

Intellectual Property Rights for Plant Biotechnology: International Aspects

**Sara Boettiger, Gregory D. Graff, Philip G. Pardey, Eric Van Dusen
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Intellectual Property Rights for Plant Biotechnology: International Aspects

Sara Boettiger,¹ Gregory D. Graff,¹ Philip G. Pardey,² Eric Van Dusen¹
and Brian D. Wright²

¹*Department of Agricultural and Resource Economics and Policy,
University of California, Berkeley, CA, USA*

²*Department of Applied Economics, University of Minnesota, St. Paul, MN, USA*

The 'protection against imitators' is necessary because 'he who has no hope he shall reap will not take the trouble to sow.'

Jeremy Bentham (1843, quoted by Machlup 1958 p. 19)

It might be 'fair and economically advantageous for a nation to compensate the inventor' for efforts and expense, but it was 'very questionable whether monopolization of his invention is the right kind of compensation.'

Johan Friedrich Lotz (1822, quoted by Machlup 1958 p. 20)

INTRODUCTION

Research and development in the agricultural sector is unique among industries in at least two respects: the truly global reach of a majority of agricultural R&D and the historical success of what has been largely a public enterprise. In relation to other industries, research and innovation in agriculture are far more geographically dispersed. Private sector firms make up roughly one-third of global agricultural R&D expenditures, while public research institutions make up the other two-thirds, evenly split between developed and less developed countries (Pardey and Beintema, 2001). Intellectual property rights (IPR) are important internationally, in public, nonprofit and private

institutions, both as incentives for innovation and as constraints on freedom to operate in agricultural R&D.

This is a recent phenomenon. Private intellectual property rights have historically been of little relevance in agricultural research. For more than a century, mechanical inventions, produced mainly by farmers and mechanics, could be protected in many countries via utility patents. But the financial rewards were only modest, at best. Inventions tended to be easy to copy, and licensing contracts difficult to enforce.¹ Biological innovations such as novel crop varieties were not patentable and had no protection from duplication or breeding by purchasers of seeds or other germplasm. Financing expensive work in innovation by licensing or sale

of resulting germplasm was infeasible since the results were freely available to competitors as free riders. Achieving the scale and power necessary for the private integration and monopolisation of the whole production chain, including commercial farming, was impractical. So advancements in crop breeding were dominated by the public sector.

Although personal or corporate intellectual property rights for plant biotechnology are recent phenomena within most countries, attempts at asserting national property rights over breeding materials internationally are nothing new. Monopolisation of valuable markets has long been accomplished by nation-states prohibiting access to breeding materials. Examples include the Dutch monopolisation of the European tea supply, (Juma, 1989), the Italian prohibition on rice seed export famously violated by Thomas Jefferson (Fowler, 1994; Root and de Rochemont, 1976), and more recently Ethiopia's ban on export of some coffee tree varieties (Fowler and Mooney, 1990). These cases are, however, atypical; in general, traders, collectors and breeders have had free access to land races and farmers' varieties from around the world.

Characterisation of genetic resources as the 'common heritage of humankind' appears to originate only in the 1970s, when the term was borrowed from earlier applications to air, sea and other open-access natural resources. The globalisation of trade, migration and communication witnessed in the last few centuries had already made national monopolisation of genetic resources an anachronism. Innovations such as the Wardian case (the precursor of today's terrarium) had facilitated the transportation of live plants over vast distances. As modern varieties spread throughout the world, a large set of farmer-bred varieties or land races was replaced by a much smaller set of modern varieties in farmers' fields.

The Southern corn leaf blight infestation of 1970 revealed the genetic vulnerability of the large portion of the US corn crops that relied on cytoplasm male sterility for its production. A US study (National Research Council) was organised to assess the genetic diversity of major crops, and found them excessively genetically uniform and vulnerable. In response, the United States and other national governments and non-profit foundations have supported unprecedented efforts, following the pioneering efforts of Nicolai Vavilov in the early

twentieth century, in the *ex situ* conservation of germplasm in botanical gardens and seed banks. They have also made these collections broadly available. The cost of exchange is now so low that thousands of sets of plant varieties can be distributed and tested simultaneously in many countries and environments. Seed banks can safely preserve thousands of key cultivars by depositing 'back-ups' at other locations. And breeders can access countless cultivars from major seed banks at the cost of dissemination (Koo *et al.*, 2002).

The globalisation of germplasm exchange began in the last century (Juma, 1989), and was consolidated as systems for large-scale exchange (Evenson, 2000). But rights of access to germplasm have become progressively restricted. Early 20th century progress in plant breeding and genetics led to the development of hybridisation, which increased yields while providing an important physical means of restricting the reproduction of plant genetic resources. Subsequently, in countries around the world the expansion of 'intellectual property rights' (IPR) has created several other means of restricting the reproduction and trading of plant genetic resources.

MEANS OF DEFINING AND PROTECTING INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

Hybridisation

Prior to the 1980s, even if legal protection had been given to seed producers against unauthorised use of new varieties, enforcement would have been hampered by the difficulty of identifying proprietary germplasm as the parent of a new commercial variety. Until the advent of biotechnology, only hybrid seeds, which do not breed true upon replanting, were protected against this type of misappropriation. With the case of corn in the United States as the most prominent example, protection via hybridisation was strong enough to foster the growth of a profitable private agricultural seed breeding industry in the 1930s, well before the effective strengthening of legal intellectual property protection for these types of plants.

In developing countries, such as India, hybridisation offers less protection because parent lines cannot be effectively protected from

misappropriation for more than a few years. Until the 1980s, misappropriation of parent lines was a problem in the United States. Defence of parent lines via trade secrecy has become more feasible, now that proof of infringement is possible using the tools of biotechnology. Some critics have argued that pursuit of hybrid breeding strategies was motivated by capitalistic designs to monopolise germplasm commercially (Kloppenber, 1988). The development under communism of the hybrid cultivars that now constitute large fractions of China's rice and maize crops has been largely ignored by such writers.

In the twentieth century, a major innovation in intellectual property rights for germplasm was the United States Plant Patent Act of 1930, which gave protection from unauthorised use of many kinds of clonally propagated plants for the life of the patent. This form of protection was useful principally in horticulture, and has been important, for example, for strawberry breeding in the University of California. In many other countries, protection of clones has since become available via plant breeders' rights which, like plant patents (but unlike utility patents) do not protect against use of the protected material for sexual reproduction or use of germplasm to breed new cultivars, if that is possible.

Plant Breeders' Rights (PBR)

Plant breeders' rights include protection provided to plant breeders by nations, almost all of whom are members of the International Union for the Protection of New Varieties of Plants (commonly known by its French acronym UPOV) founded in 1961. PBRs protect varieties that are deemed new, uniform, stable and distinct against unauthorised sale for replanting. In one notorious US case, a soybean cultivar was approved as distinct based only on its blue flower colour, a trait not generally considered meaningful in commercial soybeans.

Use of germplasm as breeding stock for producing new varieties is not prohibited. An exception introduced in the 1991 version of UPOV is the breeding of a variety 'essentially derived' from a protected parent. This exception might cover a similar cultivar derived from a simple back-cross, differing by a small amount of transgenic DNA, but its scope is yet to be legally established. It is not well

recognised that the requirements for evaluation in each country, and the need for local legal representation, can render broad international application for plant breeders' rights comparable in cost to patents, and is time consuming (Margeules, 2002).²

In the United States, restrictions are placed on the use of sexually propagated seed germplasm for reproduction by way of Plant Variety Protection Certificates (PVPCs). PVPCs are administered by the United States Department of Agriculture under the legal authority of the Plant Variety Protection Act of 1970, which had liberal provisions for saving and replanting of seed by farmers. Restrictions on replanting saved seed by producers have been strengthened over time in the United States, but are still difficult to enforce.

Other countries have enacted much more liberal versions of plant breeders' rights. In India and Thailand, they cover indigenous varieties, and contain clauses for 'benefit sharing' with local communities when land races are used in commercial breeding. Indian plant breeders' rights appear to allow farmers to sell unlimited quantities of what in the United States are called 'brown bag' seeds, unidentified by variety or registration. Though India has applied for membership of UPOV, its current plant breeders' rights do not appear to conform with UPOV 1991 (GRAIN 2000). Whether or not they qualify as *sui generis* provisions acceptable to TRIPS (Trade-Related Aspects of Intellectual Property) remains to be seen.

Trade Secrets

Trade secrets are proprietary information (e.g., customer lists, business plans, manufacturing processes, inbred lines required for hybrid seed production) that have commercial value and that the firm possessing the information makes an effort to physically conceal from its competitors to prevent them from duplicating or using it (Friedman *et al.*, 1991).³ There is no property right to the secret (or information) *per se*, but a common law right to maintain secrecy, if feasible. Thus trade secrecy does not protect information as such. This means that information in a product that is revealed by reverse engineering, independent discovery or obtained by other legal means (for example, viewing a seminar presentation) is not suitable for protection by trade secrecy.

Trade secrecy protection varies by legal jurisdiction, and in particular from state to state within the United States. Trade secrecy is important in protecting research information before other means of IPR protection such as patents can be obtained. Laws are becoming more harmonised among countries and within the United States under the model statute offered by the uniform Trade Secrets Act (Maskus, 2000).

