DEFINING THE ROLE AND SCOPE OF I.P.R. IN THE RELAM OF ENVIRONMENTAL GOVERNANCE IN INDIA:

SUI GENERIS PROTECTION OF PLANT GENETIC RESOURCES

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The authors of this paper seek to examine the interplay of Intellectual Property Rights with protection of plant genetic resources both in the international and national perspective. It is our endeavor to reconcile the disparate agreements and conventions with the domestic legislations while seeking to explain the mode of ownership of such resources, thereby involving issues of governance. Newly proposed community IPR's and Material Transfer Agreements (MTAs) are evaluated, concluding with an analysis of what direction our national legislation could head in. This is especially relevant taking into consideration the dual, but not necessarily conflicting, needs of development and protection.

The paper proceeds with the following line of thought:

In the words of Indira Gandhi,

> "*The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.*" [1]

Introduction

In recent years, the international community has developed an impressive--if sometimes disorienting--array of new international instruments and initiatives focused on the connections between agriculture, food safety, and the environment. In some cases, the new legal frameworks are designed to keep up with issues presented by new technologies, such as genetic engineering.[2] In other

[1] Gandhi's quote was taken from a speech given to the 1982 World Health Assembly. R. Michael Gadbaw & Leigh A. Kenny, India, in Intellectual Property Rights: Global Consensus, Global Conflict? 186, 186 (R. Michael Gadbaw & Timothy J. Richards eds., 1988), cited in Robert Gutowski, The Marriage of Intellectual Property and International Trade in TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?, 47 Buff. L. Rev. 713, 744 (1999); see also Gary P. Nabhan, Sharing the Benefits of Plant Resources and Indigenous Scientific Knowledge, in Valuing Local Knowledge: Indigenous People and Intellectual Property Rights 186, 191 (Stephen B. Brush & Doreen Stabinsky eds., 1996).

[2] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027, available at http:// www.biodiv.org/biosafety/protocol.asp (last visited July 13, 2008) [hereinafter Cartagena Protocol], for example, focuses on issues presented by "living modified organisms" (LMOs) created through modern biotechnology. International Plant Protection Convention, opened for signature Dec. 6, 1951, 23 U.S.T. 2767, 150 U.N.T.S. 67, available at http://www.fao.org/Legal/TREATIES/004t2-e.htm [hereinafter IPPC], also has taken action recently on LMO-related matters.

cases, they reflect new perspectives on age-old problems.[3]

From this mixture, a new vocabulary has emerged. Today, major topics of international work include "agricultural biodiversity," "access- and benefit-sharing," "biosafety," and "Biosecurity." In keeping with notions of "sustainable development," debates at the international level blend economic, developmental, and environmental considerations. Policymakers in the fields of agriculture and environment must not only work with one another, but also learn the rules of the trading system and of intellectual property rights, as well as the implications for their work of the "process" we call "globalization."

Recent studies highlight the complex inter-relationships among legal regimes and institutional responsibilities in one of these areas, plant genetic resources.[4] Plant genetic resources are understood to be genetic materials of plant origin that are capable of self-reproducing; materials which may have been discovered as well as those which are yet to be discovered.[5] In fact, plant genetic resources take on a double nature: as phenotypes (individual plants) they constitute private, tangible goods; as genotypes (information embodied in the genetic makeup of a plant) they constitute a public good.[6]

An important lesson needs to be highlighted: Different legal instruments present

[3] United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, available at http://www.biodiv.org/doc/legal/cbd-en.pdf (last visited July 13, 2004) [hereinafter CBD], for example, frames environment and development issues through the perspective of the biological diversity of life on earth, viewed at the genetic, species and ecosystem levels.

[4] See Kal Raustalia & David G. Victor, The Regime Complex for Plant Genetic Resources (May 2003), available at http://iis-db.stanford.edu/pubs/20190/pgr_regime_complex.pdf (last visited July 12, 2004); see also Michel Petit et al., Why Governments Can't Make Policy: The Case of Plant Genetic Resources in the International Arena (2001), available at http:// www.cipotato.org/market/whygov/WhyGov_2001.pdf (last visited July 12, 2004).

[5] Organization For Economic Co-operation and Development, Intellectual Property, Technology Transfer, and Genetic Resources: An OECD Survey of Current Practices and Policies 12 (1996) [hereinafter OECD].

[6] See Joseph Straus, Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions, 9 Duke J. Comp. & Int'l L. 91, 104 (1998).

contrasting points of emphasis, on related topics.[7] One reason for this relates to the negotiating dynamics of individual instruments: which Ministry leads, who is involved, what precedents are already in place, the relevant rules of procedure, and participation. Instruments negotiated under the auspices of the Food and Agriculture Organization of the United Nations (FAO), for example,may come out differently than those negotiated under the United Nations Environmental Program (UNEP) or the World Trade Organization (WTO). So, while policy integration remains an embracing theme of sustainable development, it must be viewed through the reality of multiple forums addressing overlapping sets of issues.

Intellectual property issues are becoming increasingly important in the international sphere. These issues interact with environmental law in many ways. With the development of biotechnology, one particular point of convergence between intellectual property (IP) and environmental policy is plant genetic resources (PGRs). This Article explores the conflicts that have arisen over control of PGRs in recent years, drawing upon theoretical frameworks from both international relations and property to understand what has occurred in the past, to sketch what may occur in the future, and to suggest how the international regime could develop in a stable, sustainable, and mutually beneficial way.

PGRs consist of "seeds, plants, and plant parts useful in crop breeding, research, or conservation for their genetic attributes."[8] PGRs are divided into "raw" (in their natural state) and "worked" (altered by

[7] Issues relating to intellectual property rights and access(-) and benefit-sharing, for example, are addressed simultaneously in CBD, supra note 2; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 81 [hereinafter TRIPS agreements]; the International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, available at ftp:// ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf (last visited July 12, 2004) [hereinafter International Treaty]; and the World Intellectual Property Organization, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, http://www.wipo.int/tk/en/ (last visited Sept. 29, 2004).

[8] Cary Fowler & Toby Hodgkin, Plant Genetic Resources for Food and Agriculture: Assessing Global Availability, 29 Ann. Rev. Env't & Resources 143, 147-48 (2004).

deliberate human intervention) resources,[9] although the distinction can be difficult to discern in the context of agriculture. Because breeding and research of plants may be conducted for the purposes of enhancing food and agricultural products, as well as developing industrial raw material (rubber), clothing (cotton), and medicine, PGRs "encompass an unidentified range of activities."[10]

Both states and private actors have important interests in having easy access to PGRs. Intellectual property rights (IPRs) can affect this access, and thus PGRs have become a point of contention in international relations. States' principal concern with these IPRs is the need for access to repositories of PGRs to ensure food security for their populations. New crop varieties are often based on seeds from various countries. Therefore, it may be necessary to look abroad for plant resource stock that is resistant to new diseases or environmental problems.[11] When doing this, researchers prefer to obtain samples from a national or international ex situ collection, because such accessions are usually accompanied by integral information. In fact, most food crops originally come from PGRs developed in other countries. This is particularly the case in the developed world. Private interests, like corporations, also want access to PGRs in order to improve existing plant varieties and develop commercial products, such as pharmaceuticals.[12] Often, PGRs are analyzed in a laboratory so that patentable

[9] Kal Raustiala & David G. Victor, The Regime Complex for Plant Genetic Resources, 58 Int'l Org. 277, 279 (2004).

[10] Gregory Rose, International Law of Sustainable Agriculture in the 21st Century: The International Treaty on Plant Genetic Resources for Food and Agriculture, 15 Geo. Int'l Envtl. L. Rev. 583, 585-86 (2003).

[11] Gerald Moore & Michael Halewood, System-wide Genetic Resources Programme, Developing Access and Benefit-Sharing Regimes: Plant Genetic Resources for Food and Agriculture 2 (2005), http://www.ipgri.cgiar.org/policy/ABS_brief.pdf.

[12] Bellagio Group, Genetic Resources: Promoting Poverty Alleviation, Food Security, and Resource Conservation: Strategies for Achieving Balanced National Policies on Genetic Resources, at v (2004), http:/www.ipgri.cgiar.org/Programmes/grst/doc/FinalBellagio040604.pdf.

compounds can be identified. Patents are one way to protect this type of innovation.[13]

However, these patents raise benefit sharing issues, because the raw material often comes from developing countries, while the resulting profit from the patent remains with the developed world corporation that performed the research.[14] Some developing countries also have moral and cultural objections to patents on living organisms. These states resent paying for products based on their own PGRs, viewing this as theft and labeling it "bio-piracy," because developed countries did not initially recognize IPRs in wild PGRs or traditional knowledge (TK)[15] (bodies of know-how and skills that have been developed by local communities over generations).

Efforts to resolve these issues have been ongoing for some decades now. The twentieth century saw a radical change in the international law governing PGRs, a process that is likely to continue well into the twenty-first century as different interest groups negotiate over issues involving IPRs, biodiversity, and development.

