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Recent policy trends and developments related to the conservation, use and development of genetic resources

Susan Bragdon and David Downes

Abstract

The erosion of genetic resources and hence diversity continues at an alarming pace. Simultaneously, technologies which develop and make use of these resources outpace the ability of laws and societies to understand and cope with them. Spurred by technological advances, appreciation of the monetary and non-monetary value of genetic resources has grown, leading to increasing conflict over rights and responsibilities for these resources.

Developments in international and national law and policy over the past 5 years have significantly changed the policy environment relating to the management and control of genetic resources. Some of the more significant developments include: the entry into force of the Convention on Biological Diversity, the Agreement on Trade Related Aspects of Intellectual Property Rights and the 1991 version of the International Union for the Protection of New Varieties of Plants; the re-negotiation of the International Undertaking on Plant Genetic Resources; the conclusion of the 1994 FAO/CGIAR Agreements and the 1998 External Review of the CGIAR; the increasing presence and pressure by indigenous and local communities in national and international fora; the re-invigoration of the Global International Properties Issues Division of the World; and the continuing expansion of the scope and strength of intellectual property rights by national legislatures and judiciary systems around the world.

Decision-makers trying to devise good, coherent, consistent policy on genetic resources are faced with a myriad of related, rapidly evolving issues being discussed in multiple national and intergovernmental fora. The task of discerning all the issues of relevance to the conservation and management of genetic resources and then integrating them into consistent policy is extremely complex. With continuing globalization and increased understanding of the world's interdependence on all levels, few important issues can be meaningfully addressed without undertaking the complex process of unweaving and understanding relevant issues and then integrating a policy response. Better analytical tools are needed to enable policy-makers to evaluate the trade-offs and consequences of particular decisions.

Analysis of recent development need in terms of their objectives, interests and relations to one another is a necessary first step in developing better analytical tools for policy-makers. This paper analyzes developments in the past 5 years, identifying cross-cutting issues and trends that have emerged including farmers' rights, the rights and interests of indigenous and local communities, benefit-sharing, access to genetic resources, patenting and industry trends, and *sui generis* protection of plant varieties. The time is ripe for an evaluation of where we have been and where we want to go with regard to the conservation, use and development of genetic resources. The paper identifies and analyzes key decision points and critical, emerging legal and policy issues having an impact on genetic resources. It thereby provides the foundation for beginning to assess decisions, where they are leading relative to policy objectives and whether or not course corrections are warranted.

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Contents

I. Introduction	1
A. 1993: The Crucible Group is born	1
B. Developments since 1993	2
C. The need for a new assessment	4
II. Recent Trends and Developments	5
A. Convention on Biological Diversity	5
B. The World Trade Organisation (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)	9
C. International Undertaking on Plant Genetic Resources	13
D. Consultative Group on International Agricultural Research (CGIAR)	16
E. The International Union for the Protection of New Varieties of Plants	20
F. World Intellectual Property Organisation (WIPO)	22
G. Instruments established to directly address the rights of indigenous peoples	24
III. Key Issues	27
A. Farmers' Rights	27
B. Indigenous and local communities	29
C. Benefit-sharing	31
D. Access	34
E. Patents and industry trends	36
F. <i>Sui generis</i> legislation	40
IV. Conclusion	41
Acronyms	42

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This paper began at an IPGRI-sponsored meeting held at the Center for International Environmental Law in Washington, D.C. in January 1998. At the time, plans for the launching of the Crucible II Group were underway. While this paper was generated completely independent of the launching of Crucible II, the launching did raise awareness of the desirability of creating a common foundation for discussions among people from diverse backgrounds on policy issues of relevance to genetic resources. We met with Cary Fowler, Michael Halewood and Hope Shand and outlined a paper that aimed to cover recent policy trends and developments of particular significance to genetic resources. It was agreed that the paper would need to be reviewed by the people coming from a variety of backgrounds and perspectives and that IPGRI would provide the paper as a discussion draft at the first meeting of the Crucible II. What became clear at the Washington meeting – and the writing of the paper confirmed – is there is a need for a concentrated effort to understand the implications of recent trends and options for moving forward. Only then can conscious, informed choices be made. It is hoped that this paper will help provide the background to begin that deeper analysis.

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Susan H. Bragdon and David R. Downes
With contributions by Hope Shand and Michael Halewood

I. Introduction

A. 1993: The Crucible Group is born

In April 1993 an informal group of individuals representing diverse backgrounds and interests had its first meeting to begin addressing the critical policy concerns related to intellectual property rights over biomaterials raised by a number of political, economic, legal and technological changes. The group, known as the Crucible Group, was charged with distilling viewpoints and recommendations on this issue with the goal of producing a non-consensus document helpful to policy- and opinion-makers. One year later, "People, Plants and Patents: the impact of intellectual property on trade, plant biodiversity and rural society" was published. With 28 individuals including representatives of grassroots organizations, agricultural researchers, trade negotiators, agricultural researchers, intellectual property specialists and agricultural policy analysts from South and North, it is not surprising that the group's members had varied points of view. Nevertheless, the group did develop consensus on a number of important issues including:

1. The primacy of specific national conservation strategies for plant genetic resources and the need for the participation of local communities and private companies in those strategies.
2. The inappropriateness of compelling nations to adopt intellectual property protection for plant varieties through pressure of possible exclusion from a multilateral trade agreement and the right of countries to protect their environment and the well-being of their citizens if they feel that trade rules threaten security.
3. Support for the joint initiative of the Food and Agriculture Organization (FAO) and the member institutes of the Consultative Group on International Agricultural Research (CGIAR) to establish an in-trust agreement for the benefit of developing countries.
4. The conviction that holders of *ex situ* germplasm collections should develop equitable partnerships with indigenous and rural societies and make their collections available to them.

B. Developments since 1993

Developments in international and national law and policy over the past five years have significantly changed the policy environment relating to the management and control of genetic resources. Some of the most significant recent developments include:

1. *The Convention on Biological Diversity*: The CBD entered into force just prior to the publication of "People, Plants and Patents." The objectives of the CBD are threefold: conservation and sustainable use of biodiversity and benefit-sharing arising from its use. The Conference of Parties has met three times and will hold its fourth meeting in May 1998. In addition, there have been numerous regional meetings and meetings of the CBD's subsidiary bodies.
2. *The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)*: The Final Act Embodying the Results of the Uruguay Round of Trade Negotiations including TRIPS was signed at the Marrakech Ministerial Meeting in April 1994. The *raison d'être* of the World Trade Organisation (WTO) and related agreements is trade liberalization. The TRIPS Agreement requires all parties to meet certain minimum standards for protecting intellectual property rights (IPRs). Parties are required to protect plant varieties either by patents or by an "effective *sui generis* system or by any combination thereof."
3. *The International Undertaking on Plant Genetic Resources (IU)*: The IU is currently being revised under the auspices of the FAO Commission on Plant Genetic Resources for Food and Agriculture to bring it in harmony with the CBD. The objective of the IU as adopted in 1983 is to promote the conservation, exchange and use of plant genetic resources for food and agriculture. The hope is to conclude the revision in two more negotiating sessions. The next negotiating session is scheduled for June 1998.
4. *The 1994 FAO/CGIAR Agreements and 1998 External Review of CGIAR*: The mission of the CGIAR is to contribute to promoting sustainable agriculture for food security in developing countries. Agreements with FAO placed designated material in CG collections under the auspices of FAO and in trust for the world community. The Agreements will be reviewed in light of the outcome of the IU negotiations. The difficulty of the CGIAR in policy formulation and coordination will likely be addressed by an

External Review of the CGIAR System initiated in 1996 and currently underway.

5. *The International Union for the Protection of New Varieties of Plants (UPOV)*: UPOV aims to maximize plant breeding efforts. It provides a model for securing protection under UPOV for plant breeders' rights for plant varieties. The UPOV Secretariat conducts training seminars in developing countries to familiarize them with UPOV requirements and the drafting of national legislation.
6. *The World Intellectual Property Rights Organisation (WIPO)*: WIPO was established in 1967 to promote the protection of intellectual property worldwide. In March 1998, the WIPO General Assembly approved a reinvigorated programme for the Global International Property Issues Division that will address biodiversity, human rights and indigenous rights. WIPO has experience, staff and resources to support technical assistance on national intellectual property laws and institutions.
7. *Indigenous and local communities including farmers and farm communities*: Indigenous and local communities are struggling to have their concerns incorporated into negotiations at both the national level and the international level (e.g. the CBD, the IU, ECOSOC's Working Group on Indigenous Populations and the Subcommission on Prevention of Discrimination and Protection of Minorities).
8. *National legislatures and court systems*: National systems (both in response to and because of their effect on international debates) are growing more formal and complex with respect to the ownership of and access to genetic resources. In developed countries – largely as a result of private sector pressure – both the scope of what can be protected and the strength of the protection are expanding. In developing countries, laws are emerging governing ownership, access and benefit-sharing. IPR protection is expanding in the more industrialized developing countries as well.

C. The need for a new assessment

We are approaching the 21st century with substantively related issues de-linked procedurally through their consideration in separate fora. Laws and policies affecting genetic resources are being debated in the context of intergovernmental bodies with:

- diverse objectives
- diverse yet overlapping actors and interests
- different power balances
- different acceptable "moral" stances where the types and tones of arguments vary depending upon the culture of the particular forum.

Simultaneously (and interconnected with the international debate), national legislatures and courts are making rules about the ownership and control of plants, animals and their component parts. The situation continues to evolve rapidly.

Policy-makers are faced with active debates in multiple intergovernmental fora, and with legal regimes for ownership, control and intellectual property rights over genetic resources in a state of flux. This makes even more difficult the task of developing good, coherent, consistent policy on the conservation, development, use and exchange of genetic resources and products derived from them. The identification of the optimum mix of policy options specific to a particular country is likely to be one of the most difficult tasks facing a national policy-maker. Better analytical tools are needed to enable policy-makers to evaluate the trade-offs and consequences of particular decisions.

As a first step, recent developments need to be analyzed in terms of their objectives, interests and relations to one another. Gaps in knowledge where further information and research are needed should be identified and initiative taken to fill the gaps. How and where objectives and obligations (both nationally and internationally) can be made mutually supportive or at least harmonized so as to not be contradictory should be explored. Areas where society seems inexorably headed on a collision course of conflicting goals must also be identified and addressed.

