The International Breeder's Rights System and Crop Plant Innovation

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The legal institutions affecting plant breeding and seed production—a complex of national plant patents, national certification procedures, international agreements, and development institutions—are now being discussed and reviewed in the United States and abroad. The United States has just changed its plant variety protection law amidst rather bitter controversy (1) and, by executive decision, has also accepted the Inquirements of the regular patent law; for example, as an analog to the novelty principle, the courts apply a principle of distinctness (5). A patent under this act conveys the right to exclude others from asexual reproduction of the patented plant, so that an orchard owner who reproduces new trees from a patented tree he or she holds legitimately would infringe the patent. On the other hand, a new mutation or sport deriving from a

Summary. Legal arrangements governing a plant breeder's intellectual property rights to his inventions are likely to affect the future of crop research. Such systems, although controversial, are probably currently desirable for the developed world. The new genetic technologies may change this judgment, and certainly require redefinition of the lines between plant patents and regular patents. Several safeguards, present in the United States breeder's rights law, should be applied more broadly. A new safeguard—of ensuring that material be entered into germplasm banks—should be applied everywhere. For the developing world, the desirability of a plant patent system is much less clear; new agreements may be desirable to ensure the free flow and collection of germplasm.

ternational Convention for the Protection of New Varieties of Plants (UPOV) (2). This convention reflects a global, but not uncontested, trend toward plant patents. New genetic technologies are further likely to reshape this entire body of law; the ambiguities of the recent Supreme Court case *Diamond* v. *Chakrabarty* (3) are but the beginning.

Breeder's Protections in the

United States

Traditionally, there were two different ways to reproduce plants: through asexual reproduction and through seeds. Because the asexually reproduced plant is genetically the same as its parents, it has long been viewed as distinct and uniform enough to be patentable, and has been legally protected in the United States since a 1930 amendment of the basic patent laws (4).

This act, the Plant Patent Act of 1930, generally follows the conditions and re-

patented plant can be reproduced and sold without infringing the original patent (6).

For crops propagated through seeds, several different breeding patterns are possible: open pollination, inbred lines, and hybrids. In open pollinated species, fertilization occurs by chance in a population that normally includes many heterozygous individuals. Because each of the plants reproduced in this way may be different, these crops are given no patent protection.

Professional breeders often use inbred lines, usually produced by self-pollinating a plant for several generations and selecting for the desired traits. Offspring are produced in which the two alleles in many of the gene pairs are identical. Since the seeds produced by these plants will also have the same genome, the inbred line will be identifiable, uniform, and stable, so it is possible to apply a patent system, as the United States did in 1970 (7). A farmer, however, can practically (and in the United States legally as well) use the harvested crop to provide seed for the next generation.

In hybrid breeding, two or more inbred lines are crossed to produce seeds whose gene pairs contain an allele from each parent. Since the seeds of the hybrid crop will not breed true to type, the farmer cannot effectively reuse the seeds. This has often been a barrier to the use of hybrids in the developing world, where farmers frequently lack the ability to purchase seeds each year. But, from the viewpoint of the seed producer this annual requirement for new seeds provides a form of economic protection that is more effective than a patent system. There has even been some question whether this feature of hybrids has caused a diversion of private breeding resources into hybrids (8).

In the United States, the Plant Variety Protection Act of 1970 provides patentlike protection for sexually reproduced types. This act defines a specialized review procedure and awards a 17-year certificate (with the effective meaning of a patent) to a protectable variety, defined in terms of distinctness, uniformity, and stability. Since a hybrid will not be stable, it cannot itself be patented. The act, however, permits control of the direct use of patentable inbred lines in the production of a hybrid, and thus provides effective protection for the hybrid.

The statute explicitly limits the certificate holder's rights to those needed to prevent unauthorized sale of the protected seed for seed purposes or for use in producing a hybrid. A farmer is thus entitled to save the seed produced by his lawfully acquired seed and to use it himself to grow a new crop so long as he does not sell the crop for seed purposes. Moreover, anyone may use the protected line as a reasonably remote parent in developing new hybrids or lines, which can then be protected and sold as seeds without infringing the original certificate. Again in contrast to the usual patent pattern, the Secretary of Agriculture can direct compulsory, reasonable-royalty licensing, when he finds such a step necessary "to insure an adequate supply of fiber, food, or feed" in the United States and that "the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair." Further, as a form of disclosure and as a way to encourage the preservation of germplasm resources, regulations authorized by the act require the certificate applicant to provide sam-

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ple seed which goes into a germplasm repository. Practical limitations significantly affect this law: since it is difficult to say conclusively that two plants are identical, the breeder's protection is realistically as much a protection of the name as of the variety (9).