Advances in biotechnology in the past few decades have strengthened the extension of trade secret protection to plants and plant breeding. The revolution in analysis of genetic material has created genetic fingerprinting technologies well suited to detection of unauthorised reproduction or breeding. These methods have already been effective in enforcing state trade secret law in the protection of inbred parent lines for hybrid corn breeding. But the genetic information contained in commercial seeds sold to farmers is generally not possible to protect as a trade secret unless the farmer is somehow prevented from using the seed for reproduction or for breeding a new variety.

Much of the current laboratory work in agricultural biotechnology is covered by trade secrecy as firms seek to protect research materials prior to patent filing. The objects protected under trade secrecy can range from lab books to transformed materials. Some researchers have decried trade secrecy as undermining the fundamental academic approach to research, especially when it curtails publication of results and participation in academic conferences.

Utility Patents

Patents protect inventions of both processes and products (composition of matter) that must be embodied in tangible things. They confer a legally enforceable right allowing the owner of a patent to exclude others from practising the invention as described and claimed in the patent document. However, these property rights apply only for a limited period of time, generally 20 years from the date of filing, and only in a specific jurisdiction. The scope of the property rights is circumscribed by the claims made in the patent which, in the event of litigation, may be subject to interpretation by a court of law. In agricultural biotechnology, utility patents now cover many kinds of different

innovations including research tools, transformation processes, vectors, components of vectors such as markers, promoters and genes of interest, as well as organisms and their parts.

Although international treaties and conventions govern international aspects of patenting, patents are awarded by national governments, and the protection conferred by a patent extends only to the national jurisdiction in which the patent is awarded. To protect an innovation in more than one country, a patent must be obtained in each. Applications in more than one country are facilitated by the Patent Cooperation Treaty, administered by the World Intellectual Property Organization (WIPO). Applications in multiple European countries can be lodged in each country or be sent for examination by the European Patent Office with subsequent registration on a country-by-country basis.⁴ English-speaking African nations that are members of the African Regional Industrial Property Office (ARIPO) headquartered in Harare can file patents through that office subject to confirmation. Similarly, Francophone African members of the Yaoundé, Cameroon-based organisation *Africaine de la Propriété Intellectuelle* (OAPI), can file a single application with designations to member states.

The cost of obtaining a patent varies from country to country; the cost of obtaining protection in all important markets can be very substantial, reaching hundreds of thousands of US dollars. Beyond the actual filing fees for each country, translation and local legal fees are important components of this cost. The EPO, ARIPO and OAPI are means of reducing the transaction costs associated with patenting in multiple international jurisdictions.

In jurisdictions covered by TRIPS, inventions, not discoveries, are patentable. Inventions have the legal requirements of utility (i.e., have an industrial application), novelty and non-obviousness and must be adequately described and disclosed to enable the making and using of the invention by a person ordinarily skilled in the relevant arts. These criteria and their implementation vary among countries. For innovations in biotechnology, some observers believe the US standards of novelty and non-obviousness are particularly weak (Barton, 2003). In many other countries things occurring in nature, such as genetic material, are deemed discoveries and not subject to patenting.⁵

In 1980 the United States Supreme Court ruled that utility patents could apply to life forms. Then in 1985, the United States Patent Office Board of Appeals ruled that this utility patent protection could be applied to sexually-propagated seeds, plants, and cultured tissue. Now, in the United States, DNA sequences and transgenic animals are also patentable. In Europe, the European Patent Office has ruled that plant varieties are not patentable, although it has also held that transgenic methods and plants are not *per se* unpatentable (Santaniello, 2000). DNA sequences and amino acid sequences corresponding to the peptides or proteins produced by a naturally occurring organism are unpatentable in a number of countries including Brazil, Cameroon, Colombia, Cuba, Guatemala and Uzbekistan (Thambisetty, 2002).

The distribution of patents by value is highly skewed. While, for example, the widely-licensed Cohen-Boyer patent earned more than \$200 million in royalties, most patents generate values ranging from zero to just tens of thousands of dollars. It is not surprising then, that most inventions are patented in just one or a few developed countries with large markets. The chance that relevant biotech patents have been protected in developing countries is currently quite small, even where patenting of the relevant type of technology is available. For example, none of a set of key *Agrobacterium* technologies is patented or pending in more than four jurisdictions outside Europe, while the very popular CaMV 35S promoter is patented only in European countries and the United States (Pardey *et al.*, 2003).

The availability and actual utilisation of patents to protect plants and plant biotechnologies is proliferating worldwide, as illustrated in Figure 56.1, but is by no means uniform. Utility patent grants in the United States show strong growth trends in all the four technology categories examined, including plant cell and tissue culture technologies, enabling plant biotechnologies, genetic traits and germplasm. By contrast, Europe and Japan show significantly less utility patenting of enabling biotechnologies and genetic traits and none whatsoever of plant germplasm. The WIPO (WO) applications are utility patent applications filed in more than one country through the application process of the Patent Cooperation Treaty. The numbers of these WIPO applications tend to follow US patent granting trends, with the notable

exception of germplasm where multiple country filings are limited. These PCT filings reflect the activity of US firms filing at home and abroad as well as European and Japanese firms filing at their home offices and the United States. Interestingly, plant cell culture technologies are more intensively patented in Japan than anywhere else in the world, while in the other three plant technology categories the Japanese patent office shows very little or no activity.

Genetic Use Restriction Technologies (GURTs)

Despite the expanding scope of legal protection, enforceability and the cost thereof are still major issues. This is especially true when considered at the farm level. Even in the mature institutional environment of the United States, it is generally not directly cost-effective to sue farmers in court for IPR infringement, because the sums at stake and the limits on infringing farmers' assets are usually less than the cost of an average suit. Only the deterrent effects on others' behaviour can justify such actions. In developing countries such as China and India, even hybrid parents cannot be defended against misappropriation for more than a few years. As an alternative to legal and traditional biological measures (i.e. hybridisation), the biotechnology sector is researching new biological means of restricting the copying of germplasm and thus appropriating the returns to innovation. These technologies are collectively dubbed as genetic use restriction technologies (GURTs) (UNEP/CBD/SBSTTA 1999), and they have generated considerable debate, even though no farm application has thus far been developed.

There are two lines of GURTs under development, varietal GURTs (V-GURTs) and trait specific GURTs (T-GURTs). In 1998, US patent number 5,723,765 was granted jointly to the USDA and Delta and Pineland (D&PL), the largest US supplier of cotton seed, for a patent called 'control of gene expression', the first patent awarded to a V-GURT technology (Jefferson, 2001). If a seed producer wishes to protect the genetics embedded in a V-GURT protected seed, she inoculates the seed with a specific regulator that renders the plant infertile before delivery to the farmer, thus making seed-saving infeasible. This type of physical protection, and other variants that require

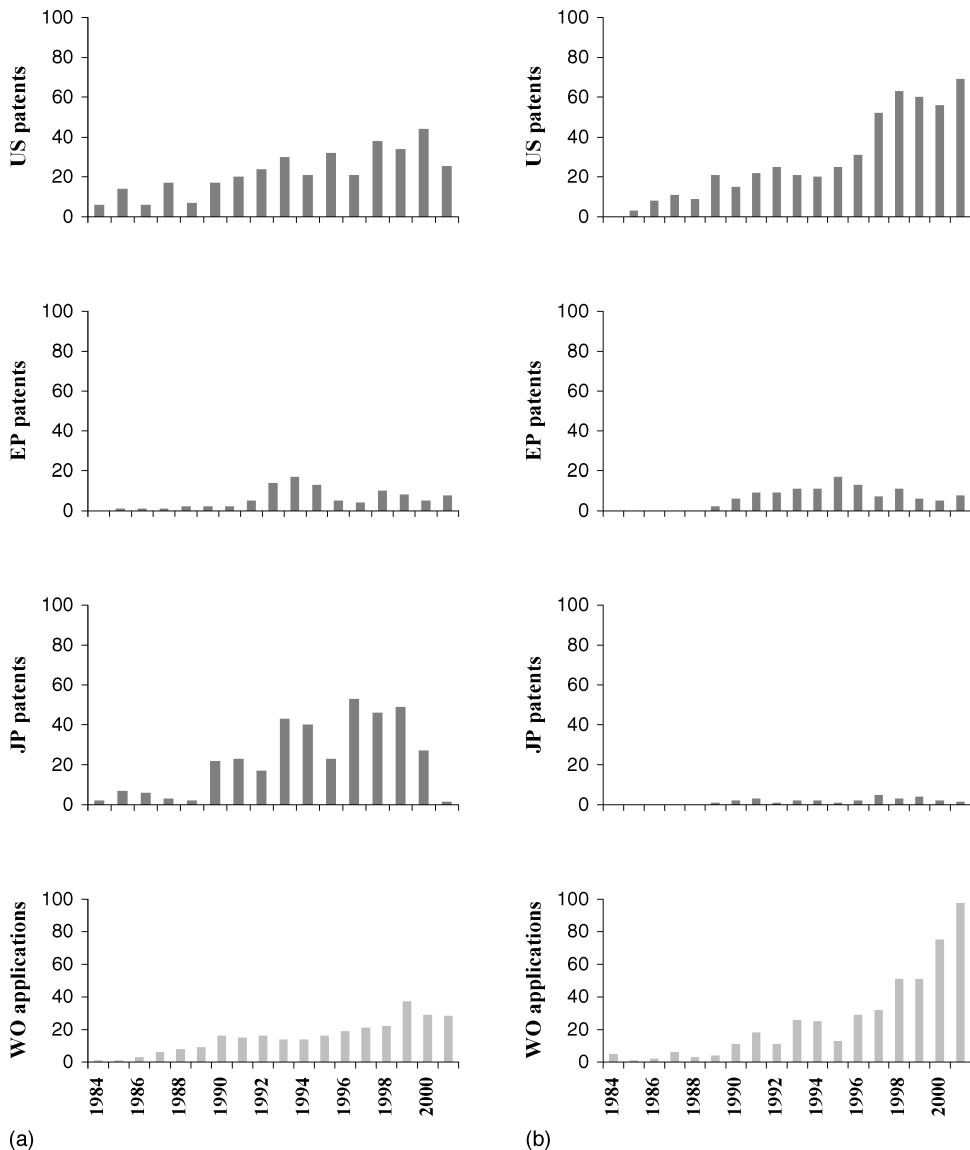


Fig. 56.1 Utility patents granted in the United States, Europe, and Japan and applications filed internationally through WIPO in four major technology areas annually from 1984 to 2001. From a comprehensive dataset of plant biotechnology intellectual property documents by Aurigin Systems, created using rigorous queries based on international patent classification (IPC) codes and technology-related search terms and then organised into technology areas by thematic cluster mapping algorithms. (a) Plant cell and tissue culture technologies. (b) Enabling biotechnologies: vectors, plasmids, transformation, promoters. (c) Plant genetic traits: Bt, herbicide resistance, pathogen resistance, quality modifications. (d) Plant germplasm: primarily soya and maize varieties (Source: Aurigin Systems/MicroPatent).

