



Asia-Pacific
Economic Cooperation

**The Australian APEC
Study Centre**

 **MONASH** University

Retarding Development

**Compulsory disclosure in IP law of ownership and
use of biological or genetic resources**

**Alan Oxley
Chairman
Australian APEC Study Centre
Monash University**

The Australian APEC Study Centre, Monash University
Level 12, 30 Collins Street
Melbourne, Victoria 3000 AUSTRALIA
Phone: +61399038757
Fax: +61399038813
Email: apec@apec.org.au
URL: <http://www.apec.org.au/>

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Executive Summary

“Disclosure” – a radical change, not an adjustment

India and Brazil want the WTO TRIPs agreement amended to require “disclosure” if any biological resource (including genetic resources) has been used to develop a process or product for which a patent is sought. Several other developing countries support this.

A new Protocol is also being proposed for the Convention on Biological Diversity to create an international regime to impose more onerous controls on genetic resources. The change to the WTO is represented as an “adjustment” which would not be burdensome.

The consequence of the changes is radical. The capacity to use IP law in important industries would be seriously restricted. Transfer of ownership of ordinary products, particularly food, would have to be regulated, overturning long established conventions in all societies that exchanges of goods should be free. If African countries have their way, ownership of genetic resources will be socialized.

Constraining development

The point of these changes is to control biopiracy so developing countries can reap the benefits of their natural biodiversity – “green gold”. By regulating intellectual property law, “misappropriation” of genetic resources in industrialized economies will cease.

There is a weak case for such radical change. The concept of “biopiracy” is contested and the incidence of events adduced to demonstrate it is small. The impact of these changes on development has not been considered. They are serious.

The new system will regulate property rights and intellectual property rights of any product containing biological resources in all countries. Under the CBD proposal, any national in a developing country with a property right to a genetic resource, would have the right to block applications for patents relating to any part of it by any other national.

This system will deter researchers and investors in developing countries. Many developing countries have patents that protect inventions and property rights. They also have rights which are important for securing benefits from research in agriculture. This is demonstrated in this report.

The system will be detrimental to development of any industry in which intellectual property is important – food and food processing industries, biotechnology and pharmaceutical industries. These are important for growth in developing countries.

New international rules to manage use of genetic resources

The change to TRIPs would require a new system of international regulation. Each



government would be obliged to ensure demonstration of every transfer of ownership of any product which is a “biological resource”. That could include many ordinary products, such as fruit and vegetables and plants and animals.

This has not been obvious from discussions in the WTO TRIPs Council because there has been no systematic analysis of the impact of requiring disclosure. Proposals to create parallel legal commitments for genetic resources have been made in the CBD where the regulatory implications are clear. The economic implications of disclosure have not been considered in either the WTO or the CBD.

The impact on agriculture

The regimes proposed in the WTO and the CBD would weaken the capacity of countries to benefit from innovation in agriculture.

The UPOV Convention (the Convention of the Protection of Plant Varieties) enables countries to protect new varieties of plants. UPOV research shows how developing countries using its rights increase production and exports.

The model of regulation proposed in the CBD would inhibit operation of UPOV. New varieties of plants are derived from large numbers of other plants, the owners of all whom would need to be consulted before a new variety could be protected. This would undermine research in new plant varieties which is vital for agricultural science.

The FAO has recently established a global system of gene banks to provide ready and cheap access to a large number of agricultural genetic resources. It is an international public good. The disclosure requirements would hinder access by all countries to it. Multiple approvals would be required to release agricultural genes which are currently freely available. Researchers in poor countries would be most disadvantaged.

A disproportionate response

The need for such a burdensome system of international regulation has not been demonstrated. There is no legal case to alter the TRIPs Agreement. India and Brazil argue it is a duty of the Doha Round to act to fulfil the intentions of parties to the Convention on Biodiversity. It is not. Even if it were, there is no agreement in the CBD on what action it should take.

There is an easy and simple way for governments to protect genetic resources. They can adopt national laws that delineate property rights to genetic resources and traditional knowledge and set rules on transfer of those rights. There is no need to hobble intellectual property. The CBD has developed guidelines on how to do this. Most members of the CBD have not applied them, although a few have¹.

¹ The CBD’s “Bonn Guidelines” have been followed by Australia and South Africa where national rules providing for recognition of ownership of genetic resources and traditional knowledge, prior informed consent of traditional owners and benefit sharing have been enacted.



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List of Acronyms

ABS:	Access and Benefit Sharing
AHOWG:	Ad Hoc Open-Ended Working Group
CBD:	Convention on Biological Diversity
CGIAR:	Consultative Group on International Agriculture Research
COP:	Conference of Parties
DDA:	Doha Development Agenda
EC:	European Community
EU:	European Union
FAO:	Food and Agriculture Organisation
IFOAM:	International Federation of Organic Agriculture Movements
IP:	Intellectual Property
LMMC:	Like-Minded Megadiverse Countries
MAT:	Material Access Transfer
NGO:	Non Government Organisation
PhRMA:	Pharmaceutical Researchers and Manufacturers of America
PIC:	Prior Informed Consent
PVP:	Plant Variety Protection
R&D:	Research and Development
TK:	Traditional Knowledge
TRIPs:	Trade Related Aspects of Intellectual Property Rights
UPOV:	The International Union for the Protection of New Varieties of Plants
US:	United States of America
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



Introduction

India and Brazil want the TRIPs Agreement amended to require “disclosure” of any biological resource or associated traditional knowledge and transfer of ownership whenever a patent is granted.

In the CBD, developing countries have proposed a Protocol on “Access and Benefit Sharing” of genetic resources (a leading sub set of biological resources) to the Convention on Biodiversity to serve the same purpose.

The concepts are closely related and would produce the same result – an international regime to regulate property rights for biological and genetic resources and to regulate the granting of intellectual property rights on any product or process which was related to a biological or genetic resource or any derivative.

Neither the impact of these far-reaching proposals, nor the need for them, has been assessed in the WTO or the CBD.

They have significant implications for property rights, intellectual property rights and the development interests of developing countries. The aim of this report is a preliminary look at those implications.



Proposals in the WTO

The TRIPs Agreement under the WTO allows for countries to deny patents to biological products and processes. Article 27.3(b) of the TRIPs Agreement allows “Members to exclude from patentability ... plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.” The TRIPs Agreement requires that this subparagraph be reviewed 4 years after the Agreement came into affect. This review is now being conducted.

In the 2001 Doha Declaration of the WTO the TRIPs Council was instructed to “examine the relationship between the TRIPs Agreement and the Convention on Biological Diversity”. This has also been included in the review of Article 27.3(b).

The current debate on the relationship between TRIPs and the CBD is focussed on the issue of disclosure of ownership of genetic resources². There are three proposals currently being considered. The WTO Secretariat, in its Summary IP/C/W368/Rev.1 titled them:

1. The TRIPS disclosure proposal under the WTO (primarily supported by Brazil and India);
2. The Patent Co-operation Treaty (PCT) disclosure proposal under WIPO (primarily supported by Switzerland); and
3. The Mandatory disclosure proposal (primarily supported by the European Community).

Brazil and India, supported by Pakistan, Peru, Thailand and Tanzania, have proposed an amendment to TRIPs.³ It is to require disclosure of the country of source of a biological resource or associated traditional knowledge and transfer of ownership before any patent with any association with that class of material can be considered, and requires penalties for failure to comply.⁴ As well, parties would be obligated to report any new knowledge about such disclosure on pre-existing patents. Failure to do so implies annulment of patents.

² It has been regularly asserted that there is conflict between the provisions of the WTO (TRIPs) and the CBD. There is no conflict between the obligations. This was implicitly recognized by India (see IP/C/W/459) when it based its case for conflict on the grounds that WTO members should assume the obligation for “fulfilling” the intentions of the CBD and that it is the failure of the TRIPs agreement to advance CBD interests that is where the conflict between the two regime lies. Perhaps India is envisaging a CDB with the ABS Protocol it favors in force. Then there would certainly be a conflict between it and TRIPs. Perhaps it reveals an aspiration of India and others that the CDB should go as far as proscribing use of patents.

³ WT/GC/W/564. TN/C/W/4, 31 May 2006

⁴ The Proposal relates to three classes of material – one, biological resources and associated traditional knowledge; two, biological resources; and three, “associated traditional knowledge”. It is unclear what this third class would constitute.



The concern of these countries is that a person can claim patent rights over a genetic resource that is under the sovereignty of another country⁵ and that “genetic resources and traditional knowledge are erroneously dealt with as if they formed part of the public domain”⁶. This is resulting in piracy of genetic resources and traditional knowledge.

