

Who Owns Biodiversity, and How Should the Owners Be Compensated?

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At the World Summit on Sustainable Development, held in Johannesburg in 2002, the Secretary General of the United Nations, Mr. K. Annan, outlined five major areas slated for progress in achieving a sustainable future for humanity. These five areas were water and sanitation, energy, health, agricultural productivity, and biodiversity and ecosystem management. Agricultural productivity depends in part on the availability of biodiversity for the development of improved cultivars. Hence, it has become clear that biodiversity has become one of the cornerstones of sustainable development. Biodiversity is defined here as the sum of genetic and phenotypic differences existing in living organisms (including viruses, although they do not fit the precise definition of a living organism) at the molecular, individual, population, and ecosystem levels. The increased emphasis on biodiversity is the result of, on the one hand, an increased demand, driven by factors as diverse as plant breeding, drug development, and ecosystem services, and, on the other hand, by decreasing supplies, caused by overpopulation and globalization and the ensuing habitat destruction and cultural homogenization.

Until the 1970s, biodiversity was considered to be part of the “common heritage of humankind.” Under this regime, biological resources are treated as belonging to the public domain and are not owned by any individual, group, or state. Its consumption is “non-rival” (its use by one person does not compete with its use by another) and nonexcludable (no person can exclude other persons from its use; Herdt, 1999). For millennia, common heritage has been implicitly used as the principle governing the diffusion of crop and animal genetic resources from centers of domestication, their exchange among farmers, and their introduction into new continents, in particular between the Old and the New Worlds after 1492. The common heritage principle has also been used in the development of international and national gene banks, which still operate in the spirit of this principle (Shands and Stoner, 1997). Furthermore, this concept was given legal status in international conventions, such as the 1972 UNESCO Convention for the Protection of the World Cultural and Natural Heritage, the 1979 Moon Treaty, and the 1982 Law of the Sea

Convention. Included in these treaties are several legal elements, including the availability, free of national sovereignty or private property claims, management for the benefit of mankind as a whole, exclusive use for peaceful purposes by all states, and free and openly accessible scientific research. Contrary to popular belief, common heritage does not imply a lack of rules regarding the management and access to the shared resources. For example, one of the essential rules is the reciprocity in access among farmers and plant breeders across economic sectors and national borders (Brush, 2003). Furthermore, Brush (2003) points out that common heritage is logical within farming communities where land and other natural resources are communally owned, seed is exchanged or shared, invention is collective, provenance is ambiguous, and natural and artificial selection are intertwined. Because of the transaction costs of proprietary management of seed, common heritage arguably is the best way to satisfy the frequent necessity to change or acquire seed in nonmarket economies.

There have been exceptions to the rule of open access (Brush, 2003). These have included restrictions by countries to the export of planting materials (e.g. *Cinchona* by Peru and Bolivia in the 19th century and coffee [*Coffea arabica*] by Ethiopia in the 20th century) or attempts by colonial powers to monopolize certain resources (e.g. nutmeg [*Myristica fragrans*] by England, The Netherlands, and Portugal in the 17th century). Nevertheless, the overarching principle has always been one of free access and exchange. The last three decades have seen a significant change in the regime governing access to biodiversity. From a common heritage of mankind, biodiversity is evolving into a resource under the sovereignty of nation states and is subject to intellectual property rights (IPRs). This change is not without controversy. How and why this evolution is taking place and what type of ethical issues it raises is the topic of this essay.

THE MOLECULAR BIOLOGY-INTELLECTUAL PROPERTY RIGHTS-GLOBALIZATION JUGGERNAUT

In the last three decades, with the coming of age of molecular biology, there have been major scientific but also policy and judicial changes that have led to a deeply modified international technological and political landscape. The development of tools to

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manipulate DNA, such as restriction enzymes, cloning vectors, and high-throughput sequencing, has allowed the isolation and characterization of a high number of gene sequences and, in certain organisms, of whole genome sequences. Development of transformation systems has led to the production of transgenic plants, which can complement natural sources of genetic diversity in plant breeding programs, leading to improved cultivars (Gepts, 2002; Mirkov, 2003).

The key contribution of molecular biology—within the framework of this discussion—is the ability to isolate a gene sequence in purified form, in contrast to its presence within a living organism. Indeed, the U.S. Patent and Trademark Office (USPTO) has treated gene sequences as if they were manmade chemicals based on jurisprudence dating back the 1912 case *Parke-Davis v. Mulford*, in which the applicant was awarded a patent on purified adrenaline. The fact that the applicant had been able to purify adrenaline in a form that did not exist in nature and that under its purified form it could be used in treatments was deemed to satisfy the novelty, nonobviousness, and utility criteria needed for the award of a patent (Andrews, 2002). This view was later extended to genes, despite the fact that genes are natural entities and would seem to fall outside the scope of IPRs (Hughes, 2002). Information on the sequence of a gene is deemed to satisfy a patent's novelty requirement in contrast with earlier times, when the presence of a gene in an organism was assessed on a purely phenotypic basis.

If genes can receive intellectual property (IP) protection, what about whole organisms? In reality, some plants have been patentable since 1930, when "plant patents" were instituted for new and distinct cultivars of asexually propagated crops, principally ornamentals and potato (*Solanum tuberosum*). In 1980, a landmark U.S. Supreme Court case (447 U.S. 303) instated the award of a utility patent for a genetically engineered *Pseudomonas* bacterium capable of breaking down crude oil (U.S. Supreme Court, 1980) and initiated a new era, in which "utility patents" for life forms, including plants and crop cultivars (Ex parte Hibberd decision: 227 USPQ 443,447; Bd. Pat. App. & Int. 1985), could be obtained in the United States. Patents are awarded for inventions that are novel, in that they must not have been made public for more than 1 year. They should also be useful and non-obvious to someone skilled in the art (35 USC § 101, 102, 103; U.S. House of Representatives, 2002). The spirit of the patent's legislation involves a compromise between the government and individual inventors, whereby the government awards the inventor a temporary monopoly (20 years) over the invention against "enablement" of the invention, i.e. a description in the patent application of the invention in a "manner that would enable one with ordinary skill in the art to make and use the invention without an undue amount of experimentation." Presumably, this description would allow individuals experienced "in the art" to experi-

ment or tinker with the patented inventions and develop further improvements.

