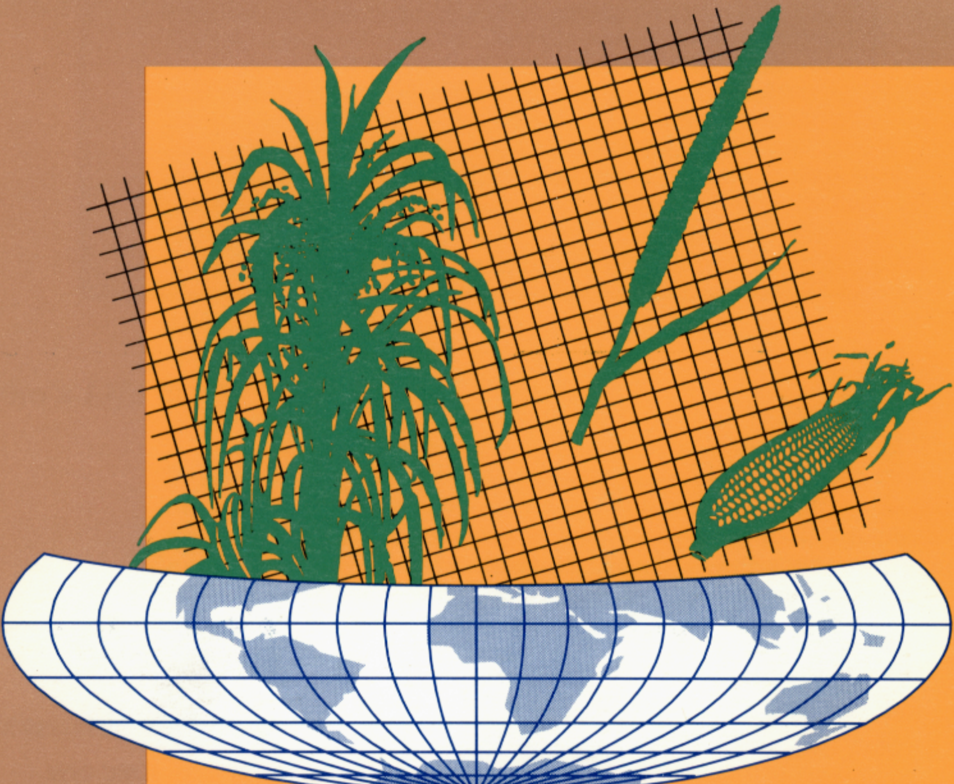
A Patent on Life

Ownership of Plant and Animal Research



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IDRC-269e

Patent on life : ownership of plant and animal research. Ottawa, Ont., IDRC, 1991. 40 p. (Searching series / IDRC)

/Bioengineering/ , /genetic engineering/, /research/ , /plant breeding/, /intellectual property/ — /legal aspects/ , /patents/ , /public sector/ , /private sector/ .

UDC: 66.098:347.77 ISBN: 0-88936-595-4

A microfiche edition is available.

Il existe également une édition française de cette publication.

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Brian Belcher and Geoffrey Hawtin

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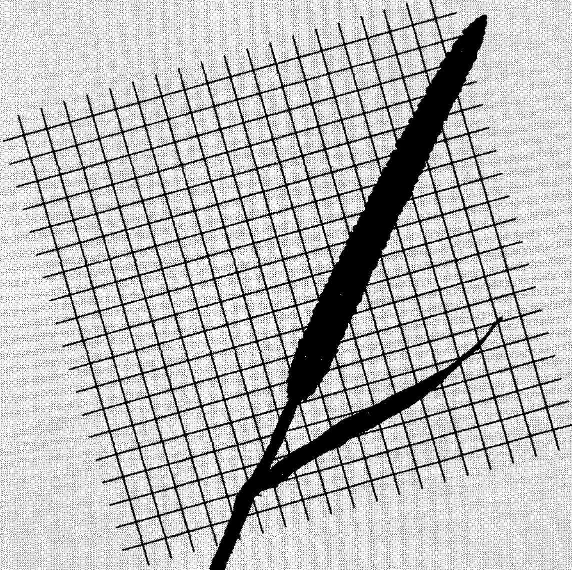

Biotech: The Commodity

Changing the Rules

The life sciences are changing in their fundamental character, and at a rapid rate. These changes are of two principal kinds. First, tremendous technical advances have been realized over the past couple of decades. It is now possible and, indeed, is common practice to transfer genetic material between completely dissimilar organisms: from fish to plants, from microorganisms to animals, from humans to other organisms, and, theoretically, from other organisms to humans. It is also possible to isolate and to multiply for commercial use parts of organisms to, for example, mass-produce chemicals that are otherwise produced in much smaller quantities by plants. For instance, vanilla, an expensive flavouring that comes from the bean of the vanilla orchid, can now also be produced in a vat from masses of vanilla orchid cells. These technical advances have served to blur the distinctions between natural and man-made, between life and chemistry, and between living and nonliving.

The second change, intimately connected with these scientific breakthroughs (to the extent that it is difficult to separate cause and effect) is a strong and escalating trend toward the commercialization of the life sciences. There are large profits to be made. Spurred on by advances in the science, investment capital has been mobilized in a way unprecedented in the history of biological science.

The hype surrounding the new "biotechnologies," much of it generated in the interests of stimulating investment, has led to strong political support. An obvious prerequisite for investment is some assurance that the investment will be rewarded. In biotechnology, the investment is in research and development, and the assurance needed is some form of intellectual property protection.

Mechanisms to protect new varieties of plants have been available in some countries for many years. In 1980, however, the U.S. took a new tack, using utility patents, formerly reserved for inanimate inventions, for microorganisms. Other industrialized countries soon followed suit. Canada has granted patents on microorganisms since 1982, and has even granted patents on human cell lines. Then, in 1987 the U.S. Patent Office announced that it would allow the industrial patenting of higher life forms, including pets and livestock. In 1988, a patent was actually granted for a genetically engineered mouse that contains human genes and has value because it is especially susceptible to cancer (and so is useful for research).

Although the argument for intellectual property protection is often couched in terms of increasing incentive to research, in many ways the motivations and the pressures are much more commercial and trade oriented; patents are being used to protect investment. This is reflected in the very strong pressures being exerted, by the U.S. and others, in bilateral and multilateral trade negotiations for international "harmonization" of intellectual property protection. Patent protection on living organisms is definitely included.

Patenting Life Forms

Patent protection on living organisms raises a number of immediate and disturbing questions. Quite simply, the patent system was not designed to deal with living organisms. The laws are being used in ways that were not anticipated by the legislators, and the necessary public debate has not been undertaken. There is a series of profound ethical and moral questions raised by the spectre of patenting life forms. These questions have not been answered. Indeed, in light of the uniqueness of the issue, there has not been time even to formulate the questions adequately. Beyond the ethics issues, there is also a whole host of very important questions relating to the direction and focus of research in the life sciences.

These issues are very disturbing from a Canadian perspective. The issues are magnified, and may even be of a different kind when one considers the implications of a strengthened intellectual property protection system covering the developing world as well. What is being contemplated within the General Agreement on Tariffs and Trade (GATT) and within bilateral trade negotiations is the wholesale transplantation of a system of legal protection to be used under very different social and economic conditions from those for which the system was designed. The system in question has not even been endorsed by the people of the exporting culture. The implications for the adopting culture may be quite severe and even countries that resist the pressure to adopt will not escape the effects.

"Biotechnology promises to become an effective weapon in fighting such major evils as disease, malnutrition, plagues, energy deficits and pollution. Ergo, no country can afford not to consider it as a high priority." So begins a recent IDRC publication about biotechnologies for developing countries (Sercovich and Leopold 1991). Statements of this kind are ubiquitous in government studies and reports, company strategies, and, especially, in the media and have been since the invention of a technique for "splicing genes" by Boyer and Cohen in 1973. There is great faith that science and technology will continue to lead to economic and quality-of-life improvements; biological-based engineering has been anointed as the way to improve the production of surplus in the industrial, agricultural, and health sectors. The hype, and that seems to be an accurate term, has been generated by biotech companies but has been willingly accepted by the public.

The Lure of Profits

The first biotech company, Genentech, out of California, was established by Herbert Boyer, one of the inventors of the process for splicing genes, in partnership with a venture capitalist. Ohio State University Researcher Dr Martin Kenney, in his 1986 investigation of the "University-Industry Complex," traces the history.

The two principals each invested $500 in the fledgling company and managed to get some startup capital from six investors. Boyer used the laboratory of the university where he was employed and, as Kenney puts it "Boyer, the officer of Genentech, contracted with Boyer, the professor, to perform research that would be proprietary, that is, patented private property at a public university." Genentech went public in October of 1980, offering one million shares at $35 a share. The price rocketed to $89 and settled at $70 at the close of the market day. Genentech, and many other such "startup" companies, benefited greatly from the public's willingness to believe in the potential of biotechnology. More than one hundred of these companies were formed in the U.S. in the 7 years following the establishment of Genentech, all involving university professors who brought with them knowledge generated during their employ in universities. A whole new class of millionaires was created, most of whom really had no product to sell. More than a decade later there are only eight biotech products on the U.S. market (Sercovich and Leopold 1991).