A patent would not be approved until these requirements had been met. The amendment proposed to TRIPs would entail incorporation into national intellectual property regimes systems regulation of transfers of ownership of genetic resources. It would also oblige national authorities to require patent holders to report knowledge of previous transfers.

India and Brazil argue that these arrangements are necessary to fulfil the objectives of the Convention on Biodiversity⁷. India and Brazil contend that such a system of international regulation is necessary to ensure members of the WTO enact the changes necessary and should not be burdensome.

There are no legal provisions in the CBD which require this. (There is a proposal on the table in the CBD to adopt a decision to negotiate a legally binding regime which is discussed in the next section). India and Brazil present a political argument that the terms of the CBD make create an implicit obligation for WTO members to amend the TRIPs Agreement⁸.

TRIPs reform and the Doha Round

India has sought to make the “disclosure” question a core issue for the conclusion of the Doha Round in the WTO. At the Hong Kong WTO Ministerial India’s Minister for Commerce and Industry, Kamal Nath, stated the “Hong Kong Ministerial must pave the way for the launch of negotiations on the issues pertaining to the relationship between the TRIPs Agreement and the Convention on Bio-Diversity”⁹. In a submission by Brazil, India and others to the Committee on Trade and Development at the Hong Kong Ministerial titled “Reclaiming Development in the WTO Doha Development Round”, TRIPs was highlighted as “imbalanced” and amendments were sought to “prevent bio-piracy” through “disciplines on disclosure for the source and country of origin of genetic resources and traditional knowledge”¹⁰.

⁵ Council for Trade-Related Aspects of Intellectual Property Rights, “The relationship between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge”, World Trade Organisation, IP/C/W/356, 24/06/2002, p1

⁶ Council for Trade-Related Aspects of Intellectual Property Rights, “The relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Technical Observations on the United States Submission IP/C/W/459 by Bolivia, Brazil, Colombia, Cuba, India and Pakistan”, World Trade Organisation, IP/C/W/459, 18/11/2005, para 2

⁷ IP/C/W/459, para 10

⁸ A lengthy exposition of the Indian/Brazilian position was provided to the TRIPs council (document IP/C/W/495) in response to comments on the proposal by the US. It shows that it is the opinion of India and Brazil that such changes are necessary, not that there is a pre-existing obligation.

⁹ Nath, K., “Statement by HE Mr Kamal Nath Minister of Commerce and Industry”, World Trade Organisation Ministerial Conference, Sixth Session, WT/MIN(05)/ST/17, 14/12/2005

¹⁰ Committee on Trade and Development, “Reclaiming Development in the WTO Doha Development Round – Submission by Argentina, Brazil, India, Indonesia, Namibia, Pakistan, the Philippines, South Africa and Venezuela to the Committee on Trade and Development”, World Trade Organisation, WT/COMTD/W/145, 01/12/2005



A major proposal

The proposal has major consequences for intellectual property law, exercise of property rights over “biological materials”¹¹ and, as this report shows, development.

India and Brazil are proposing a system that will require development of national systems of regulation in each member of the WTO to govern the transfer of ownership of genetic resources. It is to be bound by international rules.

The full dimensions of what is entailed is implicit from their proposed changes to TRIPs, but have not been fully discussed in the TRIPs Council. A clearer idea has emerged in discussions in 2006 in the Convention on Biodiversity over a proposal to negotiate an international Protocol to the Convention on Biodiversity (CBD). It would create rights and obligations to regulate Access and Benefit Sharing of Genetic Resources (ABS) parallel to the “disclosure” amendment to TRIPs. This is discussed in the next section.

There has been virtually no analysis in the WTO or the CBD about the dimension of the “problem”, the economic interests at stake, the consequences of an international regulatory solution or other options. There is no agreement on several fundamental questions. This is discussed in Section 6.

The case that such a major issues should be bound into the Doha Round, and at such a late stage, when it was clearly not what was envisaged in the Declaration launching the Doha Round, has not been made.¹²

¹¹ The CBD definition of “Biological resources” is “includes genetic resources, organisms or parts thereof, populations, or any other biotic components of ecosystems with actual or potential use or value for humanity” (Convention on Biodiversity, Article 2).

¹² India, Brazil et al, propose in WT/GC/W564 that the amendment to be made in the TRIPs agreement include “Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.” The operative provisions of the CBD are more important and they expressly provide in Article 15 that any measures adopted in the CBD should enable the functioning of intellectual property law and respect obligations under other international conventions. This amendment would reflect agreement by members of the WTO that implementation of TRIPs should be in accordance with the objectives of the CBD. This was not the intention of the parties which agreed on the CBD or the Agreement on TRIPs.



Proposals in the CBD

The Convention on Biological Diversity obliges parties to facilitate access to genetic resources and benefit sharing. Its basic proposition is that national laws are to be used to meet these goals. It also states that parties to the Convention should facilitate the enjoyment of benefits by the providers of genetic resources if patents are taken out on genetic resources but qualifies this elsewhere by stating that patents need to respect intellectual property law and that the Convention should not diminish rights and benefits under other international treaties.

Ministers decided at the Johannesburg Summit in 2001 to adopt an international regime on access and benefits sharing of genetic resources. Parties to the Convention decided to begin work to implement that commitment in 2002. Parties to the CBD are still to decide if that regime should be legally-binding. There is already a form of international regime set out in the non-binding “Bonn Guidelines on Access and Benefit Sharing of Genetic Resources” which have been adopted by the CBD¹³.

In the lead up to the eighth meeting of parties of the CBD (held in Curitiba, Brazil in 2006), Ethiopia, on behalf of the African Group, tabled a draft Protocol of a legally binding instrument on Access and Benefit sharing of Genetic Resources. It was supported as well by India and Brazil.

That Protocol showed how the international regime envisaged in the Indian/Brazilian disclosure proposal, might look. Details of the Protocol are set out in Appendix 1. The draft Protocol formally elaborates the Indian/Brazilian TRIPs Disclosure proposal in three important ways.

First it proposes an international system for regulation of transfers of genetic resources (by parties within and across national jurisdiction). Discussions in the CBD show an expectation that this would be achieved through a system of certificates which verify the authenticity of transfers of ownership. Second it is explicit that the system of regulation will apply to any derivative of a genetic resource when it comes to granting patents. Third it quantifies the share of royalties (half) that should be paid to providers of genetic resources.

It is also notable the Protocol envisages the possibility of the socialization of the ownership of all genetic resources. There is no agreement about this proposal. Investigative work will continue in the CBD and the question will be re-examined at the tenth meeting of parties in 2010. There are a large number of unresolved issues.

¹³ These guidelines were developed by members of the CBD pursuant to obligations under the CBD. They set guidelines for members to follow when implementing arrangements in national law on access and benefit sharing. The handful of parties to the CBD which have implemented national laws for ABS have generally followed the Bonn guidelines.



Regulating Genetic Resources - Unresolved Issues

What Bio-Piracy?

Control of biopiracy is the primary justification for a new international system for regulation of genetic resources. There is no agreement on what constitutes “biopiracy”. Previous research by the Australian APEC Centre¹⁴ revealed no instances of the forcible, illegal removal of genetic resources in any jurisdiction. Leading technical agencies like the Food and Agricultural Organization (FAO) do not use the term. Alternatives are being used instead. It is common now to refer to “misappropriation” of intellectual property¹⁵. Increasingly the use of the term is also qualified. The Third World Network, a leading NGO proponent of international regulation of transfers of genetic resources and an advisor to the African Group in the CBD, issued a report at Curitiba listing a number of instances which it only described as “suggestive” of biopiracy. Those who coined the term made clear it was a political concept. Others, like the Third World Network use it that way¹⁶.

Even the term “misappropriation” is troubling. This is another term for theft and when applied to foreign IP processes constitutes an accusation of theft by the Governments administering those schemes. It is an extreme suggestion.

Proponents of regulation point to misuse of patents and trademarks as evidence of “misappropriation” and “biopiracy”. Yet, patents and trademarks have been revoked when basic requirements in sound intellectual property law, for example that a patent can only be granted when there is no invention or innovation or that a trademark may not be registered for commonplace names, have not been satisfied. These cases, which are not numerous¹⁷ given how many patents and trademarks are registered, neither demonstrate that there is a systemic problem with compliance with the provision of IP law or with the basic notions in IP law. Patents over products derived from the Neem tree are regularly cited as evidence of biopiracy. Appendix 2 shows they do not demonstrate theft or systemic malfunctioning of intellectual property procedures.