This paper seeks to provide background for these steps. Section II analyzes developments since the conclusion of Crucible Group, looking specifically at the CBD, WTO/TRIPS, the revision of the IU, the CGIAR, UPOV, WIPO and instruments established to directly address indigenous rights issues. Section III examines cross-cutting issues and trends that have emerged during this same period including farmers' rights, the rights and interests of indigenous and local communities, benefit-sharing, access to genetic resources, patenting and industry trends, and *sui generis* protection of plant varieties. Section IV attempts to draw some general conclusions about the challenges facing decision-makers.

II. Recent Trends and Developments

A. Convention on Biological Diversity

The CBD is one of the two legally binding agreements signed in Rio de Janeiro at the Earth Summit in 1992. It has 170 countries and the European Union as parties. The objectives of the CBD are the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits of the use of genetic resources.

In general terms, the CBD's origins can be classified into categories corresponding to its three objectives. One major source was conservationist concerns that existing international law for protection of wildlife was a patchwork that covered only selected issues, areas and species. They called for a more general agreement that would embrace a broader concept of nature and its value – including the full diversity of life at the level of genes, species and ecosystems – and protect the many elements of biodiversity not covered by existing laws.

Second, there was a move to incorporate the goal of sustainable use of biological resources into conservation policy, recognizing the need of local people living amidst biodiversity for sustainable development, and conversely the need to mobilize support for conservation by providing local benefits. Third, international debate on the terms for exchanging and sharing benefits from plant genetic resources for use in agriculture created pressure to include in the treaty obligations on these issues. Ironically, some key issues relating to agrobiodiversity – such as the status of pre-CBD *ex situ* collections and Farmers' Rights – were left outstanding.¹ Developing countries pressed for measures to ensure that countries of origin of genetic resources – most of which are developing countries – gain a greater share of the benefits from their use, including new biotechnologies.²

The resulting agreement establishes a range of general, flexible obligations that emphasize national action within national jurisdiction for conservation and sustainable use, in recognition of sovereign rights to set environmental policy and exploit natural resources. It also sets up a framework of general principles for structuring the international exchange of genetic resources, premised upon the national sovereignty of each country over genetic resources originating

¹ See Section II.C International Undertaking.

² Developing country support for national restrictions on access has not, however, been unequivocal. Some biodiversity-rich developing countries tempered their support for the CBD's emphasis on national sovereignty over genetic resources when they realized that it might lead to greater restrictions on access to germplasm they needed from other countries to maintain genetic diversity in important domestic crops. The emphasis on national sovereignty has also troubled some developing countries that do not have significant plant genetic resources.

within its jurisdiction. While the general principles on access emphasize national action, they do not mandate bilateral transactions nor do they preclude parties from establishing or entering into a multilateral system of regulating access. These principles require, for instance, that those seeking access to genetic resources gain the prior informed consent of the country of origin.

Finally, the CBD provides for a set of international institutions to support the elaboration and implementation of these obligations; these include the Conference of the Parties (COP), the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), the Secretariat, the Clearing-House Mechanism for Scientific and Technical Cooperation (CHM), and a financial mechanism which is operated by the Global Environment Facility (GEF).

The CBD is an ambitious attempt to integrate previously distinct policy goals. It recognizes the pervasive importance and distribution of biodiversity and requires protection of all biodiversity in all types of ecosystems and habitats. Implementing its obligations will affect a wide range of government laws, policies and programmes, and a wide range of human activities.

Since the CBD entered into force in 1993, its implementation has proceeded slowly. In the CBD, as in the UN Commission on Sustainable Development established in the aftermath of Rio, governments have found it difficult to bring together the many disciplines and policy measures needed to achieve sustainable development. Tension remains about the CBD's three objectives. Different governments select different priorities from among the broad array of possible initiatives within the scope of the CBD. As a result, there is little focus on implementation in any specific area. There is no shared vision of where this new, relatively weak instrument and associated institutions should focus their energies in order to make a real difference.

Biodiversity relates to the missions of many different agencies whose activities are traditionally compartmentalized, such as agriculture, trade, forests, fisheries and environment. Officials from ministries and international agencies besides those concerned with environment have sometimes seemed to fear that the CBD is a new competing programme or agency that threatens their traditional turf.³ In fact, the CBD does not establish an implementing agency. The CBD can only be implemented by its Parties, at the national level through governments, and at the regional and international levels through regional and international agencies. Far from being an implementing agency, the Secretariat exists merely to support the Parties' meetings by providing information in response to COP requests and identification of agenda items.

³ The tension stems from substantively different orientations as well. From FAO's vantage point, the CBD's emphasis on sovereignty and a bilateral approach for access to genetic resources would destroy the unity of developing countries, many of which are not rich in biodiversity. If development is a goal, then this approach would not benefit biodiversity-poor developing countries.

There has been some progress in building collaborative relationships between the CBD and relevant intergovernmental institutions. FAO is taking a major role in the work program on agricultural biodiversity agreed on at the COP III in 1996. The CBD Secretariat has signed memoranda of understanding outlining areas for potential cooperation with several other secretariats of international environmental agreements. Particularly important for consideration of IP issues is the relationship between the CBD and the negotiations on the international undertaking (IU). The CBD COP has indicated its willingness to consider the outcome of the IU negotiations as a possible protocol to the CBD. There has been some tension, however, between the officials and institutions involved in the CBD and the IU. The CBD discussions are dominated by environment ministries while IU talks are dominated by agriculture ministries. Each group sometimes feels that the other undervalues its objectives.

With the advent of the TRIPS Agreement, trade institutions have become important for IPR. At the national level, trade and environment ministries typically have little or no communication. At the international level, contacts have begun. The Secretariats of the CBD and the WTO have exchanged documents and the CBD Secretariat attended the WTO Committee on Trade and Environment in the fall of 1997 as an observer and made a presentation. WIPO made an intervention at the intergovernmental workshop on traditional knowledge under the CBD in Madrid in November 1997.

The CBD, like most other multilateral environmental agreements, provides for periodic meetings of the Parties to monitor implementation and review effectiveness of the agreement. Intergovernmental and non-governmental organizations may participate in these meetings as non-voting observers. A number of intergovernmental organizations attend regularly, such as the World Bank, the FAO and UNEP. The process has been fairly open to NGOs and they have been fairly active in CBD meetings. NGOs have, however, been excluded occasionally from some contact groups on sensitive issues such as financing, biosafety and intellectual property. Most participating NGOs are conservation or development groups. A few industry representatives attend, typically from biotechnology or plant breeders' trade associations. Also participating are representatives from scientific associations and universities.

Indigenous peoples' organizations have been very active in the CBD process. In particular, they were a vocal and organized presence at COP III in Buenos Aires in November 1996. As a result, the COP agreed to begin a process of discussing implementation of Article 8(j) of the CBD, which calls for protection of the knowledge, innovations and practices of local and indigenous communities. Many indigenous groups have focused on CBD because the language of Article 8(j), while extremely limited compared with indigenous aspirations, is one of the most powerful references to their interests in international law. At meetings of the CBD, many indigenous groups have presented demands on issues ranging from land rights to political autonomy, which extend well beyond the narrow confines of the

language of Article 8(j). Many governments have resisted these efforts to expand beyond the scope of the Article. Because of the diversity of viewpoints among indigenous groups and the resistance of governments, there has been little progress to date in defining the terms of reference for a work programme on Article 8(j).

A few parties, such as the Philippines and the countries of the Andean Pact, have adopted measures to implement the provisions on genetic resources of the CBD. Because of the innovative nature of these provisions, however, and the complex policy and legal issues that they raise, most Parties have moved slowly to implement them. It is also difficult to assess the effect of access legislation when experience is so recent. For example, it is unclear:

- to what extent benefits have actually accrued from access transactions
- the effect of legislation on the number of request for access (e.g. are transaction costs reasonable and the procedures sufficiently clear and efficient or has the legislation caused parties to look elsewhere for access to genetic resources?)
- to whom benefits have actually accrued (e.g. have indigenous and local communities benefited from the transactions?).

At the international level, the COP has for the most part limited its decisions to requesting the collection of information about national initiatives. This work has sparked the beginnings of an analytical framework for studying such measures, but there has been no move to establish principles or criteria for implementation. There has been only limited attention to the IPR issues. One exception arises under the Philippines executive order on genetic resources, which provides that a foreign access-seeker may obtain a permit to collect genetic resources only on condition that it agrees to confer a licence to the Philippines to manufacture any patented product that may be derived from the samples collected under the permit.⁴

The COP included IPR on the agendas of its second and third meetings. At the second meeting, the COP requested the Secretariat to review the relationships between the Convention's objectives and IPRs, and to review the relationships between the TRIPS Agreement and the Biodiversity Convention. At its third meeting, the COP held contentious discussions on these topics. In the end the governments agreed upon some very limited steps. The COP asked the Secretariat to apply to the WTO as an observer to the Committee on Trade and Environment.⁵ The COP also called on Parties and intergovernmental organizations to conduct case studies on issues linking IPR, biodiversity and traditional knowledge. These studies could include consideration of issues such as the modification of existing IPR or creation of sui generis alternatives.

⁴ Malacanang, Manila, Executive Order No. 247, Section 5(l)(1995).

⁵ See Section II.B on The World Trade Organisation (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) below.

B. The World Trade Organisation (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

The TRIPS Agreement is one of the agreements of the WTO adopted in 1994 at the close of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade (GATT). It entered into force in 1995, simultaneous with the inauguration of the WTO, the creation of which was also an outcome of the Uruguay Round. The TRIPS and other WTO agreements are binding upon the 131 countries that are members of the WTO.

The TRIPS Agreement is innovative from both a trade and intellectual property (IP) perspective. From the trade perspective, the TRIPS Agreement embodies the relatively novel and counterintuitive notion that trade *restrictions*, such as embargoes on "counterfeit" goods that imitate copyrighted or trademarked products, are necessary to promote trade *liberalisation*.⁶ Intellectual property had previously been seen as a domestic policy to be tailored to fit a country's level of development and technological goals, not as a matter of trade policy.⁷ The TRIPS Agreement, like several other of the WTO Agreements, expands the scope of international trade rules into previously unaffected aspects of domestic production and marketing. For instance, a WTO Member is obligated under the TRIPS Agreement to provide effective legal mechanisms by which a patentholder from another WTO Member can prevent unlicensed persons from using or marketing the invention within the member's territory.

From the IP perspective, the TRIPS Agreement places far more pressure on countries to adopt standards than did previous agreements on IP such as the Paris Convention on Industrial Property, because countries must assume the obligations of WTO Agreements such as TRIPS in order to gain WTO membership. It creates unprecedented strong incentives for compliance, through its relatively strong dispute-settlement mechanism, which provides for the imposition of trade sanctions (including sanctions on trade in unrelated products) against a Member found in violation of the Agreement. Finally, it establishes standards for IP that are stronger in some respects than those found in previous international agreements on IP.