The implications of publicly supported research being turned to private gain are discussed later. At this point, it is important to note that with very high levels of investment in biotechnology there is also strong political support. An obvious prerequisite for investment is some assurance that the investment will be rewarded. Biotechnology requires high levels of investment in research, but the results are easily and cheaply copied. The main requirement to ensure a return on the investment in research is some form of intellectual property protection. Governments of countries with well-developed research and development establishments have been quick to offer this protection to stimulate further investment.

Creativity Rewarded

As far back as 300 B.C., cooks were granted exclusive rights to prepare "any peculiar and excellent dish in order that others might be induced to labour at excelling in such pursuits."

The concept of intellectual product as property, that the benefits to creativity and ideas should be "protected," is not a new one. As far back as 300 B.C., cooks were granted exclusive rights to prepare "any peculiar and excellent dish in order that others might be induced to labour at excelling in such pursuits" (Price 1991). "Letters of Patent" were granted by monarchs in the Middle Ages giving exclusive rights to merchants to sell commodities and inventions (later limited to inventions). The modern patent system traces directly back to a statute from the republic of Venice, 19 March 1474. The concept of intellectual property protection governing living "inventions" is much newer, however. The first example of patents being applied to living organisms occurred in 1873 when Louis Pasteur was granted patents in the U.S. on some yeast strains that were "free from organic germs," but institutionalized mechanisms for the protection of plant varieties only really began in the 1930s, and that outside the patent system.

Ours is a society with a well-developed appreciation for ideas and technology. The benefits of research to society are recognized, and intellectual property rights are granted in this light. Ideas themselves may be expressed in artistic form, as music or literature, or may be embodied in products or processes. The latter we typically call "inventions," and this category will be the focus of this discussion.

A Social Incentive

The "exchange for secrets" thesis, holds that intellectual property protection is provided as society's part of a bargain with the inventor.

Within the contemporary debate on intellectual property, two main rationale are typically used in defence of intellectual property rights: the "monopoly profit incentive," and the "exchange for secrets" theses (Primo Braga 1991a). The first assumes that without social incentives for the development of useful ideas, in reality incentives for research, there would be less investment in research than is socially desirable. The second, the "exchange for secrets" thesis, holds that intellectual property protection is provided as society's part of a bargain with the inventor. The inventor discloses technological secrets that might otherwise not be made available to society in return for an exclusive right to use and profit from the invention for a specified period of time. In many discussions these two notions, of incentive and of reward, are melded together. Intellectual property protection is seen as both incentive and reward for invention and disclosure.

As in any contract, each side works to improve their position in the bargain. For the biotechnology industry, this means maximizing the protection afforded by society while minimizing the disclosure required. As will be discussed later, patents on living organisms seem to favour the inventor more than patents on other things.

A variety of mechanisms has been devised for the protection of intellectual property. These fall into five major categories: patents (or industrial patents), plant breeders' rights (PBR), copyrights, trademarks, and trade secrets. The two main systems of interest for this discussion are patents and plant breeders' rights.

Patenting Products or Processes

A patent is intended to protect a particular product or a process that is the result of inventive thought. The patent permits the holder to forbid commercial exploitation (use, sale, manufacture) of the protected product or process by others in the country or countries where the patent is granted for a limited period (normally 17–20 years, but the period varies by country and product). Three specific conditions of eligibility must be met for patents. These conditions are fairly standard between countries, and include the following:

- Novelty — the invention must be new
- Utility — it must be useful

- Inventiveness (or nonobviousness) — it must represent a real advance that might not have been reached without the inventor's creative insight.

The patent application demands that the invention be disclosed in a way that enables the skilled public to reproduce it. The scope of the protection granted is proportional to the degree of inventiveness.

Finally, the patent must relate to a technology for which patents are permitted. This is the area in which the most variation occurs between countries' patent legislation. Usually, the invention must be capable of industrial application — for example, an industrial process or product, and not merely an idea, discovery, artistic work, or business scheme. Each country has the responsibility to decide on the appropriate scope of patentability to suit its own particular socioeconomic situation.

Such things as food, drugs, and agriculture have at various times and places been excluded to keep prices down (to make it cheap and easy to imitate and adapt existing technologies and products). Most developing countries currently do not grant patents on pharmaceuticals for this reason. Similarly, some prohibit patents on agricultural innovations. Rapid changes, however, are occurring in the scope of patentability, with an evident trend to encompass all products and processes, including living organisms.

Plant Breeders' Rights

Plant breeders' rights (PBR), known in Europe as plant variety protection (PVP), is a specific system of protection designed for plant varieties. It has analogies to patents, but also some important differences. As with patents, rights are granted for a limited period of time (typically 17–20 years) to the breeder of the specific unit of plant material that constitutes a plant variety.

To be eligible for protection, a variety must be:

- New — the variety must not previously have been exploited commercially
- Distinct — it must be clearly distinguishable from all other varieties known at the date of application for protection
- Uniform — all plants of the variety must be sufficiently uniform to allow it to be distinguished from other varieties taking into account the method of reproduction of the species
- Stable — It must be possible for the variety to be reproduced unchanged.

The Paris and UPOV Conventions

Although each of the foregoing intellectual property protection mechanisms are written and treated as national laws, international agreements are in effect and are designed to broaden coverage to the international level. The two main international agreements of interest are the Paris Convention concerning patents and trademarks, and the International Convention for the Protection of New Varieties of Plants (UPOV Convention), which covers plant breeders' rights.

The Paris Convention, originated in 1883, now has 99 signatory nations. Signatories retain a high degree of flexibility and autonomy in setting national laws (e.g., determining what will be patentable). The main provisions are for national treatment (nonnationals from signatory countries are to be given the same treatment as nationals) and priority rights when filing for a patent that has already been filed for in another signatory nation. A specialized agency of the United Nations, the World Intellectual Property Organization (WIPO), administers the convention along with most other international treaties on patents and trademarks.

The UPOV Convention, which deals only with plant varieties, is much more rigid, requiring that members adopt its standards and scope of protection as national law. In spite of this requirement, national laws have not been absolutely standard in their application. The UPOV convention was adopted initially in 1961 by five European countries, and membership was restricted to European countries until 1978. At that time, the convention was revised and membership opened to all countries.

There are currently 20 member states including most EC countries, several other European countries (Hungary, Poland, Sweden, Switzerland), Japan, the U.S., and a few others. Canada became party to the Convention on 4 March 1991. Although UPOV is open to all countries with compatible plant breeders' rights legislation, there are no developing-country members. None so far have been convinced that the benefits of membership outweigh the costs of administration and the lost opportunity of free use of varieties protected elsewhere. UPOV maintains a secretariat in the WIPO offices.

The UPOV Convention has resulted in a high degree of standardization among the 20 developed-country signatories. There are a few other countries that have analogous legislation (e.g., Argentina, Chile, Cuba). Patent legislation, however, is much more widely utilized, but there is a very low level of standardization; the level and scope of patent protection available, especially with regard to living organisms, is extremely variable and rapidly changing.

Patents and plant breeders' rights have quite different implications with regard to breadth of coverage and utilization of the protected material in subsequent research and production of propagating materials and of crops for sale. In theory at least, any product or process can be patented, but only plant varieties are covered by plant breeders' rights.

Canada and UPOV

After two failed attempts (in 1980 and 1988 bills for plant breeders' rights were introduced in Parliament but died on the order papers), Canada adopted a Plant Breeders' Rights Act on 19 June 1990.

Bill C-15 provides for the granting of plant breeders' rights to new varieties of plants that meet the criteria of distinctiveness, stability, and uniformity; the variety must not have been previously exploited commercially; it must be clearly distinguishable from other varieties known at the date of application; and all plants of the variety must be sufficiently similar to one another in a single generation and must not change significantly over time. The holder of the right is granted the exclusive right to advertise, sell, and produce reproductive material of a protected variety in Canada for 18 years. The holder also has the right to authorize others, with or without condition, to use the protected material. In addition, a compulsory licence may be granted by the Commissioner to any person; the Commissioner must consider the availability to the public of propagating material at reasonable prices, the distribution of the variety, and the reasonable remuneration of the rights holder.

The regulations pursuant to the Act are expected to be passed in the fall of 1991 (Mooi 1991). Initially, six categories of plants will be eligible for protection: wheat, canola, soybean, potatoes, roses, and chrysanthemum. New categories will be added on a regular basis.

With the passage of the Plant Breeders' Rights Act, the door was open to membership in UPOV. Canada became signatory to that Convention on 4 March 1991 under the conditions of the 1978 Convention. In March, there was a Diplomatic Conference in Geneva at which further revisions to the Convention were approved.

These revisions effectively strengthen the protection afforded by plant variety protection legislation. The main changes are:

- A provision was added to prevent the unauthorized exploitation of any variety that is "essentially derived" from a protected variety (a variety is considered to be essentially derived for this purpose when it is derived from the protected variety and retains virtually the entire genetic structure of the protected variety).
- The revised Convention extends the breeder's right to harvested material produced from propagating material whose use was not authorized by the breeder, unless the breeder has had reasonable opportunity to exercise his or her right in relation to the propagating material. The breeder's right, under the revised Convention, could be used to restrict the import of harvested material resulting from the unauthorized use of propagated material of his or her variety.
- The revised Convention now extends the breeder's right to cover the use of farm-saved seed as planting material. Countries are free to limit the breeder's right (to specify that farmers can replant seed of a protected variety that they have grown), and most countries are expected to do so (Keystone 1991).
- The 1991 Convention now lifts the prohibition on plant variety protection for patented varieties (ban on double protection); UPOV member states accordingly can offer patents as an optional alternative to plant breeders' rights for plant varieties or to grant both plant variety and patent protection for the same variety.

