Study on the Inter-Relations between Intellectual Property Rights Regimes and the Conservation of Genetic Resources

Contract No.: B7-8110/2001/326404/MAR/E3

Prepared for the European Commission
Directorate-General, Environment ***

Final Report

31 December 2002

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1 Introduction

It is now commonly agreed that intellectual property rights (IPRs) are part of the economic and policy landscape in which the conservation of genetic resources takes place. This paper will assess the linkages between intellectual property rights (IPRs) and the conservation of genetic resources, and make recommendations on harnessing the positive elements, while militating against the negative ones.

The interplay between IPRs and the conservation of genetic resources occurs at local, national, regional and global levels. Accordingly, it involves a whole range of actors – also spanning the spectrum from local to global. The issues are legal, political, economic, as well as scientific, creating a complex set of challenges. To be effective, the responses to these challenges must be integrated, but differentiated so as to address the various needs and stakeholders. So far, however, a string of competing policy perspectives has emerged, as have numerous initiatives. More often than not, the focus has been on benefit sharing, technology transfer and conditions of access, rather than on ensuring that intellectual property rights act as an effective incentive for the conservation of genetic resources.

Creating the most appropriate balance between conservation of genetic resources and intellectual property protection primarily revolves around two main questions: (a) whether, and to what extent, the conservation of biological diversity provides a justification for IPRs, or their limitations, which goes beyond their classic economic justifications; and (b) whether, and to what extent, it is necessary to create a *sui generis* right for traditional ecological knowledge. This inquiry should shed light on how, if at all, biodiversity conservation could be integrated into intellectual property protection, such that adequate social and economic incentives are provided to corporate entities, as well as to local and indigenous communities.

This study has been prepared with the support of the European Commission, DG Environment. It is a desk study based on readily available scientific and policy literature, although in some cases this information has been supplemented by personal interviews and responses to a set of questionnaires sent out to key stakeholders. The paper seeks to provide an in depth evaluation of the issues, and derives a broad set of recommendations aimed at relevant international processes and actors. An earlier draft was discussed at an expert workshop convened by Ecologic – Institute for International and European Environmental Policy and the International Centre for Trade and Sustainable Development (ICTSD) in Geneva in October 2002.

This study examines the interactions between intellectual property rights and the conservation of genetic resources at both a general level and on a sectoral basis – agriculture, pharmaceutical, botanical and horticultural. This sectoral distinction is important because each raises different issues for biodiversity conservation, as well as the entitlements and means available to control the use of traditional knowledge. In addition, each sector tends to be characterised by particular IPRs, e.g. patents are predominant in the pharmaceutical sector, as is plant variety

protection in the agriculture sector. As such, a two-step analysis will be carried out in respect of each sector. The first is an assessment of the research and development process in order to assess the role of intellectual property rights in creating externalities and promoting innovation relating to the use of biological resources. The second step is to evaluate evidence of traditional ecological knowledge and its contribution to the conservation of biological diversity, especially genetic resources.

Accordingly, this study is divided into several chapters. Chapter 2 will provide a survey of the main international instruments and actors. Chapter 3 will put forth the main arguments concerning the negative impacts of intellectual property rights on the conservation of biological diversity (and consequently, genetic diversity). It will also contain a detailed evaluation of those claims as they relate to the pharmaceutical, botanical, agricultural and horticultural sectors. Chapter 4 will focus on the potential positive linkages between IPRs and the conservation of genetic resources. It will also contain sectoral analyses, as well as a survey of instruments that seek to leverage these linkages. Chapter 5 asks whether *sui generis* systems can protect traditional ecological knowledge. Chapter 6 distils the evidence from the preceding examinations and lists the general recommendations. Chapter 7 puts forth a set of more specific recommendations aimed at relevant processes and actors. The appendix includes a compilation of responses to a questionnaire.

2 Intellectual property rights and the conservation of genetic resources in international law and policy: an overview

There are several international instruments and institutions that deal with intellectual property rights and the conservation of genetic resources. In most cases the general parameters are laid out in the text of applicable treaties, however, debate on the further development of these regimes, and on how they should be interpreted and applied, is ongoing. These instruments and institutions are surveyed in the remainder of this chapter.

2.1 Convention on Biological Diversity (CBD)

2.1.1 The provisions of the Convention

The Convention on Biological Diversity seeks to create a holistic legal regime for the genetic, species and ecosystem levels of biodiversity with the following objectives:

> ... the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[1]

Achieving these objectives has several implications for IPRs and the conservation of genetic resources. Amongst the provisions most relevant to IPRs is the general regime on access to genetic resources and benefit sharing.[2] In this regime, a framework for bilateral negotiations between provider and user countries is set forth. The elements include:

- An affirmation of the sovereign rights of States over their genetic resources;
- The obligation to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties;
- Where a Party agrees to allow access to its genetic resources, this access shall be on mutually agreed terms and subject to its prior informed consent (PIC).

The only provision of the Convention that relates directly to intellectual property rights is stated in Article 16, whose title is "Access to and transfer of technology". Article 16 (5) states as follows:

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1 Article 1.

2 Article 15.

> The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Notwithstanding this title, the provision itself appears to apply more generally than only to technology. While it suggests that intellectual property rights will not be created by the CBD itself, the provision does appear to emphasise the need for positive action in developing positive synergies between IPRs and the objectives of the CBD.

Another key CBD provision concerns Article 8(j), which relates to traditional knowledge. This provision calls for Parties to:

> Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices."

To facilitate the implementation of this Article, the Parties established an *ad hoc* Working Group on Article 8(j). Three key elements of the work programme subsequently adopted are to: ensure that indigenous and local communities obtain a fair and equitable share of the benefits arising from the use and application of their traditional knowledge; ensure that private and public institutions interested in using such knowledge obtain the prior informed approval of indigenous and local communities, and; assist Governments in the development of legislation or other mechanisms to ensure that traditional knowledge, and its wider applications, is respected, preserved, and maintained.[3]

CBD Article 11 calls for Parties to adopt economically and socially sound measures that act as incentives for conservation and sustainable use. This provision is linked to the very heart of the relationship between IPRs and genetic resources: are IPRs a positive or negative incentive for the conservation of genetic resources?

Finally, Article 22(1) is relevant in defining the CBD's relationship to other treaties, including those that relate to IPRs. It provides that the CBD does not affect the rights and obligations of any Party "except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."

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[3] Decision V/16, UNEP/CBD/COP/5.

2.1.2 Key decisions of the CBD COP

The CBD COP has taken a number of decisions relating to IPRs. Decision III/17 on Intellectual Property Rights called for case studies to be developed on the impacts of IPRs on achieving the CBD objectives, including the relationship between IPRs and traditional knowledge relevant for the conservation and sustainable use of biological diversity. In particular, these case studies are to consider the development of intellectual property rights, including *sui generis* systems or alternative forms of protection, consistent with international law, that could promote the achievement of the Convention's objectives. Furthermore, the Decision called for further work to develop a common appreciation of the relationship between IPRs, the TRIPS Agreement, and the CBD. This last point was reiterated in COP Decision IV/15.[4]

At CBD COP-6, Decision VI/24 on Access and Benefit Sharing as Related to Genetic Resources was adopted. This followed deliberations by an Expert Panel and an Ad Hoc Working Group on the topic. Decision VI/24 includes the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization and a section on the Role of intellectual property rights in the implementation of access and benefit-sharing arrangements. Although the Guidelines are not legally binding, per se, they can be considered as reflecting an authoritative interpretation of the relevant CBD provisions.

The Bonn Guidelines include several references to IPRs. According to Paragraph 16(d), Parties should consider taking "measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights." Paragraph 43(c) stipulates several parameters to form the basis of the contractual arrangements between providers and users. These include: "Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained, to provide licences by common consent" and the "possibility of joint ownership of intellectual property rights, according to the degree of contribution." In addition, national monitoring can include applications for IPRs relating to the material sought.[5] The section on the role of intellectual property rights calls for Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights in order to help track compliance with requirements relating to prior informed consent and the mutually agreed terms. It further calls for relevant traditional knowledge to be also disclosed during IPR applications.

The Decision also lists a number of issues that are to be further examined:

- Impact of intellectual property regimes on access to and use of genetic resources and scientific research;

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[4] Decision IV/15, UNEP/CBD/COP/4, para. 10.

[5] Decision VI/24, UNEP/CBD/COP/6, para. 55(c).

- Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;

- Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;

- Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;

- Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;

- Feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms; and

- Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.

WIPO is further requested to examine a number of issues relating to disclosure requirements. Finally, the Decision calls on the Executive Secretary to renew its request for observer status in the WTO TRIPS Council. Until now, the necessary consensus has not developed within the WTO to grant this request.

2.2 WTO Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS)

The WTO TRIPS Agreement is a global agreement that establishes minimum requirements for IPRs. It is powerful not only because of its substance, but because disputes under it are resolved by the effective WTO dispute settlement body. There have already been some WTO disputes involving the TRIPS Agreement,[6] but so far none of them have related directly to the conservation of biodiversity, or genetic resources.

Article 7 lays out the objectives of the Agreement, which are to:

> ...contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

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[6] E.g. WT/DS50 – India - Patent Protection for Pharmaceutical and Agricultural Chemical Products, 31, WT/DS114 – Canada - Patent Protection of Pharmaceutical Products, etc. A number of consultations pending at time of writing relate to the TRIPS Agreement – e.g. 12. WT/DS233 – Argentina – Measures Affecting the Import of Pharmaceutical Products – although these too do not concern the conservation of genetic resources.

Although this provision does not create any specific rights or obligations, it can be a useful aid to the interpretation and application of the Agreement. Article 8(1) lays out certain priority public interests, including those determined to be priorities at the national level, but clarifies that the TRIPS Agreement is not to be violated by legislating in these areas.[7]

The Agreement establishes several forms of IPRs, including copyright,[8] trademarks,[9] geographic indications,[10] trade secrets,[11] and patents.[12] Of these, patenting is likely to be the most relevant to the conservation of genetic resources, although some of the other forms of protecting industrial property, such as trademarks, geographic indications, and trade secrets, could also be relevant. These rights are to be enforced by civil penalties and in some cases, by criminal penalties.

2.2.3 Patents

Patents are exclusive rights granted to inventors that prevent others from making, using, selling or importing the patented invention, for a term of at least 20 years. The criteria for granting patents are novelty, inventiveness and industrial applicability.

Article 27 establishes what can be patented and the scope for exceptions:

> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,

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7 "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

8 TRIPS, sec. 1.

9 TRIPS, sec. 2.

10 TRIPS, sec. 3.

11 TRIPS, Article 39.

12 TRIPS, sec. 5.

provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

...

(b) 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 provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

This provision contains several elements. The first is the presumption that patents are to be available for any invention meeting the substantive conditions. Secondly, patent rights are to be enjoyed without discrimination. Thirdly, a general exception to this presumption is provided for inventions whose commercial exploitation would violate *ordre public*, public morality or would seriously prejudice the environment. A key term in that paragraph is "necessary"; GATT/WTO jurisprudence suggests that this may set a high threshold.[13] Fourthly, a set of specific exceptions from patentability is provided: plants, animals and essentially biological processes. Plant varieties may be protected by patents or "effective" *sui generis* systems. No definition of "effective" is provided, and some commentators have suggested that to meet this threshold, the minimum principles of the TRIPS Agreement must be respected.[14] Finally, the provision stipulates that the WTO was to review Article 27.3(b) in 1999.

In addition to Article 27.3(b), the TRIPS Agreement contains two general provisions that may limit patent rights. One is specified in Article 30, which allows Member to provide limited exceptions to the exclusive rights conferred by patents "provided that such exceptions to do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties." Secondly, Article 31 allows Members to issue "compulsory licenses", whereby use is made of the subject matter of the patent without the authorisation of the rights holder. Several conditions are placed on the use of this instrument, including:

- Such an authorisation should be based on a consideration of individual merits;

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[13] See, e.g. BISD 39S/155 –United States– Restrictions on Imports of Tuna (circulated on 3 September 1991), which applied the "least trade restrictive" test. More recently, the decision WT/DS135 –European Communities- Measures Affecting Asbestos-Containing Products, applied a modified test, based on balancing several criteria. Although these interpretations are instructive, caution is, however, called for, since this term may be interpreted differently in the TRIPS Agreement than in GATT Article XX.

[14] E.g., Leskien, D. and Flitner, M., *Intellectual Property Rights and Plant Genetic Resources*, Issues in Genetic Resources No. 6, International Plant Genetic Resources Institute, Rome.

- The proposed user will have made efforts over a reasonable period of time to secure a voluntary license on reasonable commercial terms, except in cases of national emergency, extreme urgency or public non-commercial use

- The right holder will be paid adequate remuneration

- The legal validity of the license and the remuneration will be subject to judicial or other forms of independent review.

There is little practice in implementing these limitations for purposes relating to the conservation of genetic resources. It should be emphasised, however, that in conformity with general rules of international law, such limitations and exceptions are to be interpreted narrowly so as not to interfere with the object and purpose of the treaty.

2.2.4 Trademarks

Trademarks are marketing tools, whereby a registered sign is attached to a product, which confirms that the product is authentic or distinctive. Local and indigenous communities, which choose to register, could potentially use trademarks, but they do not create intellectual property rights in the products themselves. Their attractiveness is based mainly on the ability of the trademark to increase market share. Their life span can also be extended indefinitely. Several cases exist of traditional artists establishing trademarks, but none exist yet for products derived from genetic resources.

2.2.5 Geographic Indications

A further intellectual property right that might eventually be attractive to holders of traditional knowledge are Geographic Indications (GIs). GIs are those which identify a good as originating from a Member or a region or locality in the territory of a Member, where a "given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin".[15] In other words, they do not focus on individual inventions, but rather reward a community adhering to traditional practices. These are considered attractive because the rights are held in perpetuity and the holders of the GI cannot assign the right to non-local producers.[16] However, a major drawback is that the knowledge itself is not protected, and therefore GIs cannot prevent misappropriation. These are currently limited to select products – mainly beverages and foodstuffs – although there is now a debate going on in the WTO about extending the coverage. So far, the positions are wide apart.

Some attention is now being paid to the potential to link the mechanisms for establishing geographic indications, especially appellations of origin, with criteria aimed at enhancing conservation. This is an area where further empirical

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15 TRIPS, Article 22.1.

16 Rangnekar, D. *Geographic Indications: A Review of Proposals at the TRIPS Council (draft),* 2002, at p. 15.

research is necessary, so as to develop proposals on enhancing the potential synergies.

2.2.6 Trade Secrets

More interesting for indigenous and local communities is the protection provided by the TRIPS Agreement for trade secrets. Article 39.2 provides that this protection applies to information that is secret, has commercial value because it is secret and has been subject to reasonable steps to keep it secret. Beyond this, there are no substantive standards that trade secrets are required to meet. Trade secrets also have the advantage of having no time limit – i.e. they do not contain any "novelty" requirements. However, the protection is only for the knowledge held by that entity – it does not extend to others who make the same discovery through independent means, such as reverse engineering.

2.2.7 Petty Patents

It has been argued that a further type of IPR that may be useful in protecting traditional knowledge is the "petty patent".[17] Petty patents differ from conventional patents in that the non-obvious requirement is less stringent and may be discarded in favour of a less demanding "innovative step"; the period of protection is shorter; and the patent examination is replaced by a registration system. However, this type of protection is not sanctioned by TRIPS or any international agreement and is only recognised in a few countries, such as Kenya for traditional medicinal knowledge.

2.2.8 Further developments in the WTO

The relationship between the TRIPS Agreement and the CBD has also been debated in various WTO fora. The Committee on Trade and Environment has this as a standing item on its agenda, although no resolution has been reached.[18] More meaningful developments have taken place in the contexts described below:

2.2.8.1 Review of Article 27.3(b)

This review has begun but, so far, has not produced any specific outcome. The general dynamic has emerged, whereby developed countries seek to ensure strong protection of intellectual property, while developing countries seek to broaden the flexibility of the standards. There are, however, nuances and differences from within these groupings.

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17 UNEP/CBD/WG8J/2/7. *CBD Executive Secretary,* 2001.

18 See, e.g. Report of the CTE to the WTO Ministerial Conference, 1996, para. 206-209

The EC, for example, seeks to maintain existing standards,[19] but has indicated its willingness to be flexible in applying the patent system in support of achieving the objectives of the CBD.[20] The United States has sought to tighten up the provision, so as to eliminate the exclusion for plants and animals, and to incorporate the UPOV 1991´ (discussed below) standards into TRIPS.

Developing country submissions have sought to change the paragraph to allow them greater flexibility. For example, Brazil argued that Article 27.3 (b) should contain an interpretative note that discoveries or naturally occurring materials are not patentable.[21] It further called for flexibility for members to decide on the most effective *sui generis* systems to be retained (i.e. not necessarily UPOV). The African Group sought to add a footnote to Article 27.3(b) providing for the protection of community rights and the flexibility to protect farmers' rights and traditional knowledge in *sui generis* systems for plant varieties.[22] It also called for IPRs to be consistent with the CBD, the FAO International Undertaking and the OAU Model Law on Farmers', Breeders' and Community Rights. Venezuela called for introducing a mandatory system of IPR protection for traditional knowledge, based on recognised collective rights.

2.2.8.2 Other Relevant Debates in the TRIPS Council

The relationship between the TRIPS Agreement and the CBD has been debated extensively in the TRIPS Council.[23] In this context, several interventions have been made regarding the patentability of genetic materials. Some developing country Members have argued against granting patents over genetic material, out of concern that it might limit access and benefit sharing as called for under the CBD.[24] Others have argued that if the criteria for patentability are rigorously applied, there should be no conflicts with the CBD.[25]

Another issue that has been debated is the introduction of a requirement that patent applications be accompanied by disclosures regarding source of origin,

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19 See, e.g. WTO, WT/GC/W/193; Preparations for the 1999 Ministerial Conference: *EC Approach to Trade-Related Aspects of Intellectual Property in the New Round*, 2 June 1999, para. 3

20 See Communication by the European Communities and Member States on: *The Relationship Between the Convention on Biological Diversity and the TRIPS Agreement*, 3 April 2001, para. 22.

21 WTO, IP/C/W/228. Submision by Brazil.

22 WTO, IP/C/W/163. Submission by Kenya, on behalf of the African Group,.

23 See WTO, IP/C/W/368. *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity* – Summary of Issues Raised and Points Made, Note by Secretariat, , 8 August 2002

24 See WTO, IP/C/W/163. Submission by Kenya.

25 See WTO, IP/C/M/30. Submission by Switzerland.

any related traditional knowledge, evidence of PIC of the country of origin, and evidence of fair and equitable benefit sharing. Several developing country Members have sought to introduce this requirement. Some developed country Members have argued that if these requirements are conditions for patentability, they violate the TRIPS Agreement, in that Article 29 sets forth rules on disclosure, Article 62.1 allows for only "reasonable" procedures, and Article 27.1 provides for non-discrimination in patent availability.[26] Other Members have sought to achieve this requirement by amending the TRIPS Agreement,[27] although not all countries have agreed that these proposals would violate the TRIPS Agreement. Beneath this legal argument lies a deeper policy conflict over whether patent officials should be tasked with this level of examination and whether contractual arrangements are to be preferred to a system of institutionalised PIC.

2.2.8.3 Doha Development Agenda

Paragraph 19 of the Doha Ministerial Declaration states:

> We instruct 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 ... 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.

This wording confirms the view of those Members who were arguing for a broad Review of Article 27.3(b). It is now clear that the Review should consider a variety of factors including the CBD, the public interest aspects identified in the TRIPS Agreement, and development.

Furthermore, the Doha Declaration also calls for addressing the relationship between WTO rules and multilateral environmental agreements, although this is not meant to alter the balance of rights and responsibilities of WTO Members.[28]

2.2.8.4 "Implementation" Agenda

One of the key themes that dominated the discussions leading up to the Doha Ministerial and subsequently are the set of issues known as "implementation" concerns. These are issues put forward by developing countries to rebalance existing agreements or to address implementation problems with these agreements. These are referred to in Paragraph 12 of the Doha Declaration, and are part of the ongoing negotiation process, although the precise negotiation

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[26] See WTO, IP/C/M/29. Submission by Japan.

[27] See WTO, IP/C/W/228, IP/C/M/32 and IP/C/M/33.Submission by Brazil; and WTO, IP/C/W/356. Submission by Brazil, China, Cuba, et al.

[28] WTO, WT/MIN(1)/DEC/1, Para. 31.

modalities are not yet clear.[29] The Compilation of Outstanding Implementation Issues is not yet a finalised text,[30] and has not formally been adopted. Nonetheless, the Compilation is a useful indicator of developing country positions, and it can be expected that many of these will be put forth in the current WTO negotiations.

Two "Tirets" and one proposal are directly relevant to IPRs and genetic resources. Tiret 88 stipulates that a "clear understanding in the interim that patents inconsistent with Article 15 of the CBD shall not be granted." This suggests that a mechanism to ensure consistency should be established until the completion of the formal reviews of the TRIPS Agreement and other relevant negotiations. In addition, two alternative formulations have been made to amend TRIPS Article 27.3(b) so that it is consistent with the CBD and the International Undertaking on Plant Genetic Resources.[31] Finally, there is a proposal of least-developed countries to establish a review process that clarifies that: " all living organisms, including plants, animals and parts of plants and animals, including gene sequences, and biological and other natural processes for the production of plants, animals and their parts, shall not be granted patents."

These proposals reflect by developing countries to modify the balance of power in the WTO on these issues in their favour – i.e. the focus of discussion is now mainly on implementation of existing IPR standards rather than new stricter standards. Uncertainty and disagreement over legal mechanisms to protect traditional knowledge may be a contributing factor to this situation. One result is that no

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29 Vivas Eugui, D.. *Issues Linked to the Convention on Biological Diversity in the WTO Negotiations: Implementing Doha mandates*, CIEL, 2002, available on http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf.

30 See WTO, JOB(01)/152/Rev.1, 27 October 2001.

31 "...Article 27.3(b) to be amended in light of the provisions of the Convention on Biological Diversity and the International Undertaking. Also, clarify artificial distinctions between biological and microbiological organisms and process; ensure the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest; and prevent anti-competitive practices which will threaten food sovereignty of people in developing countries, as permitted by Article 31 of the TRIPS Agreement."

"...Article 27.3(b) should be amended to take into account the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources. The amendments should clarify and satisfactorily resolve the analytical distinctions between biological and microbiological organisms and processed; that all living organisms and their parts cannot be patented; and those natural processes that produce living organisms should not be patentable. The amendments should ensure the protection of innovations of indigenous and local farming communities; the continuation of traditional farming processes including the right to use, exchange and save seeds, and promote food security."

challenges have emerged yet to the many developing countries that have not met the 2000 deadline for protecting plant varieties.[32]

2.2.8.5 "TRIPS-Plus" Implementation

Some bilateral trade and investment agreements contain so-called "TRIPS – plus" obligations. These are obligations that go beyond the minimum standards set out in the TRIPS Agreement, including the tightening of the exception provisions in Article 27. Examples include Article 45 of the Cotonou Agreement (EU – ACP Partnership) and Chapter II of the Agreement between the 2000 US and Vietnam on Trade Relations.[33] It has recently been argued that the United States and the European Union have been very successful in ratcheting up international IPR standards through bilateral investment treaties and bilateral intellectual property rights agreements.[34]

2.3 UPOV System

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) establishes UPOV,[35] which creates plant breeder's rights (PBRs), is one possible *sui generis* system that would appear to meet the requirements of Article 27.3(b) of the TRIPS Agreement.

The UPOV Convention was developed in 1961, but has been revised several times, most recently in 1978 and 1991. It provides for PBRs over new varieties of plants. Since 1998, when UPOV 1991 entered into force, new parties to the Convention must adhere to the 1991 version, rather than that of 1978. Currently, the membership of UPOV 1991 consists mainly of developed countries, however, according to UPOV, most parties to the previous Acts are in the process of adhering to the 1991 version. Nonetheless, most developing country members of UPOV have adhered so far only to the 1978 Act.

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[32] Dutfield, G. *TRIPS-related Aspects of Traditional Knowledge, 33 Case W. Res. J. Int'l L. 239,* at p. 280.

[33] See Articles 1.3 and 7.2(c)Exclusions are provided for essential biological processes for the production of plants or animals other than non-biological and microbiological processes; animal varieties; and plant varieties. The exclusion for plant varieties is limited to those plant varieties that satisfy the definition provided in Article 1(vi) of the UPOV Convention (1991); which applies *mutatis mutandis* to animal varieties. The exclusions for plant and animal varieties do not apply to plant or animal inventions that could encompass more than one variety. Moreover, the Parties are to provide for the protection of plant varieties by an effective *sui generis* system as defined by the Agreement (subparagraph 3.D of Article 1 of Chapter II).

[34] Drahos, P. *BITs and BIPs: Bilateralism in Intellectual Property*, 4 Journal of World Intellectual Property, 2001, at p. 791, *et seq*.

[35] Union Internationale pour la Protection des Obtentions Végétales or the International Union for the Protection of New Varieties of Plants.

There are significant differences between UPOV 1978 and UPOV 1991. UPOV 1991 generally creates a higher standard of protection for PBRs. One difference is that under the 1978 Act, a breeder is entitled to protection through being the "discoverer" of the new plant variety, whereas under the 1991 Act, mere discovery is not sufficient. Nonetheless, the criteria for "novelty" appear to emphasise commercial considerations,[36] rather than testing for inventiveness.

Another important development is the rule on "essential derivation" in the 1991 Act. Under the 1978 Act any protected variety could be freely used as a source of initial variation to develop further varieties, so that such further varieties can be protected by the subsequent breeder without any obligation towards the breeder of the initial variety. Under Article 14(5) the 1991 Act, the essentially derived variety, which meets the normal protection criteria, may be the subject of protection, but it cannot be exploited without the authorisation of the breeder of the original variety. Some authors have expressed the concern that the determination of whether the new varieties are essentially derived from an earlier one is likely to be done through agreement between the breeders or litigation, rather than by the examination process. If this is the case, the relative bargaining strength of the breeders may become a factor that is to the disadvantage of developing countries.[37]

Under UPOV 1978, it was possible for farmers to practice the custom of saving part of their harvest so as to have seed to plant for the following season, the so-called "farmers privilege". This is not expressly provided for under UPOV 1978, but its wording did not prohibit it,[38] and this was the practice in many Member countries. Under the 1991 Act, governments are expressly provided the discretion to decide whether or not to restrict a breeder's right:

> in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting... the protected variety...[39]

Indeed, some governments have decided to use this provision to enshrine the "farmer's privilege".[40]

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[36] The test for novelty in Article 6(1) is that the "propagating or harvested material of the variety has not been sold or otherwise disposed of to others ..."

[37] Dhar, B. and Chaturvedy, S. *Introducing Plant Breeder's Rights in India:A Critical Evaluation of the Proposed Legislation*, Journal of World Intellectual Property, 1(2), 1998; cited in Dutfield, G. , Intellectual Property Rights, Trade and Biodiversity,(1999), at p. 28.

[38] UPOV, Article 5(1) sets out what the breeder's authorisation is required for.

[39] UPOV, Article 15(2).

[40] E.g. See EC Regulation 2100/94, *EU Biotechnology Inventions Directive*, Article 11, on community plant variety rights, which applies to main food crops. Under these rules, small farmers are not required to pay any remuneration to the right holders, whereas other farmers must pay an "equitable" amount; see also Australia's Plant Breeder's Rights Act of 1994, allows famers to save the seeds from a protected variety for next year's crop without

The 1991 Act also provides for exceptions for (a) acts done privately and for non-commercial purposes, (b) acts done for experimental purposes and (c) acts done for the purpose of breeding other varieties, subject to specific conditions. Furthermore, it allows for the restriction of PBRs in the public interest.[41]

Finally, under UPOV 1978, any varieties eligible for PBRs protection could not be patented, whereas UPOV 1991 is silent on this question. As such, the possibility for double protection for plant varieties exists.

2.4 World Intellectual Property Organization

Under its programme relating to new intellectual property issues, WIPO has begun looking in depth at the intellectual property aspects of access to genetic resources. As a result of controversies arising from proposals by some developing countries during the negotiations of the WIPO Patent Law Treaty to require certificates of origin for patent applications involving genetic resources, it was agreed to establish a process under WIPO for considering these issues in greater depth. This led to the creation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, whose first session was held in 2001.

The Intergovernmental Committee has proven to be a venue for debating key issues, enabling information gathering, and commissioning further analytical work. So far, it has been unable to forge consensus, although it is still at an early stage of its work. Its mandate contains the following elements:

(a) *With respect to genetic resources*:

Considering the development of "best contractual practices", guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources and different transfers within different sectors of genetic resources policy;

(b) *With respect to traditional knowledge*:

- Determining the scope of "traditional knowledge" in order to discuss the type of protection which can be awarded by intellectual property rights.

- Compiling, comparing and assessing information on the availability and scope of intellectual property protection for traditional knowledge.

- Considering the revision of existing criteria and developing new criteria, which would allow the effective integration of traditional knowledge documentation into searchable prior art.

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paying a royalty to the breeder and UNEP/CBD/COP/3/Inf.20. *Biological Diversity and Intellectual Property Rights: Issues and Considerations*.

41 UPOV, Article 17(1).

- Considering ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.

It should be noted, however, that the level of stakeholder participation in this body is less than what is common practice in meetings of Conferences of Parties in international environmental agreements, partly on account of the complexity of these issues.

Currently, negotiations are also ongoing in WIPO to develop the Substantive Patent Law Treaty (SPLT). Whereas the TRIPS Agreement establishes the minimum required elements of national laws on intellectual property rights, the SPLT will spell out the full substance of these rights in an effort to harmonise them. In its present form, the draft treaty does not allow parties to make any further demands on patent applicants other than those found in the treaty.[42] This would preclude countries from requiring the disclosure of country of origin of genetic materials and proof of prior informed consent in their acquisition as part of the patent process, as these are not included in the current criteria.

2.5 International Treaty on Plant Genetic Resources for Food and Agriculture

After years of negotiation, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted on 3 November 2001. The treaty aims at the conservation and sustainable use of plant genetic resources for food and agriculture, the fair and equitable sharing of benefits arising out of their use, and sustainable agriculture and food security.[43] At the heart of the Treaty is a Multilateral System (MLS) that seeks to facilitate access to a negotiated list of plant genetic resources, annexed to the treaty, as well as the fair and equitable sharing of benefits arising from their use. Genetic resources listed on the MLS are to be circulated freely. Developing countries are encouraged to place germplasm in the MLS in exchange for benefit sharing in areas of information exchange, technology transfer, and capacity building. *Ex situ* collections that existed prior to the CBD, which are excluded from the application of the CBD,[44] may now be dealt with under this treaty.

Article 9 of the treaty addresses the contentious issue of “farmers' rights”. It places the responsibility for realising these rights on national governments. Article 9 (2) states:

> ... In accordance with their needs and priorities, each Contracting Party, should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

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[42] GRAIN "WIPO moves toward "world" Patent System", available on http://www.grain.org/publications/wipo-patent-2002-en.cfm, 2002.

[43] Article 1.1.

[44] CBD, Article 15(3).

(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;

(b) the right to equitably participate in sharing of benefits arising from the utilization of plant genetic resources for food and agriculture; and ...

Article 12.3 (d) stipulates that access to genetic resources from the MLS be provided on the condition that intellectual property or other rights that limit facilitated access to the genetic resources, or their genetic parts or components, "*in the form received from the MLS"* are not to be claimed. As such, it would appear that such genetic material received from the MLS can be claimed for IPRs that have been modified in some way from the form they were received from the MLS.[45] The EU, which supports this interpretation, stated that this interpretation will not remove plant genetic resources for food and agriculture from the MLS and will be fully in compliance with continuous easy access to them.[46] However, a recipient who commercialises a plant genetic resource for food and agriculture that incorporates material from the MLS is to pay to a financial mechanism an equitable share of the benefits arising from commercialisation.[47] If the product is such that there is no restriction on the availability to others for research or breeding, such as those protected under the UPOV system, then the recipient is encouraged, but not required, to pay benefits.

2.6 Consultative Group on International Agricultural Research (CGIAR)

The CGIAR, established in 1971, seeks to contribute to food security and poverty eradication in developing countries. Currently, there are 16 International Agricultural Research Centers (IARCs), which are autonomous institutions, that form the CGIAR system. In 1992, the CGIAR adopted the "CGIAR Working Document on Genetic Resources and Intellectual Property, which stated, *inter alia*, the following:

- Material from the gene banks at the centres will continue to be freely available in accordance with the 1989 CGIAR Policy on Plant Genetic Resources
- Centers do not seek intellectual property protection unless it is absolutely necessary to ensure access by developing countries to new technologies and products
- any IPRs acquired by a Center are exercised without compromising in any manner whatsoever the fundamental position of the CGIAR regarding the free

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[45] Kalpavriksh, and GRAIN. *The International Treaty on Plant Genetic Resources: a challenge for Asia,* 2002.

[46] EU Statement at the FAO Conference 2001 (English Translation) SANCO-2002-02081-00-00-EN-TRA-00 (FR) jpc.

[47] Article 13(d).

access by developing countries to knowledge, technology, materials and plant genetic resources.

In 1994, the IARCs signed agreements with the FAO that placed most of their collections in the International Network of *Ex-situ* Germplasm Collections. These agreements state that the Centre holds the germplasm in trust for the benefit of the international community,[48] and bind the IARCs not to "claim ownership, or seek intellectual property rights over the designated germplasm and related information."[49] The one exception is when the germplasm is repatriated to the country that provided it.[50] What is unclear is whether there should be any IPR protection for technologies and materials developed by CGIAR scientists.

The issue of IPRs over germplasm held by CGIAR system has been controversial, and has not been resolved yet. Concern lies over the potential conflict between holding their collections in trust for humanity and the growing trend of public-private partnerships that involve commercialisation. But the difficulties in resolving these issues are complicated by the lack of legal status of the CGIAR System, and the opposing views of the members.

Actual compliance with the contractual conditions including those relating to IPRs has also been one of the key concerns relating to the CGIAR collections. Many IARCs lack the capacity or have no mechanisms in place to ensure that those who receive genetic resources from them comply with the contractual requirements. Several high profile violations have recently come to light.[51] The Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture is mandated to amend the MTAs currently in place between the IARCs and the FAO for plant genetic resources not listed in Annex I of the Treaty, and which were collected prior to the Treaty's entry into force, inter alia, to improve compliance.[52]

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48 Article 3(a).

49 Article 3(b).

50 Article 10.

51 Grain, *Biopiracy by another name? A critique of the FAO-CGIAR trusteeship system*, available on http://www.grain.org/seedling/seed-02-10-2-en.cfm.

52 Article 15(iv).

3 Negative Linkages between IPRs and the conservation of genetic resources

Much of the literature on IPRs and biodiversity focus on claims of negative impacts of IPRs. This chapter will survey these claims, as well as the counterclaims, and then provide a detailed analysis of them in a sectoral context.

Intellectual property rights on biotechnological inventions are meant to be the primary incentive for research initiatives based on genetic resources. Biotechnological firms use various forms of intellectual property protection to protect their investments. Whereas pharmaceutical firms rely mainly on patents once the drug is discovered, in the case of agricultural varieties, plant variety protection and patents are used.[53] For agricultural varieties, many jurisdictions do not allow for hybrids to be protected by plant variety rights since they do not fulfil the requirement of stability (that is, the offspring does not have the same property). Also, hybrids prepared by classic crossing are not patentable since they do not fulfil the requirement of non-obviousness or inventive step.[54] In the case of the botanical sector, almost all herbal medicinal preparations are in the public domain, i.e. medicines that have been in use for a long time already and are described in written documentation. These are not patentable since patent law does not allow patenting of known compounds or known preparations. In the few cases in which a patent is indeed issued, this is usually directed to a new form of pharmaceutical preparation.[55]

But to the extent that they promote biotechnological research, intellectual property rights can be linked to the effects, positive or negative, that the R & D processes, as well as the products themselves, have on sustainable use and conservation of genetic resources. The responsibility to ensure that the granting of intellectual property rights takes into account these effects is further compounded by the fact that intellectual property rights are one of the main sets of property rights being defined on genetic resources.