⁶ Downes, David. 1997. Using Intellectual Property as a Tool to Protect Traditional Knowledge: Recommendations for Next Steps: CIEL Discussion Paper prepared for the Convention on Biological Diversity Workshop on Traditional Knowledge, Madrid, November 1997. CIEL, Washington. Discussion draft. Page 6.

⁷ One practical reason for this change is that developed countries, such as the United States, wished to add intellectual property (IP) to the issues on the table in the Uruguay Round in order to achieve negotiating gains in their goals through trade-offs with other goals of interest to developing countries such as reductions in barriers to textile imports. The United States had previously had little success in gaining its IP goals within the WIPO, where such trade-offs were impossible.

Strengthened standards that are particularly important for PGRFA are found in Article 27 of TRIPS. Paragraph 1 provides in part that "patents shall be available for any inventions, whether products or processes, in all fields of technology."⁸ In response, developing countries in particular have had to make significant changes to their laws, removing exceptions from patentability for certain categories of products such as pharmaceuticals or agricultural technologies.

Most important, Article 27.3(b) of TRIPS provides that Members may exclude from patentability

plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.⁹

While providing for exclusions from patentability, this language in fact narrows the scope of exclusions previously maintained by many countries. A number of countries must modify laws excluding living things from patenting; their laws will have to be revised to provide for patenting of microorganisms. The requirement of IP protection for plant varieties – in the form of either patents or a *sui generis* system – will also necessitate legislative changes in a number of WTO Members.

WTO Members have grace periods for phasing in changes required by TRIPS standards. All countries had a one-year grace period under Article 65. Under Article 65 developing countries have an additional four years, while least-developed countries have an extra ten years under Article 66 (there are narrow exceptions to these grace periods).

The WTO, based in Geneva, comprises a number of institutions for monitoring implementation of WTO agreements, modifying or interpreting them if needed, negotiating new trade agreements and resolving disputes under existing ones. Most relevant here is the TRIPS Council, established to monitor the operation of the TRIPS Agreement and Members' compliance with its terms, to give Members a forum for consulting on TRIPS issues, and to provide assistance to members as requested including assistance regarding dispute settlement. The Council generally meets formally four times a year, and also holds several informal

⁸ Members do, however, retain the power to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." The scope of this power, and the meaning of terms such as "morality," have not yet been defined.

⁹ See also Sections II.E on UPOV and III.F on *sui generis* legislation.

sessions. NGOs may not attend Council sessions. Inter-governmental agencies may, however, attend, and the Secretariat of the Convention on Biological Diversity has been accepted as an observer.¹⁰ The WTO also includes a Committee on Trade and Environment (CTE) which has the relationship between WTO rules and multilateral agreements and the relationship between IPR and the environment upon its agenda. The CTE has failed to address these policy issues to date.

The WTO Dispute Settlement Body (DSB) establishes perhaps the strongest dispute settlement mechanism in international law. A Member has the right to bring another Member before a dispute settlement panel if consultations fail to resolve a complaint of non-compliance with a WTO Agreement. If the panel decides that a Member has violated its WTO obligations, and the appellate body upholds the decision, then the ruling becomes legally binding unless the WTO General Council – the highest authority in the WTO system – takes the unlikely step of overruling it by consensus. A Member found in violation of its WTO obligations must correct the offending measure. If it does not do so, it will be subject to a requirement that it pay compensation for harm to the challenging Member, or the challenger will be authorized to impose retaliatory trade measures. The DSB recently upheld a US complaint that India failed to comply with certain TRIPS requirements.

In the view of most WTO members, the establishment of the WTO system including the DSB precludes Members from unilaterally adopting trade measures to enforce trade goals. The United States, however, has taken the position that it retains the power to take unilateral measures, such as punitive measures under "special 301" against trading partners the United States feel are failing to provide adequate and effective protection to IPR.

TRIPS Article 27.3(b), which concerns life patents and plant variety protection, provides that its provisions "shall be reviewed four years after the date of entry into force of the WTO Agreement." The first review will therefore take place in 1999. This language was included largely because the United States, under pressure from private industry, was dissatisfied with the subparagraph's requirements, and wished to have another chance to negotiate stronger life patenting requirements without exclusions for plants and animals. Thus, one outcome of a review might be a recommendation to remove the discretion now contained in Article 27.3(b). Conceivably, the review could also produce a recommendation to amend the agreement in another way or to adopt an interpretation of the existing language rather than an amendment to it.

Regardless of the formal rules, the Council strives for consensus decision-making. An interpretation of a WTO Agreement becomes binding only if three-quarters of the Members vote to adopt it in a Ministerial Conference. An

¹⁰ As of February 1998, the CBD Secretariat had not attended a Council session, according to WTO Secretariat staff.

amendment to an Agreement must be approved by three-quarters of the members at a Ministerial Conference.¹¹ Such an amendment may become binding upon all Members, including the minority that voted against it, if the majority so decides.

As of late February 1998, no Member has made a formal suggestion about how the 1999 review might take place. Based on informal comments from Members and others, however, it appears unlikely that there will be consensus within the TRIPS Council regarding amendments or interpretations of Article 27.3(b). Thus, observers suggest it is unlikely that the Council will agree on any significant steps regarding those provisions in 1999. In contrast to the Uruguay Round, the 1999 TRIPS review does not offer significant opportunities to make tradeoffs between different issues, thus reducing the chance that developed countries can add to the gains they obtained in the Uruguay Round. The next opportunity for such trade-offs and hence amendments to 27.3(b) would be the next round of negotiations scheduled to begin in 2000; thus some countries may try to place IP on the agenda for the "millennial round".

¹¹ If the TRIPS Council recommends an amendment by consensus, however, then the Ministerial Conference may adopt the amendment "without further formal acceptance process." WTO Agreement Article X, Para. 6; TRIPS article 71(2). This exception is minor in this context because it is unlikely that the Council could achieve consensus on significant amendments relating to PGRFA.

C. International Undertaking on Plant Genetic Resources

The FAO International Undertaking (IU) is a non-binding intergovernmental agreement to promote the conservation, exchange and utilization of plant genetic resources. In the resolution by which the IU was adopted, Member States recognized that "plant genetic resources are a heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations" and was intended to facilitate the conservation and sustainable utilization of plant genetic resources. As of April 1998, 113 countries are signatories to the IU. The body overseeing the IU is the FAO Commission on Genetic Resources for Food and Agriculture. As of April 1998 the Commission had 157 member countries (including the European Union). Since the mid-1990s, the Commission has been engaged in a negotiating process to revise the IU to bring it in harmony with the CBD, perhaps eventually becoming a protocol to that treaty. That negotiation process is now moving ahead quickly and a key extraordinary session of the Commission was convened from 8 to 12 June 1998.

The IU and the Commission were conceived in controversy during FAO meetings between 1981 and 1983 as developed and developing country governments debated the ownership and control of plant germplasm in a highly politicized environment concerned with Plant Breeders' Rights, genebank safety, the management of genetic resources flows by the International Board for Plant Genetic Resources (IBPGR, forerunner to IPGRI), and national germplasm embargoes. Adopted in late 1983, the IU was not so much a compromise text as a hasty manifesto. In the years following its adoption, many governments have come to recognize that the IU is incomplete and contains ambiguities requiring clarification. Indeed, during the ten years after its adoption three interpretative resolutions were adopted in attempts to clarify concepts and terms in the IU. The resolutions themselves were the result of several years of discussion.¹²

The CBD leaves several issues of relevance to the IU and FAO outstanding. The CBD negotiators were aware of these outstanding issues – including the question of Farmers' Rights and the status of *ex situ* collections in existence prior to the CBD – and passed a resolution¹³ requesting these issues be resolved within the context of the FAO Global System for the Conservation and Sustainable Use

¹² C4/89 was the first resolution adopted. It provided an agreed interpretation which recognized that Plant Breeders' Rights were not necessarily inconsistent with the IU. It also recognized Farmers' Rights and defined them in a second resolution (C5/89; see discussion under Section III.B). A third resolution reaffirmed the sovereign rights of nations over their genetic resources and agreed in principle that Farmers' Rights should be implemented through an international fund.

¹³ Resolution 3 of the Nairobi Final Act for the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.

of Plant Genetic Resources for Food and Agriculture. It is in this context that the negotiations to revise the IU were initiated.

At the outset of the process leading to the 1996 Leipzig Conference on Plant Genetic Resources, it was hoped that the evolution of the Global Plan of Action (GPA) would be linked with the revision of the IU. In the end, this proved impossible and the GPA was finalized and adopted with the IU facing an uncertain future.¹⁴ The continuing uncertainties surrounding the IU have, unfortunately, delayed implementation of the GPA.

Three outstanding issues dominate the current IU negotiations: scope and access, benefit-sharing and Farmers' Rights. The scope of what the IU will cover and the question of how access will be regulated is one of the dominant issues in the negotiations. Some governments would prefer to confine the scope of the IU to a relatively small number of critical food crops, possibly categorized on two or three lists, for whom the conditions of access vary. Other countries would like to have all plant germplasm associated with food and agriculture incorporated into the IU with "unrestricted" access.

Among those preferring restricted lists, there is a growing willingness to accept a relatively free flow of germplasm among signatory states for those food crops already widely dispersed and utilized by plant breeders. However, plant species less widely available and/or having high commercial value would have their access controlled. Advocates of three-tier germplasm exchange see the degree of access ranging from "free" under a multilateral system to a "not free" system subject to bilateral agreements possibly monitored or maintained with the assistance of a multilateral facility.

In recent months, support for a multilateral mechanism has increased and governments have been willing to consider species lists that might be associated with the multilateral arrangement. Nevertheless, there are numerous nuances and variations in viewpoint between and among negotiators.

Generally speaking, developing countries have approached "scope and access" defensively – concerned that they are being asked to donate their germplasm freely while industrialized countries privatize the same material through intellectual property regimes. A number of independent studies have suggested that, while germplasm is collectively invaluable, it is next to impossible to determine the commercial worth of accessions and that the monitoring costs of tracking geneflows could exceed the actual financial returns to countries of origin, if they can be identified in the first place. At the same time, those developed countries advocating wide scope and access for genebank accessions and Farmers' Varieties generally argue that germplasm under intellectual property protection should be outside of the "free" multilateral exchange system.

In the midst of this, still others offer another range of views moving from those who believe that farming communities should either have their own

¹⁴ See Section III.C on Benefit-sharing.

intellectual property regimes for Farmers' Varieties – or should adopt non-IP *sui generis* mechanisms to defend their rights – to those who regard any non-traditional constraints to germplasm exchange (be they IP or non-IP *sui generis*) as self-defeating since such approaches potentially undermine community plant breeding.