Canada will have to amend the Plant Breeders' Rights Act to accommodate these changes before ratifying the 1991 version of the UPOV Convention.

Patents Unlimited?

Patents are available on processes used to develop modified organisms or to produce biological products. Such patents, often described as "process patents," in general fall within the category of procedures for which patents were designed and are not particularly controversial. Arguments against such patents, which are sometimes raised, are more correctly arguments against biotechnology per se.

In the U.S., patents have been granted for specific plant and animal varieties. These varieties could be protected using plant breeders' rights but, claiming a degree of inventiveness, patent protection has been granted. This seems to give the patent holder the authority to restrict use of the patented variety for breeding purposes, protection not offered by plant breeders' rights.

Patent protection is also available in a number of countries for plants that contain a novel gene. For a gene to qualify as something "not found in nature" it must be either novel in and of itself (i.e., created by the inventor), or transferred to a species in which it is not found in nature (Barton and Siebec 1991). Such patents (on genes) seem to imply that the holder of the right could prohibit others from engaging in unauthorized commercial activity involving any plant material of the protected species. Protection may extend to cover closely related species to which the transferred gene could be moved using conventional breeding techniques.

Finally, and most controversial, the U.S. Patent and Trademark Office has granted a patent on a plant characteristic. The American biotechnology company, Molecular Genetics Inc., developed a variety of maize that produces high levels of the amino acid tryptophan. The company's patent claims a monopoly over any high, tryptophan-producing maize regardless of the process by which this characteristic is achieved. This broad claim remains to be challenged in court. With similar broad claims in the area of chemical production, the courts have tended to find evidence of infringement only when the product in question has been made by the process described in the patent (Barton 1991).

The U.S. has the strongest intellectual property protection, considering all "non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter" (OTA 1989). Patents in the U.S. may be granted to anyone who invents or "discovers" any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.

As it stands in Canada, microorganisms are considered patentable, and have been since 1982. This includes viruses, bacteria, fungi (including yeasts), unicellular algae, protozoa, or cell lines. In fact, human cell lines are considered to fall within this category and have been patented in Canada. As long as the cells possess uniform characteristics (do not differentiate), they are considered patentable. Higher life forms are currently not considered patentable by the Canadian Patent Office.

The breeder of the first blue rose, for instance, cannot monopolize blueness.

In Europe, patents are granted for microorganisms. Although the European Patent Convention excepts patent protection for plant and animal varieties (Art.53(b)), several patents have been granted by the European Patent Office on plants (DGIS 1991). A patent application on the "Harvard Mouse" was rejected under this article. Decisions on both plant and mouse patents are being appealed. In Japan, plant varieties per se are protected under plant breeders' rights, whereas processes for developing new varieties may be patented.

Under plant breeders' rights (and unlike the case of patents in the U.S.), the breeder of a protected plant variety cannot seek exclusive rights in a unique characteristic of his or her variety. The breeder of the first blue rose, for instance, cannot monopolize blueness. It is open to all other breeders to breed and protect blue roses that are distinct from the first such variety.

Encouraging Further Research

Patent laws in most nations provide research exemptions that allow the use of a patented innovation for experimental purposes (Barton 1991). After all, the purpose of the patent system is to stimulate innovation. Yet biotechnology-industry lobbyists are pushing for wider patent-holder control of patented organisms.

The U.S. law does not have any research exemption, and case law precedents (principally in the area of pharmaceuticals) suggest that "experimentation is permissable only to satisfy academic curiosity and not for commercial purposes" (Barton 1991). In the U.S., a patented blue rose could not be used for further development without the permission of the patent holder and probably a royalty payment.

Protecting Plant Varieties

Plant variety protection legislation, however, has important limits designed to facilitate continued improvement of protected varieties. Under the so-called Breeders' Exemption, any protected plant variety can be freely used as a plant genetic resource for the purpose of breeding other varieties; i.e., the blue rose referred to in the foregoing could be used in a breeding program to develop, for instance, a thornless blue rose. A provision is made to prevent the unauthorized exploitation of any variety that is considered to be "essentially derived" from a protected variety (a variety is considered to be essentially derived for this purpose when it is derived from the protected variety and retains virtually the entire genetic structure of the protected variety). The breeder's permission is required for the repeated use of his or her variety as a parent line to produce, for example, a hybrid.

A safety feature designed into plant breeders' rights legislation and into most patent systems (including the Canadian laws) allows the state to grant the same rights that the holder of the patent or plant variety protection certificate might grant. A "Compulsory Licence" of this type is used to ensure maximum benefit to society from an invention; i.e., the patent holder is prevented from using his or her monopoly in an exceedingly exploitative way or from withholding the invention from the public. The grantee of a compulsory licence must pay "reasonable" royalty fees to the patent holder.

Reproduction Control

Normally, with patents on nonliving things, the purchaser of a patented product can use the product without any restriction, but is prohibited from copying it for commercial use. Living organisms, however, are self-reproducing; they copy themselves. To uphold the rights of inventors to exclusive rights over their invention means abrogating the purchaser's right to unrestricted use of his or her purchase. As it now stands, patents on living organisms may permit the holder to restrict use of a protected variety for breeding purposes. Under this interpretation, a farmer purchasing seed of a patented variety may plant the seed and sell the crop as a crop, but would be prohibited from selling seed (or other propagating material). In fact, strictly speaking, the farmer may be prohibited from using that crop as seed for a subsequent planting (Barton and Siebeck 1991). Thus, current patent laws would seem to make patents on living organisms more far reaching than patents on nonliving things. Case law will eventually define the bounds.

This idea of restricting farmers from replanting their own seed is very much contrary to the traditions of North American farmers (using nonhybrids) and farmers throughout much of the world. For example, Canadian wheat farmers buy only about 15–20% of their wheat seed from a seed company. Most of their seed is saved seed from the previous year's crop.

Thus, current patent laws would seem to make patents on living organisms more far reaching than patents on nonliving things.

Under the 1978 version of the UPOV Convention, there was no mention of restricting farmers from planting saved seed. There have been some serious abuses of the right of farmers to plant their own seed, referred to as plantback, particularly in the U.S., with some very large-scale corporate farms producing their own seed. To deal with this, the 1991 UPOV revision extends the Convention to cover farmer plantback and could be used to prevent farmers from replanting seed of a protected variety that they have grown. Countries, however, are free to limit the breeders' right to permit farmer plantback; most countries are expected to do so for most varieties (Keystone 1991). In any event, a law to prohibit individual, small-scale farmers from planting saved seed would be virtually unenforceable. Advocates for small-scale farmers in developing countries, however, have expressed concern that laws of this type could provide a means of harassment for political or other ends (Montecinos, personal communication).

It is the effects on trade, however, and the incipient pressures that developed countries are able to put on developing countries to adopt intellectual property protection that causes the greatest concern.

In the case of either plant variety protection or patents, no direct mechanism prevents the use of protected material outside of the jurisdiction of the protection. An animal variety patented in the U.S. can be used in a breeding program in Argentina without infringing Argentinean patent law. As described later, however, any attempt to export the progeny to the U.S. may be considered a contravention of U.S. trade law, with strong sanctions.

In theory, it could be argued that plant variety protection and patents in developed countries pose little threat for developing countries. It is the effects on trade, however, and the incipient pressures that developed countries are able to put on developing countries to adopt intellectual property protection that causes the greatest concern. This is discussed in more detail later.

Trade Secrets

No discussion of patent protection would be complete without some mention of the alternative — trade secrets. This is the option of not disclosing information or not making materials available. Information can be protected by physical measures of secrecy and by restrictive contracts entered into with employees, users, and others to whom the secrets may be revealed. At its broadest, a trade secret is anything that is secret and confers upon its owners a competitive advantage. Trade secret laws are in place in many countries as a means of applying sanctions to those who improperly reveal or acquire trade secrets. For example, the law may be used to protect confidential information held by an employee hired by a competitor. National laws may protect trade secrets as legal property (e.g., U.S.), as a contract, or as an aspect of ethical business practices (e.g., Germany) (Lesser 1991a). Once a secret is lost, however, no protection applies, unless it can be shown that the secret was improperly acquired. This is also true if valuable information can be deciphered by examining products in which the information is used; i.e., reverse engineering.

It is effective "secrecy," for example, that enables breeders of hybrid varieties to ensure their exclusive use. Hybrids, the first generation from a cross between specific lines, often have a large potential yield advantage over conventional varieties. If seeds of the next generation are sown, however, much of this advantage is lost. Thus, by keeping strict control of the parent lines, breeders of hybrids are able to maintain effective "rights" over the hybrid variety itself.

It is this option that concerns the proponents of strengthened intellectual property protection. Information kept secret can not be used by society except in the form of the ultimate product of the invention (which may or may not be marketed). There is the potential for unnecessary duplication of research. Patents offer an incentive to the private sector to make public the results of their research.

Patents and Free Trade

A number of bilateral and multilateral initiatives have been taken, and others are currently underway, designed to "harmonize" intellectual property protection worldwide. "Harmonization" for most if not all countries will mean introducing much stricter intellectual property protection.