Mainly due to this, as Miller (1997) notes, biotechnology presents a "product-versus-process" dilemma, that is, of encouraging the industry while simultaneously catering to the environmental risk that could arise from its activities.[56] Within this, the product proponents have focussed mainly upon the benefits of newer medical products, overall well being, increased agricultural efficiency and the amelioration of environmental damages through biotechnology. The process proponents have, on the other hand, concentrated largely upon the harm

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53 Patents on new varieties are allowed for example, in the USA.

54 Personal communication with Dr. Konrad Becker, Patent Attorney, 23 December 2002.

55 Ibid.

56 Miller, H. I. *Policy Controversy in Biotechnology: An Insider's View, Landes Bioscience Publication,* 1997, p. 1.

caused by such research to sustainable use and conservation of genetic diversity and the protection of traditional knowledge.

A closer look at the critiques reveals that less is actually known about what concrete effects genetically modified crops or pharmaceutical research may have upon sustainable use and conservation of genetic diversity, and the protection of traditional knowledge.[57] The main reason for this is the complex inter-relationship between IPRs and conservation of genetic resources.

To be able to capture all facets of this complex relationship, the first part of this Chapter will sum up the various claims and counterclaims found in the literature relating to the negative impacts of IPRs on conservation of genetic resources. The second part of the Section will then try to assess these claims, using an objective framework – the processes of R & D in four different biotechnological sectors.

3.1 Claims and Counterclaims

Two primary strands of argument appear in the literature. One focuses on IPRs in the agricultural context, while the other emphasises the inability of IPRs to adequately protect traditional knowledge against misappropriation, mainly in the agricultural and pharmaceutical sectors.

As regards agriculture, several arguments have been put forward:

- *IPRs promote harmful agro-chemical use*. The claim is made that IPRs encourage the development of seeds by industry based on hybrids and other modern varieties that depend on the use of agrochemicals to achieve high yield. This claim is countered, however, by the experience with the Green Revolution that encouraged high yield varieties that were not IPR protected.

- *IPRs are an incentive to develop genetically modified crops, which may be harmful to biodiversity.* This can also lead to growth in an accompanying market for pesticides. A well-known example is Monsanto's Roundup Ready products (soybeans, canola, and cotton). Buyers of those products were contractually required to purchase a Roundup pesticide.[58] Although the counter-claim is made that genetically modified seeds can also lead to the development of varieties that require less pesticide use,[59] not all environmentalists are convinced. Dutfield (2000) has catalogued these concerns as: (a) encouraging excessive use of herbicides that may kill other plant varieties and species, (b) accelerating the development of resistance among pests, (c) creating the possibility of herbicide resistant genes crossing

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[57] Refer to discussion of claims and counterclaims in Chapter 3.1.

[58] Dutfield, G., "Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India" in Blakeney, M. (ed.), Intellectual Property Aspects of Ethnobiology, 1999, page 46-47.

[59] E.g. Monsanto's NewLeaf potato, which is claimed to provide protection against the Colorado Beetle or Bt corn, patented by Novartis, which resists the European corn borer pest.

over to other plants, and (d) linkages between these products and other proprietary agriculture inputs represents a shift to more capital intensive agriculture, which increases the cost of farming.[60] In addition, there have been developments in technology that enable the creation of "terminator" seeds, which cannot be re-harvested. However, as a result of controversies, "terminator" technologies are not being applied at present.[61]

- *IPRs are an incentive for the development of monocultures.* It has been claimed that there is a connection between IPRs and centralised research and crop breeding which diminishes the diversity of available seed.[62] Further, it is argued that IPRs contribute to creating incentives for the private sector to create uniformity in seed varieties. This trend is the result of business strategies that seek to ensure maximum demand for their products. Decreased crop diversity could lead to erosion of genetic, insect, soil, and ecosystem diversity. Kothari and Anuradha (1999) argue that IPRs can also encourage displacement of wild diversity of traditional local and landrace varieties. However, the counter argument is that using high yield varieties reduces pressure to convert biodiverse ecosystems into agricultural land. In any event, the precise impact of IPRs in the decision-making of both breeders and farmers in this context has yet to be empirically measured.

- *Strong plant variety protection creates disincentives for farmers in developing countries to conserve biological diversity*. This is said to occur because of the potential for reduced opportunity to cultivate traditional variety on account of the economic pressures to use industrialised seed. In addition, it is claimed that plant variety protection provides reduced opportunities to exchange certain seeds between developed and developing countries, which leads to a narrower spectrum of seeds on offer to farmers. However, the counter argument is that if the conditions for the supply of industrial seed become too unbearable for developing country farmers, their needs will push them to return to more traditional methods of cultivation. A further claim is that the wide breeder's exception in UPOV 1991 encourages the use of genes already in circulation, rather than bringing in new ones. There may indeed be credible evidence that breeders are now adopting built-in obsolescence strategies, by maintaining broad portfolios of constantly changing variety with significantly reduced life spans, combined with a lax approach to breeding versatile disease resistance.[63] At the very least, the result of both of these factors is that

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60 Dutfield, op. cit. footnote 58, at p. 47.

61 E.g. CGIAR decision in 1998 not to incorporate such technologies into their breeding materials, the 1999 statement by Zeneca not to develop such technologies, and the October 1999 announcement by Monsanto that it would not be commercialising the "terminator" technology.

62 Reid, W. V, et al. (1993), Biodiversity Prospecting: Using genetic Resources for Sustainable Development, World Resources Institute, National Biodiversity Institute of Costa Rica, Rainforest Alliance, and African Centre for Technology Studies, p. 150.

63 Rangnekar, D. *Planned Obsolescence and Plant Breeding: Empirical Evidence from Wheat Breeding in the UK (1965-1995)*, draft on file with the authors.

processes appear to be in place that do not seek to maximise genetic diversity.[64]

- *The low threshold for "novelty" under UPOV 1991 causes the displacement of local varieties and land races.* The argument is made that the inequitable differences in strength and capacity between large companies and local farmers will allow these companies to appropriate traditional varieties with minimal modification. This situation is further exacerbated, it is argued, by the reality that many landraces are acquired from *ex-situ* collections, rather than from the farmers, thereby avoiding benefit-sharing arrangements with the farmers themselves. However, for this claim to be substantiated, there would need to be a detailed examination of the characteristics of the particular landraces involved, the interest of local communities in acquiring plant variety protection for them, and the amount of actual work needed to modify them to be applied in more than just local conditions. A further claim, similar to that described above, is that the criterion of homogeneity reinforces the trend towards genetic uniformity – however, loosening this criterion risks leading to broader property claims, that might potentially "lock up" the system.[65]

- *IPRs stifle research and innovation.* This phenomenon is said to be a consequence of the current trend of broadening patents of biotechnology for plant agriculture, which is contributing to a concentration of actors in the industry.[66] For example, as described by the Crucible Group (2000),[67] the world's top ten agrochemical corporations account for 91% of the global market and the top ten seed companies control an estimated 25-30% of the commercial seed trade. Furthermore, the top five vegetable seed companies control 75% of the global vegetable seed market, four companies control 69% of the North American maize seed market, while in 1998 a single company controlled 71% of the US cotton seed market. These facts are to be considered within the overall context of the restructuring in the life sciences industry, such that a blurring of difference between sectors is taking place. This allows the major life science companies to apply complementary technologies to these sectors. In the process, they are increasingly securing IP assets to the extent that they have become more valuable than physical assets.[68] At the same time, the increased market dominance by a few large companies can put

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64 G. Dutfield, personal communication, 4 September 2002.

65 Bragdon, S and Downes, D. *Recent policy trends and developments related to the Conservation, Use and development of genetic resources*; Issues in Genetic Resources No. 7, IPGRI, 1998.

66 Barton, John H. *The Impact of Contemporary Patent Law on Plant Biotechnology Research, Intellectual Property Rights III Global Genetic Resources: Access and Property Rights*, 1998.

67 Crucible Group II, Seeding Solutions. Volume 1. Policy for genetic resources (*People, plants, and patents* revisited), IDRC, IPGRI and Dag Hammerskjöld Foundation, 2000, pp. 16-17.

68 Ibid.

considerable pressure on farmers from developing countries, by restricting choice and fixing prices. The burden will then lie on national authorities, which may lack capacity to regulate against such adverse effects.

The second area of concern is that IPRs are a means for appropriating traditional knowledge, and thereby create counter incentives for traditional and local communities to conserve biological diversity. In particular, two claims are made:

- *Conventional IPRs do not allow traditional communities sufficient protection for products based on their knowledge.* This claim is based on several arguments. The first is that traditional knowledge does not sit easily with convention IPR law.[69] It has been widely argued that inventions involving traditional knowledge face two fundamental problems in meeting IPR requirements. The first is that it can be unclear who the "inventor" is, i.e. who is entitled to apply for the patent. Much of traditional knowledge has been developed collectively and not always in discrete groupings with a legal personality. A second problem is that traditional knowledge may be ancient, and may therefore not be "novel". Furthermore, in some jurisdictions, such as the United States, oral evidence of prior art – which is all that may exist of some traditional knowledge – is not admissible in the patent process. In addition, even if IPRs are theoretically available for some types of traditional knowledge, in practice local and indigenous communities lack the resources to apply for and enforce these rights.[70] By contrast, the private commercial sector, with its greater technical and legal capacity, is more likely to be able to seek patent protection for inventions that involve some traditional knowledge,[71] without indigenous peoples always being aware of this. Thus, in some cases, IPRs not only protect traditional knowledge insufficiently, but may also actually encourage its misappropriation. However, one counterclaim is that one should not take an overly simplistic view of how indigenous communities develop and transmit their knowledge. These communities can have rather complex systems for rewarding innovators, individually, their families, as well as the community as a whole.[72] In addition, simply taking a collectivist view of traditional knowledge ignores the inevitable power differences within communities.

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69 See, e.g. CBD Secretariat, (UNEP/CBD/COP/3/19). *Knowledge, Innovations and Practices of Indigenous and Local Communities: Implementation of Article 8(j).* It was concluded that there were "no international legal instruments or standards which adequately recognize indigenous and local communities' rights over their knowledge, innovations or practices "It went on to observe that "...current systems of intellectual property rights alone are not sufficient to ensure that benefits flow back to indigenous and local communities."

70 Ibid.

71 There are indeed some celebrated cases of this: e.g. turmeric.

72 Downes, D. *Using Intellectual Property as a Tool to Protect Traditional Knowledge: Recommendations for Next Steps*; CIEL Discussion Draft, 1997.

- *IPR rules do not support placing safeguards that would ensure that the access and benefit-sharing arrangements under the CBD are being properly implemented.* This claim is advocated by those who are urging two instruments to be incorporated into the process of acquiring IPRs over inventions involving genetic resources: a certification of the origin of the genetic resources, which shows that they were acquired in accordance with the CBD, and proof of the prior informed consent of the local community with stewardship over these resources. These claims are currently the subject of negotiation in several international fora. As mentioned above, the CBD COP has recommended consideration of these instruments, but it has yet to be determined whether this constitutes a reason for adding further conditions on patenting to the exhaustive list set out in the TRIPS Agreement.[73]

A final, general claim, applicable to the pharmaceutical sector, is that IPRs harm wild ecosystems through harmful bioprospecting techniques and encouraging the over-harvesting of species.

These claims, many of which are somewhat speculative, suggest that at the very least there is sound reason to be concerned about the harmful impacts IPRs may have on biodiversity. Application of the precautionary approach to these developments, as advocated by the CBD COP[74], seems therefore appropriate in this context.

However, the more fundamental questions still remain: to what extent are IPRs responsible for these negative impacts on biodiversity and, as a result, to what extent should modifications to the IPR process ensue? In other words, should those who administer the grant of IPRs, e.g. patent examiners, be put in a position where they take these policy decisions, or are they better taken by other types of regulators? For example, in the case of agricultural biotechnology other policies have been identified as having major impacts on the use of new crop varieties and the loss of traditional ones, such as:

(a) government farm credits and subsidies, and extension services;

(b) the policies and programs of international agencies and donor institutions; and

(c) the marketing and research and development policies and programmes of transnational corporations.[75]

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[73] See, e.g. R. Wolfrum/ G. Klepper/ P.-T. Stoll/ S. Franck, Implementing the Convention on Biological Diversity: Analysis of the Links to Intellectual Property and the International System for the Protection of Intellectual Property, available on http://www.biodiv.org/doc/meetings/abs/abswg-01/information/abswg-01-inf-03-en.pdf, 2001.

[74] See UNEP/CBD/COP/4, Decision IV/6 on agricultural biodiversity.

[75] UNEP/CBD/COP/3/22. *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits From Its Use.*

Undoubtedly, reliable answers to these questions will depend on increased data. But they will also require an approach that focuses on differentiated impacts between the actual genetic resources in issue, the particular industry structure, and the impacts on particular regions and communities. The next section will be using such an approach, assess some of the claims and counter claims set out here. The claims and counterclaims regarding the impact of IPRs on traditional knowledge and benefit sharing is evaluated in Chapter 5.

3.2 Evaluating Claims: The Process of Research in the Agricultural, Pharmaceutical, Horticultural and Botanical Sectors

There are, indeed, potential risks associated with biotechnology. But regulatory efforts that do not test these claims using proper research and development (R & D) procedures in the various biotechnological sectors can lead to, as Miller (1997) puts it, "...science policy built on a foundation of invalid scientific assumptions, pseudo-controversy and political and ideological goals".[76] Sorting out the inter-linkages between the R & D processes within the various biotechnological sectors and the risk they impose on sustainable use and conservation of biological resources is therefore critical, if such discriminatory, unscientific regulations and undue restrictions of IPRs are to be avoided.[77]

The identification of these interrelationships and risks is best done within a framework within which the cumulative effects of biotechnological products vis-à-vis conservation and sustainable use of genetic resources and traditional knowledge can be predicted.[78] The R & D processes in various biotechnological sectors offer an objective and scientific basis on which to develop such a framework. Therefore, this Section will focus upon processes of biotechnological R & D in four main sectors: pharmaceuticals, agriculture, botanical medicines and horticulture. [79] In what follows, each of these biotechnological sectors will be assessed and the scope they create for negatively impacting conservation of genetic resources is reviewed. The positive effects of such R & D on conservation and sustainable use of genetic resources are addressed in Chapter 4.

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[76] Cf. Miller, H. I. op. cit. footnote 56, p. 155.

[77] Miller, H. I. and Congko, G. *The Science of Biotechnology Meets the Politics of Global Regulation", Issues in Science and Technology*, Fall 2000, p. 1-4, at p. 1.

[78] Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants et al. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*; National Academy Press, Washington, D.C., 2002, p. 20.

[79] There are many other sectors in which biotechnology is being used successfully (for a description, see TenKate and Laird, The Commercial Use of Biodiversity, Earthscan Publications, 2000. The selection here in this study is has been made according to sectors in which biotechnological applications could have an impact upon firstly, the use of genetic resources and traditional knowledge and secondly, the conservation of genetic resources.

The evidence of both negative and positive impacts derived here and in Chapter 4 respectively forms the basis of recommendations for regulation of biotechnological research to minimise potential harm on genetic diversity.

3.2.1 Biotechnological Research and Development in the Pharmaceutical Sector

The success of biotechnology as a promising venue for drug research is set against the backdrop of an ailing pharmaceutical industry in the 1960s and the 1970s, struggling to find cures for emerging diseases like different forms of cancers. In such a setting, biotechnology offered a newer and more precise set of techniques to explore the potential of genetic resources as sources of drugs.

3.2.1.1 Research and Development of Pharmaceuticals

The research and development of pharmaceuticals is a lengthy process that comprises four main stages. This ranges from the pre-screening stage, where using specific search techniques, potentially valuable genetic resources are selected for research to the last stage that involves the development of the final product.

3.2.1.2 Search Techniques and Selection of Genetic Resources

The selection of plants for purposes of further research and development is carried out through different kinds of selection/ survey techniques.[80] Surveys can be of two types – random and targeted. As Cox (1990) notes, in random surveys, plants are collected and screened without regard to their taxonomic affinities, ethnobotanical context or other intrinsic qualities.[81] But random selection is considered to be a risky method because the chances of finding chemicals that yield a potentially valuable lead are remote.

Targeted surveys, in contrast, seek to collect and analyse plants for valuable chemical compounds based on specific kinds of taxonomic or chemical information. These can be of three kinds: phylogenetic surveys, ecological surveys and ethnobotanical surveys.[82] Phylogenetic surveying implies a process where close relatives of plants that are known to produce useful compounds are collected and analysed for either new compounds or increased concentrations of the already useful compounds. In ecological surveys, plants living in particular habitats or possessing certain growth habits are chosen for studies. In ethnobotanical surveys, plants used by indigenous peoples in traditional medicines are chosen for further research. Biotechnological research generally employs targeted surveys to narrow down genetic resources for further research.

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80 Cox, P.A. *Ethnopharmacology and the Search For New Drugs*; in: Chadwick, D. J. and J. Arsch, J. (eds.). *Bioactive Compounds From Plants*, Cambridge University Press, 1990, p. 42.

81 Ibid., p. 42.

82 The definitions of the three targeted surveys here is taken from Cox, Ibid., p. 42.

3.2.1.3 Screening and Secondary Screening

Screening refers to the process where drug candidates are tested for bioactivity of interest. As Tenkate and Laird (2000) note, the development of a drug through screening involves two steps - the development of the screen itself to detect biological activity, and then finding the chemical compounds to test in the screens.[83] Screening offers a highly versatile starting point for drug discovery since screens can be prepared to detect the specific kind of bioactivity required, be it anti-microbial, anti-fungal or other.[84]

This stage is followed by advanced screening where the detected biological activity is tested against the diseases that the research programme is trying to find a cure for, what is also called as the "target" of the R & D programme. If there are any samples that showed positive activity in the screening, these are re-tested at this stage more rigorously and made subject to detailed biochemical analysis.[85]

This process of screening and isolating a valuable compound that fits the target of the drug programme is also called drug discovery. Once drug discovery is complete, the focus shifts to the development of the drug.[86]

3.2.1.4 Pre-Clinical Drug Development and Clinical Trials

In the development stage, the structure of the isolated agent is analysed in detail so that the target of the programme and the successful compound can be matched on a one-to-one basis to assess the viability of development. Here, attempts are made to modify the chemical structure of the compound using biotechnological techniques, if the match is not as precise as desired. In most cases, product development can take as long as 12 years.[87]

This is followed by clinical trials, which consist of three more sub-stages to test the drug against various toxic reactions.[88] The first stage involves the testing of the drug's pharmacological activity on healthy living organisms (other than humans). The second stage, often also known as pilot efficacy studies, involves the testing of the drug on a large number of human volunteers. In this stage, around 200

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83 TenKate, K. and Laird, S. op. cit. footnote 79 p. 49.

84 Ibid., p. 49.

85 Ibid., p. 49.

86 US Congress, Office of Technological Assessment. *Biotechnology in a Global Economy*, OTA-BA-494, Washington, DC: US Government Printing Office, October 1991, p. 75.

87 Halliday, R.G., Walker, S.R. and Lumley, C.E. *R & D Philosophy and Management in the World's Leading Pharmaceutical Companies*; Journal of Pharmaceutical Medicine, 1992, Vol. 2, p. 139-174, at p. 166-167.

88 The three stages mentioned here are based on TenKate, K. and Laird, S. op. cit. footnote 79 p. 55 (box 3.10).

volunteers are normally administered the prescribed dosage of the drug and human studies on the drug's safety and efficacy are corroborated with practical evidence. This phase lasts around 2 years.

Finally, in clinical trials III, larger numbers of patients are tested to determine the side effects of the drug. For this, the drug is administered to varied groups of people in very large numbers. This phase again takes up to three more years. [89]

3.2.1.5 Efficacy and Drug Marketing

If the trials end successfully, the drug is filed for approval (in the USA, this is called a FDA approval and in Europe it is the European Agency for the Evaluation of Medicinal Products (EMEA) that deals with this), only after which it is allowed to be marketed. This can be done either through the firm's own marketing department (which is the case with many large pharmaceutical firms) or through licensing out the production of the drug. [90]

3.2.1.6 The Potential Impact of the Pharmaceutical Process on Conservation of Genetic Resources[91]

There are numerous cases of drugs discovered out of genetic resources, where the potential demand for raw material has led to its extinction.

The need for genetic resources arises at two stages in the drug R & D process: pre-clinical and clinical testing and for large-scale production of the end product.[92] In these two stages, wherever the laboratory synthesis of the discovered compounds is not possible, the drug R & D process requires huge amounts of raw genetic material to produce minimal quantities of the drugs in question.

Many times, it is possible that firms cannot use *in vitro* techniques usually due to the expenses involved or due to the difficulty in synthesis itself. But at the same time, there is evidence that firms prefer to collect raw material from the wild, since it often cheaper for them in the long run. [93] Such sourcing of genetic resources for R & D is done with the help of several collector intermediaries in source nations, which may range from university-based plant collections, to private individuals/

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89 Ibid., p. 55.

90 TenKate, K. and Laird, S. op. cit. footnote 79 p. 54-55.

91 For a detailed treatment of this issue, see Gehl Sampath, Biodiversity Prospecting Contracts for Pharmaceutical Research: Institutional and Organisational Issues in Access and Benefit Sharing, Forthcoming.

92 Cragg, G. M., Newman, D. J. and Snader, K.M. *Natural Products in Drug Discovery and Development*; Journal of Natural Products, 1997, Vol. 60, No. 1, p. 52-60.

93 Sheldon et al. *Medicinal Plants: Can Utilization and Cultivation Co-Exist?* Advances in Economic Botany, Vol. 12, 1997, p. 7, note that firms prefer to collect from the wild since it requires low financial commitments and almost no infrastructure, even in cases where laboratory synthesis is possible.

brokers who collect for small-time profits to public research institutes or small firms.[94]

It is feared that as a result of their reliance mostly on harvests from the wild, firms which hold intellectual property rights on specific products based on genetic resources may end up exploiting natural reserves of the plant material for its production or altering local habitats by introducing mass cultivation. Although not so grave, this threat can exist at the stage of conducting R & D based on genetic resources itself; during the clinical stages. Therefore, the most important question that such intellectual property rights on pharmaceutical products raise is to what extent species should be exploited without becoming extinct.[95]

Some other cases of such over-collection as a result of medicinal values are presented in Table 1 below.[96]

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94 TenKate, K. and Laird, S. op. cit. footnote 79 p. 105.

95 See in this context, Dhillon, S. and Amudsen, *Bioprospecting and the Maintenance of Biodiversity*; in Svarstad, H. and Dhillon, S. (eds.), *Bioprospecting: From Biodiversity in the South to Medicines in the North*, 2000, p. 103-132, at p. 103.

96 Please note that Dhillon, S. and Amudsen, op. cit. footnote 95, present a more elaborate list of species, out of which only a few selected have been reproduced here. For another exhaustive survey of the medicinal species which have grown to become extinct as a result of their medicinal value; see also: Ayensu, E. S. *Endangered Plants Used in Traditional Medicine*; in Bannermann et al. *Traditional Medicine and Health Care Coverage*, WHO, 1983, p. 175-280.

Table 1: Endangered Medicinal Plants and Compounds Derived From Them

Endangered Medical Plant Species	***Name of Compound and Commercial Use***	***Traditional Medical Use***	***Plant part used (P), Life form (L)***	***Distribution (D) and Known Source (KS)***
Catharanthus roseus(rosy periwinkle) Apocynaceae	Vinblastine, cristine, aimaline, cancer, vasodialator, leukaemia, Hodgkin's disease	Madagascar, West Indies, Tooth aches, diabetes, wasp stings, worms, constipation, stops bleeding, induces vomiting.	P: whole plant L: annual herb H: warm climate, dry soil	D: pantropical KS: Madagascar, Mozambique and India Cultivation in US by McAllen
Prunus africana Rosaceae	Sterols, triterpenes, n-docosanol benign prostatic hyperplasia	against fever and madness	P: bark L: tree H: montane forest, light demanding, late-secondary/disturbed forest	D: Cameroon (KS), mainland Africa, Zaire (KS), Madagascar (KS) the Cape
Pilocarpus spp. Rutaceae	pilocarpine, induces salivation, treats heartbeat, glaucoma	Northern Brazil; induce salivation and sweating	P: leaves L: shrub/tree H: poor sandy soils, sensitive to water shortage	D/KS: Brazil and Paraguay
Podophyllum hexandrum (Himalayan Mayapple) Berberidaceae	podophyllin; treats veneral warts, etoposide, antitumour agent	Himalaya emetics; catartics, skin diseases, tumours, warts, jaundice, fever, syphillus, and liver problems	P: roots and rhizomes L: perennial herb H: rich, moist soil, moderately forested areas	D/KS: Afghanistan, Northern India, Nepal, Bhutan and China
Ravoulfina Serpentina (Indian Snakeroot)	reserpine; anti-hypertensive, lowers blood pressure and is used against	sedative, spiritual use in meditation, treats snake bites, poisons,	P: roots L: shrub H: tropical moits	D: Bhutan, Nepal, Bangladesh, SriLanka, Andaman,

Apocynaceae	mental diseases	epilepsy, insanity, insomnia, anxiety and intestinal disorders	deciduous forests	Burma, Thailand, Malaysia, Java, and Indonesia. KS: Indian Subcontinent

Source: Dhillon, S. and Amudsen, Bioprospecting and the Maintenance of Biodiversity; in Svarstad and Dhillon (eds.), Bioprospecting: From Plants in the South to Medicines in the North, 2000, p. 114-117.

3.2.2 The Botanical Sector

Botanical medicines are "...bulk, laboratory preparations of simple remedies in traditional medicine, like plants to treat common cold, fatigue, stress, or even botanical preparations for skin and face problems".[97] The major selling point for botanical medicines is that they are based on time-tested "traditional usages".[98] This explains the boom in the industry[99] as a result of re-emerging emphasis on overall health in Europe and the USA.[100] It also is the reason why in many cases, it is not possible to protect botanical medicines using patents since the knowledge in question is already in the public domain.[101] In the strict sense, patents on botanical medicines come into play when companies come up with original preparations using already existing information.

3.2.2.1 The Process of R & D in the Botanical Sector[102]

Although these products are based on modern scientific findings (activity found in a chemical or chemical group present in an herb that is found to possess certain pharmacological properties), the information is mostly derived from/ based on traditional systems of medicine. As a result, they are largely comprised of homeopathic products or factory-based traditional medicinal preparations[103] and the main stages involved in research and development of botanical medicines are as follows.

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97 Cf. TenKate, K. and Laird, S. op. cit. footnote 79, p. 79.

98 Ballance, R. et al. op. cit. footnote 98, p. 16.

99 Brevoort, P. *The Booming US Botanical Market: A New Overview*. Herbalgram, 1998, No. 44, Fall Edition; cited in TenKate, K. and Laird, S., op. cit. (footnote 79), p. 79; see also: Balance, R. et al. *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, Edward Elgar, 1992.

100 Etkin, N. L. and John, T. *Pharmafoods and Nutriceuticals: Paradigm Shifts in Biotherapeutics*; in Prendergast, H. D. V., Etkin, N. L., Harris, D. R. and P. J. Houghton, P. J. (eds) *Plants for Food and Medicine*. The Royal Botanical Gardens, Kew, 1998, p. 3-16; see also: McCaleb, R. S. *Medicinal Plants for Healing the Planet: Biodiversity and Environmental Health Care*; in Grifo, F. and Rosenthal, J. *Biodiversity and Human Health*. Island Press Inc., 1994, p. 221-242, at p. 228, notes that the trend in increased herb usage is a consumer-driven trend.

101 Personal communication with Dr. Konrad Becker, Patent Attorney, 23 December 2002.

102 The information in this sub-section is based on TenKate, K. and Laird, S. op. cit. footnote79, p. 84-85.

103 Ballance, R. et al. op. cit. footnote 98, footnote 40, p. 16.

3.2.2.2 Information Gathering and Testing

The first stage involves gathering information on useful properties of plants. More often than not, traditional knowledge plays a very important role in botanical medicines, since in many cases, the entire product may be based on the traditional usage itself. Traditional knowledge can also play a major role in proving safety and efficacy of botanical medicines. [104]

The plant is then tested to check if the activity can be found in a chemical or chemical group present in an herb, or if known chemicals in the herb possess certain pharmacological properties. If this turns out to be the case and the plant does contain pharmacological properties of commercial interest, development of the botanical medicine requires large quantities of raw plant material.

3.2.2.3 Cultivation or Wild-Crafting and Processing

Similar to the situation in the pharmaceutical industry, botanical companies seem to prefer wild collections of the required plants since it is the cheapest way to source them, unless they are confronted by regulatory hurdles or problems of unreliable supplies.[105] In this sector too, a large network of intermediaries helps to source the plants. There are traders in tropical countries who act on behalf of purchasing companies buying plant material that is collected/ wild-crafted and dried. Wholesalers, importers and exporters also act as intermediaries and sell raw materials to one or a few companies.[106]

At the next stage, the processing companies test plant material for contamination (e.g., pesticides). This stage is also usually undertaken by intermediaries, for example brokers who specialise in preparation of extracts. In the final stage, the processed ingredients are first supplied to the companies who then manufacture the finished products (by fixing the form and the consistency according to in-house formulae).

3.2.2.4 The Impact on Sustainable Use of Genetic Resources

The production of botanical medicines, as the R & D process reveals, is incumbent upon the availability of large amounts of dried plant material. Hence, the main issue that the botanical medicine industry raises is also one of sustainable supplies. This issue becomes all the more pertinent when the rising demand for botanical medicines over the world is taken into account. TenKate and Laird (2000) estimate that annual growth rates for the botanical industry are between 10-20% in most

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104 TenKate, K. and Laird, S. op. cit. footnote 79, p. 92, also note that "Traditional Knowledge is widely used in the botanical medicine industry as the basis for determining safety and efficacy, to develop agronomic practices for the cultivation of materials, and to guide the development of new products."

105 TenKate, K. and Laird, S., op. cit. footnote 79, p. 84-85

106 TenKate, K. and Laird, S., op. cit. fotonote 79, p. 84-85

countries.[107] According to figures cited therein, the global consumer sales for botanical medicines are estimated to be as high as US$40 billion[108] and the largest global markets for botanical medicine are found in Germany, China, Japan, France, Italy, UK, USA and Spain. Of these, Germany is the largest consumer of botanical medicines and in 1996, the combined markets for Germany (US$3.6. billion) and France (US$1.8 billion) accounted for 75% of EU consumption.[109]

Therefore, the potential of those firms who hold IPRs on botanical medicines to pose a threat to those plants whose medicinal value has been discovered has to be considered. Although there is always the possibility of tissue culture and laboratory synthesis of the plants whose medicinal properties are in demand, it is not always clear whether this option is viable for a given plant and, in situations when the option is viable, whether the firms really use it - similar to what we noted in the case of pharmaceutical medicines.

The case study below of the *Kanis and the Arogyapanc*ha presents an example where laboratory synthesis of the plant was not the desired option for the manufacture of the medicine since the concentration of the required compounds is best when the plant is harvested in its natural site of occurrence.

Case Study: The Kanis and the Arogyapancha

The Kanis are a tribal community that lives in the forests of Thiruvananthapuram district of Kerala, south-western India. Their use of the fruit of Trichopus zeylanicus travancoricus, a plant found in the forests where they live led the scientists of Tropical Botanical Garden and Research Institute (TBGRI), which is a plant research institute situated in Kerala, to investigate further and to identify its active ingredients. The TBGRI developed a drug called Jeevani from the plant and resolved to share fifty percent of any commercial returns that they get from the drug with the Kanis. In 1995, with the approval of the Chief Minister of Kerala, this technology was transferred for manufacturing purposes to a local drug company, Arya Vaidya Pharmacy. The duration of the license is seven years and the TBGRI is to receive a two percent royalty on any future drug sales, half of which are to be given to the Kanis.

Most of the areas in and around which the Kanis live have been declared as Reserved Forest under the Indian Forest Act, 1927. There is also a proposal to designate these areas as a biological park (the Agasthyavanam Biological Park). The implications of an area being a reserved forest are that in such an area acts, not

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[107] TenKate, K. and Laird, S., op. cit. footnote 79, p. 78.

[108] NBI, Raw Materials II, June 1998 Vol. 3, No. 6, cited in ten Kate and Laird, op. cit. footnote 79, p. 78.

[109] Grünewald, J. and Büttel, G. T*he European Phytotherapeutics Market.* Drugs Made in Germany, 1996, Vol. 39, No. 1, p. 6-11, cited in TenKate and Laird, op. cit. footnote 79 p 78.

permitted by the Forest Officer or the State Government, are prohibited.

Jeevani is a herbal formulation and therefore its production is incumbent on regular supply of leaves of the plant, Trichopus zeylanicus travancoricus. The need to cultivate the plant has been felt. Since the quantum of this plant occurring in the wild may not satisfy production needs, due to the specific conditions that the plant requires for its growth, the scientists at the TBGRI have expressed the need to cultivate the plant in its natural habitat to retain the maximum potency. Since the plant requires only shady areas of the forest and only the leaves are required for the production, community techniques for commercial cultivation were promoted by the TBGRI and supported by the Integrated Tribal Development Programme, Directorate of the Tribal Welfare of the Government of Kerala. This can be a sustainable option for the harvesting of the leaves since no part of the forest needs to be cleared – only clear patches of land within the forest are identified and the plant is cultivated.

But after some initial collections, the idea of commercial collections was discarded due to objections by the Forest Department, which has the authority to do so, since minor forest produce falls within its jurisdiction. The main concern of the forest department has been the possibility that commercial pressure from outside might lead to the depletion of the plant in the area.

The fear of unsustainable use in the Kani case seems to be rather hypothetical due to two main reasons. The plant is perennial in nature and can be harvested 2-3 times each year and there are clear patches in the forest where it can be planted without endangering other plants or animals. Secondly, the Kani case has been the object of intense public scrutiny, both, national and international. This ensures that the collection process falls within the parameters laid out by the CBD.

The salient point of all this for IPRs is that a *de facto* right of the Kanis was recognised, despite the absence of a formal legal title over the land, resources or knowledge.

Sources: Personal Interview, Anuradha, R. V., 13 June 2002; Anuradha, R. V. A Study for the CBD Secretariat, 1999; Dutfield, G. (1999), Trade, Biodiversity and Intellectual Property Rights, London, England: Earthscan Publishers.

In contrast to the care being taken in the Kani case to avert any damage to the forests, the case of Panax Vietnamenis[110] is one where its medicinal value seems to be leading to apprehension about the availability of the plant in Vietnam.

As the Kani study above reveals, two factors – the perennial nature of the plant and the intense public scrutiny – have been instrumental in ensuring that the collection process falls within the parameters laid out by the CBD. The interesting question for legal policy making is whether the sustainable harvesting of *Arogyapancha* would still be possible if both these factors were absent. Would the absence of these factors have lead to a gradual reduction in the plant's

110 See TenKate, K. and Laird, S. op. cit. footnote 79, p. 112-113, for a detailed study of the Panax Vietnamenis; a plant with a discovered botanical use in Vietnam.

occurrence, as is being observed in Vietnam? How this can be avoided is an issue for regulation to solve and will be dealt with in Section 7.