The 1980 amendments to the act were very minor, clarifying a number of relatively technical points, extending the act to certain vegetables excluded in 1970, and modifying the period of protection to the 18 years for woody plants required by the UPOV convention (10). Nevertheless, the bill became surprisingly controversial; the hearings became a forum for debate covering the desirability of the plant patent system, the need to preserve germplasm, and the take-over of a number of small breeders by multinational firms. Congress did pass the amendments, but insisted informally on further studies and hearings (11).

The new DNA technologies widely expand the traditional possibilities of asexual and sexual reproduction. The new technologies will probably make it possible to transfer specific genes across much wider species barriers, as in transferring a disease resistance from one species to another or giving nitrogenfixation capabilities to new combinations of hosts and nitrogen-fixing organisms.

In Diamond v. Chakrabarty, the Supreme Court upheld the patentability of a microorganism modified by DNA engineering. In this five-to-four decision, the Court rejected the argument that the 1930 and 1970 acts implied that plants and microorganisms were excluded from the basic U.S. patent law. The Court's test was (3):

Here by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under [the basic patent law].

Conceivably a breeder, reading this language, might try to obtain the broad rights available under the regular patent statute rather than the more constrained rights under the plant patent act. It is difficult to see how the Court could extend its logic so far in the face of the detailed plant patent provisions, but the case blurs an already complicated line between the plant patent laws and the regular patent laws.

Industrial processes, such as fermentations, using specific strains of microorganisms have long been held patentable (12). Processes of gene insertion are also patentable under the basic patent laws, as exemplified by the Stanford DNA engineering patent (13). The legal position of a new seed line produced through such a patented process is at best unclear. The point is far more than academic: the regular patent laws lack the special protections for farmers and for further breeding found in the plant patent law.

New technologies might also make the traditional plant patent system really enforceable. Presumably, it will soon be possible to map the entire gene structure of an organism and therefore to define a plant perfectly and identify an infringer decisively. This would allow plant protection to be placed on a technological base rather than a trademark-type base; it would also enable patent holders more effectively to protect their home market against infringing seeds grown abroad.

Evaluating the U.S. System in Its Domestic Context

In evaluating the patent system, the obvious question is whether the research incentive created by the patent monopoly is substantial enough to outweigh the costs of the patent monopoly. Although the issue is to be examined in the current studies (11), evidence to date suggests substantial benefits, at least in the developed world. The British found that their private breeding industry was in trouble before adopting a breeder's rights system in 1964, and appear to have found that the new legislation helped (14, 15). The U.S. statistics presented to Congress in 1980 are impressive: three to six times more new varieties of wheat, soybeans, and cotton were produced in the decade after passage of the 1970 act than in the preceding decade. And private investment in plant research has increased by a factor of 2 to 3 in the decade since the 1970 act (10). This is probably a case in which a patent system actually achieves the intended goal of increasing research investment.

Two points, however, concern U.S. critics. One is a possible trend toward economic concentration in the seed industry. Although the 1980 act report notes that only 20 percent of the plant patent applications came from large businesses (10), small seed firms are frequently being taken over by other firms, sometimes by multinationals (16). Beyond the concern that decreased competition may produce price increases (which have occurred), there are arguments that firms with interests in energy or in agricultural chemicals as well as in plant breeding might have little incentive

to develop varieties which require less use of their other products (17).

This issue is also on the current study agenda. At present, there is little evidence that the new concentration, if it exists, is more than part of a general merger trend, independent of the plant patent structure. The new genetic technology, however, may increase concentration. Some of the current firms are not much larger than a substantial single farm, with a small number of breeders and an associated sales and administrative group. The new technology will require that the firm also support several biological scientists and substantial laboratory equipment. This will necessarily mean larger firms and greater integration (18). Market entry today is still easy enough that price increases in seeds are unlikely to go beyond a share of the increased productivity of the seeds. But greater concentration might come.

What could make this concentration issue serious is the possibility that DNA engineering will be applied to make the second generation of a seed artificially sterile. Plausibly, any seed might be designed to make it biologically impossible for a farmer to reuse his crop for seed purposes. Such an "innate plant patent system" could pose enormous social costs in a concentrated industry.

The second point that concerns critics is fear that the patent system will tie up and hide germplasm, at a time when diversity of germplasm is badly needed. As a domestic matter, this concern is undoubtedly overstated.