A third way in which IP can be claimed for plants is by Plant Variety Protection (PVP), which falls under the International Union for the Protection of New Varieties of Plants (UPOV) convention. To obtain a PVP certificate, a cultivar has to be distinct, uniform, and stable. Furthermore, it cannot be "essentially derived," i.e. representing primarily a previously existing cultivar but with minor modifications, such as the introduction of a single gene by backcrossing or genetic engineering (corrective breeding). In this case, the ownership remains with the owner of the original cultivar. Unlike patents, PVP recognizes both a farmer's and a breeder's exemption. Farmers can harvest seeds and use them for planting the crop of the following year (although they cannot sell them). Plant breeders can use the cultivar as a progenitor in further cycles of cultivar development. Thus, PVP offers less stringent protection than patents. However, the breeder's exemption offers an opportunity for further progress in improvement while avoiding infringement. In addition to these legal means of protection, biological means also exist. These include the capability of using F₁ hybrid seeds and the use of Genetic Use Restriction Technologies. The former has been used for several decades in maize (*Zea mays*), whereas the latter have been proposed but not implemented, in part because of international controversies regarding the deployment of such technologies, which involves the invariability of the seed, although alternative, useful applications of this technology exist as well (<http://www.biodiv.org/programmes/areas/agro/gurts.asp>).

The three juridical ways of protecting novel cultivars share territorial limitations, in that patents and PVP certificates are only valid for the jurisdiction in which they were awarded. For example, American patents are only enforceable in the territory of the United States. To broaden the geographic scope of the protection of an invention, patents must also be applied for in other countries. This assumes two important points: first, that other countries have an IPR legislation and, second, that they actually enforce this legislation. Many industrialized countries have such legislation; however, many developing countries do not. Therefore, to promote international trade on a global level, transnational seed companies and their respective governments in developed countries are pressuring developing countries to establish their own IPR legislation. This pressure is actually part of a broader strategy destined to open up global markets to free trade. This effort has culminated in the so-called Trade-Related Aspects of Intellectual Property Right (TRIPs) agreement, which falls under the purview of the World Trade Organization and came into force in 1995 (http://www.wto.org/english/tratop_e/trips_e/trips_e.htm). The TRIPs agreement is a partial compromise between developed and developing countries. On one hand, the developing countries have committed themselves to developing an IPR system. On the other hand, they

can refuse to include plants, animals, and “essential” biological processes as patentable subject matter (but strangely enough microorganisms and nonbiological and microbiological processes, including genetic engineering techniques, have to be eligible for patents). Crop cultivars have to be eligible either for patent protection or through a system created specifically for the purpose (“sui generis”), or a combination of the two. The sui generis system is generally believed to be akin to a PVP system.

Two additional international treaties are relevant to this discussion. The Convention on Biological Diversity (CBD; <http://www.biodiv.org/>) was signed in 1992 and came into force in 1993. The objectives of this convention are the conservation of biological diversity, the sustainable use of components of biological diversity, the fair and equitable sharing of benefits arising out of the use of genetic resources, and appropriate transfer of relevant technology. In its Article 15, the CBD states that genetic resources are subject to the sovereignty of individual states and that collection of these resources requires prior informed consent. This article—as well as the TRIPs agreement—made obsolete the nonbinding International Undertaking on Plant Genetic Resources, adopted in 1983 under the auspices of the Food and Agricultural Organization (FAO) of the United Nations. This agreement had stated that biodiversity is the “common heritage of humankind.”

The CBD focuses on sovereignty over individual plants and animals as tangible goods in contrast with TRIPs, which seeks to govern access by internationally standardized IPR rules (Strauss, 2001). The CBD further stipulates that there should be a quid pro quo in the acquisition of germ plasm. In exchange for germ plasm, some technology should be transferred from the country acquiring the germ plasm to the country providing the germ plasm. This is, however, a weak stipulation because parties are only required but not obligated to cooperate. Furthermore, the CBD also recognizes the contribution of local and indigenous communities to conservation and sustainable utilization of biodiversity. It accords traditional knowledge (TK), a status comparable to that shown to other types of knowledge, particularly scientific knowledge. TK should, therefore, be entitled to some form of IPR in the same way that technological knowledge is according to this convention. Thus, the CBD—presumably inspired by “The Tragedy of the Commons” of Hardin (1968)—substituted the common heritage regime governing biodiversity with a property regime focused on decentralized bilateral contractual agreements to assure conservation of biological diversity. A further impetus toward privatization was provided by the general political climate in the 1980s and 1990s, which emphasized free market solutions. Central to these biodiversity agreements are IPRs (Boisvert and Caron, 2002).

More than 180 countries have become party to the CBD, the United States being a notable exception. The reluctance of the United States can be traced back,

in part, to strong reservations on the part of the pharmaceutical and biotechnology industries with regard to some CBD provisions related to IPRs, which could allegedly lead to a weakening of IPR, particularly for biotechnology, and open the door to compulsory licensing arrangements imposed by developing countries (Miller, 1995; Verma, 2001). Because the CBD is a framework agreement, identifying overall goals and policies, specific details have been discussed further at Conferences of the Parties and have led to the development of “decisions” and “protocols” (e.g. <http://www.biodiv.org/convention/cops.asp>). One of these protocols is the so-called Cartagena protocol, which deals with the handling, transfer, and release of transgenic organisms (<http://www.biodiv.org/bio-safety/>; Cosbey and Burgiel, 2000).