3.2.3 Agricultural Biotechnology and Its Impact on Sustainable Use and Conservation of Genetic Resources

Conventional breeding techniques suffer from one important deficiency: they do not allow for precisely controlling the characteristics of the crop varieties in question. In contrast, biotechnological tools make it possible to identify the aim of the breeding programme and to use genetic engineering techniques to achieve the required traits. Transgenic/ GM crops are crops that result from the insertion of genetic material from another organism in such a way that the plant exhibits desired traits.[111] Due to this advantage, genetic engineering techniques are gaining popularity in agriculture.[112]

As Pardey and Beintema (2001) note, some of the key traits that crop improvement generally focuses upon are: delayed ripening, increased resistance to pests and diseases, modified colour, reproduction and dormancy (specifically male sterility, like in the varieties of corn) and resistance to environmental factors such as droughts.[113] But as recent estimates show, the major traits are herbicide resistance and insect tolerance: out of more than 40 transgenic plant varieties that were approved of by the US federal agencies as of 2000, 17 contained transgenes for pest protection and 14 contained the gene, Bt, for insect resistance.[114]

3.2.3.1 Development of New Plant Varieties: The Process

The research and development of a new plant variety for agricultural purposes consists of three main phases, which spread over a period of 10-15 years: selection and pre-breeding, breeding and product approval.[115] As TenKate and Laird (2000) note: “Plant breeding involves the identification and crossing of plants each of which exhibit different useful characteristics, to generate populations of

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111 Fernandez-Cornejo, J. and McBride, W. D. *Genetically Engineered Crops for Pest Management in U. S. Agriculture: Farm-Level Effects.* Agricultural Economic Report, No. 786, U. S. Department of Agriculture, April 2000, p. 2.

112 TenKate, K. and Laird, S. op. cit. footnote 79, p. 128, note to the same effect, for example, that Novartis Seeds has increased its genetics research from 15% to 30% in the last 10 years with a reduction in traditional breeding from 85% to 70%.

113 Pardey, P. G. and Beintema, N. M. *Slow Magic: Agricultural R&D a Century after Mendel*: Agricultural Science and Technology Indicators Initiative. International Food Policy Research Institute, Washington, 2001, p. 18 .

114 Committee on Genetically Modified Pest Protected Plants, Board on Agriculture and Natural Resources and the National Research Council. *Genetically Modified Pest-Protected Plants: Science and Regulation*. National Academy Press, Washington, 2000, p. 32.

115 TenKate, K. and Laird, S. op. cit. footnote 79, p. 126-127.

genetically recombined individuals. A small proportion of the population will display the desired characteristics of both parents within the individual plants. The breeder's task is to then identify and select those plants with the right combination while discarding the rest."[116] In other words, the focal point of breeding is to ensure that only the desired traits are passed on to the plant variety that is being derived.

The breeding process consists of a continuous process of crossing and back-crossing between the native parent varieties and the new variety that has retained some of the traits desired, until the new variety finally retains only the desired traits and eliminates all the undesired ones.[117] As a result, it is very difficult, in most cases, to trace back the new variety to a set or a group of parent varieties, since the genes chosen to create a new variety are a result of permutation and combination in tens and hundreds of plants.

In this process, using genetic modification techniques, including recombinant DNA techniques (also known as rDNA) helps the targeted introduction of genes from distantly related species or even totally different species. [118] They also help in generating detailed knowledge of plant traits. The detailed knowledge thus generated helps make plant breeding efficient in two ways. Firstly, it aids in a more efficient pre-selection of varieties for breeding purposes, and secondly, it helps breeders to avoid or eliminate undesired traits effectively from offspring.

These expanded possibilities of introducing novel genes into plants that could not previously be found in the entire gene pool of the crop concerned[119] have opened up opportunities of creating "made-to-order" plant varieties that exhibit all desired characteristics like greater productivity and increased pest resistance.[120] Using genetic modification techniques also helps to eliminate all undesired traits with accuracy; breeds can be derived which lack allergic and toxic compounds, or that require lesser farming inputs, such as fertilisers, water and energy.[121]

At the end of many generations of re-crossing, when cultivars are obtained that are superior to their parents, product approval is applied for. This stage mainly

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116 TenKate, K. and Laird, S. op. cit. footnote 79, p. 127.

117 See here the description in Dutfield, G. *Intellectual Property Rights and the Life Science Industries* (Forthcoming), p. 145.

118 Committee on Genetically Modified Pest Protected Plants et al. op. cit. footnote 114, p. 24.

119 Hawtin, G. *Biotechnology in the Maintenance and Use of Crop Genetic Diversity*; in Hardy, R. W. F., Segelken, J. B. and Voionmaa, V. (eds.). *Resource Management in Challenged Environments*, NABC Report 9, 1997.

120 Juma, C. *Modern Biotechnology: Appropriate Technology for Sustainable Food*. Brief 4, August 2001, p. 2.

121 Tenkate, Initial. and Laird, S. op. cit. footnote 79, p. 128.

involves verifying whether the GM plant variety in question is likely to cause any environmental and health risks.[122]

3.2.3.2 The Impact of New Plant Varieties on Agricultural and Non-Agricultural Landscapes

The impact of agricultural biotechnology on biological and genetic diversity is probably the least understood issue within the debate on environmental effects of biotechnology.[123] As our earlier discussion in section 3.1 reveals, most studies mention or discuss the impact of GM crops on agro-ecosystems only, in terms of monocultures or invasive weeds. But mostly, the potential impact of GM crops on natural ecosystems is a topic that has not received much attention. Therefore, even the approval processes, employed to check varieties for release into the environment, are not tailor-made to address the impact of such varieties. [124]

Agricultural ecosystems have the potential to adversely affect or even destabilise the resilience (the capacity of an ecosystem to return to normalcy after disturbances) of surrounding ecosystems.[125] This is because agriculture is characterised by larger outflows of material than other natural ecosystems owing to heavy inputs of nutrients, pesticides and other materials that are used to ensure high-yields.[126] The discharge of these inputs into surrounding ecosystems can have from the most marginal to the most powerful of ecosystem effects.[127] Therefore, although marginal effects are negligible, the stronger effects can introduce changes to surrounding ecosystems that distort their balances, drastically.[128]

When agriculture is characterised by large-scale introduction of GM crops, this can influence genetic diversity in many important ways due to the discharge of farming inputs into the surroundings. Traits of herbicide resistance, tolerance and insect resistance that are new to the ecosystems in question can lead to the

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[122] See Miller, H. I. and Congko, G. op. cit. footnote 77, p. 1-10, for a review of the different kinds of regulations that may come into play at this stage. Also note that the approval process for GM crops is very different from seed certification mechanisms prescribed for non-GM crops.

[123] Royal Society of Canada (hereafter RSC). *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, 2001, p. 129.

[124] See Chapter 7 for recommendations relating to these aspects.

[125] Committee on Genetically Modified Pest Protected Plants. Board on Agriculture and Natural Resources and the National Research Council. *Environmental Effects of transgenic Plants: The Scope and Adequacy of Regulation.* National Academy Press, 2002, p. 22.

[126] RSC Report, op. cit. footnote 123; Committee on Genetically Modified Pest Protected Plants et al, op. cit. footnote 125, p. 23.

[127] Committee on Genetically Modified Pest Protected Plants et al., op. cit. footnote 125, p. 24.

[128] Ibid., p. 24.

introduction of 'biological novelty' and thus create invasive species of weeds and insects. Genetic alterations can also be induced into wild plant populations, or even wild gene pools of the world's major crops may become contaminated, leading to far-reaching consequences in non-agricultural genetic diversity. [129] Insect resistant Bt crops can also lead to severe changes in soil geochemical cycles.

3.2.3.2.1 Biological Novelty and the Problem of Invasive Weeds

Herbicide-tolerant crops are designed to survive certain herbicides that would otherwise have killed the crop, too, while targeting the weeds in and around the farms.[130] In certain cases, herbicide-resistant crops can be beneficial in terms of reducing the use of harmful herbicides, but such herbicide tolerant crops can pass on their genes to weedy relatives. This sort of introduction of one gene/ set of genes into recipient ecosystems is called biological novelty and can lead to the creation of invasive, herbicide-resistant weeds. [131]

But the risk that GM crops cause problems of invasiveness in recipient ecosystems is high only when the crop variety in question has a short history of domestication.[132] In other words, most major crops of today, like rice, wheat and corn are a result of intensive artificial selection over a long period of time. These selection methods ensure many traits that reduce the survival value of these varieties in natural conditions. As a result, scientists estimate that although vast pieces of land are under cultivation world-wide, there is very little chance that these species will survive more than a few seasons without planned cultivation. As a result, domesticated plants do not have the potential to become the world's threatening plant invaders.[133] Owing to this, the insertion of some transgenes into a crop that has a long history of domestication is unlikely to alter its ecology in such a way that it becomes transformed into an aggressive invasive species.[134]

In contrast, there is a very high probability that crops that have only recently been brought under cultivation can become invasive and weedy. According to the RCS Report (2001), invasiveness requires that genetic modifications increase the survival and reproduction chances of cultivars in natural ecosystems.[135] The

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129 RSC Report, op. cit. footnote 123, p. 130.

130 Gaisford, J. D., Hobbs, J. E., Kerr, W. A., Perdikis, N. and Plunkett, M. D. (2001), *The Economics of Biotechnology*. Northampton, USA: Edward Elgar, p. 55.

131 Fernandez-Cornejo, J. and McBride, W. D. op. cit. footnote 111, p. 3.

132 RSC Report, op. cit. footnote 123, p. 122.

133 Ibid., p. 121.

134 Ibid., p. 121.

135 To demonstrate this, the Report cites the example of Canola and the problem of weediness. Canola has a relatively shorter history as a domesticated plant, when compared to other crops like rice, wheat, etc. It is reported that there are two wild traits in many Canola cultivars – those of weak seed dormancy and seed shattering – as a result, a

numbers of crop varieties being approved worldwide with newer traits has been constantly on the rise.[136] Given this scenario where GM crops are becoming more and more common, the possibility that long processes of artificial selection have not reduced the tendencies of species to survive beyond plantation periods is potentially larger. Whenever these plants contain herbicide resistance genes, the risk that such species survive beyond crop cycles and pollinate with weeds around farming areas is high. Such uncontrolled cross-pollination is the main reason for the rise of herbicide resistant weeds. These resistant weeds then invade natural plant communities around farms.

Invasions of natural plant communities by aggressive weed varieties can have varied effects on genetic diversity from the most direct ones, such as rapid loss of genetic resources and reduction in forest diversity, to indirect ones, like increased forest fires.[137]

3.2.3.2.2 Transgenic Crops and Genetic Alterations in Wild Populations and Non-Target Organisms in Non-Agricultural Landscapes

The risk that transgenic crops may contaminate wild crop pools of the same species is not large in the case of many major crops in the developed nations, since they originally did not belong to these regions. But when transgenic crops are reintroduced in tropical nations, where wild crop gene pools of the same variety exist, the risk of genetic alterations in wild populations of the same species is high due to cross pollination between the GM crop and its wild relatives.[138]

A good example is the extinction of Taiwanese wild rice, *O. rufipogon* ssp. *Formosana.* It is reported that the steady increase of domesticated rice varieties caused collections of *O. rufipogon* ssp. *Formosana* to gradually exhibit traits of the cultivated species along with a decrease in fertility of seed and pollen that leads to the near extinction of the naturally occurring populations of this sub-species.[139]

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large number of seeds can enter the soil, persist within and emerge in the subsequent season as volunteer Canola plants. It is also feared that, due to the presence of many herbicide-resistant traits in the Canola cultivars, the emerging volunteers can be resistant to several herbicides, making it very difficult to get rid of them. See also: The Royal Society of Canada reports that Canola could become one of Canada's most serious weed problems; RSC Report, op. cit. footnote 123, p. 122.

[136] According to Pardey, P. G. and Beintema, N. M. op. cit. footnote 113, p. 18, for example, 180 crop changes involving 15 basic physical characteristics have been approved for planting, feeding and food use in at least 27 countries and for at least 14 crops in the year 2000.

[137] Committee on Genetically Modified Pest Protected Plants et al. op. cit. footnote 125, footnote 66, p. 26.

[138] Ibid., p. 26 and RSC Report, op.cit. footnote 123, p. 130-131.

[139] Committee on Genetically Modified Pest Protected Plants et al., op. cit. footnote 125, footnote 66, p. 32.

Although the example demonstrates the risk to wild crop pools from GM crops, it is difficult to generalise the effects since they are varied and unpredictable. There are various ecological and environmental factors that can affect the reaction of a recipient ecosystem to a new gene/ set of genes making these changes unpredictable. Despite this, scientists feel that the ecological impact of transgenes on wild populations is the most important issue in assessing the environmental impact of GM crops.[140]

Herbicide-resistant crops also have other effects - usage of newer herbicides for GM crops can lead to the extinction of some plant species in the surroundings that affect the organisms, birds or even animals that may depend on such weeds for their staple diet.[141] A controversial example in this regard is that of the Monarch Butterfly. One laboratory study indicates that *Bt* cotton can lead to high mortality amongst monarch butterflies. But according to the Committee on Genetically Modified Pest Protected Plants (2002), the relationship between the two is still unclear and a very high density of Bt cotton pollen is required to cause this effect.[142]

3.2.3.2.3 Bt Crops and Agro-Chemical Linkages

Insect resistant crops or simply *Bt* crops are essentially those crops that are genetically modified to contain the gene from the soil bacterium *Bacillus thuringiensis.* This bacterium helps the plant to produce a protein that is toxic for certain kinds of insects. *Bt* crops are more effective in providing protection against insects since the entire plant is protected this way and that, too, for the entire cropping season. This makes farmers less reliant on weather conditions or external insecticides to guarantee a reliable harvest.[143]

The main risk of *Bt* crops is that they can gradually promote insect resistance to *Bt* and these resistant insects could make crops more vulnerable over a period of time.[144] Given that there are vast amounts of agricultural inputs that flow out into the surroundings, such aggressive insect populations find their way into the surrounding natural communities. Invasive insects that enter other ecosystems have properties, similar to those of invasive plants and therefore can cause sufficient harm to genetic diversity.[145]

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140 RSC report, op. cit. footnote 123, p. 129; Committee on Genetically Modified Pest Protected Plants et al. op. cit. footnote 125, p. 49.

141 RSC report, op. cit. footnote 123, p. 130-131.

142 Committee on Modified Pest Protected Plants, op. cit. footnote 114, p. 37.

143 Fernandez-Cornejo, J. and McBride, W. D. op. cit. footnote 111, p. 1.

144 Ibid.

145 Committee on Genetically Modified Pest Protected Plants et al. op. cit. footnote 114, p. 26.

Bt crops also raise concerns regarding soil biogeochemical cycles. Toxic proteins from such transgenic plants can be released into the soil through their roots to the soil along with other proteins that the roots of the plant may have.[146] Otherwise, toxic proteins can also reach the soil through decomposition of the crops after harvest.[147] Although laboratory evidence is inconclusive until now, the potential of such releases to impact genetic diversity is disconcerting. [148] For example, one harmful effect of Bt toxins in the soil can be to delay the natural decomposition processes of the soil microbial community, thus creating effects on a range of interacting species ranging from bacteria and viruses to protozoans and insects.[149]

3.2.3.2.4 Impact of Monocultures on Loss of Genetic Diversity

Modern farming based on agricultural biotechnology promotes the large-scale usage of hybrid seed varieties, due to their high-yield characteristics. These monocultures, it has been claimed, leads to a loss of genetic resources because of the neglect of hitherto existing landraces.[150]

A deeper assessment of the situation reveals an interesting trade-off, because although monocultures reduce genetic diversity, they do so only indirectly. Varieties of major crops promoted world-wide as a result of agricultural biotechnology have led to a situation where farmers have to discard of several landraces or older conventional varieties to opt for more varieties with higher output-lower input ratios.[151] This has led to the gradual neglect of some of the varieties/ landraces that used to exist earlier. Such species tend to gradually disappear if left uncultivated because, as noted earlier, agricultural plants that have long been under cultivation have recessive survival characteristics.

The interesting question in this regard is whether the introduction of more efficient varieties is to be critiqued on the basis of the choice that it induces farmers to make. If farmers choose these varieties out of free will, the option of *ex-situ* conservation can help create a balance between efficient high-yield farming and the losses that can be caused through gradual neglect of older races.[152]

It has also to be pointed out that the much of the criticism levied on impact of monocultures on genetic diversity also refers to the effect of outflows from

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146 RSC report op. cit. footnote 123, p. 110.

147 Ibid., p. 110. See the Report for a detailed analysis of these effects.

148 Ibid., a very detailed assessment of these effects and the probability of their occurrence is provided on p. 110-111.

149 Ibid., 110-111.

150 Refer to Section 3.1.

151 See for example, Kloppenburg, J. R. Jr. (1988), *First the Seed: The Political Economy of Plant Biotechnology, 1492-2000*. Cambridge, Australia: Cambridge University Press.

152 The limitations of ex-situ conservation are discussed in Chapter 6.2.1.

monoculture cropping systems. Monoculture cropping systems are indeed agricultural ecosystems with the highest outflow potential of nutrients, herbicides and insecticides – inputs that are used for crops in very high concentrations. But the specific impact of these outflows on neighbouring landscapes depends on the sort of GM crops that are being cultivated as the foregoing sub-sections have shown. In criticising the impact of monocultures this fact is not taken into account very often.

3.2.4 The Process of R & D in the Horticultural Sector

The exact difference between agriculture and horticulture still remains to be determined. As TenKate and Laird (2000) note, whereas tomatoes that are used for pulp and juice fall under agriculture, tomatoes for salad are horticultural. Broadly speaking, the scale of production is one differentiating factor, although this may cease to be the case, since horticultural varieties are gaining more and more popularity. Another distinction is the nature of the crops. Whereas crops that easily perish – like flowers, fruits and vegetables – are considered to be horticultural, crops with produce that lasts longer, like cereals and corns, are classified as agricultural.[153] Thus, within horticulture, it is still possible to differentiate between vegetable horticulture and ornamental horticulture. The focus here is on ornamental horticulture.

3.2.4.1 The Process of R & D[154]

The main products of ornamental horticulture are herbaceous plants (mainly potted plants), woody horticulture (shrubs and trees of ornamental significance), cut flowers, foliage plants (non-flowering potted plants) and bulbs (exotic bulbs that can either be sold as potted or as cut flowers).

Breeding creates most ornamental varieties, some of these varieties being the result of very detailed programmes that use biotechnological techniques and genetic engineering and some others the result of smaller and shorter programmes where a new variety is produced within two years using vegetative propagation. The former method of expansive breeding using biotechnological techniques, such as micro-propagation and transgenic breeding, is getting increasingly popular in this industry.

Generally, the companies perform R&D in-house; i.e. varieties are bred in facilities in the country where the company is based. But the varieties (like the F1 hybrids that are the most popular) may require hand-pollination of the female plants. So the large-scale production of these varieties is still carried out in developing countries where several thousand employees are employed for large-scale production purposes.

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153 TenKate, K. and Laird, S. op. cit. footnote 79, p. 159.

154 This section is based on TenKate, K. and Laird, S. op cit. footnote 79, Chapter 6 on Horticulture, p. 158-187.

Companies are beginning to evolve on a large-scale unusual exotic species – and the pedigree of these varieties can be extremely varied and complicated.

3.2.4.2 The Threat of Biological Invasion

Horticulturists are constantly in search of new and exotic ornamental plants since the demand in the horticultural industry is determined by growing consumer desire to access unusual yet aesthetic plant species. In their endeavour to meet the demand, the industry causes the introduction of totally unrelated species into pre-existing ecosystems all over.

As in the case of agriculture, when new varieties of plants are added to already existing ecosystems, this becomes a source of biological novelty.[155] Such species can interact with other plants in the ecosystem setting off another type of biological novelty through the ecosystem components, similar to the impact of transgenes in wild populations (see 3.2.3.2 above). However, this is the most drastic form of addition of biological novelty. The term usually used to denote the impact of exotic alien species into recipient ecosystems is 'biological invasion'. As the term indicates, the impact is grave and according to Schmitz and Simberloff (1997), is the second largest reason for loss of biodiversity worldwide, after habitat conversions.[156] In Florida, whole ecosystems have been replaced by near monocultures of Brazilian pepper (Schinus terebinthifolius) and melaleuca (Melaleuca quinquenervia), which alter hydrology, microclimates, and fire regimes.[157] But because it is difficult to immediately notice the impact of such species on ecosystems and because the impact may vary not only from one exotic species to another but also from one recipient landscape to another, the problem still has not received the kind of attention it seems to deserve.

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155 Committee on Genetically Modified Pest Protected Plants et al. op. cit. footnote 114, p. 29.

156 Schmitz, D. C. and Simberloff, D. *Biological Invasions: A Growing Threat*; Issues in Science and Technology, Vol. XIII, No. 4, 1997, p. 33-40, at p. 33, estimate that exotic species have contributed to the decline of 42 percent of U. S. endangered and threatened species.

157 Ibid., p. 33.

4 Conservation of Genetic Resources and Intellectual Property Rights: Harnessing the Positive Linkages

Article 16(5) of the CBD not only sets out that IPRs should not run counter to the objectives of the Convention, but also calls for IPRs to be supportive of the objectives of the Convention. The previous Chapter has looked into whether IPRs on biotechnological products promote practices that run counter to the objectives of the Convention. This Chapter focuses on the positive linkages between IPRs and the conservation of genetic resources to analyse the ways in which IPRs can be supportive of the objectives of the Convention. First, it reviews the claims and counterclaims made on the issue of advantages of IPRs on genetic resources. It then assesses the potential positive impacts of IPRs on the conservation of genetic resources and surveys the main instruments and initiatives that seek to harness these impacts.

4.1 Claims and Counterclaims Regarding the Positive Impacts of IPRs on Sustainable Use and Conservation of Genetic Resources

As indicated above, most claims made in the literature are about negative impacts of IPRs on conservation, but some positive ones are also to be found:

- *IPRs can help attain to the objectives set forth in Article 1 of the CBD*. It has been claimed that this is the case particularly since IPRs can help facilitate the transfer of knowledge and technology.[158] Through licences, joint ventures, R&D projects, and disclosure of the protected invention in public patent specification, knowledge and technology of importance to sustainable use and conservation can be shared with providers of genetic resources.

- *IPRs create value in genetic resources and, thus, an incentive to conserve.* The argument is that by attaching IPRs to inventions involving genetic resources, these resources increase in value and, therefore create are an incentive to conserve such resources.[159]

- *IPRs can promote research in areas of importance to developing countries, such as their medical priorities.* Biotechnological tools may hold the answer to two exigent issues that confront the world today – rampant food shortage and development of medicines for major illnesses like AIDS, malaria, and tuberculosis. In the pharmaceutical sector, it is estimated that the cost of developing a single drug is somewhere between US$231 and US$500 million.[160]

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[158] Seiler, A. and Dutfield, G. *Regulating Access and Benefit Sharing*: *Basic issues, legal instruments, policy proposals*, BfN - Skripten 46, 2001, p. 30.

[159] Stone, C., *What to do about biodiversity: Property Rights, Public Goods, and the Earth's Biological Riches*, 68 Southern Calif. Law Review 577.

[160] According to the Tufts Center for the Study of Drug Development (2001), the average cost of developing a drug in the United States has risen from US$54 million in 1979 (in 1976 dollars) to $231 million in 1991 (in 1987 dollars) and as much as $802 million in 2001; see Dutfield, G. op. cit. footnote 117, p. 91.

The importance of IPRs in this sector is significant because although it takes large finances and years of effort to develop a drug, it is a relatively easy task to produce a copy in the market. It has been argued that global pharmaceutical firms would be more willing to invest in priorities of developing countries, if IPRs were duly recognised in these countries, reducing the perils of inadequate protection.[161] Similarly, newer plant varieties are also extremely research and capital intensive.[162] Recognition of breeders' rights might act as an incentive to breeders to invest in agricultural priorities of developing countries. One of the benefits of this for conservation could be, for example, that varieties with higher yields are created such that fewer forest areas in developing countries are converted into arable land, thus helping conservation.

- *IPRs promote biotechnological research which will help us conserve biodiversity better.* Biotechnology could also help us understand biodiversity and its components better. Using these insights, it may be possible to gather better data on biodiversity and to improve strategies and policies that promote sustainable use and combat species extinction in a more meaningful way.[163]

But how do these *a priori* arguments stack up against the realities of the biotechnology industry? Biotechnological products do require considerable research and capital investments irrespective of the sector one might be talking of.[164] Depending on the overall policy environment, IPRs can ensure continuous investment of both, capital and intellectual efforts in the production of socially useful information.[165] Viewed from this perspective, intellectual property right on biotechnological inventions, as recognised by Article 27(3)(b) of the TRIPs

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161 Maskus, K. E. (2001), "Parallel Imports in Pharmaceuticals: Implications for Pharmaceuticals and Prices in Developing Countries, Final Report Submitted to the World Intellectual Property Organisation.

162 The CIPR Report (2002), p. 60 estimates that the world-wide private research expenditure totals to $11.5 billion presently, out of which only about $0.7 million is attributable to developing countries.

163 Conway, W. *Can Technology Aid Species Preservation?* In Wilson, E. O. and Peter, F. M. (eds.). *Biodiversity*, National Academy Press, 1988, p. 263-268, at p. 265.

164 Dutfield, G. (Forthcoming), Intellectual Property Rights and the Life Sciences Industry.

165 Conventionally, the grant of an intellectual property right creates a balance between the static versus the dynamic gains of production of information: the gains to society by encouraging the dynamic production of many types of information exceeds the static costs of creation and distribution, thereby making it desirable to design appropriate incentives for its production. See May, C. A. *Global Political Economy of Intellectual Property Rights: The New Enclosures?* Routledge, 2000, and Calandrillo, S. P. *An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System.* Fordham Intellectual Property, Media and Entertainment Law Journal, Vol. IX, Autumn 1998, No. 1, for a specific US analysis of justifications of IP rights.

Agreement, are an effective means to encourage R & D of biotechnological tools and techniques.

It must be acknowledged, however, that there are many who are sceptical about these assertions. At present, there is no data that convincingly links IPRs to improved conservation of genetic resources. There is not even convincing data that situates IPRs into a more effective policy environment to conserve genetic resources.[166]

4.2 The Advantages of Intellectual Property Rights on Genetic Resources

That many developing countries are rich in genetic diversity required for biotechnological research, be it in the agricultural, pharmaceutical, horticultural or botanical sectors, can be used to work in their favour. As Juma (2000) notes, it is unfortunate that until now the debate on biotechnology (as well as other emerging forms of technology like molecular technology) has focused much more on their disadvantages and not on their potential benefits.[167] There are many important ways in which agricultural biotechnology, pharmaceutical research and an increased knowledge of biodiversity linkages can help further the aims of sustainable use and conservation. Taking into account only the negative impacts of biotechnological research and neglecting these positive implications can result in a loss to mankind, since the potential of biotechnology for creating better living conditions in developing countries has hardly been explored. [168]

4.2.1 Benefits of Agricultural Biotechnology

Genetic improvements in crops have the potential to create varieties that meet the world food demand not only for more food, but also help the environment through safer kinds of food that can be grown on lesser land area. The best proof of this can be seen in the industrialised countries - since the inception of newer farming techniques, it is estimated that more than half of the food shortage in northern America and Europe has been solved.[169] Needless to say, higher yields of this kind mean that lesser land has to be converted to agriculture.

Agricultural biotechnology also offers the possibility of developing varieties and techniques that reduce the use of fertilisers and pesticides at the same time

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166 GAIA/GRAIN, *Intellectual Property Rights and Biodiversity: The Economic Myths*, Global Trade and Biodiversity in Conflict, Issue no. 3, October 1998, available on www.grain.org/publications/issue3-en-p.htm.

167 Juma. C., "Biotechnology and Sustainable Agriculture: Developing Country Perspectives", Congressional Briefing, Washington, DC., 24 January 2000, p. 2, notes that development of sustainable farming techniques for developing countries requires an open and unbiased assessment of all technologies.

168 Juma, C. op. cit. footnote 167, p. 3-4 and Pardey, P. G. and Beintema, N. M. op. cit. footnote 113, p. 19.

169 Fernandez-Cornejo, J. and McBride, W. D. op. cit. footnote 111.

conserving other natural resources like soil, water and genetic diversity.[170] For example, herbicide-resistant crop varieties can, in some cases, contribute to a dramatic reduction in pesticide usage.[171] It has also been noted that some of these crops allow farmers to use more benign herbicides than the more harmful ones that were in use earlier. For example, Glyphosate, one such herbicide that is being used with GM crops presently is considered to be totally environmentally benign.[172] It has also been felt that new cultivars can have increased resistance to other biotic stresses increasing the possibility of farming with lesser inputs like water and energy. [173]

All these features are especially important to meet the long-term food needs of developing countries because they can help design more productive farming systems.[174] Increased yields may just hold the answer to many of the food problems faced by developing nations. According to the FAO (1995) estimates, the per capita food availability in developing countries has increased by a mere 20% since the 1960s[175], therefore new cultivars may just hold the key to increases that could solve food shortage in all parts of the world. The urge to explore this potential of GM crops is also corroborated by the changing perception of some developing countries. As the CIPR Report (2002) notes, Bt characteristics are considered beneficial by some developing countries.[176] Therefore, the potential of creating pest-resistant and drought-tolerant varieties of crops that are more geared towards developing country needs is huge and this can make farming more flexible and less reliant on adverse weather exigencies in these countries.

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170 Cook, J. R. *Towards a Successful Multinational Crop Initiative* Colloquium Paper of the National Academy of Sciences, USA, Vol. 95, March 1998, p. 1993-1995, at p. 1993.

171 Fernandez-Cornejo, J. and McBride, W. D. op. cit. footnote 111, p. 1, note that although this was the case in herbicide-tolerant soybeans, herbicide-tolerant cotton did not result in any noticeable change in pesticide usage. Also note here that the degree of pest infestation is a huge factor in determining the effects of pesticide resistant crops. Generally, as the authors noted, farmers who suffer from high degrees of pest infestation were more satisfied with the performance of these crops than farmers who suffer from medium or low infestation levels.

172 Ibid., p. 3.

173 Fraleigh, B. *Issues in Agricultural Biotechnology and Biodiversity for Sustainable Agro-Ecosystems*; in Hardy, R. W. F., Segelken, J. B. and Voionmaa, V. (eds.), *Resource Management in Challenged Environments*, NABC Report 9, 1997.

174 Ibid.

175 FAO, *Dimensions of Need: An Atlas of Food and Agriculture*, FAO, Rome, 1995 cited in Herdt, R. W. *Assisting Developing Countries Toward Food Self-Reliance,* Proc. Natl. Acad. Sci. USA, Vol. 95, March 1998, p. 1989-1992 at p. 1989.

176 According to the report, some five developing countries are now growing Bt Maize and India has just now approved the planting of Bt Cotton. See CIPR Report op. cit. footnote 162, p. 64.

4.2.2 Pharmaceutical Self-Sufficiency

Intellectual property rights on pharmaceuticals and botanical medicines are very important to foster a large amount of private research initiatives.[177] At a general level, fostering biotechnological research through such intellectual property rights leads to greater societal welfare as a result of medicines that have already been discovered and others that are in the pipeline.[178] But in the genetically rich, developing nations, where health is still the largest issue, such intellectual property rights can have two advantages. Both of these are spelt out in Article 1 of the CBD - the possibility of scientific and technological capacity building as well as benefit-sharing to promote *in-situ* efforts in return for efficacious access to genetic resources.

Public-private partnerships in biotechnological research hold the promise of serving the interest of technology transfer and capacity building as well as research on pressing health issues of the developing nations. One good example, where this is the aim, is the Program of the International Biodiversity Co-operative Groups (hereafter, IBCG) in Peru. As will be discussed in Section 4.4.4, the ICBGs are an endeavour of the Government of the United States to develop a cooperative programme that combines biodiversity use and conservation, ethnobotanical knowledge and pharmaceutical drug discovery.[179] An interesting feature of the ICBGs is the focus on diseases of both local and international significance.[180] More of such public-private partnerships could raise the hope for similar advances in the case of other tropical diseases.

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177 Biotechnological firms consider intellectual property rights as important assets. Comment by Graham Dutfield at the Expert Workshop on Trade, Intellectual Property and Sustainable Development, Geneva, 14-15 October, 2002.

178 According to TenKate, K. and Laird, S. op. cit. footnote 79, p. 42 recent estimates of top-selling drugs derived from genetic resources include Bristol-Myers Squibb's cholesterol reducing drug Pavachol (US$1.437 Billion in annual sales in 1997), Merck's other top-selling drugs with natural origins include Zocor (US$3.56 billion) and Mevacor (US$1.1 billion). Similarly, Novartis's Sandimmune and Neoral had sales of US$1.3 billion.

179 Timmerman, B. N. *Biodiversity Prospecting and Models for Collections of Resources: the NIH/NSF/USAID Model*; in Hoagland, K. E. and A.Y. Rossman (eds.), *Global Genetic Resources: Access, Ownership and Intellectual Property Rights*, 1997, p. 219-302, at p. 219.

180 Rosenthal, Personal Interview, 02 October 2002; Rosenthal, J. P. *Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources*; in *OECD, Investing in Biodiversity: The Cairns Conference*, OECD; Paris, 1997, p. 253-274, at p. 255. According to Rosenthal, other factors that are included in the design of the ICBG programs are: (a) active participation of host country individuals and organizations from the planning stage onward, (b) local training and infrastructure development in both drug discovery and biodiversity management, (c) biodiversity inventory and monitoring; and finally, (d) equitable intellectual property and benefit-sharing. In this spirit, the different ICBGs display the various possibilities of contractual structures (ranging from advanced payments to royalties to scientific capacity building arrangements in the source nations) and protection mechanisms for ethnobotanical knowledge.

A second positive contribution that pharmaceutical biotechnology has is to improve our understanding of disease causation, thereby helping us to identify more targets at which to aim research. For example, biotechnological research is helping in identifying features of HIV and HIV behaviour for which chemicals can be designed for attack in a more precise way.[181]

4.2.3 Biotechnology and its Role in Aiding Biodiversity Conservation

There are many reasons for loss of habitats and species world wide; agricultural conversion, population expansion, cultural practices, economic value, being some of them.[182] According to Pardey and Beintema (2001), the world used about 1.4 billion hectares of land for crops in 1961 and only 1.5 billion hectares in 1998 to get twice the amount of grain and oil seeds.[183] Increased productivity and lesser inputs can therefore help in buying time (gradual erosion) and probably even aid in preventing such conversion in the mid-term or long term.

Biotechnology has been and can continue to be critical in increasing our understanding of species, genetic and ecosystem diversity.[184] Such information can be used to devise better "intervention strategies" that could target species' extinction, in many cases.[185] Conway (1998) suggests that such intervention strategies based on technological insights can help to relocate, sustain or even help propagate threatened species, thus saving them from extinction.[186] The information so generated through biotechnological techniques can be used to compliment national efforts to protect *in-situ* biodiversity. The synergies between biotechnological insights on species, ecosystems and habitat conservation as well as traditional ecological knowledge can hold the key to successful in situ conservation in tropical nations.

Another way in which biotechnology can help preserve genetic diversity is through *ex-situ* centres where species that are estimated to have special significance are preserved for scientific use. This may sound disappointing from an ideal conservationist's perspective since more than 90% of existing species have not been examined. Biotechnology and ex-situ preservation may not be able to

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181 We are thankful for the comments made by Graham Dutfield, Senior Fellow, Queen Mary Westfield College, UK and Dr. Rosenthal, Director of the National Institute of Health, USA.

182 Fernandez-Cornejo, J. and McBride, op. cit. footnote 111; Conway, op. cit. footnote 163 p. 263-264.

183 Pardey, P. G. and Beintema, N. M. op. cit. footnote 113, p. 1.

184 Conway, W. op. cit. footnote 163, p.265-267.

185 Ibid., p. 265.

186 Ibid., p. 265. Also see Dresser, in Wilson, E. O. *Biodiversity, National Academy of Sciences*, 1998.

cater to all of them or to help preserve habitats, but it can at least help in retaining some species of importance for future use. [187]

4.2.4 IPRs and the promotion of technology transfer to enhance conservation of genetic resources

Article 16(1) of the CBD calls on Parties to provide or facilitate the transfer to other Parties of technology that is relevant for the conservation and sustainable use of biological diversity or makes use of genetic resources, and do not cause significant damage to the environment. Article 16(2) clearly anticipates that the technology to be transferred includes that which is subject to intellectual property rights, although the transfers themselves are to be consistent with "adequate and effective" protection of IPRs. And, as noted above, Article 16(5) calls for IPRs to be supportive of the objectives of the Convention.