The case for onerous regulation of transactions of genetic resources is weak. There are simpler ways to ensure parties have the necessary rights to genetic resources to secure the benefits they offer.

¹⁴ Bowen, B., “Developing an effective international regime for access and benefit sharing for genetic resources using market-based instruments”, The Australian APEC Study Centre, Monash University, 12/12/2005, at <http://www.apec.org.au/docs/051031%20-%20REPORT%20-%20CBD%20ABS.pdf>

¹⁵ The term is used in a major recent commentary by developing countries in the TRIPs Council. See IP/C/W/459

¹⁶ This was made clear by the Canadian NGO which coined the term. The Third World Network refers to the ‘phenomenon of bio-piracy’ where corporations from developed countries patent genetic resources and knowledge for their profit. www.twinside.org.sg/title/undp4.htm

¹⁷ The developing country case for disclosure presented to the WTO TRIPs Council list only 15 prospective instances. See IP/C/W/459.



What is a genetic resource?

The CBD treats it a leading biological resource and describes it as genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity – i.e. genes) with prospective or real value. One agricultural scientist has observed that genes are not specific¹⁸. Research on the human genome has shown that genes are widely shared among all living things.

Until there is greater functional specificity of what should be regulated, current proposals envisage the prospect of a global system to regulate every transaction of any product containing genes. For a start this would mean regulation of every transfer of ownership of any agricultural product which contains a gene or derivative of a gene (every strand of DNA?) in any product or process to be patented.

This does not seem practical. What principle warrants the overlaying of all commercial transactions of products containing biological (and thereby genetic) resources with such a system of regulation?

Finally, who is entitled to claim prior right of ownership of a genetic resource? What is the significance of reporting the country of origin of a biological resource? What principle states the significance of that? Very few products can be claimed as belonging exclusively to any national jurisdiction.

How valuable is “Green Gold”?

The underlying concern of the proponents of disclosure is to ensure their nationals (or the State) secure the benefits from exploitation of biological and genetic resources. While widely asserted as very commercially valuable, no efforts have been made to estimate the value of commercialization of each country’s biological or genetic resources.

One measure is the level of commercial interest in bio-prospecting, the principal means of discovering valuable genetic resources. A Columbian University study reported that “some pharmaceutical companies have recently cut back on their bio-prospecting activities because costs are higher than expected”. This lack of desire to maintain bio-prospecting springs from findings suggesting that, “no compound has been advanced into the commercialisation phase” as of yet, no royalty or commercialisation-derived monetary benefits have resulted from any of the agreements. The odds of finding a new drug from botanical samples are still very low (between 1/80,000 and 1/250,000 in plant samples)¹⁹.

¹⁸ Hardon, J. cited in Stannard, C., van der Graff, N., Randell, A., Lallas, P. and Kenmore, P., “Agriculture biological diversity for food security: Shaping International Initiatives to help agriculture and the environment”, *Howard Law Journal*, v48, i1, pp397-430, Fall 2004, p411

¹⁹ Feinsilver, J. cited in Environmental Policy Studies Workshop, “Access to Genetic Resources: An evaluation of the Development & Implementation of Recent Regulation and Access Agreements”, Columbia University School of International and Public Affairs, Environmental Policy Studies, Working Paper Number 4, 06/1999 at <http://www.biodiv.org/doc/case-studies/abs/cs-abs-agr-rpt.pdf>, p87



At a side event at the eighth meeting of parties to the CBD in Curitiba officials from Brazil, Costa Rica, Peru and Colombia, Brazil reported on the extent of bio-prospecting in their countries. Brazil reported there were 100 applications a year for bio-prospecting. In Costa Rica, 19 licences were current and there were only one each in Peru and Colombia. Research last year by the Australian APEC Centre reported interest by companies in bio-prospecting was falling. A major deterrent was excessive regulation of bio-prospecting.

To apply the “green gold” analogy, there seems little evidence of a “gold rush”. If there were, there would be thousands of applications for bio-prospecting worldwide.



IP in Developing Countries

It is a popular misconception that developing countries do not use or need intellectual property. There are more patents in industrialized economies than developing economies. However IP does matter to developing countries.

Appendix 3 show the number of patents granted to residents and non-residents in a selection of economies. The following counties have a significant number of patents: Argentina, Brazil, Chile, China, Colombia, Korea, Malaysia, Mexico, Pakistan, the Philippines, Singapore, South Africa and Thailand.

Patents taken out by Residents demonstrate commercialization of research and invention by domestic groups.

Patents taken by non-Residents indicate the interest of international businesses in operating in those countries. They are also shown in Appendix 3. Foreign companies will not bring products and technology nor invest in other countries unless they consider their intellectual property will be protected. In the global economy, these inputs are vital drivers for growth.

If regulatory processes are too onerous or undermine the value of intellectual property, business, national or foreign, with valuable technology or brands simply will not invest or do business.

Any country adopting the systems of regulation of property rights and intellectual property proposed would be wise to weigh up the consequences before doing so.



Implications for Agriculture

As far back as civilization dates, human society has depended on exchange in agriculture. Today, on average, 70% of crops derive from other regions²⁰. This has been and remains an essential feature of agricultural production.

The current concept underpinning the proposals for international regulation of access to genetic resources is that every transaction of a genetic resource needs to be recorded and (as proposed in the CBD) the conditions of transfer (authentication of ownership, securing prior informed consent, and agreement on benefit sharing) verified before a patent can be issued. In the proposal to amend TRIPs these obligations would apply where national law so stipulated. These disclosure processes require prior knowledge of these matters. Systems would need to be established to provide that prior knowledge.

It is an inescapable conclusion that evidence of transfers of ownership of most food products would be necessary. Patents and trademarks are extensive for food products. No patent could be provided on a food product or process until the legitimacy of ownership of the biological material (in TRIPs) and genetic material (in the CBD) concerned was verified.

It is evident that such a system of regulation would greatly impede the granting of patents. The cost of compliance would in many cases outweigh the benefits. The reduction of financial reward from patents would deter use of the patent system.

The process also opens the possibility that the cost of acquiring property rights (i.e. ownership) to agricultural products would rise. The implications of this have not been considered in the WTO or the CBD. The FAO has pointed out that in order to meet ethical imperatives of feeding future generations, it is necessary to reduce to a minimum the transaction costs involved in accessing & using agricultural genetic resources²¹.

Other international systems which create property rights to plant varieties and access to agricultural gene pools would also be adversely affected.

Plant Breeder Rights created by UPOV

The Union for the Protection of New Varieties of Plants (UPOV) was formed in 1961. It administers a convention that allows for new varieties of plants to be protected.

UPOV has 60 members. Between 1992 and 2003, membership increased from 20 to 50 countries. By late 2005, 18 more states had lodged applications to join and another 47 had made enquiries about membership. The members of UPOV are listed in Annex 4 of this report.

²⁰ Commission on Genetic Resources for Food and Agriculture, "Transaction Costs of Germplasm Exchange Under Bilateral Agreements", Background Study Paper No.14, Global Forum on Agriculture Research, 06/2001, at <ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp14e.pdf>

²¹ *ibid*



Since 1992, the number of plants protected has risen from just over 20,000 to around 60,000.

The aim of the convention is, “to provide & promote an effective system of Protection of Varieties of Plants with the aim of encouraging the development of new varieties of plants, for the benefit of society”. It reflects the philosophy that genetic materials contribute to the common heritage of mankind.

Breeders of new varieties of plants are granted them an intellectual property right (Plant Variety Protection or PVP), on the basis of a set of clearly defined principles:

- (i) distinct from existing, commonly known varieties
- (ii) sufficiently uniform
- (iii) stable
- (iv) new in the sense that they have not been commercialized prior to certain dates established by reference to the date of the application of protection.

Under the regime, protected varieties of plants will still be available for private or non-commercial acts, or experimental acts. Subsistence farmers are eligible to use protected varieties.

A recent study by UPOV of the impact of membership on some new members (Argentina, China, Kenya, Poland and Korea) showed that after membership, the number of varieties protected had increased significantly²².

For instance in Argentina, production of soybean increased by 350 percent and exports by 400 percent. In Kenya, exports of cut flowers increased by 240 percent. These were important contributors to economic growth.

Undermining of UPOV

The implementing mechanisms proposed in the Protocol to the CBD would overlay the UPOV system with the requirement to demonstrate prior approval of the owners of genetic resources.

It is common for new plant varieties to draw on tens of other plant varieties. This is a natural feature of the science of plant breeding. UPOV officials do not consider the system could function with such additional requirements. UPOV set its views out to the CBD and they are summarized in Appendix 6.