The second additional treaty is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA; <http://www.fao.org/ag/cgrfa/itpgr.htm>), signed in 2001 by 140 countries but not yet entered into force. This treaty is a revision of the original International Undertaking on Plant Genetic Resources mentioned earlier. One of the revision’s principal goals was to harmonize the Undertaking with the CBD. In contrast with the CBD, which revolves around country-to-country relationships, this treaty is a multilateral agreement. Governments agree to provide other governments or “legal persons” within those countries with “facilitated access” to genetic resources belonging to a list of more than 100 crops and forages. Recipients of these genetic resources agree to pay into an international fund (Global Crop Diversity Trust) an equitable share of benefits arising from the commercialization of a crop that incorporates genetic material from the multilateral system and is protected by IPRs. Funds from the fund will be used for programs in germ plasm conservation and capacity building agreed upon by a governing body. The list of crops includes most major crops, such as rice (*Oryza sativa*), maize, wheat (*Triticum aestivum*), potato, banana (*Musa* spp.), and common bean (*Phaseolus vulgaris*). Among the crops missing are soybean (*Glycine max*), sugarcane (*Saccharum officinarum*), groundnut (*Arachis hypogea*), tropical forages, tomato (*Lycopersicon esculentum*), grape (*Vitis vinifera*), cocoa (*Theobroma cacao*), coffee, and industrial crops such as oil palm (*Elaeis guineensis*) and rubber (*Hevea brasiliensis*). For the latter crops, certain countries felt that they could gain more from selling resources bilaterally than by including them in a multilateral exchange system (Fowler et al., 2003).

The strengthening of IPR protection for living organisms, especially plants, limits the possibilities of free acquisition or exchange. Access must now be gained through patent licenses, material transfer agreements (MTAs), bag-label contracts, and technology use agreements (Wright, 1998). Here again, molecular biology techniques provide an important tool, in that DNA fingerprinting provides important information as to the origin of genetic resources (e.g.

Pallottini et al., 2004). Thus, a system of biodiversity ownership is now being put into place that consists of three mutually reinforcing components—molecular biology, IPRs, and international treaties. This system is leading to an increased commoditization of biodiversity and allows inventions, including those based on living organisms or biodiversity and crop cultivars, to receive intellectual protection and be distributed throughout the world. This system is not fully established at this date and is not without its detractors. In the following sections, I discuss some of the aspects that are currently under discussion regarding this new biodiversity ownership landscape.

INEQUALITY OF THE TERMS OF EXCHANGE BETWEEN DEVELOPED AND DEVELOPING COUNTRIES

The push for IPRs for biodiversity, in general, and crop cultivars, in particular, was opposed early on by a range of countries, groups, or individuals for a number of reasons, the main one relating to the widespread inequality in the terms of exchange between the North and the South. For plant genetic resources, the terms of exchange have been described by, for example, Fowler and Mooney (1990) and Kloppenburg (1988), as in Figure 1.

On the one hand, the South is generally rich in biodiversity, but it has contributed this asset, voluntarily or involuntarily, without cost in the spirit of the common heritage. Furthermore, biodiversity is closely associated with cultural diversity and TK (biocultural diversity; Maffi, 2001). This TK is an integral part of biodiversity and is a resource in its own right. For example, Fabricant and Farnsworth (2001) determined that 80% of plant-based drugs in Western medicine have had an ethnomedical (i.e. non-Western) use identical or related to the current use of the active elements of the plant. On the other hand, the North is rich in technology to utilize biodiversity, for example, to identify potential pharmaceuticals or traits or genes to introduce into improved crop cultivars by hybridization or genetic engineering. In addition, the results of these activities are now increasingly protected by IPR in developed countries, the goal being to safeguard and encourage investments and generate a revenue stream. Current globalization efforts also aim at extending this IPR system on a global scale.

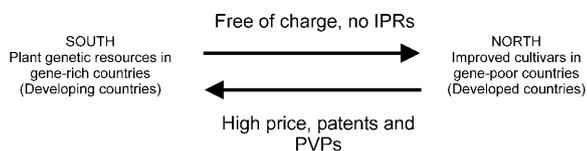


Figure 1. Simplified description of supposed terms of exchange for plant genetic resources between developing (gene-rich) and developed (gene-poor) countries.

To what extent does this picture reflect the actual situation? Genetic diversity is unevenly distributed around the planet, with most of the diversity located in tropical and subtropical regions (Williams et al., 1997), where most developing countries are located. In addition, centers of crop genetic diversity, which often coincide with centers of agricultural origins, are generally located between 30° north and south: Mesoamerica, Andean South America, Sahel and Ethiopia, Southwest Asia, Southeast Asia (including parts of India), and China (Gepts, 2004). In these centers of diversity, crop diversity includes not only bred cultivars but also landraces (farmer cultivars) and various wild populations with varying degrees of relationships with the domesticated type. Plant breeding is focusing increasingly on these “exotic” or unadapted genetic resources to broaden the genetic basis of crops and assure continued progress from selection, with or without assistance of marker-assisted selection and genetic engineering (Tanksley and McCouch, 1997; Kelly et al., 2003). Wild germ plasm is currently underrepresented in gene banks (Gepts, 2000). As wild germ plasm becomes more important with time in breeding, one can expect the role of germ plasm from the South to increase as well because they would have easier access to these resources by additional botanical explorations.

Likewise, a quarter to a third of medicines are currently extracted from plants, many of which have a tropical distribution. Examples are vinblastine (rosy periwinkle [*Catharanthus roseus*]; Hodgkin’s disease), vincristine (rosy periwinkle; leukemia), tubocurarine (*Chondodendron tomentosum*; muscle relaxant), quinine (*Cinchona ledgeriana*; anti-malarial), pilocarpine (*Pilocarpus cearensis*; glaucoma), morphine (opium poppy [*Papaver somniferum*]; analgesic), and taxol (Pacific yew [*Taxus brevifolia*]; ovarian cancer). Thus, developing countries, as a whole, have direct access to the bulk of biodiversity resources on this planet.