The debate over the role of IPRs in technology transfer has been raging for many years. Actors that favour strong IPRs tend to argue that technology transfer is facilitated when the recipient country has a strong IPR regime, e.g. to ensure that the technology is not subsequently copied.[188] Although the full extent of this proposition is difficult to prove, i.e. how much IPRs really do encourage technology transfer, it does seem to make intuitive sense that private firms would be unwilling to transfer technologies to countries where IPRs are inadequate.[189] Others argue that IPRs, by virtue of mainly being privately held, hinder the transfer of needed and valuable technology.[190]

The key issue for this study is whether IPRs have an impact on technology transfer relevant to the conservation of genetic resources. This aspect has not received very much attention from analysts, and it is likely that this is justified. Often, technologies relating to *in-situ* conservation, which seek to conserve genetic resources in their habitat, relate to the establishment and management of protected areas. The hard technologies generally applied, such as aerial survey equipment, geographic information system and fencing equipment are widely available, including in developing countries.[191] Indeed, the difficulties in using these technologies effectively relate to lack of adequate and reliable taxonomic information.[192] Much of the technology relating to *ex-situ* conservation is science

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187 Ibid., Conway, W., p. 268.

188 Ewing, K, and Tarasofsky, R., The Trade and Environment Agenda: Survey of Major Issues and Proposals -- From Marrakech to Singapore, IUCN, Gland, 1997, at p. 53

189 Lesser, W. The Role of Intellectual Property Rights in Biotechnology Transfer under the Convention on Biological Diversity, ISAAA Briefs No. 3, ISAAA: Ithaca, NY, 1997, p. 22 et seq.

190 Op. cit. footnote 187.

191 CBD Secretariat, UNEP/CBD/COP/3/21. *Promoting and facilitating access to, and transfer and development of technology*, , 15 September 1996.

192 *Ibid.*

or knowledge-based, rather than in a form of hardware or machinery. Some of these technologies, such as DNA hybridisation, do not appear widely available in developing countries, although others are.

In sum, it generally appears that IPRs are not decisive in the transfer of technology aimed at the conservation of genetic resources. It may indeed be so in individual cases, but according to the CBD Secretariat, the largest challenges relating to applying the relevant technologies in developing countries are mainly associated with the development of human capital, rather than problems of acquisition from the international market.[193]

4.3 Implications of *Ex-Situ* Conservation on *In-situ* Conservation of Genetic Resources

In principle, countries should have an integrated approach towards their in situ and ex situ conservation strategies.[194] However, the interaction between e*x-situ* conservation activities and *in-situ* conservation in developing countries has not yet been optimal. One aspect of this relationship is that collections have not, by and large, stimulated the level of innovation and funds to help support in-situ conservation in developing countries.

Some of these issues arise in the ambiguities relating to the legal arrangements on commercialisation of products derived from IARC gene banks, discussed above, including those relating to IPRs. More generally, the issue of how IPRs on products derived from ex-situ collections can be a positive incentive in the context of in-situ conservation of genetic resources in the country of origin requires further research.

4.4 The Relevance of Incentives for the Conservation of Genetic Resources: General Introduction

But these advantages of biotechnology that have been enumerated above will not automatically accrue to developing countries. In a similar way, the incentives that IPRs, in both, conventional and sui generis regimes can create for biodiversity conservation in developing countries also need to be harnessed. One way that both these purposes can be served is through contracts for access to genetic resources and traditional knowledge. The last part of this chapter provides an overview of existing contractual arrangements that try to balance these two objectives.[195] In this regard, countries should consider the option of public-private partnerships since, in the long run, it may be a more promising alternative than private sector contracts with pharmaceutical firms.

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193 *Ibid.*

194 See, e.g. Glowka, L. et al. *A Guide to the Convention on Biological Diversity*, IUCN, 1994, at p. 52 *et seq*.

195 See the case study on ICBGs in section 4.4.4. Other ways that developing countries have to harness the positive advantages are discussed in subsequent chapters.

Even apart from that, countries (especially the ones rich in biodiversity) have to resolve, as part of their obligations under Article 11 of the CBD, the potential of conventional and sui generis IPRs as measures to promote conservation of genetic resources. This involves a two-step process. Firstly, the positive incentives, both, social and economic, that conventional and sui generis IPRs can create for conservation of genetic resources has to be resolved. Secondly, in those specific instances where conventional IPRs may lead to negative impacts on sustainable use and conservation of genetic resources, countries should consider designing incentives in their biodiversity regimes that change resource-use patterns towards long-term sustainable use options.[196]

This will require that the debate on the impact of IPRs on conservation of genetic resources shifts from the bioprospecting (those who focus on economic incentives) versus biopiracy (those who focus on social incentives) to one that considers the relationship between IPRs and genetic resources in its entirety.[197] Incentives can be positive incentives, like property rights and reforms, negative incentives like fees, taxes and regulation as well as framework incentives like capacity building and stakeholder participation.[198] Within the context of operationalising Articles 16(5) and 11 of the CBD, it seems appropriate to consider IPRs as a package of incentives that reflect a balance between economic and social incentives. This approach seems justified, when the available instruments are reviewed.

That IPRs are indeed part of such a package of incentives can be derived from a survey of the various instruments that exist today. A variety of instruments have been developed to use IPRs or similar rights to create incentives for conservation. When assessed closely, they all focus on creating a combination of incentives, with IPRs playing a central role. These include binding instruments, e.g. created by governments, regional treaties and by contract, as well as voluntary ones at international and local levels. The spectrum contains "positive", "negative" and "framework" incentives. Since each one of these instruments contains a different combination of incentives, the interesting question: is there an optimal combination of incentives to allow IPRs to promote conservation? The answer for both *sui generis* IPRs and conventional IPRs will be dealt with in detail in Chapters 5, 6 and 7. This following section provides a context for that examination by reviewing various instruments that seek to create such incentives. The review is not absolutely comprehensive; the intention is to set forth the most prominent examples.

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196 See the case study on Philippines in this section on this point and also see the analysis in Section 5.1.1.1 on the role of incentive measures under the CBD.

197 Biopiracy can be defined as granting "bad" patents, which are those that are not truly novel by virtue, being based on traditional knowledge, or patents for inventions based on traditional knowledge where patent standards are too low or where the prior informed consent of the source community was not received.

198 OECD; *A Handbook on Biodiversity Incentives*, Paris, 1995, p. 36-37.

4.4.1 National legislation to harness IPRs for conservation

Over the past ten years, a number of countries have enacted legislation that aims at harnessing IPRs for the purpose of conservation. Some of these pieces of legislation can be considered as efforts to develop *sui generis* protection of traditional knowledge. In this regard, the first meeting of the CBD Panel of Experts on Access and Benefit Sharing identified several possible elements of *sui generis* legislation for the protection of traditional knowledge:

- Recognition of ancestral community rights over knowledge, innovations and practices related to genetic resources.
- Recognition that such rights exist, even where information may be in the "public domain".
- Establishment of the principle that such rights may be collective in nature.
- Distinction between the rights over genetic resources (where vested in the State) and rights over knowledge associated with such resources (vested in local and indigenous custodians).
- Presumption that use of genetic resources implies use of associated knowledge, innovations and practices.
- Establishment of administrative and judicial review processes to resolve disputes regarding the granting of access on the basis of potential environmental, economic, cultural or social impacts.
- Creation of benefit-sharing mechanisms/obligations to ensure equitable distribution of benefits among custodians, whether parties to access agreements or not.
- Establishment of local and centralised registers of traditional knowledge, innovations and practices of local and indigenous communities.
- Creation of programmes and processes for the strengthening of traditional knowledge systems.
- They should be developed in close collaboration with indigenous and local communities through a broad-based consultative process that reflects a country's cultural diversity.

Such legislation in existence mainly recognises and establishes collective rights for indigenous people over their knowledge, and include the Costa Rican Biodiversity

Law, [199] the 1998 Constitution of Ecuador,[200] and the 1999 Constitution of Venezuela.[201] Brazilian legislation provides for the protection of traditional knowledge by indigenous and local communities, but indicates that this is not meant to prejudice or limit rights pertaining to intellectual property.[202] This right includes entitlements to prevent unauthorised access by third parties and to derive profit from economic exploitation by third parties where the community owns the rights.[203] Many of these laws also codify the concept of prior informed consent and benefit sharing, such as the Costa Rica Biodiversity Law.[204]

In the Philippines, rules relating to IPRs and genetic resources have been established by the Wildlife Resources Conservation and Protection Act (Republic Act NO. 9147 of 2001) and the Indigenous Peoples Rights Act of 1997. The Wildlife Resources Conservation and Protection Act establishes, among others, the terms for prospecting of biological and genetic resources including those related to prior informed consent.[205] This is complemented by the Indigenous Peoples Rights Act of 1997, and the Traditional and Alternatives Medicine Act of 1997, which institutionalises ownership by indigenous peoples of their knowledge of traditional medicines. Outsiders seeking to use such knowledge must acknowledge its source and provide a share of the financial return of commercial use.[206]

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[199] Article 82: "...the State expressly recognizes and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration; therefore, it can include practices which in the future require such status. This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices."

[200] Article 84 recognizes "...collective intellectual property rights" on communities' ancestral knowledge."

[201] Article 124 stipulates as follows: "The collective intellectual property of indigenous knowledge, technology and innovations is guaranteed and protected. Any work on genetic resources and the knowledge associated therewith shall be for the collective could. The registration of patents in those resources and ancestral knowledge is prohibited."

[202] Article 8(4) of Provisional Measure on the genetic heritage, associated traditional knowledge and technology transfer, No. 2.186-16, 23 August 2001.

[203] Article 9.

[204] See Articles 63, 65, 66 and 72; see also: Cabrera Medaglia, J. A. *Access to Genetic Resources, Protection of Traditional Knowledge, and Intellectual Property Rights: Lessons Leaned From the Costa Rican Experience,* draft on file with the authors.

[205] Section 1.

[206] Section 2.

Case Study: The Philippines Framework on Access to Genetic Resources and Protection of Traditional Knowledge

The Philippines framework on access to genetic resources and protection of traditional knowledge is comprised of two laws: The Wildlife Resources Conservation and Protection Act (Republic Act No. 9147 of 2001) and the Indigenous Peoples Rights Act of 1997. The Wildlife Resources Conservation and Protection Act of 2001 is based upon the earlier Executive Order 247 and its Implementing Rules and Regulations, 1995 and has had the effect of replacing it.

The Act of 2001 is based on a national biodiversity strategy identified by the Philippines government that pins down the priorities of the country in areas of sustainable use and conservation of biodiversity. The Act does not have a national system of prior informed consent as stipulated under some other access regimes, like the Andean Decision 391. Section 14 of the Act that refers to bioprospecting mandates that it shall be allowed only after prior informed consent is obtained from the concerned indigenous cultural communities, local communities, management board or private individual and entity. This has to be read with Section 35 of the Indigenous Peoples Rights Act that makes it mandatory to seek prior informed consent for both tangible access to territories occupied by indigenous cultural communities and to their traditional knowledge. It also looks into issues such as introduction of exotic wildlife into ecosystems in Philippines and mandates environmental impact studies, in case such wildlife is introduced, for the monitoring of biological novelty and any impacts that it may have on the native ecosystems (Section 13). A similar restriction is placed on commercial breeding and propagation of wildlife resources (Section 17).

The Act also regulates the collection of economically important species whether by a national or foreign entity in a strict way. Section 18 that deals with 'Economically Important Species' requires that the Secretary, within one year of the Act, establish a list of economically important species. A population assessment is to be conducted on these species within a reasonable period of time and these are to be regularly reviewed and updated. The collection of species is to be allowed only when the assessment shows that, despite the collections, the species can still recover its numbers. If this is not the case, in the interest of sustainable use and conservation, the collection permits are to be rejected except for purposes of conservation breeding and propagation (Sections 23 and 24).

Section 27 onwards deal with penalties for possessing or knowingly exploiting wildlife in violation of the provisions of the Act. The penalties set out by the Act can be a very efficient way to deal with unauthorised collections of species that have economic value against the provisions of the Act – the minimum imprisonment period is six years and this may be in certain circumstances coupled with monetary fines (Section 28). If implemented, this holds the promise of dealing with the issue of unsustainable use of genetic resources in the

aftermath of their discovered pharmaceutical value. Section 25 that deals with the establishment of critical habitats also gives the Secretary the authority to designate threatened habitats as "critical habitats" and gives his office the autonomy to pursue any policies – including acquisition of land – to prevent its erosion. It also envisages the protection of such critical habitats through local government units and other concerned groups.

Although the Act does not deal with the issue of intellectual property rights in any way, it is to be read in conjunction with the Indigenous Peoples Act which recognises the right of indigenous cultural communities and indigenous peoples over their intellectual capital, along with many other provisions that deal with general development of such communities. The regime also makes a distinction between farming and other communities and issues related to farming communities that have been dealt with in the recently enacted Plant Variety Act. Finally, the funds are collected through fines or other activities such as bioprospecting are to be used to further the goals and priorities of the national biodiversity strategy. All in all, the Philippine regime shows promise on a wide range of aspects that are very critical in creating the right incentives for sustainable use and conservation of biodiversity. Its effective implementation is the only factor that can determine its effectiveness over time.

Source: Dr. Tony Lavina, World Resources Institute, formerly, Under-secretary for Legal and Legislative Affairs of the Department of Environment and Natural Resources in the Republic of the Philippines.

In addition, some countries have clearly outlawed or severely restricted the patenting of life forms.[207]

In Europe, the Danish Patent Act is noteworthy. Without changing the substantive criteria for granting patents, it places an enforceable civil obligation on the applicant to disclose the source of origin of any genetic resources relevant to the patent application.[208] In addition, a bill before the Belgian parliament in 2000 would have deemed a breach of Article 3, 8(j), 15 and 16 for inventions involving biological resources as contrary to morality or *ordre public*.[209] Such a provision

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[207] E.g. the Costa Rica Biodiversity Law exempts from IPR protection DNA sequences, plants and animals, non-genetically modified organisms, essentially biological processes for the production of plants and animals, and natural processes or cycles *per se*. Brazil only permits patenting of genetically modified micro-organisms, and not plants or animals.

[208] See *BEK nr 1086 af 11/12/2000 (Gældende)*. Informal translation on file with the authors. Denmark's Civil Procedure Code makes it incumbent on citizens to disclose all available information in dealings with its civil offices, a failure of which is deemed to be an offence. Accordingly, the failure to disclose information on the source of origin would amount to an offence under the law of Denmark.

[209] Dutfield, G. *Sharing the Benefits of Biodiversity: Is there a Role for the Patent System*, 5 JWIP, 2002, p. 899 et. seq., at p. 919. Van Overwalle, G. *Belgium goes its own way on Biodiversity and Patents*, EIPR 5, 2002, p. 233.

would likely require further interpretation, since in many countries, exceptions based on "ordre public" and morality are intended to address extreme cases, whereas not all breaches of the CBD provisions cited above would meet such a threshold.

Similarly, Brazilian legislation obligates applicants of industrial property rights to specify the origin of genetic material and associated traditional knowledge.[210] The Indian Patent (Amendment) Act 2002 also provides for revocation of patents that do not adequately disclose the geographic source of origin of the biological material involved. In addition, it prevents IPRs from being attached to traditional knowledge by clarifying that inventions do not cover innovations that are in effect traditional knowledge or which aggregate or duplicate known properties of traditionally known components.

Many developed and an increasing number of developing countries have developed plant variety legislation in conformity with UPOV 1991 standards. There are important exceptions, however, which seek to create alternative sui generis systems. The Indian Protection of Plant Varieties and Farmers' Rights Act contains a number of important provisions. Section 18 requires the applicant to declare the origin of the genetic material and that it does not contain any "terminator technology". It further provides for the "Farmer's Privilege" to save and sell the seed of a variety, and contemplates rewarding farmers who are engaged in conservation and preservation of genetic resources of land races and wild relatives of economic plants.[211] It further allows for compulsory licensing if the reasonable requirement of the public for seeds is not satisfied.[212]

A 2001 bill to create a sui generis system of plant varieties has also been deliberated in Namibia, which is based on a OAU Model Law. It seeks, *inter alia*, to create Farmer's Rights to provide incentives to communities to conserve, develop and sustainably use genetic resources. These include the right to protect traditional knowledge, obtain equitable benefit sharing, participate in decision-making processes on matters relating to conservation of genetic resources.[213]

4.4.2 Regional legal instruments that harness IPRs for conservation

The Andean Pact is the pre-eminent example of a regional legal approach to IPRs and genetic resources. Decision 391 on the Common System for Access to Genetic Resources, adopted in 1996, establishes a set of procedural and substantive requirements for granting access to genetic resources. Among the

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210 Article 31, Provisional Measure 2.186-16.

211 Dhar, B. *Sui Generic Systems for Plant Variety Protection: Options Under TRIPS*, Quaker United Nations Office, 2002, p. 17, et seq.

212 Ibid.

213 Ibid.

requirements is that applicants must submit a signed contract (which itself is subject to conditions imposed by the Decision) in their application for permission to have access to genetic resources. The Decision also calls for a refusal by all countries to recognise IPRs over genetic resources, derivatives and intangible components acquired in contravention of the Decision; and a member can request the revocation of such rights granted under another member's intellectual property laws.

Decision 486 on a Common Industrial Property Regime, which entered into force on 1 December 2000, reinforces Decision 391. It provides that the granting of IPRs based on traditional knowledge must be based on acquisition done in compliance with international, Andean Community and national law.[214] Furthermore, it provides that indigenous and local communities have the right to decide on the use of their collective knowledge.[215] Any IPR applications must include a copy of the document that certifies the license or authorisation to use the traditional knowledge pursuant to Decision 391 where such knowledge is the basis of the product or process.[216] National authorities can nullify the IPRs, through decree, in cases where the contract for access to genetic material or the license or authorisation to use the traditional knowledge involved is not filed[217]

In addition, the Organization of African Unity has developed Draft Legislation on Community Rights and Access to Biological Resources. It establishes "community rights" and farmer's rights, to be defined by the national competent authority.[218] According to Article 16, community rights include rights to knowledge, innovations, practices, and technologies, and to collectively benefit from their utilisation. Article 26 defines farmer's rights extensively, to include protection of traditional knowledge relevant to plant and animal genetic resources. According to Article 9, patents over life forms and biological process cannot be applied for. No other IPR can be applied for that derives from biological resources or community innovation without the prior informed consent of the providers.

The European Union has a number of instruments that seek to leverage positive impacts of IPRs. For example, the Preamble of the EC Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions provides a non-binding call for the patent application to include information on the geographic origin of biological material of plant or animal origin. More fundamentally, the recently formulated instrument" Life Science and Biotechnology – A Strategy for Europe sets out the EC's overall

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214 Article 3.

215 Article 3.

216 Article 26(i)

217 Article 75.

218 Article 58.

objectives.[219] In particular, paragraph (a) of Action 26 states that The Commission and the Member States will support the conservation and sustainable use of genetic resources in developing countries and their equitable sharing of benefits arising from their use,

> ... by supporting the development and enforcement of effective measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge, as well as to share equitably the benefit arising from them, including income generated by intellectual property protection.

In the negotiations on the Free Trade Agreement for the Americas, several proposals have been tabled relating to IPRs and genetic resources, although none have so far been agreed.[220] These include proposals that the grant of IPRs should be done with respect for genetic resources or be in conformity with the provisions of the CBD. Other relevant proposals have been made in parts of the chapter. For example, in Part I, it has been proposed that in granting, protecting and enforcing of IPRs, Parties are to give effect to several other international agreements, including the CBD.[221]

Finally, the Like Minded Group of Megadiverse Countries, although spanning more than one region,[222] issued the Cancun Declaration in 2002. It contains several provisions relating to influencing the global negotiations on biodiversity, including several which relate to IPRs. It calls for an international regime for benefit sharing arising from the use of biological resources, which should include the following elements: certification of the legal provenance of biological materials, prior informed consent and mutually agreed terms for the transfer of genetic material, as requirements for the application and granting of patents, strictly in accordance with the conditions of access agreed by the countries of origin.[223] In addition, it encourages the current system of intellectual property rights to take into account the traditional knowledge related to biological diversity when evaluating requests for patents and other related rights.[224]

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219 Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, COM(2002) 27 final, 23.1.2002.

220 See section 6 of Chapter on Intellectual Property Rights, Second Draft Agreement.

221 Article 5.2(p).

222 Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela.

223 Paragraph (h).

224 Paragraph (n).

4.4.3 Private initiatives and codes of conduct

Many private initiatives have been taken relating to IPRs and genetic resources, particularly in relation to traditional knowledge. These have generally been designed to ensure that entitlements to knowledge of the providers of genetic resources are respected. Some of the most important ones are described below.[225]

One important initiative is the development and use of registries of traditional knowledge. Registries, in principle, are repositories of information, and usually the inclusion of a record in a registry confers some legal status on that record, by asserting a legal claim.[226] The registries developed by private initiatives tend not to be formally legal, but they can help clarify for patent offices what knowledge is already prior art or in the public domain. In addition, they can help maintain and preserve traditional knowledge, raise awareness of communities as to the value of traditional knowledge, and be a component in a *sui generis* system for protecting traditional knowledge. However, these tools are controversial, because it is not always clear what the legal status of these registries are and the extent to which the knowledge contained in them is protected. A prominent example is the voluntary establishment of the People's Biodiversity Register in India, established by WWF India, which seeks to document the knowledge, skills and techniques of local communities relating to biological resources. It aims to provide a record of local knowledge, promote the revitalisation of such knowledge, and protect local knowledge from misappropriation. Information in the Register is to be used only on consent of the local community.[227] Other initiatives are in Peru, the Philippines, and the Inuit of Nunavik and the Dene of Canada. Governmental initiatives that include registers include Namibia and Venezuela.

The International Society of Ethnobiology has developed a Code of Ethics[228] aimed at achieving meaningful relationships between ethnobiologists and other researchers, business leaders, policy makers and others with indigenous and local communities. The "Principle of Prior Rights", recognises that indigenous peoples, traditional societies, and local communities have prior proprietary rights and interests over all air, land and waterways, and the natural resources within them that they traditionally inhabited or used, "together with all knowledge and intellectual property and traditional resource rights associated with such resources and their use." The "Principle of Inalienability" recognises the inalienable rights of these people over their traditional territory, natural resources within them and

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[225] For a more complete list of these initiatives, see http://www.biodiv.org/programmes/socio-eco/traditional/instruments.asp#GLN.

[226] Downes, D. and S. Laird, S. *Community Registries of Biodiversity-Related Knowledge. The Role of Intellectual Property in Managing Access and Benefit*, UNCTAD Biotrade Initiative, 1999.

[227] Described in Anuradha, R. V. *Intellectual Property Rights in India in the Context of the Biodiversity Convention and the TRIPS*, on file with the authors.

[228] Adopted at the Annual General Meeting of the ISE held at Whakatane, Aotearoa/New Zealand, 28 November 1998.

associated traditional knowledge. These principles are reinforced by principles calling for full disclosure to the indigenous peoples about the research and their right to give their prior informed consent or exercise a veto over any research. A later addition to the guidelines states that no research should take place until there is agreement on relevant benefit sharing from, and compensation for, any collection, database or publication.

The Pew Conservation Scholars Initiative developed a set of Suggested Ethical Guidelines for Accessing and Exploring Biodiversity, which also call for full disclosure to the indigenous and local communities of the nature and purpose of proposed research, including potential commercial value.[229] They further call for equitable sharing of benefits.[230] The Suggested Guidelines state: "The community's right to any organism or part thereof extracted by any biotechnological or other method must not be exhausted merely by publication or collection. The community can assign these rights or associated intellectual property rights to anyone it feels appropriate."[231]

The FAO International Code of Conduct for Plant Germplasm Collecting and Transfer is a voluntary instrument that sets forth responsibilities of collectors, donors, sponsors, curators and users of germplasm so as to ensure that the collection, transfer and use of plant germplasm is carried out with maximum benefit to the international community and minimal adverse effects on the evolution of crop plant diversity and the environment.[232] During collection, collectors are to respect local customs, traditions, values and property rights, and should demonstrate a "sense of gratitude" towards local communities, especially if use is made of local knowledge.[233] It further calls for users to "consider providing some form of compensation for the benefits derived from the use of germplasm," although none of the suggested forms includes royalties or some form of sharing of IPRs resulting from commercialisation.[234]

The Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct[235] is a voluntary set of provisions that aims to facilitate access to microbial genetic resources (MGRs) and to help partners reach agreements within the framework of the CBD and other international and national laws. A key element of the code is an agreement on prior informed consent between competent partners. Specific recommendations relating to IPRs are made in the section on commercialisation. These include recommendations that partners

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229 Paragraph 2.

230 Paragraph 4.

231 Paragraph 4.

232 Article 4.1.

233 Article 10.1.

234 Article 14.

235 Dated, November 2000.

agree on the IPRs of the MGRs and/or derived technology before investing in research and development; agreements could range from single to shared IPR-ownership; allocate IPRs to the inventing partners, while potentially allowing for other partners to profit monetarily (e.g. royalties) or from licences on concessive or preferential terms; and to apply for a patent in a timely fashion. The Code also recommends that partners include local and indigenous communities where the community is the owner or usufructuary of the area where the *in situ* MGRs were accessed; well represented by officially recognised representative(s); and willing to preserve and maintain knowledge, innovation and practices relevant for the conservation and sustainable use of MGRs (in accordance with CBD Article 8(j)).

A number of major botanical gardens have agreed on Principles of Access to Genetic Resources and Benefit Sharing.[236] These principles include only acquiring genetic resources only with the prior informed consent of the source government or other relevant stakeholders, in accordance with applicable law and practice. Furthermore, benefits should be shared with the country of origin and other stakeholders, including monetary benefits where commercialisation takes place. The sharing of benefits arising from genetic resources acquired prior to the entry into force of the CBD should be, as far as possible, be in the same manner as those acquired subsequently. The Participating Institutions also agreed Common Policy Guidelines to Assist in the Preparation of Institutional Policies Based on he "Principles of Access to Genetic Resources and Benefit Sharing."

Finally, the Third World Network has developed a model Community Intellectual Rights Act, by which local communities are vested with custodianship over all innovation.[237] The burden of proof is on a challenger to show that a local community that has declared itself as custodian of the invention is in fact not so.[238]

4.4.4 Private contractual arrangements

A number of important private contractual arrangements relating to access to genetic resources have been developed between industry and provider countries or communities. One of the first, and most well known, is the one concluded between Merck Pharmaceuticals and INBio, the organisation which manages Costa Rica's protected areas. The arrangement calls for INBio to provide Merck with "a limited number of plant, fungal, and environmental samples from Costa Rica's protected areas for scientific evaluation" in return for US$ 1 million over two years and an additional US$ 135,000 in equipment and training. Merck would also pay INBio 50% of the royalties of any commercial products and 10% of its total budget for biodiversity prospecting projects to the Ministry of Natural Resources and Environment. INBio abstains from claiming IPRs on the products developed by Merck.

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236 Available on http://www.isu.ru/insts/botsad/cbd/principles2000_e.htm.

237 Article 1.

238 Article 6.

Some material transfer agreements that have emerged as a result of contractual negotiations are considered noteworthy. They tend to be agreements between private firms and developing countries to share both genetic resources and the gains from products derived from those resources. Typically, these include payments for genetic materials, technology transfer agreements, and patent protection for private firms. Their proponents argue that they are better than Farmer's Rights in that they compensate a developing country directly for its genetic resources.[239] They can provide compensation for traditional knowledge, even if such knowledge is not protected by standard IPRs and they can require the prior informed consent of local and traditional communities.[240] However, it must be recognised that contract law governs MTAs, and their relationship to IP law is not always clear.

A further tool found in contracts is “know how” licensing. These involve granting knowledge rights to another institution to commercialise a product or process. The most well known example is that involving the Aguaruna people of Peru. The license provided that plants and knowledge were passed on to Searle in exchange for an annual fee. The license is non-exclusive, allowing the community to dispose of the plants and knowledge to anyone else. A trust fund is to be established to distribute the benefits to the community.

An option that seems promising to further conservation aims, drug discovery as well as scientific and technological capacity building in the field of biotechnology parallel to one another is the use of public-private partnerships. The International Co-operative Biodiversity Groups, an experiment of the United States government, is one such example. Although some programs of the ICBGs are controversial, given the nature of traditional knowledge and the marginal probability that private firms would indeed continue to partake in ventures that cater to all these three demands, other such public-private or public-public partnerships should be explored.

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239 Friesvold, George B. and Condon Peter T. *The Convention on Biological Diversity and Agriculture: Implications and Unresolved captivates*, 26 World Development, 1998, p. by 51-570, at p. 559.

240 See also Appendix I: "Suggested Elements For Material Transfer Agreements" of the Bonn Guidelines on Access and Benefit Sharing. In addition, a standard MTA is to be adopted by the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (Article 12.4).

Case Study on the International Cooperative Biodiversity Groups (the ICBGs)

The International Cooperative Biodiversity Groups is an experiment that seeks to integrate pharmaceutical and agricultural discovery with economic development and biodiversity conservation. The experiment is funded by the National Institutes of Health (NIH), the National Science Foundation (NSF) and the Department of Agriculture (USDA) of the United States of America. The ICBG Program has three explicit goals:

? to improve human health through the discovery of new pharmaceutical, agricultural and veterinary agents to treat diseases of importance in both developed and the developing countries,

? to promote scientific and economic activity in less-developed countries by sharing the benefits of the drug discovery and conservation research process and products; and

? to conserve biological diversity through the understanding and valuation of diverse biological organisms and the development of local capacity to manage these natural resources.

The main ICBG programs are: Biodiversity Utilization in Madagascar and Suriname (1993-1998, 1998-2002), Peruvian Medicinal Sources of New Pharmaceuticals (1994-2000), Chemical Prospecting in a Costa Rican Conservation Area (1993-1998), Drug Development and Conservation of Biodiversity in West and Central Africa (1994-1998, 1998-2002), Bioactive Agents from Dry Land Biodiversity of Latin America (1993-1998, 1998-2002), Drug Discovery and Biodiversity Among the Mayans of Mexico (1998-2002), Ecologically Guided Bioprospecting in Panama (1998-2002) and Biodiversity of Vietnam and Laos (1998-2002).

All eight programs use a diversity of approaches and contractual arrangements to bring together researchers from Western institutes, researchers from institutes and universities in developing countries, indigenous and local communities, governmental agencies and industrial partners. For example, the ICBG Program on the Peruvian Medicinal Sources of New Pharmaceuticals (1994-2000) had a partnership amongst five organizations – the Washington University, Museo de Historia Natural, Universidad Peruana Cayetano Heredia, G. D. Searle/ Monsanto Co. and the Confederacion de Nacionalidades Amazonicas del Peru which represented the Aguaruna communities that supplied ethnobotanical knowledge to the other partners. The five partners were bound together through the Biological Collecting Agreement between the Aguaruna people and the Washington University in collaboration with the other two partner universities, a know-how license between the Aguarunas the Searle and a license option between Searle and the university partners.

The Peruvian ICBG has been criticised for the way the ethnobotanical components were handled in the screening and post-screening stages by Searle, the industry partner, and for the bargaining disadvantages that the communities faced in negotiating upon the terms for the know-how license (Greene, 2001). The Mayan ICBG comprising of the Mayan people, University of Georgia, Molecular Nature Ltd., and El Colegio de la Frontera Sur (ECOSUR) had to be cancelled after a two year long protest by several Mayan communities (RAFI, 2001). One fundamental issue in the Mayan ICBG has been whether a group of traditional Mayan healers (called OMIECH) can claim property rights over Mayan knowledge. This issue was hard to resolve since the Mexican Law on Access is silent on this issue of intellectual property rights and questions of benefit-sharing.(Berlin and Berlin, 2000).

One of the main reasons for these conflicts seems to be the neglect of the concept of sui generis intellectual property rights and bargaining mechanisms in the programs. One reason for this may be that the initial set of the ICBG programs were initiated when the host countries did not have detailed laws on access to genetic resources and traditional knowledge. More importantly, in the ICBG framework, conservation-promoting incentives are mainly the building up of scientific, legal and commercial capacity, those that educate users and regulators about the alternatives to unsustainable practices and those that provide financial or other benefits to stakeholders. The second reason for the failure of some of the ICBGs seems to be a general distrust that developed in the post-TRIPs atmosphere between the developed and developing countries on issues of access and benefit-sharing.

Despite this, the ICBGs still represent a window of opportunity for developing countries to use public-private partnerships of a similar kind to channel benefits for traditional knowledge as well as to build capacity in biotechnology. National laws that deal with issues of PIC, clear-cut procedures for PIC within communities and a democratic decision process that takes their perspectives into account in the bargaining procedures can ensure their effective representation in such contracts.

Main Sources: Personal Interview with Dr. J. P. Rosenthal, ICBG Program Director, National Institute of Health, USA on 02 October 2002; J. P. Rosenthal (ed.), Drug Discovery, Economic Development and Conservation: The International Cooperative Biodiversity Groups, Pharmaceutical Biotechnology, Special Supplement, Vol. 37, 1999.

5 Can Sui generis Regimes and IPRs Protect Traditional Ecological Knowledge?

Traditional knowledge of local and indigenous communities has assumed much importance because of its potential to be made use of in commercial sectors such as pharmaceutical and agricultural biotechnology. Although very difficult to define and categorise precisely,[241] the international debate on sui generis community intellectual property rights, biopiracy and benefit-sharing usually refers to traditional knowledge of potential commercial value. Such traditional knowledge can contribute largely to in-situ biodiversity conservation in developing countries by enabling developing country partners to share in the benefits that arise out of commercialisation of genetic resources.

But traditional knowledge also comprises traditional ecological knowledge, which as Posey notes are those aspects of traditional knowledge that are directly related to management and conservation of the environment. [242] These may or may not be commercially valuable. There is enough evidence to show that such systems of traditional ecological knowledge of conservation and sustainable use can be of huge significance to in-situ conservation efforts.

The protection under Article 8(J) of the Convention on Biological Diversity extends to all "...knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity". But national laws that have been enacted to realise the mandate of Art. 8(j) recognise a community intellectual property right on traditional knowledge[243] and grant a community intellectual property right that in some cases extends only to those aspects of traditional knowledge that are commercially valuable.[244] In some others, it extends to all knowledge, innovations and observations, thus covering traditional ecological knowledge too. [245]

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241 For a detailed assessment of the various interpretations and their validity in the context of traditional knowledge and folklore, see, Dutfield, G., "Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation", Paper presented at the Expert Workshop on Trade, Intellectual Property and Sustainable Development, Geneva, 14-15 October 2002.

242 Posey, D. A. *National Laws and International Agreements Affecting Indigenous and Local Knowledge: Conflict or Conciliation?* Green College Centre for Environmental Policy and Understanding, On file with authors.

243 Refer to the discussion in Section 4.4.1 on national initiatives.

244 The Philippines Executive Order 247 and its Implementing Rules and Regulation recognise the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices *when this information is directly and indirectly put to commercial use.*

245 For example, according to Brazil's Bill on Access to Genetic Resources, Bill of Law No. 306/95, traditional knowledge is defined as "...any knowledge, innovation, or individual or collective practice of an indigenous population or local community, having

Is there a substantive difference between laws that recognise a community intellectual property right only on commercial traditional knowledge and a community intellectual property right on traditional knowledge and traditional ecological knowledge? Specifically, what is the impact of protecting all of traditional knowledge only through a community intellectual property right on biodiversity conservation? It is critical to understand how a community intellectual property right and the commercialisation of traditional knowledge impact traditional ecological knowledge in order to design and promote proper in-situ conservation of genetic resources. This is why the main focus of this Chapter is to analyse the impact of a sui generis community intellectual property right on traditional ecological knowledge and conservation of genetic resources. The commercialisation of traditional knowledge no doubt has an impact on in-situ conservation and sustainable use of resources, but that is more a matter of enforcing parts of the benefits into biodiversity conservation programmes.

