INTELLECTUAL PROPERTY

# Plants and Intellectual Property: An International Appraisal

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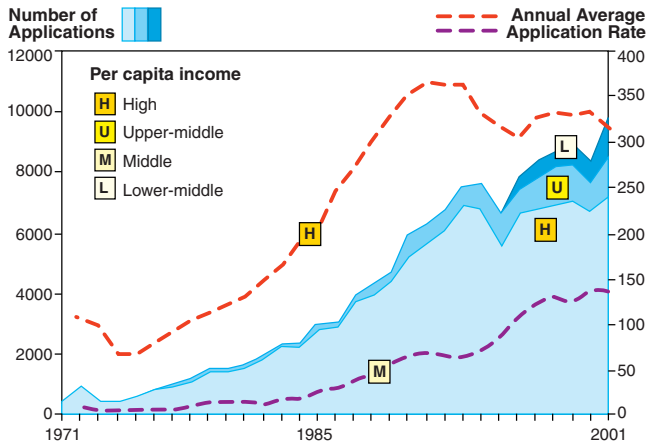
The era of free and unencumbered access to new crop varieties appears to be passing. This development in intellectual property (IP) has raised a chorus of concerns about the implications for food production and human health, especially throughout the developing world. The downsides of IP have been emphasized by a series of articles in *Science* (*1*–*4*). However, much of the debate occurs in the absence of an understanding of the specifics of the rights available in particular jurisdictions, a practical sense of the rights actually claimed or granted, and their evolution over time. Existing information highlights rich-country developments, with little, if any, attention to developing countries.

Enhanced online at www.sciencemag.org/cgi/content/full/306/5700/1295

While protection of a piece of IP is limited to the countries or regions that grant the protection, international aspects of IP can affect use and especially transfer of the technology or products. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which came into effect in 1995 and is a requirement for members of the World Trade Organization (WTO), inextricably tied trade with patent protection by providing patent owners the right to prevent others from importing a patent product and a product obtained directly from a patented process. Thus, if a producer wants to export a genetically modified crop to a country where there is a patent on the process to make that crop, importation requires the permission of the patent owner.

TRIPS requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology" [Article 27(1)], but also provides added protections for plant varieties by mandating their protection "by patents or by an effective *sui generis* system or by any combination thereof." Sui generis is a term literally meaning "of its own kind" or "unique." Systems for plant variety protection that satisfy the sui generis requirement of TRIPS are often called plant breeders' rights. Although the minimum criteria for patents are set forth in TRIPS, no criteria are elaborated for what constitutes an "effective" sui generis system. There is considerable variation among countries in the implementation and application of these forms of protection. To illustrate the variety of plant-related IP protection on offer worldwide, we describe the different approaches to awarding patents for plants in the United States, Canada, Europe, and the Andean Community; illustrative sui generis systems from the United States (*5*), Europe, and India are contrasted.




**Plant breeders' rights.** Applications for countries grouped by income (*15*). See notes to Table 1 for criteria used to classify countries. Data for 2002 and 2003 were omitted because of likely underreporting stemming from lags in recording rights claimed or granted.

*Utility patents.* In most countries, plants and inventions directed to plants or plant products (e.g., seed) are not eligible for a patent. In the United States, however, any living organism that is the product of human intervention (such as by breeding or laboratory-based alteration) is patentable (*6*). In particular, plants and plant parts, including seeds and tissue cultures, have been explicitly held to be patentable (*7*). Plant varieties can also be patented, and, since a recent ruling (*8*), there is no prohibition against obtaining multiple kinds of protection on the same variety. Other plant-related patentable subject matters include plant groups, individual plants and their descendants, plant parts (e.g., specific genes or chromosomes), plant material used in industrial processes, transgenic plants, and particular plant traits.

For patents obtained through the European Patent Office, allowable subject matter is controlled by the European Patent Convention (EPC). Under the EPC, individual plant varieties per se are not patentable; however, claims directed to broader plant groupings are allowable (*9*). Thus, as long as required criteria are met, a claim to "transgenic corn having an insect-resistance gene," for example, is patentable. Plant cells, unlike plant varieties, are patentable because they can result from microbiological processes.

Canadian patent law does not allow patenting of "higher life forms," e.g., plants and animals. In a recent, highly publicized case, *Monsanto* v. *Schmeiser*, the Canadian Supreme Court confirmed this policy but then found that Schmeiser infringed Monsanto's patent claiming a herbicide-resistant gene by growing transgenic canola plants that contained the gene (*10*). Notwithstanding Canadian patent law, this ruling appears to effectively extend Canadian patent protection to plants if they contain a patented gene (*11*).

