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Intellectual Property Rights in Plant Varieties: International Legal Regimes and Policy Options for National Governments

Laurence R. Helfer

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International legal regimes
and policy options for
national governments

Laurence R. Helfer

for the
Development Law Service
FAO Legal Office

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PREFACE

This study describes and analyses the various international legal regimes governing intellectual property rights in plant varieties and sets forth regulatory options for national governments to protect plant varieties while achieving other public policy objectives relating to plant genetic resources. It identifies different sets of policy options for governments based upon the specific constellation of treaty commitments they have undertaken. The study includes tables to convey complex information in a clear and easily understandable format.

Part I of the study reviews rationales for granting intellectual property rights in new plant varieties and the policy objectives that may be in tension with such rights. It also identifies the international institutions and intergovernmental organizations that regulate intellectual property rights in plant varieties and plant genetic resources generally, and describes the core obligations set forth in international intellectual property agreements.

Part II discusses the provisions of the relevant international intellectual property agreements in greater detail. These agreements include the 1991 and 1978 Acts of the *Union internationale pour la protection des obtentions végétales* (“UPOV”), which protect plant breeders’ rights, and the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPs”), which permits World Trade Organization Members to protect plant varieties with either patents or a *sui generis* system of intellectual property protection. Part II also includes a discussion of so-called “TRIPs plus” bilateral and regional agreements as they relate to plant variety protection.

Part III of the study begins with a brief overview of the international legal rules governing cumulative and conflicting treaty obligations. For each of the relevant international intellectual property agreements, Part III then identifies: (1) the implementation measures that are mandatory for member states; (2) the implementation measures that member states may but are not required to adopt; and (3) a range of policy options for national governments consistent with the treaty commitments that they have undertaken. Part III also includes a discussion of recent trends in national laws relating to the protection of new plant varieties.

Part IV looks to the future and considers the Doha Round of trade negotiations now under way at the World Trade Organization as well as the International Treaty on Plant Genetic Resources for Food and Agriculture, which entered into force in June 2004. It explains how these two developments may lead to a revision of existing legal rules and policy options for national governments in the area of plant variety protection and it explores the possibilities for harmonizing conflicting treaty commitments.

Part V summarizes the study, which concludes that the options available to national governments are dependent upon the international agreements to which they are parties.

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1. RELATING TO THE PROTECTION OF PLANT VARIETIES AND PLANT BREEDERS' RIGHTS

1.1. Intellectual property rights: philosophical and policy underpinnings

Intellectual property rights (IPRs) are legal rights granted by governmental authorities to control certain products of human intellectual effort and ingenuity. (OECD 1996, p. 12). An in-depth discussion of the philosophical and policy goals served by granting legal protection to these products is beyond the scope of this study. However, a basic familiarity with these goals is necessary to grasp how national and international intellectual property systems and institutions have evolved into their present forms and to understand the constraints that those systems and institutions place on governments seeking to implement competing policy objectives in tension with IPRs.

Two broad philosophical approaches underlie the decision to grant IPRs in the products of human intellectual effort and ingenuity. Elements of these two approaches can be found to different degrees in all national laws and international agreements relating to IPRs.

The first approach to IPR protection predominates in many civil law legal systems, including continental Europe. It takes the position that the products of the human mind are stamped with the personality of their creator, inventor or author, thus endowing him or her with a moral as well as an economic claim to exploit those products to the exclusion of third parties. Under this view, legal protection flows from a state's commitment to protect human rights, a fact reflected in the wording of article 27 of the Universal Declaration of Human Rights, which guarantees to everyone "the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." Legal protection also rewards creators, inventors and authors for their intellectual efforts as well as their expenditures of time and money. From these underlying premises flows a desire to provide robust intellectual property protection that includes, for example, a broad and expansive range of exclusive rights, long terms of protection, limits on mandatory licensing and narrow exceptions and limitations to exclusive rights.

The second approach to IPR protection takes as its starting premise an instrumental view of intellectual property. Legal protection for the products of human intellectual effort and ingenuity is granted not because of a moral commitment to compensating creators or innovators, but rather because the products they create enrich a society's culture and knowledge and thus increase its welfare. Perhaps the most well-known manifestation of this approach is found in the Intellectual Property Clause of the United States Constitution, which authorizes the United States Congress "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

This instrumentalist philosophy shapes the structure of many national intellectual property systems. The grant of IPRs in nations following an instrumentalist approach is intended to provide adequate incentives for creators, inventors and authors to invest the time, resources and intellectual capital needed to create intellectual property products. In the absence of a grant of exclusive rights over those products, so-called "free riders" who have not made such investments could exploit inexpensive distribution and reproduction technologies and sell others' intellectual property products at a much lower cost.

However, the ultimate goal of legal protection is not remunerative reward for creators but the enhancement of social welfare through access to the ideas and information contained in their products. Instrumentalist intellectual property systems often tailor the scope of legal protection to achieve this goal, for example by placing certain limits on the scope of protection or recognizing situations in which consumers or second-generation creators may access and use intellectual property products for socially valuable purposes.

1.2. Policy objectives favouring IPRs in new plant varieties

The policy goals of granting IPRs to plant varieties are grounded principally on an instrumentalist approach to IPRs. This is true both for patents and plant breeders' rights.

Under this instrumentalist approach, new plant varieties are afforded legal protection to encourage commercial plant breeders to invest the resources, labour and time needed to improve existing plant varieties by ensuring that breeders receive adequate remuneration when they market

the propagating material of those improved varieties. In the absence of a grant of exclusive rights to breeders, the dangers of free riding by third parties would be considerable. This is because the genetic material within plants that specifies their distinctive and commercially valuable features is naturally self-replicating, for example by reproduction of seeds or other propagating material. Self-replication makes innovations incorporating biological material particularly susceptible to exploitation by parties other than the innovator.

IPRs in plant varieties thus provide some assurance to breeders that they will be able to recoup the risks and costs of a value-added innovation that is based upon an underlying biological resource. (Lesser 1997; OECD 1996)

Ultimately, however, the grant of exclusive rights to plant breeders is designed to benefit the society granting the rights. It provides an incentive for private research and development into new breeding techniques, thereby reducing the need for government funding to subsidize these activities. It encourages the development of new and beneficial plant varieties for use by farmers and consumers. And it furthers the society's development of agriculture, horticulture and forestry.

An international system of IPR protection for plant varieties expands these benefits by facilitating access to new varieties created in other states. Once breeders are assured that their rights will be protected in other states, breeders will be more willing to make their new varieties available in those states (assuming they have access to a distribution and marketing infrastructure). This benefits farmers, consumers and researchers in many more jurisdictions. (Lesser, 1997, pp. 8 and 10)

1.3. The evolution and structure of the international intellectual property system

The different policy objectives underlying the protection of IPRs have shaped the structure and evolution of the international intellectual property system. Most early domestic intellectual property laws provided no legal protection to intellectual property products created in other nations, thereby permitting those products to be exploited by free riders operating outside the state in which the products were created. The

unfairness of this result prompted governments in the late nineteenth century to consider an international approach to protect IPRs.

1.3.1. Limited treaty obligations

The drafters of the first multilateral intellectual property treaties quickly realized, however, that there was insufficient political support for reconciling many of the differences that existed among national IPR laws. For this reason, the drafters abandoned the idea of harmonizing diverse national laws to create a single, international IPR applicable in all signatory states. They fashioned instead a system that creates a limited set of treaty-based obligations that each member state of that system is then required to implement in its national IPR laws.

Implementation of treaty-based obligations in national IPR laws can occur in one of two ways. In some nations (often referred to as "automatic incorporation" states), treaties become binding as a part of domestic law as soon as formal ratification procedures have been adopted. In these nations, treaties are considered to be "self-executing" or capable of being given "direct effect" in domestic law such that courts and administrative agencies can construe the treaty directly and enforce the rights it grants to the owners of intellectual property products. In other nations, however (often referred to as "legislative incorporation" states), treaties are considered to be "non-self-executing" and can only become binding in domestic law once the parliament or legislature has adopted legislation to implement the treaty. In these nations, owners of intellectual property products rely on this domestic legislation rather than on the treaties themselves when they seek to enforce rights granted to them under the treaties.

1.3.2. The territoriality of IPRs

Because of the limited scope of international IPR agreements, there are to this day (with the limited exception of the European Union) no *international* IPRs available to inventors and creators who seek to market their products across borders; rather, IPRs are territorial in nature and are acquired and enforced on a country-by-country basis under territorially-circumscribed *national* IPR laws.

Thus, for example, the inventor of a genetically enhanced variety of corn who seeks patent protection for that variety must apply for protection in each country in which he or she hopes to sell the corn. The inventor

must comply with all of the requirements that each country imposes for granting patent rights to the new variety. Similarly, once protection is granted, issues such as the scope of the exclusive rights the inventor enjoys in the patented plant variety, the term of patent protection and the limitations imposed on the inventor's rights are all determined by the different national laws. Recent international agreements have achieved some modest forms of procedural harmonization, but they have not altered the fundamental premise that national laws rather than international treaties are the immediate source of nearly all private rights in intellectual property products.

Two basic principles flow from this territorial approach to protecting IPRs. First, where national laws differ as to the scope or content of the protection they provide to intellectual property products, the rights enjoyed by the owners of those products will vary in different national jurisdictions. Second, territoriality implies that each nation has the right to decide on the form of IPR protection to be granted within its own borders, provided that it complies with the obligations contained in international IPR agreements to which it is a party.

Although territoriality thus gives governments some autonomy to set national IPR policies within their own borders, states often view the policies other governments choose as a subject of concern. Indeed, the global reach of markets for intellectual property products makes this concern a necessity. To take just one example, most patent laws grant inventors owning patents within a state the right to prevent the importation into that state of products created in other nations that contain the patented invention. Thus, where distribution markets transcend national borders, an industry may find itself precluded from distributing products in other jurisdictions as a result of patent rights, as occurred when Indian cotton producers were precluded from importing certain forms of transgenic cotton into the United States. (Correa, 2000, p. 176).

1.3.3. Core obligations imposed by international intellectual property agreements

The territorial approach to IPR protection appears at first to present myriad difficulties for creators and owners of intellectual property products. In fact, however, the content of each nation's IPR laws are often quite similar since they have been shaped by international IPR

agreements ratified by many states. In addition, the obligations these agreements impose have expanded over time, thus narrowing (although by no means eliminating) the differences among national intellectual property systems. The following sections briefly explain the core obligations contained in most international IPR agreements. More detailed information concerning the rights and obligations contained in specific IPR agreements relating to plant varieties is provided in Part II below.

1.3.3.1. *National treatment*

One of the cornerstones of international IPR agreements is the national treatment principle. National treatment bars discrimination against foreign IPR owners by requiring that each state provide the same IPRs to private parties from other member states as are provided to the state's own nationals. National treatment levels the playing field among treaty parties and prevents a state from giving its own creators and inventors unfair advantages over foreign creators and inventors. In the absence of national treatment, for example, domestic firms could freely exploit intellectual property products created in other member states while simultaneously enjoying legal protection within their own domestic markets.

1.3.3.2. *Reciprocity*

The provisions of several intellectual property treaties contain a limited exception to national treatment known as reciprocity. Where a treaty permits reciprocity, State A may condition the grant of legal protection to intellectual property products from State B upon State B's granting of legal protection to intellectual property products from State A. Reciprocity is often applied to new IPRs as means of encouraging other nations to recognize the new rights and extend their protection to foreign nationals. Once a large number of states have recognized the new IPR, they may revise the treaty to eliminate the reciprocity option and impose a national treatment obligation.

1.3.3.3. *Most favoured nation treatment*

The most favoured nation ("MFN") principle is a common feature of international trade agreements but has only recently been applied to IPRs. The principle extends the national treatment rule by compelling a

government that provides a privilege or benefit to *one* state within a treaty system automatically to grant that same privilege or benefit to *all* states within the same system. The MFN principle thus prevents a subset of states within a larger treaty system from entering into bilateral or other special agreements among themselves, unless they grant the rights contained in those agreements to all other parties within the larger treaty system.

1.3.3.4. *Subject matter and eligibility requirements*

Intellectual property agreements specify the subject matter characteristics of the products that are eligible for legal protection. In the context of patents, for example, a treaty may specify the types of inventions (such as products and processes) to which states parties must grant legal rights. These subject matter requirements are generally drafted using language that instructs member states concerning the basic characteristics that a product must possess for it to merit protection under domestic IPR laws, while preserving sufficient flexibility for states to tailor the details of protection to the particularities of their national legal systems.

1.3.3.5. *Exclusive rights*

Where an intellectual property product satisfies a treaty's subject matter eligibility requirements, states parties are required to grant an enumerated set of exclusive rights with respect to that product. These exclusive rights grant to the product's owner the power to exclude all third parties from engaging in the activity that the right covers (such as reproducing or modifying the product or distributing it to others). It is the exclusivity of the rights granted that allows IPR owners to recoup the investment of time, money and resources required to create intellectual property products. The particular exclusive rights mandated by IPR agreements differ depending on the specific type of IPR product at issue. They are drafted with greater or lesser degrees of specificity depending on the degree of consensus among member states' national IPR laws, thus affording varying levels of discretion to governments to implement the rights in their domestic legal systems.

1.3.3.6. *Terms of protection and the public domain*

Intellectual property agreements also specify for their states parties the minimum term of years during which intellectual property products must

receive legal protection. Once that term has expired, the treaties do not require states to grant legal protection to the products. Thus, unless the state adopts a longer term of protection, after the expiration of the initial term of protection the product may be freely used by anyone for any purpose, including as a source for creating new products or simply for consumption. A corollary of this rule is that national IPR laws do not permit putative inventors and creators to claim IPRs in materials as they are found in nature or where they are already part of the public domain.

1.3.3.7. *Exceptions and limitations to exclusive rights*

International IPR agreements constrain the ability of national governments seeking to restrict the exercise of IPRs to achieve competing social or policy objectives, such as access to information, research, education and cultural development. Restrictions designed to achieve these objectives are generally known as "exceptions and limitations" to exclusive IPRs. These exceptions and limitations generally appear in two forms. The first form permits third parties to engage in specified uses of intellectual property products without the permission of the rights holder and without the payment of remuneration. The second form is known as a "compulsory licence." Compulsory licences allow third parties to use intellectual property products without the owner's permission, but only upon the payment of adequate compensation. To prevent both forms of exceptions and limitations from eviscerating IPRs altogether, intellectual property agreements impose specific constraints the ability of member states to adopt them.

1.3.3.8. *Enforcement provisions*

The grant of IPRs in national laws would be meaningless without adequate and effective mechanisms to enforce those rights. For this reason, recent intellectual property agreements specify the types of enforcement provisions that member states must adopt in their national laws. These provisions include the imposition of civil and criminal penalties against any person who engages in acts of exploitation reserved to the owner of an intellectual property product without the owner's authorization. The penalties include civil judicial proceedings for monetary damages or an injunction to prevent the continued unauthorized use of the product and criminal proceedings commenced by the government itself.

1.3.4. The "minimum standards" framework of multilateral IPR agreements

Taken together, these core provisions of international IPR agreements impose significant legal obligations on member states. The agreements do not, however, purport to definitively address all of the issues raised by the grant of legal protection to intellectual property products. For this reason, the treaties are often referred to as "minimum standards" agreements in that they create only a basic floor of legal protection to which all member states must adhere.

There are three important consequences of this minimum standards framework. First, it allows member states the discretion to interpret and apply those provisions of the treaties that are ambiguous or that reasonably permit more than one construction. Second, a minimum standards approach permits, but does not require, states to grant additional IPR protections within their national laws. And third and perhaps most importantly, the framework leaves member states free to enact laws that serve other political, economic or social objectives, even where those objectives are in tension with IPRs, provided that those laws are not inconsistent with the terms of IPR agreements.

In the last five years, however, an increasing number of developing countries have entered into bilateral or regional trade and investment treaties with the United States or with the European Community. These treaties often contain higher standards of intellectual property protection than those specified in multilateral intellectual property agreements. (Drahos, 2001; GRAIN, 2001) They thus restrict the minimum standards approach contained in the multilateral agreements, for example, by requiring states to enact specific intellectual property protection rules in their national laws or by requiring developing countries to follow the standards contained in multilateral agreements to which they are not parties. (For a more detailed discussion, see para. 2.3.1.6 below.)

The minimum standards framework (as limited by bilateral or regional treaties requiring higher standards of protection) provides a methodology for analysis but not a solution for every potential clash between IPRs and other governmental policies. This is particularly true for plant varieties and plant breeders' rights, an area of intellectual property protection regulated by several international IPR agreements and subject to diverse standards of legal protection under different domestic laws. To

understand how national governments can reconcile competing and sometimes conflicting domestic laws and objectives consistently with the obligations imposed by different international IPR agreements, it is first necessary to examine other international agreements and international institutions relating to plant genetic resources that have promulgated policies in tension with IPRs.

1.3.5. Identifying the relevant international agreements and institutions relating to intellectual property rights in plant varieties.

Before turning to a more detailed discussion of policy objectives, it is important first to identify the principal international institutions and international agreements that generate legal rules and standards relating to IPRs in plant varieties and plant genetic resources, as well as the institutions and agreements that generate rules and standards in tension with IPRs. Although a comprehensive discussion of these institutions and agreements is beyond the scope of this study, a basic familiarity with their most important elements is necessary to understand the legal regime of intellectual property rights in plant genetic resources for food and agriculture. (For a more detailed analysis, see Helfer, 2004, pp. 34–42)

1.3.5.1. *World Intellectual Property Organization ("WIPO")*

The World Intellectual Property Organization ("WIPO") is a specialized agency of the United Nations charged with "promot[ing] the protection of intellectual property throughout the world." (WIPO Convention, art. 3(i)). The WIPO Secretariat undertakes wide variety of activities relating to IPRs, including hosting diplomatic conferences of government representatives seeking to negotiate new international treaties. WIPO's staff also provide technical assistance and training to member states and their national intellectual property offices, especially in developing countries. More recently, WIPO has created standing, expert and intergovernmental committees that conduct studies on particular intellectual property topics and generate nonbinding guidelines and recommendations for consideration by WIPO members.

WIPO's recent activities in the area of plant genetic resources have been considerable. Issues relating to the intersection of IPRs and PGRs have been raised during the negotiation of two multilateral patent agreements (the Patent Law Treaty and the Substantive Patent Law Treaty) and have

been a principal subject of discussion and study in the recently created Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("IGC").

Developing states first sought to raise issues relating to the intersection of IPRs and PGRs during the WIPO-sponsored negotiation of the Patent Law Treaty in 1999. They proposed the addition of an article in the treaty requiring applicants for inventions derived from genetic resources to demonstrate that they had received permission to access those resources from the country of origin. Industrialized countries opposed the proposal, arguing that it addressed substantive law issues that were inappropriate for inclusion in a treaty largely devoted to procedural issues. As a compromise, the WIPO Secretariat proposed the creation of a new intergovernmental committee (the IGC) to study the intellectual property aspects of genetic resources and traditional knowledge. (Helfer, 2004, pp. 69 and 70)

During the IGC's first five sessions between April 2001 and July 2003, WIPO members have supported a wide-ranging work programme for the Committee, including: (1) creating a searchable database of clauses in contracts that regulate access to genetic resources or require benefit sharing; (2) studying technical issues raised by the disclosure of biodiversity-related information in patent applications; (3) creating databases of traditional knowledge; (4) identifying ways to document genetic resources and traditional knowledge in the public domain; and (5) studying the appropriate legal rules to protect traditional knowledge. Most recently, the WIPO General Assembly extended the IGC's mandate and authorized it to accelerate its work, which may include the development of new international agreements. (Helfer, 2004, pp. 70 and 71)

1.3.5.2. *World Trade Organization ("WTO")*

The WTO is a global intergovernmental organization dealing with the rules of trade between nations. It was established in 1994 at the conclusion of the Uruguay Round of trade negotiations held under the auspices of the General Agreement on Tariffs and Trade ("GATT"). As of July 2004, 147 states and customs territories ("WTO Members" or "Members") had joined the organization. The WTO's substantive obligations are contained in a series of treaties relating to international trade, including agreements on trade in goods, services, agriculture, sanitary and phytosanitary measures, trade-related investment measures,

technical barriers to trade, textiles and clothing and intellectual property rights. These treaties are linked together as annexes to the Agreement Establishing the WTO. Disputes between WTO Members relating to any of these treaties are to be resolved by the WTO Dispute Settlement Body, which is composed of *ad hoc* dispute settlement panels and a standing Appellate Body of trade experts. A WTO Member whose national laws or practices are challenged by another WTO Member and found to be incompatible with its WTO treaty obligations by the Dispute Settlement Body must modify those laws or practices or face the prospect of trade sanctions.