FAO programs to protect agricultural genetic resources

The Food and Agricultural Organization (FAO) leads international efforts to help developing countries modernize and improve agriculture. In 1983 FAO established the Commission on Genetic Resources. A major gene bank is administered under FAO resources by the Consultative Group on International Agricultural Research

²² “UPOV Report on the Impact of Plant Variety Protection”, International Union for the Protection of New Varieties of Plants, 2005



(CGIAR). It holds six hundred thousand samples of major crops²³. Banks like this are vital public goods.

In 1995 the mandate of FAO's Commission was extended to cover all components of biodiversity related to food and agriculture. It facilitated the International Treaty on Plant Genetic Resources for Food and Agriculture which was adopted by the FAO conference in 2001.

The objective of the Treaty is the conservation and sustainable use of plant genetic resources for food and agriculture. Its primary mechanism is a multilateral system of access to agricultural genetic resources including information exchange, access to and transfer of technology, capacity building, and sharing of benefits derived from commercialization²⁴.

The Treaty creates an international network of publicly owned gene banks. Membership gives farmers rights of access and easy access for researchers.

Researchers can search these banks to locate disease resistant varieties from which to breed new varieties: as they did to replace potato varieties in Europe in the nineteenth century after the Irish potato famine and varieties of peanuts in North America in the twentieth century when local varieties were wiped out by disease.

Maintenance of biodiversity in agricultural plant varieties is very important because commercial crops typically depend on few varieties. A wide gene pool is important for maintaining the effectiveness of current breeds (when for example they are struck by disease or pests) or when new varieties need to be developed to increase productivity. It is essential infrastructure to maintain the capacity of agriculture to meet global demand for food.

Agricultural specialists have expressed two major concerns about the philosophy of managing genetic resources which underpins the approach of India and Brazil in the CBD.

The first is the relative ineffectiveness of identifying ownership of specific genes of agricultural species for the purpose of securing value, as is implicit in the approach of India and Brazil. Diversity within species for crops and domestic animals is at least as important as diversity among species (inter-specific diversity). Intra-specific diversity results from incremental improvement of crops/animal breeds from crossing and selection from a wide range of sources to improve varieties²⁵.

Samples of genetic resources infrequently provide large-scale appropriable benefits, and it is impossible to identify the parent varieties, origins of genes, and relative value in the finished variety.

²³ Stannard, C., van der Graff, N., Randell, A., Lallas, P. and Kenmore, P., "Agriculture biological diversity for food security: Shaping International Initiatives to help agriculture and the environment", *Howard Law Journal*, v48, i1, pp397-430, Fall 2004, p404

²⁴ This is evidence of a standard Material Access Transfer (MAT)

²⁵ Stannard, 2004, p403



The second concern is that it is typical of agriculture genetic materials to draw on a very large set of genetic sources. Any system that required approval of the owners of all those sources would delay or block access.

Undermining FAO strategies to protect biodiversity

The FAO has argued to the CBD that the system of regulation proposed in the Protocol will conflict with international systems that have been established to protect biodiversity in agriculture and to provide access from public sources for agricultural genetic resources. Details are provided in Annex 7.

It also seems clear that the related process of prior disclosure of ownership of genetic resources does not take account of the reality of the technical foundations of development of new varieties of plants. The multiplicity of approvals the may be required are likely to hold up approvals.



Consequences

Two erroneous suppositions

A. Developing countries have nothing to lose and a lot to gain

The general argument to support these changes is that controls are required over IP law to protect the interests of developing countries. The device is to choke the award of intellectual property where a biological or genetic resource has been drawn upon and to create processes which regulate transfer of property rights to biological or genetic resources related to the award of intellectual property rights. The aim is to enable the owners of genetic resources to lay a claim to a revenue stream from a patented product or process. This is unstated in discussions in the TRIPs council, but is overt in discussions in the CBD.

The supposition is that by regulating all IP processes associated with biological and genetic material in this way, developing countries will benefit because industrialized countries are the major users of IP and the costs of this system of regulation will be carried by them.

This overlooks the fact that developing countries have substantial interests in the provision of intellectual property rights within their own jurisdictions.

While many developing countries issue more patents for foreign applicants than national applicants, many larger developing countries have issued a significant number of patents for residents. Furthermore, this is not a symptom of lesser standard of development in developing countries. It is a function of the size of the economy. Most middle-sized and small industrialized economies also have issued a larger numbers of patents for foreign applicants than national applicants.

The system proposed would also deter research by nationals in developing countries. Owners of genetic resources within national administrations would also have the capacity to constrain other nationals from securing intellectual property rights. Owners of biological resources would likely acquire the right to litigate failure to disclose prior ownership by patent holders under the regime implicit in the Indian/Brazilian TRIPs disclosure amendment.

The capacity to provide such rights is necessary to support development of business by companies, both national and foreign, which bring technology into the economy which must be protected. This is important to support investment.

The proponents of these systems have disregarded a very well-established system of intellectual property to support research in agriculture and an innovative and valuable system to protect biodiversity in agriculture by establishment of a system of simple access to a network of global banks of agricultural genetic materials. These provide important benefits to developing countries.

The new system would significantly inhibit the capacity of developing countries to enjoy these benefits.

B. The concept is technically sound

The second erroneous supposition is that the technical understanding of the nature of “genetic material” was sufficient to construct a system of allocating rights to those materials and governing use of them.

Experts in agriculture have amply demonstrated that allocation of rights according to their genetic composition does not work in the case of agriculture. As one expert notes, “genes are not specific”. This proposition has wider application than to agriculture. The implication that ordinary transactions and thereby ownership of genetic materials need to be recorded and regulated as a prior condition for successful regulation of the award of intellectual property is warning enough that there is a fundamental flaw in the concept. Like “biopiracy”, the desire to regulate genetic materials appears driven more by political considerations than scientific and technical considerations.

Heavier burden on developing countries

Developing countries would be the primary losers if such a system were introduced. Growth would slow in all industries in all countries dependent on research using biological or genetic materials under such a regime. It would deter research on genetic materials and investment in industries that developed them. Industrialized economies can afford measures which restrain growth. But developing needs higher average rates of growth to raise living standards.

Where governments had options about introducing such a system, for example electing to accede or not to a Protocol to the CBD which mandated introduction of such a system, it is a fair bet the countries with significant interests in industries most affected by a choking of intellectual property law would not accede. Governments that did accede would be committing to systems that would deter research and investment by nationals as well as foreigners.

These countries would be closing off an important support for development. It is noticeable that as economies develop, the level of intellectual property in the economy rises. This is clear in East Asia and Latin America.

Developing countries which today considered that restrictions on intellectual property would not be of much consequence are overlooking the fact such a system of regulation will deter research and investment for which there will be greater need as the economy advances.



Practical Options

There is a very simple option for governments that wish to protect exploitation of genetic resources and traditional knowledge. They can simply clarify property rights to genetic material and traditional knowledge and, if they wish, impose national conditions on the acquisition or disposal of these property rights.

This can be done where there is a desire to protect traditional knowledge and to ensure that traditional owners are involved in benefit sharing arrangements. South Africa has built such provision into its IP law. Australian federal authorities and the state of Queensland have regulated a similar requirement.

It has been pointed out that traditional commercial contracts (i.e. purchase of the right to own a genetic resource) are also an effective device for ensuring benefits is shared.

In a number of countries, the failure to “protect” genetic resources or traditional knowledge is simply a failure to create clear property rights and to ensure they are protected. When property rights are secure, owners can decide their own terms for securing benefit from any transfer of ownership.

India and Brazil argue that relying on national administration alone to establish such rights is not enough; international regulation is necessary to secure compliance²⁶. This flies in the face of experience. International regulation is the most inefficient means of securing change given the remoteness, complexity and cost of administration. It is only warranted when the cost of compliance is outweighed the benefits of the system. That is clearly not the case with the proposals to require compulsory “disclosure” in TRIPs and negotiation of a Protocol to the CBD.

Making regulation of the transfer of ownership of a biological resource (which thereby devalues the right of ownership) a necessary precondition for the granting of intellectual property rights is an oblique rationale for regulation. One must wonder why. The only rational answer is offered by the effect of the regulation. It curbs the exercise of intellectual property law.