This article considers these general provisions from the specific viewpoint of India, a megabiodiverse country. The maintenance of the fine balance between conservation and economic development is one of India's major concerns.

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[13] Laurence R. Helfer, Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments 1-2 (FAO Legal Papers Online No. 31, 2002), http://www.fao.org/Legal/prs-ol/lpo31/pdf.

[14] See generally Gavin Stenton, Biopiracy Within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process Can Be Towards Countries of the South, 26 Eur. Intell. Prop. Rev. 17 (2004) (arguing for greater protection of traditional knowledge in undeveloped countries).

[15] Klaus Bosselmann, Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity, 7 Colo. J. Int'l Envtl. L. & Pol'y 111, 132 (1996).

Like many developing nations, India is home to many diverse ecosystems, species and genes, as well as diverse cultures. With its population having crossed the one billion mark (the second country after China to do so), the country's cultural diversity is stupendous: 4635 distinct ethnic communities, 325 languages belonging to twelve language families, six 'major' religions and dozens of smaller independent faiths, three racially distinct resident populations, and ways of life ranging from ancient hunter-gatherer to modern urbanism.[16] Thereby, in itself, India is representative of the range of diversity, both biological and cultural, found in many developing countries.

In articulating the Indian experience with the implementation of the various international agreements regarding PGR's, this article will document the several changes in law and policy that have been initiated or are in the process of being put in to place at the domestic level since the country ratified the Convention in February 1994, as well as the people's movements for biodiversity rights. It will also review India's positions through the negotiating process of the CBD.

There have been amendments to India's Constitution that seek to decentralize democratic decision-making on biological resources. Through such legislative and constitutional measures India has strengthened the rights of its people and thus asserted its biodiversity rights. All this has run parallel to the structural adjustment programmes and economic reforms initiated in 1991 in response to conditions imposed by the International Monetary Fund (IMF). Post-1995 entry into the World Trade Organization (WTO) has posed newer challenges to India and other developing nations with far-reaching ramifications on their biodiversity rights. The interface of the WTO and CBD, particularly in regard to intellectual property rights, will be examined from the Indian perspective.

At the outset, it may be said that developing nations, typically characterized by their low per capita incomes and defined as those that are attempting to improve their positions by industrialization, may well have chosen an alternative path of

[16] Singh, K.S., People of India: An Introduction. Anthropological Survey of India, Laurens and Co., Calcutta (1992).

development if they perhaps had the right to do so. With freedom to set their own policies and priorities they perhaps would not have hastened themselves into changing their laws and policies and with it the very rubric of their polities in the name of conservation. These are the realities that international law and law-making must acknowledge.

Indian civilization has long recognized the intrinsic right of nature to exist. This recognition and respect is deeply interwoven with the cultural and material dependence of the majority of its people on biodiversity. As such, in India the ethical, economic, social, and cultural aspects of biodiversity are hard to separate.

2. Various Intellectual Property Rights available to protect PGR's

Intellectual property rights include a wide variety of laws intended to promote technical ingenuity and cultural creativity by granting private ownership rights. These include national laws regarding patents, copyrights, trademarks, trade secrets, and related subjects.

2.1. General Rationale and Criticisms

Intellectual property laws may also serve as tools to promote conservation of biodiversity while promoting sustainable development and the equitable sharing of benefits.[17] A summary overview of the principal issues involved in the interaction of biodiversity prospecting and intellectual property rights follows.

It is a testament to the vigor and adaptability of intellectual property that people are looking to intellectual property rights systems as instruments of environmental conservation and advancement of human rights, in addition to

[17] Michael A. Gollin, An Intellectual Property Rights Framework for Biodiversity Prospecting, in BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 159, 163 (Walter V. Reid et al. eds., 1993)

their traditional role of fostering innovation, creativity, and commerce. The public policy rationale for intellectual property rights laws, which usually are complicated and expensive to administer and enforce, is generally that each intellectual property right helps society fulfill several of the following somewhat overlapping policy goals:

Provide incentives for people to be creative	The prospect of exclusive rights or a competitive advantage secured by an intellectual property right is a potent motivator to encourage people to engage in creative endeavors.
Reward creativity	Linked with the incentive function, rewarding people for their completed creative acts encourages them and others to do more
Allow individuals to own the products of their creative "sweat of the brow:"	If a person labors to produce a creative output, society may find it fair to grant that person some form of ownership, instead of allowing the product to go into the public domain, thereby leaving the laborer empty-handed.
Satisfy principles of moral or natural rights:	Artists, inventors, and other creative people often feel a sense of parenthood toward their work, a relationship that goes beyond tangible property rights, and society can support this relationship by imposing restrictions on the use or destruction of intellectual property.
Promote public disclosure of new information	Sharing of new information is enhanced if people are encouraged to disclose it and can do so on their own terms.
Facilitate technology transfer	By establishing assignable property rights, intellectual property laws allow people to buy, sell, lease, or trade intangible property as they would real or tangible property.
Facilitate technology development	Development and dissemination of technology requires investment, and intellectual property rights encourage investment by offering investors a way to obtain financial returns.
Implement industrial policy	By establishing, strengthening, weakening, or eliminating intellectual property protection, industries and activities can be supported or discouraged.

Criticisms

Intellectual property rights have been subject to many **criticisms**, particularly when applied to biological resources, indigenous knowledge, and national heritage. Some criticisms are that they:

Keep technology out of the public domain	This typical characteristic of intellectual property rights allows the owner to obtain a competitive advantage, and is critical to serving the public policy goals outlined above.
Increase the costs of technologies	As with the previous point, the increased cost to the consumer is an instrument of incentive and reward to the intellectual property owner.
Create monopolies	This is similar to the previous point, but also concerns economic centralization.
Concentrate industry on protectable, rather than environmentally or socially appropriate chemicals, cultivars, or other species	A technology subject to intellectual property protection is more likely to be commercialized and disseminated than a public domain technology, because of the prospect for higher economic return.
Push people from cooperation into competition	At the individual level, intellectual property rights can be tools for commercialism, which can cause biodiversity providers, collectors, and biotechnology researchers to deal more sharply with each other and their competitors than they would in a mere academic relationship. At the societal level, however, the goal of

	advancing technology may be better served, on balance, by such competition.
Are expensive to obtain and maintain	Although copyrights and trade secrets are relatively simple to protect, patents are expensive and complex, and therefore poor and unsophisticated individuals or organizations may be put at a disadvantage compared to multinational corporations and other biodiversity end users.
Require elaborate national legal and regulatory institutions	A patent and trademark office, copyright registry, and a court system able to handle intellectual property cases all require substantial commitments of national funds and expertise.
May conflict with moral views opposing property rights in innovations involving living organisms, medical inventions, and traditional knowledge.	

These criticisms bear on the political process of legal reform of intellectual property rights, and can shape the outcome of a system. Base-line standards for the principal types of intellectual property rights are already established by the TRIPS agreement, however, and it will be very difficult for signatory countries to avoid those standards in domestic legislation.

Applying these issues to biodiversity prospecting, intellectual property rights can also promote ingenuity in finding, identifying, developing, and

commercializing genetic and biochemical products. A principal concern should be whether a particular country's intellectual property laws are adequate to promote a sustainable biodiversity prospecting trade, or whether reform is necessary.

For example, patents may cover too much or too little, and their duration may be longer or shorter than ideal. There may be no legal recourse for violating a trade secrecy agreement, or there may be too many people claiming rights to the same invention.

Countries reform their intellectual property laws as their technology and cultural practices change. It is important for those involved with biodiversity prospecting to understand the basic sources of intellectual property law, and their application to biodiversity conservation and development. It is equally important to remember that "the devil is in the details" and that generalizations without closer examination are suspect.

It is simplistic to say that intellectual property laws are "good" or "bad" in general, without reference to a particular law as applied in a particular situation.

The aspects of biodiversity to which intellectual property laws may be applied include: an ecosystem; the species comprising it; knowledge pertaining to a habitat or species; inventories of plant, animal, and microbe species and their place and time of collection; information about a species' usefulness; extracts and purified compounds; methods of preparing such materials; and methods of administering them. Protection may also apply to seeds, plasmids, and isolated genes, pure-bred or hybrid crops or animals, synthetic derivatives of compounds and genetic material, and products prepared from such compounds. These components may be important in medicine, agriculture, or industry. Cultural resources such as traditional knowledge, art, and music may also be protected.

The basic types of intellectual property are described below.

2.2. Trade Secrets

Under Art. 39 of TRIPS, member nations must protect trade secrets. Information is subject to protection if it:

1. is secret in the sense that it is not generally known or accessible to persons who normally deal with that kind of information;
2. has commercial value because it is secret; and
3. has been subject to reasonable steps, under the circumstances, by the person lawfully in control of the information, to keep it secret.