A more detailed discussion of the dispute settlement process in the context of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPs" or "TRIPs Agreement"), is provided in paragraph 2.3.1.3.3 below. TRIPs is the WTO agreement that addresses IPRs. It is discussed in detail in section 2.3 below.

1.3.5.3. *Convention on Biological Diversity ("CBD")*

The CBD was opened for signature in 1992 and entered into force in 1993. As of July 2004, 188 states had ratified this agreement.

The CBD's main objectives are the conservation of biological diversity, the sustainable use of its components, the fair and equitable sharing of benefits arising out of the utilization of genetic resources and the preservation of indigenous knowledge. (art. 1) The CBD also recognizes that nation states have the sovereign right to exploit their own resources and the authority to determine the conditions of access to them. (arts. 3 and 15)

One of the mechanisms by which the CBD achieves its objectives is *in situ* conservation of plant genetic resources. Conservation *in situ* involves the preservation of ecosystems and natural habitats and the maintenance of viable populations of species in those settings. Such conservation occurs, for example, where farmers and indigenous communities safeguard traditional plant varieties in the locations where they grow naturally or are cultivated.

Although the CBD does not expressly refer to any international IPR agreements, it contains numerous provisions relating to IPRs, principally in article 16. In particular, article 16(5) recognizes that IPRs "may have

an influence on the implementation" of the CBD. The article obliges member states to cooperate in order to ensure that IPRs are "supportive of and do not run counter to" the treaty's objectives. Other provisions make clear that the CBD is to be interpreted so as to preserve the rights of IPR owners recognized in international law. For example, articles 16(2)–(4) state that the transfer of technology and measures taken to gain access to such technology shall be consistent with the adequate and effective protection of IPRs recognized in international law. Thus, for example, where a government encourages foreign direct investment in industrial technologies (such as a biotechnological process used to insert new genetic sequences into existing plant varieties), it must respect any patent rights that the owner of that technology has acquired to protect it.

Over time, the biodiversity regime's approach to intellectual property protection has evolved beyond the text of the CBD. The Conference of the Parties (COP) – the convocation of CBD members that determines how the Convention should be applied and implemented – has given detailed attention to harmonizing IPRs with the CBD's objectives. In particular, developing countries active in the COP, together with the support of nongovernmental organizations, have expressed concern about the adverse effects of IPRs and have sought to harness intellectual property rules to promote compliance with the Convention.

In response to this concern, official COP statements have stressed the need to "promot[e] increased mutual supportiveness and integration of biological diversity concerns and the protection of intellectual property rights." (CBD Decision IV/15, para. 9) Members of the COP have worked toward this objective by gathering information, commissioning case studies, holding workshops and drafting guidelines and recommendations. For example, in April 2002, the COP adopted the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization." (CBD Decision VI/24, App. II, Annex, Part C) The Guidelines' most important recommendation encourages applicants for IPRs such as patents or plant breeders rights to disclose the country of origin of the genetic resources or the traditional knowledge upon which those IPRs are based. The Guidelines advocate these disclosures to monitor whether applicants for IPRs have obtained the prior informed consent of the country of origin and complied with the conditions of access (if any) that that country has adopted. (Id.)

Although the COP members adopted the Bonn Guidelines by consensus, the Guidelines' reliance upon intellectual property laws to promote compliance with the obligations of the CBD remains controversial. For example, a 2003 Communication from the European Commission to the European Parliament on the EC's implementation of the Bonn Guidelines considers whether to adopt "a self-standing disclosure requirement" for patent and plant variety protection applicants. (EC Implementation of Bonn Guidelines, COM (2003) 821) If adopted, such a disclosure requirement would not, however, be incorporated into national or European intellectual property laws. To the contrary, the failure to comply with the new disclosure requirement would, according to the EC Communication, "only have consequences outside the field of patent law." (Id., p. 5) However, the EC Communication also states that the EC and its member states "should be ready to discuss, in the relevant international fora, the possibility of introducing *under intellectual property law* the same disclosure requirement . . . as a formal condition for patentability and not only as a self-standing obligation." (Id., p. 19, emphasis added)

1.3.5.4. *The Consultative Group on International Agricultural Research ("CGIAR")*

CGIAR is an informal association of public and private donors founded in 1971 that supports an international network of agricultural research centres, each with its own governing body. CGIAR's mission is to engage in research, in partnership with other public and private entities, to promote sustainable agriculture in developing nations. With respect to plant genetic resources, CGIAR's principal method for achieving this objective is *ex situ* conservation. Networks of gene banks within CGIAR store and conserve seeds and propagating materials outside of their natural habitat for future use by farmers, researchers and breeders. The CGIAR network holds the world's largest *ex situ* collection of plant genetic resources for food and agriculture.

1.3.5.5. *International Plant Genetic Resources Institute ("IPGRI")*

IPGRI is the world's largest international institute dedicated to the conservation and use of plant genetic resources. Founded in 1974, IPGRI focuses on conservation, management and preservation of the diversity of plant genetic resources, through domestic, regional and international programmes and research initiatives.

1.3.5.6. *The International Undertaking on Plant Genetic Resources (the "Undertaking")*

FAO has helped to generate several nonbinding international instruments relating to plant genetic resources. The Undertaking, the first of these instruments, was adopted in 1983. As of 2000, 113 states were signatories to the Undertaking, thus pledging themselves to implement the recommendations it contains. For many years, the Undertaking served as the central legal instrument in FAO's global system for plant genetic resources, a system that includes a fund for the equitable sharing of benefits and a mechanism to give early warning about genetic resources under threat.

The Undertaking's principal objectives are to ensure that the need for conservation is globally recognized and that sufficient funds for this purpose are made available; to assist farmers and farming communities in the protection and conservation of PGRs and of the natural biosphere; and to allow farmers, their communities and countries to participate fully in the benefits derived from improved uses of PGRs, including through plant breeding. (WT/CTE/125, para. 11)

In its initial formulation, the Undertaking challenged a private property rights approach to plant genetic resources by declaring that all such resources, whether as cultivated by farmers in the field or modified through breeder innovations, were part of the "common heritage of mankind and consequently should be available without restriction." (art. 1). An interpretation issued adopted by FAO in 1989, however, clarified that plant breeders' rights were not incompatible with the Undertaking. (Resolution No. 4/89 adopted by FAO Conference 25th Session, Rome, 11–20 November 1989) It also recognized the interrelationship between the rights of traditional farmers (whose practice of saving seeds provided the raw genetic materials for innovation) and the rights of plant breeders (who use technology to achieve that innovation).

1.3.5.7. *The International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGR")*

On 3 November 2001, an intergovernmental conference sponsored by FAO adopted the text of a legally binding international agreement on plant genetic resources. The ITPGR entered into force on 29 June 2004. As of July of that year, the treaty had been ratified by 55 states and

signed by an additional 50 countries. The ITPGR not only codifies and updates the nonbinding principles set out in the Undertaking and its subsequent revisions, but also contains provisions relevant to IPRs in plant genetic resources and plant varieties. Because of its importance to the subject of this study, an extended discussion of the ITPGR appears in section 4.3 below.

1.3.6. Specific policy objectives in tension with IPRs

Having identified the principal institutions and agreements relating to plant genetic resources, the next sections address specific critiques of IPRs as applied to plants and plant varieties and the policy arguments that inform those critiques.

1.3.6.1. *Preserving genetic diversity*

Granting IPRs to plant breeders has uncertain consequences for preserving plant genetic diversity. Given the incentives that IPRs create for private parties to invest in research and breeding techniques relating to new plant varieties, it might be thought that IPRs would lead to an increase in plant genetic diversity over time.

A number of commentators have argued, however, that diversity is eroded rather than enhanced by granting IPRs to plant breeders. According to this view, *in situ* conservation by indigenous farmers diminished as they began to rely on commercial plant breeders for seeds and other propagating material. Rather than using informal breeding techniques to experiment with the creation of new varieties suitable for local growing conditions, indigenous farmers came to depend upon third party plant breeders to provide them with seeds possessing uniform genetic characteristics. The plant varieties that have come to dominate agriculture as a result of this dependence may possess many beneficial characteristics, but they do not enjoy the adaptive abilities of less well known and informally bred varieties. (Fowler, 1994, p. 118)

To evaluate these competing assertions about the effects of IPRs on plant genetic diversity, empirical testing would be useful. Unfortunately, empirical studies of the causal impact of IPRs on plant genetic diversity are difficult to devise because of the uncertainty of screening out other relevant causal variables. Empirical studies that do exist often focus on industrialized countries rather than developing states and tend to rely on

anecdotal evidence. As a result, the broader applicability of their conclusions is uncertain and often controversial. (See IP/C/W/175 reporting results of national plant variety protection studies in Argentina, Kenya and the United Kingdom)

1.3.6.2. *Farmers' rights*

A second challenge to IPRs concerns the relationship between farmers' rights and IPRs in plant varieties. The concept of farmers' rights was developed to reflect the contributions that traditional farmers, particularly in the developing world, have made to the preservation and improvement of plant genetic resources. FAO 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 centers of origin/diversity." (Resolution No. 5/89 adopted by FAO Conference, 25th Session, Rome, 11–20 November 1989) Such rights are also recognized in article 9 of the ITPGR.

Farmers' rights are in tension with IPRs for plant breeders because many farmers and farming communities do not claim exclusive rights in the cultivated landraces (also known as traditional cultivars, see Dutfield, 2000, p. 50) and plant varieties they have cultivated over time. Moreover, the subject matter requirements of existing IPR laws, which as explained below are designed to protect innovations in new and clearly distinguishable plant *varieties*, often cannot accommodate contributions of individual farmers using more informal methods to select for better crops or sought-after plant *characteristics*.

Advocates of farmers' rights have developed different approaches to address this situation and to reward farmers for their contributions to plant genetic diversity. The first approach involves situating the traditional practices of farmers as exceptions to the exclusive rights of plant breeders under existing IPR laws. In other words, breeders are precluded from demanding payment from farmers who engage in certain farming practices, such as saving seeds and planting seeds saved from prior purchases, or informally exchanging seeds. A second approach seeks to modify existing IPR laws so as to permit farmers themselves to claim exclusive rights in the plant varieties they cultivate informally. A third approach involves recognizing farmers' rights not through IPRs but through benefit sharing mechanisms, such as financial payments and

technology transfers, that compensate farmers for their contributions to plant genetic diversity. This last approach – which is recognized in article 9 of the ITPGR – questions whether farmers in fact have "rights" as that term is understood within an intellectual property paradigm, while acknowledging the need to reward their contributions to plant genetic diversity. (Blakeney, 2002, pp. 9–11)

1.3.6.3. *Traditional knowledge*

An issue closely related to farmers' rights is the recognition and protection of the plant-related knowledge, innovations and practices of indigenous and local communities. (Cottier & Panizzon, 2004) Advocates assert that those claiming IPRs in plant genetic resources and plant varieties often utilize such knowledge without adequately acknowledging the contributions of the communities who possess it. Mechanisms to redress this problem are similar to those discussed above relating to farmers' rights, a linkage reflected in article 9 of the ITPGR. They include modifying existing IPR laws to recognize traditional knowledge as a form of intellectual property and protecting traditional knowledge through *sui generis* national laws that recognize the communal ownership of much of traditional knowledge. In the fall of 2000, the World Intellectual Property Organization (WIPO) established a new Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to study these issues. (See para. 1.3.5.1 above)

1.3.6.4. *Regulating access to plant genetic resources*

Plant breeders and others seeking to develop plant-related innovations need access to existing stocks of plant germplasm for breeding, research and development. Access issues arise for both *in situ* and *ex situ* collections of seeds and plant propagating material.

With respect to *in situ* collections, a number of states have enacted national access laws and regulations to control third party access. These access controls are consistent with the CBD, which grants states the sovereign right to control their plant genetic resources. They also further the CBD's benefit sharing objectives by conditioning access upon the current or future payment of compensation or the transfer of technology to the state providing access. (OECD, 1996, p. 27) The specific conditions of access are often specified in Material Transfer Agreements

("MTAs") entered into between the entity (whether governmental or private) that owns or controls the germplasm and the entity (usually private) that seeks access to it. (Barton & Siebeck, 1994)

Similar access issues arise with regard to *ex situ* collections of plant germplasm, including the seed banks maintained under the auspices of CGIAR (see para. 1.3.5.4 above). Although pursuant to a 1994 agreement between CGIAR and FAO the autonomous agricultural research centres under CGIAR's auspices each create their own access regulations, certain designated germplasm is to be held by the centres "in trust for the benefit of the international community." (art. 3(a)) With respect to IPRs, the 1994 agreement provides that a centre "shall not claim legal ownership over the designed germplasm, nor shall it seek any [IPRs] over that germplasm or related information." (art. 3(b)). The centres also commit to apply the same restrictions on IPRs in MTAs with third parties to whom the centre transfers designated germplasm. (art. 10)

1.3.6.5. *"Biopiracy" and property rights in unimproved plant materials*

Issues of access to plant genetic resources are linked to larger controversies concerning the propriety of granting IPRs in the raw materials accessed.

Under settled principles of intellectual property law, unimproved plant germplasm already in the public domain cannot be removed and privatized. Nevertheless, there are several reported cases and one empirical study which indicate that plant breeders and commercial entities have on occasion been granted IPRs in wild plant varieties or in germplasm found in CGIAR seed collections. It is unclear whether such rights were granted because of inadvertence, insufficient or inaccurate information provided by the IPR applicant or particularities in national laws that limit the sources to which granting authorities may refer in determining what materials are in the public domain. (Correa, 2000, pp. 188–189; Plant Breeders Wrongs, 1999) Where such rights have been granted, however, states and interested NGOs have often succeeded in petitioning the authorities in other nations to remove legal protections they had previously granted. (Dinwoodie, Perlmutter & Hennessey, 2001, p. 1418; Blakeney, 2002, p. 12)

Attempts to claim IPRs in unimproved plant genetic resources have often been labeled as a form of "biopiracy." (Correa, 2000, p. 172) Biopiracy is not a legal term of art, however and has been loosely used to refer to any act by which a commercial entity seeks to obtain IPRs over biological resources, including plant varieties, that are seen as "belonging" to developing states or indigenous communities. (CEAS Consultants, 2000, p. 70) Thus, even where an IPR claim relates to improvements to raw plant materials, certain governments and NGOs have labeled the entity seeking legal protection as a biopirate if it has not provided a fair return to those who granted access to the raw materials.

1.3.6.6. *Plant breeders' research interests.*

Even as between groups of plant breeders, the scope of IPRs in plant varieties can be controversial. Tensions arise between first generation breeders who have secured legal protection for new varieties and second generation breeders who seek to utilize those new varieties to develop still more varieties. As with farmers' rights, it is possible to use the exceptions and limitations provisions of national IPR laws to permit second generation innovators to engage in such activities without the authorization of first generation breeders.

2. PART II – INTERNATIONAL IPR AGREEMENTS REGULATING PLANT VARIETIES AND PLANT BREEDERS' RIGHTS

2.1. Introduction and overview

This section identifies and discusses the provisions of three different international IPR agreements that protect plant varieties and plant breeders' rights.

The two major treaty systems that regulate these issues are the agreements established under the auspices of the *Union internationale pour la protection des obtentions végétales* ("UPOV"), and the TRIPs Agreement included within the family of treaties administered by the World Trade Organization ("WTO"). (see para. 1.3.5.2 above) These two treaty systems each contain a comprehensive set of rules for their members regarding IPRs over plant varieties.

In short, the UPOV treaties adopt a *sui generis* system of protection (that is, a system that is unique, or of its own kind) especially tailored to the needs of plant breeders. The TRIPs Agreement requires WTO Members to protect new plant varieties using patent rights, a *sui generis* system or some combination thereof. Because TRIPs provides states with this flexibility and because the treaty has an uncertain relationship to the previously adopted UPOV conventions, national governments face a wide array of options in choosing the intellectual property regime applicable to plant varieties. This section of the study outlines the requirements imposed by these two treaty systems, and Part III of the study then identifies and analyses these options.

2.2. The UPOV Acts

The first UPOV Act was drafted in 1961, principally by industrialized governments seeking to provide protections for plant breeders in their own and overseas markets. The UPOV was later revised in Acts adopted in 1972, 1978 and 1991.

As of July 2004, 55 states were parties to UPOV – 29 to the 1978 Act, 24 to the 1991 Act and 2 to the 1972 Act. (States Parties to the UPOV, Status on 30 June 2004). As a result, this study will focus on the two most recent UPOV Acts. Many of the accessions to these Acts are quite recent, with a number of developing states and countries in transition to a market economy acceding in the 1990s. The 1991 Act entered into force on 24 April 1998 and on that same date the 1978 Act was closed to future accessions except by a few states already in the process of adhering to it.

As explained in section 1.3.1 above, countries generally give domestic effect to the UPOV Act to which they are a party in one of two ways. In "automatic incorporation" states, courts and administrative agencies directly apply and enforce the Act, although implementing legislation is often needed to authorize administrative agencies to process applications to protect new plant varieties. In "legislative incorporation" states, by contrast, the UPOV Act does not become enforceable in domestic law until the state enacts a national plant variety protection law that conforms to the Act's requirements.

2.2.1. The 1978 UPOV Act

The 1978 UPOV Act adopts most of the international IPR obligations set out in Part I above, including a definition of the applicable subject matter and protected material, eligibility requirements, exclusive rights, national treatment, reciprocity, terms of protection and exceptions and limitations to exclusive rights. It does not, however, contain any provisions on MFN treatment or enforcement.

2.2.1.1. *Subject matter requirements*

Limited number of protected genera or species. Not all plant varieties must be protected under the 1978 Act. Rather, article 4 provides that member states are to progressively extend protection to an increasing number of genera or species, beginning with five on the date the treaty enters into force for that state and ending with twenty-four within eight years. In addition, member states are free to limit the Act's application within a particular genus or species to varieties with a particular manner of reproduction or multiplication, or a certain end-use.

Preclusion of dual protection with breeder's right and patent. The 1978 Act permits its signatories to protect plant varieties either with a distinct breeder's right or with a patent. However, article 2(1) precludes member states from granting both forms of protection "for one and the same botanical genus or species."