Attempts to strengthen intellectual property protection regimes globally have been underway for more than a decade. Initially, WIPO served as the main forum, with a "committee of Experts on Biotechnological Property and Industrial Property" established in 1984, and efforts to develop a new treaty on the protection of industrial property since 1985 (DGIS 1991). Conventions, however, require wide approval. Industrialized countries have been unsuccessful in getting the higher intellectual property protection standards they would like adopted in other countries through WIPO.

Some countries, led by the U.S., have subsequently embarked on bilateral negotiations to secure stronger protection for the intellectual property of their nationals. The U.S. uses its General System of Preferences (GSP), granting favoured-trading status only to those nations who meet rigid intellectual property protecting standards. Following strengthening of U.S. trade law in 1988, some 42 countries were identified as having intellectual property laws deemed harmful to U.S. interests. Pressure has been exerted on these countries, through the GSP, with punitive duties on imports from the countries in question. The EC has similar commercial policy instruments available to deal with intellectual property rights issues. In 1987, for example, the EC suspended GSP benefits for Korean products to retaliate against Korea's provision of preferential intellectual property protection for American intellectual property, itself won through the imposition of trade pressures (Primo Braga 1991b).

Potentially more far ranging in its effect is that intellectual property considerations are included as one of 15 negotiating subjects in the current (Uruguay) round of the GATT. A negotiating group on Trade-Related Aspects of Intellectual Property (TRIPS), including Trade in Counterfeit Goods, was established at the insistence of the U.S., with support from Japan and the EC, and is considered one of the top priorities by the U.S. By bringing intellectual property protection issues into the GATT discussion, industrialized countries can pressure developing countries to strengthen their intellectual property protections. Although no country would have to sign any final GATT agreement, there may be strong pressures, and clear benefits in other areas, to do so.

Within these discussions, very little attention has been focused on property protection as related to living organisms. Far from calming fears, this fact underlines the danger that patent protection applicable to living organisms will be adopted on a very wide scale as an almost incidental part of a much larger trade deal. It is very likely that the profound and far-reaching questions raised by this issue will not even be evaluated before the decision is taken.

Even though the discussion is wanting, the positions have been mapped out. Everything should be patentable according to the U.S., Japan, and Switzerland (presumably excluding human beings as in current U.S. law). The EC position has been more moderate. They would leave decisions on exclusions of animals and biological processes up to individual countries (DGIS 1991). Fourteen developing countries (Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay, and Zimbabwe) propose to exclude materials existing in nature, along with plant and animal varieties and processes for the production of plant and animal varieties, from patent protection.

Canada's position has been that patents should be available for all products and processes in all fields of technology, but that countries should be free to exempt certain things, including multicellular life forms or processes for producing new multicellular life forms (GATT 1989). In light of the incomplete analysis that has been done on the potential implications of such legislation (including the ethical implications), Canada supports the view that countries should be free to develop legislation appropriate to their own needs.

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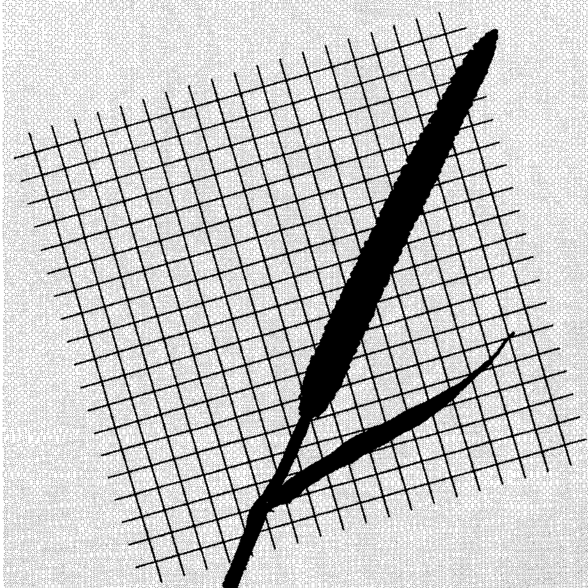
With or without GATT TRIPs, it appears quite likely that many developing countries are going to be coerced into adopting strengthened protection regimes. Intellectual property is being treated as a trade issue and not as a research issue. Under these kinds of conditions, with the principal focus on trade-related issues, it is very unlikely that adequate consideration will be given to the needs or design of the resulting protection systems. Intellectual property protection for living organisms is likely to be included as part of the overall package, with serious ethical implications and with considerable potential to alter the research environment globally.

This trend to link intellectual property protection relating to living organisms to trade agreements, both bilateral and multilateral, is cause for serious concern. Every country should decide whether and to what extent they should adopt such protection on its own merit. The issue must be given adequate discussion and evaluation at the national level before any action is taken.



Who's Life Is it?

Life As Property

The concept that an individual could "own" a piece of land was foreign to North American natives and probably quite incomprehensible.

The concept of patenting a living organism strikes many as being somehow wrong. Western society has a long tradition of ownership of physical property. Indeed, everything on earth has at one time been considered eligible to be treated as property. Human beings are now excepted, but only after a long and very painful period during which human beings too were subject to treatment as commodities.

This tradition of property is not shared by all societies. Aboriginal societies the world over have had much narrower definitions of private property. North American native peoples have suffered enormously because they did not have a system of land ownership and suddenly came up against a rapidly expanding culture that treated land and everything on it as a commodity. The concept that an individual could "own" a piece of land was foreign to North American natives and probably quite incomprehensible.

That kind of foreignness seems to be manifest in the reactions even of many Westerners, accustomed as we are to crass commercialism, when introduced to the concept of ownership of a variety of plant or animal. That every offspring of every offspring of an individual which has been modified in some way should, in a sense, "belong" to he or she who did the modifying seems wrong to many.

The debate on this issue really only began in 1980 when the American Supreme Court ruled that a living organism, in this case a genetically engineered bacterium, could be patented *(Diamond v Chakrabarty)*. In 1985, the same court ruled that plants and seeds were eligible for patent coverage *(Ex parte Hibberd)*, and, finally, in 1987, that animals could be patented *(Ex parte Allen)* (Lesser 1991b). In this last case, a patent was granted for a genetically engineered mouse that contains human genes.

Because it is such a new area, the issues are still in the process of being defined. Neither side in the debate has adequately marshalled their arguments on the ethical and moral aspects of patenting life forms. A recent statement by religious leaders in the U.S. called for a moratorium on animal patenting to allow time for thoughtful reflection and judgement (Brody 1989). It will be useful to examine and weigh some of the main arguments.

Patents for Mousetraps, Not Mice

First of all, it must be made clear that utility patents were not designed for living organisms. Patent laws were drafted before the advent of technologies that made possible the wide genetic recombinations and other genetic manipulation techniques that are now practiced.

The language of the laws does not indicate that the legislators considered the laws that they were drafting to be applicable to living organisms. Indeed, the act of passing plant breeders' rights legislation suggests that Parliament recognized that plants at least are not eligible for patent protection.

The divergence of current practice from the intent of the law is demonstrated well by the difficulties encountered with the disclosure requirements of patent law. The Canadian Patent Act requires an applicant to "...correctly and fully describe the invention and its operation or use as contemplated by the inventor..." and to "...set out clearly the various steps in a process, or method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to make, construct, compound or use it...." The U.S. law is similar in substance.

Complete Disclosure?

For some biological inventions though, adequate description is practically or even technically impossible. To overcome this difficulty, it has become common practice in some countries to allow a deposit of the biological material to supplement the disclosure. The sample is made available to others so that they may reproduce the organism and thus have access to the invention for research purposes and unlimited use once the patent expires.

Canada's Patent Act does not mention deposits but, as a matter of practice, the Canadian Patent Office was accepting reference in a patent disclosure to a deposit of biological materials. This practice was specifically addressed by the Commissioner of Patents in 1982 in *Re Application of Abitibi Co.* This case concerned an application for a patent on a process for biodegrading waste from the manufacture of wood pulp, including the microbial culture system composed of five species of yeast. The patent on the process had been accepted but, the Patent Examiner rejected the claim on the microbial culture system on the grounds that living organisms were not considered patentable subject matter. The Commissioner overturned the rejection, and in the decision affirmed the practice of using deposits.

A subsequent Supreme Court decision has raised doubts about the practice. The case of *Pioneer Hi-Bred Limited v The Commissioner of Patents* is interesting both from the perspective of the disclosure issue and because it serves well to illustrate the uncertain situation in Canada on patenting of multicellular organisms. The initial application by Pioneer Hi-Bred for a patent on a new soybean variety was rejected by the Patent Office Examiner and then by the Patent Appeal Board, both finding that the invention was not patentable within the meaning of the Patent Act. The Patent Appeal Board further indicated that a limited interpretation should be given to the word "invention," and that the soybean variety did not qualify. (Canada had not enacted its plant breeders' rights legislation at the time.)

Pioneer brought an appeal to the Federal Court of Appeal in 1987, which was rejected, and in the process new issues were raised. Two judges gave the opinion that Canadian Patent Legislation does not expressly exclude living organisms from patentability, but ruled that the soybean variety could not be regarded as an invention.

> Besides, speaking of the intention of Parliament, given that plant breeding was well established when the Act was passed, it seems to me that the inclusion of plants within the purview of the legislation would have led first to a definition of invention in which words such as "strain," "variety" or "hybrid" would have appeared, and second to the enactment of special provisions capable of better adapting the whole scheme to a subject matter, the essential characteristic of which is that it reproduces itself as a necessary result of its growth and maturity. (Marceau 1987)

The minority judge raised the issue of disclosure and stated both that "...even a complete and accurate disclosure by the appellant of everything that the alleged inventor did to develop the new plant would not enable others to obtain the same results unless they, by chance, would benefit from the same good fortune.", and "The use of seeds deposited by the appellant is, in a sense, the use of the invention itself. Subsection 36(1), as I read it, requires that the description be such that third persons, who do not have access to the invention or anything produced by it, be enabled to reproduce it."