application of a regulator to induce fertility, have generated substantial opposition on a number of grounds from farmers' groups and other non-governmental organisations. While directly addressing concerns about transgene flows to

second-generation seeds (of the same crop or a cross-fertilised weedy relative), a downside of these 'terminator technologies' is the concern that neighbouring non-transgenic crops may be partially sterilised by a drifting pollen.

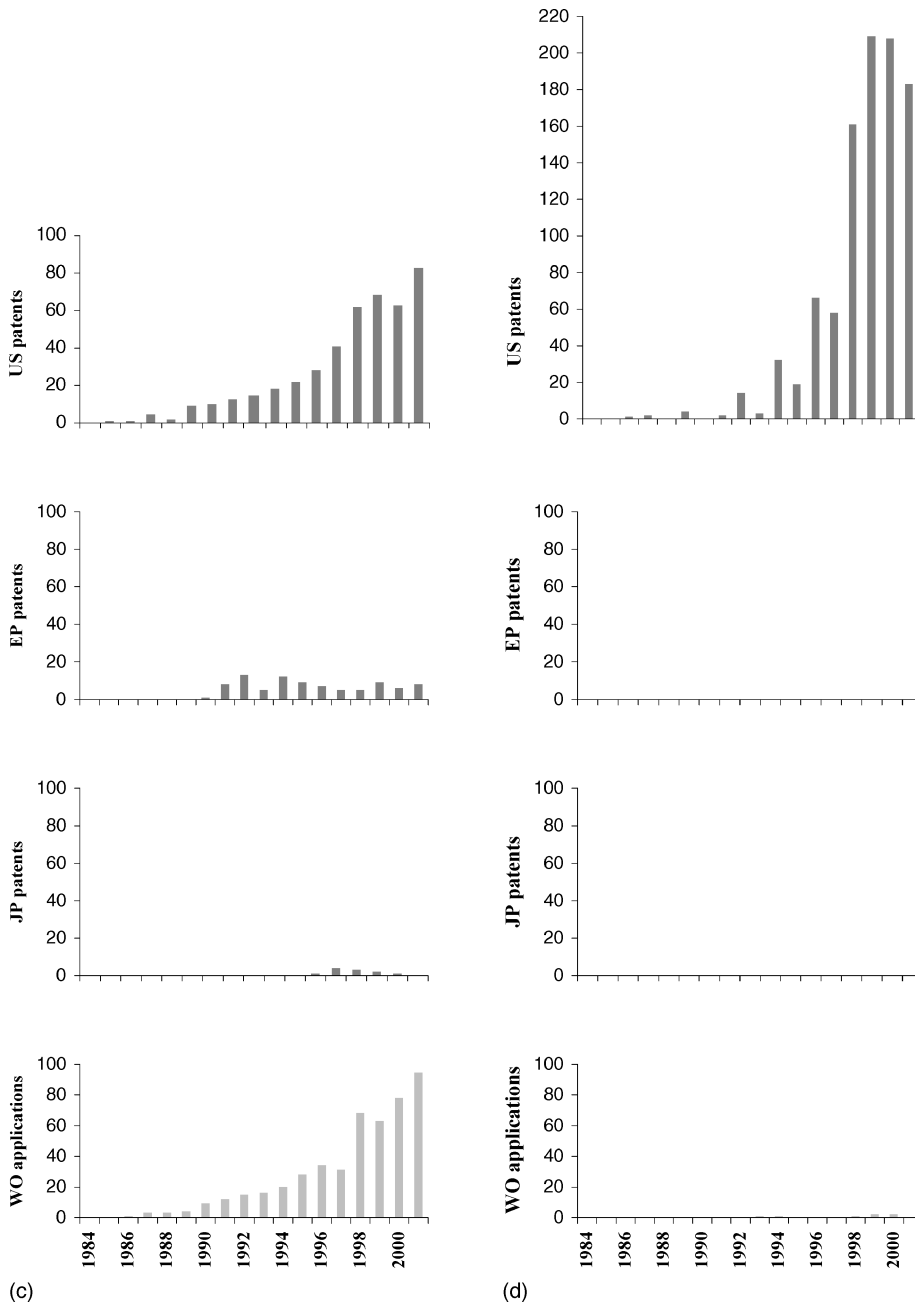


Fig. 56.1 Continued

T-GURTs do not present such a threat of negative externalities. The plant system can be designed so that subsequent generations will be fertile even though they contain the trait gene,

but in an inactive state. Thus, to use a trait in a given year, the farmer must apply an activator purchased from the biotechnology provider. Jefferson (2001) classified these technologies, and patent

applications have been lodged. In addition, USDA (Shoemaker, 2001) suggests that a T-GURT may be activated by a farmer spraying a 'standing crop' with a highly specific and proprietary compound, wherein the fee for using the gene is collected as part of the purchase price of the activator. If such a technology is feasible, the farmer might be able to wait until he is sure the trait, such as disease resistance, is needed before purchasing and applying the activator, in essentially the same manner as a chemical biocide. In this case such a targeted strategy might help reduce selective pressure and the build-up of resistance in the target population. Economic analyses of GURTS include Srinivasan and Thirtle (2000).

Trademarks and Geographical Designations

The identification of a product by the consumer has important bearing on the value of that product. Thus, a registered trademark or geographical designation under which a plant variety or genetic trait is sold can be a significant means of protecting the genetics embodied in the product. Even under conditions where copying of an underlying innovation is extensive, in order to assure quality or performance purchasers will often pay more for a brand name version with a good reputation as compared to a generic or knock-off version, especially when the quality or trait being purchased is not immediately observable. Also, growers will often pay more for a trademarked variety in order to be able to label their produce with the trademarked name because it is known and desired by food consumers and will capture a premium on the final food market. The situation is similar for varieties protected under geographical designation laws: genetically identical varieties not grown in the designated region are unable to claim the designation, and consumers are willing to pay a premium for 'the real thing.'

Tangible Property Rights

Finally, it should be noted that the exercise of rights over physical property can be invoked to prevent dissemination of genetic or intellectual constructs embedded within such physical property. This can be relevant in the research setting, where

a particular vector or other biological material created by a researcher may be treated as their or their employer's physical property (Kryder *et al.*, 2000). This can also be of relevance on the farm, where a supplier of germplasm may lease or lend plants to the farmer under contract, actually retaining legal physical ownership and thus a right to reclaim the property at the end of the contract, or if the contract is breached (Margeules, 2002).

TRANSACTING IPRs

An IPR has value only to the extent that a product or service relying on the underlying technology is profitably commercialised. In agriculture the ultimate commercialisers are usually farmers, and in general it is not feasible for biotech innovators to integrate forward to such an extent that they monopolise production of a given crop. Therefore, transactions in the rights to use the technology in further innovation or production are a key element of modern agricultural biotechnology in the private sector. As countries follow the lead taken by the United States, in the Bayh-Dole Act of 1980 and a series of other legislative initiatives in encouraging the patenting of publicly supported research (see Mowery *et al.*, 2001), such transactions are becoming increasingly important for public and non-profit research organisations as well.

IPR transactions involve a formal or informal contract by which the rights holder waives the right to exclude another party from practising and profitably using the specified invention or technology under specified conditions. In essence it grants permission for the use of an innovation in return for a royalty payment or some other agreed form of compensation. Thus, the transactability of IPRs depends in large part on the ability of the rights holder to detect violations and enforce those rights. This in turn hinges on the nature of the technology (process versus product), the strength of the legal system and the cost of establishing and evaluating an allegation that someone has violated the IPR. We have seen that biotechnologies such as genetic fingerprinting have helped to prove IPR violations, and others such as GURTs could be used to prevent violations directly. The various instruments used in IPR transactions include the following.

Licenses

Licenses are formal contracts between a technology owner and a licensee extending permission to use technology covered by any form of property right according to the terms and conditions of the contract. Permission may be granted on an exclusive or non-exclusive basis, and the conditions of the contract may define or restrict the scope of use allowed by the patent monopoly. Payment for licenses can take many forms, from an up-front lump sum to a running royalty, dependent on value or volume of production. US courts have held that royalties and patent fees cannot be collected beyond the life of a patent, or once a patent has been declared invalid.