The fluxes of biodiversity resources are, however, much more complex than the South-North direction portrayed above. Within the South, there have been significant fluxes as well, such that no region or society is entirely self-sufficient for its crop genetic resources. For example, the Mesoamerican crops maize and common bean and the South American crop cassava (*Manihot esculenta* Crantz) play a significant role in the diet of African people. Sugarcane and coconut (*Cocos nucifera*), two domesticates of Southeastern Asia, now have a broad tropical distribution. Kloppenburg (1988) and Flores Palacios (1998) have shown, in the best case, a dependency of only 30% for the Southwest Asian center of agricultural origin (i.e. only 30% of crop production in that area relies on nonindigenous crops). In other cases, they estimated about 60% of dependency in the Latin American and Chinese centers (Fig. 2). Crop improvement in developing countries most certainly also relies on nonindigenous resources. Thus, there is an interest in maintaining open

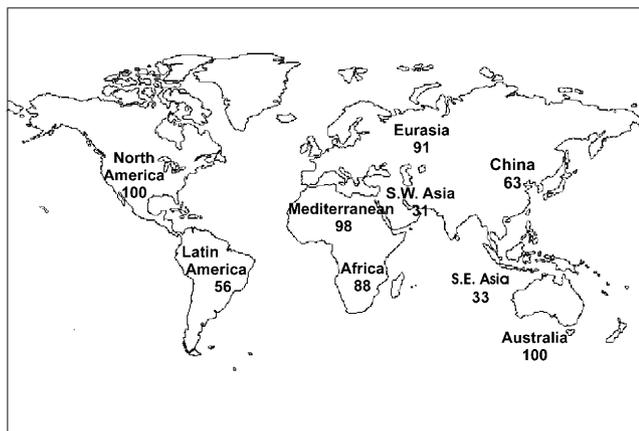


Figure 2. Dependency of crop production in major centers of agricultural origins or other geographic regions on introduced crops (map based on data of Kloppenburg, 1988). Values indicate percentage dependency.

exchange channels for genetic resources. The dependency of the North on the South's genetic resources is also reduced by the existence of gene banks that contain a large number of entries of a wide variety of crops (FAO, 1998). In these gene banks, samples are—with a few exceptions—still distributed freely and free of charge to any individual in the common heritage spirit. Furthermore, the gene banks of the centers belonging to the Consultative Group for International Agricultural Research (CGIAR), such as the Centro Internacional de Mejoramiento de Maíz y Trigo (CIMMYT; Mexico), the International Rice Research Institute (IRRI; The Philippines), and the Centro Internacional de Agricultura Tropical (CIAT; Colombia), which hold more than 500,000 germ plasm accessions, have instituted an MTA (http://www.sgrp.cgiar.org/MTA_E.pdf). This MTA seeks to protect the germ plasm or breeding lines and associated information distributed by the CGIAR center from ownership or IP claims by the recipients of this material. Obviously, this MTA does not cover further breeding uses leading to improved materials. A further situation limiting the relative importance of the South as a source of diversity is that, in private breeding programs, exotic germ plasm is used rarely, and when used almost always constitutes a small percentage of the genetic background (Duvick, 1984). In summary, developing countries are generally a rich source of biodiversity; however, this statement needs to be tempered by some of the realities of the actual distribution of genetic resources and the practices of crop improvement.

On the other side of the equation, developed countries hold a disproportionate share of the capabilities in pharmaceutical sciences and genetic crop improvement (including plant breeding and genetic engineering), two of the major uses in developed countries of biodiversity from developing countries. For example, the 10 major pharmaceutical companies

originate in the United States, United Kingdom, Switzerland, Sweden, France, and Germany. The 10 major seed companies come from the United States, Switzerland, United Kingdom, France, Mexico, Japan, and Germany (Fulton and Giannakas, 2001). With the exception of one company (Semini, Mexico), they deal mostly with field crops, such as maize, soybean, and cotton (*Gossypium hirsutum*). Many of them have significant biotechnology investments, which have resulted in the release of transgenic cultivars that occupy a large portion of the cultivated area in the United States. Transgenic soybean, cotton, and maize were planted on 81%, 73%, and 40%, respectively, of their respective areas in 2003 (U.S. Department of Agriculture Economic Research Service, 2003). Worldwide, the United States grew 66% of the total area grown with transgenic crops, followed by Argentina with 23%. All other countries had a participation of less than 10% (James, 2003).

The combination of the molecular technology and the capability of protecting molecular inventions by IPR has led to significant activities in the private sector in the area of genetic engineering of crop plants. While large chemical companies did have the financial wherewithal to engage in genetic engineering research, they have had to complete their IPR portfolio by taking over biotechnology companies (often start-ups). They also had to acquire capabilities in classical plant breeding in order to develop cultivars as vehicles to deliver the results of their genetic engineering technology, such as herbicide tolerance or insect resistance. They also needed the necessary seed marketing channels. The last two objectives were achieved by buying smaller seed companies, which had neither the financial wherewithal nor technological track record to survive in this new environment. This has led to a situation in which only five major firms now sell genetically improved seeds: Monsanto, DuPont/Pioneer, Aventis, Syngenta, and Dow. These same companies account for about a quarter of total seed sales (Fulton and Giannakas, 2001; Falcon and Fowler, 2002; Pingali and Traxler, 2002). For example, in 1998, Monsanto and Pioneer-HiBred controlled 15% and 39% of the U.S. maize seed market, respectively. For soybean seed, these companies controlled around 24% and 17%, respectively, of the market. For U.S. cotton, Delta & Pine Land and Stoneville had 71% and 16%, respectively, of the seed market (Kalaitzandonakes and Hayenga, 2000). In 1999, 61% of the cotton area in the United States was planted to a small number of closely related cultivars in which transgenes had been introduced, such as Deltapine 90 and DES56 (U.S. Department of Agriculture Agricultural Marketing Service, 1999). Thus, while the availability of IPR has allowed the private sector to step in the crop improvement area beyond hybridization (maize and vegetables), there has been an apparent price to pay in the reduction of the number of cultivars grown by farmers. This reduction would be of major concern if it were extended to centers of crop origins, where a wealth of

genetic diversity among landraces is still grown by farmers (Gepts and Papa, 2003).