The subsequent appeal to the Supreme Court of Canada (judgment rendered in 1989) was also rejected on similar grounds. The Supreme Court considered that the breeding techniques used to develop the variety were not adequately described and further ruled that the deposit of seed did not comply with the requirement for complete description. The Court distinguishes the Pioneer ruling from the Abitibi case on the grounds that the patent application in the latter was not for the microorganism deposited but for a process that used that microorganism. In fact, this distinction does not seem to be correct (Morrow 1991).

The Supreme Court did not rule, as many had hoped that they would, on the patentability of plant varieties or multicellular organisms generally. The justices found it neither "necessary nor desirable...to consider...whether this new soybean variety can be regarded as an invention...."

In spite of the distinction made from the Abitibi case, the Canadian Patent Office has tightened its criteria for disclosure. Reference to deposits in recognized depositories continues to be accepted, but the written description must stand on its own — at least until the law is changed. The disclosure requirements of the Patent Act are in the process of being amended to allow for the deposit of biological material as part of a patent application and to consider that deposit as part of the written description.

Moreover, a recent meeting of the Intellectual Property Advisory Committee favourably reviewed a proposal for Canada to join the Budapest Treaty. (The 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure allows for a single deposit of a microorganism with an International Depository Authority in any member state and obviates the need to make a separate deposit in every country where patent protection is sought.) This is a very significant change and would open the door to broader use of patent law to protect living organisms.

Devaluing Life

Yet patents on living organisms do not reflect the distinction that our society has traditionally made between living and nonliving, between animals and machines.

One of the principal arguments against patents on life forms is that they devalue life. Patents, as a mechanism of social policy, should reflect a society's ideals and traditional values. Yet patents on living organisms do not reflect the distinction that our society has traditionally made between living and nonliving, between animals and machines. Canadian and U.S. law authorizes patents on any new "machine, manufacture or composition of matter." The Canadian decision on patenting microorganisms was somewhat ambiguous, referring to them as "manufactures or compositions of matter." The American court put microorganisms, and higher forms, within the category of "compositions of matter." Obviously, such a reduction in the legal definition of life raises serious questions.

The responses to the argument that patents on life devalue life have not been particularly strong. Baruch Brody (1989), an American professor of philosophy and an expert in biomedical ethics, addresses this argument and dismisses it in the following way: "Even those who believe that living beings are more than compositions of matter believe that they are at least compositions of matter, and it is only as compositions of matter that we patent them." This rebuttal seems to be flawed. We do not, and certainly should not, apply the law in such a reductionist manner. Otherwise, there could be no argument against patenting human beings, as we too are "at least compositions of matter."

Brody himself later turns to a different argument, quoting Leroy Walters (Committee on the Judiciary 1988): "When compared with the ethical issues involved in our breeding, buying, selling, confining, eating, and performing research on animals, the ethical questions surrounding animal patents seem relatively less important...." This is a very weak position, suggesting that the ethical considerations are relatively less important than others and should, therefore, be dismissed.

Barry Hoffmaster (1989), associate professor of philosophy at the University of Western Ontario, seems to miss the point in his effort to rebut the arguments against patenting life. He starts by citing Jeremy Rifkin, a leading opponent of patents on life in the U.S., who has criticized the patenting of animals on the grounds that the decision legitimizes the privatization for commercial profit of the entire animal kingdom. Hoffmaster selects this quote, characterizes it as typical of the argument, and quickly dismisses it because animals are already marketplace commodities. He confuses the concept of physical property, the buying and selling of individual animals, with the very different concept of intellectual property and the extension of that idea that vests exclusive rights of exploitation of an organism and all its progeny to an "inventor" who has "modified" that organism.

None of the arguments cited in the foregoing seem to invalidate the concern that patents on living organisms reduce society's concept of life and serve to blur the distinction between the animate and the inanimate. The main concern of this argument is not with the patents per se, but with the institutionalization of a reduced definition of life. This naturally leads to concerns that social barriers preventing maltreatment of other living organisms will be lowered and to related concerns that human life will be similarly devalued.

Simultaneous to this discussion on patents and their implications there has been a much larger "revision," at least in some quarters, of human relations with the larger environment. This is expressed in a variety of ways, from "deep ecology," increasing concern for animal rights, to the growing environmental movement. These new ideas should be considered in the debate on patenting life as legitimate antitheses to the commercial and trade interests.

Religious Arguments

There is a family of arguments based on metaphysical and theological grounds that rejects the idea that humankind should tamper with God's creation. These include the notion that a species has a right to exist as a separate species and that the introduction of genes from another species contravenes this right; humankind is entrusted with the responsibility to preserve the integrity of life; humankind should not attempt to usurp the organic, natural, or God-given powers of reproduction and species evolution; producing new life forms simply for the sake of profit is morally offensive; and it is inappropriate to grant a patent for an invention that involves transferring human genetic material to animals (Hertz, unpublished).

If a society determines that it does not approve of certain technologies, it should assess very critically all policy instruments that may encourage the technologies in question.

Many of these are more correctly arguments against recombinant DNA work than they are against patents (Brody 1989; Hoffmaster 1989). However, insofar as patents countenance and, indeed, encourage biotechnology, including biotechnology that is not widely approved of (e.g., transferring human genes to animals), there is a danger of sending a mixed policy message. If a society determines that it does not approve of certain technologies, it should assess very critically all policy instruments that may encourage the technologies in question.

A number of other concerns fall into the antibiotechnology category as well. These revolve around the environmental and health implications of releasing genetically engineered organisms and the potential that recombinant DNA technology will lead to increased suffering by animals.

Fairness

There is a very strong "fairness" issue that must be considered. Every living organism is a product of millions of years of natural evolution and, in the case of most domesticated species, considerable human selection and human-induced change as well. Now, by generating a relatively very small change in an organism, it is possible to gain legal control over the exploitation of the modified organism and all of its progeny (for 20 years or so). What was considered the common heritage of humankind becomes the private property of a few.

Referring to the landmark Chakrabarty case in the U.S. in which the court found that Chakrabarty "has produced a new bacterium with markedly different characteristics than any found in nature...", Key Dismukes, Study Director of the Committee on Vision of the National Academy of Sciences in the U.S. said:

> Let us at least get one thing straight: Ananda Chakrabarty did not create a new form of life; he merely intervened in the normal processes by which strains of bacteria exchange genetic information, to produce a new strain with an altered metabolic pattern. "His" bacterium lives and reproduces itself under the forces that guide all cellular life. Recent advances in recombinant DNA techniques allow more direct biochemical manipulation of bacterial genes than Chakrabarty employed, but these too are only modulations of biological processes. We are incalculably far away from being able to create life de novo, and for that I am profoundly grateful. The argument that the bacterium is Chakrabarty's handiwork and not nature's wildly exaggerates human power and displays the same hubris and ignorance of biology that have had such devastating impact on the ecology of our planet.

A somewhat related point on fairness is that much of the background research that underlies any patentable development has been, and will probably continue to be, publicly funded. Such "upstream" research, without the possibility of immediate application, does not lend itself to research that is privately funded. Yet the results are often employed in applied research that does result in patentable discoveries, the rewards of which are appropriated privately. At best this can be seen as a public subsidy to industry. In other cases, such as where university and other publicly supported researchers form companies to exploit the results of "their" research, it appears both inequitable and unethical.

Genetic Erosion

Since the dawn of agriculture, many thousands of years ago, farmers have continually sought to improve the crops they have grown. As agricultural communities have spread around the globe, they have taken their crops with them and, through continual selection, have developed a vast array of different types, known as landraces, adapted to different environments and needs. This variation provides the main raw material for crop improvement today and for the future.

Unfortunately, much of this diversity is now threatened. Many of the traditionally grown landraces no longer exist. They have been replaced by "modern" varieties — indeed it is ironic that the success of plant breeding has itself been the major cause of the loss of the raw material on which future advances in crop improvement depend. Instead of a huge patchwork of different landraces of a crop, many parts of the world are now covered by a comparatively small number of varieties that themselves are often closely related.

The requirements of modern agriculture for uniform product, whether for field mechanization or processing, have further exacerbated the situation. In addition, for a variety to be eligible for plant breeders' rights, it must be sufficiently uniform to be able to distinguish it from other varieties — again resulting in less variation than is commonly found within traditional landraces.

As modern plant breeding extends its impact to more and more crop species and in ever more agricultural environments, so traditional genetic diversity is being progressively lost. The situation, referred to as genetic erosion, is now critical for many species and in many parts of the world.

The replacement of landraces by new varieties is, however, not the only cause of genetic erosion. As food habits change, or as shifts occur in the profitability of certain crops compared to others, so the total area grown to a particular crop can change dramatically. As farmers, for whatever reason, abandon certain crops there is a great danger in losing the variation that originally occurred within them. If, in the future, trends are reversed, much of the variation needed to revive a crop and to adapt it to the new conditions will no longer occur.