²⁶ See IP/C/W/459



Bibliography

1. Bowen, B., “Developing an effective international regime for access and benefit sharing for genetic resources using market-based instruments”, The Australian APEC Study Centre, Monash University, 12/12/2005, at <http://www.apec.org.au/docs/051031%20-%20REPORT%20-%20CBD%20ABS.pdf>
2. Conference of the Parties to the Convention on Biological Diversity, “Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity”, Convention on Biological Diversity, UNEP/CBD/COP/5/23, 22/06/2000
3. Commission on Genetic Resources for Food and Agriculture, “Transaction Costs of Germplasm Exchange Under Bilateral Agreements”, Background Study Paper No.14, Global Forum on Agriculture Research, 06/2001, at <ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp14e.pdf>
4. Committee on Trade and Development, “Reclaiming Development in the WTO Doha Develop Round – Submission by Argentina, Brazil, India, Indonesia, Namibia, Pakistan, the Philippines, South Africa and Venezuela to the Committee on Trade and Development”, World Trade Organisation, WT/COMTD/W/145, 01/12/2005
5. Council for Trade-Related Aspects of Intellectual Property Rights, “The relationship between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge”, World Trade Organisation, IP/C/W/356, 24/06/2002
6. Council for Trade-Related Aspects of Intellectual Property Rights, “The relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Technical Observations on the United States Submission IP/C/W/459 by Bolivia, Brazil, Colombia, Cuba, India and Pakistan”, World Trade Organisation, IP/C/W/459, 18/11/2005;
7. Environmental Policy Studies Workshop, “Access to Genetic Resources: An evaluation of the Development & Implementation of Recent Regulation and Access Agreements”, Colombia University School of International and Public Affairs, Environmental Policy Studies, Working Paper Number 4, 06/1999 at <http://www.biodiv.org/doc/case-studies/abs/cs-abs-agr-rpt.pdf>
8. Executive Secretary of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, “Compilation of submissions provided by parties, governments, international organizations, indigenous and local communities and relevant stakeholders related to the International Regime on Access and Benefit-Sharing”, Convention on Biological Diversity, UNEP/CBD/WG-ABS/4/INF/3, 14/12/2005
9. Executive Secretary of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, “Compilation of submissions provided by parties, governments, international organizations, indigenous and local communities and relevant stakeholders in preparation for the Third Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing”, Convention on Biological Diversity, UNEP/CBD/WG-ABS/3/INF/1, 08/12/2004
10. Gerhardsen, S., “India, Brazil, Peru Set to Table Proposed TRIPS Amendment on Biodiversity”, IP Watch, 05/05/2006



11. Nath, K., “Statement by HE Mr Kamal Nath Minister of Commerce and Industry”, World Trade Organisation Ministerial Conference, Sixth Session, WT/MIN(05)/ST/17, 14/12/2005
12. Palacios, X., “Contribution to the estimation of countries’ interdependence in the area of plant genetic resources”, Commission of Genetic Resources for Food and Agriculture, Background Study Paper, W/W5246/e, n7, r1
13. Secretariat of the Council for Trade-Related Aspects of Intellectual Property Rights, “The relationship between the TRIPs Agreement and the Convention on Biological Diversity – Summary of issues raised and points made”, World Trade Organisation, IP/C/W/368/Rev.1, 08/02/2006
14. Shiva, V., “The Neem Tree – A case in history of biopiracy”, <http://www.twinside.org.sg/title/pir-ch.htm>
15. Stannard, C., van der Graff, N., Randell, A., Lallas, P. and Kenmore, P., “Agriculture biological diversity for food security: Shaping International Initiatives to help agriculture and the environment”, Howard Law Journal, v48, i1, pp397-430, Fall 2004
16. “UPOV Report on the Impact of Plant Variety Protection”, International Union for the Protection of New Varieties of Plants, 2005
17. India, Brazil, Peru, Thailand and Tanzania, WTO, “Doha Work Programme– The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity”. WT/GC/W564, 31 May 2006



Appendices

Appendix 1 Convention on Biological Diversity – Article 15 and proposed Protocol on Access and Benefit Sharing on Genetic Resources

Article 15 of the Convention on Biodiversity sets general obligations of parties to the Convention to facilitate access to and benefit sharing from use of genetic resources.

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

At their seventh meeting, the parties to the Convention on Biodiversity established an open ended working group to consider the question of access and benefit sharing of genetic resources. The fourth meeting of the Working Group was held in Granada, Spain in January 2006.

At that meeting, Ethiopia, on behalf of the African Group, tabled a draft Protocol to the CBD on Access and Benefit Sharing.²⁷ The text was supported by India and Brazil and several other developing countries, but not all members of the Group of “Like Minded Mega Diverse Countries which support a disclosure amendment to TRIPs.

²⁷ Executive Secretary of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, “Compilation of submissions provided by parties, governments, international organizations, indigenous and local communities and relevant stakeholders related to the International Regime on Access and Benefit-Sharing”, Convention on Biological Diversity, UNEP/CBD/WG-ABS/4/INF/3, 14/12/2005



The African Group Proposal

Article 2 of the Protocol explicitly extends its terms to cover derivatives of genetic resources. Article 4 states any biological resource shall remain owned by the people of the country of its origin, defined as “the provider”, and cannot be “used by” or transferred without their “written prior informed consent”. Article 7 states any results from R&D will be half owned, including the IP, by the provider. Article 10 stipulates any rights to the use of the biological resource will only be assigned to the individual recipient and additional written permission from the provider is required. Article 11 stipulates that if research into a licensed biological resource is published, copies of “every manuscript” must be submitted 45 days prior to its submission to the provider who can exercise editorial control and the right to keep components of the research confidential.

Article 13 of the protocol provides significant financial benefits for the provider through remuneration in both monetary and non-monetary forms. Article 14 provides that monetary benefits include costs associated with collecting a biological resource, upfront license fees and half of profits following commercialisation of derivatives which will half be paid to the “community or communities concerned”. How these communities are identified is unclear.

Article 15 stipulates non-monetary benefits include complete access to all research and development, requirements for R&D to be conducted in the provider’s country, participation in product development, including joint ventures and transfer of any technology used on the object to the country of origin.

Operational provision of the draft declaration follows:

Operational provisions of the draft Protocol on Access and Benefit-Sharing to the Convention on Biodiversity

Article 1

Objectives

The objectives of this Protocol are the facilitated access to, and the fair and equitable sharing of the benefits arising from, the use of biological resources and community knowledge and technologies for improving human life and for the conservation and sustainable use of biological diversity.

Article 3

Scope

1. This Protocol shall apply to the facilitation for users of access to objects and the fair and equitable sharing by the providers and users of the benefits that accrue from the commercial and other applications by the users of the accessed objects.
2. This Protocol shall also apply to cooperation between providers and users in accessing biological resources for conservation, research and teaching.
3. Any use of accessed objects for any purpose not covered by the provisions of this Protocol is prohibited unless it is covered by an agreement based on a prior informed consent between the country of origin and the user.
4. This Protocol shall not affect the customary access, exchange or use of any object among local communities.

Article 4

Ownership

1. Any biological resource, including any modifications thereof or any parts or genetic or biochemical components derived there from, whether incorporated into any other organism or not, whether located within the country of origin's territory or not, shall, at all times, be the property of the people of the country of origin and shall not be used by, or transferred to, third parties without the written prior informed consent of the provider and the concerned local community or communities of the country of origin.



2. Any community knowledge or technology, whether imbedded in a biological resource or not, belongs to the concerned local community or communities, and shall not be used by any person in another country without the written prior informed consent of the concerned local community or communities, as the case may be.

Article 5

Conditions Governing the Use of the Accessed Objects

1. Any accessed object shall be used only for the purposes specified in a written prior informed consent. Uses not foreseen during the first written prior informed consent shall be covered by subsequent written prior informed consents. If subsequent negotiations aimed at updates or new versions of written prior informed consent fail, then the recipient shall refrain from any use of the object in question for purposes other than those covered in an existing written prior informed consent.
2. No accessed object shall be used by, or be transferred to, any third party without the provider signing a prior informed consent with that third party.
3. The recipient shall be responsible for the scientists or other persons, whether employed by the recipient or not, who may handle or know of the accessed object and the recipient shall ensure that the accessed object is always used only as provided for by the terms of the written prior informed consent.

Article 7

Rights and Obligations of the Provider and the Recipient

1. Both the provider and the recipient shall use every reasonable means to protect each other's interests that have been specified in the written prior informed consent. Failure by either side to do so shall be fully compensated for by the failing side.
2. Both the provider and the recipient shall have joint and equal rights over the results arising from the use by the recipient of any object supplied by the provider and accessed by the recipient through a written prior informed consent.
3. Both the provider and the recipient shall jointly and equally own any intellectual property rights over new varieties, modifications, products or process arising from the use by the recipient of any object supplied by the provider and accessed by the recipient.
4. Either the provider or the recipient may, if he so wishes, prevent the obtaining, or forgo his own inclusion as a co-owner, of any intellectual property right, provided, however, that this is not done in violation of a written prior informed consent.