The central issue in maintaining genetic diversity is to preserve genes bearing novel possibilities. In the United States, the preservation process is carried out through such facilities as the National Seed Storage Laboratory at Fort Collins, Colorado, and the Germplasm Resources Laboratory at Beltsville, Maryland. Although significant limitations evidently remain (19), the United States has recently sought to rationalize the process through creating a National Plant Germplasm System (20).

Genetic diversity for the farmer is also lost if only a very few strains are actually used in a geographical area. This risks vulnerability to disease; it is not just one farmer's crop that may be destroyed by a new disease; rather it is a large portion of the nation's crop (20, 21). This problem can be resolved by regulation to ensure that diverse varieties are planted in an area (22) or, better, by production of many varieties and of mixed varieties. The last approach is in some conflict with the uniformity theme logically inherent in any patent system. One cannot be certain about the effect of plant patents on this diversity, at least on the domestic level. One argument is that breeders once exchanged germplasm in a casual, friendly fashion; the patent right now confers a value on secrecy. The counterargument is that the patent also permits a firm to reveal a new line safely. Moreover, to the extent the patent system does encourage the development of more new varieties, it helps diversify germplasm, at least if a breeder can use another's patented material for research purposes.

On balance, and looking at the balance for the developed nations alone, a plant patent system is probably currently desirable. The benefits are rather persuasive, while the current costs are subject to some doubt. One can perhaps go further: pressures on government budgets and the global shift of political power from rural areas to urban areas may create such severe political barriers to the continued public funding of plant breeding that incentives for private funding become crucial.

However, the current status of the law presents severe definitional issues, posed by both Diamond and the new genetic technologies. For cases such as a new plant variety produced by a regularly patented process, or a new nitrogenfixing process in which the host plant is modified by traditional breeding while the nitrogen-fixing bacterium is modified by DNA manipulation, which patent law is applicable? These definitional problems may require revision of the entire existing patent structure in the DNA, plant patent, and microorganism area, and may particularly require legislative revision of Diamond. The various applications of DNA engineering, such as the production of new plant lines, the production of chemicals, and the curing of human genetic disease, may pose such different policy questions that the patentability answers might also reasonably differ.

It is especially important to extend the special safeguards of the plant protection laws to agricultural innovations produced by DNA engineering. And there should be firm legal efforts to discourage the artificial sterilization of second-generation seeds. In contrast, there are also situations where the current lack of patent protection may be unwise: consider the possibility of a hybrid, not now patentable, being cloned by means of a new technology and sold by a competitor of its developer. It might also be desirable to define the patent system in a manner more conducive to diversity within the single field, as by protecting mixtures.

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Finally, the desirability of plant patents should be reexamined if a serious concentration problem emerges with the new technology.

The Foreign and International Laws of Plant Breeding

Each of the developed and major developing nations has long supported a national agricultural research and extension system following upon the genetic advances of the turn of the century. This system has become international with the creation of a large network of breeding research centers now under the auspices of a consortium of donors, the Consultative Group on International Agricultural Research (CGIAR).

Interest in plant patent systems has also been spreading. Although a Canadian breeder's rights bill has met severe resistance (23), the approach has long been followed in Europe (14). The UPOV convention, designed to support plant patent systems, was negotiated in December 1961 and entered into force in August 1968. Until recently, its parties were nine West European nations and South Africa, but some 27 other states, including the United States and a number of developing nations, met during the mid- and late 1970's to revise the convention in the hope of encouraging more nations to adhere (24). The causes of this interest are unclear. Possibly, public financing is slowing down, and incentives to private research are needed. There may be a "normal" commercialization of a technology that had earlier been a domain of hobbyists and public agencies. Moreover, many nations are philosophically committed to notions of intellectual property. The private breeding firms probably believe the legislation will help their position in new foreign markets. There are also some indications that developed nations are pressing developing nations to move toward plant patent systems.

Great Britain's plant breeder's rights system is an example of contemporary European systems. Under this system, created by Part I of the Plant Variety and Seeds Act of 1964 (25), the requirements for protection are close to those of the U.S. system: distinctness, absence of previous commercialization, uniformity, and stability. Again parallel to the United States, the right conveyed is the right to exclude others from selling the reproductive material of the plant and from producing that material in Great Britain for the purposes of sale. The statute lays down no position on whether a farmer can multiply protected seed for his own use or can multiply a protected orchard plant for sale of the fruit; the regulatory authorities can make this decision on a crop by crop basis, and can even go further to give the breeder exclusive control over sale of the crop. A breeder, however, can use another's protected plant for development of a new line. There are also provisions for compulsory licensing, and requirements that the breeder provide a living sample of the protected material.