In addition to the loss of landraces, many wild species, relatives of cultivated types and, hence, also of value in future crop improvement, are also threatened. This can occur through the destruction of the habitats, for example, through the expansion of urban areas, deforestation, or the widespread degradation of ecosystems caused by overgrazing. The situation is expected to get worse in the future if global climatic change occurs and leads to major shifts in plant ecosystems. Again, an ironic situation — climate change resulting in the loss of genetic diversity that itself will be badly needed to tailor our crops to produce adequately under new climatic regimes.

The seriousness of the situation is being increasingly recognized and attempts to redress it are taking place throughout the world. Many countries have established gene banks to preserve traditional landraces, varieties, and wild species in cold storage. Increasingly, efforts are also being made to conserve materials in the field, either on farm in the case of traditional landraces and varieties, or in special habitat reserves in the case of wild species.

These efforts, however, although impressive, remain inadequate. Additional funding and other resources, as well as further knowledge about optimum conservation methods and strategies, is urgently required. The situation is especially acute in some of the developing countries — the very countries that have given rise to so much of the genetic variation used throughout the world today.

The fairness issue is particularly acute when patents are considered from the perspective of developing countries. Almost all the major agricultural crops originated in the tropics and subtropics in areas that are now developing countries. Most of our domestic animals originated in these regions as well. These regions remain centres of diversity from which germplasm has been collected over the years and adapted, through selection and breeding, to use in European and North American conditions. In Canada and the U.S., as well as in northern Europe, Australia, northern Asia, and the Mediterranean, more than 90% of agricultural production is derived from introduced species (Reid 1991).

Of course, efforts have also been directed at developing improved varieties for use in tropical conditions, with considerable success in a number of cases. Perhaps the most noteworthy of these has been the development and spread of the dwarf, high-yield potential rice and wheat varieties in the late 1960s and 1970s, which gave rise to the "green revolution." The results have had mixed reviews; it has certainly been possible to feed many more people than would have been possible without these improved varieties and associated chemical inputs, but there have also been some undesirable distribution inequities. Furthermore, the improved varieties have been so successful that in many places they have displaced the traditional varieties and many have died out. These varieties, each with its own particular genetic characteristics, unless conserved, for example, in a genebank, are lost to the world forever. These genebanks, however, are costly to develop and run and, for this reason, many of the largest and most effective are situated in developed countries.

Much more needs to be done. Indeed the research system that gave rise to the "green revolution" in the first place — the Consultative Group on International Agricultural Research (CGIAR) — also places a high priority on the conservation of plant genetic resources. The CGIAR is an internationally supported network of research centres dedicated to contributing to sustainable improvements in the productivity of agriculture, forestry, and fisheries in developing countries. One of the CGIAR centres, the International Board for Plant Genetic Resources (IBPGR), has a specific mandate for plant genetic resource conservation.

By the early 1980s, developing countries began to feel threatened by the ongoing loss of genetic diversity in agricultural crops and the disparity of designated storage facilities between North and South and the related issues of access and control; the countries where many crops originated felt they were losing physical control of their plant genetic resources. At the same time, advances in biotechnology were drawing attention and giving more value to genetic diversity at the gene level. The developing countries' concerns were intensified by the efforts by many industrialized countries to establish patenting systems for varieties, genes, characteristics, i.e., the developed countries appeared to be gaining legal as well as physical control of plant genetic resources (Berg et al. 1991). These factors coalesced, mainly within the forum of the FAO, precipitating what has become a very important international political debate over access to and control of plant genetic resources.

Without going into the details, one of the main outcomes has been the wide recognition, and the adoption by the FAO, of the concept of "farmers' rights." Farmers' rights recognizes that farmers have over the millennia been the primary developers of agricultural plants; it stands as an analog to "breeders' rights." Farmers have contributed to the genetic diversity available to plant breeders and biotechnologists, and this diversity is not only a product of nature as is suggested by patent law (Berg et al. 1991). This has become the basis of a political argument for a system of compensation to parallel that of formal intellectual property protection.

Keystone Issues

Since the early 1980s, the issue of ownership and control over the world's plant genetic resources has been an extremely contentious one. Developing countries in centres of diversity were and remain very concerned over their loss of legal and even physical control over germplasm. There was a widespread perception that the industrialized countries were employing a double standard, treating elite breeding lines and patented material as private property but insisting that the landraces (sometimes called "primitive cultivars") and the wild plant genetic resources of the developing world should be treated as the "common heritage of mankind."

This issue was debated extensively in the forum of the Food and Agriculture Organization of the United Nations (FAO). One of the outcomes of the debate was the recognition by FAO of the concept of "farmers' rights" as a parallel to breeders' rights.

In essence, the term farmers' rights encompasses the view that farmers both past and present are plant breeders and that they have made valuable but unrewarded contributions to the development and maintenance of crop plants. The question remained of how to institute the reward component, of how to channel the "royalties." Obviously, it would not be possible to reward individual innovators or even individual nations. Rather, the best approach would seem to be to channel money into programs to improve the conservation and utilization of plant genetic resources in the centres of diversity.

Such a fund was established by FAO in 1989; the International Fund for Plant Genetic Resources. It is designated for genetic conservation and utilization work and is administered by the FAO Commission on Plant Genetic Research.

The fund, however, has been relatively inactive. It is currently a voluntary fund and has not received large contributions. In the meanwhile, the standoff has continued.

In an attempt to resolve this issue, the Keystone International Dialogue Series on Plant Genetic Resources was initiated in 1988. At the request of several companies, personnel in the U.S. Department of Agriculture and the U.S. National Academy of Sciences, the Keystone Center, a U.S.-based organization specializing in conflict mediation, brought together individuals representing the various viewpoints in this debate. →

The intention was to engage these diverse interests in a structured, off-the-record, consensus-building dialogue with the objective of promoting a strong international commitment to plant genetic resources conservation.

Three main ground rules were applied to facilitate the consensus process: participants attend as individuals, all conversations are off-the-record and not for attribution, and no documents are made public without the consensus of all participants.

The first plenary session, held in Keystone, Colorado, resulted in a widely distributed consensus report covering such critical issues as refinements to the understanding of farmers' rights and breeders' rights, along with a number of recommendations to improve the global system of plant genetic resource conservation.

A second plenary session was held in Madras, India, in 1990, which further refined the earlier recommendations and added specific recommendations on intellectual property rights, recognition of the role of informal innovation systems, and the need for funding and institutional mechanisms that address plant genetic resources as a critical aspect of overall concerns regarding biological diversity.

A series of working group meetings were held during 1990 and early 1991 leading up to the final plenary session. These included two sessions on intellectual property issues (one hosted by IDRC), a session on "sharing the benefits of plant genetic resources," and a session on institutional mechanisms.

The final plenary session was held from 31 May to 4 June in Oslo, Norway. This session dealt extensively with the idea of making the fund work. Recognizing that the fund is designed to act as an analog to breeders' rights and patents with mandatory royalty payments, the group argued that the fund should be mandatory. An institutional structure and implementation mechanism was designed to implement a global plant genetic research initiative that will utilize, build upon, and improve existing institutional structures at all levels (community, national, regional, and global). It is hoped that the Keystone recommendations will be adopted by the international community.

Copies of the Keystone reports are available from the Keystone Center, Box 606 Keystone, Colorado, USA 80435

Culture Shock

Intellectual property law is a product of Western society and Western ideals. We have seen that within the Western cultural tradition there are serious concerns raised by the concept of patenting life. The social and ethical implications of transferring patent policies designed in the West to completely different cultural and social environments must be greater by orders of magnitude, if not completely different in kind. Other societies have very different concepts of life and of ownership that may not correspond with those inherent in patent policy.

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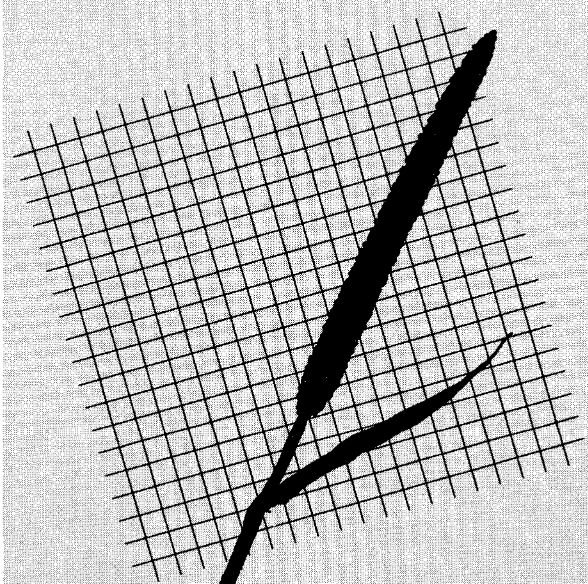
These ideas simply have not been explored. In addition, it must be remembered that the innovation systems in many developing countries are quite different from those of developed countries. There is a strong informal system, with small-scale farmers, aboriginal herbalists, and others, developing an enormous range of useful innovations, many of them involving the use of biological materials.

These innovations are not now protected by any intellectual property law, and so would be very vulnerable to being improperly appropriated by others in the wake of strengthened national intellectual property protection. The innovators themselves may not use the new laws to their advantage for a whole range of reasons: they may not be able to afford the costs of applying for (and certainly not of defending) a patent, they may be unaware of the market potential of their innovation and unwilling or unable to market it, they may be barred by language or geographical barriers from applying for coverage, they may be unaware of the implications, or they may simply not want to become involved in the market system. The point is that the system could be difficult for the informal innovators of developing countries to use to advantage, but there is a risk that it may be used to their disadvantage.

