected by trade secret, it maintains that status so long as it is not publicly disclosed. This can stifle the spread of knowledge about software state-of-the-art and in turn can adversely affect knowledge of prior art for patent examinations as discussed earlier (11).

<sup>2</sup> Prior art is that which is known or available to a person skilled in the relevant field of technology. Evidence of prior art (e. g., existing patents, publications) is evaluated not only for what it expressly teaches, but also for what it would fairly suggest to one of Ordinary skill in the relevant field of technology (11).





oto credit: Steven Bent

inventions have become highly visible. A concern is the incomplete "prior art" available to patent examiners.

software

## INTERNATIONAL PROTECTION FOR COMPUTER SOFTWARE

The United States is a major international competitor in computer software development and sales. In 1987, about 40 percent of the U.S. software developers' revenue came from foreign sales (13). Many multilateral and bilateral treaties help protect the intellectual property of software developers through patent and copyright.

Copyright is the predominant form of software protection in the United States and abroad. In most countries, computer programs per se are not eligible for patent protection. However, in some countries, including the United States, certain types of computer-implemented processes and algorithms can be patented.

Copyright and patent protections abroad are very similar in form to those in the United States and have most of the same advantages and liabilities. Copyright protection abroad is provided principally through the Berne Convention and the Universal Copyright Convention. The United States joined the Berne Convention in March 1989. The treaty was first established in 1886 and is the primary multilateral agreement in the world dealing with copyright.

The United States is also a member of the Universal Copyright Convention (UCC), which was established and adopted by the United States in 1955. UCC provides less protection than the Berne Convention and has lower minimum standards. In nations that agree to both Berne and UCC, Berne takes precedence.

The Berne Convention is recognized in 79 nations, and gives U.S. software developers protection in 24 countries where there was no previous copyright agreement. The United States has bilateral agreements with 33 nations as well, often in addition to common Berne or UCC membership. The procedures are simple: once a copyright exists for a work in a member nation, it applies in all signatory nations, according to their own laws. Computer programs are not specifically mentioned in either convention, but are commonly acknowledged to be included.

Securing patent protection in foreign countries is a difficult process. Patents for any invention are difficult to obtain due to the rigorous standards of novelty and nonobviousness. A patent must be applied for in each country where it is to be valid—there is no universal patent process.

**in most countries, software** per se is not considered patentable. The United States is a member of the oldest and most extensive patent treaty, the Paris Convention, established in 1883. There is no requirement in the Convention that software-related inventions be considered patentable.

Trade secret has been the traditionally favored method of protection for mainframe and minicomputer software developers in the United States. However, most countries outside of the United States and Western Europe do not recognize either domestic or international trade secret protection. No international conventions for trade secret exist.

International standards for intellectual property law are important to encourage and to protect U.S. inventions. The United States is attempting to include intellectual property in the General Agreement on Tariffs and Trade (GATT) treaty and is engaged in bilateral negotiations as well (11).

## ISSUES AND POLICY OPTIONS FOR COMPUTER SOFTWARE

### *Copyright and Patent Issues*

Rapid technological advances in computer software are challenging the intellectual property laws in the United States and internationally. Copyright law offers straightforward remedies for the literal copying of program code, although enforcement remains a problem, especially overseas. Functional aspects of computer programs pose difficult questions for the application of copyright. The traditional “fuzzy” line between idea and expression in copyright is confounded by the need to determine an appropriate scope of protection in light of the intent of current law.

The protection of software-related inventions by patent is a fairly recent and controversial development. The PTO faces considerable challenges in examining applications for computer-related inventions. PTO has an incomplete data base of “prior art” for computer-related inventions. Much of what constitutes prior art historically has been in the form of products, not literature or issued patents. This makes it very difficult for examiners to judge whether an application describes a “novel” and “nonobvious” invention. Improving electronic search and retrieval capabilities for PTO’s own database is critical since it is used by the patent examiners during the application process. Currently, PTO is unable to provide statistics on the number of patents issued for software-related inventions except through time-consuming man-

ual search, review, and selection from various large patent subclasses (12).