Licenses might be restricted to research uses, or permit commercial use. Contrary to popular perceptions, few countries have liberal legal exemptions for use of patented technology in research, even research done by public or non-profit agencies. For instance, the US Congress has the authority to legislate a general research use exemption, but has enacted only a few very narrow exemptions to date (Nottenburg *et al.*, 2002). A recent US judicial decision held that a university could not claim a 'research exemption' as practice of the invention is within its normal business of teaching, raising grant funds and so on.⁶ In 1984, the Drug Price and Patent Term Restoration Act allowed drug companies to proceed with pre-market approval testing of a drug during the life of the relevant patent: in the absence of the exemption, the patent term of a drug was inadvertently lengthened because a generic manufacturer could not otherwise begin testing a product until the patent expired. However, it is unlikely this exemption would apply to patented assays or genes or other inventions that are not themselves the product for which government approval is being sought. In addition, very recently Congress has legislated a highly limited exemption for certain users of patented inventions such as medical or surgical procedures performed by medical practitioners. Among other limitations, this exemption does not include uses of patented machines or compositions of matter, nor 'practice of a process in violation of a biotechnology patent'.

Where offered, research licenses that do not permit any form of commercialisation are often cheaper and easier to get than commercial licenses.

But research exemptions and research licenses are a dubious blessing: Any innovations achieved under the research license may be blocked from subsequent commercialisation by refusal of the rights holder to sign a commercial license. The innovator, with sunk costs of research and dependent on someone else's permission for commercialisation, is thus in a very weak bargaining position, and indeed may be blocked from application of the technology (see Wright, 1998).

An owner of a patent on an enabling technology might offer a license in exchange for royalties on products generated from innovations achieved using the technology. Such 'reach through' licenses are controversial. They give the enabling technology inventor some control over other inventions enabled by their technology, essentially setting up a tollbooth that increases the costs and decreases the incentives for follow-on innovative work. Yet in some circumstances the reach through provisions might be a reasonable means of sharing risk and reward from an uncertain research path. Patents on inputs used in subsequent patented innovations can be quite effective in allocating incentives to both stages of innovation (Koo *et al.*, 2003).

Internationally, patent licenses are often traded in combination with 'know-how' contracts, generating royalties and fees that are major sources of revenue flows for technology providers. In 2001, royalties and fees received by the United States, the largest technology providing nation, were US \$38.7 billion, while it paid US \$16.4 billion to other countries, the bulk of it going to other developed nations. However, US \$21.5 billion of those receipts came from foreign affiliates of US firms and about half (US \$8.6 billion) of US payments went to foreign affiliates of US firms (US Census Bureau, 2001). These figures might well be distorted because of transfer pricing schemes by the parent organisation and its affiliates to minimise worldwide tax payments, taking advantage of differences in tax rates between countries. According to the reported figures it seems that a net US \$9.4 billion of receipts came from arms-length transactions (predominantly non-agricultural).⁷ Given the prominence of international technology transfer issues in international negotiations, some perspective on the potential role of private technology transfer may be gained by noting that this net figure, in which agricultural technologies no doubt have only a minor share, is

substantially less than the US \$11.8 billion spent by developing countries on public agricultural research alone in 1995 (Pardey and Beintema, 2001).

Material Transfer Agreement (MTA)

An MTA is a contract for transfer and use of an input to the research process, either for basic research or for commercial use. The transferred material must have some independent means of intellectual property protection (for example, a patent or trade secrecy), or be a defined piece of tangible property, to provide a basis for preventing its appropriation by third parties. MTAs are often means of transferring material under trade secret protection. They may restrict the user's rights to modify, improve, resell or commercialise the biological material. MTAs are being used by the research centres of the Consultative Group on International Agricultural Research (CGIAR) to control the use of plant varieties held 'in trust' on behalf of the countries of origin in their genebanks (Binenbaum *et al.*, 2003). If access to the materials is not otherwise available, this protection may be effective in preserving the provider's rights over the germplasm. MTAs typically prohibit transfer of material to third parties, although recipients do not always pay attention to these restrictions.

Bag-Label Contract

In selling seeds in developed countries, a contract is often described on a seed bag label. Users of the product are presumed to have agreed to comply with the contract if they break the label to open the bag. Thus, a bag-label contract seems analogous to the 'shrink-wrap' contract common in software transactions. If use of the seed for breeding is found to violate such a contract, then bag label contracts are an additional means of protection of intellectual property. The strength of such contracts is not yet firmly established in case law.

Technology Use Agreement

In recent years in the United States producers of transgenic traits have implemented and enforced 'technology use agreements,' an innovation in

property rights enforcement designed to control the right to plant a given seed type on a specific area of land for a certain period. Their provisions can include compliance with resistance management plans, restrictions on the use of proprietary traits in the reproduction of seed or creation of new varieties, as well as permission for access to the relevant property to check for violations. The latter provision is not popular with farmers. These agreements have the efficiency advantage that royalty collection does not distort seeding rates. The more popular fixed running royalties included in the price per bag of seed, on the other hand, give an incentive to reduce seeding rates below their efficient levels.

EVOLUTION OF INTERNATIONAL ARRANGEMENTS FOR PROTECTING INTELLECTUAL PROPERTY

The current international environment for intellectual property relevant to plant biotechnology is a snapshot of the results of continuing complex interactions between many sets of actors representing many different interests, in many different settings. Before trying to predict how this environment will evolve, it is useful to try to form a balanced appreciation of the current situation. This is in itself a real challenge. Our approach here is to consider in turn four quite distinct, and in some ways conflicting, international agreements.

International Union for the Protection of New Varieties of Plants (UPOV)

Before the International Union for the Protection of New Varieties of Plants (UPOV) came into being, intellectual property protection for plants varied widely between countries. A few countries gave limited rights to plant breeders and (as noted above) the United States had in 1930 legislated a plant patent specifically for asexually propagated plants. But commercial plant breeders and seed sellers considered the general level of protection insufficient. An international standard for plant IPR was sought by these interested parties in 1961. UPOV member nations agreed to institute exclusive property rights in the form of Plant Breeders' Rights (PBRs) to cover plant varieties that satisfy the criteria of distinctness, uniformity,

stability and novelty in the sense that the varieties must be neither found in nature nor previously bred by another breeder.

Over the decades, UPOV has undergone two major revisions—one in 1978 and another in 1991. Table 56.1 provides a summary of the changes. New UPOV members must abide by the version of the treaty in force at the time they joined the Union. Table 56.1 lists the current members of UPOV and indicates which version of the treaty each member has adopted. Membership in UPOV has risen markedly in recent years, with many developing countries now adopting UPOV standards of PBRs. Since admission to the Union under the 1978 Convention has officially closed, most developing countries now joining UPOV must enact national legislation consistent with the 1991 Act, which confers significantly stronger intellectual property rights than the earlier versions.

Differences among versions of the UPOV Acts are a significant bone of political contention between North and South. The 1991 Act extended the length of protection from 15 to 20 years (from 18 to 25 for trees and vines) as well as increased the scope of protection. UPOV 1978 addressed protection for vegetative and reproductive propagating material. UPOV 1991 also included the protection of harvested material as well as anything directly made from the harvested material *and* any variety that is ‘essentially derived’ from the protected variety. According to the 1991 Act, essentially derived varieties may be obtained, for example by a genetically engineered transformation.⁸ If, for instance, the holder of a patent on a gene were to insert the gene into a variety that was protected under PBR, it seems that the gene patent holder would have produced an essentially derived variety and would not be able to exploit the new variety without permission from the person holding the PBR (Jordens, 2002). The language ‘essentially derived’ has not yet been clarified in judicial decisions, but the effect is to bring plant breeders’ rights a little closer to patent rights, strengthening the bargaining power of holders of PBR in negotiations with biotechnology providers.

The 1991 Act also strengthens PBRs by broadening protection to encompass the reproduction, conditioning, exporting, importing and stocking as well as the commercial production and sale of the protected variety. For developing countries, changes in the UPOV Acts with regard to farmers’

rights are particularly relevant. The 1978 Act implicitly provided exemptions for farmers to save seed for replanting, and many countries maintain this convention in some form. The 1991 Act explicitly prohibits farmers from exchanging seed protected by a PBR. The language leaves open the possibility that member countries require farmers to compensate breeders for the replanting of saved seed on their own land.

The structure of protection afforded by UPOV is consistent with the interests of seed producers who desire open access to breeding materials but protection against competition from other commercial seed sellers who might buy their seed and reproduce it for sale or export, or use it for repetitive production of hybrids (as distinct from breeding a novel cultivar). PBRs offer at best only modest incentives for innovative breeding—though this might not be important for clonally propagated plants—not least because they make protected parents freely available for subsequent rounds of breeding and experimentation. A study of the United States wheat market indicates that the introduction of plant breeders’ rights in 1970 in the form of plant variety protection certificates did not have any significant effect on breeding performance (Alston and Venner, 2002).