The main questions that the chapter will address are: What is the precise contribution of traditional ecological knowledge towards conservation of biodiversity? What is the interface between commercially valuable traditional knowledge and traditional ecological knowledge of importance to conservation of biodiversity and its components? What is the impact of a *sui generis* intellectual property right on traditional knowledge on promoting conservation through traditional ecological knowledge? If this impact is not optimal, what other form of protection is more suitable to tap the potential of traditional ecological knowledge for conservation of genetic resources?

Biodiversity and its three major components, namely, species, ecosystems and genes, possess use values that can be broadly categorised into direct and indirect use values. The main issue in incentive design aimed at promoting sustainable use and conservation of biodiversity or any of its components is that it should take into account the indirect values into account as well. Traditional ecological knowledge is a system of organisation and management that has emerged over time as a result of the dependence of these communities on their resources and their environment. It demonstrates what natural resource economics calls common property management – an incentive combination that takes into account both direct and indirect values of biodiversity. If a sui generis regime ought to strengthen such a complex incentive system like community resource management, an intellectual property right has to be construed as one important measure in a larger package of incentives.[246]

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real or potential value, associated with a genetic resource or derived product, protected or not by intellectual property legislation." Similarly, the Costa Rican Biodiversity Law defines sui generis community intellectual property right over the knowledge, innovation and practices of indigenous people and local communities (Articles 82-85). But The OAU African Model Legislation defined community rights to include the rights of communities to all knowledge, innovations, practices and technologies, as well as to collectively benefit from their utilisation and to use them in the conservation and sustainable use of biodiversity, among others. See also: Seiler, A. and Dutfield, G. op. cit. (footnote 158), p. 69-97.

[246] See discussion in Chapter 4 on different kinds of incentives.

5.1 The Nature of Traditional Ecological Knowledge and the Relevance of a Hybrid Solution

The rationale behind having intellectual property rights, as one measure in a larger package of measures can be understood better by taking a closer look at the nature of biodiversity and traditional ecological knowledge. Therefore, a review of biodiversity and its components like genetic resources, their direct and indirect values for human beings and the relevance of hybrid incentive instruments in which intellectual property right is one measure are dealt with in Section 5.1.1. Section 5.1.2 looks at the nature and scope of traditional ecological knowledge and its contributions to in-situ conservation. Section 5.1.3 explores the following questions: What are the factors that have historically sustained it? Then the focus shifts to whether an intellectual property right on traditional knowledge can sustain and enhance such conservation systems in the same way? Finally, if not, what other incentive instruments should supplement an IPR such that in-situ conservation can occur? – is a question that is dealt with in 5.1.4.

5.1.1 Biodiversity and Common Property Resource Management

From an economic perspective, biodiversity has been historically characterised by non-exclusivity (it is almost impossible to exclude) and non-rivalry (because its components could regenerate and adapt) in consumption. But the expanding needs of population and development have changed the nature of biodiversity drastically. Beyond a moderate level of consumption (such that the consumption rate of the resources is equal or lesser than the renewal rate of biological resources), biodiversity assumes the nature of a rival good.[247] Therefore, in today's dynamic perspective, biodiversity is an open-access resource characterised by non-exclusivity and rivalry in consumption.[248]

Dealing with issues of biodiversity conservation necessitates an understanding of the different values of biological resources from both an individualistic and a social perspective.[249] Use values/ benefits of biodiversity are those that can be appropriated easily by individuals or groups of individuals. Use values can be further divided into direct use values and indirect use values.[250] *Direct use values*

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[247] Robert, S. P. and. Rubinfeld, D. L. *Microeconomics,* Prentice-Hall Inc, New Jersey, 1995. In economic terms, pure public goods are characterised by non-excludability and non-rivalry in consumption. Open-access goods are characterised by non-excludability and rivalry in consumption. Common property resources are characterised by rivalry in consumption and excludability by the use of non-price/ non-market mechanism. Private goods are characterised by rivalry in consumption and excludability by the use of the price/market mechanism.

[248] Bromley, D. W. and Cernea, M. M. *The Management of Common Property Natural Resources: Some Common Conceptual and Operational Fallacies*, World Bank Discussion Papers No. 57, 1989; OECD, *Handbook of Incentive Measures for Biodiversity: Design and Implementation*, OECD, Paris, 1999, p. 27.

[249] Ibid., OECD, p. 27.

[250] Ibid. p. 28.

consist of those parts of biodiversity which can be appropriated as goods (such as genetic resources) and can be traded in the market.[251]

Indirect use values of biodiversity can be of two types.[252] The first kind of indirect use values are those provided by ecosystem services. Ecosystem services are all those functions of a given environment that contribute to the creation of direct values, like aspects that control floods, droughts, soil erosions, etc.[253] The second indirect use value of biodiversity is the option value or a quasi-option value of biodiversity.

A quasi-option value is the value that postponing an option of making an irreversible investment in biodiversity to a later point of time can have for an individual, a firm or even a country. The value that can potentially be created by retaining this option over a period of time considering that the environment and the state of research technology is constantly changing and making certain resources far more valuable than they are currently considered falls under the category of quasi option value.[254]

In contrast to use values of biodiversity, "*non-use values"* of biodiversity consist of values of biodiversity that cannot be easily valued in monetary terms – these mainly are existence or bequest values.[255] The economic value of biodiversity is the sum total of the use and non-use values including existence and bequest values.[256]

5.1.1.1 Capturing Use an Non-Use Values: The Role of Property Rights and Other Incentive Measures

Genetic resources predominantly possess private use values because the benefits derived from them are directly tradable in markets. But it would be wrong to assume that private property rights for genetic resources will lead to their efficient utilisation due to their indirect use values that are left uncaptured by market transactions.[257] That is, even if we assume that private property rights on genetic

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251 Mountford, H. and Keppler, J. H. (1999), "Financing Incentives for the Protection of Biodiversity". *The Science of the Total Environment*, Vol. 240, pp. 133-144, at p. 135-136.

252 Ibid., p. 137.

253 OECD, 1999, op. cit. footnote 248, p. 29.

254 Swanson, T. *Appropriation of Evolution's Values*; in Swanson, *Intellectual Property Rights and Biodiversity Conservation*, Cambridge, 1995, p. 161.

255 "Non use values" is a term that refers to the value that is created by ensuring continued existence of biodiversity to others. See OECD, 1999, op. cit. footnote 248, Box IV.3 on p. 30 and 31 for a detailed description of non-use values of biodiversity.

256 Swanson, T. and S. Johnston, *Global Environmental Problems and International Environmental Agreements*, Edward Elgar, 1999, p. 48.

257 See, Lassere, P. (2002), "Evaluation of Biodiversity: A Real Options Approach", Paper presented at the MERIT Seminar, University of Maastricht.

resources are well defined, market prices will be based only on those values that directly benefit the owner. Indirect use values in terms of social benefits that can be derived from the sustainable use of the resource like retaining animal and bird populations, preventing soil erosion and other ecosystem services are left out of the market calculus.

This negative impact of direct use values on indirect use values of ecosystem, species and genetic diversity is what economists term an "externality".[258] Private property rights will not internalise these externalities because an individual's concern in exploitation of the resource will not take into account its potential impact of that resource on the availability of the same or related resources to others which he/ she does not own.[259] Therefore, although private property rights are an important incentive measure for the realisation of direct use values, they fail to capture indirect use values of genetic resources.[260] As a result, given these varied values, private property rights can only be one measure in a set of incentives if sustainable use and conservation of genetic resources is to result.

As the OECD (1999) notes, the three main objectives of the CBD as enshrined in Article 1 recognise this disparity between use values and the necessity to design successful incentive measures that align private and public use values carefully.[261]

As noted therein, "Conservation under the Convention is not so much understood as an attempt to protect any particular status quo in museum-like perfection, but rather to conserve and enhance the ability of ecosystems to regenerate themselves as living systems."[262] Successful conservation efforts are thought to begin with ecosystem conservation such that conservation of species and genetic resources can automatically follow.[263] This is why *in situ* conservation is accorded

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258 Swanson, T. and Johnston, op. cit. footnote 256, p. 95, note, "An externality represents the failure of the producer to take into account the full social cost of the use of some factor or factors in production. An externality arises when the decisions of some economic agents (individual, firms or governments) – whether in production, in consumption or in exchange – affect other economic agents, and are not included in the price system of commodities, that is they are not compensated."

259 For a more detailed discussion on these aspects, see again OECD, OECD, Handbook of Biodiversity Valuation: A Guide for Policy Makers, Paris, 2002, p. 32-38.

260 Mountford, H. and Keppler, J. H., op. cit. footnote 251, p. 136.

261 Ibid., p. 34.

262 Ibid., p.34.

263 It is widely acknowledged now that conservation of ecosystems is one of the pre-condition for conservation of genetic resources. This is because ecosystems that are diverse exhibit the resilience to respond to shocks both climatic and man-made, whereas those, which are not so diverse, tend to collapse easily when confronted by such pressures. Thus, more diverse the ecosystems, the more diverse the genetic resources within and the better the chances of their survival. See OECD, 1999, op. cit. footnote 248, p. 34 and Holling et al., *Biodiversity in the Functioning of Ecosystems;* in C. Perrings, C. Folke,

such special status within the Convention.[264] Furthermore, the notion of sustainable use as defined under Article 2 is meant to complement the conservation aim of the Convention. Sustainable use refers to "...activities that are privately profitable but contribute at the same time to the conservation of biodiversity."[265] Taken in this sense, sustainable use does not correspond to the short-term profit-oriented perspective of individual users, but conceives that individuals or firms abstain from the more profitable but unsustainable use of biodiversity.[266] It is the task of incentive measures to bridge this gap between a short-term profit orientation and a long-term sustainability perspective. [267]

5.1.1.2 The Relevance of Hybrid Incentive Instruments

Hence, although the grant of a property right is a powerful incentive measure, only private property rights and a market place for genetic resources cannot be expected to incorporate the indirect use values of genetic resources in private transactions. Using a combination of incentives, also called 'hybrid instruments,' to combat issues related to genetic resource use increases the chances that all aspects of unsustainable use and loss are targeted.[268] These hybrid instruments can be a combination of positive incentives like property rights and reforms, negative incentives such as fees, taxes or regulations and framework incentives such as capacity building, valuation measures or stakeholder involvement.[269]

Successful approaches to promote sustainable use and conservation of genetic resources will therefore require a combination of incentive measures that recognise the interdependence between the various components of biodiversity and bridge the gap between sustainable use and unsustainable use of biodiversity while promoting conservation.

The CBD too recognises the importance of combination of incentives in many of its provisions. For example, seen in incentive terms, Article 8(j) is a combination of a property right, stakeholder involvement and economic benefits.[270]

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et al., *Biodiversity: Economic and Ecological Issues*, Cambridge University Press, 1994, p. 44-83.

264 OECD, 2002, op. cit. footnote 260, p. 34.

265 Ibid., p. 34.

266 Ibid., p. 35.

267 Ibid., p. 35.

268 OECD Report, 2002, op. cit. footnote 260, p. 36.

269 Ibid., p. 37.

270 Article 8(j) suggests local and indigenous communities be given a right over their traditional knowledge subject to national legislation. Stakeholder involvement is evident from the promotion of use with the wider consent and economic benefits by way of benefit sharing are also provided for.

5.1.2 Traditional Knowledge and Traditional Ecological Knowledge: The Internal Dynamics

Local and indigenous communities have nurtured and sustained some of the world's most pristine ecosystems that surround them. This contribution of their traditional ecological knowledge to the existence and continued preservation of genetic diversity can be traced back several millennia.[271] As Etkin (1998) notes, "paleobotanical research shows that humans and plants have interacted from the start in a way that reflects the selection of species and their manipulation in numerous ways to assure conservation".[272] It is an established fact now that such communities possess a range of information on various aspects of sustainable use and conservation of biological resources. Studies conducted by various biological and social science disciplines reveal the existence of sophisticated systems of indigenous management,[273] germplasm improvement[274] and soil fertility management[275] among others.

How these systems of use and management emerged and what factors were critical in sustaining it are two sets of considerations that any attempt to protect and promote traditional ecological knowledge has to take into account. The importance of *in-situ* biodiversity conservation in the social, cultural and economic lifestyles of communities has to be understood in the context of the symbiotic relationship that communities share with their immediate environments. Historically, the resources in their immediate environments sustained these groups of people by providing resources that they directly lived upon or that they could exchange in return for other necessities through the market mechanism. This interdependence is the main factor that promotes co-operation amongst members of such groups, creating the optimal conditions for resource management within territories that they occupy.[276] This is precisely what authors term common property theory; that is, how to manage the use, how intensely to

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271 See Posey, D. A., op. cit. footnote 242.

272 Etkin, N. L. *Indigenous Patterns of Conserving Biodiversity: Pharmacologic Implications*, Journal of Ethnopharmacology, 63, 1998, p. 233-245, at p. 235.

273 Mundy, P. *Indigenous Communication Systems: An Overview, Development,* Journal of SID, 1993, p. 3.

274 Izac, A. M. N. and Sanchez, P. A. *Towards a Natural resource Management Paradigm for International Agriculture: The Example of Agroforestry Research*, Agricultural Systems, Vol. 69, 2001, p. 5-25.

275 Lamers, J., Bruentrup, M. and Buerkert, A. *The Profitability of Traditional and Innovative Mulching Techniques Using Millet Crop Residues in the West African Sahel*, Agriculture, Ecosystems and Environment, Vol. 67, Issue 1, January 1998, p. 23-35.

276 Bromley, D. W. and Cernea, M. M., op. cit. footnote 248.

allow for regeneration, in which ways and by whom.[277] In common property resource management, private individuals co-operate and invest together in sustainable and prolonged use of the resource such that each of them could better benefit for a longer time from resource use. The system of common property resource management has thus historically catered to both – the capturing of the private use value of biodiversity and its components like genetic resources situated within commonly controlled territories through the market mechanism and the realisation of the public use value of biological resources through rules for the management of its use and conservation.

It is through this mechanism that the communities convert biodiversity from an open-access resource to a common property resource within territories they occupy. And joint custody of resources situated within are determined through factors such as village or tribal boundaries, or groups that could be identified using other such external demarcations.[278] The management systems developed by them clearly reflect the overlapping contexts of private and public values in which plants, especially wild species, were understood and used by local and indigenous communities.[279]

Therefore, at a general level, it is still possible for all of traditional knowledge to be called traditional ecological knowledge, since all of the knowledge stems from their deep understanding of the functioning of their environment.[280] But if we would demarcate the various components of traditional knowledge further, a distinction can be made between knowledge, innovations and observations that relate to the commercial use of the environmental components and traditional knowledge, innovations and observations that govern primarily resource use and conservation. Clearly this demarcation cannot be established in a strict sense when we talk of the communities and their relationship with their genetic resources because the two are overlapping knowledge structures. The resource management aspect comes into play because of the dependence and use needs of the communities on their resources. But looking at it from a user

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277 See, for details, Bromley, D. W.; Cernea, M. M. op. cit. footnote 248, and Jodha, N. S. *Common property Resources*, World Bank Discussion Papers, World Bank, Washington, 1992.

278 In a common property resource, in contrast to open-access resources, although there is rivalry in consumption, there is excludability. The members of the group are in a position to exclude outsiders and form rules amongst themselves for the use of the resources. In this endeavour, even if common property resource management does not take into account all of the public value (like existence value is not really probably a consideration), a large part of the incentive to conserve the public value is present because of the long-term benefit calculus.

279 Etkin, N. L. op. cit. footnote 272, p. 235.

280 Many scholars do use the term traditional ecological knowledge in this way. See for example: Dutfield, G. *Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights an Community Knowledge Databases in India*; in Backeney, M. (ed.), *Intellectual Property Aspects of Ethnobiology, Perspectives on Intellectual Property*, Vol. 5, Sweet and Maxwell, 1999.

perspective in the practical context of contracts for traditional knowledge, the demand is mainly for the specific use of the plants/ animals etc. in a forest and not for the resource management techniques developed for the management of the forest as such.

5.1.3 The Impact of a Community Intellectual Property Right (CIPR) on Conservation and Sustainable Use of Genetic Resources

Biotechnology and the realisation of the value of traditional knowledge in specific applications mostly relate to the private value of genetic resources in territories occupied by indigenous and local communities. These uses can be traded within the market as part of bioprospecting contracts with either national or foreign firms. A community intellectual property right on traditional knowledge, therefore, is an instrument that predominantly protects only those aspects of traditional knowledge that are commercially valuable. Even in cases where national laws do not restrict the scope of protection to commercially valuable knowledge, this will be the case in practice due to the fact that the market demand is mainly for such aspects of traditional knowledge. From this it flows that those aspects of traditional ecological knowledge that are commercially valuable will also get covered by such a sui generis community intellectual property right, but those traditional ecological knowledge applications that are not directly tradable will be left out of its purview.

This takes us to two very interesting questions: what is the impact of the insufficient coverage offered by such a community intellectual property right on the promotion of traditional ecological knowledge and conservation of in-situ biodiversity by indigenous and local communities? Secondly, if such a community intellectual property right is not enough, what sort of combination of incentives is required for sui generis regimes to take into account traditional ecological knowledge as well?

The grant of a community intellectual property right can have some advantages and some disadvantages for maintenance of traditional ecological knowledge and in-situ conservation. On the negative side, such a community intellectual property right has the potential to distort or undermine the symbiotic relationship between communities and their immediate environment. To the extent that it distorts this equation, it may not result in incentives for in situ conservation and sustainable use of biodiversity.

5.1.3.1 The Positive Impact of a Community Intellectual Property Right on Biodiversity Conservation

It is true that when certain groups of stakeholders are denied participation in the distribution of benefits that accrue from preservation of genetic resources, this clearly acts as a disincentive to conserve biodiversity.[281] It is also true that indigenous communities possess resource management systems that are at stake

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[281] Mountford, H. and Keppler, J. H., Initial. op. cit. footnote 251, p. 137-138.

when property rights are not granted.[282] The lack of due recognition and benefit sharing can cause disincentives to communities to continue in their efforts to conserve biodiversity in the same way as before.[283] Therefore, the recognition of a community intellectual property right on traditional knowledge can create an incentive for effective local implementation of incentive measures aimed at in-situ conservation.[284]

This is also in accordance with the third objective listed in Article 1 of the CBD: the sharing of benefits arising out of the commercialisation of genetic resources. Benefit sharing is clearly an incentive measure for parties who own genetic resources to conserve and sustainably use them.[285]

5.1.3.2 The Negative Impacts of a Community Intellectual Property Right on Biodiversity Conservation

At the same time, a sui generis community intellectual property right has the potential to distort already existing, well-functioning traditional ecological knowledge systems amongst communities for in-situ biodiversity conservation. Some of the main reasons for this distortion are as follows.

- ***Neglect of applications of traditional ecological knowledge as a result of reduction/ negation of interdependence on in-situ resources.*** When communities possess traditional knowledge of commercial importance for biotechnological innovations, their dependence on their environment for their immediate survival is negated. The introduction of direct commercial value for some uses of their resources acts as a heterogeneous element in a hitherto homogeneously organised group of people. The communities may lose incentives to further promote traditional management and conservation techniques due to the fact that the need to ensure long-term survival of in-situ resources for their own existence is diminished.[286] Additionally, in certain communities, recognition of a community intellectual property right to

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282 Dutfield, G. op. cit. footnote 58, p. 101-122.

283 Gadgil, M. *Recognising and Rewarding Common Pool Knowledge Resources*, Paper presented at the IUCN-Kalpavriksh Workshop on Biodiversity Conservation and the Intellectual Property Regime, 1999.

284 Marguiles, M. *Protecting Biodiversity: Recognising Intellectual Property Rights in Plant Genetic Resources*, Michigan Journal of International Law, 1993, p. 322-356, who argues that the grant of a right to traditional knowledge will create incentives for conservation of biological diversity.

285 OECD Report, 2002 op. cit. footnote 260, p. 34.

286 Kanbur, R. *Heterogeneity, Distribution and Cooperation in Common Property Resource Management*, Working Paper Series of the World Bank, 1992, WPS, p. 844, notes that in the case of common property resources, heterogeneity issues arise within otherwise homogenous groups as a result of external exchanges in the economic environment. Especially those leading to some members of the community benefiting at the expense of the rest.

traditional knowledge may create perverse incentives for individual parties to divulge to outsiders parts of the knowledge known to them,[287] as a result of which sustainable use is lucrative only to some and not to the others.

- ***Internal Tensions and eventual destabilisation community structures due to governmental and/ or market interventions.*** Communities and their common property management systems are extremely sensitive to factors like increasing population and governmental policies, apart from sudden market interventions.[288] All these factors cause sudden shocks or large changes that community structures fail to cope with.[289] As Kothari and Das (2000) note, local institutional structures and rules of resource-use restraint tend to break down in the face of such changes.[290] This sort of destabilisation as a result of external forces can be observed especially in communities that demonstrate considerable internal inequalities vis-à-vis access to resources and decision-making.[291] In these communities, the commonly observed phenomenon is that the more deprived use the developments to break away from existing community structures. For example, it has been noted that in India, changing situations in common property resource management has led to different reactions by different groups in the face of decline in area, productivity and scope of management. Whereas the rural rich totally withdrew from the use of common property resources, the rural poor, who depended on the use of common property resources for their sustenance, resorted to the use of common property resources as open-access resources. This has led to a lack of user obligations and gradual over-exploitation of resources, which were once very well managed and preserved.[292]

- ***Identification of Beneficiaries and the Problem of Free Riders.*** An intellectual property right on traditional knowledge that is not accompanied by rules that clearly lay down who the beneficiaries are and how they are to be identified and segregated can work against the goal of promoting in-situ conservation. When a given community cannot be clearly identified and demarcated, sharing of benefits that accrue from commercialisation of traditional

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287 Gadgil's account of the two main medicine men of the Kanis and their popularity ever since the Arogyapancha became famous shows that these effects are indeed observable. See Gadgil, M. op. cit. footnote 284, footnote 167, p. 7.

288 Arnold, J. E. M. and Stewart, W. C. *Common Property Resource Management in India*, Tropical Forestry Papers, No. 24, Oxford Forestry Institute, Oxford, 1991, p. 21.

289 Kothari, A. and Das, P. In: Posey, D. A. (ed.), *Spiritual and Cultural Values of Biodiversity*, UNEP, 1999.

290 Ibid.

291 These exclusions may be justified on grounds of caste, economic class or gender differences. See Ibid.

292 Jodha, N. S. *Management of Common Property Resources in Selected Areas of India*; in Dani, A. and Campbell, J. G. (eds.), *Local Institutions and Resource Management*, ICIMOD, Nepal, 1989: Arnold, J. E. M. et al, op. cit. footnote 289, p. 21-24.

knowledge of that community may have to be shared with peripheral members/ groups. In such circumstances, the incentive to conserve that is supposed to accrue through the recognition of an intellectual property right for communities can be lost, since those who conserve have to share the benefits with the peripheral free riders.

Thus, the recognition of a property right over traditional knowledge can in some cases, but not necessarily so automatically, lead to biodiversity conservation.

5.1.4 A Hybrid Package of Rights to Promote *In–Situ* Conservation Using Traditional Ecological Knowledge

The analysis until now reveals three interesting results that are of relevance to policy-making. Biodiversity is a resource with intricately connected components and these necessitate the provision of "hybrid incentive instruments" to achieve sustainable use and conservation. Secondly, traditional ecological knowledge, although a part of traditional knowledge, is a public good that is produced because of the dependence of the communities on their environment and sustained through common property resource management.[293] A community intellectual property right over traditional knowledge does not capture much of traditional ecological knowledge applications, since it caters only to those aspects that are commercially valuable and can be traded in a market, just like any other private property rights allocation on genetic resources. Apart from not capturing the traditional ecological knowledge aspects, a community intellectual property right has the potential to distort the symbiotic relationship that the communities share with their immediate surroundings.

Does this imply that an intellectual property right is not an appropriate incentive instrument to protect traditional ecological knowledge?

A community intellectual property right can only be one measure in a larger package of incentives to protect traditional ecological knowledge. An intellectual property right, whether conventional or sui generis, is mainly targeted at creating incentives for either the production or dissemination of commercially valuable information. Traditional ecological knowledge of importance to conservation and sustainable use of in-situ genetic resources, on the other hand, has been embedded in community management mechanisms, which prescribe the conditions for use. A closer look at common property management reveals it to be a hybrid instrument for management of biodiversity.[294] It is hybrid because it combines, traditionally, a collective territorial right with a right to the usufruct according to specific norms of usage.

Therefore, an intellectual property right alone cannot automatically help create incentives for *in situ* conservation and sustainable use of genetic resources, because (a) it does not cover all of traditional ecological knowledge, and (b) it

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293 See footnote 247 for a definition of the term 'public good'.

294 OECD Report, 1999, op. cit. footnote 248, p. 27.

amounts to replacing a hybrid incentive instrument (common property management) with a single incentive (private property right).

Adequate protection of traditional ecological knowledge and incentives for in-situ conservation requires that communities be granted packages of rights in order to implement common property management systems.[295] This has to be accompanied by supportive regulation that mitigates/ cushions the shocks of contact of such systems with the economic exchange process. Governmental regulation should complement communities' techniques of conservation of resources while addressing their deficiencies for example, they may even have the tendency to over-use certain species due to traditional practices.[296] Governmental regulation should support community-based techniques while eradicating their deficiencies.[297]

One good example of a group of indigenous people who have controlled their territories and knowledge effectively according to common property resource management way so as to commercialise traditional knowledge are the UZACHI. The case of the UZACHI demonstrates that communities can use benefit sharing to directly help in situ conservation.

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295 See in this context, Gehl Sampath, Forthcoming, op. cit. footnote 91.

296 Kothari, A. and Das, P. op. cit. footnote 289.

297 Ibid.

Case Study on Novartis And UZACHI

The UZACHI are a set of indigenous people who have initiated, on their own, the establishment of a laboratory and a field capacity to capitalise on the vast range of fungal species that surround them. They seek to do this through the use of microfungi for the discovery of drugs through bioprospecting, promotion and study of wild mushrooms for their local consumption capacity, management of micorrhizal, edible mushrooms for international markets. Critical in this initiative is the UZACHI sustainable management plan that covers both their commercial and conservation activities.

The genesis of the facility was the Novartis-UZACHI agreement. The contract for bioprospecting contains an up-front payment, royalty (in terms of mile stone payments), provisions of training and capacity building. The agreement for initial collection started in 1995 and ended in 1998, where NOVARTIS mainly focussed on fungal resources of the UZACHI. Collections were part of the BIOLOEAD Project of Novartis. There was no traditional knowledge in the agreement since UZACHI wished so, but the conservation of biodiversity using the funds generated by the agreement employs traditional knowledge.

The success of this agreement in terms of benefit-sharing for the communities and the channelling of these benefits into in-situ conservation is to be attributed to the fact that the communities had a integrated conservation-related management plan at the inception of the agreement that Novartis had to merely support through its revenues. The management plan of the UZACHIs has been quite a success. For the UZACHI, the main achievement of the project until now has been the realisation that their fungal resources are very valuable. The UZACHI have been successful in channelling the limited funds (in terms of upfront payment) and the capacity building exchange that took place between the two parties to establish the Mycological Facility: Oaxaca (hereafter, the MFO). Through the MFO, the community has developed their own cadre of technicians and also hired professional people from other cities of Mexico. But these outsiders are not constant in the MFO, the UZACHI maintain the organisation completely. The MFO has been running now for 15 years and is completely supported through UZACHI funds that come from other activities of the communities, such as forest produce. The communities use the MFO not only to explore commercial potential of their resources but also to research and enhance their in-situ management strategies. In 1997, using the funds generated through the Novartis agreement, the UZACHI established a DNA capacity for genetic analysis of crop diversity in the MFO.

The main problem in the UZACHI- Novartis Agreement is monitoring. Although 120 new chemical compounds were identified during initial collections, the collections ended in 1998 and until now, the UZACHI have not heard back from Novartis. They also have extreme difficulty in tracing their partners in Novartis since the three main people who were responsible for the BIOLEAD project at Novartis and had originally contracted with the UZACHI have either changed jobs or have been transferred to other positions within the company.

Case Study on Novartis And UZACHI

The UZACHI themselves understand the difficulty of keeping tabs on the company's R & D when their main contacts are no longer in place.

The community structures in the UZACHI are remarkably horizontal with decision-making process and their internal governance is largely democratic and merit-based. Their management, administration of the MFO as well as decisions to allow bioprospecting or not are all completely based on community management techniques and effective rules of common property resource management.

Source: Personal interview with Mr. I. Chapela, Department of Environmental Science, Policy and Management, University of California, Berkeley, 13 May 2002.

5.2 The Impact of Conventional Intellectual Property Rights on Traditional Ecological Knowledge: An Investigation

There are two possible ways in which conventional intellectual property rights can impact upon the protection of traditional ecological knowledge.[298] The first one is associated with obstructing the grant of a right over traditional knowledge. It has been proposed that intellectual property rights on biotechnological inventions as granted by the TRIPs Agreement or the UPOV may inhibit the protection of traditional knowledge within national jurisdictions.[299] Intellectual property rights under the TRIPs Agreement or the UPOV can affect the protection of traditional knowledge in yet another way. It may be used to undermine the traditional knowledge, prior informed consent and mutually agreed terms provisions of the CBD as well as to evade benefit-sharing.[300]

Section 5.2.1 will investigate whether intellectual property rights as granted under Article 27(3)(b) of the TRIPs Agreement impede meaningful protection of traditional knowledge and traditional ecological knowledge. A sectoral assessment of traditional knowledge use, PIC possibilities and benefit sharing and the impact of conventional IPRs as under the TRIPs Agreement towards undermining these provisions is conducted in Section 5.2.2.

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298 Refer to the discussion on claims made on the negative effects of IPRs in Chapter 3.

299 Kothari, A. and Anuradha, R. V. *Biodiversity, intellectual property rights, and the GATT agreement: how to address the conflicts?* Biopolicy, Vol. 2, Paper 4, PY97004, 1997, Online Journal, URL: http://www.bdt.org.br/bioline/py and Mooney, P. *The Law Of The Seed, Development Dialogue, 1983,* among others.

300 WWF International and CIEL, *Biodiversity and Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*, Joint Discussion Paper, March 2001, p. 12.

5.2.1 Article 27(3)(b) of the TRIPs Agreement and the Protection of Traditional Knowledge

Article 27 of the TRIPs Agreement lays down the terms of mandatory patent protection in general by defining "patentable subject matter.[301] Apart from laying down that patents should be made available for any inventions, products and processes, as long as they are new, involve an inventive step and are capable of industrial application,[302] exceptions to patentability are set out in Articles 27(2) and 27(3). [303]

An exception to mandatory patent protection as laid out under Art. 27(3) is Article 27(3)(b) that allows for "effective" *sui generis* system for plant variety protection.[304] Member States have the option to determine what an effective *sui generis* system for plant variety protection would look like, subject to the general restrictions of the Agreement.

Although a strict reading of Article 27(3)(b) suggests that a *sui generis* system is contemplated only for plant varieties, the TRIPs Agreement establishes "minimal standards" only.[305] As a result, it is possible for countries to create laws that protect traditional knowledge in general, through appropriate sui generis laws. The other exceptions contained in Article 27 regarding patents on life forms, namely, Article 27(2) and Article 27(3)(a) can help countries make a case for the protection of traditional knowledge, as long as the exercise of other rights in the Agreement is not affected. [306]

By virtue of Art. 27(2),[307] an exception on grounds of animal, human, plant life and the environment is established. But the Agreement has not defined the terms "ordre public" and "morality".[308] It has been argued that the implementation of

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301 See Article 27 of the TRIPs Agreement.

302 Article 27(1) of the TRIPs Agreement.

303 See Tansey, G. *Trade, Intellectual Property, Food and Biodiversity*, Quaker Foundation, 1998, for a discussion of Art. 27, the possible interpretations of the terms thereunder and permissible exceptions.

304 According to Article 27(3)(b), "...[M]embers shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof" .

305 See Preamble, TRIPs Agreement.

306 See Tansey, G. op. cit. footnote 303, p. 6.

307 Art. 27(2): "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

308 Dutfield, G. *op. cit. footnote 27*, p. 24, notes in this regard that the wordings of Art. 27(2) are very similar to that of the European Patent Convention (Art. 53, in particular), and

Art. 27(2) at the national level mandates the resolution of the meaning of the term "ordre public"- which could either be interpreted as being mainly linked to security reasons (as under the Guidelines for Examination of the European Patent Office) or as general public order or public interest.[309] A limitation of the exception under Art. 27(2), however, is that Members are not allowed to refuse patent to a commercial invention merely because it is prohibited under national law. The diagnostic, therapeutic and surgical methods for the treatment of humans or animals can be excluded.[310]

While contemplating protection for either plant varieties or traditional knowledge, the general restrictions of the TRIPs Agreement contained in Article 8 should be taken into account by developing countries. The 'Public Interest' Principle embedded in Art. 8(1) allows Member States, when formulating or amending their national laws and regulations on intellectual property, to adopt measures necessary to protect public health and nutrition; and to promote the public interest in sectors of vital importance to their socio-economic and technological development.[311] But at the same time, the flexibility Article 8 allows countries on grounds of "public interest" is extremely limited since it does not allow any amendment of the minimum standards of the Agreement.[312] From Article 8, it follows that any *sui generis* right on traditional knowledge has to be in compliance with the minimum standards of intellectual property rights as set out under the Agreement.[313]

From this it follows that if the sui generis intellectual property right created to protect traditional knowledge does not comply with the minimum standards of the TRIPS Agreement, it will be in violation of Article 8 of the Agreement. But at the same time, this caveat does not automatically preclude sui generis community intellectual property rights on traditional knowledge. Any right can be created by countries for this purpose as long as it does not, as Art. 8(2) prescribes, "...result in any complications that may result in a lesser compliance with the terms of the Agreement, as such."

Whether or not a community intellectual property right ends up complicating and obstructing other forms of intellectual property rights that the TRIPS Agreement protects depends mainly on the definition of "invention" in the traditional context,

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that even within Europe, the true meaning and content of the terms "ordre public" and "morality" is unresolved.

309 See the discussion in Correa, C. *Patent Rights*; in Correa and Yusuf (eds.), *Intellectual Property Rights And International Trade: The Trips Agreement*, 1998, p. 189-221, at p. 192. Also see Dutfield, G., op. cit. footnote 27, p. 24.

310 Article 27(3)(a).

311 Tansey, G. op. cit. (footnote 301), p. 14-15; also see Drahos, P. F. *The TRIPs Review*, Draft, 1999, who note the same.

312 See Chapter 4.4 on national initiatives to gear IPRs towards their public interest relating to traditional knowledge and disclosure of source of origin.

313 See Article 8 of the Agreement.

especially since many proposals relating to traditional knowledge protection are very broad-based. The legal situation is complicated and not free of ambiguity. Tansey et al. (2000) argues that according to Article 30 of the Vienna Convention on the Law of Treaties, the TRIPS Agreement is would prevail over the CBD since it is the latter Agreement and the more detailed one for intellectual property protection. The counter argument to Tansey *et al* is that the CBD prevails on the basis of being *lex specialis*, since it is more specific than TRIPS on addressing IPRs in the context of biodiversity conservation. In addition, the provisions of CBD Article 22(1) may also merit consideration in the event of actual conflict between the CBD and TRIPS. If a country determines that implementing the TRIPS Agreement will result in serious damage or threat to biological diversity, this provision would appear to grant the CBD with priority. Such a situation, however, would be very exceptional. A more nuanced and potentially more likely argument could be that the TRIPS Agreement may in some cases prevent a country from taking action to protect indigenous and local knowledge in an appropriate and effective manner. However, it is unclear whether CBD Article 22(1)I applies in this situation.

5.2.2 A Sectoral Assessment of Scope for Usage of Traditional Knowledge, PIC and Benefit-Sharing

If IPRs promote the neglect of provisions of PIC and benefit sharing in commercial transactions relating to traditional knowledge and genetic resource use, this can have a direct impact on the incentives as well as the capability of communities to continue preserving biodiversity.