Options for congressional action are presented in the OTA report *Finding A Balance: Computer Software, Intellectual Property and the Challenge of Technological Change* and are incorporated here by reference. If Congress chooses not to act, the status quo is maintained but uncertainty as to how current intellectual property law applies to computer software remains. On the other hand, taking action may reduce some uncertainties but add others, especially if additional bodies of case law or international agreements have to be developed. If Congress chooses to take action, it must decide how comprehensively to act. Actions might take the form of measures to address ongoing institutional problems (e.g. prior art and examination quality issues facing PTO) or legislative measures to amend current copyright and patent statutes or to create *sui generis* (of its own kind or class) protection. Generally, congressional action might

1. explicitly affirm the status quo and course of case law;
2. make small adjustments at the margins of copyright and patent law possibly through procedural changes;
3. clarify or modify the scope of patent or copyright but leave the basic paradigms unchanged;
4. introduce one or more *complementary, sui generis* protection tailored specifically at certain aspects software innovation; and
5. develop *sui generis* protection to *substitute* for copyright and/or patent protection.

(See the above referenced OTA report for a discussion of the issue areas in the context of these choices. )

### ***Liability Issues***

It has been said: "To make a mistake is human, but to really mess things up requires a computer. Unfortunately, mistakes can occur in using advanced computer technologies, and some mistakes can lead to personal injury or financial loss. The liabilities associated with such 'torts' need to be examined. This issue is not specific to agriculture but applies to the computer industry in general.

The issue of personal injury arises in areas such as medicine where a computer application is controlling a patient's treatment (e.g., the level of radiation in cancer treatment) but is unlikely to arise in business applications such as agriculture. Therefore, the main concern will be with financial loss as a result of bad advice (4).

To recover in negligence, the plaintiff must show that the defendant did not take sufficient care in developing the system to prevent injury (4). The courts have not established standards for adequate care, but developers would be advised to maintain detailed records of knowledge sources, verification tests, and validation procedures. Inclusion of a disclaimer at the beginning of each program has been suggested to insulate the developer from such litigation. Gemignani (4) suggests the following:

**SOFTWARE IS INTENDED TO BE USED BY LICENSED PROFESSIONALS ONLY. THE USER ASSUMES SOLE RESPONSIBILITY FOR DECISIONS CONCERNING ADVICE OR TREATMENT. IF YOU DISAGREE WITH THIS POLICY, YOUR LICENSE FORBIDS YOU TO USE THIS SOFTWARE**

The issue of liability has not been a major problem in agricultural computer applications, possibly as a result of the small amount of activity in knowledge-based systems. However, it is a topic frequently mentioned among program developers. Stressing the view that these are decision support systems that provide advice to professionals is important. In this light, such systems are similar to a colleague who provides advice.

A related issue in software development is the lack of regulation. Software must conform to standard regulations (e. g., patents, fraud, etc. ) but need not be approved by any Federal agency. The medical field is a potential exception. The Food and Drug Administration proposed reviewing software that is the component of a medical device or that is used in the clinical management of patients. Therefore, it is likely that software that claims to make medical decisions will be regulated (4). Government regulation is unlikely to protect a developer from negligence claims; however, it may relieve some of the paranoia that exists among developers.

### ***User Issues***

When advanced computer technologies are developed, they will be available to agribusiness professionals and agricultural producers. An interesting negligence liability issue may exist if the consultant making the recommendation to a producer chooses not to use an available technology (4). The argument stems from an historic case where a tugboat lost the barges it was towing in a storm. The situation might have been avoided if the tugboat had a radio on board. The owner of the tugboat was held liable because of failure to use an available technology—even though radios were not yet standard equipment on

tugboats. According to this case, three criteria must be proven to establish negligence in not using a technology:

1. The technology must be readily available.
2. The technology must be reliable.
3. The cost of using the technology must bear a reasonable relationship to the harm that might be suffered in the absence of the technology.

Thus far, this precedent has not been tested with computer technologies. However, this suggests that for those who advise farmers, such as Extension agents, consultants, input suppliers, processors, etc., they may be obligated to adopt these technologies.

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