Article 8

Rights and Obligations of the Provider

1. The Provider shall have the following rights:
 - a) On behalf of the State or the local community or communities, as appropriate, to maintain ownership of the object provided;
 - b) to act on behalf of the State and/or the local community or communities, as appropriate, in exercising the ownership provided under subparagraph 1 (a) and other rights over the object accessed;
 - c) to grant third parties access to the object specified in the written prior informed consent for uses other than those specified in the written prior informed consent;
 - d) to grant third parties access to the object specified in the written prior informed consent for the same uses as those specified in the written prior informed consent or for other uses in areas of the world not covered by that written prior informed consent.
2. The provider shall have the following obligations:
 - a) to give to the recipient the object specified in the written prior informed consent;
 - b) when the object in the written prior informed consent is a biological material, upon the submission of the recipient's research proposals related to its use, to inform the recipient of any existing relevant community knowledge or technology, as well as propose a new written prior informed consent for providing that relevant community knowledge or technology so as to avoid any possible confusion between that item of existing community knowledge or technology and the recipient's research innovations.



Article 9

Rights and Obligations of the Recipient

1. The recipient shall have the following rights:

- a) to use the object he has accessed from the provider according to the terms of the written prior informed consent;
- b) to use the object he has accessed from the provider for purposes other than those specified in an existing written prior informed consent only based upon a new written prior informed consent.

2. The recipient shall have the following obligations:

- a) to refrain from using of, or claiming any rights over, the accessed object other than what is specified in the written prior informed consent;
- b) to acknowledge in any publication or package that the accessed object belongs to the country of origin;
- c) to assist in identifying or in bringing to court infringes upon the rights of the country of origin over the accessed object;
- d) to refrain from any claims for intellectual property rights that exclude the provider over any innovations which involve the accessed object;
- e) to keep the provider fully informed of any improvements or new developments arising from the use of the accessed object;
- f) to keep as well as promptly communicate to the provider any data regarding the use of the accessed object;
- g) to seek and obtain a written prior informed consent before accessing any additional object from the country of origin of the already accessed object in conformity with the relevant laws of that country of origin and international agreements to which that country of origin is a party.

Article 10

Assignability

- 1. All rights and obligations in a written prior informed consent are personal to the respective provider and recipient and cannot be assigned, transferred, pledged or otherwise disposed of by either one of them without a new written prior informed consent by the other.
- 2. Rights or obligations under a written prior informed consent may be assigned to a third party when both the provider and the recipient are parties to the agreement of assignment.

Article 11

Publications

- 1. The recipient shall provide the provider with every manuscript resulting from any research using the accessed object at least 45 days prior to submission for publication or presentation
- 2. The provider reserves the right to review any such manuscript and to require that any part of it be kept as confidential in order to protect his proprietary rights and interests.
- 3. The provider shall notify the recipient in writing within 30 days identifying the information in the manuscript, if any; he wants kept confidential and suggesting editorial modifications, if any.
- 4. The recipient shall keep as confidential any information identified by the provider under sub articles 2 and 3 of this article except what is required by the law of the country where the recipient is operating.

Article 12

Guarantee

Each contracting party to this Protocol shall ensure that the commitments entered into by its citizens in written prior informed consents as providers or recipients fulfill his obligations.

Article 13

Principle of Benefit-sharing

The benefits that shall accrue to the provider from the use by the recipient of the accessed object shall have both monetary and non-monetary components.



Article 14

Monetary Benefits

1. Any costs borne by the provider in collecting or compiling the object accessed shall be charged to the recipient at the time of access or at any other time that the provider and the recipient mutually agree to.
2. The provider may require a specified up-front payment from the recipient. The amount will be mutually agreed.
3. When commercialisation starts, a royalty equal to half of the net profit from the monetary benefits that accrue from the object accessed shall be paid each year to the provider.
4. The provider shall pay directly to the local community or communities concerned at least half of the royalties earned under Sub article 3. If the local community or communities concerned so desire, this money shall be used to implement programmes that they determine; otherwise, it will be made available to them as cash.

Article 15

Non-monetary Benefits

Non-monetary benefits shall accrue to the country of origin of the accessed object and shall include:

- a) Complete access to all research and development results;
- b) Capacity building in research and development through the recipient carrying out all research and development activities wished by the country of origin of the accessed object in that country with the participation of those of its citizens its government specifies;
- c) Participation in product development, including the establishment and running of joint ventures that the government of the country of origin wishes to join in or wishes any of its citizens to join in;
- d) Transfer of any technology used on the accessed object to the country of origin of that accessed object.

Article 16

Confidential Information

1. Neither the provider nor the recipient shall directly or indirectly divulge to unauthorized persons any information which has been identified as confidential and mutually agreed by both parties, except when otherwise required by the laws of their respective countries.
2. Information identified by either the provider or the recipient as confidential shall be notified to the other side and agreed to in writing within 30 days except when national law prevents such recognition, in which case the situation shall be explained by the recipient or the provider, as the case may be, in writing within 30 days after receipt of notification.
3. The provisions of Sub articles 1 and 2 shall not apply to any:
 - a) confidential information which has become part of the public domain independently of the recipient or the provider as the case may be;
 - b) information of which either side was in prior possession independently of the other side's identification of that information as confidential;
 - c) situation where either side obtains such information from a third side as a matter of right; or
 - d) situation where such information is generated by either side independently of any disclosure made by the other side under the written prior informed consent, as evidenced by written records. In the case of the provider, the evidence shall include oral traditions of local communities.

Article 17

Disclosure of Confidential Information to a Third Party

1. Either side may disclose information classified as confidential only to its representatives, including employees, director, agents, consultants or advisors for the purpose of evaluation.
2. any of the representatives to whom such information is disclosed shall:
 - a. be informed about the proprietary nature of the information;
 - b. agree to hold such information in confidence.
3. Either side shall be responsible for any breach of confidence by his respective representatives.



Article 18**Use of Confidential Information**

Neither side shall:

- a. use confidential information received from the other side for any purpose except for evaluation, testing, research and related activities;
- b. disclose such information to any one except its representatives as provided in Article 17 of this Protocol unless a written prior informed consent has been obtained from the other side or it is required by law.

Article 19**Handling of Confidential Information**

Both the provider and the recipient shall exercise all reasonable precaution to protect the confidentiality of the information identified as such by either side according to article 16 of this Protocol.



Appendix 2 The Neem Tree

Perhaps the most renowned example of ‘bio-piracy’ is the native Indian Neem Tree. Since 1985, at least 10 patents have been taken out for a new compound (made from the Neem Tree, allegedly on the basis of Traditional Knowledge) to extend the shelf life of a natural pesticide found in the Neem, most famously by W.R Grace. This modern extraction process was seen as a great scientific innovation. NGO’s such as IFOAM and The Third World Network viewed these patents as being granted on false terms without acknowledgement of traditional knowledge.²⁸ Despite protests, most Neem-related patents have been upheld, and it has transpired that the increased demand by the west has indeed raised the cost of Neem Seeds, and therefore injected money into the Indian economy. This demonstrates the potential commercial benefit for developing countries from bio-prospecting.

