Policy Issues Regarding Property Rights in Biological Inventions

Terence J. Centner
College of Agriculture Experiment Station, University of Georgia, Athens, GA 30602

Advances in biotechnology have led to the development of biological innovations that have been difficult to categorize and regulate under existing institutions. Considerable attention has been given to environmental issues regarding the release of organisms or materials into the environment, but more subtle issues concerning ownership and use of inventions pose additional challenges. Existing property-rights legislation is not completely amenable to recent inventions. Proposed and expected changes may lead to adjustments in breeding programs and market structure. Changed legislation also may present plant breeders and nurseries with opportunities for increased profits or may cause existing operations to become unprofitable.

Scientists, breeders, and growers have varied but significant reasons for participating in the structuring of new property-rights legislation. The most important property-rights legislation for scientific inventions is patent law. Since 1790, American patent law has recognized the rights of inventors to practice their inventions to the exclusion of others, and subsequent state and federal legislation has created a complex system of intellectual property rights. Recent interpretations of this legislation, judicial acceptance of utility patents for living subject matter, and proposed legislation before the U.S. Congress raise several significant issues that affect the rights of scientists and inventors and may be expected to have an impact on future research.

What institutional devices have an impact on scientific discovery? What property interests should American law grant to inventors? How may scientists assist in the differentiation and delineation of new organisms and the enforcement of property rights in protected organisms? Legal provisions governing American intellectual property rights, recent institutional developments, and broad policy issues important to the horticultural industry and scientific community are briefly outlined in this article.

Intellectual property rights

Intellectual property rights is a collective term used to refer to rights granted under various state, federal, and international laws to persons who develop or create new ideas, processes, or inventions. Society grants innovators rights to encourage discovery and invention. Patents, certificates of plant variety protection, trademarks, trade names, and trade secrets constitute the most important devices for horticulturists in creating intellectual property rights.

Patents establish proprietary rights for an inventor by providing for the exclusive control over making, using, and selling the subject material for 17 years. Two Federal Patent Acts are important for horticultural inventions: the general Patent Act (PA), and the Plant Patent Act of 1930 (PPA). Novel, useful, and unobvious subject material may be patented under PA (13). New asexual plants, including cultivated sports, mutants, hybrids, and newly found seedlings may be patented under PPA (14). Both patent acts are administered by the U.S. Patent and Trademark Office.

Congress has also enacted the Plant Variety Protection Act of 1970 (PVPA) for the protection of the rights of inventors of new and distinct cultivars of sexually produced plants (11). The PVPA enables inventors of seed plants to apply for certificates of plant variety protection that provide inventors patent-like protection of the plant and seed for 18 years. The PVPA is administered by the Plant Variety Protection Office of the USDA. Since PVPA does not involve patents, it is not part of U.S. Patent law, although some people use the term "patent law" in a generic sense to include PVPA.

A third major device establishing property rights that is important in the horticultural industry is a trademark. A trademark includes any words, names, symbols, or devices adopted and used by a manufacturer or merchant to identify and distinguish goods from those manufactured or sold by others and to indicate the source of the goods (15). Trademarks exist under state law, but federal registration is the most likely apparatus employed to effectively preclude producers of similar products from adopting another's trademark in the same geographic market. Brand names, although not defined by federal trademark law, are colloquial terms generally used as a synonym for trademark (4).

Trademark also is used as a general term to refer to other types of mark: certification marks and collective marks (15). Certification marks may be registered by qualified nonproducers of a product; i.e., nations, states, municipalities, or other groups who exercise legitimate control over the use of the mark sought to be registered. Certification marks certify the product's origin, quality, or characteristics that distinguish the product from others. Collective marks are marks used by the members of a cooperative business organization or other collective group or organization.

Literature Cited

Trade names are used to refer to individual names, surnames, and business names adopted by persons, firms, and organizations (1). Trade names denote an appellation rather than a product, and hence do not qualify for registration as a trademark. A word or term may be used as a trade name to refer to a company and as a trademark to refer to a product.

