

Intellectual Property Rights and Biodiversity: Processes and Synergies

**Background paper¹ for
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1 Introduction

Of the many issues contained in the *Convention on Biological Diversity* (CBD, 1992), the relationships between intellectual property rights (IPRs, especially as part of the *Agreement on Trade Related Aspects of Intellectual Property Rights*, TRIPs) and biodiversity, particularly in regards to access to genetic resources and benefit sharing (ABS) and traditional knowledge (TK), have been, arguably, the most persistent, controversial, expanding, creative, productive and interesting over the past few years.

Finding technical, policy and legal solutions that ensure complementarity and positive synergies between IPRs, ABS, and TK issues remains a key component of the agendas of international, regional and national processes and organizations. Some countries have already enacted specific legislation on these closely related matters.

The main purpose of this paper is to provide with a brief overview of key processes where discussions on protecting TK, development of IPR policy, and linkages to IPRs are taking place (including the main components of the debates) and to assess the most critical substantial issues. In this regard, CBD, WIPO and WTO are the most important intergovernmental forums for policy making.

This document does not make a detailed and comprehensive analysis of all processes and issues. However, it is intended to assist readers in understanding some of the more important and salient points and having a clear “picture” of the progress being made in the policy and legislative fronts. References are included for further detailed reading and, where available, web sites are also pointed out in order to provide easy and immediate access to more detailed information and documents.

2 The foundations for the continued debate on intellectual property rights (IPRs) and biodiversity

Discussions related to IPRs and biodiversity can be organised into three fundamental “issues”: a) property and control of genetic resources, b) impacts of IPRs on conservation and c) benefit sharing

from access to these resources (and related TK). Policy and legal questions are basically associated to these issues.

2.1 Property and control

Historically, two very distinct phases or periods can be considered. A pre CBD period, when due to unquestioned international practices, genetic resources in general were considered to be part of a common heritage of mankind and deemed to belong to everyone and no one at the same time. This principle – recognised in international law as part of the 1983 FAO *International Undertaking on Plant Genetic Resources* (see footnote 4) – helps explain the free, unregulated flows of biological riches and genetic resources from continent to continent².

Until 1992, when the CBD was adopted, the flow of and trade in biological materials worldwide was generally and for all purposes, an uneventful occurrence, governed by international trade rules and practices (including trade treaties); phytosanitary measures in some cases ; CITES regulations) and, at the national level, by scientific research, collection and export (import) permits. During the pre CBD period, administrative and legal requirements were a significant burden only in the very worst of and exceptional cases, and mainly in the context of scientific research.

However, the recognition of the economic, ecological, policy and cultural importance of genetic resources and biological derived materials as such, particularly since the adoption and entry into force of the CBD (1993), mostly but not exclusively associated to their use in biotechnological applications, has given place to a new scenario where sovereignty, property and control concerns have paved the way to new conceptual and practical policy and legal questions, dimensions and challenges. The “biologically poor but industrialised and technologically rich North, *vis a vis*, the biologically rich but technologically poor South” paradigm, has contributed significantly to shape this new scenario. In this new context, evidence seems to suggest administrative and practical burdens to carry out scientific research are now the norm.

² To better understand the details of the historical movement of biological and genetic resources throughout the world see : Hobhouse, H. 1992. *Seeds of Change : Five Plants that Transformed Mankind*. Papermac. MacMillan, London.

2.2 The impacts of IPRs on biodiversity

This has also been the subject of intense debates among countries and commentators. Although reliable data and information has been produced regarding the social and economic impacts and importance of IPRs in developing countries³, limited information actually exists regarding impacts of IPRs on conservation and sustainable use of biodiversity *per se*.

One verified impact of IPRs (specifically patents) on the principle of sovereign rights of countries over their genetic resources and to some degree on sustainable use (not directly on conservation *per se*), has been the direct and indirect misappropriation of biological and genetic resources and traditional knowledge^{4 5} or what has been called “biopiracy”. Arguments regarding the negative impacts of IPRs (including plant breeders rights - PBRs) over biodiversity conservation, specifically in the area of agrobiodiversity, also point out to: a tendency to homogenize agricultural diversity; displacement of native and traditional crops ; restriction to exports of traditional medicinal plants (thereby impacting *in situ* conservation efforts); restrictions on saving, using and selling farm saved seeds by small farmers and indigenous communities, among others.