Individuals and organizations may prevent information lawfully within their control from being disclosed to, acquired by, or used by others without consent in a manner contrary to honest commercial practices. "A manner contrary to honest commercial practices" is defined to mean at least breach of contract, breach of confidence, inducement to breach, and acquisition of information by individuals who knew or were grossly negligent in failing to know that such practices were involved in acquiring the information.

Governments are also required to protect the secrecy of undisclosed data regarding chemicals when the information is submitted to obtain marketing approval for pharmaceutical or agricultural products.

In practice, particular measures are necessary to establish a trade secret. For example, documents must be marked "CONFIDENTIAL" and separated; access to a building or plantation may be restricted; and any disclosure should be subject to a confidentiality agreement. A trade secret may endure forever provided that the information, formula, or device remains secret. The owner of a trade secret may license or assign the right to use the trade secret, subject to an agreement to keep the information secret.

Trade secrecy law may be difficult to apply to ethnobotanical knowledge. If an extractive technique and treatment method is handed down from generation to generation of traditional healers, it might be protectable. If the information is published by a researcher, government entity, or anyone else, however, the trade secret rights are permanently extinguished. Thus, immeasurable damage to the legal rights of indigenous peoples may be caused by the careless publication of information that was learned in confidence. Prior informed consent should always be sought when indigenous knowledge is recorded, and the implications of publication should be made clear to all involved.

2.3. Patents

A patent conveys from the government to an inventor the right, for a limited time of usually ten to twenty years, to exclude others from making, using, or selling an invention. The subject matter of a patent may be a composition of matter, a method, or an apparatus.

The TRIPS Agreement contains detailed provisions regarding patent protection, and developing countries must come into compliance with TRIPS within five or ten years, depending on their current legal system. Under TRIPS, member nations must make patents available for any invention that is new, useful, and nonobvious. Countries must provide for the protection of plant varieties and microorganisms, but may otherwise exclude from patentability other plants and animals, biological processes for producing plants and animals, and methods for treating humans and animals. At the time the TRIPS Agreement went into effect, there were about twenty countries that did not allow patents for pharmaceutical compounds, and about twenty that restricted patents for biotechnology products and processes. This number should approach zero in the coming years.

To obtain a patent, the inventor must submit an application describing the invention in a manner sufficiently clear and complete to enable a person skilled in the technology to carry out the invention. If the patentee is successful, the term of a patent will last at least twenty years from the date the application is filed.

Patent laws usually require some inventive step. Wild habitats, species, and raw biological materials cannot be patented, because they are not new, and they are "products of nature" falling outside most patent laws. Indeed, some countries choose not to allow any plant and animal patents. Other aspects of biodiversity from the above list can be protected by patents, however. For example, a purified compound, and methods of obtaining it and using it, might be new, nonobvious, and not products of nature, because compounds are not generally found in nature in their purified form. Likewise, a microbe and genetic material will be subject to patent protection when the provisions of TRIPS are implemented.

From the perspective of providers of biological material, a key problem in patents related to biodiversity prospecting arises when a sample is obtained from a source country, and then extracted and studied elsewhere, leading to the discovery of a new useful compound. Derivative products, analogs, and synthetics may be obtained, or new agricultural crops produced, and patents sought by the recipient of the materials to protect them.

Such patents, however, may be subject to the contractual obligations of a biodiversity prospecting agreement. Patent disclosure rules may be interpreted to help ensure that the source or leads for these secondary products is identified.

Although environmental impact assessments may be important at the points of collection and use of biological materials, it does not make administrative sense to include an environmental impact review in the process of obtaining a patent. Moreover, most patents are not used

commercially, so it would be wasteful to routinely review their environmental impact as a condition of patentability.[18] Also, the expertise and public interest involved in determining patentability are far different from those relating to environmental impact. The two functions should, therefore, be kept separate in most cases.

A patent on a purified compound, or a species of microbe or plant, or a new method, removes that new invention from the public domain. Some people fear that as a result, farmers and local residents in developing countries will be precluded from using existing species or practicing traditional methods of agriculture.[19] To the contrary, while a properly issued patent covers the new innovative invention, the prior material remains available for use in the public domain.[20] The best way to prevent the creation of a monopoly over too broad an area is to ensure that each issued patent covers only the new aspects of an invention.

2.4. Plant Breeders' Rights

New sexually reproduced plant varieties are subject to the 1961 International Union for the Protection of New Varieties of Plants ("UPOV"). A breeder may obtain exclusive rights to a novel plant variety if it is distinctive, uniform, and stable. Plant breeders' rights are relevant to biodiversity prospecting in that a wild variety may be bred out for several

[18] For instance, a series of germplasm preservation experiments was found not to constitute a federal program requiring an environmental impact statement. Foundation on Economic Trends v. Lyons, 943 F.2d 79, 86 (D.C. Cir. 1991). It probably will be even more difficult to argue that the granting of patents is a major federal action significantly affecting the environment.

[19] *See* Steven M. Rubin & Stanwood C. Fish, *Biodiversity Prospecting: Using Innovative Contractual Provisions to Foster Ethnobotanical Knowledge, Technology, and Conservation,* COLO. J. INT'L ENVTL. L. & POL'Y 23, 28 (1994).

[20] *See* Mercoid Corp. v. Honeywell Co., 320 U.S. 680, 684 (1944). It is a common fallacy to believe that a patent removes prior technology from the public domain. *See, e.g.*, Michael D. Lemonick et al., *Seeds of Conflict: Critics Say a U.S. Company's Patent on a Pesticide from an Indian Tree is "Genetic Colonialism,"* TIME, Sept. 25, 1995, at 50 (petition to revoke a patent on new insecticide extracted from neem trees was based on threat to farmers using crude extracts).

generations and then protected. In addition, TRIPS requires members to provide some form of plant variety protection. Amendments to UPOV made in 1991 put plant breeders' rights at the discretion of contracting states.

2.5. Trademarks

Most countries provide some form of protection for trademarks. Under Art. 15 of TRIPS, any mark distinguishing a person's goods or services from those of another is eligible for registration as a trademark. The owner of a registered trademark may prevent others from using any mark that is identical or so similar as to cause a likelihood of confusion in the marketplace.

Certification marks and denominations of origin resemble trademarks in that they are affixed to goods and signify a certain quality. Examples include the French system of Appellation Controllee, the United States Good Housekeeping Seal, the Rainforest Alliance Smart Wood Program, and organic certifications. These certifications differ from trademarks in that the certifying organization is independent from the entity marketing the product or service. Nations or regions should consider encouraging the establishment of certification standards that apply to sustainably harvested products, and to products from research conducted in a sustainable manner. This will include consideration of local economic and cultural concerns.

2.6. Copyright

Copyright laws protect original works of authorship expressed in a tangible medium, but not the underlying ideas. Copyright covers literary and artistic works and computer programs. TRIPS articles 9-14 detail the

minimum standards countries must apply. The term of a copyright is typically the life of an author plus fifty years.

Copyright protection applies to compilations of genetic data and biological information in various data banks, but will not apply to the data itself because it is not original to the author. In other words, it would not be a copyright infringement to reorganize data from a number of sources in a new compilation, but it probably would be an infringement to copy a compilation outright. The protection of copyright law thus provides a means to commercialize information relevant to biodiversity prospecting by means of a private clearinghouse or the like.

3. What are the fora where they are discussed?

There are three main fora in which PGRs have been discussed: the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the United Nations (UN) Food and Agriculture Organization (FAO). Because different fora are the responsibility of different civil servants, they can have quite varied negotiating dynamics.

3.1. WIPO

WIPO exists to administer various international IP treaties, to assist members in drafting IP legislation, and to promote global IP harmonization.

Its roots are in the Paris Convention of 1883 and the Berne Convention of 1886. The *Bureaux Internationaux reunis pour la protection de la propriete intellectuelle (BIRPI),* which administered the aforementioned agreements, became an international IP organization and specialized agency of the United Nations in 1970.

Membership is open to members of the Paris or Berne Unions, members of the United Nations or its specialized agencies, members of the International Atomic Energy Agency, any party to the Statute of the International Court of Justice, or any other state by invitation of the WIPO General Assembly. The treaties administered by WIPO deal with substantive international IP standards, single global IP registration, and standards for classification of IP.

WIPO's involvement in the PGR debate stems from two initially unrelated strands of work on genetic resources and biotechnology: the intersection of IP and TK and a long-running collaborative effort with the United Nations Educational, Scientific, and Cultural Organization to protect folklore. Recognizing that these efforts were related, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2001. After gathering a great deal of information, the IGC reported to the WIPO General Assembly in autumn 2003 and currently continues to work toward an international treaty.

Although the negotiation of TRIPs might be seen as superseding WIPO, it has simply led to the creation of a new forum. Since the inception of TRIPs, WIPO has sought to reinvent itself by finding new topics and taking on new roles. It has tried to exploit its expertise in IP to develop a niche in the post-TRIPs system, which has suited developed countries. As part of this process, it has launched a Patent Agenda, created a framework for the future development of international patent system, completed work on the Patent Law Treaty, reformed the Patent Cooperation Treaty, and negotiated the Substantive Patent Law Treaty.