But both the use of traditional knowledge and the possibility of national laws to enforce requirements of PIC and benefit sharing is very sector-specific. Traditional knowledge, when used, often constitutes only a part of the knowledge that goes into the invention process in both the pharmaceutical and agricultural sectors.[314] In this section, a sector-wise assessment is made of the scope of usage of traditional knowledge in the various sectors and of the viability of PIC as a tool to ensure benefit sharing and conservation. Whether PIC can indeed be introduced in those sectors where it is promises to promote both is discussed in Section 6.1.2.

5.2.2.1 Pharmaceutical Sector

On the one hand, there is no dearth of studies that elaborate upon the immense contribution of ethnobotanical knowledge to modern medicines.[315] It has been estimated that by consulting indigenous peoples, bio-prospectors can increase

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[314] Dr. Konrad Becker's Presentation at the Ecologic/ICTSD Expert Workshop on Trade, Intellectual Property and Sustainable Development, 14-15 October 2002.

[315] For example, see Farnsworth, N. R. *Screening Plants For New Medicines;* in Wilson, E. O. (ed.), *Biodiversity*, National Academy Press, Washington, 1988; among others.

their success ratio by 400 percent.[316] On the other hand, there seems to be a declining interest of the industry in entering into natural products research, especially those that concern traditional knowledge. [317]

Although TenKate and Laird (2000) note that traditional knowledge has more potential to be used only in targeted drug development programs,[318] studies that assess the profitability of researching and developing new chemical entities point out that drug companies might want to focus upon particularly promising targeted research programs to keep risks to a minimum.[319] According to estimates, as of 1991 over half the drugs in development processes in the United States of America were reported to have targeted cancer or cancer-related conditions,[320] and most others target AIDS and AIDS related conditions, diabetes, wound healing, hypertension and nervous disorders.[321]

But this is, as Dutfield (forthcoming) notes, a confusing situation.[322] Rational drug design and combinatory chemistry are seen as technologies that are more compatible, but given that the molecules that natural resources provide are most unique, natural products research may still continue to be important.[323]

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316 According to Ried, W. V., et al. op. cit. footnote 52, p. 150, given the need to screen roughly 10,000 chemicals to find a single lead, a one in a four chance of a lead being developed into a commercial product, a 5% discount rate, a ten-year wait before a product is ready to be marketed, and fifteen years of patent protection while it is being marketed, and on the assumption that a drug, if discovered, generates $10 million net annual revenues, the present value of the agreement to the supplier is only $52,200. Therefore, there is a 97.5% chance that the 10,000 chemicals will not turn up any commercial product at all. Contrasting this with natural products, they conclude that "the prospects for success are raised, since any extract from a species will contain hundreds or thousands of different chemicals that may result in a pharmaceutical "lead". Thus, the probability of success could easily be ten times that of the example above, thus producing promising leads of about 1 per 1000 samples. The probability of developing at least one commercial product in the example would then rise from 2.5% to 22%."

317 Dr. Konrad Becker's Comment at the Expert Workshop on Trade, Intellectual Property and Sustainable Development, 14-15 October 2002.

318 TenKate, K. and Laird, S. op. cit. footnote 79, p. 61.

319 Balance, K. et al. op. cit. footnote 98, p. 97-98. See Gehl Sampath, Forthcoming, op. cit. footnote 91 for a discussion on this.

320 OTA Report, US Congress, Office of Technological Assessment, *Biotechnology in a Global Economy*, OTA-BA-494, Washington, DC: US Government Printing Office, October 1991, p. 76.

321 1990 Annual Survey of the Biotechnological Medicines in Development, Pharmaceutical Manufacturers Association of the USA, cited in TenKate, K. and Laird, S., op. cit. footnote 79.

322 Dutfield, G. op. cit. footnote 117, p. 77.

323 Personal Interview with Dr. Rosenthal, Director, ICBG Program of the NIH of the USA, 2 October 2002.

Given that most of these transactions are transnational in nature, PIC mechanisms that work in tandem with sui generis laws could help enhance trust of national agencies/community representatives with almost no knowledge of biotechnological know-how in bioprospecting contracts.[324] In such a setting, prior informed consent both at the local and national levels, if well designed and implemented, can be a very effective monitoring tool to trace usage and to trigger off fair and equitable benefit-sharing, in case these products are eventually developed and marketed.[325]

5.2.2.2 Agricultural Sector

There is no doubt that traditional land races, cultivated and conserved by farming communities, are a very useful input for the development of new varieties. Despite this, benefit-sharing in the agricultural sector can be problematic because tracing the source material in plant varieties is a very difficult task. As our discussion in Section 3.2 reveals, plant varieties are the product of many generations of variations, and the parent varieties used to derive a new cultivar may be numerous. Thus, unlike pharmaceutical products, a clear-cut link between the product and the inputs is hard to establish.

The only viable option is the declaration of the source of origin by the firm in question, and this too is enforceable when the firm is able to specify one single/ several specific sources of the genetic material used for the production of the plant variety.[326] Failing this, benefit-sharing is at best going to be hap-hazard and difficult to forecast.

But it is not clear how far only benefit-sharing without clear-cut ownership rights is an optimal solution in this case. Dutfield *et al* (1996) note in this case that some essential elements of an expanded farmers' rights concept should include full participation in benefits from the improved use of these genetic resources, control of access to their lands, water and genetic resources, and determination of their own production and consumption patterns.[327]

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[324] Mooney, P. *Why We Call It Biopiracy*. In Svarstad and Dhillon (eds), *Bioprospecting: From Biodiversity in the South to Medicines in the North*, 2000, p. 37-44, at p. 40.

[325] Refer to Chapters 6 and 7 on the issues and difficulties in introducing prior informed consent at both levels and for recommendations on this issue.

[326] Tarasofsky, R. G., Glowka, L., Gehl Sampath, P., Choudhury, K. and Marr, S. *Legal Analysis of the First Meeting of the Working Group on Access to Genetic Resources*, BfN Report (Unpublished), 2002, p. 57.

[327] Posey, D. A., Dutfield, G., Plenderleith, K., Willard, T. et. al. op. cit. footnote 296, p. 20.

5.2.2.3 Botanical Sector

The botanical sector makes the most lucid case for benefit-sharing in many cases, traditional usage is also used to get mileage for marketing purposes.[328]

But in this industry too, tracing material and information is a very difficult task, albeit due to other reasons. In contrast to the kind of information required to do pharmaceutical research based on genetic resources, relatively less information may be required to develop a botanical product – many times, just the plant and its most direct use might be sufficient. [329] This kind of information can be obtained through various means, through journals and publications or even defecting members of communities, most of which are unverifiable or uncontrollable.

But since the product is based on the raw material, here too PIC can be very helpful means to complement *sui generis* laws on traditional knowledge to ensure benefit-sharing. As an access restriction tool, it can also help communities keep a check on third parties resorting to indiscriminate collections on their lands. But then again, this will be limited only to cases where the firms cannot produce plants in question using tissue culture.[330]

5.2.2.4 Horticultural Sector

TenKate and Laird (2000) note that there is probably no scope to use traditional knowledge in the horticultural sector, unless people are interested in the story behind the plant.[331] That is, traditional communities may have specific myths or other historic events attached to certain species that may contribute to enhancing sales. Furthermore, similar to the situation in agricultural varieties, the scope for benefit-sharing also remains unclear since many of these varieties too go through a complicated and long breeding process. Most importantly, as TenKate and Laird note further, the issue of benefit-sharing in the horticultural sector is quite new.[332]

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328 Refer to the discussion in 3.2.2.

329 Elisabethsky, E. *Folklore, Tradition or Know-How?*: *Cultural Survival Quarterly*, Summer 1991, p. 9-13.

330 On the market for raw materials and its positive and negative implications, see Ried, W. V. (1996), "Gene Co-ops and the Biotrade: Translating Genetic Resource Rights into Sustainable Development". Journal of Ethnopharmacology, Vol. 51, p. 75-92.

331 TenKate, K. and Laird, S. op. cit. footnote 79.

332 Ibid.

6 Intellectual Property Rights and Conservation of Genetic Resources: Preliminary Evidence and Options

Undoubtedly, IPRs are still the best economic incentive society has to encourage the production of useful information. But can IPRs create adequate economic and social incentives for conservation of genetic resources?

The study has started out with general claims made about the negative impact of intellectual property rights on conservation and sustainable use of genetic resources. To assess whether intellectual property rights on biotechnological inventions indeed create negative incentives for conservation and sustainable use, the analysis in Section 3.2 has focussed upon an assessment of the R & D processes in four biotechnology-based sectors that use genetic resources in their R & D processes. Chapter 4, on the other hand, has taken aboard the positive claims and counterclaims and evaluated them, along with the kinds of national attempts that could be put in place to realise them.

Chapter 5 has then focussed upon the conditions under which indigenous and local communities can continue preserving and enriching in-situ genetic resources through their traditional ecological knowledge.

Corrective intervention that can rectify the negative inter-linkages is the first step towards harnessing the positive effects of biotechnology and *sui generis* regimes on conservation and sustainable use of genetic resources. This Section will discuss the various options available to regulators and the optimal combination of property rights, regulation and other incentives to achieve this result. Since the nature of research in the pharmaceutical and botanical sectors and their impact on genetic resources are similar they are dealt with together in this Section, whereas the agricultural and horticultural sectors are dealt with together for similar reasons.

6.1 Conservation Aims and Intellectual Property Rights: Findings and Recommendations

Chapter 3 has elaborated upon the claims made in the context of negative, indirect impact of IPRs on conservation and sustainable use of genetic resources. Our assessment of the R & D processes in Section 3.2 reveals that many of these claims can be supported by evidence from the processes of R&D in the pharmaceutical, agricultural, horticultural and botanical sectors.

Based on this, our first main finding is that there can be several negative effects of biotechnology on conservation and sustainable use. One could argue that to the extent IPRs stimulate such research, they are responsible for it. But a closer look at the process and the causative factors reveals that the link between IPRs and the harmful impact on sustainable use and conservation of genetic resources is more indirect. The positive effects of IPRs on genetic resources - whether it is the impact of biotechnology in understanding disease causation and cures better or the potential of agricultural biotechnology in creating plant varieties that cater to the

needs of developing countries – do not also flow automatically. They will need to be leveraged by other policy measures.

The first two sub-sections will deal with the findings and options for regulators to combine intellectual property rights on genetic resources with other incentives to mitigate their negative effects and to encourage conservation of genetic resources. Section 6.1.3 will then deal with the problems and options available to policy makers to better harness the positive effects of intellectual property rights on biotechnological inventions in favour of developing nations.

6.1.1 Environmental Justifications for Restrictions of IPRs for Biotechnology: The Findings

In the main, our findings show that in the case of the agricultural and horticultural industry, the issue is one of biosafety. Therefore, regulating biotechnological activities in the agricultural and horticultural sectors becomes necessary at the industry level, in terms of establishing better standards for approval of crops, monitoring biological invasions, recording ecosystem impacts of approved GM crops, and so on.[333] In contrast, the impact caused by pharmaceutical and botanical research on scarcity and eventual extinction of plants with medicinal properties seems more to be a matter of effective regulation of national biodiversity conservation.

A general consideration relating to IPRs for all sectors is whether countries have sufficient mechanisms in place to assess whether certain patent applications should be rejected in order to protect *ordre public* or morality. As indicated in TRIPS Article 27(2), one aspect of this relates to significant damage to the environment. Implementing this exclusion implies that countries have developed procedures to assess whether the exclusion is merited. In practice, it appears that many countries do not have these procedures in place in general; *a fortiori*, such procedures should also be able to assess the implications for genetic resources, as a vital component of the environment.

6.1.2 Pharmaceutical and Botanical Sectors

Section 3.2.1 and 3.2.2 has revealed the scope for indiscriminate harvesting/ collections and the presence of intermediaries in the pharmaceutical and botanical sectors. In the pharmaceutical sector, this can happen at two important stages – pre-clinical and clinical trails and the production of the drug. In the botanical sector, cultivation of wild crafting of the plant is essential for the production of the drug since it is directly made out of the raw plant material. Several cases of drugs that have led to unsustainable use of the plant species in question have received wide spread attention. But at the same time, it is very hard to say what percentage of the total number of research and development projects/ drugs discovered require genetic resources for either higher research or production purposes because they cannot be in-vitro synthesised.

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[333] The levels at which such regulation should be directed at are discussed in Chapter 7.

Until more empirical information on this issue is generated, the main issue to be resolved here is if such R & D practices result in unsustainable use, is that a function of the law of intellectual property? Our answer to that is negative.

In other words, in the pharmaceutical and botanical sectors, it is the legal vacuum in biological resources that allows parties to trade with resources that they neither hold nor are accountable for. Therefore, the issue is not of IPRs encouraging such unsustainable use, but rather, how national biodiversity laws should eliminate incentives amongst users to treat such biological resources as a public good in source nations.[334]

6.1.3 Plant Variety Protection and Horticulture

The impact of GM plant varieties on conservation of genetic resources can be far graver than general literature on the topic seeks to highlight because of two main reasons. Firstly, the harmful effects depend upon the kind of transgenes we are talking of and this is not generally taken into account in policy discourses that address this issue. For example, as Section 3.3.2 has revealed, the impact of Bt genes on biodiversity is different from the impact of herbicide-tolerant plant varieties. More importantly, agricultural plant varieties have the capacity to deeply influence the functional components of non-agricultural ecosystems. This can have severe consequences for genetic resource conservation and therefore deserves more attention.

To keep the debate in perspective, one should note that problems such as the creation of invasive weeds were also a by-product of conventionally bred crops and normal chemical pesticides could also cause insecticide resistance.[335] The point of departure in the case of transgenic crops is that they have a higher potential for creation of such invasive varieties and their ecological effects are also higher because they posses one/ more novel genes that contain insecticidal properties that can affect non-target plant communities and organisms. As noted in Section 3.3.2, Bt crops can cause insecticide resistance but with very high magnitudes and they can also pose a threat to non-target organisms by affecting soil geochemical cycles.

The problem in the case of horticultural varieties is very similar to that of plant varieties. The introduction of exotic species into new and fragile recipient ecosystems amounts to biological novelty at its strongest and can have dire consequences on the original organisms of those ecosystems. These effects depend as much upon the ecosystem in question as they do upon the introduced species. As a result, the same species may evoke different reactions in different ecosystems. This calls for stricter regulation until frameworks for assessment of causative factors can be clearly established.

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[334] See Gehl Sampath, Forthcoming, op. cit. footnote 91, for a detailed treatment of the issues in this regard.

[335] RSC Report, op. cit. footnote 123, p. 124.

6.2 Options for Regulators Aimed At Industry For Encouraging Conservation of Genetic Resources

Whereas in the case of the pharmaceutical and botanical sectors, options need to be evolved to strengthen national biodiversity regimes, in the case of agricultural and horticultural sectors, specific areas where more information is necessary to cope with the potential negative impacts need to be identified. These are dealt with below.

6.2.1 Pharmaceutical and Botanical Medicines Sector

One of the main proposals by some developing countries is to include the proof of source of origin and prior informed consent at the patent grant stage. Although the views on this topic are diverse and divergent, the legal status of an international system of certification and its viability remains unclear, particularly relating to enforcing such a system internationally. The main objection is that such a requirement may add a fourth condition for the grant of patents to the already exclusive list of conditions in the TRIPS Agreement.[336] As such, it is disputable that a new condition, beyond those specified in the treaty, may not be enforceable vis-à-vis the patent itself.

Given the uncertainties in setting up an international system that can enforce PIC requirements, two other options – albeit not related to IPRs -- should be considered by countries and international forums.

One viable option which is available to countries but has received little attention until now is the possibility of considering PIC as a requirement in the product approval process. There are specific product approval regulations that have to be complied by firms in all sectors that use genetic resources. For example, in the pharmaceutical sector, the stage at which a new material which is found to have a biological activity indicative of a positive clinical potential is usually when an appropriate specification defining the invention will be prepared and the patent filing effected. But until the product is certified and approved of by the relevant regulating agencies, its production or distribution will be prohibited, despite a successful patent claim.[337]. Although until now, in the pharmaceutical and botanical sectors, these agencies have been mainly concerned with the regulation of products from a human health safety perspective, it remains to be explored why environmental sustainability cannot be made one such criteria. At a first glance, it seems quite a viable alternative, since in the product approval process agricultural varieties are tested by agencies against both factors – environmental safety and human health.

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336 Refer to the negotiations of the Bonn Guidelines on Access and Benefit Sharing. Also see, Tarasofsky, R. G., Glowka, L, Gehl Sampath, P. et al. op. cit. footnote 326, p. 52-57.

337 In the case of the pharmaceutical industry, the various federal agencies are listed out by TenKate, K. and Laird, S. op. cit. footnote 79, p. 54. Similarly, in the case of plant varieties, the release of GM varieties into environment is closely monitored by several other approval agencies in the developed nations. Also refer to Miller and Congko, op. cit. footnote 77, for an overview of the various regulatory agencies in this sector.

Secondly, to make PIC work at the national levels, along with the requirement that all such activities should be conducted only with the prior approval of the national access authorities; more emphasis should be laid upon contractual mechanisms that can solve this issue effectively. Special focus should be placed upon evolving contractual approaches between national governments and firms/ collection agencies that build more trust between source countries and firms paving the way for better production mechanisms. Contractual clauses have the advantage that they can be tailor-made to address the concerns of the contracting parties in each kind of access and benefit-sharing agreement. That is, specific distinctions can be introduced depending on whether the contract is for access only or for traditional knowledge only or for both. As a result, contractual clauses, when supplemented by suitable national contractual frameworks, give more flexibility to parties to incorporate their mutual concerns.[338]

The EC strategy has been to make PIC a voluntary option has been described above, as has the Danish variant of enforcing such an obligation through non-IPR law. However, even if such a condition is applied, two practical obstacles exist. One is that the provider country bureaucracy may be incapable of implementing such PIC procedures in an efficient manner. A potential alternative might be to have a PIC certificate being issued by the local and traditional community, rather than by the State – although this too is not without practical difficulties. A second practical difficulty is whether patent offices receiving such certificates will have the capacity to meaningfully verify their accuracy and authenticity.

The potential of these proposals as effective solutions should be made an issue of peer review and debated more in international forums.

6.2.2 Plant Variety Protection and Horticulture

In agricultural biotechnology, it is the increased threat of plant varieties and GM crops on agricultural and non-agricultural biodiversity that makes the case for a closer assessment of plant variety protection.[339] Specifically, the recommendations made by the RSC Report to the Government of Canada seem universally applicable. In plant variety protection, more information should be generated on:[340]

- Ecological effects of transgenic biotechnology on agricultural and non-agricultural biodiversity.

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338 Tarasofsky, R. G., Glowka, L, Gehl Sampath, P. et al. op. cit. footnote 326, p. 53.

339 Note here that patent protection on plant varieties is allowed only in the United States, Japan and Australia. In all other jurisdictions, it is mainly plant variety protection that is afforded for such inventions.

340 RSC Report, op. cit. footnote 123, which makes these recommendations to the Canadian government, p. 151.

- Whenever environmental risks are product specific – such as Bt products and their impact on soil geochemical cycles – these effects should be thoroughly explored before allowing such varieties to be planted.

- In evaluating risks, much more emphasis should be placed on scientific evidence. Focus should be on evolving scientific criteria for evaluation purposes. A good way to do this would be through the association of research agendas with policy-making initiatives.

The regulatory environment on protection of plant varieties ought to be designed in a way that takes such risks into account. If information on some of these aspects is not conclusive, protection of plant varieties, whether through patents or other mechanisms, should be restricted until more information on such aspects is generated.

In the specific context of plant variety protection and monocultures, if farmers choose specific plant varieties due to their distinct economic advantages over native ones, other ways of conserving agricultural biodiversity have to be considered. But one major concern in this regard is to ensure that the international seed market does not operate in a way that limits the choice of the farmers.

To deal with the threat of invasive species in agriculture and horticulture, regulations should be aimed at the post-IPR application stage, to check the production and sale of plants and seeds similar to the way the EU deals with horticultural species. [341]

But in the case of ornamental plants in horticulture, although there are phytosanitary regulations,[342] more research should be carried out on the effects of invasive species on recipient ecosystems. Specifically, since these effects may vary from species to species and ecosystem to ecosystem, introduction of regular monitoring systems should be considered. One interesting regulatory proposal has been the establishment of National Biological Invasion Centre that can regularly monitor the state of invasive species in the nation and alert in cases where immediate intervention is required.[343] According to this proposal, such centres work in close contact with research institutes and university counterparts such that all new scientific evidence can be effectively taken into account to plan timely actions.[344]

Countries should also consider introducing environmental impact assessment and monitoring requirements in their biodiversity regimes in cases where novel species

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341 As TenKate and Laird (2000) note, the EU has a set category of "standard seed" for horticultural vegetables. See Tenkate, K. and Laird, S. op. cit. footnote 79, p. 166.

342 TenKate, K. and Laird, S. op. cit. footnote 79, p. 167.

343 This has been proposed for the United States, by Schmitz, D. C. and Simberloff, D. *Needed: A National Center for Biological Invasions", Issues in Science and Technology*, Summer 2001.

344 Ibid.

are introduced. Scientific community should be encouraged to generate more information and these should be taken into account by legal policy making to prevent inadequate regulation of IPRs in this area.

Developing countries should focus on devising sui generis systems for PVP based on national requirements. The most important issue here is whether the sui generis system for plant variety protection should be a UPOV or non-UPOV one. Any proposed alternatives to UPOV should take into account the definition of breeder in a way consistent with national requirements.[345]

6.3 Harnessing the Positive Effects of Intellectual Property Rights for Developing Countries

Intellectual property rights are an economic incentive addressed to the private sector only. Private research initiatives, in turn, are motivated primarily by commercial gains. Firms will only invest in activities that are profit maximising for them and developing drugs or seed varieties for a set of consumers who cannot pay the desired market price is not a profit-maximising decision. The disparity of investment in the pharmaceutical sector between diseases of relevance to the western world and those of importance to the developing countries demonstrates precisely this.

In contrast, there seems to be a higher investment in the agricultural biotechnology sector for varieties of importance to the developing countries. The reason for this, as the CIPR Report (2002) notes, is that the investment costs are lower in the agricultural biotechnological sector and the potential market in developing countries for the products is relatively higher. These two factors seem to be responsible for the production of several varieties, such as the Bt varieties, that are viewed by the farmers in developing countries as advantageous.[346] But the point to be noted here is that the varieties developed by western firms until now are more so motivated by reasons of commercial gains and the benefits accruing from such varieties to farmers in developing countries is merely incidental. This is not to say that the benefit to farmers may not accrue in the future, but rather to caution that such a result is certainly not automatic.

The potential of intellectual property rights to stimulate research that serves the needs of developing countries depends largely on two main factors: the spillover effects of patents on biotechnological R & D on commercial sectors in the developing countries leading to learning processes; and secondly, more direct R & D investment in areas of relevance for developing countries.

Although frequently advanced in defence of allowing patents on biotechnology, the argument of spillover effects seems rather doubtful in the pharmaceutical industry. There is no clear empirical evidence on spillover effects, whereas there is

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345 See the recommendations in Chapter 7 on the factors that should be decisive in devising such systems.

346 The CIPR Report, op. cit. footnote 162, p. 64, lists that up to 5 developing countries are presently planting Bt Maize varieties and India has just now approved Bt cotton.

a lot of negative evidence on the impact of biotechnological patents. Since any given innovation may involve more than one patent, access to patents held by other firms may become necessary for incremental innovation. Empirical evidence in this regard suggests opportunistic firm behaviour in making their patents available to others for innovation purposes.[347]

Given the bias in research expenditures towards a predominantly western audience and the absence of any evidence on plausible spillover effects, developing countries should push for the assessment of spillovers in international fora. The developing countries should explore the scope of technology transfers and compulsory licensing mechanisms in the fields of agricultural biotechnology and pharmaceutical biotechnology. Specifically, Art. 31 of the TRIPs Agreement and its provisions should be revisited within the Doha agenda and the implications of technology transfers and compulsory licensing to further the learning process of basic research in developing countries should be reassessed.[348]

In this context, some sort of international agreement on funding of public research and/or making basic research findings available to developing countries should also be explored.

6.4 Conservation Aims and the Protection of Traditional Ecological Knowledge: Findings and Recommendations

If we would demarcate the various components of traditional knowledge further, a distinction can be made between knowledge, innovations and observations that relate to the use of the environment and traditional knowledge, innovations and observations that govern the resource use and conservation. Clearly this demarcation cannot be established in a strict sense when we talk of the communities relationship with their resources because the two are overlapping knowledge structures. But looking at it from a user perspective in the practical context of contracts for traditional knowledge, the demand is mainly for the specific use of the plants/ animals, etc. in a forest and not for the resource management techniques developed for the management of the forest as such.

If the granting of sui generis intellectual property rights can result in distorting the relationship between communities and their attempts to conserve genetic resources, this deserves as much attention as the harmful impact of conventional intellectual property rights on genetic resources does. How this can be rectified and what sort of governmental intervention is required to achieve this has to be the paramount concern of every national attempt to protect traditional knowledge.

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347 Dumont and Holmes, *The Scope of Intellectual Property Rights and Their Interface with Competition Law and Policy: Divergent paths to the Same Goal*, Econ. Innov. New Techn., 2002, Vol. 11(2), p. 149-162 who note the evidence from firms creating patent portfolios in the pharmaceutical industry solely for the purpose of opportunistic behaviour.

348 See Chapter 7 for more concrete suggestions.

6.4.1 Environmental Justifications for the Establishment of Community Intellectual Property Rights Through Sui Generis Systems: The Findings

Traditional ecological knowledge is a component of traditional knowledge that has been devised and enriched by indigenous and local communities due to their direct dependence on their environments. Whereas other aspects of traditional knowledge relate to the use of their genetic resources in a particular product/ process of relevance to the communities, traditional ecological knowledge has been the system of common property resource management that has ensured the sustainable use and continued existence of these resources. Designing a suitable property rights system for traditional ecological knowledge to promote conservation would be synonymous with designing a system which takes into account the full social and economic costs of their the communities' behaviour yet allows them to reap the benefits for the same.

Therefore, although a collective property right is the most important aspect of empowering communities, an intellectual property right alone cannot ensure in-situ conservation. This is because it will amount to replacing a complex management system (a hybrid incentive instrument) with a single property right (a positive incentive). Thus, it will not manage to equate both direct and indirect use values of genetic resources in situ in community resource use calculations. For an intellectual property right to be effective in promoting traditional ecological knowledge and in-situ conservation, it has to be accompanied by other incentives that promote common property resource management systems which have possessed historically and supportive regulation. Continuance of community management structures despite economic and governmental interventions is the main factor that will ensure the sustainable use and conservation of their genetic diversity.

To ensure the control of local and indigenous communities in real transactions, countries should focus on the inclusion of prior informed consent of communities within processes in which community intellectual property rights are devised and enforced. Due to the difficulties in devising an effective PIC system, countries should rely as much as possible upon enhancing existing community management structures for this purpose.

Furthermore, an intellectual property right has certain practical limitations – such as the heterogeneous element introduced by sudden commercial value and the inability of communities to cope with sudden shocks introduced by economic transactions, mainstream intrusions and other such exogenous pressures. Due to this aspect, in addition to the two components suggested above, national governments should provide supportive regulatory intervention to cushion these shocks. Most effective in this regard are participatory regulatory approaches to use and conservation that also rely largely on community management structures.

6.4.2 Options for National *Sui generis* Regimes on Traditional Knowledge

National policy attempts to protect traditional knowledge have to create a framework wherein all three elements – a community intellectual property right, a participatory mechanism for prior informed consent of communities and a reinforcement of community management structures – flourish in parallel to one

another. The main aspects that such a property right system has to take into account are listed below.

6.4.2.1 Creation of Participatory Approaches to Benefit-Sharing and Biodiversity Conservation: The Requirements

Experience in most developing yet tropical countries have endorsed this point that requirements for prior informed consent as well as rules of benefit sharing should be based on existing community structures since they might indeed be the best way to organise biodiversity management and benefit-sharing initiatives. For example, R. V. Anuradha notes that in the case of the Kanis the fact that they have no traditional governance structures has made the evolution of benefit-sharing structures very difficult.[349]

As noted earlier on, these existing structures may suffer from two problems – firstly, they may be based on some inequalities, often creed-based or gender-based. Secondly, the communities may sometimes have tendencies to over-use themselves[350] and may exhibit ignorance of some elements of biodiversity.[351] Therefore, while community autonomy is very critical, government institutions have to check that the communities do not over-exploit the resources and that their knowledge of how to conserve is supplemented by modern scientific biodiversity-related information and techniques.

These synergetic effects between traditional management structures and legal institutions created for traditional knowledge can then help cushion the shocks caused by external intervention and market forces.

Participatory approaches devised on the basis of traditional systems of organisation can also ensure more effective participation of communities in decision-making. This will help them keep a check on their national representatives. This kind of transparency and accountability is very important since in most developing nations, local and indigenous communities continue to remain the most marginalised segment of the general population.

National governments also have a very important role in monitoring - to keep tabs on R & D progress and to check if benefit sharing is taking place in the best interests of their communities. This goal can be hindered in contractual settings where national governments are part of the bioprospecting contracts – like

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349 Personal Interview with R. V. Anuradha who has worked most extensively on the issue of traditional knowledge and benefit-sharing among the Kanis of Kerala, India.

350 Kothari, A. and P. Das, op. cit. footnote 289. Note that in North-east India, for instance, there is an overhunt of several species of hornbills as many tribal communities value the 'horned' beak of these species for their alleged medicinal properties as well as for use as part of their traditional headgear.

351 It has been noted that while a large range of biodiversity is used, there are also gaps in local knowledge; these relate especially to species which are not in use or not in some way impinging on the lives of the villagers, such as small fauna or micro-organisms. See again, Ibid.

CONABIO in the ICBG Program for Drug Discovery Amongst the Mayans of Mexico.[352] This is because this puts the national authority in a serious conflict of interest. Such authorities can represent the communities neutral and best when they stay out of the fray of such contracts altogether and monitor full time.

6.4.2.2 Distinguishing Between Farming Communities and Indigenous People in Sui Generis Systems

Given that the needs as well as structures of local and indigenous communities and farming communities are different, devising participatory mechanisms for prior informed consent and reinforcement of community management structures cannot be efficiently designed if these communities are not dealt with separately.[353] The demands of indigenous communities and farming communities as regards property rights over traditional knowledge and benefit sharing are different.[354] The issues raised by conventional intellectual property rights on medicinal products and agricultural varieties are also very different. Whereas the former raises issues of definition of "prior art", co-invention status in cases of collaboration and issues of autonomy, the latter raises issues of seed monopolies, right to sow saved seeds, implications of UPOV 1991 as the new *sui generis* system, and so on.[355] All these factors support the separation of farming communities from indigenous communities in devising protection mechanisms at the national levels.

Since most traditional knowledge is oral in nature, developing countries should push for oral prior art to be considered by the Patent Offices in the industrialised countries while determining the novelty requirement in the patent approval process.[356] Presently, whereas the European Union is open to considering oral

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[352] Personal Interview, I. Chapela, Main Negotiator of the NOVARTIS-UZACHI Contract, 13 May 2002. Also see, Berlin and Berlin, 1999.

[353] Posey, D. A., Dutfield. G., Plenderleith, K. et al. op. cit footnote 296.

[354] Ibid.

[355] See for example, Godden, D. *Growing Plants, Evolving Rights: Plant Variety Protection in Australia*, Australian Agribusiness Review, Vol. 6, 1998, p. 7.

[356] This would also be in keeping with WIPO's definition on "prior art". According to the WIPO (2001), "the term "prior art" generally refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for certain industrial property titles, principally patents, utility models and industrial designs." See, WIPO, "Progress Report on the Status of Traditional Knowledge as Prior Art", Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Second Session, Geneva, 10-14 December 2001. But in some jurisdictions, like the United States of America, only the body of knowledge that is made available to the Patent Office is considered to be part of "prior art".

"prior art",[357] the United States of America only considers information made available to them as "prior art".

In the case of farming communities, as suggested earlier, developing countries should devise the sui generis system for PVP based on national requirements. The most important issue here is whether the sui generis system for plant variety protection should be a UPOV or non-UPOV one. Any proposed alternatives to UPOV should take into account the definition of breeder in a different way. The key considerations for countries should include: the types of domestic seed industry, the public breeding sector and seed-supply systems, the extent to which farm-saved seed is used by its farmers, the current capacity of breeders, the objectives of local breeders, the quality of external inputs to agriculture (whether these are low or high), domestic production needs and objectives, domestic biotechnology capacity and objectives, the type of agricultural economy (i.e. industrialised or small-scale mainly subsistence farming) and the administrative costs of such a system.[358]

If countries consider UPOV 1991 as the sui generis system for plant variety protection, changing the definition of a plant breeder should be considered, because as the CIPR report indicates, the model of UPOV 1991is best suited for developed countries only.[359] In developing countries, heed should be paid while: (a) defining uniformity and stability and (b) setting the threshold of innovation. Developing countries may raise the threshold particularly so that protection is given only to varieties that are really innovative in a socially useful sense and do not base themselves simply on product differentiation, as the varieties protected under UPOV generally do. One option might be to consider replacing "uniformity" with "identifiability", which might encourage heterogeneity by not containing a test relating to physical characteristics.[360]

In addition, developing countries may need to weigh the advantages and disadvantages of strong property rights over PVPs (as in the UPOV 1991) system, versus a weaker protection. IPGRI suggests that those with industrialised agriculture bases may prefer the former, while those with traditional agricultural bases might prefer the latter. The implications for genetic resources would need to be assessed empirically, but *prima facie*, ensuring the continuation of traditional agriculture might have positive impacts on genetic diversity.

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[357] According to Art. 45(2) of the European Patent Convention, the state-of-the-art is deemed to consist of everything made available to the public by means of written or oral description or use or in any other way.

[358] IPGRI (1999). Key Questions for Decision-Makers. Protection of Plant Varieties under the WTO Agreement on Trade Related Aspects of Intellectually Property Rights.

[359] CIPR Report, op. cit. footnote 162, p. 61.

[360] Op. cit. footnote 358, p. 15.

7 Conclusions: Implications for Policy Makers

The foregoing suggests that fundamental consideration and, in some cases, reconsideration of the relationship between IPRs and the conservation of genetic resources ought to be undertaken. This is in line with calls from many quarters, most recently the Commission on Intellectual Property Rights, for a fundamental re-think of the role of IPRs in the context of sustainable development. This chapter draws conclusions from the previous chapters and sets forth a set of specific recommendations aimed at various levels and actors.

7.1 Action at the Global Level

7.1.1 Ensuring that the WTO TRIPS Agreement does supports and does not undermine the conservation of genetic resources

Debate within the WTO, and in the literature, largely focuses on the impact of IPRs on equity, such as benefit sharing and preventing biopiracy. The conservation of genetic resources has been considered to some extent in this context, but a more directed assessment of the impacts of TRIPS requirements and exceptions on conservation is needed. In general, the TRIPS Council has a role to play in this, but so too do other institutions. Given the complexity and diversity of the issues involved, the TRIPS Council must adopt a participatory and detailed assessment of the issues. At the very minimum, this would entail the participation of the secretariat of the CBD in the relevant deliberations. The CBD secretariat has a standing request to the TRIPS Council to be accredited with observer status, but so far, the request has not been granted.

The situation is currently very dynamic, with the Doha Development Agenda providing an important opportunity to address the many proposals that have been made. The dynamics are such that developing countries, as the *demandeurs* for ensuring, and possibly widening, flexibility of the TRIPS Agreement, will need to ensure they act strategically as a group. The first step in doing so is to reach consensus on the IPR elements of the "Implementation" agenda. Most of the proposals made have sought to address a variety of concerns, whereby conservation may be one, but generally not the paramount objective. Accordingly, the Committee on Trade and Environment, with its special role in the DDA, as well as the CBD, UNEP and the FAO should ensure that conservation aspects receive their due attention during the negotiations.