The debate over benefit-sharing is another dominant issue in the negotiations and closely associated with the issue of scope and access. Some industrialized countries believe that developed countries are adequately compensated for their germplasm merely by having access (free or royalty-tied) to the information and breeding material created by open international exchange. Some developing countries consider this a "trickle-down" approach which does not adequately recognize the contribution of farming communities and national governments. Efforts to proportion the contribution and benefits from germplasm exchange and plant breeding have left all sides uncertain and frustrated.

Other parties have suggested that benefit-sharing might best be achieved through the full implementation (including new and additional financing) of the GPA. Various scenarios have been devised under which industrialized countries would make financial contributions to the GPA through membership fees to the multilateral exchange "club" while developing countries (as well as developed countries) would make its germplasm available to club members. In effect, the membership "fee" of developing countries would be germplasm rather than money. Again, conditions for scope and access might vary and one or more species categories could be entertained. All club members would be able to access the germplasm and the funds on the basis of approved programmes and projects in line with the rolling GPA. Not surprisingly, there are many nuances to this scenario and many concerns about IP claims on "club" germplasm.

Although this issue is addressed elsewhere in this paper, it is worth noting that Farmers' Rights is referenced in the current IU and remains something of a "wild card" in the negotiations for revision. Suggestions have been made that farming communities might have special access to resources and special recognition in the governance structure for the multilateral exchange system or "club".

D. Consultative Group on International Agricultural Research (CGIAR)

The CGIAR, established in 1971, is an informal association of public and private donors that supports a network of 16 international agricultural research centres (IARCs), each of which has its own governing body. The CGIAR's mission is to use science and technology, in partnership with other organizations, to increase food security, alleviate poverty and protect the environment. With a budget of approximately US \$328 million per annum, the CGIAR oversees the largest agricultural research effort in the developing world. The CGIAR Secretariat is housed in the World Bank (Washington, DC) and the group's major donors include the World Bank, Japan, USA and The European Union. The general trend in membership has been increasing participation of developing countries. In 1997, 23 countries from the North and 19 from the South comprised the formal State membership of the System.

Through the 16 IARCs, the CGIAR conserves approximately 600 000 seed samples which may amount to as much as 40% of the world's unique germplasm in storage worldwide. Because these genebanks contain "inventoried" germplasm, their collections are considered among the most valuable genetic materials simply because they are more readily identifiable and accessible to institutional plant breeders than farmers' varieties or "wild" crop relatives.

Because the CGIAR is one of the largest and most important institutions in both the conservation and development of genetic resources, international policies and policy debates can and do have a profound impact on the CGIAR's programmes, priorities and day-to-day work. Likewise, the CGIAR can play an influential role in shaping policies concerning genetic resources for food of agriculture.

When it comes to setting policy, the CGIAR frequently acts not as one institution but as many. Recent unsuccessful attempts to develop an official IP policy for the CGIAR point to the difficulties posed when the views of donors are in conflict. As the CGIAR grows in membership and takes in more developing countries, these problems are likely to increase. The autonomy of individual centres, including different boards, mandates and constituencies, makes policy-formulation and development extremely difficult. In addition, there are at least 14 "policy-making" fora within the CGIAR.¹⁵ In 1996, the Group initiated an

¹⁵ For example, the members of the CGIAR, the cosponsors, the Technical Advisory Committee, the individual Centre Boards of Trustees, The Committee of Centre Board Chairs, the Committee of Centre Directors, individual Centre Directors, the Genetic Resources Policy Committee, the Inter-Centre Working Group on Genetic Resources, the System-wide Genetic Resources Program, IPGRI (as the "lead" Centre on genetic resources and biodiversity issues), the NGO Committee and the Private Sector Committee.

External System Review, which is currently underway, and will most certainly be examining how policy is formulated and developed within the system.

The lack of a mechanism to coordinate policy is also noticeable as the CGIAR grapples with what its role in the world is and should be. At least one *political* rationale for the CGIAR at its inception reflected Cold War security-driven concerns to ameliorate world hunger that otherwise might spark a communist revolution.¹⁶ With the end of the Cold War, an unspoken struggle has begun over the CGIAR's focus. On the one hand, there is support for a focus on maximizing food production where the benefits are likely to predominantly accrue to large farmers, and perhaps to the urban poor. On the other hand, there are those who feel the CGIAR should concentrate on more marginal areas that are still self-provisioning in terms of seeds and have been largely untouched by the green revolution. With little means to coordinate, there is no real mechanism by which to determine a focus from a diversity of possible objectives. The lack of clarity on focus (combined with shrinking aid budgets) may be causing more donors to earmark funds to the CGIAR for specific purposes rather than giving unrestricted financial support.¹⁷

There is no dispute that the vast majority of crop germplasm held in the IARCs was collected from the fields and forests of the South's farming communities. But to whom that treasure ultimately belongs, to whom CGIAR is accountable, and whether or not CGIAR's germplasm can be subject to intellectual property protection by any party, remains a topic of controversy and debate. The status of the collections of PGRFA made prior to the coming into force of the CBD was left as an outstanding matter in the CBD negotiations. Negotiators adopted Resolution 3 which requested that this (and other) issues be addressed through the FAO Global System for the Conservation and Utilization of PGRFA. As most of the accessions held by CGIAR Centres were collected prior to the entry into force of the CBD, the status of these collections, including questions of ownership, terms of access and benefit-sharing, remains uncertain pending the outcome of the ongoing negotiations on the IU at FAO.

As an interim measure, the FAO Commission and the CGIAR decided to develop Agreements that would keep Centre-held material in the public domain for the benefit of all humanity in line with the mission of the CGIAR system. In 1994 the CGIAR and FAO entered into an agreement whereby most of the materials ("designated material") in the Centres are held in trust for the world community. By the terms of the FAO/CGIAR agreement, the Centres have agreed to conserve this genetic material in conditions meeting international standards, to not take out any form of intellectual property protection on them

¹⁶ This political motivation is not exclusive of other more genuine concerns which also motivated the establishment of the CGIAR.

¹⁷ For IPGRI, for example, in 1993 the ratio of donor support was 84% unrestricted/16% restricted. In 1996 it was 61%/39%.

and to pass this obligation on if the material is transferred further. The agreements were designed to ensure the relatively unrestricted flow of germplasm to all countries in the new bilateral-oriented context reflected by the entry into force of the CBD. Without these Agreements, the role of the Centres might well have been reduced to the level of brokers for individual countries in bilateral exchange transactions. It is understood that these FAO/CGIAR Agreements will be modified, if necessary, according to the outcome of the IU negotiations.

A rapidly changing IP environment and increasing privatization of agricultural research have forced the CGIAR to develop its own policies and procedures on IP over the past decade. The process has been complicated by the fact that the CGIAR system has no legal status, and its members often represent opposing sides of the highly politicized IP debate. After years of discussion and debate by numerous committees, the CGIAR system is still in the process of developing a coherent, comprehensive policy on IP. The CGIAR's guiding principles on IPR are:

1. Reaffirm that the fundamental objective of the CGIAR is to ensure access to knowledge, technology and materials in the interest of developing countries.
2. Reaffirm that materials from the Centre genebanks will be freely available.
3. Recognize that the sovereign rights of states over their genetic resources and that the acquisition of germplasm, after the coming into force of the Convention on Biological Diversity, are subject to the Convention's provisions.
4. Recognize both Plant Breeders' Rights and Farmers' Rights in accordance with the IU.
5. State that Centres will not claim ownership nor apply intellectual property to the germplasm held in trust, and will require recipients to observe these same conditions.
6. Regard the results of their work as international public goods and thus disclosure of information is the preferred strategy. Intellectual property rights will only be sought for Centre research products when this is in the best interests of developing countries. In all such cases the reasons for seeking protection will be disclosed.
7. State that plant variety protection may be sought by recipients who have used Centre materials for breeding but this may not prevent others from using the original material in their own programmes.

8. Provide that material will be distributed only on the basis that recipients seek Centre approval prior to patenting any cells, gene or other derivative.
9. State that Centres will enter into agreements with holders of protected materials which recognize restrictions on the use and distribution of such materials only when this is in the best interests of developing countries

It should be noted, however, that with no centralized policy authority, CGIAR Centres remain free to interpret and apply the guiding principles as they deem fit.

In late 1997 and early 1998, several cases came to light and were publicized wherein recipients of designated germplasm from a CGIAR Centre sought plant breeders' rights for that germplasm in alleged contravention of the 1994 FAO/CGIAR agreements. These cases raised serious questions about the Centres' effectiveness in implementing the 1994 agreements and, in particular, their use of material transfer agreements (MTAs) to implement those agreements. In response to PBR abuses, the Chair of CGIAR, Dr Ismail Serageldin, called for a moratorium on the granting of IP rights on designated plant germplasm held in the collections of CGIAR agricultural research centres around the world. The parties seeking PBRs in these cases withdrew some of their applications. Unfortunately, these high-profile cases do not appear to be isolated incidents. There is clearly an urgent need to strengthen and enforce the international agreement that places the South's germplasm "in trust" for the world community.

E. The International Union for the Protection of New Varieties of Plants

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization based in Geneva, Switzerland. It is based on the International Convention for the Protection of New Varieties of Plants, as revised since its signature in Paris on 2 December 1961. UPOV had 32 members as of May 1997, most of which are from the developed world.

The original impetus for creating UPOV came from three organizations: a commercial plant breeders' trade association formed to promote plant variety protection, an organization with a mandate to promote industrial patents, and the International Chamber of Commerce. Six countries from Western Europe founded UPOV.¹⁸ UPOV encourages the adoption of *sui generis* laws for protecting new plant varieties by creating its own distinct system outside of patent law. There are four versions of UPOV. Until recently both the 1978 and the 1991 versions were open to new members. The 1991 version will enter into force on 24 April 1998, technically closing the 1978 version to new members.¹⁹

All four versions of UPOV require that a plant variety be new, distinct, homogenous (uniform) and stable in order to be eligible for protection. The original Crucible Group noted that the criterion of homogeneity reinforces the trend towards genetic uniformity, thus leading to a higher degree of vulnerability in farmers' fields. The criterion also excludes the possibility of protecting most landraces and traditional varieties. On the other hand, loosening the uniformity criterion would likely lead to broader property claims. If claims were broader there might be a need for a corresponding limitation of the nature of the right granted in order to prevent an unacceptable "locking up" of the system.