Because WIPO has begun to allow the development of soft law norms through resolutions and recommendation, it offers a flexible forum to avoid the delay involved in negotiating treaties. There is a perception that its International Bureau is more sympathetic to certain members and interest groups, such as those who are pushing for higher levels of IP protection. In addition, the International Bureau has taken actions that seem hostile to the developing countries.

However, in 2004, the WIPO General Assembly adopted a Development Agenda, strongly opposed by the United States. This agenda is designed to ensure that IPRs are used to advance development. It was proposed by a group of developing countries and considered at special meetings. To date, little concrete progress has been made, but a Provisional Committee on Proposals Related to a WIPO Development Agenda has begun to meet, and its mandate was just continued for a further year. The committee faces a number of significant challenges, such as a tight schedule, difficulties in building alliances, the need for informed debate, and opposition from within the WIPO secretariat.

3.2. W.T.O.

The WTO works to liberalize international trade by lowering barriers and settling disputes. Its roots are in the United Nations' efforts to make world trade more efficient after World War II, which led to the General Agreement on Trade and Tariffs (GATT) and the formation of the International Trade Organization (ITO). The former was intended only as an interim measure until the ITO took effect, but due to lack of support from the United States, the latter failed. As the globalization of trade progressed, the need to replace the GATT system led to the negotiation of the WTO Agreement. Unlike GATT, this operates as a single body of law and thus is much stronger. Despite this structural advantage of the WTO, "GATT has remained the dominant forum for trade negotiations."

The United States and the European Union moved from WIPO to GATT to further their intellectual property agenda for two reasons: their dissatisfaction with the WIPO and the attraction of the dominant GATT institutions. GATT had four advantages from their perspective. First, it allowed for rapid globalization of standards because the Uruguay round agreements came as a package. Second, there was more opportunity for bargaining on non-IPR issues. Also, GATT was more developed and friendly to developed countries than the United Nations Conference on Trade and Development (UNCTAD), a "UN forum ... which would have been a far more attractive place for developing countries to negotiate new

global IPR norms," because it tended to favor developing countries. Finally, GATT had a well-developed dispute settlement mechanism. This focus on IPRs was driven by domestic industries concerned about piracy in the developing world. The end result was TRIPs, which seeks to establish minimum levels of patents and other types of IP protection across its membership.

The United States has taken a leading role in driving the IPR agenda in the WTO, often at the insistence of commercial interests. However, the continued raising of levels of intellectual property protection has been criticized as harmful to the interests of both developed and developing countries.

3.3. The U.N. Food and Agriculture Organization

The Food and Agriculture Organization (FAO) is a specialized agency of the United Nations, which works to defeat hunger through negotiations and serves as an information resource on agriculture, forestry and fishing practices. Political strategies, however, have limited the number of occasions the FAO has been called upon since its establishment in 1946. Although some FAO conferences were organized in the 1960s, the FAO did not become active in the area of PGRs until the 1980s. In 1983, the FAO set up a Commission on Plant Genetic Resources. The Commission was designed to be an expert body open to all, undertaking preparatory work for the FAO. The FAO prepares an annual report on The State of the World's Plant Genetic Resources. The FAO has also established an Early Warning System (drawing attention to specific hazards) and a Global Plan of Action (GPA) (coordinating worldwide activities). It has recently produced the **International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR**), which may have a substantial impact on PGRs.

4. What are the agreements they have reached?

Over the years, the international community has developed a number of international agreements governing IPRs and PGRs that together do not comprise a coherent whole system reflecting a single set of principles but rather a dynamic regime complex reflecting the different priorities and interests of the various international actors.[21]

4.1. UPOV

One of the first agreements in the general area of PGRs is the Convention of the International Union for the Protection of New Varieties of Plants (UPOV). This agreement was adopted in order to promote patent protection for new plant varieties, which the international community increasingly desired.[22] It provides minimum standards of sui generis intellectual property rights to commercial plant breeders, commonly called plant variety rights or plant breeders' rights (PBRs).[23] These protections from the original 1961 agreement have been extended over time by the revisions in 1972, 1978, and 1991.

4.2. Convention on Biological Diversity

The United Nations Convention on Biological Diversity (the Biodiversity Convention or CBD) was established in May 1992. Under the CBD, genetic

[21] Kal Raustiala & David G. Victor, The Regime Complex for Plant Genetic Resources, 58 Int'l Org. 277, 279 (2004).
[22] Klaus Bosselmann, Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity, 7 Colo. J. Int'l Envtl. L. & Pol'y 111, 132 (1996).
[23] Laurence R. Helfer, Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments 1-2 (FAO Legal Papers Online No. 31, 2002), http://www.fao.org/Legal/prs-ol/lpo31/pdf.

resources are a part of national sovereignty, and thus are not common property.[24] The CBD's objectives are the conservation and sustainable use of plant and animal biodiversity and the fair and equitable sharing of the resulting benefits. Moreover, the CBD promotes free trade to finance conservation and the transfer of technology. Although the technology transfer provisions are limited, they have led to efforts promoting the conservation of biodiversity. The CBD does not directly deal with intellectual property,[25] but the Conference of the Parties (COP) adopted the so-called Bonn Guidelines in 2002, dealing with "Access to Genetic Resources and Benefit Sharing" and setting out recommended terms for the transfer of genetic material.[26]

The CBD was agreed to by the developing countries in the hope that making genetic resources a matter of national sovereignty would ensure profit from bio-prospecting. However, the CBD has not yielded the expected benefits.[27] This shortcoming is blamed on the operation of the Convention, which seems to have created bureaucratic impediments to commercialization and a reluctance of countries to commit to risky benefit-sharing arrangements.[28] As a result, there is a perception that the CBD has reduced the availability of PGRs from in situ sources.[29] The returns from field work can be quite low, as such work requires assistance and access from local communities. In addition, the availability of material and information from seed banks and scientific literature may make field work unnecessary.

There are indications that patents on biotechnology in the United States have led to an anticommons, where "upstream" patents over essential building blocks such as genetic sequences prevent development of "downstream" projects such as

[24] Gregory Rose, International Regimes for the Conservation and Control of Plant Genetic Resources, in International Law and the Conservation of Biological Diversity 145, 150 (Michael Bewnaan & Catherine Redgwell eds., 1996).
[25] John Linarelli, Treaty Governance, Intellectual Property and Biodiversity, 6 Envtl. L. Rev. 21, 22 (2004).
[26] Id. At 39,30.
[27] Rex Dalton, Bioprospectors Hunt for Fair Share of Profits, 427 Nature 576, 576 (2004).
[28] Id.
[29] Cary Fowler & Toby Hodgkin, Plant Genetic Resources for Food and Agriculture: Assessing Global Availability, 29 Ann. Rev. Env't & Resources 143, 147-48 (2004).

medical treatments.[30] The same phenomenon may be occurring in the international regime governing PGRs, as too many acquire the right to exclude. In fact, one of the reasons why bio-prospecting has not worked as well as expected may be that researchers are put off by the difficulties involved in negotiating with all of the groups involved and simply avoid it as an activity. Solving this problem may prove complex, as it is difficult to untangle all of the rights involved in a fair way.

4.3. Agreement on TRIPS

TRIPs is a WTO agreement adopted in 1994. Its objective is to establish uniform international standards of IP protection. In the area of PGRs, article 27 provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology" but that "plants and animals other than micro-organisms" may be excluded. However, there is a requirement to "provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof." (The mention of a sui generis system was probably a reference to UPOV, and has led to some developing countries signing up to UPOV, which allows members to draft supplementary unilateral treaties within the UPOV framework.)

The developing countries most likely accepted TRIPs, despite their misgivings about IPRs, for two reasons.

First, TRIPs is part of a packaged whole, and the benefits of the other GATT agreements are weighty in comparison.

On the other hand, they may have been motivated by the improved access to markets in developed countries, wanting to avoid trade barriers that might result if they stayed out of the new system.

"In short, TRIPS was a loss but the WTO package of agreements was a net gain."

[30] Sabrina Safrin, Hyperownership in a Time of Biotechnological Promise: The International Conflict To Control the Building Blocks of Life, 98 Am. J. Int'l L. 641, 653 (2004).

Implementation of TRIPs was delayed by increasing transaction costs and a resurfacing of developing nations' initial reservations. Despite the additional time which some states were given to comply, a negative perception of TRIPs still arose in developing countries. This animosity was driven by slow, costly implementation, domestic opposition, and pressure from the United States and the European Union to sign "TRIPs plus" bilateral agreements that contained still higher intellectual property standards.[31] The developed countries' assumption that levels of IPR protection will become progressively higher has produced a hostile reaction from these countries. As the developing countries question the claim that these higher standards encourage the transfer of technology from developed to developing countries, LDCs are reconsidering TRIPs. Some developing countries want to amend TRIPs to lower the level of IP protection currently required. Despite the objections of the United States and other developed countries, some developing countries are pushing for TRIPs Council discussions of the relationship between TRIPS and the CBD. The Doha Declaration on the TRIPs Agreement and Public Health, granting developing countries another ten years within which to protect pharmaceutical drugs, may be an indication of efforts to deal with this.