Trade-Related Aspects of Intellectual Property (TRIPS)

The second and currently most influential major international treaty affecting plant-related intellectual property is Trade-Related Aspects of Intellectual Property (TRIPS), a multilateral agreement between the 134 WTO member countries negotiated during the 1986–94 Uruguay round of the General Agreement on Tariffs and Trade (GATT). TRIPS requires member countries to pass legislation setting minimum standards for all major types of intellectual property rights (copyright, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits and trade secrets). Further, it details how countries should enforce these rights and how disputes are to be resolved. In this respect it carries substantial legal weight; countries can be penalised with trade sanctions if they do not comply with TRIPS. As with UPOV, the language of the agreement does not mandate global harmonisation

Table 56.1 Affiliation of countries with major international intellectual property agreements as of 2002

	UPOV act in force	Deadline to join TRIPS	CBD*	IU
Argentina	1978	2000	•	•
Australia	1991	1996	•	•
Austria	1978	1996	•	•
Belarus	1991	Non-member	•	
Belgium	1961/1972	1996	•	•
Bolivia	1978	2000	•	
Brazil	1978	2000	•	•
Bulgaria	1991	1996	•	
Canada	1978	1996	•	•
Chile	1978	2000	•	•
China	1978	2000	•	
Colombia	1978	2000	•	•
Croatia	1991	2000	•	
Czech Republic	1991	1996	•	
Denmark	1991	1996	•	•
Ecuador	1978	1996	•	
Estonia	1991	2000	•	
Finland	1991	1996	•	•
France	1978	1996	•	•
Germany	1991	1996	•	•
Hungary	1991	1996	•	
Ireland	1978	1996	•	•
Israel	1991	2000	•	
Italy	1978	1996	•	•
Japan	1991	1996	•	
Kenya	1978	2000	•	
Kyrgyzstan	1991	1998	•	
Latvia	1991	1999	•	
Mexico	1978	2000	•	
New Zealand	1978	1996	•	
Nicaragua	1978	2000	•	•
Norway	1978	1996	•	•
Panama	1978	1997	•	
Paraguay	1978	2000	•	•
Poland	1978	2000	•	
Portugal	1978	1996	•	•
Republic of Korea	1991	2000	•	
Republic of Moldova	1991	2001	•	
Romania	1991	1996	•	
Russian Federation	1991	Non-member	•	
Slovak Republic	1978	1996	•	
Slovenia	1991	1996	•	
South Africa	1978	1996	•	
Spain	1961/1972	1996	•	•
Sweden	1991	1996	•	•
Switzerland	1978	1996	•	•
The Netherlands	1991	1996	•	•
Trinidad & Tobago	1978	2000	•	
Ukraine	1978	Non-member	•	
United Kingdom	1991	1996	•	•
United States of America	1991	1996	•	•
Uruguay	1978	2000	•	•

Source: UPOV information: <http://www.upov.int/en/about/members/pdf/members.pdf>

TRIPS information: <http://www.wto.org/english/tratop e/trips e/tripfq e.htm#Transition>

CBD information: <http://www.biodiv.org/world/parties.asp>

IU information: <http://www.fao.org/Legal/treaties/033s-e.htm>

* Indicated countries are parties to the CBD. The United States has signed the Convention, but has not yet agreed to be legally bound by it.

Table 56.2 Parallel evolution of the four major international agreements

Year	UPOV	TRIPS	CBD	IU/IT
1961	<i>Established</i>			
1972	<i>Revised</i>			
1978	<i>Revised</i>			
1983				<i>IU starts as non-binding FAO resolution: "Common Heritage of Humankind"</i>
1986		<i>Uruguay Round GATT negotiations begin</i>		
1988			<i>Formal negotiations begin</i>	
1991	<i>Revised (breeders' rights strengthened)</i>			<i>Amended by FAO resolution "subject to sovereignty of states over genetic resources"</i>
1992			<i>Opened for signature</i>	
1993			<i>Entered into force</i>	<i>In light of CBD, IU needs to be revised IT negotiations start</i>
1994				
1995	<i>Closed to entrants under UPOV 1978 except for exceptional circumstances.</i>	<i>Entered into force subject to extensions for certain countries</i>		
2000		<i>Developing countries & some transitioning economies with extensions must comply with TRIPS</i>		
2001				<i>IT is signed</i>
200?				<i>Enters into force when ratified by 40 countries</i>
2006		<i>Least developed countries with extensions must comply with TRIPS</i>		

of intellectual property rights. Rather, it leaves individual member countries the flexibility of designing their own legislation as long as they are effective in meeting certain minimum standards. Developed countries were required to comply by 1 January, 1996, while developing countries were

given time till 2000 unless they were extending patent protection to previously uncovered areas. In such a case they received an extension until 2005. Countries in the 'least developed' category were granted a further extension until 2016 for pharmaceuticals. Table 56.2 lists WTO members

and their dates of compliance. Note that not all developing countries are members of the WTO.

Background of TRIPS

As Braithwaite and Drahos (2000, pp. 203–4) noted, ‘It was an implausible accomplishment to persuade a trade liberalisation regime to incorporate a major new form of trade regulation, to persuade a body concerned to increase competition in the world economy to extend the life of patent monopolies and other intellectual monopoly rights. Moreover, it was a remarkable accomplishment to persuade 100 countries who were net importers of intellectual property rights to sign an agreement to dramatically increase the cost of intellectual property imports’.

The accomplishment appears even more impressive if one accepts recent evidence that GATT and the WTO have had no similarly transformative effect on trade policy (Rose, 2002a,b). To understand the evolution of this and other relevant agreements it helps to know something about how the TRIPS process was initiated. Part of the answer lies in the spread of the economic idea that regulations (including GATT regulations) do not necessarily hamper market performance; some rules are often needed to make markets work at all. Part lies in the Schumpeterian notion that monopoly can be an instrument of ‘creative destruction’, encouraging innovation that ultimately benefits consumers as prices are lowered and product quality improved over time—dynamic benefits that outweigh the static losses incurred when products embodying protected IP are sold at prices above their marginal costs of production.

It was less widely recognised that the theoretical economic argument for using patents to spur private innovation (rather than relying on public provision, research grants or contracts or prizes to inventors) depended on the existence of information on the value of innovations held by innovators but inaccessible to the public sector (Wright, 1983). Nor was empirical evidence about patents a major influence on the strengthening of patents and their worldwide proliferation. Indeed, while the treaty was being negotiated, a comprehensive survey was revealing that patents were not considered by firms in most sectors of US business to be a major incentive for innovation, with the prominent

exceptions of chemicals and pharmaceuticals (Levin *et al.*, 1987). Economists were (and remain) far more ambivalent on the desirability of patent systems than they are on the merits of freer trade.

Dutfield (2002) provides an informative account of the origins of TRIPS, starting with the story of how groups favouring stronger IPR protection were able to define the problem as trade-related and link it to the GATT negotiations.⁹ The first attempt to do so was part of an anti-counterfeiting push by Levi Strauss, anxious to defend its trademark worldwide. The firm led a coalition to include the issue in the 1973–1979 GATT Tokyo round (Doremus, 1996). Though this failed, the copyright, semiconductor and patent-holding interests joined in framing the lack of overseas IPR protection as an important trade-related issue for the United States. In this environment, difficulties presented to subsequent innovators by excessive, incompatible and overlapping IPR were not a major concern. The prime movers in this effort were Edmund Pratt of Pfizer and John Opel of IBM together with influential lawyers and consultants (Braithwaite and Drahos, 2000, pp. 203–4). The developed country and internationalist orientation of GATT (versus UNCTAD as an alternative) had the advantages of inclusion of all IPR concerns in a single package, the opportunity for linking IPR with trade access benefits, and the GATT dispute resolution mechanism.

Then, as now, the principal advocates of IPR expansion were parties with existing IPR assets rather than those busy constructing new IPR portfolios. Motivation for the policy seems to be more the potential profits from existing assets rather than encouragement of innovation. This orientation fit the national mood of the United States in the 1980s, beset by high-tech competitors, distressed at a perceived decline in national innovation and resentful that others seemed to have prospered at the expense of the United States by stealing, or paying too little for, its vast existing stock of IPR. Capitalising on this emerging political climate, corporate interests expressed their influence on Congress in the 1974 Trade Act and the 1988 Omnibus Trade and Competitiveness Act. These industrial interests gained disproportionate weight via creation of the office of the US trade representative (USTR), weakening the power of the State Department to bring broader national interests to bear on trade policy. Power over

trade was also shifted from the treasury, with an economy-wide mandate, to commerce, with a more focused business orientation.

Section 301 of the 1974 Trade Act, strengthened in 1984 under pressure from the copyright industries (Ryan, 1998, p. 11), and again in 1988, defined failure to protect IPR as an unfair trade practice to be investigated and, if necessary, sanctioned. Though, as a group, developing countries resisted the inclusion of IPR in GATT, the threat of bilateral Section 301 sanctions by the United States, and their actual imposition on Brazil, helped bring the developing countries to the negotiating table. As US observer Ryan (1998, p. 108) put it, the Brazilian sanctions were part of a plan 'to bully developing countries to the GATT negotiating table. The action was intended to signal that negotiations could go on one-by-one under threat of bilateral trade sanctions, or they could take place within the GATT round, but negotiations would take place'. For developing countries, the choice of forum was not between GATT and WIPO, but between GATT and USTR. Forced into the latter choice, developing countries saw more bargaining leverage in GATT (see Ryan, 1998, pp. 110–11).

As in the GATT negotiations generally, bargaining over the TRIPS agreement did not necessarily reflect the national interest of the United States or the countries of the North, but was closely monitored and influenced by members of highly interested parties in the North, in this case the international pharmaceutical, chemical, semiconductor, trademark and copyright industries. In the words of one participant (Enyart, 1990 quoted in Dutfield, 2002) 'Industry has identified a major problem for international trade. It crafted a solution, reduced it to a concrete proposal and sold it to our own and other governments'. Poor countries, in collaboration with some rich country interests, including environmentalists, were quick to learn the benefits of forum shifting and seizure of the initiative in the international arena, as will become evident below.