Some developing countries also have biotechnology capabilities, such as China (Huang et al., 2002) and Brazil (Simpson et al., 2000), as well as smaller countries (da Silva et al., 2002). Plant breeding capabilities exist as well, both in national and international research programs (Morris and Ekasingh, 2002). Yet, these capabilities remain quantitatively well below those of developed countries. Hence, there is a tremendous need for capacity development in the areas of biotechnology and breeding in developing countries. Is the introduction of IPRs in exchange for access and benefit sharing related to biodiversity a vehicle toward the development of such capacity? In order to answer this question, additional characteristics of Western-style IPRs need to be discussed, as well as the current ownership rules, if any, of biodiversity in developing countries, which harbor the major part of biodiversity on the Earth.

FURTHER ISSUES ASSOCIATED WITH INTELLECTUAL PROPERTY RIGHTS ON BIODIVERSITY

Discovery or Invention?

A first issue relates to the nature of patents, especially patents awarded for elements of biodiversity. Patents are awarded for novelty, inventiveness, and utility. Patents for biodiversity, whether at the gene or organismal levels, challenge these three main criteria, yet they have become increasingly frequent. For example, in 1980, 16 patents were awarded for gene sequences. In 1990, the number was more than 6,000 and in 2000 more than 355,000 (Dutfield, 2002). As stated by Demaine and Fellmeth (2003), "subtly and without fanfare, the prohibition on patenting products of nature has fallen into desuetude." Those in favor of patenting of genes argue that locating, isolating, and describing genes require ingenuity. The U.S. Patent and Trademark Office (2001) agreed with this interpretation and extended to genes earlier findings stating that purification of a compound (e.g. adrenaline, prostaglandins, etc.) outside of its natural state could make this compound eligible for a patent. In the case of genes, it is also argued that if the gene was previously unknown, isolation of this gene can now lead to an explanation of its function, mode of action, and possible industrial application. If the application relies not on the gene but on the corresponding cDNA, then a case could be made for an invention based on a synthetic chemical. Furthermore, supporters of gene patents argue that biotechnology research is risky and expensive and that the promise of a temporary monopoly provided by a patent is a necessary stimulus for this type of research.

By contrast, critics argue that DNA sequence isolation and characterization, including by reverse transcription, is now a routine operation even for those

with "average skills in the art" and does, therefore, not qualify as an inventive step (Dutfield, 2002). After all, private companies sell kits that help achieve some of the steps of the procedure of DNA sequence isolation. DNA sequencing is such a routine operation that it generally is done by public or private service labs, and whole genome sequencing has been achieved for an increasingly large number of species. To this objection, the U.S. Patent Trademark Office (2001) replies that obviousness does not depend on the amount of work required to characterize the DNA molecule: "Patentability shall not be negated by the manner in which the invention was made," and "The existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious." (see 35 U.S.C. 103(a); U.S. House of Representatives, 2002). In Europe, an isolated gene or gene sequence or other element isolated from an animal or plant is patentable, provided that its function is known and a suitable industrial application is derived from that product. However, no rights are given to that product when found in its natural environment. The European Commission Directive also allows for the patenting of plants and animals, provided that the application of the invention is not technically confined to a single plant or animal variety. This means that a patent for a novel gene sequence that confers a benefit to a plant will extend to any plant in which the gene has been artificially inserted (European Commission, 1999, 2002).

It can also be argued, however, that a mere routine purification does not warrant novelty or nonobviousness. Instead, some have argued that the claimed product should represent a substantial modification of the natural substance to become eligible for a patent (Demaine and Fellmeth, 2003). Based on this test, called the Substantial Transformation Test, a product is substantially transformed only if it has a new and distinct character or use. There have also been questions about the proof of utility provided by patent applicants. The U.S. Patent and Trademark Office (2001) states that "when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. (A) 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." This statement raises the question as to how the USPTO gains evidence to be able to rebut a utility claim. Whereas the USPTO has access to published information (including the scientific literature and previous U.S. and foreign patents), it does not have research capabilities of its own or may not be able to rely on outside expertise. It raises the question as to whether some utility claims are guided more by desirability than real-world utility. In effect,

the burden of proof for utility is still fairly low even after the tightening of the rules by the U.S. Patent and Trademark Office (2001). The lightness of this original burden of proof contrasts with the burden associated with either patent infringement or challenges.

Discussions on the patenting of biodiversity also involve patenting of whole organisms. With Japan and Australia, the United States is the only country awarding utility patents for plant cultivars. In other countries, such as the European Union, plant cultivars can only receive IP protection under the PVP legislation. The European Patent Convention explicitly prohibits patents on plant but also animal varieties. This was further clarified by the European Commission biotechnology directive (European Commission, 2002), which specifically states that the following are not patentable: (1) plant and animal varieties; (2) essential biological process for the production of plants and animals; (3) the human body at various stages of formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene; and (4) inventions the commercial exploitation of which would be contrary to "ordre public" (roughly translated as "public good") or morality. In the United States, animals are also patentable subject matter since the award of a patent to Harvard University for the "onco-mouse," genetically engineered to have an increased risk of malignancies. The onco-mouse is a biological model for testing carcinogenicity of different compounds and is a useful model for researchers trying to develop treatments and cures for cancer. It has been patented in the United States, Europe, and Japan but not in Canada. Harvard University had asked not only to patent the process used to engineer the mouse but also the mouse itself, as well as all other nonhuman mammals rendered susceptible to cancer. The Canadian Supreme Court refused to grant a patent on the grounds that a higher organism cannot be considered a "manufacture" or "composition of matter" (Supreme Court of Canada, 2002)."

The Canadian onco-mouse decision raises two issues. First, for certain patents such as the onco-mouse patent, there are prominent ethical issues. In this case, one can raise the question whether living organisms should be patent subject matter. Furthermore, the pain and suffering imposed on individual animals of the onco-mouse strain, which were engineered to be susceptible to cancer, is also an ethical issue. A different issue is raised by the case of *Moore v. Regents of the University of California* (Dorney, 1990), namely the issue of prior informed consent by a patient and fiduciary duty (breach of trust) on the part of the treating physician. In the U.S. patent legislation, such considerations are not taken into account, and a review of the case law suggests that economic and policy concerns drive patenting first and foremost, for example, to promote certain industries such as the biotechnology industry, in line with the overall free-

enterprise ideology of the country (Curci Staffler, 2002). Presumably, there are other venues, such as the courts, where ethical concerns can be addressed in the United States. Yet, the European Patent Convention explicitly states that patents shall not be granted in respect "of inventions the publication or exploitation of which would be contrary to ordre public." The concept of ordre public is defined as covering the protection of public security and the physical integrity of individuals as part of society. It also encompasses the protection of the environment. Accordingly, inventions, the exploitation of which was likely to seriously prejudice the environment, are to be excluded from patentability as being contrary to ordre public (European Patent Office, 1999). It should be noted here that it is not patents per se that are construed as being against the ordre public, but it is their exploitation that can be objectionable (Curci Staffler, 2002).