The review of article 27 of TRIPs, which should have taken place in 1999, was incomplete because the developed and developing world could not agree on its scope. Resolving the article 27 issues could require patent protection for plants and plant varieties, creating a direct conflict with article 12.3(d) of the ITPGR.

When this modification was discussed during the Doha round of WTO negotiations in 2001, the United States and Japan tried to limit the review to measures already adopted in fulfillment of the requirement to offer some protection for plant varieties. Developing countries (mainly India, Brazil, and African states) wanted a wider debate on whether patents on living organisms should be permitted at all and on harmonizing TRIPs with the CBD and the IU. The European Union sought compromise through harmonization by national legislation rather than through treaty amendments.

[31] Helfer, supra note 3.

The final result of the Doha round negotiations, the Doha Ministerial Declaration, set forth the agenda for the review, largely adopting the developing countries' perspective. Paragraph 19 directs

the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), ... 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. [32]

The reference to articles 7 and 8, which mention "social and economic welfare," "a balance of rights and obligations," "public health and nutrition," and "the public interest," places the review in a broader context and creates an opportunity for more even-handed policy on IPRs. **This reflects a greater international understanding of the need to ensure that the use of biotechnology does not adversely impact biodiversity.**

The TRIPs Council has reviewed the entirety of TRIPs, including article 27.3(b) on the patenting of plant and animal inventions. These reviews are being expanded in consultation with WIPO and the CBD, although some developed countries are seeking to delay this review process pending the conclusion of studies being conducted by WIPO.

4.4. International Treaty on Plant Genetic Resources

The most recent international agreement governing PGRs is the ITPGR. This treaty grew out of forum-shifting by the developing countries, led by Mexico and

[32] World Trade Organization, Ministerial Declaration of 14 November 2001, P 19, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

aided by NGOs and activists.[33] They selected the FAO as the best place to work on the new international agreement.

Developing countries had two concerns, which they wanted to address during negotiations.[34]

1. Although they held the majority of the crop collections, they carried out a minority of accessions.
2. The developing countries were concerned that developed country plant breeders were securing IPRs for their own varieties, while seeds in traditional use were not being protected.

In 1981, a resolution recommending the drafting of a legal convention focusing on these issues was approved. In 1983, this was reduced to a call for a nonbinding undertaking, and the International Undertaking on Plant Genetic Resources (IUPGR) was agreed to by over 100 countries, including many of the developed nations. The Undertaking is part of the FAO Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture.

It states that all PGRs are part of the "heritage of mankind and consequently should be available without restriction" for scientific research, plant breeding, and conservation.[35]

This agreement created a conflict with UPOV, which protects PBRs, by creating restrictions on the availability of PBRs.[36]

The Undertaking was subsequently revised to state it was "not incompatible" with the principle of common heritage, and to balance these efforts, additional rules regarding farmers' rights[37], national sovereignty, and a prohibition on IPRs in PGRs held in international seed banks were added to the initiative.

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[33] Helfer, supra note 3, at 35-39
[34] UNCTAD-ICTSD Project on IPRs and Sustainable Development, supra note 115, at 55.
[35] International Undertaking on Plant Genetic Resources for Food and Agriculture, Res. 8/83, FAO Conference, 22nd Sess. (Nov. 23, 1983), art. 1, available at http://www.fao.org/ag/cgrfa/iu.htm.
[36] Helfer, supra note 3, at 36
[37] " Farmers' rights is a loosely defined concept that seeks to acknowledge the contributions that traditional farmers have made to the preservation and improvement of PGRs... . [They] act as a counterweight to plant

In 1992, the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity adopted a resolution recognizing the need to "harmonise the International Undertaking with the CBD," particularly regarding access to ex situ collections[38] and the question of farmers' rights. In 1993, the Commission on Plant Genetic Resources (CPGR)[39], the FAO commission responsible for governing the IUPGR, recommended that the Undertaking be revised in light of the CBD. Negotiations proceeded slowly and with difficulty but produced more than a revised Undertaking; they resulted in a binding treaty, the ITPGR, implemented in November 2001.

This treaty creates "a special collective property right for a limited number of staple food and feed crops"; it is a type of *limited common property right* within these defined PGRs.

This creation is, to a certain extent, a *reversal* of the process of propertization that brought the CBD into being, caused perhaps by the prohibitive cost of segregating seeds and tracing samples to those working on core crops for the poor, and therefore, the most important PGRs were essentially placed back in the public domain. In fact, most of the movement of germplasm facilitated by

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breeders' rights, compensating the upstream input providers who make downstream innovations possible." Id. at 37.

[38] Ex-situ conservation means literally, ***"off-site conservation"***. It is the process of protecting an endangered species of plant or animal by removing part of the population from a threatened habitat and placing it in a new location, which may be a wild area or within the care of humans. While ex-situ conservation comprises some of the oldest and best known conservation methods, it also involves newer, sometimes controversial laboratory methods. Source: http://en.wikipedia.org/wiki/Ex-situ_conservation Last visited on August 05, 2008.
These are generally held in botanical gardens and seed banks.

[39] The FAO established the intergovernmental Commission on Plant Genetic Resources in 1983. Renamed the **Commission on Genetic Resources for Food and Agriculture (CGRFA)** in 1995, the Commission currently comprises 160 countries and the European Community. The CGRFA coordinates, oversees, and monitors the development of the Global System for the Conservation and Utilization of PGRFA, which is comprised of the Commission itself, the nonbinding IU, the rolling Global Plan of Action, the International Fund for Plant Genetic Resources, the World Information and Early Warning System, Codes of Conduct and Guidelines for the Collection and Transfer of Germplasm, the International Network of Ex Situ Collections under the auspices of the FAO, and the international network of in situ conservation areas and crop-related networks. Negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture: 30 October-3 November 2001, Earth Negotiations Bull. (Int'l Inst. for Sustainable Dev., Winnipeg, Can.), Nov. 5, 2001, at 1-2, available at http://www.iisd.ca/biodiv/iu-wg/ [hereinafter Negotiations].

genebanks occurs between developing countries, indicating that ease of access is in the interest of these countries.

The main achievement of the ITPGR is the establishment of a Multilateral System of Access and Benefit-Sharing (MS). This section acknowledges states' sovereignty over PGRs, but also allows access to certain material. This access only applies to a carefully negotiated list, set out in Annex I to the ITPGR, of thirty-five crops and thirty-two forages. Access to these PGRs is made available subject to several conditions, which include respecting intellectual property rights, adhering to the standard that "recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System," and accepting a Material Transfer Agreement (MTA), the terms of which are to be adopted by the Governing Body of the ITPGR. The use of a standard MTA is intended to reduce the transaction costs involved in using the Multilateral System.

During the negotiations leading to the ITPGR, some developed countries wanted the MS to include all PGRs, and as the negotiations concluded, the European Union proposed that after the treaty had been in force for five years, the list of PGRs should be expanded. This proposal was resisted by the developing world, but if the MS proves to work well and access creates tangible benefit sharing, they may agree to further open access.

As for the somewhat obscure wording limiting IPRs:

A brief review of the final stages of the treaty's negotiating history is essential to decipher this cryptic text. Two clauses at the end of the article - *"their genetic parts or components"* and *"in the form"* - were included as separate bracketed text going into the final round of negotiations. Developing states that opposed patent protection sought to retain the first clause and delete the second, whereas the United States wanted to delete the first phrase and retain the second. As a

compromise, the delegates voted to retain both clauses after defeating a proposal by the United States to delete Article 12.3(d) from the treaty altogether.

While all participating countries agreed that it should not be possible to patent genetic materials in the form received under the MS, disagreement existed among them as to whether and when DNA sequences could be patented.

There are two genetic material categories to consider: "parts and components" (patenting of raw DNA sequences simply extracted from PGRs) and "derivatives" (where extracted DNA is combined with other DNA to create a new PGR). The first category is probably excluded by the language of the ITPGR, although some developed countries interpret it as allowing some patents, even though this interpretation would seem to run counter to the spirit of the treaty. The position with the second is more vague, with the European Union taking the position that if parts and components are the subject of innovation, they can be the subject of IPRs. This position on the meaning of the treaty phrase "in the form received" was one of the most contentious issues during the negotiations, and the resulting compromise will likely need further interpretation by the Governing Body.

The ITPGR also requires that a share of the profits from commercialization of such derivatives be paid into a fund to be used for the Global Plan of Action. This fund is to be required under the terms of the MTA and must also deal with issues such as the level of IPRs permitted over derivatives, the triggers for payment to the fund, and compliance tracking.