Futhermore, patents have been critiqued as legitimising “biopiracy”, enhancing the concentration of research and development capacities in hands of private sector conglomerates (usually involving

³ Despite this, however, a recent study by Sanjaya Lall demonstrates that it is not possible to generalise a conclusion regarding social and economic impacts of IPRs in developing countries. These impacts will vary considerably depending on the structure of economic activities; technological activities; competitive industrial capacities ; technology imports ; skills and ICT infrastructure, among others. The study concludes that flexibility provided by the TRIPs Agreement should be fully exploited to encourage development and allow for longer periods for adjustment. See : Sanjaya Lall. *Indicators of the Relative Importance of IPRs in Developing Countries*. Draft. UNCTAD / ICTSD Capacity Building Project on IPR and Sustainable Development. November, 2001. Impacts on biodiversity conservation and sustainable use *per se*, might also depend on these and other specific features of countries (e.g. agricultural system structure; social and economic dynamics of indigenous populations, etc.).

⁴ Multiple examples of “biopiracy” throughout the world through the use of the patent system have been documented. A recent study on a Peruvian native crop (*Lepidium meyeri*) and patents granted in the US (and pending in Europe) demonstrates clearly how this misappropriation takes place. For a detailed review of this case see : WIPO/GRTKF/IC/5/13. Patents referring to *Lepidium meyeri* (Maca) : Responses from Peru. A Document Submitted by the Delegation of Peru. May, 2003. Online at : <http://www.wipo.int/globalissues/igc/documents/index.html>

⁵ For other specific cases where sovereign rights of countries and traditional knowledge have been affected see : Dutfield, G. 2000. *Intellectual Property Rights, Trade and Biodiversity*. IUCN, Earthscan Publications Ltd. London. Chapter, 5. Similarly, the ETC Group web site (<http://etc.org>) offers abundant information referring to cases where they have identified “biopiracy” and where indigenous peoples rights over their knowledge and countries sovereign rights over their biological and genetic resources have been affected.

biotechnology companies, universities, research institutions) or dependent on private sector funds, promote widening of the technology gaps between North and South, limit availability of research materials, etc.

The CBD has specifically recognised the complex and controversial relationship between IPRs and biodiversity (articles 15,16,19)⁶. Article 16(5) is particularly relevant in the sense that Contracting Parties “[...] recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate 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”. It is these influences (positive or negative impacts) on the CBD objectives (article 1, Objective: conservation, sustainable use and benefit sharing) which are being explored and analysed in various international forums (see Sections 5 and 6)).

2.3 Benefit sharing

Finally, the use and economic exploitation of genetic resources (and related TK) has brought a wide range of benefits to developing and developed countries alike, including economic benefits⁷. Biotechnology and non-biotechnology developments over the past two decades have contributed significantly to the generation of these benefits. At the same time, however, these developments have also exacerbated debates over the control of biological and genetic resources and use of IPRs over biological and genetic materials (and their derived products) on which biotechnology relies to continually progress. The main challenge to be confronted in implementing the ABS principles under the CBD is to determine how the benefits (in terms of sharing research results, capacity building, monetary income, IPRs, etc.) are to be effectively shared (among users and providers of these materials).

⁶ It should be noted that debates during CBD negotiation and at present, in many ways mirror concerns addressed in the early 80's when similar issues were being discussed in the context of the FAO *International Undertaking on Plant Genetic Resources*. The strengthening of the international IPR system (through TRIPs) and, especially, technological developments in biotechnology and genetic engineering, have added additional elements to the debate. For a detailed review of these discussions and the FAO International Undertaking process see : Pistorius, R. 1997. *Scientists, Plants and Politics. A History of the Plant Genetic Resources Movement*. IPGRI, Rome.

⁷ For an analysis of the benefits generated by genetic resources see: Ten Kate, K and Laird, S. 1999. *The Commercial Use of Biodiversity: Access and Benefit Sharing*. Earthscan, London.

New industrial sectors (e.g. nutraceuticals, cosmetics, genetherapy, crop protection, biorremediation, etc.) have all opened new possibilities for generating substantial economic benefits. These possibilities highlight the need for new options on the participation in these benefits by those countries which, at some point in time, have contributed to the material wealth of these sectors (through their genetic resources and derived biological materials).