Another significant device governing inventors’ property rights is a trade secret. Criteria generally necessary for trade secrets are secret information, information used in a business, and use of the information to a competitive advantage. A trade secret entitles the owner to prevent the unauthorized disclosure or use of the trade secret by other parties, and may operate to preclude divulgence of information by employees and coventurers, sanction enforcement of covenants precluding employees from disclosing trade secrets after termination of employment, and validate the enforcement of non-disclosure provisions in business contracts. An owner of a trade secret also may enjoin impending or imminent unauthorized disclosures or uses of the secret (3). If an employee or other person wrongfully divulges a trade secret, the person may incur liability for damages to the owner. Trade-secret protection is governed by state law and thus differs from state to state.

A majority of horticultural discoveries will require the technology to be available to numerous producing firms, thus trade-secret protection is not practicable for protecting the property rights of many inventors. However, trade-secret protection is consequential during the development of horticultural discoveries and for pending patent applications. But, for certain exceptions, nondisclosure of a new discovery or invention is a prerequisite for obtaining a patent so that persons making discoveries need to keep their subject matter secret until they determine whether it can be patented.

Institutional developments

A brief summary of several significant developments that have modified the scope of intellectual property institutions will provide a foundation for the exploration of current issues. Perhaps the most significant development was the 1980 Supreme Court decision in Diamond v. Chakrabarty (22), in which the court found that a living man-made microorganism could qualify as patentable subject matter under the PA. The Chakrabarty decision was followed to a high extent; however, lower courts and the Patent and Trademark Office have followed the rationale of the Supreme Court to find that multicellular plants and animals are also patentable. The Patent and Trademark Office Board of Patent Appeals and Interferences extended the Chakrabarty deduction to find that plants were patentable under PA in Ex parte Hibberd (8). More recently, the patentability of multicellular animals gained acceptance with a decision recognizing that a polyploid oyster could qualify as patentable subject matter in Ex parte Allen (9).

Progressing from these decisions, the Patent and Trademark Office issued a notice on 7 Apr. 1987 announcing that nonnaturally occurring non-human multicellular living organisms, including animals, are patentable subject matter under the PA (6).

In a related development, Ex parte Hibberd (8) makes it clear that property rights in plant materials are not limited to protection under a single federal law. In Hibberd, the inventor attempted to patent under PA several new maize technologies, including a new seed, a new maize plant, and a new maize tissue culture, even though the seed was patentable under PVPA and the plant and tissue cultures were patentable under PPA. The patent examiner and appellate tribunal assumed that PPA and PVPA were the exclusive forms of protection for asexual and sexual plant life, respectively. On appeal, the examiner’s rulings of exclusivity were reversed. The appeals tribunal found that inventors had a choice of selecting between two sets of statutes, PA and PPA or PA and PVPA, for protection of their discoveries.

Confusion and controversy concerning property rights in inventions developed with federal financial support led to legislative amendments in 1980 and 1984. Congress sought to encourage innovation by universities, nonprofit firms, and small businesses receiving federal assistance, and thereby made it possible for these firms to elect to retain title to inventions conceived or first actually reduced to practice in performance of work under a funding agreement with the federal government. The federal government did reserve “a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced . . . inventions developed in part under funding from the federal government” (12).

The problem of delayed marketing of newly patented products due to governmental safety prerequisites has led manufacturers to seek patent term restoration legislation. Such legislation provides that the term of a qualifying patent shall be extended to account for delays arising from regulatory review. Manufacturers of drugs were successful in obtaining such an exception for their products in the 1983 amendments to the Federal Food, Drug, and Cosmetic Act (16). Manufacturers of agricultural and chemical products have sought similar legislation in the Agricultural Patent Reform Act (18), Omnibus Intellectual Property Rights Improvement Act (19), and bills concerning amendment of the Federal Insecticide, Fungicide, and Rodenticide Act (20).

The desirability of encouraging research on patented plant materials has raised the question of whether Congress should adopt a broader research exception for research of patented items. One possibility would be a compromise whereby researchers would be able to experiment with patented materials 5 years after issuance of the patent, but the patent would have to be reduced to practice in performance of work under the funding agreement and the PA and PPA. This exception would allow for patent protection of new plant varieties for 17 years. Such an exception would distinguish between the length of protection regarding research as opposed to the dissemination or sales of a patented invention.