²⁸ Shiva, V., “The Neem Tree – A case in history of biopiracy”, <http://www.twinside.org.sg/title/pir-ch.htm>



Appendix 3 Domestic Patents by Country (a selection)

Country	Titles in Force, 2004 ^a	Titles Granted from 1985 – 2004 ^b			Total grants of patents in the USPTO by county of origin	
		Residents	Non-Residents	Total	Total ^c	Biotechnology ^c
Argentina	N/A	4,297	15,910	20,207	675	13
Australia	96,673	12,470	121,191	133,661	12,142	638
Barbados	N/A	N/A	N/A	N/A	N/A	N/A
Bolivia	N/A	24	145	169	N/A	N/A
Brazil	N/A	7,029	32,746	39,775	1407	40
Canada	146,017	20,557	208,916	229,473	50,298	1,903
Chile	N/A	452	4,723	5,175	167	6
China	N/A	35,384	46,463	81,847	2,881	82
Colombia	N/A	604	5,899	6,503	135	7
Costa Rica	N/A	24	36	60	60	3
Guatemala	N/A	59	794	853	24	2
Indonesia,	N/A	21	677	698	100	0
Korea	331,437	271,025	135,037	406,062	3,773	356
Malaysia	7,044	154	8,091	8,245	505	7
Mexico	38,372	3,079	49,936	53,015	1,218	41
New Zealand	14,078	4,561	39,364	43,925	1,664	85
The Netherlands	N/A	18,833	20,366	39,199	21,290	850
Pakistan	N/A	130	3,650	3,780	27	1
Paraguay	N/A	7	130	137	N/A	N/A
The Philippines	N/A	220	7,474	7,694	193	3
Singapore	39,507	863	10,550	11,413	2,878	51
South Africa	N/A	2,748	4,020	6,768	2,231	30
Thailand	N/A	429	4,525	4,954	251	6
United States of America	1,633,355	1,236,187	959,170	2,195,357	1,309,213	42,988
Uruguay	522	172	1,346	1,518	30	2

Notes:

^a Statistics for Singapore from the Intellectual Property Office of Singapore, Malaysia from the Intellectual Property Corporation of Malaysia

^b Applications to domestic offices

^c for years available

N/A – Not Available

Sources:

“Titles in Force, 2004” Statistics

1. Industrial Patents in Force under national regimes – “Patents in Force (2004)”, World Intellectual Property Organisation (WIPO), <http://www.wipo.int/ipstats/en/statistics/patents/inforce/source.html>, cited 11/05/2006;
2. Malaysian Statistics sourced from the Intellectual Property Corporation of Malaysia Statistics by email;
3. Singaporean Statistics sourced from “No of patents in force in Singapore”, Intellectual Property Office of Singapore”; <http://www.ipos.gov.sg/main/aboutus/factsnfigures/patentstats/patentinforce.html>, cited 12/05/2006;

“Titles Granted from 1985 – 2004 (for years available)” Statistics

1. “Patents Granted by Office, 1985 – 2004”, World Intellectual Property Organisation (WIPO), http://www.wipo.int/ipstats/en/statistics/patents/source/granted_national_table.csv

“Total grants of patents in the USPTO by county of origin of patent” Statistics

1. Total grants of patents in the USPTO by country of origin of patent data from the OECD Patent Database



Appendix 4 Members of the International Union for the Protection of New Varieties of Plants (UPOV) as at 03 April 2006

State / Organisation	Date on which State / Organisation became a member of UPOV	Number of contribution units	Latest Act ¹ of the Convention to which State / Organisation is party	Date on which State / Organisation became party to that Act
Albania	15 Oct 2005	0.2	1991 Act	15 Oct 2005
Argentina	25 Dec 1994	0.5	1978 Act	25 Dec 1994
Australia	01 Mar 1989	1.0	1991 Act	20 Jan 2000
Austria	14 Jul 1994	1.5	1991 Act	01 Jul 2004
Azerbaijan	09 Dec 2004	0.2	1991 Act	09 Dec 2004
Belarus	05 Jan 2003	0.1	1991 Act	05 Jan 2003
Belgium ²	05 Dec 1976	1.5	1961 / 1972 Act	05 Dec 1976
Bolivia	21 May 1999	0.2	1978 Act	21 May 1999
Brazil	23 May 1999	0.25	1978 Act	23 May 1999
Bulgaria	24 Apr 1998	0.2	1991 Act	24 Apr 1998
Canada	04 Mar 1991	1.0	1978 Act	04 Mar 1991
Chile	05 Jan 1996	0.2	1978 Act	05 Jan 1996
China	23 Apr 1999	0.5	1978 Act ³	23 Apr 1999
Colombia	13 Sep 1996	0.2	1978 Act	13 Sep 1996
Croatia	01 Sep 2001	0.2	1991 Act	01 Sep 2001
Czech Republic	01 Jan 1993	0.5	1991 Act	24 Nov 2002
Denmark ⁴	06 Dec 1968	1.5	1991 Act	24 Apr 1998
Ecuador	08 Aug 1997	0.2	1978 Act	08 Aug 1997
Estonia	24 Sep 2000	0.2	1991 Act	24 Sep 2000
European Community	29 Jul 2005	5.0	1991 Act	29 Jul 2005
Finland	16 Apr 1993	1.0	1991 Act	20 Jul 2001
France ⁵	03 Oct 1971	5.0	1978 Act	17 Mar 1983
Germany	10 Aug 1968	5.0	1991 Act	25 Jul 1998
Hungary	16 Apr 1983	0.5	1991 Act	01 Jan 2003
Iceland	03 May 2006	0.2	1991 Act	03 May 2006
Ireland	08 Nov 1981	1.0	1978 Act	08 Nov 1981
Israel	12 Dec 1979	0.5	1991 Act	24 Apr 1998
Italy	01 Jul 1977	2.0	1978 Act	28 May 1986
Japan	03 Sep 1982	5.0	1991 Act	24 Dec 1998
Jordan	24 Oct 2004	0.2	1991 Act	24 Oct 2004
Kenya	13 May 1999	0.2	1978 Act	13 May 1999
Kyrgyzstan	26 Jun 2000	0.2	1991 Act	26 Jun 2000
Latvia	30 Aug 2002	0.2	1991 Act	30 Aug 2002
Lithuania	19 Dec 2003	0.2	1991 Act	19 Dec 2003
Mexico	09 Aug 1997	0.75	1978 Act	09 Aug 1997
Netherlands	10 Aug 1968	3.0	1991 Act ⁶	24 Apr 1998
New Zealand	08 Nov 1981	1.0	1978 Act	08 Nov 1981
Nicaragua	06 Sep 2001	0.2	1978 Act	06 Sep 2001
Norway	13 Sep 1993	1.0	1978 Act	13 Sep 1993
Panama	23 May 1999	0.2	1978 Act	23 May 1999
Paraguay	08 Feb 1997	0.2	1978 Act	08 Feb 1997
Poland	11 Nov 1989	0.5	1991 Act	15 Aug 2003



Portugal	14 Oct 1995	0.5	1978 Act	14 Oct 1995
Republic of Korea	07 Jan 2002	0.75	1991 Act	07 Jan 2002
Republic of Moldova	28 Oct 1998	0.2	1991 Act	28 Oct 1998
Romania	16 Mar 2001	0.2	1991 Act	16 Mar 2001
Russian Federation	24 Apr 1998	0.5	1991 Act	24 Apr 1998
Singapore	30 Jul 2004	0.2	1991 Act	30 Jul 2004
Slovakia	01 Jan 1993	0.5	1978 Act	01 Jan 1993
Slovenia	29 Jul 1999	0.2	1991 Act	29 Jul 1999
South Africa	06 Nov 1977	1.0	1978 Act	08 Nov 1981
Spain ⁷	18 May 1980	2.0	1961 / 1972 Act	18 May 1980
Sweden	17 Dec 1971	1.5	1991 Act	24 Apr 1998
Switzerland	10 Jul 1977	1.5	1978 Act	08 Nov 1981
Trinidad and Tobago	30 Jan 1998	0.2	1978 Act	30 Jan 1998
Tunisia	31 Aug 2003	0.2	1991 Act	31 Aug 2003
Ukraine	03 Nov 1995	0.2	1978 Act	03 Nov 1995
United Kingdom	10 Aug 1968	2.0	1991 Act	03 Jan 1999
United States of America	08 Nov 1981	5.0	1991 Act ⁸	22 Feb 1999
Uruguay	13 Nov 1994	0.2	1978 Act	13 Nov 1994
Uzbekistan	14 Nov 2004	0.2	1991 Act	14 Nov 2004

Notes:

¹ “1961/1972 Act” means the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as amended by the Additional Act of November 10, 1972; “1978 Act” means the Act of October 23, 1978, of the Convention; “1991 Act” means the Act of March 19, 1991, of the Convention.

² With a notification under Article 34(2) of the 1978 Act.

³ With a declaration that the 1978 Act is not applicable to the Hong Kong Special Administrative Region.

⁴ With a declaration that the Convention of 1961, the Additional Act of 1972, the 1978 Act and the 1991 Act are not applicable to Greenland and the Faroe Islands.

⁵ With a declaration that the 1978 Act applies to the territory of the French Republic, including the Overseas Departments and Territories.

⁶ Ratification for the Kingdom in Europe.

⁷ With a declaration that the Convention of 1961 and the Additional Act of 1972 apply to the entire territory of Spain.

⁸ With a reservation pursuant to Article 35(2) of the 1991 Act.