The second issue associated with the Canadian onco-mouse decision is that it constitutes an exception to the pattern of "imitation" (Curci Staffler, 2002). Because IPRs are generally believed to stimulate innovation (see below, although opinions to the contrary exist; see, for example, Bessen and Hunt, 2003), developed countries, including Japan and countries in Europe, have followed the liberal attitude toward patenting of the United States by introducing stronger standards of IP protection and widening the patentable subject matter in order to maintain the competitiveness of their national industries. This type of arms race has an unexpected side effect, in that it further widens the chasm in technology and IPR between developed and developing countries.

Are IPRs a Stimulant to Research and Development?

As pointed out by Lesser and Mutschler (2002), patents are rated low overall as a stimulus to research and development investments, below the use of trade secrets and rapid innovation per se. There are two exceptions to this pattern. Pharmaceuticals (including their regulatory overview) are costly to develop and are easily copied. Living organisms can be reproduced without specialized skills. In both cases, therefore, patents have been actively pursued. Has the availability of IPRs for living organisms affected research?

A first observation is that it has shifted the center of gravity of plant breeding since the early 1980s from the public to the private sector, especially for non-hybrid crops (particularly soybean but also wheat and cotton; Lesser and Mutschler, 2002). A similar shift has been observed for plant biotechnologies, for which 75% of utility patents originate in the private sector (Atkinson et al., 2003). This shift coincided with the admissibility of living organism patents following the *Diamond v. Chakrabarty* and *Ex parte Hibberd* decisions in 1980 and 1985, respectively. Prior to this

period, the private sector had already played a major role in maize breeding. The difference between maize, on the one hand, and the other crops mentioned lies in the ability to economically produce F_1 hybrid seeds for the former crop. The heterozygous nature of the seeds prevents the reproduction of the cultivar and particularly its high yield potential (because the F_2 and further generations have much reduced yields compared to the F_1 generation). Concurrently, the parental lines of maize F_1 hybrid cultivars can also be protected, for example, by PVP and, increasingly, utility patents. This may be due to increased use of genetically engineered traits (herbicide tolerance and *Bacillus thuringiensis* toxin-mediated insect resistance), for which utility patents offer the strongest protection. A shift to private breeding may not have increased the quality of the product, though, as shown by wheat, where public and private breeding programs have achieved comparable yields (Alston and Venner, 1998).

A second observation made by Lesser and Mutschler (2002) is that IPRs and biotechnology each led to a round of market concentration in the 1980s and 1990s, respectively. The impact on overall biodiversity of crop gene pools and on breeding research and varietal development remains to be determined. The PVP legislation includes a research exemption, which allows breeders to use a PVP cultivar as a progenitor of new cultivars, allowing breeding programs to benefit from a cumulative progress from selection, instead of having to return to the original, nonprotected genotypes and "re-inventing the wheel." Following a series of court decisions (e.g. *Embrex Inc. v. Service Engineering Corp.*), the research exemption of utility patents only protects research of such limited magnitude that the patentee would not bother pursuing an infringement action (Arnold and Ogielska-Zei, 2002). The use of discoveries protected by utility patents requires generally the award of licenses, which have transaction costs that, depending on the product and the individuals or institutions or companies involved, may be too high, especially for public sector researchers (Lesser and Mutschler, 2002).

The development of the pro-vitamin A-rich, "golden" rice (Ye et al., 2000) provides a stark example of how quickly an invention can get lost in a "thicket" of IP rights. An analysis of the situation by Kryder et al. (2000) revealed that 70 IP or tangible property rights belonging to 32 companies and universities had been used in the development of this rice line. In addition, MTAs further complicated the situation. The integration of the high pro-vitamin A trait into cultivars adapted to farming in regions with vitamin A deficiencies required that these IPR issues be resolved, i.e. that breeders as scientific users and farmers and consumers as potential beneficiaries of the technologies would be able to use it without infringing on IPRs ("freedom to operate," or FTO). This was achieved by providing a license to a large biotechnology company, Zeneca, covering not only the pro-vitamin A pathway

in rice but also in any other crops, in exchange for a humanitarian use (defined as a maximum of U.S. \$10,000 revenue from golden rice) in developing countries (Potrykus, 2001). Clearly, such a solution was made possible in part because of public relations concerns on the part of the major holders of IPRs, mainly large, multinational biotechnology companies. However, this "segmentation" of the potential market did not solve fundamentally the issue for researchers, farmers, and consumers in developed countries.

Public institutions are faced with similar "thickets of IPRs," despite the fact that they have been responsible for much of the basic research leading to the initiation and continued development of biotechnology in the first place (Atkinson et al., 2003). The fragmentation of IPRs covering technologies (so-called "enabling technologies") and plant materials among many companies and institutions also created FTO problems. Biotechnology companies have dealt with these problems by developing their home-grown technology, licensing technology from other companies, and by acquiring or merging with other companies and, thus, assembling a complete IP portfolio allowing them to commercialize new technologies, including transgenic cultivars of major field crops such as maize, soybean, and cotton. Left out of this equation are many horticultural crops or specialty crops with smaller markets in developed countries and subsistence crops in developing countries. A recent initiative from some leading public universities and private foundations promises to address the FTO issue. The Public-Sector Intellectual Property Resource for Agriculture (PIPRA; www.pipra.org) intends to establish "best practices" encouraging the greatest commercial application of publicly funded research, while also retaining rights to allow public institutions to fulfill their responsibilities toward the public at large. It will also establish a database providing an overview of IPR currently held by public institutions, with up-to-date information on the licensing status of these IPRs. In addition, it will also attempt to pool patents or other IPRs to develop "technology packages" of complementary patents, which would provide FTO to public sector researchers and reduce transaction costs associated with obtaining licenses to develop transgenic cultivars (Atkinson et al., 2003).