At its core, many of the challenges of ensuring that IPRs support, and do not hinder, the conservation of genetic resources entail mutual supportiveness between WTO rules and those in the CBD. The overall relationship between the WTO and MEAs has been on the international agenda, and will continue to be so under the Doha Development Agenda. In principle, a global accommodation of these two regimes would also relate to the CBD and TRIPS. However, the Doha Declaration only refers to addressing the relationship in the context of "specific obligations" in MEAs – those relating to IPRs will likely relate to guidelines and other measures aimed at implementing the obligations in the CBD, rather than requirements explicitly set out in the treaty. In addition, the negotiations are not to alter the balance of rights and responsibilities already existing in the WTO. As such,

the negotiations on this specific aspect of the Doha Declaration may not resolve many of the issues discussed in this paper. Additional possible solutions to resolving uncertainties and conflicts in the MEA/WTO relationship other than the Doha Development Agenda might merit consideration in this connection,[361] but assessing them is beyond the scope of this paper.

Several specific issues are addressed below.

7.1.1.1 Use of compulsory licensing

Art. 31 of the TRIPS Agreement makes it possible for countries to get compulsory licenses subject to the conditions specified therein. Paragraph 5(6) of the Doha Declaration affirms that member countries have the right to grant compulsory licenses. However, it is unclear the extent to which compulsory licensing of technologies relevant to biodiversity conservation is necessary to ensure the conservation of genetic resources. In other words, further research is necessary to determine the extent to which affected States are deprived the opportunity to apply patented technology aimed at the conservation of genetic resources. Furthermore, the impact of licensing technologies that indirectly affect conservation of genetic resources needs to be assessed.

However, the application of Article 31 for the benefit of the genetic resource conservation remains to be assessed and clarified. Specifically, Article 31(2) should be assessed to further understanding as to how the scope of "...public non-commercial use" relates to technologies important for the conservation of genetic resources.

Attention should be paid to the possible interpretations and modifications that occur as a result of implementing the Doha Declaration on Access to Medicines. Although there has been no agreement yet on special and differentiated treatment for developing countries on essential medicines, the outcomes as they relate to Article 30 and 31 may be noteworthy. As such, there may be possible analogies to the conservation of genetic resources.

7.1.1.2 Review of Article 27.3(b)

The Doha mandate on Article 27.3(b) is broader than the original Review. This should, in principle, enable deliberation on fundamental issues. Ideally, the review of Art. 27(3)(b) should result in a consensus that the provisions of the CBD be taken into account while devising protection over life forms. That would have the advantage of giving the discussions on protection of life forms a more equitable perspective from the view of developing nations, as well as from a conservationist

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[361] WTO, TN/TE/S/1, Multilateral Environmental Agreements (MEAs) and WTO Rules: Proposals Made in the Committee on Trade and Environment (CTE) from 1995-2002., 23 May 2002.

perspective. In the absence of this, the TRIPS Council should ensure that the review of Art. 27(3)(b) does not result in reducing the limited flexibility that now exists in Art. 27. It remains unclear whether amendments or agreed interpretations are feasible during the DDA negotiations – however, Members should ensure that the rules and requirements of the CBD and other international instruments are not undermined by this provision.

Indeed, WTO Members should ensure that the Review, or other negotiations under the Doha Development Agenda, does not lead to a *requirement* that plant varieties be patented. Such a requirement would be in conflict with two provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture. Article 12.3(d) might be applied to limit patents for isolating plant genes from nature, if the material is obtained from the MLS. Furthermore, the equitable benefit-sharing requirement under Article 13.2(d)(ii) might conflict with the non-discrimination rules under TRIPS Article 27.1 in creating obligations relating to biotechnology patents that are not imposed on other types of patents.[362]

7.1.1.3 Geographic Indications

The reform of geographical indications should be considered by the TRIPS Council to include other subject matter, although it is still not clear if traditional and local communities can get benefit from use of their knowledge, since this form of protection relies mainly on a market for the good in question. The precise benefits of this to conservation will depend on the particular circumstances, and will most likely depend on the internal incentives and support for conservation within each community.

Nonetheless, there appear to be potential linkages between mechanisms to establish and administer geographic indications and the conservation of biological diversity. The preliminary experience so far suggests that these arrangements need to be devised locally in response to local conditions. Thus, the development of the global regime of geographic indications within the TRIPS Agreement might include conservation as one objective, but essentially should only leave space for this option rather than attempting to be prescriptive.

7.1.2 Further development and implementation of the Convention on Biological Diversity

7.1.2.1 Access to Genetic Resources and Benefit Sharing

The most intense discussion on IPRs and genetic resources is taking place under the implementation of Article 15, on access to genetic resources and benefit

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[362] Helfer, L. Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments, FAO Legal Paper Online #31, available on http://www.fao.org/Legal/prs-ol/paper-e.htm.

sharing. The COP should continue its effort to clarify the relationship between IPRs and the conservation of genetic resources. In this connection, the COP should leverage further case studies in all relevant economic sectors, so as to increase the knowledge base.

Among the key mechanisms the COP should continue to focus on are those aimed at giving effect to the prior informed consent requirements. Further examination of possible options should focus on their legality and practicality. As mentioned above, although an international system of certification to prove prior informed consent as part of the patent procedure has certain attractions, it may indeed add a fourth requirement to the patent approval process if it operates as an enforceable condition. Hence, its enactment may necessitate an amendment to the TRIPs Agreement, which will be difficult to achieve.

Thus, the COP could facilitate international consensus on the use and enforcement of contractual clauses, in the context of appropriate regulation, as a mechanism to ensure the prior informed consent of the traditional and local communities with custodianship over the genetic resources covered by such contracts. This strategy may prove, at least in the short term, an effective means of ensuring that PIC becomes an element in the bargaining process for genetic resources and traditional knowledge in contracts with firms. The CBD COP should examine this option and consider providing guidance, possibly in the context of establishing a new regime on access to genetic resources and benefit sharing, as called for the in the WSSD Plan for Implementation.

7.1.2.2 Article 8(j) Working Group

The main strength of the Working Group on Article 8(j) is that it is a very open process involving many stakeholders. As such, it is not likely that detailed and specific recommendations will ensue, but rather, this Working Group should continue to be a venue for information exchange and stocktaking. It should focus upon the inter-relationship of traditional ecological knowledge and intellectual property rights on traditional knowledge. This should be done with a view to promoting the incorporation of PIC of local and indigenous communities into national processes on traditional knowledge. The Working Group should also consider looking into the modalities of including such PIC into national legislation – the legal mechanisms that can help in this, the institutional and organisational problems that might arise in this, etc – and guide countries in evolving an efficient set of guidelines for this purpose.

7.1.2.3 Article 11

So far, the work on Article 11 has not focussed on IPRs as incentive for conservation and sustainable use. And yet, the role of IPRs in this context this is one of the most important aspects of the relationship between the TRIPS Agreement and the CBD. As such, the COP should instruct Parties to develop

case studies and exchange information on IPRs acting as positive or perverse economic or social incentives.

7.1.2.4 Work Program on Agricultural Biodiversity

The work programme on agricultural biodiversity, adopted at CBD COP-V, contains an element calling for developing methodologies for the assessment of the socio-economic causes of trends in agricultural biodiversity.[363] To the extent possible, the impacts of IPRs and other knowledge based rights that form part of the socio-economic landscape should also be assessed.

7.1.3 World Intellectual Property Right Organization (WIPO)

At present, it is too soon to assess whether the Intergovernmental Committee on Intellectual Property Rights and Genetic Resources, Traditional Knowledge and Folklore will lead to constructive results. However, since IPRs are only one aspect of the challenge to protect traditional knowledge, it is important that this work be integrated into other international discussions on traditional knowledge. And as an organization that seeks to promote IPRs, WIPO is not competent to fully assess the implications of IPRs on the conservation of genetic resources or to pursue alternatives to IPRs in this context. In addition, the discussions in the Intergovernmental Committee need to become as open to affected stakeholders as is commonly accepted in international environmental fora, if its work and outcomes are to be considered credible.

The development of the new Substantive Patent Law Treaty and any international patent system should contain sufficient flexibility to ensure that countries can implement instruments to protect traditional knowledge, as well as ensure that the conservation of biological diversity is taken into account.

7.1.4 Further developing the International Treaty on Plant Genetic Resources for Food and Agriculture

The adoption of the International Treaty represents an important step forward in ensuring appropriate access and benefit sharing in respect of plant genetic resources for food and agriculture. However, some key aspects of the Treaty remain to be developed and resolved in order for it to have maximum effectiveness.

The FAO should endeavour to enlist as many genetic resources as possible in the multilateral system. Since all resources that form part of the multilateral system are excluded from intellectual property protection, the system holds the promise of enhancing food security and relatively inexpensive access to resources that may be useful in research for developing nations.

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[363] See Programme Element # 1 on Assessment.

The MLS presents an important opportunity to ensure that all countries are provided access to important varieties. IPRs may otherwise have hindered this access or it would have taken place without appropriate sharing of benefits. Accordingly, for the MLS to be an effective alternative to the status quo, the Fund to which contributions are to be made in order to enhance benefit sharing will need to become operational as soon as possible. Thus, the Governing Body should, as a matter of priority, address all the modalities necessary for this Fund to come into operation as soon as possible.

Furthermore, establishing effective monitoring procedures should be a priority for the Governing Body. This monitoring needs to be built into the MTAs currently in use pursuant to the agreements between the FAO and IARCs, in order to ensure effective enforcement of the requirements relating to the transfer of genetic resources to outside scientists. The Governing Body might further consider recommending that States refuse to grant IPRs on inventions derived from genetic resources for food and agriculture obtained illegally from IARCs.

In addition, monitoring will also be needed to effectively track the genetic resources obtained from the MLS, to ensure that the stipulations under Article 12.3(d) are implemented. It would be helpful if the Governing Body were to provide guidance on the scope of this provision, for example by indicating that a significant modification of the genetic resource would be necessary for such a resource to be no longer "in the form received". Accordingly, intellectual property applications for inventions below such a threshold, e.g. for genes isolated from seeds, should be denied.

7.2 Specific Recommendations aimed at National governments

The current state of international law does permit countries some scope in defining and implementing their laws and policies on IPRs. Accordingly, countries should ensure that they take strategic decisions on IPRs in a manner that reflects their own conservation and development priorities. While designing sui generis rights over traditional knowledge, countries should keep in mind that an intellectual property right, although very critical, is only one component of a larger package of rights that will eventually help promote traditional ecological knowledge of relevance for in-situ conservation of genetic resources.

However, the findings of this study indicate that countries need to realise the limitations of IPR policy in achieving conservation ends. IPR policy will need to be complemented by other laws and policies in order to be effective. Based on the sectoral analyses, the following conclusions can be drawn.

In the case of agriculture, countries should focus on implementing and further developing the Cartegena Protocol of Biosafety and the Codex Alimentarius to derive rules on biosafety and the release of GMOs into nature. While creating biosafety rules, a proper balance should be struck between regulating potential environmental hazards of GMOs and free trade, such that these regulations do not end up becoming barriers to trade by way of undue precautions.

In the case of horticulture, more research needs to be done on the scope of usage of genetic resources and traditional knowledge, as well as benefit sharing possibilities. Also more biosafety precautions are required for this industry in order to reduce the risk of biological invasions.

For both these sectors, countries should consider having legal provisions in their biodiversity frameworks to detect and deal with biological invasions, as in the case of Philippines (see case study in Chapter 4). Countries should also focus on generating more research results on the impact of newer agricultural and horticultural varieties on ecology, agricultural and non-agricultural.

In the case of botanical medicines, since products rely largely on raw materials for production, developing countries may want to put in place stricter rules of harvest and transport of genetic material of actual or potential value that caters directly to industry demand.

7.2.1 IPR application process

All countries should review their IPR application process to ensure that it supports the conservation of genetic resources. TRIPS Article 8(1) and the CBD provide a legal basis for this review. The review should seek to make maximum and strategic use of the IPR law, including its scope for limitations and exceptions, so as to ensure that national and international conservation and development objectives are met.

7.2.1.1 Admission of oral evidence

To the extent that attaching an IPR to traditional knowledge or traditional ecological knowledge can act as an incentive for conservation, or as a defence against appropriation, it is important to ensure that this instrument can be made available. Since a large part of traditional knowledge is oral in nature, patent offices in industrialised countries should also consider oral "prior art" in determining whether a particular claim satisfies the novelty requirement set out by patent laws

7.2.1.2 Full use of legal entitlements to create exceptions and limitations to IPR requirements

The existing legal rules allow for establishing exceptions and limitations to IPRs. All countries should consider whether the exceptions in TRIPS Art. 27(2) can be applied to ensure conservation of genetic resources. This involves clarifying the meaning of the term "*ordre public*". The Belgian Bill referred to above may be a useful precedent for preventing misappropriation. The conservation of genetic resources is but one of several sustainable development objectives that countries should assess in making this determination. In this regard, countries may wish to be mindful of the precautionary approach called for under the CBD.

There are specific issues countries should consider in this respect. For example, all countries should consider whether they wish to avoid granting IPRs for

biotechnological products that contain their own technological protection, such as products that contain " terminator technology", particularly where such technology has adverse impacts on genetic diversity. This consideration should be related to a decision as to whether such products should also be approved for use. Another issue to consider is whether plants and animals should be excluded from patent protection.

Countries should assess the implications of Article 27(3)(b) for conserving genetic resources in the context of their socio-economic settings. One result might be to exercise the option of not allowing for patents on plants and animals. Finally, a restrictive interpretation of the term "micro-organism" might be appropriate to ensure that patents are not issued either for genetic material in its natural state or for genetic material that has merely been isolated and not modified. Although the ultimate impact of such actions on conservation may not be measurable, preventing such patents, and thereby attaching IPRs only to meaningful inventions involving genetic resources, might lead to more mutually-beneficial access and benefit sharing arrangements. Accordingly, a more effective incentive package for conservation might be achieved.

While devising *sui generis* systems for plant variety protection, countries should ensure that the system totally fits their domestic requirements. This involves deciding whether to apply UPOV 1991 or other alternatives, and include defining "breeder" in a manner that is appropriate to the particular development context.

Similarly, countries need to assess the relevance of abilities to limit IPRs in relation to the conservation of genetic resources. These limitations might involve applying TRIPS Article 30 to limit patent or PVP rights in the field of agriculture, e.g. in compliance with the FAO Treaty on Plant Genetic Resources for Food and Agriculture. Furthermore, in accordance with TRIPS Article 30, countries should develop concrete rules and regulations on situations that merit compulsory licensing of technologies relating to the conservation of genetic resources, particularly in the pharmaceutical and agriculture sectors.

7.2.1.3 Prior Informed Consent and Source of Origin Disclosure in IPR Applications

In order for a meaningful prior informed consent procedure to be established for agreements on access to genetic resources, countries need to develop the institutions and mechanisms in order to evaluate proposals for access to genetic resources and to enter into access agreements. To make this work, instruments need to be developed that certify the source of origin of the genetic resources and the consent of the affected communities and national authorities. These instruments must be accessible by IPR offices and other interested actors around the world.

All countries should consider implementing a requirement that supports prior informed consent and disclosure of the source of origin as part of the patent application process for inventions involving genetic resources. Since it may not be possible, strictly speaking, under the IPR regime to have such a requirement be a condition of patentability, they might wish to explore the Danish precedent

discussed above. Another option is to link the enforceability of the IPR with sufficient disclosure, which could be based, *inter alia*, on TRIPS Article 8(2) which allows Members to take measures to prevent abuse of IPRs.[364] In any event, there are no legal obstacles for instituting such a requirement for PVP legislation. Indeed, the more fundamental issue to be resolved may be the more practical one of providing sufficient resources and guidance to IPR offices so that they can reasonably administer such a system.

However, it should be noted that depending on the extent of this obligation, the actual impact of such rules on benefit sharing, and hence on conservation, may be limited, if it will only address the case where the genetic resources are acquired for the first time. A system that actually traces the use of a biological resource back to its original state, including subsequent manipulations, would be necessary, but may not be feasible.

Further empirical research is needed on whether PIC requirements in IPR applications are a helpful tool in leveraging meaningful benefit sharing and gains for conservation.

7.2.1.4 Developing international alliances and agreements

It is increasingly apparent that alliances are being developed among like-minded countries to more effectively engage in debates at the global in IPRs. This strategy is particularly important to mega-diverse developing countries, although strategic alliances may also be possible with mega-diverse developed countries. The basis for such alliances are to develop incentives to achieve conservation, preventing misappropriation and protecting traditional knowledge. In addition, like-minded countries should consider developing mutual recognition procedures and enhancing institutional collaboration across national boundaries for the protection of traditional knowledge.

7.2.1.5 Bilateral trade relations

Countries developing bilateral trade relations that go beyond the minimum standards under TRIPS in areas that relate to the conservation of genetic resources should carry out a sustainability impact assessment prior to agreeing such provisions. Developed countries may need to provide the funding of such assessments, however they should be carried out with the involvement of both parties, as well as affected right holders and stakeholders.

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[364] De Carvallo, N. P. *Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 Washington University Journal of Law and Policy, p. 371

7.2.1.6 National laws and policies aimed at traditional and local communities

Countries need to create the domestic legal and policy instruments necessary to give traditional and local communities the means to control their knowledge. The sui generis system for protection of traditional knowledge will require to be complimented by several other measures to achieve the diverse aims. The most important one of these the recognition of land rights and a system of prior informed consent. Requirements for prior informed consent as well as rules of benefit sharing should be based on existing community structures since they might indeed be the best way to organise biodiversity management and benefit-sharing initiatives. Participatory approaches devised on the traditional systems of organisation can also ensure more effective participation of communities in decision-making.

Countries should also submit surveys of traditional knowledge that can potentially be protected as geographical indications in their respective jurisdictions in order to make the case of extending the subject matters that can be protected by geographical indications under the TRIPs.

Countries should also consider means of reduction of power differences between and within communities, but only in consultation with those particular communities.

7.3 Improving and building capacity in developing countries

The issues and recommendations raised in this paper entail significant implementation challenges for developing countries. Capacity building that is focussed on ensuring that developing countries harness the positive impacts of IPRs for the conservation of genetic resources is necessary. Assistance should be provided for supporting the development of *sui generis* legislation, and for developing measures that ensure that impacts of IPRs do not harm the weakest members of society. Donors should support win-win activities that benefit local communities and industry. Technical assistance should be provided for projects relating to protecting traditional knowledge and the design of appropriate intellectual property rights institutions that can foster domestic learning processes. The guidelines on capacity building currently being developed under the CBD in relation to access and benefit sharing should contain provision for IPRs and technology transfer. In addition, other international programmes on capacity building, such as those of UNCTAD and the WTO, might usefully help to build developing country capacity in these areas. Finally, developing countries require assistance to operate effectively in relevant international fora. To this end, development assistance should seek to create networks that include civil society, industry and the public sector to evaluate the national interest and articulate it effectively at the international level.

7.3.2 Supporting Public Sector Research in Developing Countries

IPRs are incentives mainly for the private sector. Therefore, the issue of leveraging the positive impacts of biotechnological innovations fostered in the private sector to the advantage of developing countries may benefit from an international initiative on funding of public sector research in developing countries or on

making basic research findings available to developing countries to support their incremental learning processes.

7.4 Specific Recommendations aimed at Traditional and Local Communities

Traditional and local communities must become proactively engaged in efforts to control their ecological knowledge. As such, they need to take stock of the procedures and mechanisms within their communities so as to engage in strategic planning on whether, how and on what terms to allow it to be exploited by others. For example, a key issue is whether to list this knowledge in any kind of database or registry. Secondly, the sharing of benefits arising from ecological knowledge is something that should be handled in a strategic manner in accordance with community customs and practices.

These communities also should actively take part in the development of procedures developed by national authorities to give effect to prior informed consent and benefit sharing. They should develop a strategic and holistic approach to protecting their knowledge, which also involves pursuing a wider array of rights, like land rights. In many cases, this may entail providing these communities with the support and capacity to do so effectively. However, insofar as possible, top down approaches should be avoided.

8 Bibliography

Arnold, J. E. M. and Stewart, W. C. (1991), "Common Property Resource Management in India". *Tropical Forestry Papers*, No. 24. Oxford, England: Oxford Forestry Institute.

Axt and Corn (1993), *Biotechnology, Indigenous Peoples and Intellectual Property Rights*, CRS Report For Congress, Washington D.C., USA.

Ayensu, E. S. (1983), "Endangered Plants Used in Traditional Medicine". In: Bannermann et al, *Traditional Medicine and Health Care Coverage*. WHO, pp. 175-280.

Ballance et al (1992), *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*. Northampton, USA: Edward Elgar.

Bandhopadhyay and Saha (1998), "Indigenous Methods of Seed Selection and Preservation on the Andaman Islands in India". *Indigenous Knowledge and Development Monitor*. Vol. 6, Issue 1, pp. 3-6.

Barton, John H. The Impact of Contemporary Patent Law on Plant Biotechnology Research, Intellectual Property Rights III Global Genetic Resources: Access and Property Rights,1998

Bragdon, S and Downes, D.. Recent policy trends and developments related to the Conservation, Use and development of genetic resources; Issues in Genetic Resources No. 7, IPGRI, 1998,

Bromley, D. W. and Cernea, M. M. (1989), "The Management of Common Property Natural Resources: Some Common Conceptual and Operational Fallacies". *World Bank Discussion Papers*, No 57.

Brown, G. H. (2000), "Renewable Natural Resources: Management and Use Without Markets". *Journal of Economic Literature*, pp. 875-914.

Cabrera Medaglia, J. A. *Access to Genetic Resources, Protection of Traditional Knowledge, and Intellectual Property Rights: Lessons Leaned From the Costa Rican Experience*.

Commission on Intellectual Property Rights, Final Report, available on http://www.iprcommission.org/graphic/documents/final_report.htm (2002)

Committee on Environmental Impacts Associated with Commercialisation of Transgenic Plants *et al* (2002), *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. Washington, D.C., USA: National Academy Press.

Committee on Genetically Modified Pest Protected Plants, Board on Agriculture and Natural Resources and the National Research Council (2000), *Genetically Modified Pest-Protected Plants: Science and Regulation*. Washington, D.C., USA: National Academy Press.

Conway, W. (1988), "Can Technology Aid Species Preservation?". In: Wilson, E. O. and Peter, F. M. (eds.), *Biodiversity*. Washington, D.C., USA: National Academy Press, pp. 263-268.

Cook, J. R. (1998), "Towards a Successful Multinational Crop Initiative". *Colloquium Paper of the National Academy of Sciences*. USA, Vol. 95, pp. 1993-1995.

Correa, (2000), *Implementing the TRIPs Agreement in the Patent Field*. London, England: Zed Books.

Cox, P. A. (1990), "Ethnopharmacology and the Search For New Drugs". In: D. J. Chadwick and J. Arsch (eds.), *Bioactive Compounds From Plants*. Cambridge, England: Cambridge University Press.

Cox., P. A. (1995), "Shaman as Scientist: Indigenous Knowledge Systems in Pharmacological Research and Conservation". In: K. Hostettmann, A. Marston, M. Maillard and M. Hamburger (eds), *Phytochemistry of Plants Used in Traditional Medicine: Proceedings of the Phytochemical Society of Europe*. Oxford, England: Clarendon Press, pp. 1-17.

Cragg, G. M. Newman D. J. and Snader K. M. (1997), "Natural Products in Drug Discovery and Development". *Journal of Natural Products*, Vol. 60, No. 1, pp. 52-60.

Cragg, G. M. and Boyd, M. R. (1996), "Drug Development at the National Cancer Institute". In: Balick *et al, Medicinal Resources of the Tropical Forests*. New York, USA: Columbia University Press.

Crucible Group II, Seeding Solutions. Volume 1. Policy for genetic resources (People, plants, and patents revisited), IDRC, IPGRI and Dag Hammerskjöld Foundation, 2000, pp. 16-17.

De Carvallo, N. P. Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without Infringing the TRIPS Agreement: The Problem and the Solution, 2 Washington University Journal of Law and Policy, p. 371.

Dhar, B. and Chaturvedy, S. *Introducing Plant Breeder's Rights in India:A Critical Evaluation of the Proposed Legislation*, Journal of World Intellectual Property, 1(2), 1998.

Dhar, B.*Sui Generic Systems for Plant Variety Protection: Options Under TRIPS*, Quaker United Nations Office, 2002

Dhillon, S. and Amudsen (2000), "Bioprospecting and the Maintenance of Biodiversity". In: Svarstad and Dhillon, *Bioprospecting: From Biodiversity in the South to Medicines in the North.* Oslo, Norway. pp. 103-132.

Di Masi, J. A, Hansen, R. W. and Grabowski, H. G. *et al* (1991), "The Cost of Innovation in the Pharmaceutical Industry". *Journal of Health Economics*, Vol. 10, pp. 107-481.

Downes, D. Using Intellectual Property as a Tool to Protect Traditional Knowledge: Recommendations for Next Steps; CIEL Discussion Draft, 1997.

Downes, D. and S. Laird, S. *Community Registries of Biodiversity-Related Knowledge. The Role of Intellectual Property in Managing Access and Benefit*, UNCTAD Biotrade Initiative, 1999.

Drahos, P. *BITs and BIPs: Bilateralism in Intellectual Property*, 4 Journal of World Intellectual Property, 2001.

Dumont, P. and Holmes. (2002). "Sc*ope of Intellectual Property Rights and Their Interface with Competition Law and Policy: Divergent paths to the Same Goal"*. Econ. Innov. New Techn., Vol. 11(2), p. 149-162.

Dutfield, G. (1995), "Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights an Community Knowledge Databases in India". In: M. Backeney (ed.), *Intellectual Property Aspects of Ethnobiology, Perspectives on Intellectual Property*, Vol. 5: Sweet and Maxwell.

Dutfield, G. (1999), "Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India". In: Blakeney, M. (ed.), *Intellectual Property Aspects of Ethnobiology*, pp. 101-122.

Dutfield, G. (1999), *Trade Biodiversity and Intellectual Property Rights.* London, England: Earthscan Publishers.

Dutfield, G. (2001) *TRIPS-related Aspects of Traditional Knoweldge*, 33 Case W. Res. J. Int'l L. 239

Dutfield, G. (2002), *Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation*. Paper presented at the Expert Workshop on Trade, Intellectual Property Rights and Sustainable Development.

Dutfield, G. (2002) *Sharing the Benefits of Biodiversity: Is there a Role for the Patent System*, 5 JWIP, 2002, p. 899 et. seq.

Dutfield, G. . *Intellectual Property Rights and the Life Sciences Industry*, 2003 (Forthcoming).

Ellickson, R. (1994), *Order Without Law*. Harvard, USA: Harvard University Press.

Etkin, N. L. (1998), "Indigenous Patterns of Conserving Biodiversity: Pharmacologic Implications". *Journal of Ethnopharmacology*, Vol. 63, pp. 233-245.

Etkin, N. L. and John, T. (1998), "Pharmafoods" and "Nutriceuticals": Paradigm Shifts in Biotherapeutics". In: H. D. V. Prendergast, N. L. Etkin, D. R. Harris and P. J. Houghton (eds*), Plants for Food and Medicine.* Kew, England, pp. 3-16.

Ewing, K, and Tarasofsky, R., The Trade and Environment Agenda: Survey of Major Issues and Proposals -- From Marrakech to Singapore, IUCN, Gland, 1997

FAO (1995), *Dimensions of Need: An Atlas of Food and Agriculture*. Rome, Italy: FAO.

Farnsworth, N. R. (1988), "Screening Plants For New Medicines". In: E. O. Wilson (ed.), *Biodiversity*., Washington, D.C., USA: National Academy Press.

Fellows, L. and Scofeld, A. (1995), "Chemical Diversity in Plants". In: T. Swanson (ed), *Intellectual Property Rights and Biodiversity Conservation: An Interdisciplinary Analysis of the Values of Medicinal Plants*. Cambridge, England: Cambridge University Press, pp. 19-44.

Fernandez-Cornejo, J. and McBride, W. D. (2000), "Genetically Engineered Crops for Pest Management in U. S. Agriculture: Farm-Level Effects". *Agricultural Economic Report*, No. 786, U. S. Department of Agriculture.

Fraleigh, B. (1997), "Issues in Agricultural Biotechnology and Biodiversity for Sustainable Agro-Ecosystems". In: R. W. F. Hardy, J. B. Segelken and V. Voionmaa (eds.), *Resource Management in Challenged Environments*. NABC Report 9.

Gadgil, M. (1999*), Recognising and Rewarding Common Pool Knowledge Resources*. Paper presented at the IUCN-Kalpavriksh Workshop on Biodiversity Conservation and the Intellectual Property Regime.

Gaisford, J. D., Hobbs, J. E., Kerr, W. A., Perdikis, N. and Plunkett, M. D. (2001), *The Economics of Biotechnology*. Northampton, USA: Edward Elgar.

Gehl Sampath, P., Biodiversity Prospecting Contracts for Pharmaceutical Research: Institutional and Organisational Issues in Access and Benefit Sharing, Forthcoming.

Glowka, L. et al. (1994). A Guide to the Convention on Biological Diversity, IUCN, Gland.

Godden, D. (1998), "Growing Plants, Evolving Rights: Plant Variety Protection in Australia", *Australian Agribusiness Review*, Vol. 6, pp. 7.

Grain, Biopiracy by another name? A critique of the FAO-CGIAR trusteeship system, available on http://www.grain.org/seedling/seed-02-10-2-en.cfm, 2002.

GRAIN "WIPO moves toward "world" Patent System", available on http://www.grain.org/publications/wipo-patent-2002-en.cfm, 2002.

GRAIN and Kalpavriksh. The International Treaty on Plant Genetic Resources: a challenge for Asia, available on http://www.grain.org/publications/it-asia-feb2002-en.cfm, 2002.

Halliday, R. G., Walker, S. R. and Lumley, C. E. (1992), "R & D Philosophy and Management in the World's Leading Pharmaceutical Companies". *Journal of Pharmaceutical Medicine*, Vol. 2, pp. 139-154.

Hawtin, G. (1997), "Biotechnology in the Maintenance and Use of Crop Genetic Diversity". In: R. W. F. Hardy, J. B. Segelken and V. Voionmaa (eds.), *Resource Management in Challenged Environments*. NABC Report 9.#

Helfer, L. Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments, FAO Legal Paper Online #31, available on http://www.fao.org/Legal/prs-ol/paper-e.htm.

Henry, C. (1974), "Investment Decisions under Uncertainty: The Irreversibility Effect". *American Economic Review*, 64(6), pp. 1006-1012.

Institute for Biological Invasions, *An Overview of the Problem*, at www.instituteforbiologicalinvasions.uk.

IPGRI. 1999. Key questions for decision-makers. Protection of plant varieties under the WTO Agreement on Trade-RelatedAspects of Intellectual Property Rights. Decision Tools, October 1999. International Plant Genetic Resources Institute, Rome, Italy. ISBN 92-9043-420-1

Izac, A.-M. N. and Sanchez, P. (2001), "Towards a Natural Resource Management Paradigm for International Agriculture: The Example for Agroforestry Research". *Agricultural Systems,* Vol. 69, pp. 5-25.

IUCN. (1995), *Saving Biological Diversity: Economic Incentives*. Paris, France: IUCN.

Jodha, N. S. (1989), "Management of Common Property Resources in Selected Areas of India". In: A. Dani and J. G. Campbell (eds), *Local Institutions and Resource Management*. Nepal: ICIMOD.

Jodha, N. S. (1992), "Common property Resources*". World Bank Discussion Papers*. Washington, D.C., USA: World Bank.

Joglekar, P. and Paterson, M. L. (1986), "A Closer Look at the Returns and Risks of Pharmaceutical R & D", *Journal of Health Economics*, Vol. 5 pp. 153-177.

Juma, C. (2001), "Modern Biotechnology". *Appropriate Technology for Sustainable Food,* Brief 4, August.

Juma. C. (2000) "Biotechnology and Sustainable Agriculture: Developing Country Perspectives". *Congressional Briefing*, Washington.

Kanbur, R. (1992), "Heterogeneity, Distribution and Cooperation in Common Property Resource Management". *Working Paper Series of the World Bank*, WPS 844.

Kloppenburg, J. R. Jr. (1988), *First the Seed: The Political Economy of Plant Biotechnology, 1492-2000*. Cambridge, Australia: Cambridge University Press.

Kothari, A. and Das, P. (1999), In: Posey, D. A. (ed.*), Cultural and Spiritual Values of Biodiversity.* Nairobi, Kenya: UNEP.

Kothari, A. and Anuradha, R. V. (1997), "Biodiversity, intellectual property rights, and the GATT agreement: how to address the conflicts?", *Biopolicy*, Vol. 2, Paper 4, PY97004. Online Journal, URL: http//www.bdt.org.br/bioline/py

TenKate, K. and Laird, S. A. (2000), *The Commercial Use of Biodiversity.* London, England: Earthscan Publications.

Lassere, P. (2002), "Evaluation of Biodiversity: A Real Options Approach", Paper presented at the MERIT Seminar, University of Maastricht.

Leskien, D. and Flitner, M., Intellectual Property Rights and Plant Genetic Resources, Issues in Genetic Resources No. 6, International Plant Genetic Resources Institute, Rome.

Marguiles, M. (1993), "Protecting Biodiversity: Recognising Intellectual Property Rights in Plant Genetic Resources". *Michigan Journal of International Law*, pp. 322-356.

May, C. (2000), *A Global Political Economy of Intellectual Property Rights: The New Enclosures?* London, England: Routledge Publishers.

McCaleb, R. S., "Medicinal Plants for Healing the Planet: Biodiversity and Environmental Health Care". In: F. Grifo and J. Rosenthal, *Biodiversity and Human Health*. Washington, D.C., USA: Island Press Inc., pp. 221-242.

Miller, H. I. and Conko, G. (2000), "The Science of Biotechnology Meets the Politics of Global Regulation". *Issues in Science and Technology*, pp. 1-4 on p. 1.

Miller, H. I. (1997), "Policy Controversy in Biotechnology: An Insider's View". Georgetown, USA: Landes Bioscience Publication.

Mooney, P. (2000), "Why We Call it Biopiracy". In: Svarstad and Dhillon, *Responding to Bioprospecting: From Plants in the South to Medicines in the North.* Oslo, Norway, pp. 37-44.

Mooney, P. (2000), "Why We Call It Biopiracy". In: Svarstad and Dhillon (eds), *Bioprospecting: From Biodiversity in the South to Medicines in the North*, pp. 37-44.

Mountford, H. and Keppler, J. H. (1999), "Financing Incentives for the Protection of Biodiversity". *The Science of the Total Environment*, Vol. 240, pp. 133-144.

Mundy, P. (1993), "Indigenous Communication Systems: An Overview". *Development: 3 Journal of SID*.

Ning Wu (1998), "Indigenous Knowledge of Yak Breeding and Cross Breeding Among Nomads in Western China". *Indigenous Knowledge and Development Monitor*, Vol. 6, Issue 1, pp. 7-9.

OECD (2002), *Handbook of Biodiversity Valuation: A Guide for Policy Makers*. Paris, France: OECD.

OECD (1999), *Handbook of Incentive Measures for Biodiversity: Design and Implementation*. Paris, France: OECD.

Pardey, P. G. and Beintema, N. M. (2001), "Slow Magic: Agricultural R & D a Century After Mendel". *Agricultural Science and Technology Indicators Initiative*, International Food Policy Research Institute. Washington, D. C., USA.

Pindyck, R. S. and Rubinfeld, D. L. (1995), *Microeconomics*. New Jersey, USA: Prentice-Hall Inc.

Plotkin, M. (1991), "Traditional Knowledge Of Medicinal Plants --The Search For New Jungle Medicines". In: Akerele, Heywood, Synge (eds.), *The Conservation Of Medicinal Plants.* Cambridge, England: at pp.57.

Posey, D. A. (ed.*), Cultural and Spiritual Values of Biodiversity.* Nairobi, Kenya: UNEP.