5. What is the relevant legislation in India?

5.1. Introduction

The agreement on TRIPS requires that the member countries provide patents for any invention, whether process or product, in all fields of technology. As already

discussed, for plant varieties, protection should be provided either by patents or by an effective ***sui generis* (of its own kind)** system, or some combination thereof.

Since no criteria are established for an effective *sui generis* system, there is considerable variation among countries in protection of plant varieties. The International Convention for the Protection of New Varieties of Plant **(UPOV)** serves as the basis for protection of plant varieties in a growing range of countries. The UPOV has been revised three times (1972, 1978 and 1991) to successively *strengthen* **plant breeders rights (PBRs).** Almost all UPOV members follow either the 1978 or 1991 convention. The 1991 convention **introduces or extends several important restrictions**. It allows the breeder to **prohibit seed saving of protected varieties** (unless the species is specifically exempted) and it excludes any possibility of **seed exchange** for protected varieties. It also extends the protection to any harvested material and it extends the duration of protection (e g, from 15 to 20 years for field crops).

By September 2005, **33** members followed the **1991 convention** and **25** followed the **1978 convention**. The community plant variety rights (1995) in Europe and the Plant Variety Protection Act (Amendment 1994) of the US conform with the 1991 UPOV convention, while most developing countries who are UPOV members have adopted some variant of the 1978 convention. Norway recently decided against "upgrading" its law to the 1991- standards. In the US, plant varieties can also be protected by utility patents, whereas under the European Patent Convention, plant varieties per se are not patentable, but patent claims for broader plant groupings are allowable.

A recent analysis of plant variety protection (PVP) shows that most activity is still confined to industrialised countries; applications in high-income countries peaked in the early 1990s while there is still growth in the number of applications in upper-middle-income countries.

While most developing countries do not object to the idea that some form of protection should be provided to new plant varieties, issues of seed saving and exchange, research exemption, and use of domestic genetic resources, particularly by MNC's, have been the major issues of contention.

Public debate has brought increased sensitivity to these concerns, and providing an appropriate benefit-sharing mechanism for sustainable use of genetic resources and striking a balance between the commercial and farmers' interests are major challenges faced by the policymakers. Countries do not have to join UPOV to meet the requirements of TRIPS and a number of countries (e g, Indonesia, Tanzania) have enacted acceptable PVP legislation but have chosen not to join UPOV.

5.2. PVFR Act, 2001

The government has enacted all the necessary legislation to comply with the requirements of the TRIPS agreement. For protection of plant varieties, the **Protection of Plant Varieties and Farmers' Rights Act** (**PVFR Act, 2001**) and the authority to oversee its implementation are in place. The act provides protection to a new variety including an "essentially derived variety" (a variety derived from another variety while retaining expression of its essential characteristics) and a farmers' variety of specified genera and species provided it conforms to the criteria of "novelty, distinctiveness, uniformity and stability (**NDUS**)". The act also has a provision for protection of an "*extant variety*"– a variety already notified under the Seed Act, farmers' variety, or a variety about which there is common knowledge or is in public domain. The act confers an exclusive right to the breeder or his successor, agent or licensee, to produce, sell, market, distribute, import or export the variety for a period of 15 years (18 years in case of trees and vines).

The act has a unique provision of ***benefitsharing*** to recognise the rights and contributions of local communities and farmers to conserving genetic resources.

> ***Further, the act not only extends PBRs to farmers for developing a new variety, but also permits farmers to save, use, exchange, share, and sell unbranded seed of a protected variety.***

There is a researchers' exemption also, allowing the use of a protected variety for developing a new variety. Although UPOV will no longer accept applications from new members under the 1978 convention, it has agreed to make an exception for India because India started the process of developing its law before the closing date.

It remains to be seen if UPOV accepts some of the act's unique characteristics as consistent with the 1978 convention. Some observers feel that the act's requirements of disclosing the source of genetic material and depositing seed and parental lines of the protected variety with the national gene bank, along with extensive farmers' rights to sell seed and compulsory licensing have diluted the "private" interest.

India has also amended the Patent Act (1970) for the third time in December 2004 to allow both process and product patents in all fields of technology, including biotechnology. The patent granted under this act confers upon the patentee exclusive rights to prevent a third party from making, using, offering for sale, selling or importing for those purposes that product, or the use of a patented process, in India. The term of every patent granted shall be 20 years from the date of filing of patent application. The act specifies a number of inventions which are not patentable, and for agriculture these are:

"a method of agriculture and horticulture", and "plants and animals in whole or any part thereof other than micro-organisms but including seed, varieties and species and essentially biological processes for production or propagation of plants and animals".

However, any process to control a plant disease or to increase economic value of plants or their products can now be patented. This provision, coupled with the scope for patenting of a microorganism which is not a naturally occurring organism, leaves the Indian Patent Act open to patenting of DNA sequences and gene products developed after substantial human intervention and conforming to the general conditions of patentability.

It is quite likely that biotech companies will test the contours of the act in the court of law, and eventually may succeed in their pursuit to protect biotech product innovations such as genes. This will have important implications for the plant breeding industry in general, and biotech industry in particular. It is feared that broad and strategic patenting by biotech companies may erect formidable entry barriers in biotechnology, promoting monopolistic control over the seed industry.

5.3. Challenges

The implementation of PVFR Act poses some major challenges. The first is to organise the testing for distinctiveness, uniformity and stability (DUS) for a large number of varieties in a transparent and credible manner. This work shall be outsourced to ICAR/SAU system, which is already under stress due to superannuation of scientists and increasing demands on the management of the All-India Coordinated Trails for testing varieties for value for cultivation and use (related to the provisions of the new Seed Act). The DUS testing will further stretch the resources of public plant breeding programmes, and recruiting more

scientists seems unlikely under the present government policy. International cooperation provides an opportunity to reduce the cost of testing, particularly when related to foreign bred varieties. For example, UPOV member countries share their test reports, and countries like Kenya and Colombia purchase test reports for flower varieties from abroad. India could also use the international test data for vegetables and flowers – the sectors likely to benefit from introduction of foreign varieties. But for most other crops, demand for DUS testing will largely come from huge domestic plant breeding industry and therefore, substantial public investment in DUS testing facilities is inevitable. Regional cooperation could reduce the burden or create a sharing of costs.

China has made a considerable investment in personnel (about 100 full-time breeders for DUS testing) and the India case will be at least as great. The PVFR authority should be self-sufficient in terms of meeting its cost. In a large country like ours, plant breeders that expect a sizeable market for their seed will be willing to pay application fee and maintenance charges, but subsequent renewal of the rights will depend upon market conditions. Given a nominal annual maintenance cost of Rs 10,000, it may not be too expensive for a private seed company to maintain its rights over a long period for major crops. The total cost of establishing and maintaining PVP right in India for 15 years would be $ 4,440, as against $ 5,687 in China and $ 4,344 in US (Table 1). However, in India, there is an additional cost of Rs 90,000 for testing a variety for three years under the All-India coordinated trails, thus raising the cost to $6,441. It is not clear if small players catering to niche seed markets will be able or willing to invest in protection of their varieties. Discounts on fees offered to education institutions and individual breeders may provide some hope for survival of small seed companies, whether private or public. The PVP is a private right and its enforcement is not usually under the purview of the PVP office. Given India's past experience with the patents and trademarks, there is no reason to believe that the initial enforcement of the PVFR Act will be stringent. Once the right holders recognize their responsibility to identify the infringements by their competitors

and pursue cases, enforcement tends to improve. It is quite likely that a similar situation may develop in India and court cases will serve to educate the system about the issues involved. But the development of this institutional capacity entails substantial investment by both the innovators and the institutions responsible for enforcement of the IPR regime.

Table 1: Cost of Establishing and Maintaining PVP Rights
(in $)

Item	China	Colombia	India	Kenya	EU	US*
Application	217	233	–	200	1,115	432
Testing	556	1,396 (155 if done abroad)	Up to 1,111	600	1,265 – 1,490 (depending on type of crop)	3,220
Granting of rights	–	39	–	240	–	682
Annual maintenance fee (by year)	(1-3): 181 (4-6): 236 (7-9): 306 (10-12): 398 (13-15): 517 (16-18): 672 (19-20): 874	(1): 78 (2): 155 (3): 233 (4-20): 311	Individual: 111, educational: 156, commercial: 222	(1-20): 200	(1-20): 540 (flat rate beginning 2006)	None
Cost of PVP and 10 years of protection	3,340	4,311	Individual: 2,221; educational: 2,671; commercial: 3,331	3,040	7,780 (lowest example)	4,344
Cost of PVP and 15 years of protection	5,687	5,866	Individual: 2,776; educational: 3,451; commercial: 4,441	4,040	10,480	4,344

Note: * One $ = Rs 45.
Source: Louwaars et al (2005); web site of the European Community Plant Variety Office (www.cpvo.eu.int) (fees converted at 1.24$/euro); web site of Plant Variety Protection Office of USDA (www.ams.usda.gov/science/pvpo/PVPindex.htm).