3 National and international regimes on access to genetic resources and the fair and equitable sharing of benefits

Indirect or direct appropriation of genetic resources (or products containing genetic resources or biologically derived materials, including synthesised products), especially through patents and plant breeders rights - PBRs, is, as mentioned previously, one of the main reasons why ABS principles and rules were incorporated in the CBD as part of the great political “bargain” between developed (biologically poor) and developing countries (biologically rich). As a result, ABS regulations seek to ensure that access to biological and genetic resources is subject to certain conditions (sovereignty, mutually agreed terms, prior informed consent), which guarantee that benefits derived from the use of these resources are fairly and equitably shared among the user and the country providing them (based on articles 1, 15.4 and 5 of the CBD).

3.1 National and regional developments

Numerous countries have either adopted (or are in the process of developing) ABS policies and legislation⁸. Examples include the Andean Community of Nations – Venezuela, Colombia, Ecuador, Peru, and Bolivia - (*Common Regime on Access to Genetic Resources*, 1996); the Organization of African Unity – 53 countries – (*African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources*, 1998); the Philippines (Executive Order 247, *Prescribing Guidelines and Determining a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By Products and Derivatives, for Scientific and Commercial Purposes and Other Purposes*, 1996); Brazil (Medida Provisoria 2.186-16 *on access to genetic resources and traditional knowledge*, 2001) ; Nepal (*Draft*

⁸ In 1998, Glowka estimated that over 50 countries were in the process of developing their ABS policies and legislation. Glowka, L. 1998. A Guide to Designing Legal Frameworks to For a review of the actual texts of many ABS laws and policies see : <http://www.grain.org>

Policy on Access to Genetic Resources and Benefit Sharing, 2001) ; Costa Rica (*Biodiversity Law*, Law 7788, 1998); Bhutan (*Biodiversity Act of Bhutan*, 2003).

Common elements and features in these different instruments include: some general provisions (including scope, exceptions, etc.); the type of contracts, permits or authorizations through which access is permitted; the conditions under which access could be allowed; the stages and structure of an administrative procedure ; the recognition of a national competent authority ; and references to IPR and traditional knowledge.

Prior informed consent (PIC) procedures are especially critical and their features vary according to different countries. In some cases, PIC is provided by a national representative organization (e.g. Peru); in others PIC will be attained through traditional decision-making processes among indigenous peoples (e.g. Panama).

3.2 The Bonn Guidelines

The *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (COP Decision VI/24), as proposed by the Ad Hoc Open Ended Working Group on Access and Benefit Sharing⁹, are a set of voluntary, non binding guidelines targeted at assisting countries in the implementation of CBD provisions on ABS, and which include provisions on IPRs and TK. The Guidelines are to serve as an input to national (and international) ABS policy, administrative and legal processes.

The Bonn Guidelines include:¹⁰

- ❑ General provisions
- ❑ Roles and responsibilities in access and benefit sharing pursuant to article 15 of the CBD
- ❑ Participation of stakeholders
- ❑ Steps in the ABS process
- ❑ Other provisions (incentives, accountability, monitoring and reporting, dispute settlement, remedies).

⁹ See UNEP/CBD/COP/6/6

¹⁰ For the complete text of the Bonn Guidelines see: <http://www.biodiv.org/decisions>

As well as:

- ❑ Appendix I Suggested elements for Material Transfer Agreements
- ❑ Appendix II Monetary and non monetary benefits
- ❑ Annex Draft Elements for an Action Plan for Capacity Building for ABS

Much of the Guidelines derive from existing examples of policies, laws, regulations (including drafts) regarding ABS as well as from results of CBD, WIPO, WTO and other governmental and non-governmental related discussions.

Three sections are particularly relevant for the purpose of this study:

3.2.1 Users and providers of genetic resources

Section II (Roles and responsibilities), C Responsibilities, paragraphs 16 – 17 addresses the possible roles of providers and *users* of genetic resources. For the first time in the CBD context, there is an explicit, agreed reference to the need for users of genetic resources – particularly in the case of developed countries with biotechnological capacities, traditionally making use of genetic resources for research and development – to adopt measures that ensure that the interests of *providing* countries are duly respected and considered. This includes adoption of measures that ensure PIC has been provided for the use of resources (16.b. i – ix) and measures to encourage disclosure of origin in IPR applications (16.d.ii). Not only do countries of origin have the right to regulate on ABS, but now, under the Bonn Guidelines, countries in which these resources are used should adopt certain actions to assist in the implementation of the CBD ABS principles and complement regulatory actions by providing countries¹¹.