The trend, however, is toward a strengthening of the rights granted. The growth of biotechnology and the possibility of formal patent coverage created pressure leading to the 1991 revision of UPOV. UPOV 1991:

1. Extends the rights of holders beyond the reproductive material to the harvested material and products obtained through illegal use of propagating material.
2. Allows members the legal option for patent or UPOV style protection.
3. Extends coverage to cover all plant genera and species.

¹⁸ Fowler, Cary. *Unnatural Selection: Technology, Politics and Plant Evolution*. Gordon and Breach Science Publishers, Switzerland. 1994. Page 104.

¹⁹ There may be some flexibility in joining the 1978 version if interest was expressed prior to the entry into force of UPOV 1991.

Extending the rights of holders to harvested material has significant implications for the rights of farmers' to save seed for re-planting. Rather than assuring this right, UPOV 1991 gives members the option of allowing farmers to save seed for their own use. Without positive action by the UPOV member, the right is lost.

In addition, authorization of the right-holder is required for the use of the material of varieties which have been essentially derived from a protected variety.²⁰ The term "essentially derived" is not defined but was intended to halt the process of cosmetic breeding whereby one or two easy and unimportant characteristics were changed and protection sought for a new variety. Reinforced by advances in technology which make smaller differences between varieties achievable and detectable, the trend has been toward a narrowing of permissible distinctions between varieties. The criterion of distinctiveness is likely to be similarly affected.

As noted in Section II.B above, the TRIPS agreements requires parties to provide for protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. It is notable that the article does not specifically mention the UPOV Agreement (other articles do explicitly refer to other agreements) despite it being the most significant instrument for *sui generis* plant variety protection. The purposeful omission was intended to allow parties a degree of flexibility in designing a system for plant variety protection.

²⁰ The uses for which permission must be sought include for production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting or importing, and stocking for any of these purposes.

F. World Intellectual Property Organisation (WIPO)

The World Intellectual Property Organisation (WIPO) is a specialized agency of the United Nations, headquartered in Geneva, which was founded in 1967 and has 161 members. Its objectives are to promote the protection of intellectual property throughout the world and ensure administrative cooperation among the intellectual property unions (the unions created by the Paris and Berne Conventions). WIPO administers 19 international treaties concerning intellectual property, such as the Paris Convention on Protection of Industrial Property and the Berne Convention on Protection of Literary and Artistic Works.

WIPO was essentially sidelined for what was probably the single biggest step in strengthening international IPR standards, the negotiation of the TRIPS Agreement. This was in large part due to a deliberate move by IPR proponents who anticipated making greater gains on IPR through negotiated trade-offs within the Uruguay Round, and also sought to strengthen enforcement of IPR standards by making it possible to enforce them through the WTO dispute-settlement procedures.²¹

WIPO remains, however, an important arena for international standard-setting on IP. In addition, TRIPS incorporates by reference obligations found in agreements administered by WIPO, such as the Paris and Berne Conventions. Furthermore, WIPO is regaining importance as WTO Members grapple with the problems of passing national legislation to implement the far-reaching requirements of TRIPS. The WTO Secretariat, with only a handful of staff devoted to TRIPS, cannot respond to Members' needs for technical assistance. WIPO, on the other hand, has decades of experience and considerable staff and other resources to support provision of technical assistance on national IP laws and institutions. Thus, WTO and WIPO have signed an agreement committing the two institutions to greater cooperation on matters such as information-sharing and technical assistance.

Technical assistance will need to address the flexibility in TRIPS that relates to genetic resources and products thereof. For instance, Article 27.3(b) allows countries to adopt *sui generis* systems for plant variety protection, and allows them to exclude animals from patenting. Article 27 also allows the exclusion from patenting of inventions of which the prevention of their commercial exploitation is necessary to protect "ordre public" or morality, human, animal or plant life or health or the environment. Through technical assistance programmes, research and analysis, and global, national and regional consultations, WIPO could help its members explore this flexibility and make appropriate policy choices.

²¹ Jackson, John H. 1997. *The World Trading System: Law and Policy of International Economic Relations*. 2nd edition. The MIT Press, Cambridge, Mass.

Until recently, WIPO tended to avoid addressing issues relating to indigenous or traditional knowledge or to genetic resources. For example, WIPO rarely sent representatives to meetings of the CBD or FAO Commission on Plant Genetic Resources for Food and Agriculture. There are, however, signs that the organization is preparing to take a more active role in these areas. Dr Kamil Idris, appointed in fall 1997 as the organization's first new Director General in 25 years, has signalled an openness to exploring how WIPO can contribute its technical expertise and resources to the exploration of these issues. In March 1998, the WIPO General Assembly approved a reinvigorated programme for the Global International Property Issues Division that would address biodiversity, human rights and indigenous rights issues through activities such as research, publication and consultations. WIPO sent three representatives to the November 1997 intergovernmental meeting on traditional knowledge under the CBD in Madrid, and their intervention included a preliminary offer to explore how WIPO's resources could contribute to finding solutions to problems concerning traditional knowledge.

G. Instruments established to directly address the rights of indigenous peoples

The UN Commission on Human Rights and subsidiary organs

The Working Group on Indigenous Populations was established in 1982. Five individual experts from the Sub-Commission on the Prevention of Discrimination and the Protection of Minorities compose the Working Group. Its mandate is to: (1) review the developments affecting the rights of indigenous peoples, and (2) develop standards concerning the rights of indigenous peoples.

In 1984, the Sub-Commission instructed the Working Group to consider drafting principles on indigenous rights. The Working Group agreed upon a draft "United Nations Declaration on the Rights of Indigenous Peoples" in 1993. The Sub-Commission adopted it and submitted the draft to the Commission on Human Rights in 1994.²² In 1995, the Commission established an open-ended intersession Working Group of the Commission on Human Rights²³ with the purpose of considering and elaborating the draft for consideration and adoption by the General Assembly within the International Decade of the World's Indigenous People, 1995–2004.²⁴

The Working Group on the draft declaration is a subsidiary organ of the Commission on Human Rights and is composed of representatives of Member States. Organizations with consultative status with the ECOSOC may participate in the meetings as observers. The resolution establishing the Working Group also established procedures for the participation of indigenous organizations without ECOSOC consultative status. At present, over 110 indigenous organizations are authorized to participate as observers in the Working Group.

While there are provisions of relevance to genetic resources and intellectual property rights in other sections of the draft Declaration,²⁵ Part VI of the Declaration contains the bulk of the articles of relevance.²⁶ These articles touch upon the right to own and control the use of land, including flora and fauna and the right to recognition of their cultural and intellectual property.

²² Resolution 1994/45, August 1994, E/CN.4/Sub.2/1994/45.

²³ Resolution 1995/32, 3 March 1995, E/CN.4/1995/32 and ECOSOC Resolution 1995/32, 25 July 1995, E/1995/32.

²⁴ General Assembly Resolution 48/163, 21 December 1993, A/RES/48/163.

²⁵ See, for example, the Preamble; Part III, Articles 12 and 14; and Part V, Article 23.

²⁶ The draft Declaration can be found in Sub-Commission on Prevention of Discrimination and Protection of Minorities Resolution 1994/45 August 1994. E/CN.4/Sub.2/1994/45.

For example, Article 26 provides:

"Indigenous peoples have the right to own, develop, control and use the land and territories, including the total environment of the lands, air, waters, coastal seas, sea-ice, flora and fauna and other resources which they have traditionally owned or otherwise occupied and used.

Article 29 provides:

"Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property.

They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human **and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora**, oral traditions, literatures, designs and visual and performing arts." [emphasis ours]

While these articles do not contain mechanisms for implementation, they do provide the principles and foundation upon which measures can be built.

The Human Rights Commission is also considering the creation of a permanent forum within the United Nations for indigenous people.²⁷ Two workshops have been held to consider the issue, one in Denmark in May 1995 and one in Chile in June 1997. It is generally agreed that the mandate of a permanent forum should be broad – covering cultural, civil, political, social, economic and human rights as well as issues relating to health, development, education and environment. Debate continues on how membership and participation of indigenous people and member states might be governed. Positions also vary about the placement of a forum within the UN. Some feel it should be established under the ECOSOC while others support its constitution as an advisory body to the General Assembly linked to the Trusteeship Council. Still others advocate the creation of a separate body under the Secretary-General.²⁸

Taking note of these workshops, the Commission established an open-ended intersession *ad hoc* working group to elaborate further proposals on a permanent forum.²⁹ As noted in previous sections, indigenous rights and related issues are increasingly being raised in intergovernmental fora with relevant objectives. Nevertheless, the objectives of these fora and instruments usually relate to only a

²⁷ General Assembly Resolution A/RES 48/163 21 December 1993 recognizing the importance of considering the establishment of a forum and requesting the Commission on Human Rights to give priority to that process.

²⁸ E/CN.4/Sub.2/AC.4/1995/7 26-28 June 1995; E/CN.4/1998/11 30 June - 2 July 1997.

²⁹ Resolution 1998/20, E/CN.4/1998/20.

subset of the broader concerns that indigenous groups are looking to be addressed. The establishment of a permanent forum has particular relevance as indigenous groups and their advocates ponder the most fruitful and appropriate fora in which to expend energy and raise issues when faced with a growing number of possibilities.

The International Labour Organisation Convention No. 169

The Indigenous and Tribal Peoples Convention of 1989, also known as ILO Convention No. 169, is the only international treaty that is concerned exclusively with the rights of indigenous and tribal peoples. The Convention entered into force on 5 September 1991 and as of May 1998 has 12 ratifications.

Article 4 of the Convention provides that "special measures shall be adopted as appropriate for safeguarding the persons, institutions, property, labour, cultures and environment of the peoples concerned" in accordance with their own "freely expressed wishes." There is no explicit mention of intellectual property rights but Article 4 could reasonably be interpreted to include the protection of rights in traditional knowledge.

In spite of the relatively slow rate of ratifications, the Convention has influenced the domestic policy and programmes and the policy guidelines of some funding agencies. For example, in the Philippines, the Department of Labour and Employment held a training workshop and discussed how to promote the use of the Convention's policies in its programmes.³⁰

³⁰ "Indigenous and Tribal Peoples: A Guide to ILO Convention No. 169" on ILO's web site: <http://www.ilo.org/public>

III. Key Issues

As section II illustrates, numerous questions related to genetic resources are currently under debate at the national and international levels in a variety of intergovernmental contexts. The questions concern, for example, conservation, use, ownership, access, IPRs, benefit-sharing, indigenous rights and Farmers' Rights. The objectives of institutions with mandates directly or indirectly affecting genetic resources are diverse and include, for example: conservation and use, indigenous rights, maximizing profits, liberalizing trade, encouraging innovation, food security and the creation of markets. Furthermore, the issues are technically complex with several government ministries having relevant mandates.