The Andean Community, a subregional organization made up of Bolivia, Colombia, Ecuador, Peru, and Venezuela, has a common IP regime that is embodied in Decision 486 (*12*), which entered into effect in 2000. Article 20(c) of the Decision expressly prohibits patents on "plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes."

*Sui generis systems.* It is generally believed that sui generis enables member countries to design their own system of protection for plant varieties as an alternative or addition to a patent system for protecting plants (*13*, *14*). The International Union for the Protection of New Varieties of Plants (UPOV) (*15*)] established a Convention that serves as the basis for sui generis systems

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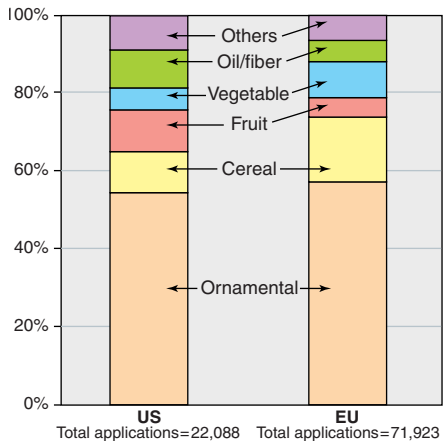
worldwide. Briefly, plant breeders are granted a legal monopoly over the commercialization of their plant varieties (*16*). Notwithstanding this, a number of exemptions from infringement are mandated (use for noncommercial acts, experimental purposes, breeding other varieties) or optional (farmers' saving of seed). Like patents, the rights granted are for a specific time only (not less than 20 years generally or not less than 25 years for trees and vines).

The U.S. Plant Variety Protection Act (PVPA) (*17*) was enacted in 1970, and revised in 1994 to adhere to the 1991 UPOV Convention. The Act provides for protection only for sexually reproduced plants, including first-generation ($F_1$) hybrids, and tuber-propagated plants (e.g., potato varieties). The counterpart protection for asexually reproduced plants (*18*) is provided by the Plant Patent Act (PPA) enacted in 1930. Probably because it was enacted primarily to benefit the horticulture industry (*19*), the Act protects new and distinct plants that are either invented or discovered, including newly found plant varieties as well as cultivated spores, mutants, hybrids, and newly found seedlings, but excluding tuber-propagated plants. Moreover, implementation of other requirements, such as written description and enablement, for obtaining plant patents is less stringent than for utility patents.

Plant variety protection in the European Union is based on the European Convention (Regulation 2100/94/EC), which in turn is based on the 1991 UPOV Convention. To harmonize and streamline plant variety protection, the Community Plant Variety Right (CPVR) was created in 1995 (*20*). It is not possible to hold simultaneous protection for the same plant variety under both the Community and national system. Furthermore, a CPVR can only be transferred or terminated within all countries of the EU Community and not within selected countries.




**Plant breeders' rights stratified by crop categories.** United States' data include total number of plant patents granted from 1930 to 2003 and plant variety protection applications from 1970 to 2003. Data for European Union include plant breeders' rights applications to national plant variety offices beginning at or near their inception dates (1942 for Netherlands, 1955 for Germany, 1970s and 1980s for most other countries) to 2003 and applications to the CPVO from 1995 to 2003 (*15*).

As opposed to basing a sui generis system on UPOV, India has chosen a more expansive approach. The Indian Protection of Plant Varieties and Farmers' Rights (PPVFR) Act of 2001 (*21*) ostensibly recognizes the contributions of professional plant breeders and farmers who actively participate in breeding efforts. Thus, the Act contains provisions for "benefit sharing" whereby local communities are acknowledged as contributors of the plants. In a major departure from UPOV, protectable plant varieties include farmers' varieties (those about which there is common knowledge) and other extant varieties including those "notified" under the 1966 Seed Act, or any other variety in the public domain. Furthermore, the Indian PPVFR has some atypical additional requirements for obtaining protection: The applicant must provide information about the origin of the genetic material as well as declare that the variety does not incorporate a restriction technology involving gene(s) that inhibit the development of viable seed.

A provision for farmers' rights in PPVFR [Article 39(iv)] entitles the farmer to save, use, sow, resow, exchange, share, or sell farm produce including seed of a protected variety. Any seeds that are sold, however, cannot be branded. The rights to sell seed appear to undermine the rights of the commercial or farmer breeder. The Act also contains compulsory licensing provisions (*22*), similar to legislation in the United Kingdom (*21*) and in Canada (although such provisions do not pertain to the PVP Act in the United States). Overall, the Indian Act seems to heavily favor "public" over "private" interests. It remains to be seen whether this will qualify as an "effective" sui generis system under TRIPS.