Protection of discovered varieties required. Although the 1978 Act focuses on plant varieties created through classical breeding methods, it is generally accepted that the treaty requires member states to protect varieties which have been discovered. This has been inferred from article 6.1(a) which indicates that a protected variety may result from a natural source of initial variation. (Crucible Group, 2001, p. 137)

2.2.2. Eligibility requirements

Assuming that a plant variety falls within a protected genera or species, it is eligible for protection under the 1978 Act only if it is: (1) new, (2) distinct from existing or commonly known varieties, (3) homogenous or uniform and (4) stable. (art. 6) When a variety fulfils these four criteria, it is listed in a national register or catalogue which publicly discloses that the variety is protected. (FIS/ASSINSEL, 2001a).

Novelty. To avoid protection for plant varieties that have already been exploited or are a matter of common knowledge, a new variety in which a breeder seeks protection must not have been sold on the market for more than a specified period of years prior to the date of application for protection. The 1978 Act specifies the maximum number of years during which such pre-application sales have occurred, with different periods of time set for different types of plants as well as for sales within the territory of the applicant state versus the territory of other states. (art. 6(1)(b)) (Leskien & Flitner, 1997, p. 50)

Distinctness. The 1978 Act states that a protectable plant variety must be "clearly distinguishable in one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for." (art. 6(1)(a)). Although the treaty itself does not further define distinctness, the Guidelines for the Conduct of Tests for Distinctness, Homogeneity and Stability (UPOV Guidelines) use both qualitative and quantitative plant characteristics, including such visible attributes as leaf shape, stem length and color, to determine if the difference between varieties is "clear and consistent." As explained below in the analysis of the UPOV 1991 Act, the concept of distinctness is critical to determining the scope of a breeder's right in plants that are closely related but not identical to a protected variety.

Homogeneity. Under the 1978 UPOV Act, a variety has to be "sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation." (art. 6(1)(c)). The UPOV Guidelines further clarify that to be considered homogeneous, the variation shown by a variety must be "as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability." The homogeneity requirement has been criticized by commentators as discouraging variability in plant varieties that are often useful for sound agricultural practices and as denying protection to breeders of cultivated landraces that exhibit diversity traits. (Leskien & Flitner, 1997, pp. 51 and 52) It is thus one of the sources for the criticisms identified in paragraph 1.3.6.1 above that plant breeders' rights are reducing plant genetic diversity by rewarding breeders of uniform plant varieties.

Stability. The stability requirement is a temporal one, requiring the breeder to show that the essential characteristics of its variety are homogeneous or uniform over time, even after repeated reproduction or

propagation. (art. 6(1)(d)) In practice, what has been shown to be homogeneous is usually considered to be stable as well. For this reason, the stability requirement has engendered the same sort of critiques as the uniformity requirement in its preclusion of protection for cultivated landraces and other traditional plant varieties. (Leskien & Flitner, 1997, p. 52)

2.2.2.1. *Protected material*

The 1978 Act requires its signatories to protect a variety's reproductive or vegetative propagating material. The Act does not require protection of harvested material, with the exception of ornamental plants that are used for commercial propagating purposes. (art. 5(1))

2.2.2.2. *Breeders' exclusive rights*

Under article 5 of the 1978 Act, any person seeking to engage in the following three acts, with respect to a protected variety's reproductive or vegetative propagating material, must obtain the prior authorization of the breeder: (1) production for purposes of commercial marketing, (2) the offering for sale and (3) marketing. The 1978 Act does not, however, require member states to extend these exclusive rights to harvested material or other marketed products.

2.2.2.3. *National treatment and reciprocity*

Member states must grant the three exclusive rights referred to in the preceding paragraph in the same manner to both national breeders and to breeders who reside in or are nationals of other 1978 Act member states. However, where a state extends legal protection to a specific genus or species, or where it provides more extensive exclusive rights to breeders than the rights required under the treaty, reciprocity is permitted. Thus, a state providing these additional rights may restrict protection to breeders from those member states that apply the Act to the same genus or species, or that provide such additional exclusive rights to their own nationals. (arts. 3 and 5(4))

2.2.2.4. *Term of protection*

The 1978 Act requires a minimum term of protection of fifteen years, with the exception of vines, forest trees, fruit trees and ornamental trees, which are protected for no less than eighteen years.

2.2.2.5. *Exceptions and limitations.*

Two major exceptions and limitations to exclusive rights exist under the 1978 Act: (1) a breeders' exemption and (2) a farmers' privilege. The Act also permits members to impose compulsory licences.

Breeders' exemption. This exemption in article 5(3) precludes member states from granting to breeders of protected varieties the right to authorize or refrain from authorizing other breeders seeking to use the protected variety to create new varieties or to market those new varieties. States are permitted to grant breeders such an authorization right only if the repeated use of the protected variety is necessary for the commercial production of the new variety. According to the International Association of Plant Breeders and the International Seed Federation, this breeders' exemption "is essential for continued progress from plant breeding." (FIS/ASSINSEL, 1999)

Farmers' privilege. The focus of the 1978 Act on commercial exploitation of protected plant varieties has been interpreted to allow the use of seeds and propagating material for noncommercial purposes without the breeder's prior authorization. (Crucible Group, 2001, p. 170) In national plant variety protection laws, this implicit noncommercial exception most frequently benefits farmers who purchase the seeds of protected varieties. The scope of this so-called farmers' privilege varies widely, however. Some nations only permit farmers to plant seeds saved from prior purchases to be used on their own land holdings, while others allow them not only to replant but also to sell limited quantities of seeds for reproductive purposes, a practice often referred to as "brown bagging." (Leskien & Flitner, 1997, p. 61)

Compulsory licences in the public interest. Article 9 of the 1978 Act permits members to restrict breeders' exclusive rights for "reasons of public interest." Where such restrictions are enacted to ensure the widespread distribution of the variety (such as where the breeder fails to supply the demand for the variety in a reasonable quantity and price or unreasonably refuses to license the variety to third parties), the breeder must receive equitable remuneration.

2.2.3. The 1991 UPOV Act

The limited scope of the 1978 Act led a number of member states of the UPOV to adopt a revised Act with enhanced rights for plant breeders. The major revisions of the 1991 Act are discussed below:

2.2.3.1. *Subject matter requirements*

Phased-in protection of all genera or species. Unlike its predecessor, the 1991 Act requires states to protect at least fifteen plant genera or species upon ratifying or acceding to the Act, and to extend protection to all plant varieties within ten years. (art. 3(2)) It also contains a definition of a plant "variety" as a "plant grouping within a single botanical taxon of the lowest known rank" which can be "defined by the expression of the characteristics resulting from a given genotype or combination of genotypes; distinguished from any other plant grouping by the expression of at least one of the said characteristics; and considered as a unit with regard to its suitability for being propagated unchanged." (art. 1(vi)) No definition of "variety" appears in the 1978 Act, which indicates that member states to that earlier treaty have greater discretion in defining the characteristics of plant groupings that qualify for protection.

Dual protection with breeders' right and patent permitted. In response to demands from breeders in industrialized countries, the 1991 Act removed the 1978 Act's ban on dual protection and now permits member states to protect the same plant variety with both a breeders' right and a patent. (Watal, 2000, p. 149)

Protection of discovered varieties. The 1991 Act makes explicit the 1978 Act's implicit requirement that discovered varieties be protected. It does so through article 1(iv)'s definition of a "breeder" as including a "person who bred, or discovered and developed, a variety."

2.2.3.2. *Eligibility requirements*

The four eligibility requirements that must be demonstrated to merit protection for a specific variety – novelty, distinctness, uniformity and stability – are preserved in the 1991 Act, subject to only minor changes in scope and wording. (arts. 7–9) Thus, the 1991 Act has received the same criticism as the 1978 Act for its encouraging of genetic

standardization and its inability to protect more diverse plant varieties, traditional varieties or cultivated landraces.

2.2.3.3. *Breeders' exclusive rights in protected material*

Extensive additions to the 1978 Act were made with respect to the exclusive rights enjoyed by breeders in protected material of plant varieties.

Enumerated exclusive rights in propagating material. The breeder's prior authorization must be obtained for the use of reproductive or vegetative propagating material of the variety for (1) production or reproduction, (2) conditioning for the purpose of propagation, (3) offering for sale, (4) selling or marketing, (5) exporting, (6) importing and (7) stocking for any of these purposes. (art. 14) (Leskien & Flitner, 1997, p. 57)

Extension of rights to harvested material and products. These exclusive rights apply not only to propagating material but also to harvested material, where the harvest has been obtained through an unauthorized use of the propagating material and the breeder has not had a reasonable opportunity to exercise his or her right in relation to that material. In addition, member states are permitted but not required to provide additional rights to breeders, including rights in products made directly from harvested material.

2.2.3.4. *National treatment required*

Whatever the particular exclusive rights member states adopt in their plant variety protection laws, those rights must also be provided to the nationals of other 1991 Act member states. Unlike the 1978 Act, granting rights only on condition of reciprocity is not permitted. (art. 4) For example, if a 1991 Act member chooses to grant more expansive exclusive rights to breeders than the exclusive rights required by the 1991 Act, it must grant those rights to breeders from all other 1991 Act member states. The state cannot choose to grant such expansive rights to only those 1991 Act states that also provide the same level of rights protection to the first state's nationals.

2.2.3.5. *Terms of protection*

The 1991 Act extends the term of protection to 20 years, and requires a 25-year term for tree and vine varieties.

2.2.3.6. *Exceptions and limitations*

A second area of major revision concerns the reduced scope of exceptions and limitations to breeders' exclusive rights, which is found in article 15 of the 1991 Act.

Private, noncommercial exception. The 1991 Act makes explicit what was only implicit in the 1978 Act, namely that private, noncommercial activities with respect to new varieties are outside of the breeder's control. This exception would presumably permit subsistence farmers to use protected seeds and other propagating material for their own consumption.

Research exception. The 1991 Act also recognizes that breeders cannot restrict "acts done for experimental purposes." This exception would permit research and testing of protected varieties for scientific purposes that does not lead to commercial exploitation.

Limited breeders' exemption. Like its predecessor, the 1991 Act recognizes the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted in its application to such new varieties as are not "essentially derived" from protected varieties. (arts. 14(5) and 15) The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control. (FIS/ASSINSEL, 1999). Nevertheless, the overall effect of this provision of the 1991 Act has been to narrow the breeders' exemption and expand the IPRs of first generation breeders.

Limited farmers' privilege. The 1991 Act recognizes an explicit farmers' privilege, but one that is limited in scope. In particular, each member state may enact a provision in its national plant variety protection laws permitting farmers to use for propagating purposes "on their own

holdings" the product of the harvest which they obtained by planting a protected variety "on their own holdings." In addition, this privilege must be exercised "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder." (art. 15(2)) Several points can be inferred from this language.

First, unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes (Watal, 2000, p. 141), a limitation that commentators have criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation. (Leskien & Flitner, 1997, p. 60)

Second, according to the International Association of Plant Breeders, the "reasonable limits" language in article 15(2) requires states to restrict the acreage, quantity of seed and species subject to the farmers' privilege, while the requirement to safeguard breeders' "legitimate interests" requires farmers to pay some form of remuneration to the breeder for their privileged acts. (FIS/ASSINSEL, 2001a) The latter assertion is controversial, however, and has not been enacted in the national laws of all the 1991 Act member states. For example, the EC's Council Regulation on Community Plant Variety Rights, No. 2100/94 of 27 July 1994, requires such payments except in the case of small farmers, whereas the United States' Plant Varieties Protection Act of 1994, 7 U.S.C. Sec. 2543, does not.

Compulsory licences in the public interest. Article 17 of the 1991 Act contains a compulsory licence provision similar to that found in the 1978 Act. It permits members to restrict breeders' exclusive rights only for reasons of public interest and requires payment of equitable remuneration to the breeder whose rights are limited.

2.2.4. Resistance to the 1991 Act

Many developing nations, particularly those in Africa, have resisted ratifying the 1991 Act or adopting it as the standard for their plant variety protection laws. The foreign ministers of the more than 50-member Organization for African Unity (now the African Union) issued a statement at a January 1999 meeting calling for a hold on IPR protection for plant varieties until an Africa-wide system has been developed that grants greater recognition to the cultivation practices of

indigenous communities. However, at a subsequent meeting of the Organisation Africaine de la propriété Intellectuelle (OAPIO), patent officials from sixteen francophone African nations recommended that their countries adopt the 1991 Act. (Machipisa, 1999). As of the date of this study, Tunisia, Kenya and South Africa are the only African UPOV member states. Tunisia ratified the 1991 Act in August 2003, whereas the other two countries are parties to the 1978 Act. Other developing states parties to the 1978 Act are Bolivia, China, Ecuador, Kyrgyzstan, Mexico, Nicaragua, Panama, Paraguay, Trinidad and Tobago and Uruguay. These and other developing countries are, however, under pressure to ratify the 1991 Act as part of bilateral or regional trade and investment agreements. (See para. 2.3.1.6 below)

TABLE 1 - Comparison of UPOV 1978 Act and UPOV 1991 Act

Subject	UPOV 1978 Act	UPOV 1991 Act
Minimum scope of coverage	Increasing number of genera or species required to be protected, from five at time of accession, to 24 eight years later.	Increasing number of genera or species required to be protected, from 15 at time of accession, to all genera and species 10 years later (5 years for member states of earlier UPOV Act).
Eligibility Requirements	Novelty, distinctness, uniformity and stability.	Novelty, distinctness, uniformity and stability.
Minimum exclusive rights in propagating material	Production for purposes of commercial marketing; offering for sale; marketing; repeated use for the commercial production of another variety.	Production or reproduction; conditioning for the purposes of propagation; offering for sale; selling or other marketing; exporting; importing or stocking for any of these purposes.
Minimum exclusive rights in harvested material	No such obligation, except for ornamental plants used for commercial propagating purposes.	Same acts as above if harvested material obtained through unauthorized use of propagating material and if breeder had no reasonable opportunity to exercise his or her right in relation to the propagating material.

Subject	UPOV 1978 Act	UPOV 1991 Act
Prohibition on dual protection with patent	Yes, for same botanical genus or species.	No.
Breeders' exemption	Mandatory. Breeders free to use protected variety to develop a new variety.	Permissive, but breeding and exploitation of new variety "essentially derived" from earlier variety require right holder's authorization.
Farmers' privilege	Implicitly allowed under the definition of minimum exclusive rights.	Allowed at the option of the member state within reasonable limits and subject to safeguarding the legitimate interests of the right holder.
Minimum term of protection	18 years for grapevines and trees; 15 years for all other plants.	25 years for grapevines and trees; 20 years for all other plants.

2.3. The TRIPs Agreement.

Although the UPOV Acts have provided IPR protection for plant varieties for more than forty years, their significance has recently been overshadowed by a different intellectual property treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs" or the "TRIPs Agreement"). Adopted in 1994 as a treaty administered by the WTO, TRIPs is the first and only IPR treaty that seeks to establish universal, minimum standards of protection across the major fields of intellectual property, including patents, copyrights, trademarks, industrial designs, integrated circuits and trade secrets. Although the TRIPs Agreement devotes only minimal attention to plant breeders' rights or plant variety protection and does not even mention the UPOV Acts, its adoption has done more to encourage the legal protection of plant varieties than any other international agreement.

2.3.1. TRIPs as a spur to plant variety protection.

TRIPs' influence on plant variety protection stems from the following sources: (1) its link to other international trade agreements; (2) its widespread adherence by states in both the industrialized and developing world; (3) its novel enforcement, review and dispute settlement provisions; (4) the requirement in TRIPs article 27.3(b) that its signatories must provide protection for plant varieties "either by patents or by an effective *sui generis* system or by any combination thereof"; and (5) a formal review of article 27.3(b) which was scheduled to be held in 1999. The following paragraphs briefly address each of these five issues. Subsequent sections devote more detailed treatment to the protection of plant varieties with patents and to the elements necessary to create an "effective *sui generis* system."

2.3.1.1. *The relationship of TRIPs to the WTO and the international trading system*

Unlike all prior intellectual property treaties, TRIPs is not a free-standing agreement concerned solely with IPRs. Rather, TRIPs is linked to a larger family of trade-related agreements concerning subjects such as trade in goods and services, agriculture, textiles and health-related restrictions on imports. All of these agreements were adopted within the WTO during the Uruguay Round of trade negotiations held between 1988 and 1994. As such, TRIPs was part of a global "package deal."

Industrialized nations secured a commitment from developing nations to provide minimum standards of effective legal protection to intellectual property products, and in exchange developing nations received a commitment from industrialized countries to open their domestic markets to goods and other products manufactured in the developing world. (Helfer, 1998, p. 377)

2.3.1.2. *Widespread adherence to TRIPs*

The result of this global bargain was widespread adherence to all WTO Agreements, including the TRIPs Agreement. As of July 2004, 147 states or customs territories were obligated to comply with TRIPs by virtue of their membership in the WTO. (Compare this to the 55 nations that were parties to the various UPOV Acts as of the same date, see para. 2.2 above.) In addition, many states (particularly those in the developing world) who became bound by TRIPs had not ratified earlier intellectual property treaties and were thus required to make significant changes to their national laws to bring them into compliance with the Agreement. In acknowledgement of this fact, TRIPs contains a phase-in provision pursuant to which most of the treaty's substantive obligations became binding for developed nations in 1996, but did not become binding on developing nations and nations in transition to market economies until 2000. Least developed nations are given the most leeway and are not required to implement the treaty's substantive obligations until 2006.

2.3.1.3. *The enforcement, review and dispute settlement provisions of TRIPs*

In addition to its widespread adherence, the influence of the TRIPs Agreement can be traced to its unique provisions relating to the enforcement of IPRs within national laws, the review of those national laws by the TRIPs Council and the mechanism for settlement of disputes between states leading to rulings backed up by the threat of trade sanctions.

Enforcement provisions. Unlike prior IPR agreements, TRIPs does not only specify the minimum substantive requirements for various forms of intellectual property. In addition, it requires WTO Members to adopt "effective" provisions within their national laws to permit the owners of intellectual property products to enforce their rights against those who infringe them. (art. 41.1) These enforcement provisions include detailed judicial and administrative remedies, border measures and criminal

procedures. (articles 41 to 61) To take just one example applied to plant varieties, a breeder whose new variety is sold commercially without permission must be able to bring a civil judicial action seeking an injunction to stop the conduct of the unauthorized seller and to recover damages from him or her.

Review provisions. Article 68 establishes a Council for TRIPs to "monitor the operation of th[e] Agreement and . . . Members' compliance with their obligations" under the treaty. Since its founding, one of the Council's principal functions has been to formally review the national laws, regulations and judicial decisions of WTO Members in each area of intellectual property covered by TRIPs.

Several goals are served by the TRIPs Council's review functions. First, the reviews create an incentive for governments to bring their national laws and practices into compliance with the Agreement so that they may present positive information to the Council. Second, the reviews identify for both the reviewed state and for other WTO Members areas of the law which may not be in full compliance with the treaty. And finally, TRIPs Council reviews provide a critical opportunity to publicize national laws and practices relating to IPRs which might otherwise be difficult to obtain.

In the area of plant varieties, the TRIPs Council has gathered and organized a considerable amount of useful information concerning national government practices. In December 1998 the Council prepared a detailed list of questions concerning plant variety protection. It asked WTO Members who were already obligated to protect plant varieties to respond to these questions by indicating the manner in which their national laws provide such protection, with other WTO Members requested to use their best efforts to furnish such information. The Council later received and published responses from 17 states and from the European Communities and its member states. (WTO Job No. 2689 of 7 May 1999). In 2001 and 2002, the Council reissued these questions and invited WTO Members that had not already done so to provide information on their plant variety protection practices. Additional responses were received from six states. (WTO Doc. IP/C/W/273/Rev. 1, pp. 1 and 2) Information distilled from some of these responses is discussed in section 3.3 below.