A. Farmers' Rights

The term Farmers' Rights emerged in 1989³¹ in the context of the IU as a political effort to right a perceived imbalance created by the growing use and expansion of plant breeders' rights (PBRs). Through Annex II of the IU, countries agreed that Farmers' Rights would be recognized through an international fund. The rights themselves were never defined in a legal sense nor was it considered necessary to do so because the term was a political and not a legal one.

Today in the IU debates there are those who use the term "Farmers' Rights" as a general political concept and those who interpret it as a legal concept. Those viewing it as a legal term make proposals such as defining the rights as an alternative form of IPR covering, for example, the products of farmer selection and breeding. Those viewing it as a political concept make proposals to establish a fund to finance PGRFA conservation and development work. The question boils down to whether the international community is being asked to establish and recognize "rights" (the legal definition) or whether it is being asked to recognize the contribution of farmers and farm communities and assume practical responsibility for this recognition (the political definition).

The CBD's emphasis on national sovereignty and action and its bilateral orientation toward access and benefit-sharing reinforced the legalistic approach to Farmers' Rights debate.³² The idea that the recognition of Farmers' Rights –

³¹ FAO Conference Resolution 5/89, 1989. Resolution 5/89 defines Farmers' Rights as "rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity."

³² The reluctance of governments to operationalize the International Fund called for in Annex II of the IU facilitated this shift in the terms of the debate. Had the Fund been up and running it is less likely that today's debates would have been found necessary.

including benefit-sharing – would come through support for PGFRA activities was joined by the idea that Farmers' Rights might be recognized in some form of direct financial benefits accruing to general coffers of governments. In this scenario PGFRA would be bought and sold on the marketplace through bilateral transactions. The transaction would be contractual negotiations between buyer and seller and would not necessarily be directly related to the conservation and use of PGFRA. The debate in the IU now includes options that Farmers' Rights be recognized not just financially but through a list of various entitlements.

How Farmers Rights will be operationalized is of critical importance to the conservation and use of plant genetic resources. Yet, it is not Farmers' Rights but the issues of scope, access and benefit-sharing that seem to be the driving force behind the IU negotiations.³³ NGOs, who were instrumental in the original promulgation of the concept in the 1980s, have been noticeably absent from the debate on how to put it into operation. This may reflect the larger number of fora to which NGOs concerned about genetic resources must devote resources, as compared with the 1980s.

Practical approaches are needed. If Farmers' Rights are de-linked from the conservation and use of PGFRA, then the IU may not be the right forum for the debate. Presently, there is no formal proposal for some IPR or other legal form of Farmers' Rights. If and when there is one, it may be appropriate to consider the most appropriate forum for the discussion.³⁴ If the issues are to be linked, more information about whether the best route is to connect the rights to individuals or individual communities (either contractually or through some sort of IPR) or through an arrangement which supports the conservation and improvement of PGFRA more generally will be needed.

³³ Those who hold positions which equate Farmers' Rights with access and benefit-sharing may dispute this conclusion. At the December 1997 negotiating session, a contact group was established to consider the critical issues of scope, access, benefit-sharing and Farmers' Rights. When it became clear that the contact group would not have time to consider Farmers' Rights, the topic was shifted to the larger working group where general statements were made but no real debate occurred.

³⁴ It has been suggested that some elements of Farmers' Rights be included in the current review of the Right to Food being jointly undertaken by the UN Human Rights Commission and the FAO.

B. Indigenous and local communities

As acknowledged by the CBD, there is a connection between the conservation, use and development of genetic resources and the indigenous and local communities inhabiting the areas where those resources are found. Increased appreciation of the non-monetary and monetary value of genetic resources has stimulated interest and conflict over the subject and content of rights to these resources. It has also become linked to debates on the rights of indigenous and local communities *per se*.

It is important to note that there is a great deal of diversity among and even within indigenous and local communities. In addition, the relationship between an indigenous group and its environment, including the extent of interdependence, depends upon the particularities of that group and its surroundings. Thus, it is unlikely that any single approach will be applicable (or acceptable) in all indigenous groups or in the case of intellectual property rights, to all forms of knowledge within a group. Clearly, cultural and biological diversity will require a corresponding diversity of systems.

In the CBD a working group including both indigenous and national government representatives was convened in November 1997. For the first time, indigenous representatives attended not as observers but as participants in the same capacity as governmental representatives serving on the Bureau, chairing sessions of the meeting and adopting the meetings' report. The significance of this change should not be underestimated. International law is traditionally characterized by relations among *States*. For a State to deliberate in an intergovernmental forum where indigenous peoples possess similar procedural rights represents the voluntary ceding – however circumscribed – of a sovereign prerogative. There are some governments which would prefer not to see the subject of indigenous and local communities raised at the international level at all. Yet the issue is now firmly there. Because of its Article 8(j), the CBD has become a significant forum for indigenous and local communities.³⁵ While the CBD Workshop's outcome is far from a resolution of the issues raised, the process represents a step toward including the groups with the most at stake in the debate.

As noted in section II above, discussion of these issues is moving forward in several fora, including the CBD and the WTO/CTE. The Conference of Parties of the CBD discussed the impact of IPRs on the Convention's objectives at its second meeting in 1996. At the same time, the Parties discussed the relationship between the CBD and the TRIPS Agreement. They made, however, very limited progress, and in the end agreed primarily that there was a need for case studies of the specific ways that IPR affects traditional knowledge and biodiversity, the specific effects that are problematical, and the specific ways that IPR systems might need to be reformed to address those problems.

³⁵ See Section II.A, Convention on Biological Diversity.

In the WTO, the Committee on Trade and Environment (CTE) has discussed relationships between IPR and environment, including traditional knowledge of local communities. The CTE made no progress, however, on these issues, as key delegations (such as the US and India) remained far apart.

FAO's Commission on Plant Genetic Resources has been hosting international negotiations on revision of the International Undertaking on PGRs. In that context there has been extensive debate on farmers' rights, with many concerns and arguments expressed paralleling those arising in the context of the CBD and the WTO/CTE.

Except for the IU/CBD relationship, there has been little effort to link the various discussions together. The COP of the CBD reviewed the relationship between the CBD and the TRIPS Agreement but could not reach agreement on how to describe them. The COP asked the Secretariat of the CBD to apply for observer status to the WTO, and the Secretariat has been accepted as an observer to the CTE.

Some indigenous activists and analysts question whether multilateral agreements negotiated among nation-states will adequately protect indigenous interests. They are disturbed that the CBD emphatically affirms national sovereignty over genetic resources, while including relatively weak, qualified provisions on indigenous rights. Indeed, the Convention has stimulated some countries to declare all genetic resources within their territory to be a national heritage without any qualification that might acknowledge indigenous claims over land or natural resources.

There is a great deal of confusion about the relationship among Farmers' Rights as expressed in the IU, indigenous and local communities as expressed in the CBD and indigenous peoples as expressed in other instruments elaborating more fully on these rights in general (e.g. ILO Convention 169). As noted in section III.A above, Farmers' Rights have yet to be clearly defined. In the CBD context, indigenous representatives and advocates on their behalf represent varying perspectives on how to define and implement the relevant commitments under the Convention. Positions range from those based on a human rights foundation and therefore focusing more on rights in general, to those based on the need for some form of IP over indigenous knowledge and innovation and therefore focusing more on the specific language of the CBD. Some advocates argue for the right of indigenous and local communities to control access to, and assert property rights over, their knowledge and genetic resources. Others consider IPR a predatory process and are concerned about freedom from impositions of IPR.

Additional thought needs to be given about the relationship among the relevant intergovernmental bodies including what issues should be addressed in each and how consistency and coherence can be better achieved.

C. Benefit-sharing

The need for and desirability of sharing benefits arising from the conservation and use of genetic resources is generally accepted. Nevertheless, there is no agreed definition of what benefit-sharing entails. The mechanisms by which it will happen, to whom the benefits will flow and what constitutes benefits are all subject to considerable debate. In the context of the CBD, benefit-sharing is generally conceived as an integral component of bilateral transactions for access to genetic resources. While benefit-sharing on a bilateral basis has been discussed in the context of the IU, attention seems to be focusing more recently on how benefits might be shared in the context of a multilateral system for access.

Benefit-sharing is one of the CBD's three objectives and is explicitly and implicitly reinforced throughout the treaty's provisions.³⁶ Nevertheless, the term is never defined or given concrete operational content. Discussions have focused on benefit-sharing resulting primarily from bilateral transactions involving access to genetic resources. "Benefits" could be any compensation, reward or recognition that flows directly or indirectly from the party seeking access to a genetic resource to the "supplier" or party in control of that resource. The possible range of benefits is therefore very broad. They could include royalties or shares of profits from the commercialization of a commodity derived from a genetic resource, flat fees for access to a controlled area for exploration, access to the supplier's technology and training, joint ventures or access to global funds for development assistance, to name just a few.

As countries struggle to give meaning to the concept, an assessment of benefits actually gained pursuant to this type of bilateral transaction would be useful. An understanding of the nature and extent of benefits that have accrued, for what types of resources and for whom (e.g. general government coffers, public or private sector institutions, indigenous peoples, etc.) would help in determining the best approaches to benefit-sharing under particular circumstances.

Benefit-sharing has also been a major topic of debate in the context of the IU. How benefits will be shared within a multilateral system for access for certain identified major crops will continue to be a hotly debated subject. Positions on what constitutes benefit-sharing in such a system vary widely. Some argue that access to genetic resources themselves is the benefit of the multilateral system. Others argue that benefit-sharing should be connected to financing PGRFA conservation and development work most logically through implementation of the Global Plan of Action for the Conservation and Sustainable Utilization of PGRFA (GPA)(see below). Still others argue that with the entry into force of the

³⁶ See Sections II.A and III.B above for discussion of Article 8(j) and rights of indigenous and local communities.

CBD, all access regimes and hence benefit-sharing should be through agreements with the "country of origin" of those resources.³⁷

The first argument (that access is the benefit) is unlikely to achieve consensus because it ignores the impetus for the negotiation of the IU in the first place. Prior to the IU, PGRFA were relatively freely exchanged. The IU was born out of developing-country demands that the exchange of genetic resources be regulated to correct for the growing asymmetry of the availability of "improved" varieties which were products of formal breeding (mostly from developed countries) and the availability of farmers' landraces and other traditional varieties (mostly from developing countries.) The insertion of the concept of Farmers Rights into the Undertaking came about as a reaction to the established benefit-sharing mechanism available to plant breeders, namely "Plant Breeders Rights." Unless the imbalance in access and the accruing of benefits is corrected in some other way, it is unlikely that "access as the benefit" will receive substantial support, at least among developing countries.