3.2.2 PIC and MAT

Sections IV. c) and d) address Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) respectively. These are the key conditions recognised by the CBD to facilitate legitimate access to

¹¹ The simple rationale behind this approach is that given the difficulties in effectively controlling and monitoring from a source country the use being given to genetic resources accessed in their territories, the countries where these resources are being used must contribute in ensuring the objectives of the CBD (including benefit sharing) are met. This implies taking actions to assist and support and complement national regulatory efforts (through policy, law or other measures).

genetic resources and, ultimately, to trigger benefit sharing possibilities. Legal certainty in regards to a national competent authority is critical to ensure appropriate operation of any ABS legal regime. But, depending on national legislation, PIC and MAT may also be required at different levels (e.g. when accessing indigenous peoples or private lands). PIC and MAT from indigenous peoples is a particularly controversial issue, mainly because of shared resources (and related knowledge). Who is legitimately entitled to consent within indigenous peoples and what is the impact on indigenous peoples who might not directly benefit from this consent or might be opposed to it? Commentarors and even legislation have been unable to offer “satisfactory to all” answers¹².

3.2.3 IPRs

Finally, Annex, Section C (Role of intellectual property rights in the implementation of access and benefit sharing arrangements), paragraphs 1 – 4 and Section D (Other issues related to ABS), paragraphs 1 – 8, specifically refer to IPRs (including TRIPs) and their relation with ABS. Disclosure of origin in patent applications is explicitly encouraged (C.1 and C.2). Furthermore, information gathering and analysis by the CBD Secretariat is requested regarding: impacts of IPR on ABS and scientific research; role of customary law and its relation to IPRs; applicability of disclosure requirement and PIC in the context of international obligations; feasibility of an international certificate of origin system; among others. Lastly, noting the interrelation among the TRIPs Agreement provisions and the CBD, the Secretariat of the CBD is requested to renew its application for observer status in the Council for TRIPs and to follow discussions within the Council and the WTO Committee on Trade and the Environment.

The International ABS regime: Calls for an international legal instrument for regulating ABS have multiplied over the past few years. The *Group of Like Minded Megadiverse Countries* in particular has played a pivotal role in promoting this view (see Section 6) below) and calling for its consideration within CBD, WIPO and other forums. Very simply, national ABS policy and legal

¹² Law 27811 of Peru (*Law for the Protection of Collective Knowledge of Indigenous Peoples*, 2002), offers an interesting but, nevertheless, questionable approach to this problem. PIC and MAT will be provided by an indigenous representative organization (article 14). In the negotiations of access agreements or projects, these representative organizations, will seek to involve the greatest number of communities and organizations (according to customary decision making processes, article 6). Recognizing that decisions will never satisfy all indigenous groups, article 37 establishes a fund for indigenous peoples to which all indigenous communities will have access and be beneficiaries. This is a “second best” solution which, at least, seeks to address benefit sharing in favour of all communities regardless of whether they consented or not to a specific agreement or project. For the complete text of the Law see : <http://www.indecopi.gob.pe>

measures and jurisdictional limitations make control of the flows of genetic resources extremely complicated therefore, international measures are necessary if, ultimately, the objectives of the CBD are to be fully achieved¹³.

The Johannesburg Plan of Implementation (World Summit on Sustainable Development, 2002), upon insistence of the *Group of Like Minded Megadiverse Countries*, explicitly recognised the need for countries to negotiate an international regime on ABS (see Section e) below). Bearing in mind the elements suggested and proposed in the Bonn Guidelines, a specific ABS Protocol to the CBD may be an option through which operationalize this regime. Focusing on obligations and compromises from countries which utilize genetic resources and harmonizing national procedures in providing countries could pave the way for an effective international instrument on ABS.

Another possibility for an international regime may be for Contracting Parties to agree on specific adjustments to national laws and regulations (in user and provider countries) as a means to facilitate the realization of the benefit sharing objectives of the CBD. This option might not require the negotiation of an international instrument *per se* but, rather, an agreement (maybe a COP Decision – with prior guidance from SBSTTA or the Panel of Experts on ABS) through which these legislative changes could be materialized at the national level but having an overall impact in ensuring an equitable sharing of benefits from the flows of genetic resources worldwide.

4 The protection of traditional knowledge (TK)

The FAO International Undertaking process in the early 80's and the CBD process in the early 90's, both highlighted the critical importance of indigenous and local communities' traditional knowledge for the conservation and sustainable use of biodiversity in general. Annex II, FAO Resolution 5/89 of 1989 recognized and internationally established Farmers Rights, as the rights arising from past, present and future contributions by farmers to the conservation and maintenance of plant genetic resources for food and agriculture (PGRFA) ¹⁴, explicitly recognising the value and importance of farmers (communities') knowledge, innovations and practices related to PGRFA.