Dispute settlement provisions. Another significant innovation of TRIPs is its dispute settlement system. Although prior intellectual property agreements, including the UPOV Acts, contained provisions for filing of complaints against non-complying treaty parties before the International Court of Justice, no state ever invoked this dispute settlement option. It was widely believed that pursuing such a complaint would be perceived as an unfriendly act, would be time-consuming and costly and that states were unlikely to implement decisions of the court. (Helfer, 1998, pp. 375 and 376) The TRIPs Agreement removes each of these concerns by linking to a WTO Agreement known as the Dispute Settlement Understanding which contains a streamlined dispute settlement mechanism that is one of the most widely used and effective interstate dispute resolution systems in international law. Indeed, the mere existence of such a system creates strong incentives for WTO Members to bring their national laws into compliance with the WTO Agreements, including TRIPs, to avoid the possibility of dispute settlement proceedings.

These strong incentives notwithstanding, some countries may not comply. In such a case, where one WTO Member believes that another Member has failed to fulfill its obligations under the Agreement, it may initiate consultations under the Dispute Settlement Understanding with a view to resolving the dispute. If the parties fail to reach agreement, the complaining state may then request the WTO to convene a three-member panel of experts to review its allegations. Such panels generally issue a decision within six months. The panel's decision is adopted by the WTO's Dispute Settlement Body unless the losing party or parties elect to appeal the decision to the seven-member Appellate Body, a standing tribunal of seven trade experts who are authorized to review the panel's findings and issue a decision within three months. If either the Appellate Body or an unreviewed panel decision concludes that a WTO Member has violated the TRIPs Agreement, the Dispute Settlement Body will recommend that the defending state bring its national laws into compliance with the treaty. If the state fails to do so, the complaining state may then commence an arbitral proceeding to specify the amount of compensation that the defending state must pay to remedy the violation, or in lieu of such compensation the complaining state may seek authorization to impose trade sanctions on the non-complying Member.

As of July 2004, WTO Members (mostly developed nations) had commenced 24 dispute settlement proceedings against both developed and developing nations concerning a wide variety of intellectual property issues. (WTO Dispute Settlement: Index of Disputes Issues: 15 July 2004) Approximately one third of these disputes were resolved prior to a decision by a panel, with the defending state agreeing to modify its laws to bring them into compliance with the Agreement. In other cases, however, WTO Members complied only after a panel or the Appellate Body had issued a decision against them. And in a few instances, Members that have not modified their laws instead have negotiated settlements involving the payment of compensation to the complaining Member. (Geuze & Wager, 1999)

As of the date of this study, there have been no TRIPs dispute settlement proceedings relating to intellectual property protection for plant varieties. Whether such proceedings will be brought in the future depends on a number of variables, many of which are still uncertain.

Three interrelated reasons suggest that a dispute settlement proceeding concerning plant variety protection is a likely possibility: first, the significant difference of views among WTO Members over the scope of legal protection to be provided to plant varieties (discussed in para. 2.3.1.4 below); second, the fact that developing country WTO Members first became obligated to protect plant varieties only in 2000 (see para. 2.3.1.2 above); and third, the absence of plant variety protection in many developing countries' national laws prior to the 2000 deadline. (See para. 3.5.2 below) Taken together, these variables suggest that the plant breeders of a developed WTO Member who learn that their protected varieties are being exploited without authorization in developing WTO Members due to inadequate national laws will pressure their governments to file a complaint against such states to compel them to adhere to their treaty obligations.

Other factors, however, suggest that a complaint over plant varieties is unlikely to be filed, particularly within the next five to ten years. First, the initiation of the Doha Round of trade negotiations in November 2001 (discussed in Part IV below) is likely to cause WTO Members to show restraint in their dispute settlement strategies while the multi-year negotiations are proceeding. This is especially so given that the Doha Round will likely provide WTO Members with the first meaningful opportunity to harmonize other international obligations (such as those

set forth in the CBD and the ITPGR) with the plant variety and other IPR protection requirements of the TRIPs Agreement. Second, past practice has shown that WTO Members are most likely to file dispute settlement complaints where they are pressured to do so by the owners of intellectual property products. It is unclear whether plant breeders can make a sufficient showing that their overseas markets are being harmed by other states' failure to provide adequate legal protection for plant varieties. Third, WTO Members are generally reticent about filing complaints where their probability of success is unclear. Therefore, given the uncertain scope of protection for plant varieties currently required by TRIPs, if Members enact *some form* of plant variety protection in their national laws, other Members are unlikely to challenge those laws unless they can identify a clear violation of the Agreement. Nevertheless, the potential for dispute settlement proceedings (and the trade sanctions they can engender) will continue to provide strong incentives for states to enact plant variety protection laws.

2.3.1.4. *The unique scope of plant variety protection required by TRIPs*

Article 27.3(b) contains the only textual provisions of the TRIPs Agreement relating to plant variety protection. The article states in relevant part:

Members may also *exclude from patentability*: (b) *plants* and animals other than microorganisms; 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 for plant varieties either by patents or by an effective sui generis system or by any combination thereof.* (emphasis added)

The meaning of this article has been the subject of significant debate among both WTO Members and nongovernmental organizations (NGOs) with differing views over the propriety of IPR protection for plant varieties. A detailed review of that debate and an analysis of article 27.3(b) is provided below. For present purposes, two overarching points are worth noting.

First, TRIPs' provisions on plant varieties do not refer to or incorporate any preexisting intellectual property agreements, including the 1978 and 1991 UPOV Acts. This omission contrasts sharply with other fields of

intellectual property, such as patents, copyrights and trademarks, for which TRIPs expressly requires WTO Members to comply with the standards of protection contained in preexisting IPR agreements, such as the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. As a result of this omission, WTO Members are neither required to become members of UPOV nor to enact national laws consistent with either UPOV Act in order to comply with their obligations under TRIPs. (However, certain "TRIPs plus" treaties do impose one or both of these requirements, see para. 2.3.1.6 below) Although the drafting history of TRIPs does not explain this markedly different treatment of plant varieties, it seems likely that compliance with UPOV was not required because so few WTO Members were party to UPOV and those who were could not agree upon which of its two most recent Acts should serve as the standard for protection.

Second, article 27.3(b) permits WTO Members to protect plant varieties using one of three distinct approaches: (1) patent law, (2) an effective *sui generis* system or (3) a combination of elements from both systems. Thus, unlike most other areas of intellectual property protected by TRIPs, article 27.3(b) expressly grants Members significant discretion to choose the manner in which they will protect plant varieties and it contemplates that that discretion may be exercised differently by different states.

This discretion and the opportunity for divergent outcomes it engenders has significant consequences. On the one hand, TRIPs' failure to incorporate and build upon the preexisting UPOV Acts may have "a deharmonizing effect," (Correa 1994a) with states within the UPOV system enacting one type of plant variety protection law and states outside of that system enacting a different kind of law (which may or may not resemble each other). This could create significant complexities and uncertainties for plant breeders seeking to market protected varieties in different jurisdictions. On the other hand, this sanctioned diversity of legal approaches allows WTO Members to balance the protection of plant breeders' rights against the other important and competing societal goals identified in Part I, many of which are found in other international agreements. Seen from this perspective, article 27.3(b) provides a much needed "safe space" for governments to harmonize conflicting norms and policies – a space that is lacking in other areas of the TRIPs Agreement.

2.3.1.5. The review of TRIPs Article 27.3(b)

The last sentence of article 27.3(b) states that "[t]he provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement." Inasmuch as the WTO Agreement entered into force on 1 January 1995, the review contemplated by this article should have been conducted in 1999. The review was commenced but was not concluded, largely as a result of disputes between industrialized and developing nations over the scope of the review process. (GRAIN, 2000, pp. 3–5). Governments submitted additional information and proposals to the TRIPs Council in 2000 and 2001, but no formal action was taken. With the launching of the Doha Round of trade talks in November 2001, however, the review of article 27.3(b) recommenced in earnest.

In June 2002, eleven developing states submitted a detailed proposal to amend TRIPs to "prevent systematic conflicts with the CBD arising from the implementation of TRIPs." (WTO Doc. IP/C/W/356, para. 11) The proposal seeks to compel all WTO Members to require applicants for patents relating to biological materials and traditional knowledge to disclose certain information as a condition of obtaining legal protection. (Id., para. 10)

The European Communities and Switzerland responded to the developing states' proposal with a compromise. The EU response calls for the negotiation of "a self-standing disclosure requirement," which, while not functioning as a new eligibility criterion for patent protection, "would allow Members to keep track, at [the] global level, of all patent applications with regard to genetic resources for which they have granted access." (EC Concept Paper, paras. 51 and 55; see also WTO Doc. IP/C/W/400/Rev. 1, p. 1) In June 2003, developing countries rejected this compromise and "reaffirm[ed] and strengthen[ed] their demand for a strong disclosure of origin mechanism" within TRIPs that would require "not only detailed information about who provided the [genetic] materials or the [traditional] knowledge used [in patent applications], but also positive proof of benefit sharing and of prior informed consent." (GRAIN, 2003, p. 1; see also WTO Doc. IP/C/W/404, pp. 4–6). African countries also proposed a new "Decision on Traditional Knowledge" to be incorporated into TRIPs. (IP/C/W/404, pp. 7–9)

2.3.1.6. "TRIPs plus" bilateral and regional agreements

In the decade since TRIPs was first adopted, the United States and the European Community have negotiated a growing number of bilateral and regional trade and investment treaties with developing countries. Many of these treaties contain provisions concerning IPRs. Commentators have referred to these treaties by the appellation "TRIPs plus" because they (1) contain intellectual property protection standards more stringent than those found in TRIPs, (2) obligate developing countries to implement TRIPs before the end of its specified transition periods or (3) require such countries to accede to or conform to the requirements of other multilateral intellectual property agreements. (GRAIN, 2001; Vivas, 2003) As one study recently noted, "[t]o the extent that ["TRIPs plus" treaties] include these additional aspects, they are pushing harmonization forward at a pace that is greater than is apparently possible within the framework of the WTO." (OECD, 2003, p. 112) In addition, once a developing state enacts this higher level of IPR protection in its national laws, TRIPs' MFN clause obligates that state to extend the same protection to *all other WTO Members*. In this way, bilateral agreements can be used to ratchet up the level of protection for IPRs beyond what is required in the TRIPs Agreement. (Drahos, 2001, pp. 794–807)

Several "TRIPs plus" treaties contain provisions relating to plant variety protection that go beyond the minimum level of intellectual property protection specified in TRIPs. For example, the recently concluded U.S.-Central America Free Trade Agreement (applicable to Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and possibly to the Dominican Republic), the 2002 U.S.-Chile free trade agreement, the 2000 U.S.-Jordan free trade agreement and the 2000 EU-Mexico free trade agreement, as well as certain Euro-Mediterranean Association agreements and the draft Free Trade Agreement of the Americas, all mandate UPOV as the appropriate mechanism to protect plant breeders' rights. (GRAIN, 2004b) The treaties also require these countries to ratify the 1991 UPOV Act within specified time frames. (GRAIN, 2004b; OECD, 2003, pp. 118 and 119) Such obligations limit the discretion enjoyed by these countries to tailor their national laws to achieve policy objectives in tension with IPRs. (See para. 1.3.6 above and section 3.4 below).

2.3.2. Patent protection for plant varieties under TRIPs

The TRIPs Agreement mandates its signatories to provide patent protection for any inventions in all fields of technology, provided that the inventions are "new, involve an inventive step and are capable of industrial application." (art. 27(1)) However, with regard to plant-related inventions, TRIPs permits Members to exclude from patentability altogether "plants," "essentially biological processes for the production of plants" and "plant varieties." (art. 27.3(b)) Thus, as presently written, the TRIPs Agreement would permit WTO Members to decline to protect plant varieties with a patent (provided, as discussed in section 2.3.3 below, that they protect such varieties with an effective *sui generis* right).

2.3.2.1. *Applicability of patent protection for plant varieties*

For this reason, it may initially appear that governments can ignore patents as they consider how to protect plant-related innovations in their national legal systems. Nevertheless, a basic understanding of the patent provisions of the TRIPs Agreement and a comparison of those provisions with the plant breeders' rights approach contained in the UPOV Acts is essential for a number of reasons.

First, extending patent protection to plant-related inventions and innovations remains an option for national governments. Recall that TRIPs' "minimum standards" framework expressly contemplates that WTO Members may provide greater protection for IPRs than are mandated by the Agreement. (See para. 1.3.4 above) article 27.3(b) in particular invites Members to protect plant varieties with patents or with a combination of patents and a *sui generis* system. A number of governments in the industrialized world, including the United States, Japan, Australia, New Zealand, Sweden and the United Kingdom, have capitalized on this opportunity by permitting plant breeders to obtain patent protection in new varieties provided that the eligibility requirements for a patent have been met. (Watal, 2000, p. 149)

Second, because TRIPs does not require any patent protection for plant-related innovations, it follows as a matter of course that the treaty does not compel WTO Members to adopt any particular form of patent protection. This allows governments the option of including plant varieties within their existing utility patent statutes and/or of enacting a

separate statute applicable exclusively to plants. (Utility patents are generally granted to "any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof . . ." (See, e.g. 17 U.S.C. Sec. 101.) In making this decision, however, it will be useful for governments to understand the traditional elements of patent law and the ways in which they may be varied within the confines of the TRIPs Agreement. The United States, for example, has enacted multiple plant variety protection laws. It was one of the first nations to adopt, in the Plant Patent Act of 1930, a unique form of protection applicable to asexually reproducing plants. In addition, since the mid 1980s, U.S. courts and the U.S. Patent and Trademark Office have concluded that plant breeders may also seek standard utility patents under the U.S. Patent Act. In December 2001, the U.S. Supreme Court confirmed that breeders could apply for both forms of protection with respect to the same variety. (See *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 122 S. Ct. 593, 2001). Such a result is prohibited by the 1978 UPOV Act but permitted under the 1991 Act to which the U.S. is a party.

Third, an understanding of patent principles is also necessary because of the difficulty in some nations of distinguishing between plant varieties (which are often excluded from national or regional patent laws) and other plant-related innovations (to which patent protection may be extended). In Europe, for example, article 53(b) of the European Patent Convention prohibits the patenting of "plant varieties" as such. Nevertheless, the European Patent Office recently confirmed that claims to patent protection that are broadly drawn to encompass "plants" or an invention broader than a single variety *may* be patented, even though such claims may encompass multiple varieties. (G 0001/98, *Novartis II/Transgenic Plant*, 2000; E.P.O.R. 303 para. 3.10; *Janis & Kesan*, 2001b, p. 35) As a result, it may be possible for plant breeders in Europe to fashion their claims to receive *de facto* patent protection for new plant varieties.

Fourth, as discussed in greater detail below and as summarized in Table 2 below, there are significant differences in approach between plant breeders' rights and patents. In the case of plant breeders' rights, the eligibility requirements for protection are not onerous, but the scope of protection granted is quite narrow, both in terms of exclusive rights and the various exceptions and limitations to those rights. Patent laws strike a very different balance. Eligibility requirements are high and difficult to meet, but once granted a patent conveys broad rights to exclude third

parties from exploiting the patented invention. Depending on the needs and level of development of plant breeder industries within its territory, a government may decide that either or both forms of protection will provide the appropriate incentives to encourage plant-related research and innovation. (See para. 3.4.4.1 below)

Fifth, and finally, a review of the TRIPs Agreement's plant-related patent rules will soon occur in the context of the Doha Round of trade negotiations. (See Part IV below). Such a review may produce an agreement to amend TRIPs to require WTO Members to extend patent protection to plant-related innovations or plant varieties. National governments which have thus far eschewed patent protection would then need to revise their national laws to make such protection available, in addition to or instead of the legal protection provided under national plant variety protection laws. At a minimum, therefore, governments interested in promoting plant-related innovations should be apprised of the relevant legal issues so that they may contribute in an informed way to the upcoming discussions.

2.3.2.2. *Subject matter eligibility requirements*

According to the text of the TRIPs Agreement and authoritative commentary interpreting it, plant-related innovations may be patented if they are "inventions" that are novel, non-obvious and useful. (TRIPs, art. 27(1); Leskien & Flitner, 1997, p. 7) Although commentators frequently assert that these cumulative requirements impose significant barriers to the patenting of plant varieties, in practice breeders have succeeded in patenting not only new varieties, but also hybrid plants and inbred and hybrid plant lines. (Correa, 2000, p. 183). As two commentators recently noted, since 1985 the U.S. Patent and Trademark Office "has granted hundreds of utility patents on all aspects of innovation relating to plant science: plants themselves, seeds, breeding methods and plant biotechnology." (Janis & Kesan, 2001a, p. 981)

Inventions. The TRIPs Agreement does not define the term "invention," thus leaving its precise meaning to national patent laws or regional patent rules such as those operating within the European Union.

All such laws recognize that an invention must be more than a mere discovery of a natural phenomenon or naturally occurring substance. Thus, for example, a breeder who merely identified the existence of a

previously unknown wild variety or a cultivated landrace that was known only to an isolated indigenous community should not be permitted to patent that variety or landrace.

The trend among the industrialized countries, however, and in the United States, Japan and the countries of the European Union in particular, is to recognize that an isolated and purified form of a natural substance may be patented. (Correa, 2000, pp. 177 and 178; Leskien & Flitner, 1997, p. 8). For example, article 3.2 of the 1998 Directive on the Legal Protection of Biotechnological Inventions states that "biological material which is isolated from its natural environment or produced by means of a technical process" may be patentable. (Directive 98/44/EC of 6 July 1998, O.J. L213) Perhaps because this approach involves making a very fine distinction between discoveries and inventions, many developing countries have declined to follow it, instead choosing to deny patent protection to plant materials found in nature even if they have been isolated or purified by human intervention. (Correa, 2000, p. 186; Watal, 2000, pp. 155 and 156) According to one commentary, this patent ban is compatible with the TRIPs Agreement provided that it does not extend to plants with modified or artificial plant gene sequences, which often significantly vary from naturally occurring substances and thus are properly classified as inventions. (Leskien & Flitner, 1997, p. 9)

A second attribute of a patentable invention is that an applicant seeking such a patent must disclose the invention in a sufficiently clear and complete manner that permits a person skilled in the art to carry out the invention. (TRIPs, art. 29(1)). In addition to ensuring that the claimed invention in fact meets patent eligibility requirements, disclosure also permits third parties to access the invention for purposes of improving it or developing new inventions. In the case of plant-related innovations, national laws permit inventors to satisfy the disclosure requirement either by a written description of the invention and/or by a deposit of the protected material (i.e. seeds, germplasm or other biological material). TRIPs does not require national governments to adopt any particular form of disclosure, nor does it specify the timing, manner or conditions of third party access. As a result, national laws vary widely on this point. (Correa, 2000, p. 191)

Novelty, inventive step and industrial application. These three cumulative eligibility requirements are mandated by article 27(1) of the TRIPs Agreement and are found in all national patent laws. Even among states

with strong patent protection laws, however, the interpretation and application of each of these steps varies considerably.

Novelty. The principal objective of the novelty requirement is to ensure that the claimed invention cannot be found in the "state of the art" or "prior art" already in existence. These terms refer to the body of knowledge which is available to the public before the date of filing of an application for patent protection. Patent examiners establish both the novelty and inventive step requirements by comparing the claimed invention to the state of the art or prior art. A critical issue for plant-related innovations concerns the form in which prior art exists and the difficulty of accessing traditional knowledge as prior art.