5.4. Biological Diversity Act (2002)

The provisions in the PVFR and the Patent Acts are also harmonised with other international agreements relating to biodiversity and trade through the **Biological Diversity Act (2002)** and the **Geographical Indications of Goods Act (1999).** Asserting ownership rights on genetic resources and sharing

of benefits accruing from their use is a major issue. The Biodiversity Act spells out the procedures for accessing genetic resources, especially for foreigners and private seed companies, and the PVFR authority will exercise its powers to decide the terms and modalities for sharing of benefits arising from commercial use of the national genetic resources.

The **Seed Act** is also under revision to make it consistent with PVFR and biodiversity acts. The **Seed Bill (2004)** has proposed compulsory variety registration and mandatory declaration of GE seed. Farmers are permitted to save, use, exchange, and sell unbranded seed of a protected variety. The bill does not make seed certification compulsory, although there is a provision for self-certification by seed producing agencies and certification by the state seed certification authority, or any other agency it has accreditated for this purpose. The Seed Act basically addresses *seed quality* (genetic and physical purity, germination, etc) and is being revised to make it consistent with PVFR Act. The objectives and scope of PVFR and Seed Acts are distinct and the latter does not overrule the provisions in the former, despite the concerns of some observers

Compulsory variety registration under the Seed Bill (Section 13.1) restricts seed sale to varieties of known origin with proven economic advantage (established under all-India trials and information provided by the breeder/producer). This registration will not establish ownership rights, unless application is made under PVFR, and therefore, any registered producer can multiply and sell seed of a registered variety with the same name.

Educational, scientific and extension organisations are exempted from all or any provision of the act, and therefore, from registration of a variety if required in some cases, and farmers are exempted from any restriction on their rights to save and exchange seed (Section 43). This may allow flow of breeding material directly into farmers' seed system. Farmers' seed is supposed to meet certain quality standards, but such concerns are neither feasible nor warranted, as farmers' seed

is not generally inferior to commercial seed. There is also concern that the new Seed Act may bypass the biosafety rules, allowing GE seed to enter the environment through provisional registration, which is not true. Section 15(1) of the bill clearly states that provisional registration of GE variety will be granted for only two years on the basis of multi-locational trials, and the variety will be registered (and hence available as commercial seed) only after the applicant has obtained *biosafety clearance* required under the ***Environment (Protection) Act (1986).*** Farmers' rights also apply to a GE variety and these cannot be restricted if the variety is developed using a protected gene. Indeed, potential owners of a protected gene may be concerned that there may be no way of keeping such a gene from being incorporated in unregistered or unprotected varieties that spread informally through farmer-to-farmer exchange.

6. What direction should our domestic legislation take?

6.1. Patent Protection

6.1.a Pro-Patent Arguments

Supporters of patents over plant genetic resources see this form of protection as both a human right and a social necessity. They embrace many of the arguments offered for the reform of Indian patent laws generally.

First, many Western countries assert a human right to IPRs, as embodied in the Universal Declaration of Human Rights and various pieces of national legislation.[40]

[40] Article 27 of the Universal Declaration of Human Rights (UDHR) protects the right to the moral and material interests resulting from any scientific, literary, or artistic production. Article I, Clause 8 of the U.S. Constitution similarly protects innovation "by securing for limited times to authors and inventors the exclusive right to their respective

Second, many supporters of patents view the prevention of free-riding on the inventions of others as an incentive to promote innovation. Supporters also argue that patent protection will result in the promotion of research and development (R & D) which will thereby result in products of better quality. In particular, many scientists argue that the level of R&D in the pharmaceutical industry is abysmal and that due to free riding, the innovative component that should be the hallmark of any new product is missing in Indian products.

Another argument made in favor of patents is India's need to usher in foreign investment to the country and promote technology transfer. Given that the level of R & D in India is suboptimal, if the interests of foreign innovators are not adequately protected through IPRs, they will resist entrance into the Indian market. Those making these arguments also assert that India actively chose to accede to TRIPS and to select this course - another indicator that there is a global movement towards free trade and market economies.

Even those who recognize TRIPS as an imposition of an unfair regime upon India agree that it is best to work within the constraints of the prevalent regime to promote Indian interests. Such plant patents are obtainable in the United States, Japan, Australia, and some other countries, excluding European countries. For practical market reasons, private enterprise would obviously prefer patents to other systems. Effective conservation, it is also argued, will require a long-term redistributive strategy for the economic development of India. Without patents, only contractual arrangements with corporations will be permitted to allow India to exploit its own resources financially. Given that raw genetic material has "indeterminate usefulness," it will be difficult to value the material at the moment the contract is sealed. Also, given the greater bargaining power of corporations,

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writings and discoveries." Also, the Preamble to the Inventors Act of Venice of 1474 has a provision recognizing the philosophical foundation for the protection of IPRs. However, others claim that IPRs cannot rise to the level of being a human right as they are limited in duration. See Gutowski, supra note 20, at 746.

there might be an incentive to undervalue the material. A patent thus allows the holder to corner the benefits of increasing value over time.

6.1.b. Anti-Patent Arguments

For many developing countries, a patent system simply does not work. This standard of protection severely discounts the contribution of local communities and farmers to the development of such resources. As one leading Indian ecologist and activist states, "ownership and property claims are made on living resources, but prior custody and use of those resources by farmers is not the measure against which the patent is set. Rather, it is the intervention of technology that determines the claim to their exclusive use."[41]

Indeed, farmers in India have clearly been opposed to TRIPS since its inception. They fear that broader patent protection will raise the price of seeds and make them dependent on varieties developed by corporations rather than allowing them to save and share seeds among themselves. Although Article 27.2 allows WTO members the ability to exclude inventions "necessary to protect order public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment," this provision cannot serve as a categorical exception for all genetic resources. Indeed, the latter part of 27.2 states that this exclusion may not be permitted merely "because the exploitation is prohibited by ... law." Thus, without recourse, many developing countries have modified their patent laws to meet the requirements of TRIPS for fear of violating this agreement and having to shoulder the consequences.

Another fear is that the granting of exclusive marketing rights will, in fact, negate any beneficial effects of increased foreign investment. The UN Conference on Trade and Development conducted a study in which it concluded that although

[41] Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge 51 (1997).

TRIPS is likely to engender positive impacts on developing countries in regards to technology transfer and local innovation, TRIPS could also precipitate negative impacts, including higher prices and lack of diffusion of products, in countries with the least developed industrial and technological bases.

Aside from the foregoing concerns, many people feel that India is not yet at a stage in its economic and technological development that it can entertain extensive patent protection. Whereas developed countries have debated issues related to the protection of plant genetic resources for decades, most developing countries have not had an equivalent debate. Despite this fact, these countries are now required to legislate for the protection of these resources without a clear notion of how to protect local interests from international, and often even national, interests.

Finally, many oppose patent protection on the basis of ethical concerns: **life forms and life processes should not be granted monopolies of ownership**. They believe that plant genetic resources should be in the public domain. Rather than constitute new information, plant genetic resources constitute existing knowledge. Thus, these resources do not meet the level of innovation required for patents under TRIPS. This form of "illegitimate" patenting of genetic resources is pejoratively referred to as *"biopiracy*", defined by leading Indian ecologist and activist, Dr. Vandana Shiva, as "a silent takeover of biological resources either by exploiting - whether deliberately or unknowingly - or by directly smuggling out and patenting of plants or seeds."[42]

Instead, Dr. Shiva and others have proposed the establishment of a sui generis regime outside the IPR framework which would, effectively, create "community intellectual rights"(**CIPRs**) which distributes rights to communities without bringing their resources into the pressures of a market economy. These rights

[42] There can be biopiracy of knowledge of how to use biodiversity, or there can be biopiracy of this biodiversity itself." Shefali Rekhi, et al., Return of the Colonists, India Today (March 23, 1998) <http://www.india-today.com/itoday/23031998/biz.html>.

would be based on the stewardship of local innovations by local communities, the free exchange of knowledge among communities, and the obligation to pay a royalty upon a commercial utilization of such knowledge.

In fact, Dr. Shiva has suggested that the establishment of community intellectual rights, which effectively grant communities the right to decide their own course of action, is the only solution to safeguard the interests of communities and prevent genetic erosion. However, given that the traditional IPR system has rewarded individual innovators, making CIPRs a tangible option has proven to be a difficult task. Rather, many countries are implementing community rights outside formal legal frameworks, such as by setting up community registers of biodiversity as a means of establishing prior art and thwarting efforts to privatize local genetic materials or knowledge by persons outside the community.

