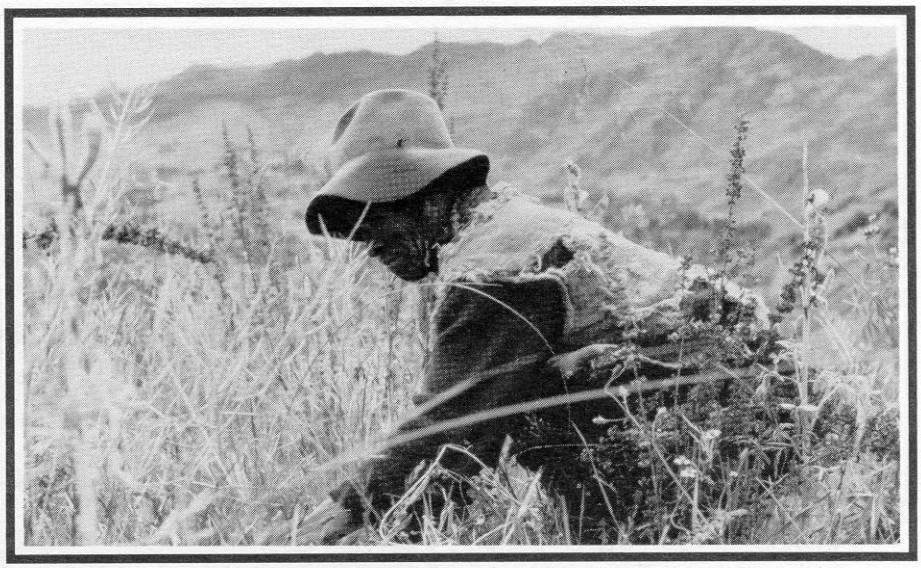
LIVING INVENTIONS

The life sciences are changing in their fundamental character, and at a rapid rate. The new biotechnologies have made it possible to transfer genetic material between completely dissimilar organisms and to modify living organisms for human purposes more rapidly and efficiently than ever before.



Small-scale farmers in the South often develop biological innovations. These innovations are not now protected by any codified intellectual property law, and so could be very vulnerable to being improperly appropriated by others.

These technical advances have served to blur the distinctions between living and nonliving and between natural and manmade. 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, and investment capital has been mobilized in a way unprecedented in the history of science.

Biotechnology requires high levels of investment in research, but the results — the intellectual property — are easily and cheaply copied. Investors in research want some form of intellectual property protection to ensure returns on their investments. Plant varieties have been eligible for protection in some countries for many years using plant breeders' rights (called plant variety protection in Europe).

Increasingly, however, industrial-style patents, formerly reserved for inanimate inventions, are being used for living organisms. In most countries where patents are being used for living things, they have been granted as the result of new interpretations of existing legislation and not through new legislation dealing specifically with the issue of patents for life forms.

Patent protection is also available in several jurisdictions, including Canada, for novel genes. As well, the U.S. Patent and Trademark Office has granted patents on a plant characteristic (e.g., high-tryptophan production in maize). The patent claims a monopoly over any high tryptophan-producing maize regardless of the process by which the overproduction is achieved. Furthermore, U.S. law allows that patents 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."

The argument for intellectual property protection is often couched in terms of increasing incentive to research. Two basic philosophies prevail. 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 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.

The alternative to effective intellectual property protection is to not disclose information or not make "new" biological materials available to prevent competitors from making use of it. Such "Trade Secrets" 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. It is this option that concerns the proponents of strengthened intellectual property protection. They argue that, if research is performed by the private sector, some mechanism needs to be in place to guarantee that the fruits of this research are made available to society.

Although this argument appeals to the need to promote research, the motivations and the pressures currently driving the strengthening patent protection for living entities are much more commercial and trade oriented than they are to promoting an effective research environment;

patents are being used to protect investment. This is reflected in the very strong pressures being exerted, especially by the U.S., in bilateral and multilateral trade negotiations, for international "harmonization" of intellectual property protection. Patent protection on living organisms is definitely included.

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 General Agreement on Tariffs and Trade (GATT). The U.S., E.C., and Japan have taken the position that all things, including plants and animals (with very narrow exemptions) should be considered patentable subject matter. Canada, on the other hand, has (so far) taken the position that certain things should be eligible for exemption at the national level (including multicellular life forms and processes for producing new multicellular life forms).

ETHICAL CONSIDERATIONS

All countries must face the very real prospect that within the GATT, and within various bilateral trade negotiations, patent protection applicable to higher life forms will be included as an almost incidental part of a much larger commercial/trade package. First of all, it must be made clear that patents were not designed for living inventions. 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 divergence of present practice from the intent of the law is demonstrated well by the difficulties encountered with the disclosure requirements of patent law. Simply stated, patent laws require that an applicant "correctly and fully describe the invention" and the process of making it such that "any person skilled in the art" could reproduce it. That is the deal.