Under United States patent law, for example, novelty can be negated if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country" (35 U.S.C. Sec. 102(b)) The important point is description: foreign *uses* of claimed inventions are not considered as part of prior art. The Patent Cooperation Treaty (PCT) adopts a similar approach, limiting prior art to "everything which has been made available to the public anywhere in the world by means of written disclosure." (Rule 33.1 of Regulations under the PCT) Thus, in the United States and in countries following the PCT, even where foreign plant-related innovations are known, used or disclosed in other than written form, it may be possible for the inventor to obtain patent protection. (Correa, 2000, pp. 188 and 189; Dutfield, 2000, pp. 64 and 68)

Article 54(2) of the European Patent Convention adopts a different approach, defining the state of the art to encompass everything made available to the public by means of written or oral descriptions, by use or indeed in any other way, prior to the filing of the application. Nevertheless, the absence of systemic databases concerning traditional knowledge, including knowledge relating to plants, has led examiners in various countries to grant patents for inventions that were later revoked after they were discovered to encompass prior art. (WIPO, Progress Report on the Status of Traditional Knowledge as Prior Art, 1 July 2001)

Inventive step. The inventive step requirement looks to the state of the art to determine whether the claimed invention is not obvious to a person skilled in the art. Although the majority of international treaties and national laws defined inventive step in this way, the application of the

standard to plant-related innovations varies and may be a significant hurdle to patent protection given "the enormous speed of technological progress" in the field. (Leskien & Flitner, 1997, p. 13)

Industrial application. The industrial application requirement is concerned with an invention's practical utility, and in particular whether "it can be made or used in any kind of industry, including agriculture." (E.g. European Patent Convention, art. 7) This eligibility requirement does not appear to pose a significant obstacle to the patenting of new plant varieties, given their ready use in the fields of plant breeding, horticulture and agriculture.

2.3.2.3. *Exclusions from patentability*

As noted above, article 27.3(b) of TRIPs permits WTO Members to deny all patent protection to "plants" and "plant varieties." Nevertheless, a state that chooses to provide such protection may nevertheless choose to exclude from patentability a narrower category of inventions, "the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect . . . plant life or health or to avoid serious prejudice to the environment." (Art. 27(2)) Some commentators have asserted that this language grants states the discretion to exclude broad categories of inventions that further the erosion of genetic diversity on the theory that issues of public policy and morality include a state's sovereign right to control its natural resources. (E.g. Cameron & Makuch, 1995; Crucible Group, 1994; Dutfield, 2000, p. 20) However, because WTO dispute settlement panels have strictly interpreted clauses in the WTO Agreements that permit states to derogate from protected treaty rights, the more persuasive view is that exclusions on this basis must be fact-specific, narrowly drawn and no broader than required to achieve their purpose. (Moufang, 1998) Resolution of this debate in the context of plant-related innovations will not occur until the WTO dispute settlement bodies issue a ruling on the matter, an unlikely prospect so long as Members are free to exclude plants and plant varieties entirely from patentability.

2.3.2.4. *Exclusive rights*

Once a patent is awarded, the owner of the patented product or process enjoys a broad panoply of exclusive rights. These include the right to prevent third parties from making the product, using the process or from

using, offering for sale, selling or importing for those purposes the patented product or the product obtained by the patented process. (TRIPs, art. 28) States that choose to extend patent protection to plant-related innovations would thus be expected to protect products composed of plants and parts of plants and processes (including biological processes) for the production of plants. (Leskien & Flitner, 1997, p. 22) Although there is some dispute over whether traditional plant breeding methods (as opposed to creating varieties through genetic manipulation) can be protected by process patents, the practice of states that do extend patent protection to plants reveals that such methods have been protected. (Compare Correa, 2000, p. 187 with Janis & Kesan, 2001a, p. 981)

2.3.2.5. *Term of protection*

TRIPs article 33 imposes a minimum 20-year term of protection from the date the patent application is filed.

2.3.2.6. *Exceptions and limitations*

As compared to limitations on plant breeders' rights permitted under the UPOV, the limitations on a patent owner's exclusive rights permitted under the TRIPs Agreement are far narrower. These limitations can be divided into exceptions to exclusive rights and compulsory licenses, which permit certain uses by third parties but require remuneration to the patent owner.

Exceptions. Article 30 of TRIPs permits WTO Members to adopt "limited exceptions" to exclusive patent rights provided that they do not "unreasonably conflict with a normal exploitation of the patent" and "do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." This three-part test is applicable to all patents protected by the TRIPs Agreement.

Canadian Patents Case. A WTO dispute settlement panel clarified the meaning of article 30 in Canada – Patent Protection of Pharmaceutical Products (Generic Medicines), WT/DS114/R (17 March 2000). The panel considered a complaint brought by the European Communities to two provisions of Canadian patent law. The first permitted uses of patented pharmaceuticals without the patentee's authorization for the purpose of obtaining approval of a generic product before the patent's

term expired. The second permitted production and stockpiling of the generic product for release immediately after the expiration of the patent. Both procedures were designed to permit the marketing of generic versions of pharmaceuticals promptly after the expiry of the patent. The panel decision confirmed that only the first exception is consistent with TRIPs. More importantly, the panel concluded that any exception that results in "a substantial curtailment" of the patent owner's exclusive rights is inconsistent with article 30. (WT/DS114/R, para. 7.36)

If TRIPs were amended to require patent protection for new plant varieties, the standard adopted by the Canadian Patents panel would preclude Members from enacting many of the exceptions that are permitted under plant variety protection laws, such as the breeders' exemption and the farmers' privilege. The same prohibition on these privileges already exists in several countries that currently protect plant varieties and other plant-related innovations in their national patent laws.

Research and experimentation exception. Most national patent laws permit third parties to engage in experimentation or research related to the patented invention. Some states, however, including the United States, narrowly construe this exception to preclude unauthorized commercialization of any products or processes that result from such research if they encompass the patentable invention. In such countries, commercial activities permitted under the breeders' exemption found in plant variety protection laws are prohibited where the variety is protected by a patent. Thus, for example, a breeder would not be permitted to cross patented seeds to produce improved varieties. (Correa, 2000, p. 192) Even in patent systems in which the experimental use exception tolerates some commercialization (Cornish, 1998), such as those found in Europe, it is likely that the commercial acts allowed under a traditional breeders' exemption would "conflict with a normal exploitation of the patent" and would thus amount "a substantial curtailment" of his or her exclusive rights in violation of TRIPs article 30. Thus, if patent protection of plant varieties were to become mandatory under TRIPs, a breeders' exemption such as that found in article 22,V of Mexico's patent law would be unlikely to survive a challenge before a WTO dispute settlement panel.

Farmers' privilege. A similar fate is likely to befall the exception permitting farmers to save and reuse seeds on their own land without the patent owner's permission, another exception traditionally allowed under plant

variety protection laws. (See paras. 2.2.2.6 and 2.2.3.6 above) The United States does not recognize a farmers' privilege under its utility patent laws. Although such an exception has been adopted in article 11 of the European Union's 1998 Biotechnology Directive (conditioned upon the payment of equitable remuneration except by small farmers), at least one commentator has questioned whether that exception is compatible with TRIPs article 30, because such an exception would unreasonably prejudice the "legitimate interests" of the patent owner. (Watal, 2000, p. 155 n.62)

Compulsory licences. TRIPs contains a complex set of rules that regulate when states may compel patent owners to license their products and processes to governments or to private parties. Although the TRIPs Agreement does not specify the grounds which justify the creation of compulsory licences (Gervais 1998, p. 165), because article 5A(2) of the Paris Convention is incorporated by reference into article 2(1) of TRIPs, it can be inferred that such licences may be granted only to prevent "abuses which might result from the exercise of the [patent owner's] exclusive rights." Even where such abuses exist, TRIPs article 31 imposes further conditions upon the granting of compulsory licences, including individual consideration of each case, prior negotiations with the patent owner seeking a voluntary licence, limitations on the scope and duration of compulsory licences and requiring their termination when the circumstances leading to their creation are no longer in effect. Most importantly, patent owners must receive "adequate remuneration," taking into account the value of the rights licensed.

One area in which compulsory licences may affect plant breeders is that of dependent patents, which are defined as patents whose use requires the authorization of an earlier patent owner. Such patents are prevalent in plant breeding, where the creation of new varieties often occurs incrementally in the form of adaptations and improvements of existing varieties, as opposed to radically new innovations. (Correa, 2000, p. 194). Because incremental innovation often requires access to protected varieties, governments may seek to impose compulsory licences in favour of third party breeders who are unable to negotiate voluntary access to patented plant varieties. However, the compatibility of such licences with TRIPs is untested and governments seeking to impose them should ensure that they comply scrupulously with each of the many requirements set forth in article 31.

Because the patent compulsory licence provisions of TRIPs are far more detailed and narrow than the compulsory licences permitted under the 1978 and 1991 UPOV Acts, commentators are divided over their usefulness in the area of plant-related innovations. Some argue that such licences will be largely irrelevant to the field (Leskien & Flitner, 1997, p. 25), whereas others claim that governments may adopt such licences "to ensure access to patented materials in order to attain specific agricultural objectives (e.g. availability of a given material for farmers) or food security" (Correa, 2000, p. 194) Even if licences to achieve these objectives are permitted, however, the restrictions that TRIPs imposes significantly limit the ability of WTO Members to grant such licences in favour of third parties

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TABLE 2 - Comparison of principal differences between plant variety protection under UPOV 1978 Act, UPOV 1991 Act and TRIPs-compatible patent laws

Subject	Breeders' rights in UPOV 1978 Act	Breeders' rights in UPOV 1991 Act	TRIPs-compatible patent laws
Eligibility for protection	Plant varieties that are novel, distinctive, uniform and stable.	Plant varieties that are novel, distinctive, uniform and stable.	Plant varieties, plants, seeds and enabling technologies that are novel, involve an inventive step and are capable of industrial application.
Minimum exclusive rights in propagating material	Production for purposes of commercial marketing; offering for sale; marketing; repeated use for the commercial production of another variety.	Production or reproduction; conditioning for the purposes of propagation; offering for sale; selling or other marketing; exporting; importing or stocking for any of these purposes.	Making the patented product, using the patented process or using, offering for sale, selling or importing for those purposes the patented product or the product obtained by the patented process.
Minimum exclusive rights in harvested material	No such obligation, except for ornamental plants used for commercial propagating purposes.	Same acts as above if harvested material obtained through unauthorized use of propagating material and if breeder had no reasonable opportunity to exercise	Making the patented product, using the patented process or using, offering for sale, selling or importing for those purposes the patented

Subject	Breeders' rights in UPOV 1978 Act	Breeders' rights in UPOV 1991 Act	TRIPs-compatible patent laws
		his or her right in relation to the propagating material.	product or the product obtained by the patented process.
Breeders' exemption	Mandatory. Breeders free to use protected variety to develop a new variety.	Permissive. But breeding and exploitation of variety "essentially derived" from an earlier variety require the right holder's authorization.	Generally not recognized, although compatibility with TRIPs not yet tested.
Farmers' privilege	Implicitly allowed under the definition of minimum exclusive rights.	Permissive within reasonable limits and subject to safeguarding the legitimate interests of the right holder.	Generally not recognized, although compatibility with TRIPs not yet tested.
Additional exceptions to exclusive rights	None specified.	Acts done privately and for noncommercial purposes, acts done for experimental purposes.	Research and experimentation. All exemptions must comply with three-part test of TRIPs article 30.
Minimum term of protection	18 years for trees and grapevines; 15 years for all other plants.	25 years for trees and grapevines; 20 years for all other plants.	20 years from date the patent application filed.

2.3.3. *Sui generis* protection for plant varieties under TRIPs

As noted above, TRIPs authorizes WTO Members to eschew patent protection for plants and plant varieties and adopt instead an "effective *sui generis* system" of protection. The following discussion identifies the core requirements of such a system, laying the groundwork for Part III which outlines the permissible options available to WTO Members seeking to grant IPRs to plant varieties while simultaneously seeking to achieve other objectives.

2.3.3.1. *Identifying and evaluating competing proposals for sui generis systems*

TRIPs does not define the term *sui generis* as it appears in article 27.3(b), nor does the treaty's drafting history shed any light on its meaning. (Gervais, 1998, pp. 147–151) As a general matter, the term *sui generis* is understood to mean "of its own kind" or "unique," a definition which does little to identify what sort of unique legal systems are permitted under the treaty. This lack of definitional clarity has allowed advocacy groups and commentators to advance different and often competing proposals for how effective *sui generis* protection should be structured, producing significant confusion for governments seeking to understand and implement their obligations under the TRIPs Agreement.

The discussion below identifies and evaluates the competing proposals. In brief, it concludes that if WTO Members choose to protect plant varieties using a *sui generis* right as opposed to a patent, they are required to create a distinct IPR applicable to plant varieties that complies with the core requirements and objectives of the TRIPs Agreement. *Sui generis* systems that do not contain these core elements or conflict with them are not TRIPs-compatible and expose the WTO Members who adopt them to challenges under the WTO dispute settlement system. Nevertheless, the mandatory requirements of article 27.3(b) preserve significant leeway for national governments to work out the precise manner in which they will balance protection of IPRs against other international obligations and national objectives.

2.3.3.2. *Sui generis systems as defined by the UPOV Acts*

Several commentators assert that a state adopting national legislation in compliance with either the 1978 UPOV Act or the 1991 UPOV Act has

satisfied its obligations under article 27.3(b). (e.g. Gervais 1998, p. 151) Those advocating for compliance with the 1991 Act stress the more extensive IPR protections it provides to plant breeders, while commentators endorsing the 1978 Act as the appropriate *sui generis* standard stress that only the earlier Act was in force at the time TRIPs was being negotiated.

In fact, however, the protection required by the two UPOV Acts is neither necessary nor sufficient for an "effective *sui generis* system." It is not necessary because article 27.3(b) does not require plant variety protection laws to contain the same subject matter, eligibility requirements, exclusive rights, terms of protection or other detailed provisions of either of the two UPOV Acts. And it is not sufficient because TRIPs requires WTO Members to structure their national IPR laws in ways that the two UPOV Acts do not.

Note, however, that developing countries that are parties to a "TRIPs plus" bilateral or regional trade or investment treaty may be required, by virtue of those treaties, either to join UPOV or to implement the standards set forth in one of the UPOV Acts. (See para. 2.3.1.6 above) A country that has undertaken such obligations does *not* possess the same flexibility in designing a *sui generis* system to protect plant varieties as a country which has not undertaken such obligations. (For a more detailed discussion of the consequences of this reduced flexibility, see section 3.4 below.)

For example, as explained in paragraphs 2.2.2.4 and 2.2.3.4 above, both the 1991 Act and the 1978 Act adopt the principle of national treatment, the same principle required by TRIPs. But under the UPOV Acts such treatment need be extended only to the nationals and residents of *other UPOV member states* and to legal persons having their headquarters in such states. Any WTO Member that limited national treatment in this way would unquestionably violate article 3 of TRIPs, which requires extension of national treatment to all other WTO Members whether or not they are also UPOV members.

However, to comply with article 3, a state whose plant variety protection law contains a UPOV-specific national treatment rule can easily amend its law to expand the number of states to which national treatment applies. Other UPOV-sanctioned rules may require more extensive changes. For example, the 1978 Act allows a state to impose a reciprocity

requirement in certain circumstances, limiting the right to apply for protection of a new variety to nationals or residents of those member states which also apply the Act to the genus or species to which that variety belongs. (See para. 2.2.2.4 above) This reciprocal protection is incompatible with TRIPs' national treatment rule, and possibly its most favoured nation principle as well, both of which are inconsistent with a system of reciprocity. (Watal, 2000, p. 141; TRIPs, art. 4(d))

That TRIPs' drafters did not intend either UPOV Act to be the exclusive model for *sui generis* protection of plant varieties is confirmed by their failure to refer to the Acts anywhere in the Agreement. By contrast, where the drafters intended Members to comply with standards found in preexisting international IPR treaties, they stated so expressly. (See, e.g. TRIPs, art. 2(1), which incorporates enumerated provisions of the Paris Convention for the Protection of Industrial Property.) Nevertheless, as explained in sections 3.3.1 and 3.3.2 below, most provisions of the two UPOV Acts are fully consistent with an effective *sui generis* system, and most countries have in fact adopted plant variety protection laws that are consistent with one or both UPOV Acts.

2.3.3.3. *Core requirements of an effective sui generis system*

According to a 1997 report prepared by two leading commentators, there are four core elements that any national plant variety protection law must contain in order to qualify as an "effective *sui generis* system" within the meaning of TRIPs article 27.3(b): (1) the law must apply to all plant varieties in all species and botanical genera; (2) it must grant plant breeders an IPR, i.e. the exclusive right to control particular acts with respect to those protected varieties, or at a minimum, the right to remuneration when third parties engage in certain acts; (3) it must provide national treatment and MFN treatment to breeders from other WTO Members; and (4) it must contain procedures that enable breeders to enforce the rights granted to them under such a law. (See Leskien & Flitner, 1997, p. 26) The paragraphs that follow discuss each of these four requirements.

Protection of all plant varieties. Although both UPOV Acts require protection of only a specific number of plant varieties (paras. 2.2.1.1 and 2.2.3.1 above), a careful reading of the TRIPs Agreement reveals that WTO Members are required to protect all varieties. (Leskien & Flitner, 1997, pp. 27 and 28) article 27.3(b) states that "Members shall provide

for the protection of *plant varieties*" (emphasis added) without any further qualification or limitation. Inasmuch as article 27.3(b) is included in a provision of the TRIPs Agreement which carves out numerous and specific exceptions to patent protection, if the drafters had intended to allow states to limit the number or type of plant varieties subject to protection, they would have said so expressly. Indeed, the drafters were aware that both UPOV Acts permitted precisely such limitations, yet they chose neither to refer to those Acts nor to their limited scope of protection. As explained in paragraph 3.4.2.1 below, however, the obligation to protect all varieties does not require states to provide *the same level of protection* to each and every variety.

Protection of plant varieties with an IPR. If protection granted to plant varieties must take the form of an IPR, WTO Members would enjoy virtually unbounded discretion to choose the manner in which to protect plant varieties, for example through a system of taxation on seeds. (Leskien & Flitner 1997, p. 32). The WTO's Appellate Body recently interpreted the text of the TRIPs Agreement, however, to require protection through an IPR. Nevertheless, because some commentators and NGOs have questioned whether plant variety protection is in fact a form of intellectual property included in the TRIPs Agreement (Correa, 1994, p. 26 n.58; GRAIN, 1998), a brief discussion of this point is needed.

Article 1(2) of TRIPs defines "intellectual property" for purposes of the Agreement as "all categories of intellectual property that are the subject of Section 1 through 7 of Part II" of TRIPs. Protection for plant varieties appears in Section 5 relating to patents, and is thus a form of intellectual property protected by the Agreement. This interpretation is confirmed by the United States – Section 211 Omnibus Appropriations Act of 1998, AB-2001-7, WT/DS176/AB/R (2 January 2002). In that case, a WTO panel concluded that trade names were not a category of intellectual property protected by TRIPs because they were not expressly referred to in article 1(2) (an omission that also applies to plant varieties). The Appellate Body reversed this finding. As an example, it referred to Members' option to protect plant varieties "by *sui generis* rights (such as breeder's rights) instead of through patents," and concluded that *sui generis* rights were in fact a form of intellectual property protected by the treaty. (Id., para. 335).