| Economies* | Countries (*n*) | | | |
|---|---|---|---|---|
| | Statutory protection | Legislation under consideration | Member UPOV | Member WTO |
| High-income economies (54) | 29 | 4 | 23 | 37 |
| OECD (24) | 23 | | 21 | 24 |
| Non-OECD (30) | 6 | 4 | 2 | 13 |
| Upper-middle-income economies (37) | 20 | 4 | 14 | 28 |
| Lower-middle-income economies (56) | 20 | 18 | 13 | 36 |
| Low-income economies (61) | 22 | 3 | 4 | 42 |
| Total (208) | 91 | 29 | 54 | 143 |

**Plant variety protection legislation worldwide (*30*).** Countries are classified into income classes according to World Bank (2004) criteria. High, upper middle, lower middle, and low income are defined as 2003 per capita gross national incomes greater than $9386; $3036–$9385; $766–$3035; and less than $765, respectively. Brackets indicate total number of countries in each income class.

## Intellectual Property Landscapes

We have conducted a survey of national IP offices, UPOV, and the WTO (see table at left). Just 91 out of 191 countries surveyed offered statutory IP protection (*23*), while another 29 countries had legislation under consideration. Countries with statutory protection are mostly high- and upper-middle-income countries; less than half the middle- and low-income countries have varietal protection legislation, and most of these are not UPOV member countries.

Although the number of applications by rich countries peaked in the early 1990s, PBR applications filed in upper-middle-income countries have grown steadily since the early 1970s, and the number from lower-middle-income countries only began to rise in the 1980s and is still negligible (*24*) (see figure on first page). From 2000 to 2002, a total of 26,192 PBR applications were lodged worldwide in each country, of which 2909 (11%) were filed in the United States and 11,300 (43%) in European member states of the CPVO, of which nearly one-third were applications made in the Netherlands and more than one-fifth lodged in France (*15*).

The principal proximate cause of the disproportionate activity in developed countries is most likely the lack of rights on offer in poor countries (only 22 of 61 low-income countries have any statutory protection in place for plants). More fundamentally, it probably reflects a range of economic influences regarding the costs and benefits of securing breeders' rights in a particular jurisdiction.

One-third of the PBR applications lodged in 50 UPOV member countries dur-

ing 1998–2002 were lodged by foreigners (see table below). Looking regionally, 31% of the applications in high-income countries were lodged by foreigners, 65% in upper-middle-income countries, 25% in lower-middle-income countries, and 38% in low-income countries. The variation is even more apparent in individual countries; for example, the share of applications filed by foreigners is 85% in Switzerland, 42% in the United States, 24% in Japan, and 11% in France (*25*). This substantial fraction of foreign applications indicates extensive potential spillovers of varietal improvement research done in one locale on seed market and production developments elsewhere in the world.

| | Applications (*n*) | | |
|---|---|---|---|
| **Economies** | **Total** | **Residents** | **Nonresidents** |
| High-income economies (23) | 39,079 | 26,893 | 12,186 |
| Upper-middle-income economies (11) | 5,583 | 1,945 | 3,638 |
| Lower-middle-income economies (12) | 6,109 | 4,592 | 1,517 |
| Low-income economies (4) | 487 | 299 | 188 |
| Total (50) | 51,258 | 33,729 | 17,529 |

**Share of plant breeder rights applications lodged by foreigners, 1998–2002.** See table 1 for country income classification criteria. Bracketed figures indicate number of countries included in the data. [Source (*33*)]

The percentage of plant patents and PBRs granted to different plant groups is similar in the United States and Europe (see figure opposite, top). Ornamental crops account for more than half the total applications in both the United States and Europe (*15*), while cereal crops (such as wheat and corn) is the next biggest group (11% in the U.S. and 17% in Europe). Other major groups of plants that are protected are oil and fiber plants, fruit crops, and vegetables. Because plant-related utility patents are a comparatively recent phenomenon in the United States, only 5% of all plant-related protection are utility patents, of which 55% pertain to corn and 40% to soybeans (*15*).

## Conclusions

International treaties like TRIPS and intergovernmental organizations like UPOV leave scope for much variation in the specifics of plant IP protection. Our review of national plant variety legislation shows that countries are exploiting these degrees of freedom, presumably tailoring plant IP legislation to local circumstances. Variations include such fundamentals as the types of IP offered, species and genera encompassed, costs, and extent of farmers' rights.