Source: The International Union for the Protection of New Varieties of Plants, <http://www.upov.org/en/about/members/pdf/pub423.pdf>



Appendix 5 Domestic Plant Variety Protection by Country or Group, 2004

Country	Titles in Force, 2004
Argentina	1,069
Australia	1,734
Barbados	N/A
Bolivia	23
Brazil	635
Canada	1,425
Chile	392
China	584
Colombia	290
Costa Rica	N/A
Guatemala	N/A
Indonesia	N/A
Korea	1,113
Malaysia	N/A
Mexico	107
New Zealand	1,320
The Netherlands	3,961
Pakistan	N/A
Paraguay ¹	97
The Philippines	N/A
Singapore ²	N/A
South Africa	1,870
Thailand	N/A
United States of America ³⁺⁴	13,895
Uruguay	191

Notes:

¹ 2003 Statistic

² Joined UPOV in July 2004

³ Under the Plant Variety Protection Act

⁴ Under the Plant Patent Act

N/A – Not Available

Sources:

1. Plant Breeder's Rights Patents in Force under national regimes – "Plant Variety Protection Statistics for the Period 2000-2004", International Union for the Protection of New Varieties of Plants (UPOV), http://www.upov.org/en/documents/c/39/c_39_07.pdf, cited 11/05/2006.



Appendix 6 UPOV's position on Access and Benefit Sharing of Genetic Resources

The following is drawn from the UPOV submission to the CBD²⁹.

UPOV considers that plant breeding is essential for sustainable use & development of Genetic Resources and that access to Genetic Resources is a key to sustainable and substantial progress in plant breeding.

The 'breeder's exemption' (in UPOV convention) where acts done with the purpose of breeding other varieties are not subject to restriction, reflects UPOV's view that worldwide breeders need access to all forms of breeding material to maximize progress and use of Genetic Resources for Society. The 'breeder's exemption' also provides inherent benefit-sharing principles, and UPOV is concerned at any other measures for benefit-sharing which could introduce unnecessary barriers in breeding progress & use of genetic resources.

There are certain measures under consideration in the international regime for ABS of genetic resources which are contrary to the UPOV convention. As it is vital the CBD and UPOV convention are mutually supportive, UPOV recommends that any international regime on ABS of genetic resources should be established in harmony with the UPOV Convention.

Notification

UPOV's approach to notification (i.e. disclosure of origin/source/legal provenance of Genetic Resources and associated TK in relation to IP) states:

- the UPOV Convention will only protect new varieties if 'distinctness' has been proven;
- Breeders are required to provide breeding history information, and encouraged to provide information of the origin of plant material. However, this could not be acceptable as an additional condition as it is not in line with what the UPOV convention already provides, and the convention does not allow for further or different conditions (i.e. for technical reasons this condition may prove impossible); and
- If a 'disclosure of origin' mechanism was introduced it should not cover plant variety protection.

Prior informed Consent

UPOV encourages application of the principles of transparency & ethical behaviour when breeding. Access to genetic material should pay respect to the legal framework of the country of origin. However, Prior Informed Consent cannot be an additional condition to providing Protection of Plant Varieties as the UPOV convention requires that a breeder's right should not be subject to any further or different conditions for protection. This is consistent with Article 15 of the CBD which requires measures undertaken pursuant to the CBD to be consistent with measure to protect intellectual property.

Benefit Sharing

UPOV's approach to benefit sharing:

²⁹ Executive Secretary of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, "Compilation of submissions provided by parties, governments, international organizations, indigenous and local communities and relevant stakeholders in preparation for the Third Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing", Convention on Biological Diversity, UNEP/CBD/WG-ABS/3/INF/1, 08/12/2004, p.104



- UPOV supports mutual supportiveness between the CBD, UPOV and other relevant IP instruments;
- Legislation dealing with genetic material and the legislation dealing with breeder's rights should be in separate but compatible instruments because of their different scope; and
- Benefit sharing should be mutually supportive and respect UPOV's PVP system, especially the provision for breeder's exemption.
- UPOV opposes any mechanism to share revenues, as it would impose an additional administrative burden on UPOV and an additional financial obligation on the breeder where varieties were used for further breeding. This would be incompatible with breeder's exemption established in the UPOV convention, and instead of creating incentives to develop new varieties, may provoke the opposite effect whereby breeders would not develop new varieties nor seek protection³⁰;
- Under the UPOV Convention, subsistence farmers are excluded from breeder's rights, and so, freely benefit from the protection of new varieties.

³⁰ This is also recognized by the FAO in the International Treaty on Plant Genetic Resources for Food and Agriculture in Article 13.2. (d) (ii) in that breeders are excepted from financial benefit sharing whenever their products are 'available without restriction to others for further research and breeding'



Appendix 7 The FAO and Agricultural Biodiversity

FAO pointed out that in Decision II/15; the CBD recognized the “special nature of agricultural biodiversity, its distinctive features, and problems needing distinctive solutions”³¹.

The FAO established a Commission on Genetic Resources for Food and Agriculture was established in 1983. In 1995 its mandate was extended to cover all components of biodiversity related to food & agriculture. Its statutes provide that it will:

- Co-ordinate and deal with policy related to conservation & sustainable use of genetic resources related to food & agriculture;
- Provide inter-government forum for negotiation, and to oversee development, codes of conduct of any other instruments appropriate to genetic resources relating to food & agriculture; and
- Facilitate & oversee cooperation between the FAO & other international government & non-government bodies dealing with conservation & sustainable use of genetic resources related to agriculture & food. (this is in the case of the CBD, the WTO TRIPs³², and WIPO).

The FAO Commission facilitated the International Treaty on Plant genetic Resources for Food & Agriculture. It was adopted by the FAO conference in 2001. The objective of the Treaty is the conservation and sustainable use of plant genetic resources for food and agriculture and a fair and equitable sharing of benefits arising from their use in harmony.

It creates a multilateral system of Access and Benefit Sharing through exchanges of information, access to and transfer of technology, capacity-building, and sharing of benefits derived from commercialization³³. A key feature is establishment of an international network of gene banks of agricultural genetic resources.

It facilitates the flow of benefits to all farmers in all countries, specifically developing nations

The FAO set out its views on genetic resources and protection of biodiversity as they related to food and agriculture in a submission to the Fourth meeting of the Ad Hoc Open Access Working Group Working Group of the CBD on Access and Benefit Sharing³⁴.

It pointed out there were special features about agricultural genetic resources which needed to be taken into account when biodiversity was to be managed. Agricultural Biodiversity is essential to satisfy basic human needs for food and livelihood. Conservation was accordingly linked to sustainable use. If agricultural genetic resources are conserved but not utilized, the world cannot be fed. If utilization is not efficient, there will not effective access to agricultural genetic, efficient use of resources by farmers, nor adequate increases in the range and quality of agricultural genetic resources.

³¹ Conference of the Parties to the Convention on Biological Diversity, “Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity”, Convention on Biological Diversity, UNEP/CBD/COP/5/23, 22/06/2000

³² The most pertinent Article in the WTO TRIPs Agreement is Article 27: “members may also exclude from patentability...plants & animals other than micro-organisms, and essential biological processes for the production of plants or animals other than non-biological and microbiological processes. However members may provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.”

³³ This is evidence of a standard Material Access Transfer (MAT)

³⁴ UNEP/CBD/WG-ABS/4/INF/3, p43



In support of this Stannard argues that in case of agricultural genetic resources, intra-specific diversity (diversity within species of crops and domestic animals) is at least as important as inter-specific diversity (diversity among species). Intra-specific diversity results from incremental improvement of crops or animal breeds through crossing and selection from a wide range of sources to improve varieties. Samples of genetic resources infrequently provide large-scale appropriable benefits, and it is impossible to identify the parent varieties, origins of genes, and relative value in the finished variety. These factors illustrate the special nature of agricultural biodiversity and should be paramount in developing policies on Access and Benefit Sharing³⁵.

The FAO observed that development of an International ABS regime should recognize the role of the FAO Commission on Genetics to ensure that it moves in a direction which supports the special needs of the agricultural sector.

On the proposed international regime on Access to Genetic Resources and Benefit-Sharing for the CBD, FAO proposed that the CDB should recognise the role of the International Treaty on Plant Genetic Resources for Food and Agriculture, not include language ‘defining’ scope of the regime; provide for the potential development of farm animal genetic resources; and, if appropriate, exclude that FAO Treaty from its coverage.

On the question of disclosure of origin of genetic resources in applications for intellectual property rights (including the proposed international certificates of origin/source/legal provenance), the FAO noted that the International Treaty provides for a multilateral system of Access and Benefit Sharing. Where disclosure of origin (or international certificate of origin/source/legal provenance) relates to plant genetic resources for food and agriculture obtained through the FAO Multilateral System, the system should be identified as the origin/source/legal provenance of that material.

³⁵ Stannard, 2004, p403