The significance of this conclusion is that IPRs for plant varieties must take the form of other IPRs protected by the TRIPs Agreement. Specifically, governments must either grant to the owners of protected varieties (1) the right to exclude all third parties from engaging in certain activities with respect to those varieties (an exclusive rights approach) or, (2) at a minimum, the right to receive equitable remuneration when a third party engages in such activities (a compulsory licence approach). (Leskien & Flitner, 1997, p. 29)

Nothing in TRIPs requires states to adopt the exclusive rights approach, nor does it indicate which exclusive rights must be granted to new varieties. Nevertheless, the vast majority of IPRs are protected by exclusive rights, with compulsory licences used only in limited areas such as new industries or distribution networks, abuses of monopoly powers or where high transaction costs preclude private licensing mechanisms from developing. (Helfer, 2000, pp. 106–109) In addition, a number of economic studies have suggested that granting exclusive rights to the owners of intellectual property products is a more efficient mechanism for creating incentives to innovate than a compulsory licence approach, in which political factors or government inertia are likely to produce skewed incentives. (Merges, 1996)

National and MFN treatment applicable to rights granted. At least one respected commentator has argued that national and MFN treatment are inapplicable to a *sui generis* system protecting plant varieties. The theory advanced is that these two forms of treatment are inapplicable to IPRs not covered by the TRIPs Agreement and that plant variety protection is an IPR that is not covered by TRIPs. (Correa, 1998, p. 5) However, the text of TRIPs article 3(1), as interpreted by WTO dispute settlement jurists, indicates that plant variety protection must adhere to such obligations. Thus, in the United States – Section 211 Omnibus Appropriations Act of 1998, AB-2001-7, 2 January 2002, the WTO Appellate Body stressed the critical importance of the national and MFN treatment rules in multilateral trade agreements (paras. 242 and 297), and it concluded that the obligation to grant such treatment applies to all subjects of intellectual property protected by TRIPs, a designation that includes *sui generis* protection of plant varieties. (See *id.* para. 360) As a result, in the area of plant variety protection, each Member must grant "no less favourable treatment" to the nationals of all other WTO Members than it grants to its own nationals and it must also grant to such foreign nationals "any advantage, favour, privilege or immunity"

provided to any other country. (TRIPs, arts. 3.1 and 4) Applied to plant varieties, this would mean that any IPR that a state grants to its own plant breeders must be granted to breeders from all other WTO Members, and that any IPR granted to breeders from one WTO Member must be granted to breeders from all WTO Members.

Enforcement of rights by private parties. The only qualification that article 27.3(b) imposes upon *sui generis* systems for protecting plant varieties is that they be "effective." Although TRIPs does not define this term, it refers to it in Part III dealing with enforcement of other IPRs against acts of infringement by third parties. For this reason, a WTO dispute settlement panel is unlikely to find a *sui generis* system to be effective unless it provides a meaningful opportunity for private parties to enforce their rights in protected varieties. (Leskien & Flitner, 1997, p. 32) Specific enforcement measures are not mandated by the Agreement, however. Had the drafters intended greater specificity, they could have easily made a reference in article 27.3(b) to the detailed enforcement rules applicable to other IPRs in Part III of TRIPs. Although a *sui generis* system must be "effective," this does not mean that a state must devote a particular level of resources to enforcement measures. In particular, article 41.5 of TRIPs makes clear that the treaty does not create "any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general." As a result, what qualifies as "effective" in a state with abundant resources and well-developed systems of law enforcement will not be required of states with more limited resources or weaker law enforcement systems.

Additional requirements of an "effective" sui generis system? Beyond effective enforcement measures, it is uncertain whether a WTO dispute settlement panel would find that article 27.3(b) imposes additional requirements for a *sui generis* system to qualify as "effective." In general, international tribunals have concluded that rights granted in a treaty must be interpreted so as to make them effective rather than illusory. (Helfer, 1998, p. 403) Thus, if a WTO Member were to grant very limited and weak rights to breeders together with broad and extensive exemptions in favour of farmers or other users of plant germplasm, its plant variety protection law might not survive WTO scrutiny. Such a possibility is likely to arise only in extreme cases in which a WTO Member has enacted a plant variety protection system that is functional in theory but non-functional in practice. States that implement the core TRIPs

requirements in good faith – that is, states that grant breeders intellectual property rights and enforcement measures applicable to varieties in all species and botanical genera and that provide those same rights and measures to breeders from other WTO Members – are unlikely to have their laws challenged successfully.

3. PART III – OPTIONS AVAILABLE TO NATIONAL GOVERNMENTS UNDER EXISTING INTERNATIONAL IPR AGREEMENTS PROTECTING PLANT VARIETIES AND PLANT BREEDERS’ RIGHTS

3.1. Introduction

In order to identify the options available to national governments under international IPR agreements, this section begins by categorizing states according to the agreements to which they are parties. This classification scheme takes into account the fact that a state may be bound by more than one IPR-related treaty, a fact that may significantly limit its discretion. The section then identifies both the mandatory actions required of national governments in each category as well as the discretionary choices available to them. It also identifies trends in national laws which illustrate the manner in which states are complying with their particular set of international obligations.

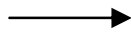
3.2. Classification of states according to their international IPR obligations

The discretion enjoyed by states to shape their plant variety protection laws to balance the protection of IPRs against other societal concerns is dependent upon the international agreement or agreements to which they are parties. The following table identifies that discretion at a broad level of generality. It does so by listing the mandatory components of plant variety protection that a state must adopt depending upon whether it is a member of (1) WTO only; (2) WTO and the 1991 UPOV Act; (3) WTO and the 1978 UPOV Act; and (4) either the 1991 UPOV Act or the 1978 UPOV Act only; or (5) no IPR agreement relating to the protection of plant varieties.

Note that some developing states, by virtue of having ratified a "TRIPs plus" bilateral or regional trade or investment treaty, may be required to adhere to some or all of the provisions contained in either the 1991 UPOV Act or the 1978 UPOV Act, *even if they are not members of UPOV itself*. (See para. 2.3.1.6 above) Developing states that are parties to such "TRIPs plus" treaties should carefully consult the text of these agreements to determine the precise scope of their supplementary IPR obligations, including for purposes of applying the classification scheme set forth below. For example, a developing country that is a WTO Member but not a member of UPOV may nevertheless be required to adhere to all of the provisions of the 1991 UPOV Act by virtue of having ratified a "TRIPs plus" treaty. In such a case, the state would be obligated to implement the mandatory components of plant variety protection contained not only in TRIPs but also in the 1991 UPOV Act, and its discretion to balance the protection of IPRs against other competing policy objectives would be reduced accordingly.

Table 3 - Classification of states according to their international IPR obligations

Increasing levels of discretion



Required IPR obligations relating to plant varieties	Member of WTO & 1991 UPOV Act	Member of WTO & 1978 UPOV Act	Member of 1991 or 1978 UPOV Act only¹	Member of WTO only	Not a Member of WTO, UPOV or other IPR agreement
Applicable subject matter	All varieties of plants.	All varieties of plants.	Lesser number of varieties as permitted under relevant Act.	All varieties of plants.	Any number of plant varieties may be protected.
Eligibility Requirements	Novelty, distinctness, uniformity and stability.	Novelty, distinctness, uniformity and stability.	Novelty, distinctness, uniformity and stability.	No mandatory requirements, but state must adopt some standard to identify eligible varieties.	No requirements for eligibility.
Protected material	Vegetative and reproductive propagating material; harvested	Vegetative and reproductive propagating material; harvested material	Material required to be protected by relevant UPOV Act.	No material required to be protected, but state must protect sufficient material	No material need be protected.

¹ See Table 1 for details of Acts

Required IPR obligations relating to plant varieties	Member of WTO & 1991 UPOV Act	Member of WTO & 1978 UPOV Act	Member of 1991 or 1978 UPOV Act only¹	Member of WTO only	Not a Member of WTO, UPOV or other IPR agreement
	material, under particular conditions.	for commercial use of ornamentals.		to grant breeders an IPR.	
National treatment and most favoured nation treatment	Applicable to all WTO Members.	Applicable to all WTO Members.	National treatment only to members of same UPOV Act; limited reciprocity under 1978 Act.	Applicable to all WTO Members.	State may deny protection to foreign breeders or protect only some foreign breeders.
Exclusive rights granted to plant breeders	All exclusive rights listed in article 14 of 1991 Act.	All exclusive rights listed in article 5 of 1978 Act.	All exclusive rights listed in relevant Act.	Not required if rights of remuneration granted.	No exclusive rights required to be granted to plant breeders.
Rights of remuneration granted to plant breeders	Not allowed as substitute for exclusive rights; allowed under compulsory licence of article 17 of 1991 Act.	Not allowed as substitute for exclusive rights; allowed under compulsory licence of article 9 of 1978 Act.	Not allowed as substitute for exclusive rights; allowed under compulsory licence rules of relevant Act.	Not required if exclusive rights granted.	No right of remuneration required to be granted to plant breeders.

Required IPR obligations relating to plant varieties	Member of WTO & 1991 UPOV Act	Member of WTO & 1978 UPOV Act	Member of 1991 or 1978 UPOV Act only¹	Member of WTO only	Not a Member of WTO, UPOV or other IPR agreement
Term of protection	20 and 25 year terms required by article 19 of 1991 Act.	15 and 18 year terms required by article 8 of 1978 Act.	Terms required by relevant UPOV Act.	No particular term required.	No particular term required.
Effective enforcement measures	Required.	Required.	Not required under either UPOV Act.	Required.	No enforcement measures required.
Exceptions and limitations	None required, but permitted only under conditions stated in article 15 of 1991 Act.	Mandatory breeders' exemption. Farmers' privilege permitted but not required.	Mandatory breeders' exemption under 1978 Act only. Other exceptions as permitted by relevant Act.	None required, but permitted in any form consistent with core elements of article 27.3(b).	None required.
Other requirements	Those imposed by 1991 Act.	Those imposed by 1978 Act.	Those imposed by relevant Act.	None.	None.

3.2.1. Cumulative treaty obligations

Table 3 reflects the well settled rule in international law that a state is bound by all of the international agreements to which it is a party, provided that the obligations in those agreements do not conflict with one another. Thus, for example, a state that is a party to a UPOV Act and also to the TRIPs Agreement must comply with its obligations under both treaties. Given that each treaty contains somewhat different but mostly cumulative and consistent rules concerning the protection of plant varieties, a state that is a party to both treaties will necessarily have more extensive obligations to protect plant varieties and thus will enjoy concomitantly less discretion.

3.2.2. Conflicting treaty obligations

Where the provisions of two treaties are in direct conflict, the rule is far less settled. If two agreements relate to the same subject matter and the states parties to both agreements are the same, article 30 of the Vienna Convention on the Law of Treaties specifies that the agreement that is later in time is given effect. The obligations in the TRIPs Agreement are thus likely to prevail over any conflicting obligations in the 1978 UPOV Act, such as the ban on protecting varieties within the same genus or species with both a breeders' right and a patent. (1978 Act, art. 2(1)) Because the 1991 Act entered into force in 1998 and TRIPs entered into force in 1995 (see paras. 2.2 and 2.3.1.5 above) it may be argued that the 1991 UPOV Act is the later-in-time agreement. However, it is unlikely that any conflicts issue will arise between the two treaties, inasmuch as nothing in TRIPs requires conduct that the 1991 UPOV Act forbids. (Such a conflict might arise, however, in the unlikely event that TRIPs were interpreted to impose more restrictive exclusions to breeders' exclusive rights than the mandatory exclusions found in article 15 of the 1991 UPOV Act.) It can therefore be argued that the two treaty systems are fully compatible, with TRIPs merely augmenting the plant variety protection requirements of the UPOV Acts.

3.3. Identifying the level of discretion available to states in each treaty classification

In general, the discretion a state enjoys in limiting the scope of intellectual property protection provided to plant varieties increases as one moves from left to right across Table 3.

3.3.1. WTO and UPOV 1991 Act members

States that are members of both TRIPs and the 1991 UPOV Act have the least discretion. This designation in Table 3 currently applies to 27 nations: Australia, Austria, Belarus, Bulgaria, Croatia, the Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Israel, Japan, Kyrgyzstan, Latvia, Lithuania, the Netherlands, Moldova, Poland, Romania, Singapore, Slovenia, South Korea, Sweden, Tunisia, the United Kingdom and the United States of America.

3.3.1.1. *Mandatory requirements*

These 27 states must extend protection to all plant varieties, comply with TRIPs' national MFN treatment obligations and adopt effective enforcement measures. (See para. 2.3.3.3 above) With regard to breeders' rights, these states must adopt all of the exclusive rights contained in article 14 of the 1991 Act and summarized in Table 1. The adoption of these rights – (1) production or reproduction, (2) conditioning for the purpose of propagation, (3) offering for sale, (4) selling or marketing, (5) exporting, (6) importing and (7) stocking for any of these purposes – fully satisfies their obligation under TRIPs to protect varieties with an IPR. Finally, states that have agreed to these dual obligations must also comply with all of the other provisions of the 1991 Act, including its terms of protection and limitations on the breeders' exemption and farmers' privilege.

3.3.1.2. *Options and implementation issues*

A state whose plant variety protection laws are already in compliance with the 1991 Act needs to take only limited steps to comply with article 27.3(b) of TRIPs, including immediate protection of all varieties and extension of national treatment to all WTO Members. The most difficult hurdle is likely to involve enacting effective mechanisms for plant breeders to enforce their rights. However, far more detailed enforcement measures must be adopted for the other forms of intellectual property protected by TRIPs. A state may therefore choose to extend to breeders the same domestic enforcement opportunities that it is required to provide to the owners of other IPRs.

3.3.1.3. *National implementation*

In information submitted to the TRIPs Council in May 1999, the following states indicated that they had adopted plant variety protection laws modeled on the 1991 Act: Australia, Bulgaria, Members of the European Communities, Japan, Morocco, Poland, Romania, South Korea, South Africa, Switzerland and the United States of America. (Other states parties to both UPOV 1991 and TRIPs did not submit information to the Council.) Of the states adopting such laws, Morocco, South Africa and Switzerland had not ratified the 1991 Act. (WTO Doc. IP/C/W/273, pp. 8 and 9)

3.3.1.4. *Bilateral IPR agreements and UPOV membership*

A separate issue concerns whether WTO Members will continue to join UPOV after the entry into force of the TRIPs Agreement. Some commentators predicted that UPOV membership would stagnate as states capitalized on the greater discretion provided to them under the *sui generis* option of article 27.3(b). (Leskien & Flitner, 1997, p. 31) Since TRIPs entered into force in 1995, however, 28 nations have become parties to the 1978 or 1991 UPOV Acts. (States Parties to the UPOV, Status on 30 June 2004) The continued expansion of UPOV membership can be traced in part to the recent proliferation of "TRIPs plus" treaties. (See para. 2.3.1.6 above)

3.3.2. WTO and UPOV 1978 Act members

This designation in Table 3 currently applies to 24 nations: Argentina, Bolivia, Brazil, Canada, Chile, China, Colombia, Ecuador, France, Ireland, Italy, Kenya, Mexico, New Zealand, Nicaragua, Norway, Panama, Paraguay, Portugal, Slovakia, South Africa, Switzerland, Trinidad and Tobago and Uruguay. States in this category enjoy somewhat greater discretion as a result of the more limited protection of plant breeders' rights contained in this earlier UPOV Act.

3.3.2.1. *Mandatory requirements*

States parties to both agreements must extend protection to all plant varieties, comply with TRIPs' national and MFN treatment rules and adopt effective enforcement measures. They must also comply with all of the other 1978 Act requirements, including its eligibility requirements,

terms of protection, exclusive rights and mandatory breeders' exemption. As compared to the 1991 Act, however, breeders' exclusive rights are more limited, terms of protection for varieties are shorter and exceptions and limitations are broader.

3.3.2.2. *Options and implementation issues*

States that become Members of the WTO after joining the 1978 UPOV Act and adopting laws to comply with that Act face a similar situation to states that are parties to both the WTO and the 1991 Act. To fully comply with TRIPs, these 1978 Act member states must modify their national laws to protect the four core requirements of article 27.3(b) and they must remove all provisions of their laws which impose a reciprocity requirement as a condition for protecting varieties of foreign breeders. In addition, states in this category may choose to modify their laws to incorporate some or all of the standards found in the 1991 Act without actually becoming a member of that Act. Their refusal to do so, however, does not violate article 27.3(b), inasmuch as the standards found in the 1978 Act satisfy their obligation to protect plant varieties with a *sui generis* IPR.

3.3.2.3. *Trends in national laws*

In information submitted to the TRIPs Council in May 1999, Canada, the Czech Republic, Hungary, Norway and New Zealand (the only states submitting information) indicated that they had adopted plant variety protection laws that complied with the 1978 Act. (WTO Doc. IP/C/W/273, pp. 8 and 9) At the time of these submissions, the Czech Republic and Hungary were members of the 1978 Act. They have since acceded to the 1991 Act.

3.3.3. 1991 or 1978 UPOV Act members only

There are few states outside of the WTO that protect plant varieties solely by virtue of being UPOV members. Only the Ukraine and Russia are currently in this category in Table 3, and both are observer governments with the WTO. These nations face a somewhat different set of international legal obligations.

3.3.3.1. *Mandatory requirements*

They must comply with all of the numerous requirements of the UPOV Act to which they are a party. However, they have no obligation to provide effective enforcement measures to breeders, their national treatment obligations are limited to those states that are members of the same UPOV Act and, in the case of those states bound by the 1978 Act, they need not protect all plant varieties and may impose certain reciprocity requirements on those varieties they do protect.

3.3.3.2. *Options and implementation issues*

Provided that their laws are in compliance with the relevant UPOV Act and unless they have ratified other international IPR agreements, these states need make no additional changes to their national plant variety protection laws.

3.3.4. Member of WTO only

States that are parties to the TRIPs Agreement but are not members of either UPOV Act enjoy considerably greater discretion than those that are members of either UPOV Act alone. By virtue of their adherence to TRIPs, these states are required only to comply with the four core obligations of article 27.3(b). This "WTO only" categorization in Table 3 currently applies to approximately 95 of the 147 Members of the WTO who are not also members of the UPOV (excluding, however, those countries that have ratified "TRIPs plus" treaties that require them to comply with one of the UPOV Acts). Given the large number of states in this category (and the additional number of states likely to enter this category if their efforts to join the WTO succeed), a more detailed discussion of the numerous options available to them in balancing protection of plant breeders' rights against the competing policy objectives is provided in section 3.4 below.

3.3.5. Not a Member of WTO, UPOV or other IPR agreements

Nations in this category have no obligation to protect plant varieties or breeders' rights in any form. Nevertheless, the mandatory requirements and discretionary choices facing other governments are likely to become matters of significant concern to these states as the world trading and intellectual property protection systems expand. Attention to IPR issues

will be of particular importance when these states implement the obligations of other international treaties to which they may be parties, such as the biodiversity goals of the CBD or the access requirements of the ITPGR. States in this category should consider whether it is sound policy to enact laws that are incompatible with TRIPs and the UPOV, since such an action will preclude their membership in these treaty systems unless they undertake a further revision of their national laws. In addition, unilateral actions by or bilateral agreements with industrialized nations may pressure these states to comply with international IPR standards even if they remain outside of the WTO or UPOV. For these reasons, states that are not yet Members of the WTO should give careful attention to the discretionary choices available to WTO Members analysed in the next section.

3.4. Discretionary choices available to "WTO only" Members

3.4.1. Introduction

This section identifies the options that states which are WTO Members (but are not a party to either of the UPOV Acts or to a "TRIPs plus" bilateral or regional agreement that requires UPOV-type protection, see para. 3.2) may adopt to tailor IPRs to the particularities of their national legal systems and economies. These mechanisms adjust the scope and content of IPRs to take into account the level of development of a nation's agricultural and breeding industries and its desire to balance IPR protection against the other important societal objectives identified in Part I. An overview of the various options that may be used to achieve these objectives is provided in Table 3 below.