Posey, D. A., "National Laws and International Agreements Affecting Indigenous and Local Knowledge: Conflict or Conciliation?" Green College Centre for Environmental Policy and Understanding.

Posey, D. A., Dutfield, G., Plenderleith, K., Willard, T. and Mcfall, S. (1996), *Indigenous Peoples and Farmers: Part A: Identifying Commonalities and Divergencies Between Indigenous Peoples and Farmers' Groups*. A Report for GRAIN.

Posey, Dutfield, et al (1996), *Indigenous Peoples and Farmers: Identifying Commonalities and Differences Between Indigenous People and Farmers' Groups*. Report for GRAIN, p. 17.

Reid, W. V, et al. (1993), Biodiversity Prospecting: Using genetic Resources for Sustainable Development, World Resources Institute, National Biodiversity Institute of Costa Rica, Rainforest Alliance, and African Centre for Technology.

Rangnekar, D. *Planned Obsolescence and Plant Breeding: Empirical Evidence from Wheat Breeding in the UK (1965-1995),* draft on file with the authors.

Rangnekar, D. *Geographic Indications: A Review of the Proposals at the TRIPS Council (draft), 2002.*

Rosenthal, J. P. (1997), "Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources". In: OECD*, Investing in Biodiversity: The Cairns Conference.* Paris, France: OECD, pp. 253-274.

Royal Society of Canada. (2001), Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. An Expert Panel Report on the Future of Food Biotechnology. Ottawa, Ontario: The Royal Society of Canada.

Sallenave (1994), "Giving Traditional Ecological Knowledge its Rightful Place in Environmental Assessment". *CARC-Northern Perspectives*, 22: 1.

Schaaf, T. (1999), "Environmental Conservation Based on Sacred Sites". In: Posey, D. A. (ed.*), Cultural and Spiritual Values of Biodiversity.* Nairobi, Kenya: UNEP.

Schmitz, D. C. and Simberloff, D. (1997), "Biological Invasions: A Growing Threat". *Issues in Science and Technology*, Vol. XIII, No. 4, pp. 33-40.

Schmitz, D. C. and Simberloff, D. (2001), "Needed: A National Center for Biological Invasions". *Issues in Science and Technology*.

Seiler, A. and Dutfield, G. (2001), *Regulating Access and Benefit Sharing. Basic Issues, Legal Instruments, Policy Proposals.* Bonn, Germany: BfN Skripten 46.

Sheldon, J. *et al* (1997), "Medicinal Plants: Can Utilization and Cultivation Co-Exist?". *Advances in Economic Botany*, Vol. 12.

Sheldon, J. W., Balick, M. J. and Laird, S. A. (1996), "Medicinal Plants: Can Utilization and Conservation Co-Exist?". *Advances in Economic Botany*, Vol. 12, New York, USA: NYBG.

Shiva, V. *et al*. (2000), *Biopiracy: The Plunder of Nature and Knowledge,* South End Press, 1997, pp. 31. Mooney, P. R., "Why We Call It Biopiracy". In: H. Svarstad and S. S. Dhillion (eds.), *Responding to Bioprospecting: From Biodiversity in the South to Medicines in the North*. Oslo, Norway: pp. 37-44.

Shiva, V. Anderson, Schuking, H. Gray, A. Lohmann, L. and Cooper, D. (Eds.), *Biodiversity: Social and Ecological Perspectives*. London, UK and New Jersey, USA / Penang, Malaysia: Zed Books Ltd. / World Rainforest Movement.

Shiva, V. (1999), *Biopiracy: The Plunder of Nature and Knowledge*. Devon, England: Green Books Ltd.

Swanson, T. (1995), "Appropriation of Evolution's Values". In: Swanson*, Intellectual Property Rights and Biodiversity Conservation*. Cambridge, England: Cambridge University Press.

Swanson, T. and Johnston (1999), *Global Environmental Problems and International Environmental Agreements.* Northampton, USA: Edward Elgar.

Tansey, G. (1998), *Trade, Intellectual Property, Food and Biodiversity*. Quake Foundation.

Tarasofsky, R. G. Glowka, L. Gehl Sampath, P. Choudhury, K. and Marr, S. (2002), *Legal Analysis* of the First Meeting of the Working Group on Access to Genetic Resources, Bonn, Germany: BfN (Unpublished).

Timmerman, B. N. (1997), "Biodiversity Prospecting and Models for Collections of Resources: the NIH/NSF/USAID Model". In: K. E. Hoagland and A.Y. Rossman (eds), *Global Genetic Resources: Access, Ownership and Intellectual Property Rights*. pp. 219-302.

US Congress (1991), Office of Technological Assessment, *Biotechnology in a Global Economy.* OTA-BA-494, Washington, D.C.: US Government Printing Office.

Vivas Eugui, D.. *Issues Linked to the Convention on Biological Diversity in the WTO Negotiations: Implementing Doha mandates*, CIEL, 2002, available on http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf .

Warren, M. (1992), "Using Indigenous Knowledge in Agricultural Development". *World Bank Discussion Paper*, No. 127.

Weldon, I. (1995), "Preserving Biodiversity: The Role of Property Rights". In: Swanson (ed.), *Intellectual Property Rights and Biodiversity Conservation*, pp. 141-175.

R. Wolfrum/ G. Klepper/ P.-T. Stoll/ S. Franck, Implementing the Convention on Biological Diversity: Analysis of the Links to Intellectual Property and the

International System for the Protection of Intellectual Property, available on http://www.biodiv.org/doc/meetings/abs/abswg-01/information/abswg-01-inf-03-en.pdf, 2001.

WWF International and CIEL (2001), *Biodiversity and Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*. Joint Discussion Paper, March.

9 Acronyms

ACP	Africa Caribbean Pacific
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
COP	Conference of Parties
CIPR	Commission on Intellectual Property Rights
CTE	Committee on Trade and Environment
DDA	Doha Development Agenda
EC	European Communities
EMEA	European Agency for the Evaluation of Medicinal Products
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FDA	US Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
GMO	Genetically modified organism
IARC	International Agricultural Research Center
IBCG	International Biodiversity Co-operative Groups
IPR	Intellectual Property Right
MEA	Multilateral Environmental Agreement
MGR	Microbial genetic resource
MLS	Multilateral System
MTA	Material Transfer Agreement

OAU	Organisation of African Unity
OECD	Organization for Economic Co-operation and Development
PBR	Plant Breeder´s Rights
PIC	Prior informed Consent
PVP	Plant Variety Protection
R & D	Research and Development
rDNA	recombinant Deoxyribonucleic Acid
SPLT	Substantive Patent Law Treaty
TBGRI	Tropical Botanical Garden and Research Institute
TEK	Traditional Ecological Knowledge
TK	Traditional Knowledge
TRIPS	Trade-related Aspects of Intellectual Property Rights
UNEP	United Nations Environment Programme
UNCTAD	United Nations Conference on Trade and Development
UPOV	Union Internationale pour la Protection des Obtentions Végétales
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WWF	World Wide Fund for Nature

10 Appendix I: Replies to Questionnaires

So as to gather a diversity of opinions and perspectives for correlation with the rest of the analysis in this study, representatives from select actors were sent questionnaires. The following are the replies received. Although the responses gathered were not sufficient to draw any specific empirical conclusions, the diversity of opinions is noteworthy.

10.1 Countries

Brazil

(Reply by: Mrs. Vanessa Dolce de Faria, Diplomat and assistant of Mrs. Elza de Castr, Primeira Secretaria, Divisao de Propriedade Intelectual e Novos Temas (Division of Intelectual Property Rights (DNT)).

We would be glad to aswear all your questions if we could. In fact, the reason why we did not respond to your first request is exacty this: our piece of legislation (PM 2186) on the subject is pretty recent, and besides it is not a law, but a "provisional measure", which means that the National Congress will still vote it. The Intergovernamental body in charge of the implementation of this provisional measure (CGEN, which stands for the Council on Genetic Resources) has just started its meetings. They first meet in March 2002. Because of this, and after informal talks to members from CGEN, we concluded that we cannot officially answer all the questions, since most of the subject is still starting to be tackled here.

Here follow some preliminary comments on some questions:

1. Does the award of intellectual property rights on biotechnological inventions encourage or hinder the conservation of genetic or other biological resources? Can you provide any specific examples?

no comments made.

2. Can other mechanisms, such as contractual arrangements, also be effective in generating incentives to conserve genetic resources? Do you have practical experience with such arrangements in your country?

Contractual agreements are the legal means of accessing RGs in Brazil, according the Provisional Measure 2186-16, from August 2001. These contractual agreements must be analysed and approved by the CGEN, in order to ensure that there is prior informed consent, benefit-sharing, and the indication of the origin of the GRs or the associated TKs. Here follows the PM mentioned.

<<provisional measure.doc>>

7. Do you think the current law on intellectual property rights on biological innovations inherently conflict with the effective protection of traditional knowledge of indigenous and local communities? Can you provide any specific examples where this may have occurred?

8 Do you think the current law on intellectual property rights on biological innovations inherently conflict with the effective protection of traditional knowledge of indigenous and local communities? Can you provide any specific examples where this may have occurred?

Answer to QUESTION 7 and QUESTION 8

We do think that the current system of IPRs does not prevent biopiracy. That is why we have been defending the implementation of a sui generis system of protection of genetic resources and traditional knowlegde (TK) . We therefore consider it necessary to amend article 27.3(B) of the TRIPs Agreement in order to make it compatible with the provisions set by the Convention on Biological Diversity. Two proposals have been circulated in the Council of TRIPs, one in 2000, the last one in the last Council of TRIPs (June 2002).

According to them, the TRIPs Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to TK shall provide, as a condition to acquiring patent rights:

(i) disclosure of the source and country of origin of the biological resource and of the TK used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes;

(iii) evidence of fair and equitable benefit sharing under the relevant national regimes.

9. Are there any non-governmental initiatives in your country that aim at ensuring that intellectual property rights enhance the conservation of genetic resources? Do you consider them to be effective?

We are not aware of the existence of such initiatives.

10. Do you have any recommendations on how intellectual property law at the national or international levels can be improved to enhance the conservation of genetic resources?

As a megabiodiverse country, we consider it necessary that the provisions set by the CBD, especially those concerning article 8 (j), 15 and 16, as well as articles 7 ans 8 of the TRIPs Agreements, be the guidance for all the negotiations undertaken at the international level concerning the relation between IPRs and GRs and TK. At the national level, as Brazil is doing with its Provisional Measure, countries should start by implementing the CBD.

Columbia

(Reply by: Mrs. Ana Maria Hernandez Salgar, Advisor, International Affairs Office, Ministry of the Environment)

1 Does the award of intellectual property rights on biotechnological inventions encourage or hinder the conservation of genetic or other biological resources? Can you provide any specific examples?

In theory, the IPRs can support the conservation and sustainable use of biodiversity if the intellectual property laws includes some requests about the legal source of the biological material or traditional knowledge that is used in inventions. Nevertheless in reality the IPRs doesn't have any tool to conserve or use in a sustainable manner the biological diversity, and in fact, this lack of specific biodiversity laws inside the IPRs, can create a big pressure over the resources.

2 Can other mechanisms, such as contractual arrangements, also be effective in generating incentives to conserve genetic resources? Do you have practical experience with such arrangements in your country?

It's supposed that the contractual arrangements can give specific tools to incentive the conservation of genetic resources. The Andean Decision 391 on a common regime on access to genetic resources (applicable for the five andean countries: Bolivia, Colombia, Ecuador, Perú and Venezuela) gives a clear mandate in that sense. Colombia doesn't have practical experiences giving contractual arrangements on access to genetic resources, but Peru, inside the same framework, has a lot of experiences.

3. Does industrial or academic research on genetic resources contribute to, or hinder, the conservation of genetic or other biological resources? If so, how? Does this vary with the sector involved (e.g. pharmaceutical, agricultural, chemical, cosmetic, or horticultural?)

Colombia as a developing country doesn't have a very important industrial biological or genetic research. At the academic research level, the country doesn't have enough resources to do a big work on biological conservation. That's why in Colombia we cannot say that the research on genetic resources, here, can either contribute or hinder the conservation of biodiversity. Of course, in Colombian the scientific and technical research includes interesting projects on conservation and sustainable use of the biodiversity through the genetic research,

but is at a minimum scale. In the industry level, some companies – most in the agriculture sector – have projects on conservation of agroecosystems.

4. Do you think traditional knowledge has a contribution to make towards *in-situ* conservation of genetic resources? If yes, in what way?

Yes, because the traditional knowledge is oriented to make a harmonic and sustainable management of the ecosystems. Also, the traditional knowledge has been a basic tool for the population control, domestication of plants and animals, and land use management through traditional productive practices. The culture reflected in myths allows the knowledge of nature and productive cycles as climate, breeding, hunting and fishing. In that sense, the traditional knowledge applied to the conservation and management of biodiversity is the most important contribution of the traditional communities to the conservation of genetic resources.

5. Do you think that the legal recognition of community intellectual property rights over traditional knowledge can provide incentives for conservation of genetic or other biological resources? Please be specific in your answers regarding the types of incentives.

Is so difficult to think that the community rights can be protected through individual and private rights, as the IPRs. There have to be an incredible change inside the intellectual property laws. Each community has the right to decide on how they want to protect their knowledge. The communities don't want "western laws" telling them what to do with their cultures. In this regard, if the communities don't feel good with the intellectual property rights (private or common ones) there are not going to be any incentive for the communities. And actually, they show their disagreement on international procedures on protection of traditional knowledge through IPRs.

6. What specific rules relating to intellectual property -- such as prior informed consent from the country or community of origin -- could help ensure that local and traditional communities effectively conserve genetic resources? Can you provide any examples of where these rules have been applied?

The previous informed consent (PIC) as other principles is not a rule related to intellectual property, in our point of view. Nevertheless, the IPRs would have, as a minimum standard, the following specific rules:

- Previous informed consent.

- Mutually agreed terms.

- Faire and equitable sharing of benefits.

- Demonstration of the legal origin of traditional knowledge and genetic resources used in an invention.

7. Do you think the current law on intellectual property rights on biological innovations inherently conflict with the effective protection of traditional knowledge of indigenous and local communities? Can you provide any specific examples where this may have occurred?

Yes. The main conflict is the different points of view between the western society and the traditional communities. The current IP laws don't take into account the spiritual values that this communities gives to the different components of the biodiversity that are used in patents and other forms of IPRs. That's why a lot of communities in deed are not agree even with the western proposals for benefit sharing, because the vital importance of biodiversity for the traditional people is more spiritual than economic. That is the case of the Yagé, a sacred plant of the indigenous people of America that was patented in the USA. The IPRs protected the USA citizen who received the patent protection, but the communities that used this sacred plant since hundred of years ago were not tooked into account. And of course, there exists the doubt about the innovative level of a plant that exists in nature.

8. Do you have any experience with *sui generis* systems for intellectual property rights over genetic or other biological resources? If so, how would you assess their impact on conservation, research and equity?

In Colombia applies the Andean Decision 345 on a common regime of plant variety protection. Is a *sui generis* law over new varieties of plants. We have a lot of experiences with the protection of varieties and as far as the Ministry of the Environment knows, the application of the Decision 345 have not causing any negative impact on conservation, research and equity. Nevertheless, we also don't have information about positive impacts.

9. Are there any non-governmental initiatives in your country that aim at ensuring that intellectual property rights enhance the conservation of genetic resources? Do you consider them to be effective?

I don't know any.

10. Do you have any recommendations on how intellectual property law at the national or international levels can be improved to enhance the conservation of genetic resources?

If the intellectual property systems can open their concepts to accept the implementation of tools for conservation and sustainable use of biodiversity and traditional knowledge inside their laws, the entire international community can avoid the very difficult negotiations in this matter. The specific recommendation is to include, at least, the rules proposed above (question number 6).

Costa Rica

(Reply by: Mrs. Silvia Rodriguez, National University)

1. Does the award of intellectual property rights on biotechnological inventions encourage or hinder the conservation of genetic or other biological resources? Can you provide any specific examples?

My opinion is that not only biotechnological inventions[365] but any kind of IPRs on life forms (i.e. Plant Variety Protection) or information related to them (patents on drugs derived from biochemical resources) hinder indirectly that conservation.

I said "indirectly" because the direct cause of genetic erosion according to many examples given by scientists like Mae-Wan-Ho[366], Brewster Kneen[367] or Pat Mooney[368] are some biotechnologies, not IPRs per se. Nevertheless, these rights are now a days a *sine quanon* condition to assure biotech companies the monopolic control of their discoveries. It seems as if without IPRs genetic engineering and some other biotechnologies could not exist. You can only observe the discussions at the Conferences of the Parties (COPs) of the Convention of Biological Diversity, at the FAO´s Commission on Plant Genetic Resources, at the World Trade Organization or at the discussions of the different

[365] I guess that you are implying here not the diverse biotechnological techniques but mainly to "modern biotechnology", specifically to genetic engineering. My answer will be done under this assumption.

[366] Wan-Ho, Mae (1997). **Genetic Engineering Dreams or Nightmares.** Resarch Foundation for Science, Technology and Ecology & Third World Network. New Delhi.

[367] Kneed, Brewster. (1999). **Farmageddon: food and the culture of Biotechnology.** New Society Publishers. Canada.

[368] Mooney, Pat. (2001). The ETC Century, Erosio, Technological Transformation and Corporate concentration in the 21sth Century. **Development Dialogue.** 1999, 1-2.

bilateral or regional free trade agreements, to conclude that IPRs are a must in order to be a member. They should be accepted without discussion; it is a "you take it or you leave it issue".

Now, I also want to stress the point that it is a "now a days *sine quanon* condition" because it might be that in the near future companies will not need this mechanism to get the control of products of biological origin. In fact, we are now witnessing that some of them are developing the so called "terminator technologies", among others the sterile seed, in view of the fact that IPRs are not working in the way they wanted.

2. Can other mechanisms, such as contractual arrangements, also be effective in generating incentives to conserve genetic resources? Do you have practical experience with such arrangements in your country?

I do not have practical experience in my country of such agreements. Are you referring to bioprospecting agreements?. Those I know. Please let me know if you want to further on my answer if that is the case.

3. Does industrial or academic research on genetic resources contribute to, or hinder, the conservation of genetic or other biological resources? If so, how? Does this vary with the sector involved (e.g. pharmaceutical, agricultural, chemical, cosmetic, or horticultural?)

The trend of industrial and in a very high percentage academic research is contributing to hinder genetic and other biological resources because they are promoting preeminently "modern biotechnologies" for the sake of an industrialized agriculture, homogeneous by nature, with patented technologies and seeds, putting out of the game to small and medium farmers. We have undergone the experience of the Green Revolution with its hybrids set forth as a supposed answer for hunger, but...did that work?. Of course not. The social gap and the environmental problems especially genetic erosion grew enormously since its launching. Unfortunately, public research at our universities is without budget and scientist are easily convinced to accept some money by private companies to make the first stages—not the leading edge technologies--[369] of GE or biochemical investigations for the sake of industrial agriculture or pharmaceutical companies, instead of working towards the solution of our own problems, it is to say, the problems of small and medium scale farmers.

Answering your last question. I think that this trend in research does not vary in general terms. I could only say that the more sophisticated the research process is, the more our countries loose its control as I explained in the case of "scientific maquila". In the case of agriculture or horticulture, if research is oriented to solve the needs of small and medium farmers, it could be different.

4. Do you think traditional knowledge has a contribution to make towards *in-situ* conservation of genetic resources? If yes, in what way?

I do not only think; it is a fact. To answer briefly, I remit you to the Web page of GRAIN: www.grain.org, where you can find eighty experiences coming from Latin America, Asia and Africa, that prove this. These eighty experiences, are only few examples of what grass roots people are doing by themselves all over the world, working with very limited resources and totally abandoned by their respective governments and local scientists whot have decided to play in the big leagues of the globalization game ignoring the needs of their peoples.

In these examples you can see how to preserve biodiversity you must also help to preserve the diversity of cultures and ecosystems, which modern biotechnology backed up by IPRs ignore.

5. Do you think that the legal recognition of community intellectual property rights over traditional knowledge can provide incentives for conservation of

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[369] In Latin America we call this type of collaboration: scientific "maquila". Maquila is a word taken from industry that is performed by parts. For instance in clothings, one country make the fabric, one cuts the shirts, another one sew the parts, and so forth. The problem

genetic or other biological resources? Please be specific in your answers regarding the types of incentives.

In our grass roots´ workshops and other seminars we have decided no to speak of "property rights" in relation with community or collective intellectual rights because that idea conveys us into the language and connotations of individual ownership which in the case of knowledge in general does not apply at all. Once I have said that, I want to stress that this idea of legal recognition, even though it could be a sign of good will, is a western trend which at the end would bring local people to play with the rules of a game set already by the WTO, UPOV or WIPO under conditions where they will not be able to compete or with technologies impossible to accept.

On the other hand, local communities and indigenous people have never needed this type of "incentives", which I would not call as such, to work for the conservation of genetic and other biological resources. It was because of the industrial agriculture, including hybrids and now GE seeds, the imposition of patents on life forms, the so called modernization of our countries, the building of big dams and roads that those communities started to loose their culture and resources.

I know that, as things are now, unjustice is very clear. Take for instance the recently approved Treaty of the Seed at FAO: local knowledge and plant genetic resources in the multilateral system are free "in the form received", but once a company introduces a small change to a seed, or takes a gene from one and places it in a different organism, then, it belongs to the company and can patent it. If we really want to help people, nature and all of us included, we need to fight among other things for a world without suicide technologies, proprietary technologies and seeds, and hands out of health and food resources as matters of exorbitant commerce in the hands of few transnational corporations.

6. What specific rules relating to intellectual property -- such as prior informed consent from the country or community of origin -- could help ensure that local and traditional communities effectively conserve genetic resources? Can you provide any examples of where these rules have been applied?

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is that there is no technology transfer in this process since each partner does not even know what they are really doing, it is to say, they do not control the whole process.

As you have noticed, I do not favour intellectual property in these issues. Mechanisms of "prior informed consent" to let people accept some contracts by which companies will keep IPRs over eventual products coming from local samples in change of company´s promise to transfer the community 0.2% of eventual royalties in 10, 12 or more years, is not a way to help communities to effectively conserve genetic resources. I can now remember Shaman Pharmaceutical deal with one Amazonian community—only one, the rest of the Confederation were not part of the contract even though they have the same ecosystems and resources--. Shaman payed some salaries, gave them a cow, and promised some royalties. The company dissolved some years later and the promises could not be kept.

7. Do you think the current law on intellectual property rights on biological innovations inherently conflict with the effective protection of traditional knowledge of indigenous and local communities? Can you provide any specific examples where this may have occurred?

Yes. I think that I gave the answer to this question in number 5, including the example of FAO multilateral system, where resources are free "in the form received" but not afterwards. We in Costa Rica have also felt the pressures given during the CDB/ COPs. In brief, we have two important conditions within the CDB: biodiverse countries should let researchers and companies come in and take what they want, once they comply with certain rules of access, that are not really still set in place in the majority of countries, provided that IPRs will be handed to industries, normally foreign. The second condition is for industrialized countries. They should facilitated technology transfer to biodiverse countries, but.... in this case, we need to pay for it at high standards because the majority of cases this is proprietary technology. As a matter of fact, we also know that these companies will never transfer to us leading edge technology....

Conditions as you can see, do not speak of "fair and equitable" deals. The rules for intellectual property rights, it is to say the control of knowledge and resources, are always on the side of industrialized countries.

8. Do you have any experience with *sui generis* systems for intellectual property rights over genetic or other biological resources? If so, how would you assess their impact on conservation, research and equity?

In Costa Rica indigenous peoples and local communities have just started a process to discuss the *sui generis* system for intellectual community rights, but it is just starting and I can not asses their impact on conservation, research and equity. They are also certain that they do not want this system as a part of TRIPs or under UPOV rules.

9. Are there any non-governmental initiatives in your country that aim at ensuring that intellectual property rights enhance the conservation of genetic resources? Do you consider them to be effective?

No. There are non-governmental initiatives to fight them because they are not at all an answer neither to enhance the conservation of genetic resources, nor for food and health sovereigny.

Answering your second question, I would consider that position not only non effective but a contradiction

10. Do you have any recommendations on how intellectual property law at the national or international levels can be improved to enhance the conservation of genetic resources?

There are laws at the national and international level in this regard that are totally incorrectly based. I mean, they are the negation of biodiversity conservation and cultural conservation. If that is the case, I can not recommend to make certain patches on them. My recommendation is to enhance a type of public research and grant awards to scientists and enterprises that really make contributions to the environment and to social justice but without granting them monopolic rights to control the basic principles of life, such as the reproductive characteristic, or to become owners of the genetic design of living organisms, just for the sake of business needs.

Research to look for new medicines and new agricultural products should not be based on monopoly rights granted to the most industialized countries and leaving biodiverse countries without the control of their own resources especially when we are speaking of food and health.

Peru

(Reply by: Mr. Ing. Eduardo Caballero, IRENA/Natural Resource Office)

Ruego disculpe la demora en darle respuesta a su cuestionario, tal vez sean ya extemporaneos mis comentarios ,motivos de viaje y otros no permitieron hacerlo antes, disculpe tambien que lo haga en español que para mi es mas comodo.

1.-

Los derechos de propiedad intelectual sobre las invenciones biotecnologicas son basados en la utilizaciòn de recursos

geneticos y deberia existir tambien el derecho al uso del recurso genetico. La conservaciòn de los recursos geneticos y/o recursos biologicos que los contienen solo serà posible si quien los provee participa de los beneficios obtenidos por ese derecho de propiedad del que lo posee. Cuando se obtienen via Biopirateria no hay lugar a una participaciòn justa y equitativa de los beneficios y por tanto no hay lugar para pensar en protecciòn alguna.

2.-

Nuestro Pais cuenta con un instrumento juridico vinculante, aprobado en el marco de la Comision Andina de Naciones, la Decision 391 "Regimen de Acceso a los Recursos Geneticos" y su Reglamento que està actualmente en vias de su aprobaciòn por el Gobierno. Con este instrumento y a traves de contratos de acceso o acuerdos de transferencia podremos establecer regulacion al acceso y obtener previa negociaciòn incentivos que permitiran entre otros la conservaciòn de nuestros recursos geneticos.

3.-

Las investigaciones pùblicas o privadas con recursos geneticos, llamese ingenieria genetica o biotecnologia buscan la obtenciòn de nuevos productos "beneficiosos" para la humanidad, sinembargo cuando nos referimos a transgenicos de uso agricola y su vinculaciòn con la conservaciòn de los recursos geneticos deben ser cuidadosamente analizados en particular cuando se trata de paises poseedores de recursos nativos y que son centros de origen como es el caso de nuestro pais.

Mientras no se tenga la evidencia de su inocuidad al ambiente (Flora silvestre parientes de los cultivados) su uso de ser evitado.

4.-

Los conocimientos colectivos tradicionales de nuestras comunidades no solamente son aquellos relacionados al uso de sus recursos sino tambien al entorno donde se encuentran los recursos que les han permitido a travès de miles de años ir obteniendo mejoras en sus variedades y por tanto bancos de conservaciòn in situ de especies silvestres afines a las cultivadas.

5.-

El reconocimiento legal a los derechos de propiedad intelectual de los conocimientos tradicionales podrà proporcionar incentivos a las comunidades poseedoras de los conocimientos para la conservaciòn de sus propios recursos geneticos, dichos incentivos pueden ser de diversa naturaleza: intercambio de informaciòn, acceso a la tecnologia y su transferencia, fomento de sus capacidades y la distribuciòn equitativa de los beneficios economicos que se obtengan de los mismos.

6.-

Ademas del consentimiento informado previo a las comunidades poseedoras de los recursos geneticos, estas deben ser participes de una distribuciòn justa y equitativa de los beneficios derivados de la utilizaciòn de sus conocimientos colectivos.La Decisiòn 391 incorpora en el contrato de acceso a los recursos geneticos un anexo como parte integrante del mismo donde se prevee la distribucion justa y equitativa del componente intangible. Por otro lado en el Perù se viene trabajando en un Regimen de protecciòn de los conocimientos colectivos de los pueblos indigenas ,amazonicos y afroamericanos donde la Autoridad Nacional Competente protegerà los intereses de las comunidades o pueblos indigenas que hayan registrado sus conocimientos

8.-

En el Peru no tenemos experiencia de la aplicaciòn de un sistema sui generis de derechos de propiedad intelectual sobre los recursos geneticos.

9.-

Existen algunas aunque aùn no se cristalizan.

10.-

Evitar la Biopirateria.

Creacion de un sistema sui generis que proteja la soberania nacional sobre los recursos geneticos, proteja los conocimientos, innovaciones y practicas tradicionales. Desarrollando sistemas de registros nacionales y regionales con el fin de proteger los derechos de los paises o comunidades sobre los recursos geneticos y/o conocimientos tradicionales. Exigiendo que al solicitarse una licencia para la utilizaciòn de un recurso genetico se presente el permiso correspondiente del proveedor del mismo.

10.2 Companies

10.2.1 Botanical

(Reply by: Mr. Pedro Vincente Azua, European Federation of Associatzions of Health Product Manufacturers)

1. Do you agree with the claim that awarding intellectual property rights over biotechnological inventions can undermine the conservation of genetic or biological resources?

2.

   I totally agree.

3. Does your company ever require substantial amounts of genetic resources for the research and development of any of your products?

   No

4. If yes, how do you organise the supply of genetic resources?

5. If you organise the supply of genetic resources through collectors or other in-country agencies in developing countries, what steps, if any, does your company take to inform yourself about the sustainability of such collections in source nations?

6. How can national legislation mitigate tendencies that might undermine the conservation of genetic resources by collectors or user firms, which may occur as a result of the potential commercial value associated with these resources?

Companies dealing with conservation and biotechnological inventions should be public companies and never private firms.

7. Can other mechanisms, such as contractual arrangements, be more effective than legislation in generating such incentives for conserving genetic resources?

Does your company have any experience in this regard? NO

8. Can intellectual property rights over biological innovations promote the conservation and sustainable use of biological and genetic resources?

NO Can you provide any specific examples where this can be the case? Look at how private companies work: everything is based on financial benefit and NEVER on human wellbeing.

10.2.2 Pharaceutical

(Reply by: Mr. Philip Grubb, Novartis Group (Switzerland)

1. Do you agree with the claim that awarding intellectual property rights over biotechnological inventions can undermine the conservation of genetic or biological resources?

No. This "claim" appears to be based on the argument "If it is patented, it must be useful, if it is useful, it will be used, if it is used, it cannot be conserved." The CBD encourages sustainable use of such resources, and patenting inventions contributes to the aim.

2 Does your company ever require substantial amounts of genetic resources for selection, pre-clinical and clinical trials for any of your products?

If by "genetic resources" you mean natural products such as extracts from plants or microorganisms, yes, we do sometimes use such resources in early stage screening. Any active material found in this was would normally then be synthesised, so that further quantities would be unlikely to be required for pre-clinical and clinical testing.

3. If yes, how do you organise the supply of genetic resources?

Either by purchase of existing natural product libraries, or by agreements with universities, etc. in developing countries.

4. If you organise the supply of genetic resources through collectors or other in-country agencies in developing countries, what steps, if any, does your company take to inform yourself about the sustainability of such collections in source nations?

Sustainability has never been an issue, as the quantities required have never been large.

5. How can national legislation mitigate tendencies that might undermine the conservation of genetic resources by collectors or user firms, which may occur as a result of the potential commercial value associated with these resources?

Really, this is a non-issue! The real threats to conservation of genetic resources (i.e. to biodiversity) are associated with changes in land use due to agriculture and human population growth. Any effect due to collection of material for pharmaceutical screening is trivial in comparison. States party to the CBD are supposed to promote conservation by legislation and other means, but proposed legislation in India, for example, seems more concerned with blocking possible use and preventing patenting than in doing anything useful.

6. Can other mechanisms, such as contractual arrangements, be more effective than legislation in generating such incentives for conserving genetic resources? Does your company have any experience in this regard?

Contracts can give incentives, for example by providing for payments to local conservation agencies. We have had some experience in this area.

7. Can intellectual property rights over biological innovations promote the conservation and sustainable use of biological and genetic resources? Can you provide any specific examples where this can be the case?

As already mentioned, in the normal situation sustainability is not an issue. Once access to the genetic resources has been given under the CBD, it is usually not necessary to have continued supplies, since microorganisms can be cultured and naturally occurring compounds can be derivatized and synthesized in most cases.

Patenting is more of an issue as regards benefit sharing, since without patents there will be no commercial products, and without commercial products there will be no benefits to share.

11 Summary

The following represents the main findings and recommendations of this study.

11.1 Main Findings

- There can be several negative effects of biotechnology on conservation and sustainable use of genetic resources. Although one could argue that to the extent IPRs stimulate such research, they are responsible for it, a closer look at the process and the causative factors reveals that the link between IPRs and the harmful impact on sustainable use and conservation of genetic resources is indirect.

- To deal with the impacts of intellectual property rights on conservation and sustainable use of genetic resources, in the case of the pharmaceutical and botanical sectors, national biodiversity regimes ought to be strengthened. In the case of agricultural and horticultural sectors, the issue is one of biosafety and regulatory environment on protection of plant varieties should be designed in such a way that all risks are taken into account.

- The positive effects of intellectual property rights on biotechnology – whether it is the impact of biotechnology in better understanding disease causation and cures or the potential of agricultural biotechnology in creating plant varieties that cater to the needs of developing countries – do not flow automatically. Additional measures are needed to leverage these.

- The potential of intellectual property rights to stimulate research that serves the needs of developing countries depends largely on two main factors. The spillover effects of patents on biotechnological R & D on commercial sectors in the developing countries leading to learning processes and secondly, more direct R & D investment in areas of relevance for developing countries. They will need to be leveraged by other policy measures.

- A community intellectual property right is only one instrument in a larger package of incentives to promote in-situ conservation and sustainable use of genetic resources. A hybrid incentive instrument is required to capture traditional ecological knowledge of local and indigenous communities of importance for in-situ conservation and to rectify the distortions introduced by community intellectual property rights and commercialization of traditional knowledge components.

- The best hybrid incentive instrument to promote in-situ conservation of genetic resources by local and indigenous communities is a combination of a community intellectual property right, community property resource management and supportive regulation.

11.2 Recommendations

- The review of Art. 27(3)(b) should result in a consensus that the provisions of the CBD should be taken into account while devising protection over life forms. In the absence of this, the TRIPS Council should ensure that the review of Art. 27(3)(b) does not result in reducing the limited flexibility that now exists in Art. 27.

- In its effort to clarify the relationship between IPRs and the conservation of genetic resources, the CBD COP should leverage further case studies in all relevant economic sectors, so as to increase the knowledge base. Among the key mechanisms the COP should continue to focus on are those aimed at giving effect to the prior informed consent requirements. Further examination of the legality and practicality of various options, including an international system of certification and contractual clauses should be conducted.

- The Working Group on Art. 8(j) should focus upon clarifying the inter-relationship of traditional ecological knowledge and intellectual property rights on traditional knowledge.

- The adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture represents an important step forward in ensuring appropriate access and benefit sharing in respect of plant genetic resources for food and agriculture. The Multilateral System presents an important opportunity to ensure that all countries are provided access to important varieties. IPRs may otherwise have hindered this access or it would have taken place without appropriate sharing of benefits.

- All countries should review their IPR application process to ensure that it supports the conservation of genetic resources. The review should seek to make maximum and strategic use of the IPR law, including its scope for limitations and exceptions, so as to ensure that national and international conservation and development objectives are met.

- All countries should consider implementing a requirement that supports prior informed consent and disclosure of the source of origin as part of the patent application process for inventions involving genetic resources. More research is needed on assessing the actual effectiveness of these measures in enhancing benefit sharing and conservation.

- Traditional and local communities must become proactively engaged in efforts to control their ecological knowledge. They should develop a strategic and holistic approach to protecting their knowledge, which also involves pursuing a wider array of rights, like land rights.