A system based on bilateral transactions with the "country of origin" of the resources in accordance with the CBD faces the practical problems with such transactions when PGRFA are involved. Article 2 of the CBD states that the country of origin of genetic resources "means the country which possesses those genetic resources in *in situ* conditions." And *in situ* conditions "means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties." Determining the country of origin for most PGRFA will be extremely complex if not impossible. In the case of most staple food crops, which have been farmed and exchanged globally for millennia, many countries can rightfully claim credit for giving rise to 'distinctive properties'. Rice, for example, today grows in more than 100 countries. Lacking a detailed history of rice over the last 10 000 years or more, it is rarely possible to know with any degree of certainty exactly where a particular 'distinctive property' first occurred.

Benefits in the form of financed PGRFA conservation and development work are yet another alternative. It is not necessarily exclusive of direct sharing of benefits with individual "owners" of the resources where readily identifiable. The GPA was adopted by over 150 governments at FAO's Fourth International Technical Conference on PGRFA in 1996. The GPA outlines 20 specific initiatives in four broad categories: *in situ* conservation and development, *ex situ* conservation, utilization of plant genetic resources, and institutions and capacity-building. The original impetus for the GPA came from the intergovernmental FAO Commission on Genetic Resources in response to the need to determine

³⁷ Under the terms of the Convention, access to genetic resources is granted by the country of origin on the basis of mutually agreed terms. Presumably it is in the negotiation of these terms that benefits are secured.

what the International Fund under the IU would support and how much money was needed.³⁸ Prior to its adoption, however, the GPA's link with the International Fund, with Farmers' Rights and with access to PGRFA was cut.³⁹ This threatened to make the GPA just another document to be filed away. Moreover, the "solution" which the GPA might offer to the benefit-sharing debate within the IU negotiations was lost. It may be recaptured in the future as FAO delegations ponder what types of benefits and benefit-sharing mechanisms are appropriate for a multilateral system encompassing major crops.⁴⁰

De-linking the GPA from the International Fund reflected the new approach characterized by the CBD's emphasis on national sovereignty and a bilateral approach to access to genetic resources. In the original discussions under the IU and in deciding to hold the Fourth International Technical Conference, the assumption was that benefit-sharing and the recognition of Farmers' Rights would come in the form of support for agreed PGRFA conservation and development activities. With the CBD came the hope that financial benefits might accrue more directly to governments to use as they saw fit. A financed GPA did not meet new expectations of direct and unearmarked financial benefits in exchange for access to genetic resources.⁴¹

It appears, however, that the debate may be coming full circle. As doubts grow about the strength of the market for agricultural genetic resources⁴² and the feasibility of identifying a country of origin, there is an increasing realization that the major source of benefits of a multilateral system may involve assured conservation, better utilization of PGRFA and improved crop varieties.

Given the peculiar characteristics of different types of biodiversity, this type of outcome for all or some subset of PGRFA would not preclude mechanisms more closely tied to country origin for other types of genetic resources. Most genetic materials of relevance to agriculture have been shifting around the globe for thousands of years, encountering and adapting to new conditions all along the way. Bilateral access and benefit-sharing arrangements in this context would be extremely complex. In contrast, access and sharing of benefits from non-dispersed, highly localized genetic resources such as those found in endemic species where the country of origin is readily identifiable, might more efficiently be determined bilaterally.

³⁸ The concept was an International Fund to recognize Farmers' Rights through promotion of conservation and development. See Sections II.C and III.A above.

³⁹ Fowler, Cary. 1997. Rights and Responsibilities: Linking Conservation, Utilization and Sharing of Benefits of Plant Genetic Resources. *In Proc. of the IPR III Conference*. Am. Soc. Agronomy, Am. Soc. of Horticultural Sci., Crop Sci. Soc. Am., Washington. Page 6.

⁴⁰ See Section II.C on International Undertaking on Plant Genetic Resources.

⁴¹ See footnote 39, Page 7.

⁴² And the related problem of multiple sources of a particular genetic resources creating competition among source countries and thus driving prices down.

D. Access

Until the negotiations for the CBD, access to genetic resources was largely characterized by free exchange. This orientation was reflected in 1983 with the adoption of the IU, the central tenet of which was plant genetic resources should be available without restriction.⁴³ Nevertheless, in the early 1980s some countries began to restrict access to their genetic resources. In addition, the free exchange principle began to experience a rather rapid one-sided contraction as biotechnology catalysed the increasing use and expansion of intellectual property rights over biomaterials. While plant genetic resources of traditional varieties, farmers' "landraces" and wild relatives were freely available, the "improved" varieties which were the products of formal plant breeding or products of biotechnology were often subject to plant breeders' rights. This trend continues today in industrialized nations with IPRs, including patents, being extended to cover a wide spectrum of living organisms. These IPR systems do not consider the contribution of indigenous peoples and farmers to the maintenance and development of genetic diversity.

Even before the CBD's adoption, the IU was evolving through interpretative resolutions to reflect the shifting terms of the access debate. In 1989 an agreed interpretation recognized that Plant Breeders Rights were not necessarily inconsistent with the Undertaking and simultaneously put forth the idea of Farmers' Rights (see Section III.A above). In 1991 Resolution C 3/91 reaffirmed the sovereign rights of nations over their genetic resources.

The CBD unequivocally reaffirmed national sovereignty over natural resources and the derivative authority of a country to determine access to the genetic resources under its jurisdiction. Article 15 on *Access to Genetic Resources* keeps to the CBD focus on national action, and through reference to mutually agreed terms and prior informed consent implies a negotiation – a bilateral approach – between source countries and recipients for access to genetic resources.

The ramifications of the CBD were felt immediately by the FAO Commission. Noting certain issues were left outstanding by the CBD, the negotiators at the time of the treaty's adoption passed a resolution calling for resolution of issues such as Farmers' Rights and the status of *ex situ* collection existing prior to the CBD's entry into force within the FAO-led Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture. In April 1993 the FAO Commission decided that the IU should be revised to bring it into harmony with the CBD.

⁴³ Article 1 of the original Undertaking states: "This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction."

Under the CBD, several countries and some regions are developing or have already promulgated legislation regulating access to their genetic resources.⁴⁴ The emphasis of these efforts has been on a bilateral approach. The failure to establish an international fund to implement Farmers' Rights reinforced the growing appeal of bilateral approaches in the context of the IU. As noted in Section III.A above, the term Farmers' Right was originally a political slogan created with the intent of balancing plant breeders' rights. The intended mechanism for recognizing these "rights" and extracting benefits was an international fund to finance PGRFA conservation and development work. The legal content of the rights was therefore not an issue until it became clear that no fund was going to materialize. Hence, as the CBD emerged with its bilateral orientation, there was also growing pressure to give definition to Farmers' Rights in the IU.⁴⁵ One approach was to "recognize" these rights through benefit-sharing linked to bilateral access agreements. The extension of a form of intellectual property to individual farmers or to communities has also been considered as a basis of controlling access and thereby securing benefits.

While the CBD's text emphasises a more bilateral approach to access to genetic resources, it does not require it. The CBD leaves Parties free to determine whatever system they deem to be appropriate in light of its obligations. Sovereign states remain free to negotiate the terms of a multilateral system if they deem this to be the most appropriate kind of system to achieve the objectives of the Convention. Recently, it seems that discussions under the IU have moved from discussions of possible bilateral approaches to focusing again on a multilateral system. Recognizing the unique characteristics of PGRFA, the negotiators revising the IU to bring it into harmony with the CBD appear to have agreed on the need for a multilateral system to facilitate access to these resources through an as-yet-to-be determined list of major crops. While many technical and legal issues remain, this consensus represents a breakthrough in the negotiations. There seems to be an increased comfort with the notion that bilateral and multilateral approaches can exist in parallel as long as their respective domains are clear.

⁴⁴ UNEP/CBD/COP/2/13, 6 October 1995 "Access to Genetic Resources and Benefit-sharing: Legislation, Administrative and Policy Information."; UNEP/CBD/COP3/20, 5 October 1996, "Access to Genetic Resources" and UNEP/CBD/COP/4/23, 5 February 1998 [advance unedited copy] "Review of National, Regional and sectoral measures and guidelines for Implementation of Article 15".

⁴⁵ And as noted earlier, this was reinforced by the adoption of Resolution 3 by the CBD negotiators at the time of the adoption of the CBD.

E. Patents and industry trends

The application of modern biotechnologies to biomaterials has brought new economic opportunities and the growth and subsequent consolidation of industry concerned with bio-industrial products. It has also brought new challenges to existing IP regimes. Driven by the private sector, the trend in industrialized countries has been towards the expansion of the scope and/or application of patents and plant breeders' rights to biomaterials. Yet, there is a noticeable lack of empirical evidence about the potential impacts of IP regimes on biodiversity, food security and development.

Patent trends

The trend toward expansive plant-related patents is most advanced in the United States. The trend is for an increasing breadth of protection. One pattern that has raised concerns involves patents on finished plants where it is possible to obtain claims covering broad groups of transgenic plants. For instance, Agracetus obtained patents on *all* transgenic cotton and *all* transgenic soybean plants. These types of claims are designed to make it impossible for another to breed with the material (the claims reach use of the material as a parent) and provide a way to protect a variety from use for breeding and from reuse by farmers thus avoiding the freedoms allowed under plant variety protection laws.⁴⁶ Another significant category of patents is those that involve basic processes and inventions. The breadth and number of these patents makes it difficult to develop new transgenic plants without infringing one or more of these patents.⁴⁷

Rather than providing an incentive for innovation, excessively broad patents could actually deter the entry of new firms and discourage innovative research⁴⁸ particularly if controlled by large corporations in an increasingly concentrated and integrated industry. Large corporations may be able to budget for the expenses associated with applying for and defending a patent but the expense of licensing fees and the risk of costly litigation forecloses entry for smaller firms or public institutions.

The expanded application of patents to plants may also affect farmers. Patents do not have a farmers' "privilege" and in some jurisdictions may also lack the research exemption. Some US-based industry has rejected traditional farm

⁴⁶ Barton, John. 1997. The Impact of Contemporary Patent Law on Plant Biotechnology Research. *In Proc. of the IPR III Conference*. Am. Soc. Agronomy, Am. Soc. of Horticultural Sci., Crop Sci. Soc. Am., Washington. Page 1.