3.4.1.1. *Established approaches to sui generis protection of plant varieties*

Once WTO Members adopt the four mandatory obligations of article 27.3(b), they are free to model their national laws protecting plant varieties and plant-related innovations on the 1991 UPOV Act, the 1978 UPOV Act, the patent provisions of TRIPs or some combination of these approaches. Each of these "established" approaches achieves, in different ways, the principal policy goal of the IPR system – the creation of adequate incentives for plant breeders to develop and market new varieties. Whether any of these established approaches is appropriate for a particular nation will depend on the needs of that nation's agricultural industry and farming sectors, its desire to encourage foreign investment

relating to plant breeding and biotechnology and its international trade objectives. These subjects are addressed in greater detail below.

3.4.1.2. *Alternative approaches to sui generis protection of plant varieties*

None of the "established" approaches to plant variety protection directly furthers the other policy objectives identified in section 1.3.6 above, such as encouraging biodiversity, promoting access to plant genetic resources on fair and equitable terms, recognizing farmers' rights or protecting the traditional knowledge of indigenous communities. WTO Members have sufficient discretion to achieve both sets of objectives, however, by deviating from strict adherence to a UPOV or a patent model and adopting instead alternative forms of legal protection tailored to the particular needs of their societies and economies. The sections below identify and discuss a number of these alternatives, including: (1) revising eligibility requirements; (2) imposing additional conditions on the grant of protection; and (3) modifying specific features of legal protection such as exclusive rights, protected material, terms or exceptions and limitations.

3.4.2. Revising eligibility requirements

As discussed in paragraph 2.2.1.2, the four eligibility requirements of the UPOV – novelty, distinctiveness, uniformity and stability – have been criticized as unnecessarily rigid, undervaluing plant genetic diversity and precluding IPR claims by traditional farmers as opposed to commercial breeders. WTO Members need not replicate these problems when designing their *sui generis* legal systems. On the contrary, they are free to improve upon each of the eligibility requirements.

For example, Members may provide protection to plant germplasm that is more heterogeneous than established plant varieties but is nevertheless sufficiently distinct to permit its identification. Extending protection to these heterogeneous varieties would enable farmers and indigenous communities to claim IPR protection in the landraces or plant varieties they have cultivated through traditional farming and breeding methods. (Leskien & Flitner, 1997, p. 53) Such protection would address demands for recognition of "farmers' rights" and "traditional knowledge" rights (paras. 1.3.6.2 and 1.3.6.3 above) by using IPRs to compensate farmers and local communities for preserving landraces and other traditional cultivated varieties and would provide them with an incentive to

continue their preservation activities. It would also prevent third parties (including breeders in other nations) from claiming exclusive rights in the varieties that farmers or indigenous communities have cultivated. It should be noted, however, that much of the plant-related knowledge possessed by these groups is unrelated to plant varieties as such, and thus demands for both sets of rights may not be fully satisfied by this approach.

A state that protects heterogeneous varieties may grant exclusive rights either to individuals who demonstrate their involvement in creating or maintaining the heterogeneous variety or to communities of farmers or indigenous populations. Under either option, states will need to develop a mechanism for distinguishing between two or more protected varieties, a task that may involve defining minimum genetic distances between varieties. (IPGRI, 1999, p. 16) And the choice of the latter option may be difficult, as recognition of group rights is a novel feature of intellectual property law and governments have only recently begun to consider how such rights might be structured. (Crucible Group, 2001, pp. 33–124; WIPO, 2001) Finally, protection of heterogeneous varieties creates greater potential for overlapping claims by breeders. It may therefore be advisable to narrow the exclusive rights or term of protection granted to such varieties to limit such conflicts.

3.4.2.1. *Altering eligibility requirements to promote genetic diversity*

States may also make more significant changes to UPOV's eligibility requirements as a means of enhancing plant genetic diversity. (See para. 1.3.6.1 above)

Distinctness and identifiability. To achieve greater genetic diversity, commentators have proposed a more flexible "distinctness and identifiability" standard which replaces UPOV's narrow focus on the specific physical properties of plant varieties with an assessment of the many different characteristics by which a particular variety may be identified. (Leskien & Flitner, 1997, p. 53)

Implementation options. A distinctness and identifiability standard permits states to encourage heterogeneity or polymorphism in non-relevant plant characteristics such as leaf shape or color. (IPGRI, 1999, p. 15) States are not, however, required to adopt this standard for all purposes. They may, for example, apply different eligibility standards to different varieties,

using UPOV-type criteria for varieties developed by classical breeding industries and more flexible criteria for more heterogeneous varieties. (Id., p. 17)

3.4.2.2. *Protection of discovered varieties*

Unlike members of the two UPOV Acts, WTO Members are not required to protect varieties that have merely been discovered. Whether such protection should be provided is a difficult question, however.

Benefits and costs of protection. On the one hand, the "discovery . . . of mutations or variants in a population of cultivated plants is a source of varieties of great economic importance for agriculture." (Crucible Group, 2001, p. 139) For this reason, it would benefit states' agricultural systems and food security in general to provide an incentive for both breeders and farmers to discover new varieties. On the other hand, the protection of discovered varieties invites abuse. For example, one empirical study has documented a pattern of breeders seeking protection in one state for the "discovery" of a landrace or other traditional variety that is generally known and cultivated in another state. (Plant Breeders Wrongs, 1999)

Implementation options. There are several options states may adopt to capture the benefits of protecting discovered varieties while avoiding potential abuses. For example, a state could bar protection for varieties "discovered in the wild" and thus focus protection of discoveries where it is needed most – on discoveries that must be evaluated and propagated before they can be commercially exploited. (Crucible Group, 2001, pp. 38 and 140) Alternatively, a state can define "prior art" for plants comprehensively and require a breeder to demonstrate that the variety in which it claims protection has not been used or known (even if not legally protected) in other states. Presumably, discovered varieties would not include varieties that are part of the "multilateral system" of plant genetic resources subject to regulation under the ITPGR. (See section 4.3 below)

3.4.3. Additional conditions on the grant of protection

In addition to the eligibility requirements imposed under the UPOV Acts, states may impose additional conditions upon the grant of protection as a means of implementing their obligations under the CBD. These conditions include a declaration of origin of the plant genetic

material in question and a requirement that the entity seeking protection have obtained the prior informed consent of the relevant country or community of origin. Such conditions further the CBD's obligation to promote fair and equitable sharing of benefits arising out of the utilization of those resources by third parties. As explained below, however, there are many unsettled questions associated with how these conditions would operate in practice.

3.4.3.1. *Declaration of origin of plant genetic material*

Under this option, a state would require breeders to submit a declaration that discloses the origin of the germplasm or other genetic material from which their new varieties are derived. (Leskien & Flitner, 1997, p. 56) The declaration could identify the country of origin, the local community of origin or both.

Providing such information will create a publicly accessible database of the geographic and genetic origins of legally protected varieties. Such a database provides a check against "biopiracy" by helping to identify breeders seeking protection of plant genetic material that is widely known or used in other jurisdictions or found in *ex situ* collections. (See para. 1.3.6.5 above) It may also facilitate the CBD's benefit sharing goal by providing information to governments or communities negotiating with private entities seeking protection over terms of access or compensation.

A declaration of origin requirement raises many implementation questions. First, it is often impossible to identify the source of genetic material with precision even using state of the art techniques. Such material may also be attributable to more than one country or local community. Moreover, even where identifying a variety's geographic origin is possible, the cost of documenting it may deter some breeders from seeking legal protection in that state or even from creating new varieties. From a practical perspective, a state would need to choose the methods used to verify the information in the declaration and, in addition, the sanctions to be imposed in the event of non-compliance. (Crucible Group 2001, pp. 158 and 159) Although most of these issues can be addressed, states may also achieve the CBD's objectives through other means, such as by adopting national access laws to regulate at the source the conditions under which private parties may access and use plant germplasm.

3.4.3.2. *Requiring prior informed consent*

A second way to promote the CBD's objectives is to require applicants for plant variety protection to demonstrate that they have obtained the prior informed consent of the country and/or community in which the germplasm originated. (Crucible Group, 2001, p. 159)

Unlike a declaration of origin condition, a prior informed consent requirement denies breeders legal protection for their innovations of plant genetic material in one state unless they have actually negotiated with the government or community in another state. It could thus become a mechanism for promoting benefit sharing relating to plant genetic resources. (Leskien & Flitner, 1997, p. 46)

Many of the same difficulties associated with a declaration of origin requirement also apply to prior informed consent. Theoretical issues include determining how far back the ancestry of a variety needs to be traced and whether to make the requirement retroactive. Practical issues include verification of information and enforcement. (Crucible Group, 2001, pp. 160 and 161) Here, too, national access laws provide a non-IPR method to achieve the same objectives. For example, access laws can require that the state or community in which plant genetic resources are located be compensated for its past efforts to preserve plant diversity by those seeking to develop such resources.

3.4.4. *Modifying exclusive rights, protected material, terms or exceptions and limitations*

Once a state chooses the eligibility requirements and conditions that determine which varieties may be protected under its national laws, it must then decide whether to modify the other elements of the *sui generis* breeders' right, including protected subject matter, exclusive rights, term of protection and exceptions and limitations to exclusive rights. Each of these elements is open to variation by WTO Members.

3.4.4.1. *Tailoring plant variety protection to a state's agricultural economy*

States with large-scale agriculture or plant breeding industries are likely to benefit by adopting relatively robust IPR protection, with a broad array of exclusive rights, an expansive list of protected material and relatively limited exceptions and limitations (with the possible exception of a

breeders' exemption, which breeders' advocacy groups have described as essential to promoting plant-related innovations). (FIS/ASSINSEL, 1999) Such strong protections will facilitate exports of harvested products, imports of propagating materials and investment by foreign firms. (IPGRI, 1999, p. 10)

States with agricultural systems that are domestically focused or rely upon the cultivation of traditional varieties by small-scale farmers face a different set of interests and incentives. Their populations are likely to prefer relatively weak IPR protection with a broad farmers' privilege that permits farmers to both save and exchange seeds. Protection that is too weak is not advisable, however, as it will discourage foreign breeders from importing seeds or other propagating material (which may be an important component of the nation's food supply) and may deter investment by foreign businesses or researchers for whom IPR protection is essential.

States with mixed agricultural economies may benefit from adopting different levels of protection tailored to the needs of their domestic industries. For example, they may adopt different standards of protection for commercial and noncommercial breeders, with higher standards for the former to compensate them for their investment of capital and distribution costs. They may also permit protection of the same variety with both a breeders' right and a patent (for example, in countries where both classical breeding methods and methods making use of genetic manipulation are prevalent). Conversely, such states may adopt different and exclusive standards for specific varieties. Strong IPR protection in the form of a patent may be used to encourage the creation of new ornamental and high-value export crops without harming domestic consumers, whereas breeders' rights may be used for other species where the state seeks to balance IPR protection against the interests of farmers. (IPGRI, 1999, pp. 6, 7 and 17)

3.4.4.2. *Additional options*

The following paragraphs discuss four additional options available to states seeking to create *sui generis* plant variety protection laws. It should be noted, however, that these options deviate substantially from established models of plant variety protection. They are thus likely to be compatible with TRIPs only if they are implemented with restraint in the manner described below.

Protecting varieties with a plant variety protection seal. One way to provide minimal legal protection to plant breeders while still complying with article 27.3(b) would be to grant breeders the exclusive right to advertise or market a variety using a seal or certificate issued by state authorities. Unlike the exclusive rights recognized under the UPOV Acts, which relate to particular uses of propagating and harvested material of a protected variety, a seal system would permit free use of such material and only require the right holder's authorization for its use together with the seal. (Leskien & Flitner 1997, p. 62) It would thus have the advantage of simplicity over the UPOV system, inasmuch as no specific exceptions or limitations would need to be recognized. In addition, because of the weaker rights that a seal provides, a state might choose to extend the terms of protection enjoyed by breeders. (Id.) However, it is uncertain whether a seal system would create sufficient incentives to breed new varieties. In markets where consumers place a premium on the quality and source of the seeds they purchase, protection of new varieties with a seal alone may provide adequate compensation to breeders. Where seed consumers are less concerned with these attributes and more focused on a variety's physical properties, a seal system would be ill-advised because consumers would be more likely to purchase seeds from any available source and less likely to pay a premium to breeders for the quality represented by seal-protected seeds.

Recognizing farmers' rights through a detailed farmers' privilege. A state seeking to recognize the concept of "farmers' rights" (see para. 1.3.6.2 above) can do so by enacting a broader or more detailed farmers' privilege than that found in either of the UPOV Acts. Unlike the protection of heterogeneous varieties cultivated by farmers (see para. 3.4.2 above), a farmers' privilege does not create incentives for farmers to preserve plant genetic diversity. It recognizes instead the claims of farmers to engage in traditional practices such as planting seeds saved from an earlier purchase, exchange of seeds and even limited sale of seeds to other farmers free from the costs and constraints that IPRs impose. However, an unduly broad farmers' exemption could significantly undermine a plant variety protection law by limiting breeders' exclusive rights over a market from which they derive a large portion of their revenue. One way to reconcile these competing interests would be to adopt a clear definition of which farmers are entitled to the privilege, with a strong preference given to small-scale farmers. According to one recent study, such farmers can be defined by reference to variables such as (1) the proportion of total yield used for personal consumption, (2) the number

of acres cultivated with a protected variety, (3) the number of harvested tonnes produced with the variety or (4) the number of harvested tonnes of all crops produced by the farmer. (Crucible Group, 2001, pp. 144 and 145)

Privileging use of varieties derived from germplasm of local origin. This privilege, which could take the form of either an exemption or a compulsory licence, would permit the residents of a state, without the permission of the right holder, to use plant varieties derived from germplasm collected in that state. The exemption provides a mechanism to realize the CBD's objective of fair and equitable sharing of benefits arising from the utilization of plant genetic resources. It achieves this objective by limiting breeders' rights in those territories that provided the raw genetic materials upon which improvements were based. There are several difficulties with this "local origin" privilege, however. First, the exemption may hurt the domestic breeding industry in states where breeders collect germplasm locally. (Crucible Group, 2001, pp. 171 and 72) For this reason, a state may be tempted to apply the local origin exemption only to foreign breeders. However, such a limitation would clearly violate the national treatment rule and thus be incompatible with the core obligations of TRIPs article 27.3(b).

Exempting customary uses of plant varieties. Another way to recognize the rights of indigenous communities would be to privilege their customary uses of plant varieties, an ambiguous term that could be defined to include uses that indigenous communities have traditionally and regularly engaged in as part of their agricultural or cultural practices. (Crucible Group, 2001, p. 168) Such an exemption would likely be compatible with article 27.3(b) only if the state defined with precision the types of customary uses permitted under its laws and provided equitable remuneration to breeders in the event that the exemption were especially broad. Leaving this concept undefined would invite abuses, particularly in states that also choose to adopt minimal procedures for breeders to enforce their rights.

Table 4 below illustrates many of the options available to "WTO only" states to achieve the societal objectives discussed in the preceding sections. It divides the options into three categories: (1) those consistent with established approaches to plant variety protection under patent or UPOV-type laws; (2) those that could be adopted under alternative approaches to plant variety protection that are nevertheless TRIPs-compatible; and (3) options at the margins of compatibility with TRIPs.

Table 4 - Achieving societal objectives under different *sui generis* systems

Societal objectives	How objectives achieved in "established" patent or UPOV-type plant variety protection laws compatible with TRIPs	How objectives achieved in "alternative" plant variety protection laws compatible with TRIPs	How objectives achieved using options for plant variety protection at the margins of compatibility with TRIPs
Protecting farmers' rights	1. Limited farmers' exemption. 2. Protection of discovered varieties.	1. Protection of heterogeneous varieties. 2. Protection of discovered varieties.	1. Detailed farmers' privilege. 2. Plant variety protection seal system.
Promoting biodiversity	Exclusive rights create incentives for breeders to invent new varieties.	1. Distinctness and identifiability. 2. Protection of heterogeneous varieties.	Local origin exemption or compulsory licence.
Preventing "biopiracy"	Expanding definition of prior art.	1. Expanding definition of prior art. 2. Declaration of origin. 3. Prior informed consent.	No options available that are at the margins of compatibility with TRIPs.

Societal objectives	How objectives achieved in "established" patent or UPOV-type plant variety protection laws compatible with TRIPs	How objectives achieved in "alternative" plant variety protection laws compatible with TRIPs	How objectives achieved using options for plant variety protection at the margins of compatibility with TRIPs
Protecting traditional knowledge & rights of indigenous communities	Not achieved unless knowledge or rights satisfy established criteria for protection as IPRs.	1. Distinctness and identifiability. 2. Protection of heterogeneous varieties.	Exempting customary uses of plant varieties.
Equitable sharing of benefits	Not achieved through IPR legislation.	1. Declaration of origin. 2. Prior informed consent.	Local origin exemption or compulsory licence.

3.5. Current trends in national laws

Although the foregoing sections have identified numerous options for "WTO only" states, thus far only a few states have chosen to exercise the discretion granted to them under the TRIPs Agreement to adopt national plant variety protection laws that do not follow one of the two UPOV Acts. Indeed, information submitted by UPOV to the TRIPs Council suggests that the number of states likely to adopt plant variety protection laws based on one of the two UPOV Acts may soon approach one hundred. (IP/C/W/305/Add. 4, 2001; see also GRAIN, 2004a (collecting texts of national plant variety protection laws))

3.5.1. Alternative plant variety protection laws

A plant variety protection law in India (the Protection of Plant Varieties and Farmer's Rights Act) provides a notable counterexample to this trend of following UPOV standards. That legislation seeks to implement both breeders' rights and farmers' rights by recognizing the concept of farmers' rights and by allowing farmers to register the varieties they cultivate. The Act also contains benefit sharing provisions that allow individuals and communities to claim compensation for their contributions to plant genetic diversity. It provides for meaningful representation of farmers in the National Biodiversity Authority. Finally, a section of a bill to amend the Indian Patents Act requires inventors to disclose the source and geographical origin of biological material used in their inventions. (Collet, 2001, pp. 219–222) Other proposed laws that deviate from strict adherence to UPOV include bills in Bangladesh, Nicaragua, Thailand and Zambia (GRAIN, 1998, p. 5; GRAIN, 1999, pp. 2–7), and a model law drafted by the Organization of African Unity which covers not only breeders' rights but also farmers' rights, benefit sharing and access to genetic resources. (African Model Legislation, 1998)

3.5.2. Failure to enact plant variety protection laws

The most notable current trend, however, is the large number of WTO Members that have not enacted *any* plant variety protection laws notwithstanding the 2000 deadline for developing nations to implement such laws. According to a May 2000 study, 80 percent of African countries, 80 percent of countries in the Asia-Pacific region and 56 percent of Latin American and Caribbean states which should have implemented TRIPs article 27.3(b) by 2000 had not done so. (GRAIN,

2000, pp. 5 and 6) This failure can be attributed to the controversial nature of article 27.3(b) and the fact that the article was scheduled to be reviewed in 1999 one year *prior* to the 2000 implementation deadline. The pace of implementation is likely to be affected by how WTO Members address the scope of plant variety protection as part of the Doha Round of trade negotiations that commenced in November 2001. (See Part IV below).