The long-term effects of these variations on the rate and direction of plant innovation are yet to be determined. Although the geographical scope of protection is expanding, IP markets are still quite segmented—the preponderance of protection pertains to rich-country jurisdictions, leaving poor countries free to tap these technologies. Moreover, a sizable share of the protected varieties are ornamentals, not food crops, and most plant varieties are afforded protection that enables rights holders to limit or exclude others from marketing but not breeding with the protected material. In addition, the lion's share of food staples produced in developing countries are consumed where grown and are not exported to rich countries (*26*). Thus, concerns that IP rights are currently limiting the freedom to research or commercialize developing-country food staples seem overstated. Misplaced concerns over IP seem to be diverting policy attention from more fundamental negative trends, notably, the slowdown in investment in agricultural R&D worldwide, especially the research targeted to poor people's food crops, and deteriorating domestic capacities—during the past decade in particular—to conduct agricultural R&D in many poor countries, especially throughout sub-Saharan Africa (*27*).

None of this is to deny that possible increases in the transaction costs of moving plant material from one IP jurisdiction to another may be slowing international spillovers, but the IP effects per se are more likely to reduce technological spillovers from poor to rich countries, rather than germ plasm flows in the other direction. Moreover, any slowdowns may be temporary. Harmonizing plant IP legislation is likely to lower these transaction costs (one variant of this being the formation of Europe's Community Plant Variety Office); increased knowledge of the details of national legislation is another avenue for improving efficiencies in the international movement of plant innovations subject to intellectual protection. In addition, the disclosure and information requirements coupled with increasing Internet access may help streamline and progress breeding efforts. At the very least, more complete examination and investigation of these changing IP landscapes internationally should be undertaken before bold assertions about the consequences of IP are taken as truths.


**References and Notes**

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2. D. Kennedy, *Science* **302**, 357 (2003).
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4. R. Beachy, *Science* **299**, 473 (2003).
5. The United States has awards called utility patents for any kind of plant and plant patents—more akin to plant breeder rights—for certain asexually reproduced plants.
6. *Diamond* v. *Chakrabarty* 447 US 303, 1980.
7. *Ex parte Hibberd* 227 USPQ 433 (Bd. Pat. App. & Int. 1985).
8. *J.E.M. AG Supply* v. *Pioneer Hi-Bred International* 122 S. Ct. 593 (2001).
9. Directive 98/44/EC (effective in all European Union member states 30 July 2000) also aims to harmonize protection for biotechnological inventions (including plant protection) among the European Union members (*28*).
10. *Monsanto Canada Inc.* v. *Schmeiser*, 2004 SCC 34.
11. C. Nottenburg, "*Schmeiser* v. *Monsanto*" in *Navigating the Patent Maze*, posted 22 July 2004, www.cougarlaw.com.
12. Decision 486, Common Intellectual Property Regime, Andean Community; available at www.comunidadandina.org/ingles/treaties/dec/D486e.htm.
13. http://www.upov.int/en/about/upov_convention.htm.
14. The Convention was established in 1961 and has been revised three times; not all UPOV member countries are bound by the latest Convention.
15. Further information can be found in the supplemental material.
16. Protection confers the right to exclude others from producing or reproducing, propagating, offering for sale, selling or other marketing, exporting, importing or stocking for any of the above purposes the protected variety [Article 14(1) of the Convention].
17. www.ams.usda.gov/science/PVPO/PVPO_Act/PVPA.htm.
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21. P. Brahmi *et al.*, *Curr. Sci.* **86**, 392 (2004).
22. Statutory Instrument 2002 No. 247 The Patents and Plant Variety Rights (Compulsory Licensing) Regulations, 2002.
23. Only 54 out of a total of 191 (28%) of the countries surveyed having legislation are members of the UPOV Convention.
24. Over time, some countries with PBRs conforming to the 1978 UPOV Convention have relaxed restrictions on the scope of crop protection offered. In China, for instance, a total of 10 species were eligible for protection in September 1999, growing to 30 species by March 2002 (including 5 major cereals, 2 oil crops, 2 roots and tubers, 10 vegetables and fruits, and 11 flowers and grasses but excluding cotton) (*29*).
25. P. G. Pardey, B. Koo, C. Nottenburg, "Creating, protecting, and using crop biotechnologies worldwide in an era of intellectual property," *Minn. J. Law Sci. Technol.* (in press).
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28. europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.
29. B. Koo *et al.*, An Option Perspective on Generating and Maintaining Plant Variety Rights in China. Department of Applied Economics Staff Paper P03-8 (Univ. of Minnesota, St. Paul, December 2003).
30. Data were compiled from on-line searches of national IP offices, (*31*), and (*32*).
31. www.upov.org/en/about/members/index.htm.
32. www.wto.org.
33. UPOV, "Plant variety protection statistics for the period 1998–2002" (C/37/7, International Union for the Protection of New Varieties of Plants, Geneva, 2003).


34. The authors thank the International Food Policy Research Institute, CAMBIA, and the University of Minnesota for financial support; and D. Ashton, J. Sharples, E. Castelo-Magalhães, and H. Wright for their help in preparing this paper.