While actions such as those proposed by PIPRA attempt to address the FTO issues, they do not fundamentally alter the framework in which current public research has come to operate. The public-sector research "culture" has a long tradition of open sharing of genetic resources, germ plasm, and research findings. This has led, among other things, to extensive genetic resources collections with broad availability. This tradition of open sharing and exchange is now severely challenged and raises several concerns with regard to the availability of biodiversity for research and cultivar development.

BIODIVERSITY, TRADITIONAL KNOWLEDGE CONCERNING BIODIVERSITY, AND THEIR COMMODITIZATION

Traditional Knowledge

Local or TK refers to information held by local or indigenous people with regard to biodiversity in this case (Brush and Stabinsky, 1996). Indigenous people are defined as descendants of preconquest, traditional people of a certain geographic area, with a common history, culture, language, and customary law. TK encompasses information about, for example, crop landraces and their agronomic or culinary characteristics or the medicinal qualities of native species. TK is an essential aspect of an indigenous group's cultural survival; it has been developed through generations of intimate contact with the biological materials (Mauro and Hardison, 2000). It is transmitted in many ways, including apprenticeship with elders and specialists and oral tradition (including poems, songs, and music; Posey, 2002). Although indigenous people comprise only some 5% of total world population, they have a disproportionately large role in the maintenance of and knowledge about biodiversity because they are located primarily, although not exclusively, in biodiversity centers. Furthermore, with regard to crop biodiversity, indigenous or local farmers play an important role in in situ (on farm) conservation of landrace varieties (Brookfield et al., 2002; Fig. 3). TK is not, however, limited to the knowledge of indigenous people but encompasses knowledge (and associated heirloom varieties) of local, nonindigenous communities in modern societies as well (e.g. Bérard and Marchenay, 1996).

Western-style IPRs for biodiversity (including TK about biodiversity) associated with local or indigenous societies are inadequate for several reasons. In the Western tradition, they recognize individuals rather than groups of individuals. In indigenous societies, the development of landraces cannot be attributed to specific individuals. They are often the result of selection generation after generation of farmers (Zimmerer, 1996; Louette and Smale, 2000; Perales et al., 2003). Furthermore, landraces or ethnobotanical knowledge are often exchanged among farmers or indigenous people, primarily from the same extended family of the same or different villages (e.g. Reyes-García et al., 2003). In addition, farmers sometimes actively promote hybridization between landraces and modern cultivars (Perales et al., 2003). Thus, there is no specific act of invention in the development of landraces that can be traced to documented events as in Western inventions. Landraces cannot be considered novelties, given their existence in prior generations of farmers. Western IPRs also stimulate commercialization, which may have adverse effects on exchange of landraces among farmers who do not engage in commercialization and those who do. Thus, indigenous societies or local farmer groups often practice an informal system of innovation and information dissemination, which

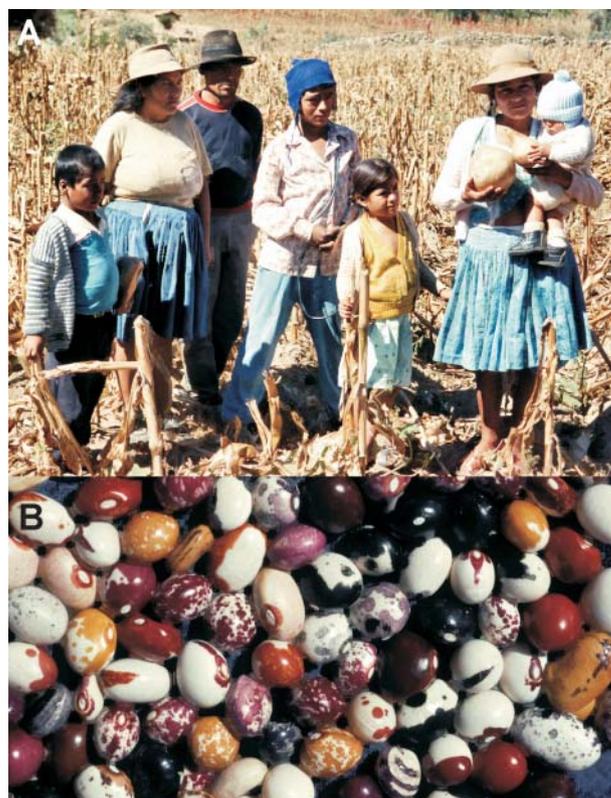


Figure 3. A, In developing countries, indigenous or local farmers play an important role in the conservation of crop genetic resources. This Bolivian family grows several crops, including maize, gourds (*Cucurbita* spp. and *Lagenaria* spp.), and beans (see B), in addition to peppers (*Capsicum* spp.; not shown). For this and other families, crop genetic resources are an important family asset used to deal with climatic uncertainties and cropping microenvironments. Different varieties may also have distinct culinary uses or be used for subsistence or sale at markets. Farmers are actively engaged in the management of these genetic resources and customarily exchange them with other farmers, who often belong to the same family in the same or a nearby village. B, Mixture of common bean grown by the family shown in A. Farmers often grow mixtures of genotypes of the same crop. This mixture is one of the most diverse common bean mixtures observed by the author in his explorations in Latin America and Africa. These beans are actually *nuña* or popping beans, which are sold as a snack in Bolivia and Peru. A controversial patent involving *nuña* beans has been awarded by the U.S. Patent and Trademark Office (Ehlers and Sterner, 2000). Photos by P. Gepts.

does not fit well into a Western-style IPR system, nor does the latter offer rewards for past efforts in innovation and conservation, on which the existence of biodiversity, in general, and crop biodiversity in centers of diversity, in particular, rests. The distinct features of the use and conservation of biodiversity in developing countries have led to a call for a separate legal system recognizing the contributions of indigenous or local communities. When dealing with crop landraces, this legal system refers to “farmer’s rights.” Indigenous rights, in general, and TK, in particular, are increasingly being incorporated in international law,

such as the CBD. Decision IV/9 of the Conference of the Parties of the CBD accords a similar value to TK as to scientific knowledge (Mauro and Hardison, 2000). In 2000, the World Intellectual Property Organization (WIPO) member states set up an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). However, so far little progress has been made in developing an enforceable legal framework to support farmers rights in practice.