These anti-patent arguments, however, have lost appeal as an increasing number of people realize that despite the inequality of bargaining power inherent in TRIPS, there is an imperative need for India to accept its obligations under TRIPS in order to profit from the trade benefits promised through GATT.[43]

New legal incentives have become indispensable to further the cause of both firms and developing countries. Firms in developed countries seek protection of their innovations in order to create fair conditions of competition among competing firms. Developing countries want to encourage foreign investment in underdeveloped sectors, such as research and development. Furthermore, much of the ethical resistance to patents is based on widespread misperceptions that

[43] Other arguments against patents also exist. For some, it is a practical concern that granting patents over such materials will necessitate a strong judicial enforcement system in order to protect these patents; many countries, including India, lack this type of enforcement apparatus. Finally, others express concern that patents on plant genes might be complicated because it is sometimes impossible to control the flow of genes between plant populations. Suppose, for instance, that a patented gene is inserted into a plant. Could someone be able to breed a new variety of that plant, or would that be an infringement on the patent of the inserted gene? This latter fear pertains to genetically modified organisms in which the genetic information embodied in a plant is patented. These issues have been taken to the international community to be addressed through a new agreement called the Biosafety Protocol. See generally Swaminathan, supra note 27. See also UNCTAD, supra note 10, at 56.

patents can be claimed over nature. In fact, Article 27(1) of TRIPS requires that only those inventions that are "new, involve an innovative step, and are capable of industrial application" be eligible for patents.

Even accounting for India's economic interests, however, patents may not be the best solution. The concept of IPRs may work on a theoretical basis; however, local and indigenous interests need more protection and applications for patents need more description of the source of the genetic resources. Also, while inventions must meet the "innovative" standard, applying this standard to plant genetic resources is often difficult in practice. Since TRIPS permits for either patents or "a sui generis system", what qualifies as an effective sui generis system will next be explored.

6.2. Other *Sui Generis* Candidates

6.2.a Plant Breeders' Rights (PBR's)

Special national laws of plant breeders' rights (PBRs) (also called plant variety rights) were established in the 1960s because the patent law in most countries was considered unsuitable for protecting new plant varieties developed by traditional breeding methods. This body of law seeks to protect the plant varieties created by plant breeders to provide incentives for innovation without the strict legal repercussions involved with the infringement of a patent. **Plant breeders can be anyone from a single farmer who has a new plant variety to a private institution engaged in breeding research**.

Though patents and PBRs share some features in common, they present some important differences.

1. First, whereas for traditional patents the standards are that the new product or process must be **novel**, involve an inventive or **non-obvious** step, and have utility or have **industrial application**, the standards for plant varieties are that the new variety be distinct from known varieties, uniform, and stable. The rationale for this different standard still rests in the desire to stimulate commercial plant breeding by providing protection to plant breeders.
2. A second difference between these types of protection is the extent to which they protect plant genetic resources. Patents may allow for the protection of particular genes embodied within an individual plant. However, PBRs only protect plant varieties, which are determined by a specific combination of genes.
3. Also, PBRs allow a protected variety to be used to create a new variety (known as a "breeders exemption") and allow farmers to reuse seeds without any adverse repercussion (known as "farmers' privilege").

Because PBRs were conceived of to lessen the effects of the rigid legal framework of patents on traditional plant breeders, the impact of a PBR regime differs from a patent regime. For example, the main beneficiaries of a PBR regime would be commercial plant breeders that employ conventional breeding techniques and farmers that develop and sell their own varieties.

In contrast, the main beneficiaries of a patents regime would be institutions and companies specializing in genetic engineering techniques. The latter bodies would be receiving more legal protection under a patents regime and therefore, more likely to invest in plant genetic resources.

a. UPOV Option

The current UPOV treaty in force is that of the 1978 Act, although it was amended in 1991.[44]

In the 1978 treaty, both the breeders' exemption and farmers' privilege mentioned above are included. Yet, the 1991 treaty restricts these provisions. The 1991 treaty does not include the farmer's privilege in its text, although industrial countries may introduce it or maintain it in their national legislation. The 1991 treaty makes it more difficult for traditional plant breeders to continue breeding plants.[45]

Finally, the 1991 treaty allows for the same resource to be doubly protected: by patents and by plant variety protection. **Thus, the 1991 treaty undermines the interests of farmers and local communities more than the 1978 treaty.**

Many developing countries have adopted the UPOV because of a perception that it is the only internationally accepted approach to a *sui generis* method of protection of plant varieties. Yet many developing countries assert that the UPOV, essentially a copy of the **European Plant Varieties Act**, fails to serve the interests of their farmers. The UPOV fails to give adequate attention to the fact that where the material for a new variety comes from farmers, the farmers' varieties are bound to be less uniform and stable than the breeders' varieties.

With this in mind, the "uniformity" requirement of a plant variety protection could be made less stringent for breeders, in favor of, perhaps, an "identifiable" requirement.

Another recommendation has been made that **geographical appellations** should be used. As the production of champagne is restricted to producers in France, so should the production of basmati rice be restricted to producers in

[44] The 1991 Convention has not yet entered into force. The ratification of five countries is needed, two of which must be new members to the Convention. However, countries have the option to voluntarily implement provisions of the 1991 Convention and many have elected to do so..

[45] The 1991 treaty extends the scope of the PBRs to include varieties "essentially derived" from the protected variety. This standard makes it difficult to freely breed without substantial changes to protected plant genetic resources. Perhaps a payment of royalties to the owner of the initial protected variety may also be required.

north India and Pakistan. **Indeed, despite these important lacunae in the UPOV treaties, the Indian Ministry of Agriculture drafted a Plant Varieties Protection and Farmers' Rights Act which is modeled on the UPOV 1991 treaty and which essentially has eliminated all farmers' rights except for acknowledging that farmers are often also breeders.**

6.2.b Farmers' Rights Options

Another option for governments is to accede to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, of November 2001.

It may become a binding protocol to the CBD. It has started to set the conditions for access and benefit-sharing as well as for farmers' rights. Such rights guarantee farmers returns on genetic material or local knowledge that is shared with any scientists or companies, national or foreign. Often, this set of Farmers' Rights is viewed as being in conflicting terms with PBRs because of the wide degree of farmers' control sought over genetic materials, local knowledge, financial resources, capacity building, and markets.

Yet, a regime of farmers' rights would alone prove to be inadequate. Indeed, although such a regime might recognize the imperative to compensate farmers' for their knowledge, it does not fully address the role of the state in preventing the misappropriation of plant genetic resources.

Furthermore, a regime of Farmers' Rights might not qualify as an effective *sui generis* system under TRIPS. Not only would it be difficult to determine who would hold the Farmers' Right-one farmer, a community of farmers-but it would also be difficult to justify protection over plant genetic resources if the farmers had not made any modifications to their breeding techniques.

6.2.c. Material Transfer Agreements (MTAs) Option

In recent years, as interest has increased in the use of genetic material for potential commercial, as well as academic purposes, the need for formal arrangements has been considered between the donors of genetic material (the provider) and individuals and organizations (the recipient) who request materials. Furthermore, these arrangements can be made whether or not intellectual property rights are subsequently given. MTAs may be viewed as bilateral contractual arrangements by which providers can receive the proportionate benefit of their contribution to the material, in the interim, before the generation of intellectual property by the recipient. These agreements are increasingly being utilized by public sector laboratories and also now appear in international genetic material exchanges, including those from developing to industrialized countries.

The advantages to this approach are that :

1. The scope of the genetic material in question can be detailed on a case-by-case basis. In essence, an MTA eases the impact of the TRIPS standards as Article 27 simply becomes a set of default rules to be bargained around in each case.

2. The agreements can be drafted to require recognition of the source country and/or local communities from which the genetic material has come (in the case of international storage facilities-i.e. genebanks).

3. Also, these agreements can specify whether intellectual property rights can generally be obtained on a particular genetic material as a query separate from an agreement to use genetic material in a particular instance.

An attractive option as it is, MTAs have several drawbacks:

1. First, although the concept of bilateral contracts is increasingly becoming popular, the issue of enforcement against third parties not privy to the contract remains unresolved.
2. Second, an MTA alone would not meet the requirements of an effective sui generis system; although it provides for access to genetic resources, it does not adequately address the issue of protection of these resources.
3. Finally, such bilateral contracts might be seen to infringe on the sovereignty of local communities. For example, if an MTA exists between India and the United States for the exchange of a particular genetic resource, the role of the local community from which the resource is taken still remains ambiguous.

7. Irreconcilable differences?

Therefore, although TRIPS and the CBD may superficially appear to be at odds with each other, a further analysis offers the possibility of reconciling the two agreements. The CBD does set down the principle of sovereign rights over genetic resources. TRIPS does require protection of genetic resources through patents or an effective sui generis system.

If member states party to both agreements are willing to allow private rights to be obtained over these resources in exchange for an equitable share in potential proceeds, they can meet their obligations under both agreements.

Even if India and other developing countries fully consider these diverse interests in developing their respective pieces of national legislation, some issues remain unresolved and outside the reach of any one country for resolution. Only global cooperation will be able to surmount these barriers.