The ethical implications of patents and patent-like protection applied to living organisms need to be articulated much more clearly and given much wider public discussion. The most important point is that patent laws that were not designed to deal with living organisms are being applied to living organisms without adequate reference to society. This is even more flagrant where intellectual property protection is "forced" on other societies. In addition to these very real but difficult to articulate ethical objections to patenting life per se, there are many "political economy" effects, with implications of consequence both in the developed world and in the developing countries.



Research: Public or Private

The Research Agenda

The agenda in biological research is increasingly being dictated by commercial imperatives. Strengthened intellectual property protection is not solely responsible for this trend; it is certainly implicated as an important element in the privatization of research.

Much of agricultural research and, in particular, plant breeding, has long been regarded as a public service. When the potential benefits of agricultural research were first being realized, farmers and rural people dependent on the prosperity of agriculture formed a large, and hence politically influential, block. Although this political power has diminished in many countries over the years, it still remains a potent force. It is well established that innovations in agricultural technology tend to benefit those first to adopt them. As more and more farmers follow suit, the benefits tend to decrease as increased production leads to a lowering of prices.

Hybrids act, in essence, as biological patents. A farmer growing hybrid varieties has to go back to the market each year for seed.

The longer term benefits thus tend to accrue more to the consumers than the producers, and it has often been argued that it is they, through taxes, who should bear the main costs of research. Of course, in the final analysis, it is the consumers who pay, even under a system of privatized research, but through higher prices for food and other commodities.

The development of hybrids in the 1930s brought the first real change to this. Here was a product that could be differentiated as a product, with a brand name and advertising. More important, the progeny of hybrid seed cannot economically be saved and replanted — subsequent generations give much lower yields. Hybrids act, in essence, as biological patents. A farmer growing hybrid varieties has to go back to the market each year for seed. Only a few species of commercial importance, however, are amenable to this, most notably, maize and some vegetable crops. The next logical step was the provision of intellectual property protection, then through the sequence to where we are today, on the brink of globally harmonized patentability of all things, living or not, and a very strong trend toward the privatization of agricultural research.

Why, if the use of intellectual property protection will reward individual innovation, and the public ultimately funds agricultural research through pricing mechanisms, should we be concerned about the increasing trend toward the privatization of research? For many aspects of agricultural research, it might be argued that this is not necessarily an unhealthy trend. The concern lies, particularly, although not exclusively, in the increasing privatization of plant breeding. Once purely short-term commercial interests dominate, there is clearly a comparative advantage to concentrate crop improvement efforts on species that are of major commercial importance and that are grown on a large acreage, generally in the more-favoured environments. Minor crops that may be of vital importance to resource-poor farmers in diverse and often harsh environments will inevitably be neglected by commercial plant breeders, leading to even greater inequities between farmers in favoured environments and those in the more marginal areas. Such a situation clearly also reinforces the trend toward a reduction in the number of crop species being grown in all areas, a trend that causes considerable concerns on environmental as well as long-term, food-security grounds.

Publish or Patent

In addition to the concerns about the focus of research, there are also concerns about the way research works. One of the first casualties of intellectual property protection is the free flow of scientific information. In the absence of intellectual property protection, a scientist's achievements are generally measured in terms of his or her contributions to the body of knowledge. The scale of achievement has been the scientist's publication record. The incentive has been to publish results as soon as possible (resulting in the extreme in the much lamented "publish or perish" scenario). This is not to suggest that scientists never withhold information — to do so would be romantic in the extreme. Numerous incentives exist, not the least being commercial incentives, to keep back findings until they can be exploited. However, the normal reward system for scientists in the absence of intellectual property protection demands the rapid publication of research results.

The introduction of an intellectual property protection system immediately changes this incentive structure. The first rule if seeking a patent is to keep the research results secret. A patent cannot be granted if the information to be patented has already become public.

Of course, the patent application demands disclosure. Indeed, that is the purpose. But, again, it is in the interests of the patent applicant to disclose only the minimum necessary. Other information may be valuable in future patents, and any extra information in the patent disclosure is fodder for the competition.

Sharing the Gene Pool

Related to this barrier to the free flow of information is the equally important barrier to the free flow of germplasm. Plant breeding, for example, requires access to the raw material, germplasm. Plant breeders' rights are designed to present as little obstruction to research as is possible; a protected variety can be freely employed as a parent in developing a new variety (although the first generation cannot be marketed). Patents, however, can have the effect of restricting further development of whatever it is that the protection applies to. If the patent is for a particular gene or characteristic, the patent holder may forbid its incorporation into a new variety.

Even if under a compulsory or other licensing agreement a researcher is allowed to use the patented gene or characteristic, there will be a royalty charge levied. Even if access is not denied, the cost of access will inevitably rise. These types of costs could develop to ridiculous proportions as more and more elements are patented.

Royalty payments will not be limited to plant parts. Processes for transforming living organisms are also subject to patent protection in the U.S. Further research building on the state-of-the-art will doubtless become more costly to undertake. In the absence of patent protection, such technology is available for use and to be improved at no charge.

In addition to this concern over the free flow of germplasm among breeders, there remains a concern over accessability to germplasm among nations. In response to the increased physical and legal control in the North over germplasm originating in the South, there have been threats of and actual restrictions on the export of germplasm from some countries, for example, coffee from Ethiopia and rubber from Brazil. Developments of this kind, although understandable, are in no one's interest. Plant and animal breeders will need as wide a gene pool as possible to draw on to adapt varieties to changing conditions. The detrimental effects of such restrictions may in fact be greatest among the countries of the South.

Plant Breeding

Ever since mankind learned to cultivate useful plants, rather than just gather them and their products from the wild, farmers have sought their improvement. Seeds of plants with particularly large yields, or that exhibited other useful traits, were saved for planting the following season. Trees with particularly large or tasty fruit were selected and propagated. In this way, over many millennia, a vast array of different types, varieties, or "landraces," were developed within each crop species. This process of crop improvement by farmers continues throughout the world today, especially in developing countries.

The number of different types, the genetic variation, within each crop is generally largest in the region of the world in which the crop was first domesticated — its Centre of Origin; in the Fertile Crescent of west Asia for wheat and barley, in the highlands of Ethiopia for coffee (arabica), in South America for potatoes, and in southeast Asia for rice. Indeed, almost all crops of agricultural significance were first domesticated in regions of the world that are today classified as "developing."

With the application of modern science to agriculture, the crop improvement efforts of farmers have increasingly been supplemented by those of scientifically trained plant breeders. In most of the more-developed countries, formal plant breeding now accounts for the majority of genetic advances achieved in crop yields and other characteristics.

The methods employed by plant breeders are many and varied. They depend on factors such as the nature of the breeding system of the crop, the specific breeding objectives, the genetic variation and nature of inheritance of the characteristics concerned, and extent of resources available to the breeder.

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All plant breeding, however, depends on the breeder having genes available for the particular traits desired. Such genes, for example, ones that confer early maturity or resistance to a disease, might be found in another locally bred variety of the crop, or in a landrace or variety originating many thousands of kilometres away, possibly in the Centre of Origin. They might even result from mutation induced by certain chemicals or by radiation.

The breeder has first to identify plants with the desired characteristic and then to incorporate the genes for the character concerned into another variety or into other plant types with which he or she is working.

This is often done by crossing two different types and selecting out of the progeny, in several subsequent generations, those types found to combine the desired characteristics. As the two parents frequently differ by a large number of genes, there may be an almost infinite number of different combinations of genes among their progeny.

A large part of the plant breeder's art is to identify those progenies that contain the most useful combinations. To incorporate a number of different characters into a single variety, breeders frequently make repeated crosses among several parents, increasing further the variation among the progenies. Modern crop varieties may have tens of different parental lines in their ancestry, originating from many countries.

Once a breeder has identified superior lines, they must be multiplied and subjected to several seasons of field testing under a wide range of conditions. Only those lines showing a definite advantage, whether in yield or some other character, compared to varieties already being grown are likely to be adopted by farmers. Such lines, once identified, must be further multiplied and the seed disseminated.

In most countries, there are national systems for releasing and registering new varieties that are designed to ensure that they are indeed superior to those already being grown.

In a few species, most notably maize and some horticultural crops, systems have been developed for producing seed that is itself the direct product, (i.e., the first generation) of a cross between two, or a limited number, of parental lines. Varieties produced in this way are referred to as hybrid varieties and often have substantial yield advantage compared to other varieties. Much of this advantage is lost in the second and subsequent generations following the original cross and thus farmers growing hybrid varieties must buy new, crossed seed each season. This confers a natural system of protection for breeders of such varieties — providing they keep control of the parent lines they cannot be copied.

Until recently, the only genes of use to breeders were those present within the concerned crop species or closely related ones. Now, with the development of new techniques for transferring genes widely among different species, and even between the animal and vegetable kingdoms, a vast, new array of genetic variation has been opened up for potential use in the improvement of crops, animals, and other life forms. Although to date genetic engineering has had little direct impact on the varieties grown by farmers, as a new tool for breeders, the potential is enormous. In spite of this, it is not a substitute for traditional methods. Even in this age of the genetic engineer, the tailoring of our crops to meet tomorrow's needs and conditions will, to a large extent, continue to depend on traditional breeding methods — on the crossing of parental lines followed by the selection and evaluation of superior progenies in a number of environments and over several seasons.