3.6. Understanding the limitations of *sui generis* IPR systems

Although non-IPR societal objectives can be incorporated into *sui generis* plant variety protection laws, such an approach is likely to be insufficient in itself to achieve these objectives. States seeking to achieve these objectives may therefore turn to other legal approaches, such as access regulations, seed laws and biodiversity legislation. (Correa, 1998, pp. 9 and 10) Governments are free to enact such laws, provided that the laws do not conflict with the requirements of any international IPR agreements to which they are a party. As explained in the next section, however, recent developments raise the possibility that international agreements may evolve in ways that limit states' discretion to adopt such laws or to give effect to non-IPR objectives.

4. PART IV – FUTURE REVISIONS OF INTERNATIONAL IPR AGREEMENTS AFFECTING THE PROTECTION OF PLANT VARIETIES: THE WTO DOHA ROUND AND THE ITPGR

4.1. Introduction

The international legal system regulating IPRs in plant varieties and plant genetic resources may be on the cusp of significant change. The sources of this change are twofold. First, in November 2001 the WTO membership agreed to a new round of multi-year trade negotiations which will include a review of the plant-related IPR obligations in the TRIPs Agreement. Second, in the same month, the FAO Conference adopted a new International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). For governments considering the propriety and scope of IPR protection for plant varieties and plant breeders, both of these events merit significant attention. Within the

WTO, states will revisit TRIPs article 27.3(b) and will consider whether to broaden or narrow it and whether to harmonize diverse and sometimes conflicting international and national approaches. The ITPGR, by contrast, seeks to establish a system of access to plant genetic resources and to further many of the other societal objectives discussed in section 1.3.6 above. In doing so, however, it attempts to limit the types of plant genetic materials that may be protected as intellectual property.

4.2. The WTO Doha Round of trade negotiations

On 14 November 2001, trade ministers from the WTO's then 142 Members meeting in Doha, Qatar agreed upon the text of several official declarations to serve as the framework for a new round of trade negotiations. These declarations do not expressly address the issue of plant variety protection. They do, however, suggest that the WTO will conduct an expansive review of the relationship between IPRs in plants and competing policy objectives as it considers whether and in what ways to revise the current text of the TRIPs Agreement.

4.2.1. Trade tensions between industrialized and developing nations

After the widely publicized failure of the WTO meetings held in Seattle, Washington in December 1999, industrialized countries were eager to commence a new round of trade negotiations to address the many issues that had arisen since the conclusion of the Uruguay Round of trade talks in 1994. Developing nations, however, had become resistant to many aspects of the international trading system and would consider negotiating new trade obligations only if they received substantial concessions to achieve their interests. According to one recent commentary, during the last two years "developing countries in general were more coordinated and outspoken, and better informed than in the past" (CIDSE, 2002, p. 2), and thus were in a more favourable position to bargain for these concessions. This coordination has continued during the Doha Round, as reflected, for example, in the creation of the "Group of 21" (or "G21") developing country governments with common negotiating positions. (WTO Under Fire, pp. 26–28)

4.2.2. Disagreements over the scope of review of article 27.3(b)

In the area of plant variety protection, the debate between developed and developing nations during the period between Seattle and Doha centred on the scope of review of article 27.3(b). The United States and Japan sought to limit that review to measures WTO Members had adopted to implement their obligations under that article, with the UPOV 1991 Act serving as a preferred benchmark for determining whether a *sui generis* system protecting plant varieties was effective. (IP/C/W/162, 1999; IP/C/W/236, 2000) Developing countries, led by India, Brazil and African states, sought a far more expansive approach to the review process. In their view, the review of article 27.3(b) presented an opportunity to revisit whether plants and other life forms should ever be protected by an IPR. Even where IPR protection was appropriate, developing nations saw the review process as a means to harmonize TRIPs with the CBD and the Undertaking in order to promote biodiversity, recognize farmers' rights and protect traditional knowledge and the rights of indigenous communities. (IP/C/W/228, 2000; IP/C/W/206, 2000; IP/C/W/161, 1999) European governments adopted a stance between these two polar perspectives, arguing that harmonization could be achieved not by revisions to article 27.3(b) but rather through national laws seeking to implement international treaty obligations. (IP/C/W/254, 2001)

4.2.3. Provisions of the Doha declarations relating to Article 27.3(b)

A review of the declarations agreed to in Doha suggests that the position of developing countries regarding the scope of review of article 27.3(b) has largely prevailed. (See para. 4.2.2 above, discussing competing proposals by WTO Members relating to article 27.3(b))

Paragraph 19 of the Ministerial Declaration directs the TRIPs Council, in conducting its review of that article, to examine:

inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension. (WT/MIN(01)/DEC/W/1)

Although this paragraph in no way predetermines the outcome of the TRIPs review process, it expressly authorizes Members to raise not only implementation or technical issues relating to IPRs in plant varieties, but also more fundamental questions concerning the appropriate scope of protection in light of other competing societal objectives and international obligations. (IP/C/W/404, 2003) The reference to the objectives and principles in articles 7 and 8 is also telling. Article 7 emphasizes that the protection and enforcement of IPRs "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . . in a manner conducive to social and economic welfare and to a balance of rights and obligations." Similarly, article 8 permits Members to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. . . ." The reference to these articles reaffirms that TRIPs is to be interpreted to permit its Members to adopt balanced systems of intellectual property protection. Two additional provisions offer further evidence that WTO ministers intended the article 27.3(b) review process to be a broad one.

First, paragraph 31 of the Ministerial Declaration contains a significantly narrower mandate for harmonizing Members' trade and environment obligations than the paragraph relating to the review of TRIPs. Paragraph 31 calls for negotiations limited to "the relationship between *existing* WTO rules and *specific trade obligations* set out in multilateral environmental agreements" while preserving the rights of WTO Members that are not parties to the treaty in question. (emphasis added)

Second, the trade ministers adopted a separate "Declaration on the TRIPs Agreement and Public Health" to address the HIV crisis in developing nations unable to afford access to medicines. The declaration stated that the TRIPs Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." It also reaffirmed "the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose." (WT/MIN(01)/DEC/W/2, para. 4)

4.2.4. Balancing IPRs and other objectives: mandatory or permissive policy options in a revised TRIPs Agreement

Taken together, the foregoing provisions suggest that the Doha Round of trade negotiations has opened a window of opportunity for states seeking to balance the protection of plant breeders' rights against other societal objectives. (See GRAIN, 2003, which discusses whether the review of TRIPs is "at a turning point".)

In achieving such a balance, the full spectrum of options discussed in section 3.4 on *sui generis* systems of protection are available as potential policy tools. To take just one example, Members might require every applicant seeking a patent or protection of a new plant variety to disclose the origin of plant genetic material upon which the invention or variety was based, or to demonstrate that the material was acquired with the prior informed consent of the country or community of origin. (See para. 3.4.3 above) These or other options could be adopted on either a mandatory or a permissive basis. Under a mandatory approach, TRIPs would be amended to require all WTO Members to change their IPR laws to include such policy-balancing provisions. Under a permissive approach, TRIPs would be amended to clarify that individual Members may implement such provisions without violating the treaty. (See WTO Doc. IP/C/W/420, 2004, listing a "checklist of issues" on the relationship between TRIPs and the CBD.)

The mandatory option would create a harmonized international solution, but one that would be extremely difficult to negotiate. In the case of disclosure or prior informed consent requirements, for example, it would have the effect of obliging one WTO Member (the state in which IPR protection was sought) to protect rights of another WTO Member (the country of origin of genetic material) that have no relation to the protection of intellectual property rights or intellectual property products. An approach that requires an intellectual property agreement to protect non-IPR interests (such as the interest in receiving compensation for preserving plant genetic diversity) has no historical precedent in the international intellectual property system and thus its adoption within TRIPs would require a significant revision of the treaty.

The permissive option has the advantage of granting governments the discretion to tailor their national laws to domestic policy objectives without fearing that those laws will then be challenged under the WTO

dispute settlement system. However, because this approach allows any Member to decline to implement the policy-balancing mechanisms, it would not provide a comprehensive international solution to the problems presented.

Whether WTO Members adopt a mandatory or permissive approach will depend not only upon the TRIPs Council's review of the provisions of article 27.3(b) relating to plant genetic resources, but also upon political compromises among WTO Members over trade issues wholly unrelated to IPRs (such as restrictions on trade in textiles). In the case of plant-related innovations, the options chosen may also depend upon the obligations imposed by other international agreements, including the ITPGR.

4.3. International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGR").

4.3.1. Overview and basic objectives

On 3 November 2001, a conference of 120 government delegates concluded seven years of negotiations and adopted the text of a binding international agreement on access to plant genetic resources. (See Mekouar 2002, p. 3) The ITPGR's principal aim is to facilitate the exchange of seeds and other germplasm to be used for research, breeding and crop development. The treaty promotes this exchange by establishing a "multilateral system" to which member states and their nationals will be granted "facilitated access." In essence, the multilateral system is a communal seed treasury composed of 35 food and 29 feed crops now held by governments (both *in situ* on public lands and *ex situ* in national seed banks) and by the CGIAR in its extensive *ex situ* seed collections. In exchange for access to this common seed pool, those who create commercial products that incorporate plant genetic resources received from the multilateral system must pay a percentage of their profits into a fund to be administered by the treaty's Governing Body. That fund will be used to promote conservation and sustainable use of plant genetic resources, particularly by farmers and indigenous communities, whose rights and contributions to genetic diversity the ITPGR expressly recognizes. (Id., pp. 5–10)

4.3.2. Intellectual property provisions of the ITPGR

As the above overview illustrates, the ITPGR seeks to achieve many of the policy objectives discussed in section 1.3.6 above. Because the treaty is founded upon open access to plant genetic resources, it is necessarily in tension with any legal system that grants exclusive rights over those same resources. The treaty's drafters were well aware of this tension, and IPRs were one of the most contentious issues during the seven years of treaty negotiations. On the one hand, the drafters recognized that the treaty could not function unless private parties were permitted to create and then commercialize derivative products using raw genetic materials acquired from the multilateral system. Only through such commercialization would sufficient revenue be generated to fund the treaty's benefit sharing, conservation and sustainable use objectives. On the other hand, the multilateral system itself would be threatened if its component parts could be privatized through the grant of IPRs. (Helfer, 2004, pp. 40 and 41)

4.3.2.1. *Debate over the patenting of isolated and purified genes*

The fulcrum of the debate quickly focused on whether the treaty would bar the patenting of isolated and purified genes extracted from germplasm placed in the common seed pool. Reasserting the positions they had adopted in the WTO, the United States and Japan argued against such a ban, most developing nations argued in favour of it and European countries sought to broker a compromise.

4.3.2.2. *Article 12.3(d)*

The final text of the ITPGR reflects the views of the overwhelming majority of governments at the FAO Conference. In particular, article 12.3(d) states that facilitated access to the plant genetic resources contained in the multilateral system will only be provided on condition that:

Recipients shall not claim any intellectual property or other rights that limit the facilitated access to plant genetic resources for food and agriculture, *or their genetic parts or components, in the form* received from the multilateral system. (emphasis added)

Not only will this provision bind states parties to the ITPGR, but it will also be included in standardized Material Transfer Agreements that all private parties seeking access to the multilateral system must execute. (art. 12.4)

4.3.2.3. *The drafting of Article 12.3(d)*

Understanding the final stages of the ITPGR's drafting history is essential to deciphering the meaning of article 12.3(d). The two highlighted phrases – "or their genetic parts or components" and "in the form" – were included as separate bracketed texts going into the final round of negotiations. Developing states opposing IPR protection sought to retain the first clause and delete the second, whereas the United States wanted the first phrase deleted and the second retained. In the end, both clauses were retained after the United States lost, by a 97 to 10 margin, a vote to have article 12.3(d) deleted from the treaty. The entire treaty was then adopted by a vote of 116 in favour, zero against and two abstentions by Japan and the United States. (Earth Negotiations Bulletin, 2001, p. 8)

4.3.2.4. *The meaning of Article 12.3(d)*

As adopted, article 12.3(d) reflects an uneasy compromise between governments with opposing positions. The critical question is whether the act of extracting a gene from a seed is, in itself, a sufficient alteration of the seed's genetic material such that the extracted genetic product is no longer "in the form" received from the multilateral system. According to one view, the article's ban on IPRs extends only to raw germplasm, not to individual genes or DNA fragments that are isolated and purified and thus altered from their natural state. Other commentators have argued for a more expansive interpretation, asserting that the article permits "breeders to take exchanged germplasm, extract commercial genes, insert them into other plant varieties, and claim a patent either *on the new variety* or on the extracted genes *as adapted to the new varieties.*" (Law of the Seed 2001, p. 4 (emphasis added)) According to this view, the original plant material, including its genetic components, would remain within the multilateral system free for others to use and exploit.

Neither textual interpretation nor national jurisprudence is likely to resolve this debate. Rather, following the ITPGR's entry into force in June 2004, its Governing Body now has an opportunity to clarify article

12.3(d) in light of the treaty's goal of facilitating access to plant genetic materials for specified purposes. In interpreting article 12.3(d), the Governing Body may seek advice from WIPO or the TRIPs Council. Alternatively, a dispute over the proper interpretation of the provision may be submitted to arbitration or to the International Court of Justice, provided however that the states concerned have accepted one of those two methods of dispute settlement. (ITPGR, art. 22) Whether the Governing Body will seek to harmonize the interpretation of the ITPGR with the work of other intergovernmental organizations such as WIPO and the WTO is at this point uncertain and raises broader questions of how international institutions compete or cooperate in the creation of new legal norms. (Mosoti, 2004).

4.3.3. The relationship between the ITPGR and TRIPs

Regardless of which interpretation of article 12.3(d) the Governing Body ultimately adopts, the ITPGR creates the potential for conflicts with TRIPs, "TRIPs plus" treaties and national IPR laws. The next section reviews the provisions of the ITPGR that address its relationship with other international agreements and then identifies the potential conflicts that may arise, both with the current text of TRIPs and in the context of possible revisions that may be adopted during the Doha Round.

4.3.3.1. *Treaty relationship clauses in the ITPGR*

The drafters were deliberately ambiguous as to the ITPGR's relationship with other treaties. The drafters intended that all international agreements affecting plant genetic resources "should be mutually supportive" (Preamble, para. 9), but they consciously avoided adopting any statements to address conflicts with other treaties. To the contrary, the drafters consciously avoided conflict, stating that nothing in the ITPGR "shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements" or as "creat[ing] a hierarchy between this Treaty and other international agreements." (Id., paras. 10 and 11) Although similarly ambiguous statements appear in environmental law agreements, they have yet to be tested in a dispute before the WTO or other international tribunal.

4.3.3.2. *Potential conflicts between the ITPGR and TRIPs*

There are two potential areas of conflict between the ITPGR and TRIPs: article 12.3(d) and the ITPGR's benefit sharing clause. Neither provision currently conflicts with TRIPs, since WTO Members may at present entirely exclude plants and plant varieties from patentability. Article 12.3(d) would, however, conflict with those "TRIPs plus" treaties that require developing countries to recognize such patents and with national IPR laws in industrialized countries that treat isolated and purified genes as patentable inventions. (See GRAIN, 2001, at 2 and 3 (identifying patent protection for plant varieties as a "TRIPs plus" standard and listing bilateral treaties that require developing countries to grant such protection.)) In addition, if WTO Members agree during the Doha Round to amend TRIPs to require patent protection for plants or plant varieties, then a conflict would arise for states parties to both agreements.

A conflict with article 12.3(d) is especially likely for states, including in particular industrialized countries, that award patents to inventors who have isolated plant genes from nature. The expansive reading of article 12.3(d) identified above is in tension with the national patent laws of such states, which grant patents to plant genetic material that has been isolated by human intervention or produced by means of a technical process. Ratification of the ITPGR would impose an obligation on these countries to refrain from granting patents in genes isolated from seeds or other germplasm received from the multilateral system. To give effect to this obligation, such states would need to amend their national patent laws to deny protection to genes isolated from such materials.

The conflict with the ITPGR's benefit sharing provisions arises from the fact that those who commercialize a product developed from genetic resources obtained from the multilateral system must pay "an equitable share of the benefits arising from the commercialization of that product." (art. 13.2(d)(ii)) This imposes an obligation in connection with biotechnology patents that is not imposed with other types of patents. For that reason, it may conflict with TRIPs article 27.1, which requires Members to make "patents . . . available and patent rights enjoyable without discrimination as to . . . the field of technology . . ." Whether such a disparate benefit sharing rule in fact conflicts with TRIPs is uncertain, however, given the decision in *Canada – Patent Protection of Pharmaceutical Products (Generic Medicines)*. In that case, a WTO dispute

settlement panel rejected the claim that a facially neutral provision of Canada's patent statute which in practice applied only to pharmaceutical patents violated TRIPs' patent non-discrimination rule in article 27.1. (WT/DS114/R) (17 March 2000). The panel expressly refused to decide whether "measures that are limited to a particular area of technology . . . are necessarily 'discriminatory' by virtue of that fact alone, or whether under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question." (Id., para. 7.105 and No.439)

A second response to the argument that the ITPGR's benefit sharing provisions violate TRIPs article 27.1 is that the TRIPs Agreement nowhere prohibits WTO Members from imposing fees or levies associated with the holding of patent rights, such as those routinely imposed by national intellectual property offices. (Lettington, 2001, p. 11) It is unclear, however, whether TRIPs requires that such fees or levies be substantially equivalent for all categories of patents.

4.3.3.3. *Harmonizing the ITPGR with a revised TRIPs Agreement?*

In an effort to avoid the potential conflicts discussed above, there is likely to be significant interaction between the government officials negotiating in the WTO's TRIPs Council and those working with the ITPGR's Governing Body. This is particularly so given the WTO ministers' broad instruction to the TRIPs Council to consider any "relevant new developments raised by Members" when reviewing the patent and plant variety protection provisions of TRIPs article 27.3(b). (See para. 4.2.3 above) However, because any agreement reached during the Doha Round of trade negotiations will incorporate numerous issues unrelated to plant genetic resources, it is difficult to predict the final form that such an agreement will take.

PART V – CONCLUSION

This study provides a comprehensive overview of the international intellectual property system regulating plant varieties and the rights of plant breeders. It identifies the essential features of this system, including the policies supporting the grant of intellectual property rights (IPRs), the societal objectives in tension with IPRs, the institutions that have shaped the international intellectual property system and the basic components contained in the relevant international treaties. The study explains in particular the different forms of legal protection required by international IPR agreements, including the system of plant breeders' rights in the 1978 and 1991 UPOV Acts, the choice between patent and *sui generis* protection created by article 27.3(b) of the TRIPs Agreement and the impact of so-called "TRIPs plus" bilateral and regional treaties.

This study is directed in particular to national governments considering how to protect plant varieties. It analyses the alternatives available to a state depending upon the different IPR treaties it has ratified. Each of these treaties grants national governments a different level of discretion to choose how to protect plant varieties as a form of intellectual property. Once a government has consulted this study to determine the degree of discretion it enjoys as a result of its treaty ratifications, it can then review those portions of the study that identify the mechanisms that it may adopt, consistent with its international obligations, to balance the protection of IPRs against other societal objectives. These objectives include encouraging biodiversity, facilitating access to plant genetic resources, recognizing farmers' rights, promoting the equitable sharing of benefits and protecting the traditional knowledge of indigenous communities.

Finally, the study explains the ways in which the international intellectual property system is on the cusp of significant change. The degree of discretion that governments currently enjoy in this area may diminish significantly depending upon the outcome of negotiations currently under way in the WTO and likely to commence now that the ITPGR has entered into force. Governments interested in retaining discretion would be advised to monitor and participate in these negotiations, with a view to harmonizing their international obligations, thereby avoiding the necessity of turning to international tribunals to settle their disputes.

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