Patentability of Plants in TRIPS

The TRIPS agreement mandates that all member countries legislate a patent system based on commonly accepted tenets of patentability. A

patentable product or process must satisfy the four traditional requirements of novelty, non-obviousness, usefulness and enablement. As discussed above, the interpretation of these requirements in the field of biotechnology differs among countries (also see Figure 56.1). Leskien and Flitner (1997) provide a detailed examination of the language of TRIPS and how it relates to plant genetic resources. Ultimately, the interpretation of what TRIPS mandates as patentable in the field of plant biotechnology will require resolution in the dispute settlement processes of the WTO. The following paragraphs highlight some areas of the language for which subsequent interpretation will have a major impact on the international structure of IPR legislation for plants.

The TRIPS agreement states that microorganisms and microbiological processes are patentable subject matter. However, no definition for microorganism is offered although one possible interpretation is that provided in 1995 by the European patent office (EPO), which defined microorganisms as 'all generally unicellular organisms with dimensions beneath the limits of vision, which can be propagated and manipulated in a laboratory'.¹⁰

Member countries are allowed to exempt from patentability several categories of inventions. 'Essentially' biological processes may be excluded. The word 'essentially' differentiates these processes from 'purely' biological processes, which would not be patentable because they would lack an inventive step. Like 'microorganism', though, the term 'essentially biological processes' is not defined in TRIPS.

Article 27(2) allows for the exclusion of inventions whose commercial exploitation will threaten *ordre public* or morality. In its guidelines for examination, the EPO interprets the term *ordre public* as referring to 'those inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour'. For 'plant cells and plant genetic systems' the EPO extended the term to cover inventions that 'seriously prejudice the environment'.¹¹ This clause allows the exclusion of transgenic plants so as to avoid possible environmental damage.

Article 27(2) has also been interpreted as permitting legislation that refuses a biotechnological patent application on grounds of 'morality' unless it discloses the source of the genetic material, along

with documented permission from the country (or community) of origin. Several countries have already introduced national legislation regulating the patenting of plants along these lines. With regard to the genetic material of microorganisms, however, the requirement of patentability is clearly spelled out in TRIPS, and thus the introduction of this 'permission for use' exclusion will depend crucially on interpretations of Article 27(2).

Perhaps most importantly, Article 27(3) of TRIPS states that all plants may be excluded from patentability, provided the member country adopts alternative intellectual property legislation such as PBRs or any other 'effective *sui generis*' system to cover plant varieties. *Sui generis* in Latin means 'of its own kind', and in TRIPS the phrase is used to indicate a flexibility whereby member countries can individually design a system of plant variety protection that works for their country. It is important to note that *all plants* can be excluded from patentability while the alternative form of protection (or a combination of forms including patents) is required to cover only new *plant varieties*. Neither of the terms 'effective' nor 'plant variety' is defined within the TRIPS document.

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) is the third major international treaty affecting plant IPRs. The CBD began as an international initiative to conserve flora and fauna *in situ*, responding to field research that suggested an alarmingly high rate of species extinction. The International Union for the Conservation of Nature (IUCN), an international non-governmental organisation, played a major role in the CBD. In 1987 the United States proposed the Convention to the Governing Council of the United Nations Environment Programme (UNEP), which began drafting an international treaty in 1989 that sought to address the conservation of biodiversity from a sustainable use perspective. The CBD was opened for signature in 1992 and entered into force in 1993. 186 countries are now party to the convention (see Table 56.1).¹² All developed countries except the United States have ratified the convention.

The language of the CBD reaches well beyond the conservation objectives envisaged by the

United States and the IUCN. Developing nations encompassing centres of biodiversity saw the initial conservation agenda as threatening their rights to exploit the economic benefits of their forests and other biodiversity resources, and pressed for fair and equitable sharing of the benefits of conservation sought by nations and non-governmental organisations based in the North. Aware that many pharmaceutical products worth billions of dollars were based on products of nature, some participants envisioned that royalties from biodiversity-derived products could be the basis for sustained *in situ* conservation of biodiversity in developing countries, and constitute a significant source of wealth for those countries rich in biological diversity. This vision was encouraged by the hugely publicised bioprospecting agreement between Merck and INBIO of Costa Rica, involving an initial commitment of over one million dollars, plus unspecified future royalties. The hostile response of many conservationists to the Simpson *et al.* (1996) valuation study—the logic of which showed how it was virtually impossible that revenues earned from bioprospecting would be sufficient to save many biodiversity hot spots—revealed how firmly the vision had captured their collective imagination, although other conservationists more experienced with the reality of bioprospecting shared their skepticism (for example, Feinsilver and Chapela, 1996).

Inspired by overly optimistic expectations, which generalised from pharmaceutical products to germplasm for agriculture, the CBD became increasingly focused on biotechnology, technology transfer, and intellectual property rights (Dutfield, 2002). One of the most noteworthy aspects of the CBD is its assertion of national sovereignty over biological resources. While this enables contractual agreements between national governments and 'bioprospecting' companies, it does not necessarily ensure that the interests of relevant parties or communities of origin (such as the indigenous peoples of Chiapas in Mexico) would be well represented.

Nevertheless, the CBD gave the claims of indigenous peoples new prominence on the international scene. In order to facilitate sustainable use, the CBD advocates the establishment of property rights for both indigenous knowledge and genetic resources. It was the first international treaty to promote the rights of indigenous populations in the debate over access to biodiversity (Diaz, 2000).

Once rights are established, contracts can exist between the nations (or indigenous populations) holding the resource rights and those standing to benefit from their exploitation (biotechnology or pharmaceutical firms in developed countries).¹³ Benefits generated from the use of the resources can then be shared with the owners and used to promote conservation (Boisvert and Caron, 2000). The CBD furnishes general guidelines that signatories to the convention are obliged to translate into national legislation. Access and benefit-sharing legislation has become an important influence on the transfer of genetic resources between countries, but not perhaps as intended by the CBD.

According to an FAO survey in 2000 (Wendt and Izquierdo, 2000), eight Latin American countries (the Andean Group, Brazil, Costa Rica and Paraguay) had adopted legislation regarding access to their country's genetic resources, including requirements that granting IPRs may be contingent on whether the origin of the genetic material is disclosed and permission for its use documented (Dutfield, 2002). The Organisation of African Unity (OAU), representing 53 African nations, has developed a model law setting detailed objectives for national legislation referring to access and benefit sharing as 'the duty of the State and its people (Diaz, 2000)'. In practice, access and benefit sharing provisions vary greatly among countries, depending in part on the significance given to environmental protection within a nation's governmental structure (Carrizosa, 2002). The main practical effect to this point has been to slow or shut down international bioprospecting activities for both scientific and business purposes in many countries, beginning with pharmaceutical bioprospecting, and extending to agricultural genetic resources.

Another notable impact of the CBD has been to inject the interests of developing countries rich in natural resources, and of environmentalists (mainly from developed countries), into the IPR debate. The biennial meetings of the conference of parties on implementation of the CBD provide an alternate forum for debate on trade and IPR policy, involving partners in developed and less-developed nations with a more conservation- and less commercially-oriented agenda than typically represented in WTO and TRIPS fora. As the debate matures and moves beyond issues of 'bio-piracy' (Odek, 1994; Shiva, 1997) and unrealistic

economic expectations from bioprospecting, there is some reason to hope that access of scientists and plant breeders to centres of diversity might be restored on terms beneficial to all parties.

The International Treaty on Plant Genetic Resources for Food and Agriculture

The fourth and final major international agreement considered here, and the one most focused on the interests of plant breeders and farmers, is the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA). This is a new agreement with a complicated history and an unclear mandate. It was denoted an 'international undertaking' when initiated by the FAO in 1983, after some developed countries and seed industry representatives opposed an earlier proposal for a legal convention. The negotiations began as a *process* or *undertaking* designed to facilitate the exchange of germplasm, and to encourage utilisation and conservation of plant genetic resources. In the 1983 version of the international undertaking, germplasm was designated 'the common heritage of mankind', a term adopted in discussions leading to the 1972 UN Conference on Human Environment in Stockholm in 1974 (Brush, 1996; Brush and Stabinsky, 1996) to denote resources such as the oceans and atmosphere that provide benefits to all humans (Joyner, 1986), with the recognition that the special conditions of agriculture made free exchange necessary. In 1993, negotiations on a legally binding treaty, the IT-PGRFA, were started as a way to keep a subset of agricultural plants in an international exchange system and not under the CBD mandate of national sovereignty. A major milestone in the process was the 1996 Leipzig Conference and the adoption of the global plan of action, a document planning for concerted international efforts on the collection, conservation and exchange of plant genetic resources for agriculture. Throughout the 1990s the tone of the international undertaking was revised to take into account changing perspectives on the ownership and international exchange of germplasm. Finally, in November 2001, a treaty emerged governing international exchange of agricultural germplasm, which becomes legally binding once ratified by 40 countries. By November 2002, one year after the

treaty negotiations concluded, it had been signed by 58 countries and accepted or ratified by eight.