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*

practice by forbidding the saving of seed for replanting.⁴⁹ In addition, on 3 March 1998, Delta & Pine Land Co. (Mississippi, USA) and the US Department of Agriculture (USDA) announced that they received a US patent (no. 5,723,765) on a new genetic technology designed to prevent unauthorized seed-saving by farmers. The patented technology, "Control of plant gene expression", genetically alters the seed so that it will not germinate if re-planted a second time. The patent is broad, applying to plants and seeds of all species. The technology is now in the product development stage.

In Europe, farmer and consumer resistance to commercialization of transgenic crops is strong. In response to the French government's decision to approve commercial sale of genetically engineered maize in late 1997, members of France's second-largest farmers' union illegally destroyed 5 tonnes of Novartis' genetically engineered maize seed in January 1998. In the developing world, where up to 1.5 billion people depend on farm-saved seed as their primary seed source, the notion of legal prohibitions on seed-saving is perceived by some as both alien and life-threatening.

Although animal patents have been granted in the US for over a decade⁵⁰ the patenting of animals is not accepted practice in most of the world. The TRIPS agreement does not require signatories to adopt patent protection for animals. In Canada, rejection of the first animal patent application (on the Harvard mouse) has forestalled the patenting of all higher multicellular organisms in that country. No consistent policy exists in the European Union, but if the European Parliament gives final approval to the Draft Directive on Biotechnological Inventions in 1998, animal patenting will be allowed. Some observers warn that patented animals and new reproductive technologies will exacerbate the problem of genetic uniformity in livestock because of over-reliance on uniform, elite breeds. Additional concerns about animal welfare are reflected in the EU's draft Directive. An ethical restraint clause would prohibit patenting in cases where genetic manipulation of animals causes suffering, or in cases where there are no medical benefits to animals or humans.⁵¹

⁴⁹ Monsanto now requires its customers to sign a licensing agreement that prohibits farmers from saving, selling or re-using patented seed for any purpose (G. Hillyer, *Progressive Farmer*, January 1998).

⁵⁰ As of 7 January 1998, over 1385 animal patent applications were submitted to the US PTO. Eighty-five animal patents were issued in the US between 1986 and 1997, over half of these (46) issued in 1997. US Patent and Trademark Office, Unpublished memorandum from Jasmine C. Chambers, US Patent and Trademark Office to John J. Doll, US PTO, dated 20 January 1998.

⁵¹ The EU Draft Directive allows for the patenting of animals. But there is the following ethical restraint to prevent patenting on "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes."

In 1995, Human Genome Sciences Inc. announced that it had sequenced the entire genome of a living organism, the bacterium *Haemophilus influenzae*, and that it had filed for broad patent claims on the medical uses of the organism's bacterial proteins. "It is the first time the entire genetic content of a free living organism has been deciphered," said William Haseltine, CEO of Human Genome Sciences.⁵² By mid-1997, HGS had sequenced the entire genome of three additional bacterial pathogens. Although patents have not yet been issued, the HGS claims include the development of diagnostics, vaccines or antibiotics related to their proprietary genomic information.⁵³ Today, whole-genome sequencing of microorganisms is commonplace. By the end of 1997, more than 50 microbial genome projects were underway worldwide.⁵⁴ The prospect of patents being issued for uses of genetic sequences where specific applications are not yet known has raised serious concern. Critics argue that such patents could stifle rather than reward innovation by setting up expensive toll-gates through which future innovators would be forced to pass.

In February 1997 the Scotland-based Roslin Institute unveiled "Dolly" – a lamb cloned from a single cell of an adult sheep. Before the February unveiling, the Roslin Institute had filed patent applications on the technique used to clone her. The patent applications filed by the Roslin Institute at WIPO were not limited to a technique for cloning farm animals – they included all mammals – and did not exclude humans.

Mergers and acquisitions

The last 5 years have been characterized by the increasing consolidation of industry involved with bio-industrial products. By 1996, the world's top 10 agrochemical corporations accounted for 82% of global agrochemical sales; the top 10 seed companies controlled approximately 40% of the commercial seed market; the top 10 pharmaceutical companies accounted for 36% of global drug sales.⁵⁵ Many firms are dominant actors in all of these categories.⁵⁶ Both firm consolidation and IP expansion enhance market power. The combination of the two trends may have synergistic effects on market power that are problematic for consumers, farmers, competitors and innovators.

⁵² Human Genome Sciences, Inc. 1995. Human Genome Sciences Announces *Haemophilus Influenza B* Vaccine Project. New Release, 28 July 1995.

⁵³ Human Genome Sciences, Inc. 1995. Human Genome Sciences Achieves Milestone. New Release, 28 July 1995.

⁵⁴ Erickson, D. 1997. Microbial Genomics. Start-Up, December, 1997. See also Culotta, Elizabeth. 1997. Science's Breakthroughs of the Year. *Science* 278(5346):2038, 19 December 1997.

⁵⁵ RAFI. 1997. Life Industry. RAFI Communique, November/December 1997.

⁵⁶ Examples of major life industry firms include: Zeneca, Novartis, Monsanto, DuPont, Rhone-Poulenc.

The push for harmonization of IP regimes

Mirroring larger trends in globalization and consolidation of world markets, many private sector interests, national governments and intergovernmental organizations are making concerted efforts to "harmonize" IP – to gain some semblance of cohesion in a field that is in flux. The TRIPS Agreement, of course, is the leading example.⁵⁷ In addition, at the end of 1997, heads of national patent offices from the USA, Europe and Japan met in Kyoto to work toward the realization of a "Common World Patent System." At the regional level, in an effort to harmonize rules on the patenting of genetic material across Europe, the European Parliament is expected to give final approval to a Biotechnology Directive in 1998.

Getting ahead of ourselves

Given the rapid pace of technological advancements in genetics and biology, it is not surprising that biological subject matter challenges us to examine legal parameters of ownership and control. Scientists are creating artificial human chromosomes, sequencing the entire genomes of living organisms, and cloning mammals to produce human proteins in their milk. Society is struggling with the social, ethical and legal implications of humankind's ability to control the genetic blueprint of life. Opinions differ sharply on the implications of new biotechnologies, but nearly everyone agrees that advances in technology are taking place at a rate far faster than social policies can be devised to guide them, or legal systems can evolve to address them.

As noted above, whether the subject is plant breeders' rights, plant and animal patenting, or monopoly claims on human genes, there is little consensus on the potential impacts of intellectual property on biodiversity, food security and development. Despite concerted efforts to achieve harmony and consistency across national and regional borders, intellectual property as it applies to biomaterials continues to be controversial and characterized by confusion and uncertainty.

⁵⁷ See Section II.B The World Trade Organisation (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

F. *Sui generis* Legislation

In frequent use since the adoption of the TRIPS Agreement, the term "*sui generis*" often causes confusion in discussions. This is because the term is used by different people to signify different things. *Sui generis* is Latin for 'of its own kind, or class'. Strictly speaking, *sui generis* legislation is any legislation that has been created to take account of a particular subject matter that can not easily be accommodated or protected within earlier, more generic legal regimes into which it would otherwise have been categorized. To a WIPO lawyer, the term is likely to signify a form of intellectual property rights designed to account for the unique nature of a new kind of innovation. In this context, UPOV legislation is one already established *sui generis* form of IPR designed to protect new plant varieties. In the context of the TRIPS Agreement, the term has a still narrower meaning, referring specifically to the discretion allowed WTO members under Article 27.3 (b) to create *sui generis* legislation to protect plant varieties. In the context of Article 8(j) of the CBD, representatives of indigenous communities typically use the term to refer to a new system of laws that would recognize the unique status of their communities and their contribution to the conservation, development and use of genetic resources. This might or might not include some form of IP.

Consequently, a first step must be to define clearly how the term will be used. This will help national governments, intergovernmental organizations and non-governmental organizations as they struggle with how the multiple yet related obligations of the CBD and the TRIPS Agreement can be coherently and consistently implemented at the national level.

IV. Conclusion

The erosion of genetic resources, and hence diversity, continues at an alarming pace. Simultaneously, technologies which develop and make use of these resources outpace the ability of laws and societies to understand and cope with them. Spurred by technological advances, appreciation of the monetary and non-monetary value of genetic resources has grown, leading to increasing conflict over rights and responsibilities for these resources.

Decision-makers trying to devise good, coherent, consistent policy on genetic resources are faced with a myriad of related, rapidly evolving issues being discussed in multiple national and intergovernmental fora. The task of discerning all the issues of relevance to the conservation and management of genetic resources and then integrating them into consistent policy is extremely complex. With continuing globalization and an increased understanding of the world's interdependence on all levels, few important issues can be meaningfully addressed without undertaking the complex process of unweaving and understanding relevant issues and then integrating a policy response.

Since the conclusion of the original Crucible Group, a number of significant developments have taken place. The time is ripe for an evaluation of where we have been and where we want to go with regard to the conservation, use and development of genetic resources.

Certain legal issues have arisen that clearly have an impact on genetic resources and therefore warrant closer examination. These include, for example: the expanding breadth of patents on genes, plans and techniques; "life" patenting generally, especially of plants and animals, and the use of plant patents versus PBRs. We need to ask if we are satisfied with the trends in IPR systems. If not, are there modifications that can be made or *sui generis* systems that can be created to address various concerns? Concerns may include concerns about innovation and competition; about indigenous rights to traditional or informal knowledge; and about North/South equity and benefit-sharing.

We may also ask what are some of the key decision points. These may be, for example: the 1999 TRIPS Review, the WTO millennial round; the FAO IU talks, future CBD talks on Article 8(j); the EU Patent Directive; and CBD and TRIPS implementation in each country. Another critical issue is whether or not current institutional linkages are adequate and, if not, what might be done to strengthen them.

Once we know what it is we want and hope to achieve, we must look at our current decisions and ask ourselves if we are heading in the right direction. If not, we need to ask why not and what we need to do to change course.

Acronyms

CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CHM	Clearing-House Mechanism for Scientific and Technical Cooperation
COP	Conference of the Parties
CTE	Committee on Trade and Environment
ECOSOC	Economic and Social Council
FAO	Food and Agriculture Organization of the United Nations
FR	Farmers' Rights
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GPA	Global Plan of Action
IARC	International Agricultural Research Centre
ILO	International Labour Organization
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual Property Rights
IU	International Undertaking
NGO	Non-Governmental Organization
PBR	Plant Breeders' Rights
PGRFA	Plant Genetic Resources for Food and Agriculture
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNEP	United Nations Environment Programme
UPOV	The International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Rights Organisation
WTO	World Trade Organisation