For many living "inventions," however, adequate description is practically or even technically impossible. Even "simple life-forms," such as yeasts or algae, are extremely complex. To overcome this difficulty it has become common practice in some countries to allow the "inventor" to deposit a sample of the "invention" in lieu of a complete patent disclosure. True, the sample is made available for others to use. Allowing a patent applicant to circumvent the disclosure requirement however, really seems to open the door to patents on organisms that may be novel and useful but that have come about by chance, i.e., the "inventiveness" criterion of the patent may not be met. This does not seem a particularly good bargain for society.

Related to this is a 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. What was considered the common heritage of mankind becomes the private property of a few.

Intellectual property law is a product of Western society and Western ideals. Other societies have very different concepts of life and of ownership that may not correspond with those inherent in patent policy. These ideas simply have not been explored adequately. In addition, it must be remembered that the innovation systems in many developing countries are quite different from those of developed countries. In many countries, there are strong informal systems, with small-scale farmers, 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 codified intellectual property law, and so would be very vulnerable to being improperly appropriated by others in the wake of strengthened, national intellectual property protection. Patent systems may be difficult for the informal innovators of developing countries to use to advantage, but there is a risk that they may be used to their disadvantage. Finally, patents should, as an important mechanism of social policy, reflect a society's ideals and maintain traditional values. Yet patenting living organisms seems to run counter to the distinction that most, if not all, societies make between living and nonliving. The effect is a reduced legal definition of life.

COMMERCIAL INTERESTS

Intellectual property protection and the priorities in biological research are increasingly being dictated by commercial imperatives. Strengthened intellectual property is not solely responsible for this trend, but is certainly implicated as an important element in the privatisation of research.

Where short-term commercial interests dominate, there is clearly a comparative advantage to concentrate research efforts in high value areas. In plant breeding this means species of major commercial importance and which are grown over a large area, 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.

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. Related to this barrier to the free flow of information is the equally important barrier to the free flow of germplasm. If 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, especially in the field of plant breeding where very wide ranges of parent material are employed.

It is important also to note that in response to the increased physical and legal control (perceived and real) of the North over germplasm originating in the South, there have been threats and actual restrictions on the export of germplasm from some countries.

Triticale, a hybrid cereal derived from a cross between rye and wheat. An example of plant breeders' innovation.

Demonstration plots of rice varieties at the International Rice Research Institute in the Philippines. The development of dwarf rice with a high-yield potential contributed to the Green Revolution of the 1960s and 70s.

Developments of this kind, although understandable, are in no one's interest. Plant and animal breeders need as wide a genepool as possible to draw on to adapt varieties to changing conditions for the benefit of all.

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."

The cost of administration and enforcement of a patent system may also be prohibitive. For example, the U.S. spends over $300 million to run their Patent and Trademark Office, and Brazil spends US $30 million on its National Institute of Industrial Property. In the absence of trade pressures, the best strategy for many developing countries would appear to be to not offer patent protection for living organisms and to use instead less strict intellectual property regimes that provide incentives for adaptive innovation.

For research purposes, any technology and any germplasm that can be obtained can be utilized without infringing any laws. Similarly, producers can utilize any materials they can get without paying royalties. However, without protection, technology holders will be reluctant to transfer proprietary technology or germplasm (an important consideration for developing countries trying to get access to new technology). Furthermore, harvested materials grown from protected varieties are not exportable to countries in which they are protected; and the trade pressures are a reality.

CONCLUSION

In weighing these concerns it is important to keep in mind the ongoing "revision," at least in some quarters, of human relations with the larger environment. This is expressed in a variety of ways, from "deep ecology," through increasing concern for animal rights, to the growing environmental movement. Furthermore, as other countries are brought into Western-style patent systems there will be encounters with a myriad of other cultural perspectives toward ownership of living things. These ideas should be considered as legitimate antitheses to the commercial and trade arguments for patenting.

Alternative forms of intellectual property protection could be designed specifically to deal with the characteristics of living organisms. In many ways, plant breeders rights laws seem to strike an appropriate balance between providing individual incentive and reward for research without seriously skewing the research agenda. Perhaps similar *sui generis* intellectual property protection systems can be designed for other areas of biological research (animal varieties, microorganisms, genes). Another option lies in the petty patent systems employed by some countries that offer somewhat less scope of protection for a less significant inventive step than industrial-style patents. Criteria for such intellectual property systems include offering appropriate incentives to research with the scope of protection limited such that the interests of the larger research system are not compromised too severely in the name of individual research efforts. Still, although modified property protection systems may answer some of the concerns raised here, others — especially ethical concerns — are fundamental to any intellectual property system applied to living organisms.

This article draws on information from "A Patent on Life: Ownership of Plant and Animal Research," coauthored by Brian Belcher who is currently a Research Officer with IDRC.