The IT-PGRFA exists in a legal and political space between the Convention on Biological Diversity and the TRIPS agreement. The treaty seeks to preserve aspects of a free exchange system for germplasm that is seen as fundamental to global food security. In parallel with the process of a TRIPS-induced strengthening of IPR in agriculture, the Convention on Biological Diversity identified property rights as a useful instrument for promoting conservation. The fundamental change in stance with respect to genetic material was the CBD's introduction of 'national sovereignty' over materials derived from biodiversity, which directly contradicted the international undertaking's idea of 'common heritage'.

The IT-PGRFA will have to address a long history of free exchange of genetic material. Free exchange was an underlying premise behind assembling global collections of agriculture, with the goal of discovering, documenting and conserving materials, while sharing the immediate benefits and future options globally. Behind the system of free exchange, however, there lay an implicit, unarticulated bargain—that primary materials from developing countries were available in exchange for access to elite materials from developed countries. While the actual flow of germplasm is much more complex, there is an impression that this bargain has begun to fall apart within the new legal environment. The system of free exchange has slowed in recent years, endangered from one side by the rise of CBD-type national sovereignty and from the other by TRIPS-mandated intellectual property rights.

The focus of the IT-PGRFA is the creation of a multilateral system where member states designate which plant materials they wish to share, and all materials included can then be accessed by all other members. Exchange of materials is to be governed by a common material transfer agreement (MTA) and without any further bilateral negotiations. If any material accessed from the multilateral system is later subject to IPR protection, the IPR holder will owe royalties to a fund managed by the treaty.

'Farmers' rights' are mentioned in the text of the agreement, but are not legally defined. However, the provisions on access and benefit sharing address equity concerns of contributing

parties, including, prominently, groups of farmers in developing countries, by designing financial instruments to compensate for the use of their primary materials. Using the IPR protection of derived material as a trigger for the payment of royalties could cause distortions in the way that the multilateral system is used. The need to develop complex and potentially costly systems to track material accessed from the system through to a final 'derived product' will be expensive, possibly to the point of limiting exchange and diverting funding away from conservation or benefit sharing. The present agreement is restricted to 40 crops, including all of the major staple crops such as rice, wheat, maize, potato and beans (but notably excluding soybeans). In the final negotiations the Latin American countries proposed to include tropical legumes in exchange for inclusions by countries of Africa of a set of tropical forage crops, but ultimately neither was included.

The germplasm collections and activities of the CGIAR centres play a special role in the multilateral exchange system. In 1994 the IPR over existing *ex situ* genebank accessions was ceded, in trust, to the FAO, which is the implementing body of the treaty. To what extent the CGIAR will now be required to track all shipments and collect royalties is unclear, but the new system will be a further development of the current process involving MTAs on all germplasm shipments. The treaty could be creating a new role for the CGIAR, as the global policeman and judge of crop genetic resource disputes. This could hinder applied development and drag the CGIAR toward a political role that it has typically avoided. The collections, the status of new accessions and the exchange of germplasm through the CGIAR are the focus of continuing negotiations, and the whole system could be jeopardised if countries seek to assert ownership over material that was previously collected under a free exchange regime.

The final negotiations of the treaty saw delegates divided into geopolitical groups. The developing countries negotiated as a single bloc, called the G-77. Among the notable countries leading the G-77 were Iran and Ethiopia, countries with large endowments of agricultural biodiversity, who sought to gain from royalties but also took a hard line against patenting of genetic material. The large number of G-77 countries that are primarily recipients of materials, such as those

in sub-Saharan Africa, followed the lead of their biodiversity-rich peers.

The European countries provided a compromise position in the negotiations. Europe had paid for the ongoing treaty negotiations and had tried to move the rest of the delegates toward compromise. The United States position had two main objectives: to protect the patenting of improved plant materials, and to preserve the free exchange of 'raw' genetic materials. Though some negotiators saw these as contradictory, they are consistent with the widely held view that discoveries should not be patentable. The support for a strong patent system, and for the TRIPS goal of expanding the international use of IP protection, resulted in strong opposition to any language that would limit the ability of private parties to patent genes. The United States was reluctant to endorse the cumbersome record keeping that the treaty could create, and to incur future liability for material already used by private breeders.

The practical mechanisms for tracking and documentation will be critical to whether or not the multilateral system can be workable, keeping the costs of each transaction low enough to approximate the system of free exchange. For any material accessed from the system, the Treaty's governing body will have to develop a common MTA, and a database to ensure that all parties involved comply with the access agreements, and to track future utilisation of material. The initial constructions of databases and legal structures are feasible. However, the longer-term tasks of tracking all materials utilised, calculation of coefficients of parentage of future cultivars released and assessment of royalty payments from the multiple parents of a finished variety will be extremely challenging.

The future of the treaty will be influenced by the evolution of the role of the United States. During the final negotiations of the treaty in November 2001, the US delegation opposed the treaty, because of reservations about the intellectual property provisions, facilitated access to private materials and, in the recent wake of September 11, 2001 insistence on a 'security clause'. The United States signed the treaty in November 2002, and will thus be in a position to attend the future negotiations of the governing body and participate in the drafting of the MTA. Whether the United States will ratify the treaty remains to be seen; it

signed the CBD, but never ratified it. During the negotiations of the International Treaty, specific provisions were included about the 'treatment of non-parties' to make it more difficult for countries not joining the multi-lateral system to access materials.

CURRENT INTERNATIONAL FREEDOM TO OPERATE IN PLANT BIOTECHNOLOGY

For plant breeders and other users of plant biotechnology, current freedom to operate internationally, especially in developing countries, is far greater than generally realised by many critics, although many firms are acutely aware of how little control they have over the copying of their technologies in most countries. Well-publicised news stories of donations of intellectual property rights for 'Golden Rice' or virus-resistant potatoes or sweet potatoes for use by poor farmers in developing countries imply that such rights would otherwise constrain such research and innovation in those developing countries. But in general that is not true, because innovators have been either unable or unwilling to file for patent protection in many developing countries (Nottenberg *et al.*, 2002). Moreover, the main staples for the poor in such countries are largely consumed domestically; the portions exported to countries such as the United States or those in Western Europe, where imports are subject to relevant domestic patents, is typically small (Binembaum *et al.*, 2003).

Nevertheless, there is a widespread belief in much of the international agricultural research community that the US patent system is hindering access to important plant biotechnologies for developing countries. For example, a survey by Taylor and Cayford (2002) shows that about two thirds of 'stakeholders' with interests in plant breeding, intellectual property and agricultural development report that US patents adversely affect the ability of researchers to access and use specific gene traits, transformation tools, transformation marker systems and genetically modified germplasm for developing country purposes (Taylor and Cayford, 2002). The survey reminded respondents that US patents are legally enforceable only in the United States. Although many of the respondents were located in developing countries, it seems that they perceived that

the United States used its funding of international aid as a means of *de facto* extension of patent rights. Taylor and Cayford (2002) referencing communications with Walter Falcon, Director of the Center for Environmental Science and Policy at Stanford University and Tim Reeves, former Director General of the International Center for Maize and Wheat Improvement (CIMMYT) in Mexico, state that 'National agricultural research systems and CGIAR institutions could jeopardise their funding if they systematically violated US patents to develop useful applications of biotechnology'. This talk of 'violation' indicates that the *de facto* reach of US patents has extended well beyond their legal, if not their political, reality.

Plant breeding is not greatly affected by developments in UPOV, because UPOV offers limited incentive to breeders of varieties where valuable traits can be acquired by cross breeding. UPOV does however have the potential to help protect the breeding of hybrids by protecting the use of parent lines, although in the United States, where they have the choice, breeders are opting for the stronger protection of utility patents in lieu of the weaker PVPCs. Indeed some observers (Janis and Kesan, 2003) view patents as virtually trumping plant breeders' rights consistent with UPOV, by effectively giving patent protection to plants via protection of their patentable elements.

The CBD and the International Treaty have little current relevance for freedom to operate because breeders in general make modest use of non-elite germplasm, and much of what they do need is already collected in *ex situ* genebanks and working collections maintained by public and private breeders (Wright, 1997). But they have created fora in which the interests of developing countries, and parties in developed countries with concerns beyond those of industry participants, gain recognition and influence. The experiences of India, China and Brazil, from their experiments with intellectual property protection, might well move them solidly into the pro-IPR camp. Following historical precedent (Lerner, 2002) the lead will be taken by emerging R&D intensive industries within those countries who find domestic protection of their own innovations more valuable than the freedom to copy technologies and sell them as generics in an environment of unfettered competition. And indeed, the size

of that domestic economy will matter in such a decision: 'Large versus small economy' may become at least as crucial a determinant of intellectual property policies as 'rich versus poor'.

The Future of International IPR and Freedom to Operate

Internationally the future of freedom to operate and private incentives in plant biotechnology hinges on the evolution of international negotiations of TRIPS and on the levels of enforcement actually exercised in countries worldwide. The developed country stance on IPR has recently been effectively spearheaded by the United States, where utility patents are coming to dominate the IPR system for plant biotechnology and breeding. The United States is pressuring other countries globally to adopt similar IP regimes.

Yet, as a template for worldwide adoption, the US patent system suffers from a number of apparent shortcomings. Foremost among these are its overly permissive patenting criteria (Barton, 2003), new and surprising evidence of which has recently come to light. Quillen (2002) estimates that in the mid-1990s the allowance rate (patents granted per patent filed with a two-year examination lag), corrected for continuing applications, was 83%, whereas the allowance rates in Europe and Japan were 68% and 65%, respectively. Critics also claim US patent examiners tend to ignore prior art beyond the scope of their own electronic database. Others point to the cursory examination processes of countries such as Australia and South Africa as being more problematic. To control against the abuse of blocking patents, the United States (along with European countries, among others) rely on their anti-trust mechanisms to control against market manipulations based on patent positions, mechanisms that are not available in many developing countries. Scientists have complained that the system hampers research by restricting access to research tools (NRC, 1998). The system depends upon the expensive court system to clean up errors and excesses allowed by a patent office that happens to be a profit centre for the federal government. And finally, US examination policy is criticised because it does not require recognition of origin of biodiversity inputs used in innovation.