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Meanwhile, as the costs of accessing the necessary material and technologies rise, with royalty payments all around, so too will the cost of "intellectual property management." CGIAR has recently completed a study on the implications of strengthened intellectual property protection to their system of donor-funded agricultural research (Barton and Siebeck 1991). The report recommends that CGIAR establish a set of intellectual property policies and guidelines that would lay out the groundrules for their relationships with research collaborators. Suggestions are given for individual centres regarding the acquisition of legal support, tracking proprietary information, patent application and litigation procedures, and staff policies. Indications of the costs involved include the cost of obtaining a typical patent, including search, filing, and attorneys' fees on the order of US $9,000–14,000 in the U.S.; the average cost of patent litigation in the U.S. is $0.5 million (each side) per claim. Presumably there will be a cost in staff time as well. All of these resources could be much better allocated to the research itself. Once again, the lawyers have the most to gain.

Public Domain

As the research conducted at the International Agricultural Research Centres (IARCs) is intended to benefit developing countries, opportunities to commercialize will be limited. It is probable that most research can be "protected" from third-party appropriation by publishing it. The objective is to keep as much as possible in the public domain.

IDRC itself faces similar challenges in intellectual property management. IDRC works with researchers in developing countries. Where appropriate, collaboration with Canadian researchers is supported. As more of the research outputs become patentable, more and more time and effort will be required to ensure that the legitimate interests of all parties are respected, while not endangering the overall objective of development.

Faced with decreasing budgets and increasing costs, there are strong pressures to commercialize research outputs.

The intellectual property management decisions faced by public research institutions (national agriculture research services, universities) may not be quite so simple. Faced with decreasing budgets and increasing costs, there are strong pressures to commercialize research outputs. As David Hopper, a former Vice President of the World Bank, and a former President of IDRC, put it

> As the intellectual property lawyers redefine what is proper behaviour for research scientists, as the patents and copyrights and trade secrets and trademarks put more of the products of bioengineering into the market place as saleable technologies, the awkward questions from the taxpaying public will eventually force major changes in how agricultural research is organized, administered and funded.

In fact, the changes are already well underway. Public funding for plant breeding is already being reduced in some countries. The Cambridge Plant Breeding Institute in the U.K., a world renowned research organization, was sold to a subsidiary of the international chemical company, ICI, by the Thatcher government. Agriculture Canada is commercializing new varieties. The department has an agreement with the Treasury Board that 60% of any royalties raised will be reinvested in research. Theoretically, this should mean more money available for varietal development. The cynics might be excused for suggesting that new funds generated this way will be used to replace funds already available.

Developing-Country Concerns

Many of the concerns over strengthened intellectual property protection discussed in the foregoing are magnified in the cases of developing countries. Public research systems are notoriously weak and private-sector agricultural research is virtually nonexistent in many countries. The ethical issues may be more pronounced, considering the vastly different cultures, and the costs of administration would be significant.

Intellectual property law in and of itself is far from adequate to provide effective protection. A variety of components must be in place to support the law, including a legal system (with a fair and impartial court system), and a political and economic system that is conducive to private business and to the protection of private property in general (Lesser 1991a).

The costs of administration and enforcement of a patent system are high. The U.S. spends more than US $300 million to run their Patent and Trademark Office (Sherwood 1990); Brazil spends US $30 million on its National Institute of Industrial Property (Primo Braga 1991b). Obviously, the costs are correlated with the size of the economy and the level of research and development activity, and intellectual property protection related to living organisms will be but a part of the system. But the returns to this kind of investment, even if at much lower levels, are dubious. In any event, in countries with poorly developed agricultural infrastructures and with low levels of social services generally, there is a large opportunity cost to such investment. Even the human resource needs to run these systems may be difficult to meet.

Very little empirical or even theoretical work has been done to date on the effects of stronger or weaker intellectual property protection on developing economies

Very little empirical or even theoretical work has been done to date on the effects of stronger or weaker intellectual property protection on developing economies (Lesser 1991a). However, a recent study by the Dutch Ministry of Foreign Affairs (DGIS 1991) shows that innovators from developing countries employ patents on a very limited basis. Investment in high technology fields is risky (for many other reasons than inadequate intellectual property protection), and established technologies can be obtained more cheaply.

Furthermore, strong intellectual property protection effectively closes off the option of low-cost imitation. The main role for a protection system in developing countries seems to be to encourage foreign investment. The DGIS review noted that in 1972 only 16% of patents registered in developing countries were registered to nationals. In 1986, developing-country nationals held slightly more than 4% of patent applications worldwide and, of these, 65% were from six newly industrialized countries (NICs).

n the absence of these rade pressures, the best trategy for many leveloping countries vould appear to be to iot offer patent rotection for living rganisms.

What are the implications for a country that chooses not to implement intellectual property protection for life forms? Any technology and any germplasm that can be obtained can be utilized without infringing any laws. Producers can use any materials they can get without paying royalties. Because there is no protection, however, technology holders will be reluctant to transfer the technology or the germplasm. This may be a significant consideration for certain developing countries trying to get access to new technology, although a more important drawback is likely to be that harvested materials grown from protected varieties are not exportable to countries in which they are protected.

In the absence of these trade pressures, the best strategy for many developing countries would appear to be to not offer patent protection for living organisms. Instead, less strict intellectual property regimes that provide incentives for adaptive innovation may be much better suited to their needs. Plant breeders' rights might be an appropriate system, possibly with certain modifications to adapt the legislation to the specific needs and circumstances of the particular country. Technology access may be achieved through licensing agreements, or other means (none without its drawbacks). The trade pressures are a reality, however, and they will have to be dealt with somehow.

Too Far Too Fast?

Although the practice of patenting living organisms has been established in some countries, most notably the U.S., the appropriateness of this practice has not been adequately evaluated. It is clear that the legislation under which these patents are being granted was not designed for this purpose. The courts are making decisions largely based on whether or not the legislation expressly prohibits such activities. The issue is real and will be increasingly important. Clearly, given the implications, a full public discussion is needed, and appropriate legislation should be drafted based on a complete evaluation of all the issues involved.

A major concern is raised by the evident trend toward global harmonization of intellectual property protection relating to living organisms. Encompassed as it is within trade-related negotiations, we are very concerned that countries may be "forced" to adopt laws that are not well suited to their particular conditions (including the research environment and the cultural heritage and value system of the nation), and that have not benefited from the necessary public discussion and evaluation.

There are many profound concerns raised by the concept of patents on life forms. The concept itself, however, is so new that neither side in the debate has adequately marshalled its arguments. There is little evidence that the majority of trade negotiators have adequately come to grips with the highly complex arguments for, and especially against, the application of patents to life forms. Such arguments range from the religious and metaphysical, through to some strong concerns that patents on life will have the effect of devaluing society's concept of life, to consideration of the "fairness" of assigning commercial control of a living organism on the basis of very small modifications to that organism.

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We consider that the ethical implications of intellectual property protection applicable to living organisms to be very important, especially in countries with completely different cultural backgrounds. These issues must be aired in public dialogue in every country contemplating such legislation. The brevity of the treatment here reflects an extreme paucity of consideration in the literature, underlining the clear need for more research and discussion.

Similarly, the potential implications to research in developing countries are very poorly understood. In many countries, indigenous research capacity is extremely weak. The reasons are manifold; put simply, these countries lack the necessary research infrastructure. The adoption of stronger intellectual property protection alone is unlikely to be adequate to stimulate much higher levels of research. On the contrary, there appears to be some danger that indigenous research capacity may actually be damaged by patents through direct mechanisms of control over information or germplasm, and through indirect mechanisms such as reduced public research expenditure and through the diversion of funds to the administration of the intellectual property protection system. Access to information may be inhibited, and exports may be threatened.

Intimately connected with the whole issue of intellectual property protection is the larger issue of the privatization and the commercialization of research. There is of course a role for private plant breeding and private research in general. Indeed, private support to research has much to offer and should be encouraged. It is essential, however, to maintain strong public-sector involvement in biological research. The private sector cannot be expected to invest in research the profits of which they cannot appropriate. Yet, there remain very important problems and situations that do not lend themselves to private, for-profit research and that require a strong public research system. Within this context, there is a real concern that publicly supported research should not be appropriated for the profit of a few.

We do not reject the notion of intellectual property protection where it is appropriate. Patent protection of processes for the utilization of biological materials seem to fall within the kind of innovation for which patents were designed, and do not introduce the complications that patents on self-reproducing organisms do. They do raise questions of the propriety of social policy that encourages activities that society may not approve of. Such a lack of approval, however, has not been determined and, anyway, it does not seem possible to have a policy, such as patents, designed to stimulate only socially acceptable innovation. Other mechanisms are needed to sanction the ultimate outcomes of research. More debate is required on genetic engineering and what the limits should be.

Where some form of intellectual property protection is deemed appropriate to stimulate investment in plant breeding and other biological research, plant breeders' rights offer certain benefits in terms of protection for the researcher with less of the attendant risk posed by strong patent coverage. We recommend that this form of protection be given careful consideration in lieu of patent protection for plant varieties. Plant breeders' rights must be modified to meet the specific needs of the country enacting the legislation. Similar approaches to legislation may be useful for animals and other life forms, offering incentives to research without the potential dangers and ethical concerns associated with patents.

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