Nonobviousness. The recent case of Ex parte Allen (9) suggests that inventors of product-by-process claims involving living organisms may have a problem meeting PA’s requirement of nonobviousness. An invention is not patentable if it is obvious to persons skilled in the relevant art. In Allen, the patent examiner and an appellate tribunal found that the patent applicant of eelgrass (Crasostrea gigas) Thunberg oysters involving the use of hydrostatic pressure was obvious from published research on polyploidy of a different species of oyster using chemical treatment. The examiner reached this decision even though the published procedure involved a different process and failed to produce polyploidy in Pacific C. gigas oysters.

Of course, what is obvious today may have been unpredictable and unobvious yesterday. Inventors must show that their innovations are not obvious from disseminated knowledge or known techniques, and may want to document their research carefully to estab-
lish proof of unpredictability and nonobvioussness.

Deposits and fingerprinting. The difficulty in writing a description for biological inventions sufficient to meet the "enablement" requirements of the PA has contributed to the development of a proposal to allow for deposits of biological material. The "enablement" requirement of PA requires every patent application to set forth sufficient information to enable a person of ordinary skill in the pertinent art to make and use the invention. The Patent and Trademark Office has proposed a new chapter for the Manual of Patent Examining Procedure entitled "Deposit of Biological Materials for Patent Purposes" (7). The new rules require a deposit whenever words alone are inadequate to satisfy PA's enablement requirements. The new rules would apply to plant tissue cells and seeds. Plant cultivars that cannot be reproduced by seeds or by tissue culture would not qualify for a deposit.

The proposed rules basically follow current practices and judicially developed principles of patent law. Left open for further consideration is whether multicellular plant deposits may be used to assist inventors in meeting the requirements of the enablement provision. The concern regarding qualifications for depository institutions and responsibilities for the maintenance of deposited multicellular materials remain unanswered. The existence of a wide range of commercially important usexual multicellular plants that may have difficulty qualifying under PA's enablement requirements raises the issue of why such inventions should be treated differently from inventions of seed plants and plants that can be grown from tissue cultures.

Enforcement tools. Major problems exist in the enforcement of property rights in plant materials. The recent extension of PA to living organisms increases the enforcement possibilities and offers inventors more protection than now exists for rights perfected under PPA or PVPA, but it does not simplify the solutions. Enforcement will continue to be a problem because of the large number of potential infringers, ease of duplicating protected materials, high costs of policing and enforcing relative to returns from successful prosecution, and difficulties of proving infringement.

Several enforcement tools may assist inventors in garnering royalties that have been assigned by law. First, inventors should consider general patents. If PA offers greater property-rights protection than either PPA or PVPA. The greater property-rights protection is possible under PA because of the wide scope of "claiming" available under general patent law. A "claim" defines the invention, thereby establishing the inventor's rights in infringement actions.

Next, inventors should use a deposit whenever possible. Third, the scientist should seek to include in the patent application a combination of quantitative chemical methods and morphological studies to identify the given cultivar. Inclusion of these means of identification gives the patent holder additional methods to establish and prove infringement. W.T. King (Disclosure by deposit and the future for fingerprinting, Fifth International Colloq. on the Protection of Biotechnological Inventions in the Field of New Plant Varieties. 1987. Washington, D.C.) suggests isoenzyme analysis, high-pressure liquid chromatography, and scanning electron microscopy as methods of fingerprinting plant materials. Horticulturists and biochemists may be able to develop additional enforcement procedures to assist inventors in safeguarding property rights in their inventions.

Consideration also might be given to the amendment of patent law and the incorporation of additional legislative enforcement tools. For example, antitrust law uses treble damages as a penalty for violation; should persons who infringe upon biological patents also be subject to such penalties? Tax law awards taxpayers attorneys fees in instances where the government has pressed a spurious claim; could patent law award fees for enforcement actions? Perhaps more severe penalties are needed to preclude the practice of stockpiling protected cultivars near the end of the protection term to give holders the full benefit of their patent term.