But the 1964 act goes further to authorize the administrative creation of a list, or "index," of legitimate seed varieties. This index, to be promulgated for different crops, lists the varieties of a crop that may be sold. It is illegal to sell any other varieties (except for research purposes), and each new variety is to be tested before being added to the list. This form of legislation, typical in Europe (26), helps protect the farmer from inferior seeds, and, to the extent that the varietal names become a more enforceable equivalent of breeder's rights, protects the breeder.

Under the early British pattern, entry to this register was fairly easy; inclusion of a plant variety could not be refused unless the variety was "not distinct" from a variety already on the list. Britain's entry into the European Economic Community modified this pattern. As part of its legal harmonization effort, the Community had in 1966 created a committee to deal with seed issues (27) and issued a series of directives that same year setting minimum standards for parallel national systems of seed certification and marketing (28). Then, in 1970, the Community, choosing the list approach, created a common catalog, requiring, with a few exceptions, that new varieties be "clearly distinguishable," and a "clear improvement" (26). Britain has therefore repealed its own list, and now uses the more stringent Community list (29).

Although a number of developing nations are now considering a plant patent program, most have only a seed certification procedure. This approach, long used in the developed world, relies on actual tests and inspections to protect farmers from inferior seeds. There are elaborately defined categories such as breeder's seed, foundation seed, and certified seed, based on differences in purity, germination, and the number of generations from the original breeder's plants (30). This system, especially if combined with review of the quality of the variety, helps protect farmers who can bear only limited risk. Nevertheless,

there have been charges that the review process, as actually applied in some developing nations, may favor varieties developed in the nation's own breeding institutions, institutions which are often the same ones as those making the certification. It may be wiser for these nations to follow the United States by making certification voluntary and giving the farmer a private right to enforce a warranty against the seed producer (31).

Plant patent laws, like nearly all patent law, provide protection only within national territory (32). Thus, it would almost certainly not infringe the U.S. certificate for an unauthorized person to multiply protected seeds abroad for sale abroad, although the import of these seeds, if detected, could probably be barred (33). Conversely, in the absence of a U.S. certificate, a holder of an analogous foreign patent would have no right to bar unlicensed use of his seed in the United States. This territorial protection pattern is typical: under the United Kingdom law, an unauthorized sale of protected reproductive material outside the United Kingdom (assuming it had not been produced in the United Kingdom) would clearly not be an infringement (25). At least for the United States, there is, however, one important limit to this territorial character: importation of the product of a patented process can be excluded if the process is practiced abroad without a license (34).

This network of national territorial legislation is integrated-to a very limited extent-by the UPOV convention, one of a series of parallel international conventions covering various forms of intellectual property. Each such convention lays down minimum standards for national laws; agreement on uniform national laws has not generally been possible. Each convention then requires each party to give the nationals of other parties the right to obtain protection as if they were nationals. In this respect, the convention fills an important need. The U.S. plant protection statute, for example, authorizes the grant of certificates to foreign nationals only if the foreign national's state of domicile reciprocally grants such privileges to U.S. nationals or if such grant is required by treaty. Usually, the treaties also give inventors a specified period to file for coverage in various nations, protecting them from an argument that the first application constituted publication that undercuts their right to claim novelty. The impact of such a convention then is to enable an innovator to obtain separate, but roughly

parallel, territorial protection in a number of different nations (35).

The revised UPOV convention thus prohibits discrimination against foreign nationals of parties and lays down easily met requirements for plant patent systems (2). A protectable line must be distinguishable, new, homogeneous, and stable. Hybrids may be (but do not have to be) patentable. The protection granted must be at least the right to control the production, offering for sale, and marketing of the "reproductive or vegetative propagating material." A breeder's right to use another's patented material in developing a new line is expressly protected (except for direct production of hybrids). However, the import of this provision is unclear, for a nation may provide more extensive patent protection than that required by the convention. This last provision may permit nations to undercut the breeding stock provision; its legislative history is unclear, however, and it may simply reflect substantial differences among the parties on issues such as whether a farmer should be permitted to carry over part of his own crop for his own seed purposes without infringing the patent on the crop (24, 36). The European system in which the patent-granting authorities actually grow a sample of the crop is accepted but not required. And the convention creates an international institution to work for harmonization of national laws.

Evaluating the International System

If the developed nations are correct in having a plant patent system, they are also wise to participate in UPOV. All the definitional questions posed earlier with respect to the U.S. system, however, are also raised at the international level. In addition to UPOV, for example, there is a parallel treaty covering regular patents, that is, the Paris Convention of 1883 (37), which lacks even the limited special protections of UPOV. Since different nations' patent systems are otherwise likely to draw the various definitional boundaries differently, a breeder's ability to obtain parallel protection may become confused unless these definitional tasks are faced internationally.