Nonetheless, there are features of the US patent system worth emulating; relatively competent examiners, well documented, consistently implemented and transparent procedures, avenues of redress, a specialised court system to hear patent appeals and internal boards of review to monitor and assess patent granting practices.

Prior to the failed 1999 Seattle WTO Conference, the United States, with some support from Europe and Japan, appeared ready to raise the standards in TRIPS by eliminating the exclusion in Article 27.3(b) with respect to the patentability of plants and animals (Dutfield, 2002). Developing countries responded with several proposals. One recommended that patents inconsistent with the CBD provision of national sovereignty over access to genetic resources should not be granted. Another sought to modify Article 27.3(b) in a number of ways: to exempt the World Health Organization's list of essential drugs, to clarify distinctions between biological and microbiological organisms and processes, to allow for seed saving and to prevent anti-competitive threats to food sovereignty in developing countries. There were also proposals to protect the traditional knowledge and resources of indigenous peoples (Dutfield, 2002).

At the November 2001 Doha meeting of the WTO, discussions related to TRIPS were dominated by health issues in general, and access to AIDS drugs in particular. The United States was fighting a post-September 11th anthrax scare, and the secretary of health and human services was threatening to source the drug ciprofloxacin (Cipro) from elsewhere if it did not receive a sufficient discount from the patent holder, Bayer. Thus, the United States was in a poor position to oppose compulsory licensing of domestic manufacturers of drugs in an emergency.¹⁴ According to Correa (2000), the TRIPS agreement allows compulsory licensing for failure to work the patent, for health or other emergency, for resolving anticompetitive behaviour, for noncommercial use and for bestowing freedom to operate on dependent patents blocked by a previous patent.

One significant achievement of the Doha conference was to publicise and confirm the power of these compulsory licensing provisions. But their use is restricted by the TRIPS requirement that the compulsory licensing be only for domestic use,

and not for import and export. This restriction precludes, for example, importation of infringing generics to ameliorate a health emergency in Africa. The poorer and smaller is the country, the less is the potential of compulsory licensing to solve problems of access to technologies. If the TRIPS restriction to domestic use were lifted or converted to a regional restriction, compulsory licensing could be used to gain freedom to operate in the complex technologies with multiple claimants of IPR, a situation commonly seen in agricultural biotechnology.

Market segmentation and price discrimination are keys to effective global provision of modern biotechnologies to farmers by the private sector. Otherwise, poor farmers are likely to be 'priced out' of the market for these technologies, input providers will make less profit, and local consumers will face higher prices. Only competing suppliers will gain. One worrisome development is that suppliers of transgenic pest resistant cotton to Argentina appear to have been charging the same price as in the United States, even though the technology is less important for crop protection in Argentina, and the price is more than double the farmers' willingness to pay (Qaim and de Janvry, 2002). This suggests that the US farm lobby is pressuring the technology supplier to effectively foreclose the technology from its competitors. The low price of Roundup Ready soybeans in Brazil has indeed led competing US farmers to press successfully for a general accounting office inquiry. Barriers to global trade in new technologies appear in this case to be extending well beyond the implications of intellectual property right laws in an otherwise competitive global market for technology.

Some kind of licensing market segmentation is also a key part of any strategy to take account of the needs of those currently not well served by commercial agricultural biotechnology. Effective segmentation could create an IP exchange mechanism whereby the public sector's two thirds of the global investment in agricultural R&D could develop and deliver biotechnological solutions that may have beneficial social impacts but that are not feasible on commercial terms. Implementation, however, might be quite problematical (Lybert, 2002). One organisation, CAMBIA in Australia, follows a price discrimination strategy in out-licensing their biotechnology innovations, differentiating on

ability to pay terms between multinational firms and non-profit organisations focused on poor countries. A collaborative effort among US public sector agricultural research institutions (Atkinson *et al.*, 2003, forthcoming) is forging a strategy of pooling patents from public sector institutions to expand freedom to operate in crops with markets that are unattractive to private biotechnology firms, in both developed and developing countries. Another initiative, developed by Lanjouw (2002a,b), proposes a US policy change whereby pharmaceutical firms would, as a condition for fulfilling the existing requirement for US approval for foreign filing of patent applications, commit not to enforce patents in countries named on the list of least developed countries. The technologies that would be covered include certain medical technologies (such as drugs for treating cancer and heart disease) with major markets in wealthy countries, but substantial numbers of potential users in poor countries. No doubt agricultural technologies could be included in this or a similar scheme.

The above strategies, by seeking market segmentation, recognise that different needs and opportunities are inherent in different situations (CIPR, 2002). Affirming this, a recent UNDP report (1999) includes proposals for an 'IP ladder' with different levels of protection for different classes of countries, or a 'TRIPS-minus model' with lower minimum protection levels and more national autonomy (Malhotra *et al.*, 2003). By contrast, however, developed country negotiators (not necessarily representative of the spectrum of opinion within national governments) appear to be pursuing a goal of international patent law harmonisation at a higher level of IPR standards than those mandated by TRIPS, via advocacy of adoption of the Substantive Patent Law Treaty developed by WIPO. At the same time, negotiators have been pursuing TRIPS-plus provisions through bilateral negotiations with individual developing countries; three examples include recent free trade agreements that the United States have struck with Jordan, Vietnam and Cambodia (CIPR, 2002). As other parties in the developed countries become better informed and less willing to leave negotiations in the hands of those domestic parties only interested in stronger IP, they might well push provisions for the disclosure of origin of genetic material as is already

required by India, the Andean Communities and Costa Rica (CIPR, 2002). They might also push for adopting an Andean perspective on nonpatentability.

It is important to recognise that aspects of recent initiatives in IPR could be very advantageous for developing countries. Harmonisation of administration and the centralisation of function (if not control) of the patenting process, as advocated by WIPO in the SPLT proposal, makes very good sense in a system where three-fourths or more of the work and the cost of national patent offices is duplicated elsewhere in the world (Correa and Musanger, 2002). Further centralisation could be especially useful for countries with scant administrative capacity. Indeed, absence of substantial investment in administrative infrastructure, it is hard to see how intellectual property regimes in conformity with TRIPS could effectively be implemented in many developing countries. Lack of such infrastructure creates a disincentive for local innovators, and countries are unable to benefit from the fruits of any domestic research or from flows of direct foreign investment and the technology transfer they often bring (Smith, 2002).

An economically optimal outcome for international intellectual property arrangements over plants and plant biotechnologies, from the point of view of global public welfare, could be the harmonisation and centralisation of functions while allowing some local choice of patentability, as in TRIPS, along with policies to encourage after-market segmentation, recognising differences between developed and developing countries and between commercial and humanitarian use.

With time, certain limitations on the scope and the value of private innovation in agricultural biotechnology will become more widely recognised. To the extent that agricultural biotechnology fulfils its great promise, most of the benefits will likely be realised in feeding a large and growing world population at low cost, and not in producer profit margins that are in any way comparable to those earned in pharmaceuticals. IPRs do have an increasingly important role in encouraging agricultural innovation, but continued and increased funding of public and non-profit research beyond a handful of high-value commercial crops will remain a crucial source of continued technical process in global agriculture.

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NOTES

1. Eli Whitney's famous cotton gin was patented, but so widely copied that Congress felt obliged to reward him with a prize to compensate him for his invention.
2. Apart from the legal and other submission costs involved, the Chinese government charges \$5,687 per variety to establish and maintain plant-related PBRs for the statutory life of the right, compared with \$2,450 in the United States and \$2957 in Brazil (Koo *et al.*, 2003).
3. For a patent attorney's perspective on this and other means of protecting inventions in biotechnology, see Evenson (2000).
4. European Union member states have recently agreed to implement a 'community patent', a true EU-wide patent. See 'The European Commission: Community Patent.'
5. For example, Decision 486, Article 15, promulgated by the Andean Community (Bolivia, Columbia, Ecuador, Peru and Venezuela) deems that biological material that exists in nature or can be isolated from any life form (such as gene sequences) are not an invention (Commission of the Andean Community 2000), whereas they may be patentable subject matter in the United States, the European Union, Japan, Canada and many other jurisdictions.
6. *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).
7. Another source reports that worldwide about 70% of total royalty and license payments flow between TNCs and their overseas affiliates (United Nations Development Program, 1999).
8. Act of 1991, International Convention for the Protection of New Plant Varieties, Article 14(5)c.
9. Maskus (2000) also provides a comprehensive account of the provisions of TRIPs and some of their implications for developing countries.
10. Case T 356/93 [1995] OJ EPO 545.
11. Case T 356/93 [1995] OJ EPO 545.
12. As of November 2002.
13. For one creative initiative, see Joe Vogel. 'Genes for Sale: Privatization as a Conservation Policy'. Oxford: Oxford University Press, 1994.
14. Compulsory licensing provisions also exist in the US Clean Air Act and Atomic Energy Act (Love and Palmedo, 2001), and more generally may be invoked for government use, antitrust purposes, or in the 'public interest' (Taylor and Cayford, 2002).

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