Commoditization

Commoditization is the process whereby an object, whether tangible, such as seed, or intangible, such as knowledge about the seed, is turned into a commodity, i.e. something that acquires an economic worth and can be bought and sold. Commoditization can be traced back to the first discussion resulting from unequal terms of exchange with regard to biodiversity between developed and developing countries. Faced with commercialization by companies from developed countries of cultivars that were at least partly based on genetic diversity originating in developing countries, the latter asserted justifiably that some form of compensation should be provided in exchange for the raw material constituted by the biodiversity originating in developing countries. This emphasis on compensatory payments was further exacerbated by the insistence on the part of pharmaceutical and biotechnology companies and their respective governments that IPR protection systems be instituted at the international level through the TRIPs agreement of the WTO (McAfee, 2003). A—hopefully positive—consequence of this commoditization is the creation, in the aftermath of the adoption of the ITPGRFA, of a Global Crop Diversity Trust (GCDT; <http://www.startwithaseed.org/items/homepage.php>), which will support, in particular, ex situ collections and related activities, such as regenerating threatened ex situ collections. The GCDDT provides an arguably more workable alternative to direct compensation of developing country farmers for their contribution to crop biodiversity conservation.

A highly unfortunate side effect of the commoditization of biodiversity is that it has led to the active pursuit of IP protection in developed country of specific crop germ plasm originating in developing countries without appropriate authorization or compensation (called by some “biopiracy”). Controversial awards of patents involving foreign genetic resources, whether or not these patents have since been rescinded, include yellow and popping beans (*P. vulgaris*; Proctor, 1999; Ehlers and Sterner, 2000), the neem tree (*Azadirachta indica*) oil (Roland and Blouin, 1996), maca (*Lepidium meyenii*; DeLuca et al., 2000), and basmati rice (*O. sativa*; Sarreal et al., 1997). Their existence suggests that more stringent criteria should be developed for such awards, especially in light of the

recent trend in international law assigning national sovereignty for biodiversity to individual countries (Convention on Biological Diversity, 1992; Commission on Genetic Resources for Food and Agriculture, 2001). Even when the origin of the plant material is mentioned in the patent application (e.g. Proctor, 1999), IP offices have awarded patents or PVP certificates. Ethical guidelines regarding the use of indigenous biodiversity and knowledge have been developed by the International Society of Ethnobiology (<http://users.ox.ac.uk/wgtrr/isecode.htm>), the Society of Economic Botany (http://www.econbot.org/ethics/professional_ethics.html), and the Biodiversity & Ethics Working Group of Pew Conservation Fellows (<http://geography.berkeley.edu/ProjectsResources/BRP/BRP.html>). Furthermore, countries or groups of countries (e.g. The Philippines and Andean Pact countries) have or are in the process of adopting specific legislation governing bioprospecting activities. In these legislations, indigenous or local people must be given information about the ultimate use and purpose of the biological resource and they must give consent (prior informed consent). In a more general sense, international guidelines have now been developed by the CBD Conference of the Parties No. 6 at The Hague in 2002, which pertain to access and benefits sharing. These are the so-called Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization (Decision VI/24; <http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp#>).

RETROSPECTIVE

This brief overview of biodiversity ownership hopefully has shown the readers that this issue is quite complex and still unsettled. Over the last 25 years, there has been a sea change in the attitude toward biodiversity. From a resource considered to be the common heritage of humanity, biodiversity is in the process of becoming a commoditized resource subject to IPRs, national sovereignty rules, and the vagaries of market pricing and compensatory fund transfers. This revolution acts as a further revelator of inherently unequal distribution of and access to resources such as biodiversity and biotechnology. It also highlights inequities between developed and developing countries and between national governments and indigenous people in their respective access to the negotiation tables of international treaties and agreements.

How far this revolution will go and the shape of its ultimate outcome are as yet unknown. For now, however, the uncertainties associated with this situation are leading to restriction on the flow of genetic diversity across borders, to the detriment of scientific research on biodiversity and further development of improved cultivars both in developed and developing countries. This revolution does, however, raise several questions, including, but not limited to, the following.

Should living organisms and any of their constituting parts (including genes) be subject matter of IPRs? In this regard, why should a distinction be made in the TRIPs agreement between microbes and microbiological processes (subject matter in any case) and higher organisms (plant and animals), for which countries can refuse to award IPRs?

Will reliance on IPRs (including the current Western-style IPRs and any alternative system that may be developed for collective, multi-generation inventions associated with local and indigenous groups) assure efficient conservation and utilization of biodiversity? Or will states and local indigenous groups have to intervene to assure that their cultural and ethical values are maintained? Will a different set of rights have to be developed to assure control over biodiversity resources and cultural knowledge (Posey and Dutfield, 1996; Greaves, 1996)?

Are the nonutilitarian functions of biodiversity, such as ecosystem health and function as well as its esthetic role, well served by a IPR regime? Because biological and cultural diversity are inextricably linked, can legal and economic frameworks be instituted that address the conservation of both types of diversity?

Will the current IPR-driven regime for biodiversity primarily benefit the most powerful actors in the debate, i.e. transnational pharmaceutical and biotechnology companies and their respective governments, or will both sides benefit? If the former is true, what can be done to develop a more even playing field that will take into account not only biodiversity and the TK associated with it, but also the rights of indigenous and local people and their efforts to conserve them?

Answers to these questions will be forthcoming in the next years. They will determine how profound the transition from a common heritage to a private regime will be with regard to biodiversity ownership.

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