Moreover, in order to protect the diversity of germplasm, it is essential to extend the protective themes of domestic legislation to the international level. UPOV ought not to permit member nations to prohibit a breeder from using another's patented plant as genetic parent material. Similarly, just as publica-

tion of patents is intended to help provide a basis of knowledge for further innovation, samples of all patented plant material ought to be maintained in central repositories. This would help conserve germplasm; it could also help breeders in further research.

Whether the developing nations should enact a plant patent system is doubtful. The trade-offs are quite different from those of the developed world. A patent system would increase the incentives for private firms to develop new varieties for the developing world. Moreover, some firms apparently refuse to export to nations without protection systems, probably fearing reexport to home markets. But without a patent system, the less-developed countries are still able to benefit from the public research institutes and also to use or even to "pirate"-quite legally-seed lines developed for the developed world. It is not clear how much new private research would be encouraged. Also, the economic costs may be high. In the developing world, there would probably be less competition among seed companies so that a patent monopoly system might significantly increase prices.

Some also fear that the existing public international system might be disrupted by a patent approach. The CGIAR, in particular, is concerned that crops developed by its network might end up being patented and that its institutes would thus be unable to market varieties on which they had done the most significant work. Whether this would actually be the case depends in part on legal interpretation of the novelty and distinctness concepts. Another concern is that the entire CGIAR system has operated informally; intensification of property interests might destroy that informality.

If a less-developed country adopts any plant patent system, it should choose the American easy-entry version rather than the European variety-review pattern. There is no need for the bureaucracy or the inflexibility of the European system. Moreover, such a system poses an unnecessary risk of corruption and can become a form of monopoly protection, hindering the ability to introduce new crop forms. If it narrows down the number of types available, it increases the crop's vulnerability to disease.

The developing nations might also consider an integrated system: a single developing-nation plant register and patent, which could be obtained through any of the participating national patent offices and would provide protection in all participating nations without further formalities. This approach would reduce administrative costs, encourage competition among varieties, and increase incentives for breeders.

The most critical global issue, however, is the maintenance of germplasm diversity. Many of the fundamental sources of diversity are in the developing world, and the nations holding these resources might become loath to permit their export. This has already happened in a few cases, probably from commercial considerations (38). Current developing world attitudes toward exporting natural resources and cultural works could also support such restraints. The availability of germplasm is further affected by the process of providing developing-world farmers with new highyielding seeds. As these new lines are spread, farmers stop using their traditional lines, which may become lost.

There has long been informal international cooperation in creating and maintaining national germplasm collections and there is now an International Board for Plant Genetic Resources, created by the CGIAR in 1974 (20). These efforts are desirable-and perhaps there should be endowment-funded collections in addition to the tax-funded collections. But there is also a need for new treaty arrangements and the current interest in breeder's rights may provide a context. As a reasonable minimum, there should be international legal requirements prohibiting any restrictions on the export of germplasm (but allowing import quarantines), encouraging or requiring the collection of native materials as part of the process of spreading new varieties, and laying down much stronger requirements for placing material into collections as part of any patent process.

The patent issues, at least at the global level, are far less important than these germplasm diversity issues, but the two types of issues might well be faced together. The Budapest Convention on the Deposit of Microorganisms (39) exemplifies such a negotiation. It was created to help satisfy patent law requirements of providing public information on inventions involving microorganisms, but may well encourage international collections of one type of germplasm. The negotiating agenda in this area goes far beyond UPOV or the breeder's rights concept.

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- 37. Treaties 1583, Treaty and International Agreement Series 6923
- According to the Far Eastern Economic Review, 115, 78 (20 February 1981), Indonesia and Ban-38. gladesh have already banned the export of teaplanting material.
- (Budapest) Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedures 1977 (not yet in force). In *Application of Argoudelis*, 434 Fed. Rep. 2nd Ser. 1390 (Court of Customs and Patent Appeals, 1970), the court approved the use of a public depository of microorganisms as a way for a process invention based on an unusual microorganism to satisfy the requireunusual microorganism to satisfy the require-ment of 35 U.S. Code, Sect. 112 that a patent reveal how to practice the invention. The Patent Office formalized this procedure, Commission-er's Notice of 29 April 1971, and a later case approved the use of an international repository, of the type now structured under the Budapest convention, *Feldman v. Aunstrup*, 517 Fed. Rep. 2nd Ser. 1351 (Court of Customs and Patent Appeals, 1975).