Infringement limitations of PPA. Inventors of sexual plant varieties under PPA are granted "the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced" (14). Two major issues have arisen with respect to the scope of this legislative grant: the unauthorized reproduction of patented cultivars in foreign countries and the sale of imported cut flowers in the United States that were reproduced from patented plant cultivars without permission.

The first issue concerns the extraterritorial application of patent law—may a patent holder preclude the unauthorized reproduction of a patented plant outside of the United States? As noted by D.D. Jeffrey (Enforcement of plant variety rights in the United States, and remedies against the unauthorized importation of plant material, Fifth Intl. Colloq. on the Protection of Biotechnological Inventions in the Field of New Plant Varieties. 1987. Washington, D.C.), PA may be interpreted to preclude such reproduction, but enforcement will require proof of asexual reproduction of patented material. The financial burden of establishing proof of such reproduction and of policing infringement may be prohibitive.

The second issue involves the importation into the United States of cut flowers reproduced from patented plant cultivars without permission. Does PPA infringement provision apply to plant parts or only "the plant"? A literal interpretation suggests that plant parts are not covered by PPA, although no known judicial precedent has confirmed this interpretation. This literal interpretation does, however, severely limit the objective rewards of a patent. This ambiguity, together with the difficulty of enforcing extraterritorial application of American patent law, has contributed to the circumvention of the payment of royalties by foreign cut-flower producers. Although a bill was introduced in Congress to rectify this problem (17), and various legal groups have made recommendations to amend PPA to cover plant parts and to adopt stronger enforcement provisions, they have not been adopted.

Term restoration. Proposals for patent term restoration for agricultural pesticides have been noted (18–20). Scientists may want to examine legislation affecting the release of their discoveries to determine whether any pre-marketing delays due to governmental regulation exist. Term restoration legislation may be appropriate for some biological inventions.

Crop farmer exception. PVPA contains an exception for crop farmers that allows them to grow and market seeds certified under PVPA without compensating the certificate holder. There are some general limitations, but the crop farmer exception clearly reduces royalties paid to holders of certificates of plant variety protection.

The magnitude of diminished royalties to certificate holders is unclear. However, a survey by Zulauf and King (23) disclosed that 15% of Ohio farmers reported growing seed for themselves or selling seed to fellow farmers. This survey also disclosed that 44% of the respondent farmers who farmed 40 to 100 ha (250 acres) purchased some seed from other farmers, while 77% of those who farmed >400 ha (>1000 acres) reported that they purchased seed from other farmers.

Other survey data reported by Houston et al. (5) disclosed that firms owning rights to seed cultivars were concerned with the laxity of enforcement of PVPA. These survey data suggest that inventors of seed certified under PVPA are losing considerable royalties due to the crop farmer exception. These data may help explain why Hibberd (8) sought a patent on his maize invention rather than a certificate of plant variety protection. The weak protection of PVPA due to the crop farmer exception constitutes a strong impetus for patenting seed under PA.

In addition, the turgid language and undefined terms of the crop farmer exception have proved troublesome. These limitations have prompted the suggestion that the exception be repealed by W.H. Elliott, Jr. (Crystal ball gazing at the next decade, Fifth Intl. Colloq. on the Protection of Biotechnological Inventions in the Field of New Plant Varieties. 1987. Washington, D.C.).

Irrigation protection. The addition of the ability to use PA rather than PPA or PVPA for protecting inventors' rights in plant inventions may be followed by dual protection: simultaneous protection under PA and PPA or PA and PVPA. Although this practice has not been reported, it may offer the maximum protection for new plant discoveries.

Length of protection. Research by Center and White (2) and Schmid (10) suggests that the 17-year and 18-year periods of property-rights protection provided by patent and plant variety protection laws may not be optimal for biological discoveries. Further consideration should be given to establishing different periods of patent protection.
for various biological discoveries.

Conclusion
Lawyers and politicians are aware of some of the limitations of existing property-rights legislation. Recent judicial developments, legislative amendments, and proposed legislation disclose that intellectual property rights need amending. This article identifies nine substantive areas where changes may occur. Scientists, plant breeders, and growers may have additional insights, may want to express concern about certain issues, and may need to become more vocal to preclude the politicization of issues.

Literature Cited