¹³ For additional details on the proposed international regime see : *International Regime on Access to Genetic Resources and Benefit Sharing* . Note by the Secretariat . UNEP/CBD/MYPOW/6 (Meeting of the Ad Hoc Open Ended Working Group on ABS – 2003).

Building upon and progressing from the FAO debate, article 8(j) of the CBD has specifically determined that subject to national legislation, Contracting Parties should “[...] *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 fair and equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices*”.

Arguably, article 8(j) – in conjunction with article 15 - has been the trigger for setting up non CBD processes addressing the protection of TK¹⁵. Furthermore, evidence and studies suggesting traditional IPR instruments (patents, PBRs, trademarks, etc.) are, in most cases, intrinsically inadequate to safeguard indigenous peoples interest and rights regarding traditional knowledge, have also contributed to these initiatives.

Most noticeably, the *World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF)* was created¹⁶ as a result of CBD articles 8(j) and 15 discussions and by Members of WIPO realizing the convenience of WIPO hosting an intergovernmental forum to discuss IPR, genetic resources, traditional knowledge and folklore related issues.¹⁷ These same issues have been

¹⁴ Article 9 (Farmers Rights) of the *FAO International Treaty on Plant Genetic Resources for Food and Agriculture* (2001) – derived from the previous International Undertaking - establishes that the responsibility for implementing Farmers Rights rests with national governments (article 9.2) and that the protection and promotion of Farmers Rights could include : protection of TK as it relates to plant genetic resources for food and agriculture ; the right to participate in benefits arising from the use of PGRFA; the right to participate in decision making (9.2, a,b,c). Article 9.3 also safeguards the right of farmers to save, use and exchange farm saved seeds subject to national law (this needs to be interpreted in the light of national legislation on PBRs and their Farmers Exemption clauses).

¹⁵ COP Decision IV/9 formally established the *Ad Hoc Open Ended Intersessional Working Group on Implementation of Article 8(j)* with a specific work program and terms of reference for its activities.

¹⁶ WIPOs’ General Assembly, at its Twenty Sixth Session, held in Geneva from September 26 to October 3, 2000 established the GRTKF. Since 2000, five meetings of the Intergovernmental Committee have taken place.

¹⁷ For detailed analysis of the different policy forums where TK is being discussed (and options for the future) see : Vivas-Eugui, D, Ruiz, M and Espinosa, M.E. *International Processes on Genetic Resources and Traditional Knowledge : Options and Negotiation Alternatives*. Informal Background Paper presented during the Fifth Session of the Intergovernmental Committee on GRTKF, Geneva, 2003.

part of agendas of other international organizations (e.g. UNCTAD, UNESCO), regional blocs (e.g. Andean Community, Organization of African Unity), international non governmental organizations (e.g. IUCN), indigenous peoples forums and organizations (e.g. COICA), among many others.

The focus of these forums has basically been to assess : how to legally protect traditional knowledge.

4.1 Positive protection of traditional knowledge: basic elements

In contrast to negative or defensive protection of traditional knowledge^{18 19}, positive protection basically refers to the development of a legal regime which assigns rights to indigenous peoples over access to and use of their TK. Depending on the scope of protection, this could imply: compensating indigenous peoples; establishing an exclusive right to impede use (similar to a patent right) ; maintain traditional knowledge (through databases or registers) or controlling the use of traditional knowledge.

As in the case of genetic resources, the issue at stake is *control* over TK and how to benefit from its use.

Although many countries have taken the first step in the development of draft policy, legal and other measures to assist in the protection of TK - Peru and Panama have specific laws in place (see

¹⁸ Defensive protection of TK basically refers to the use of the IPR system – with additional substantial or procedural requirements - to ensure legitimate and legal granting of rights (over products or processes which might directly or indirectly incorporate TK) with due recognition and consideration for indigenous peoples rights and interests over their TK. Defensive protection is a reaction to patent filing. For further discussion see : CIPR. Commission on Intellectual Property. *Integrating Intellectual Property and Development Policy*. Report of the CIPR. London, September, 2002, Chapter 4. Full text of Report at : <http://www.iprcommission.org> . Another interesting document addressing and analysing defensive protection of TK in the international context and the TRIPs Agreement is : Pires de Carvalho, N. *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*. In : Washington University Journal of Law and Policy, Vol. 2, 2000. See also : Ruiz, M. *The International Debate on Traditional Knowledge as Prior Art in the Patent System : Issues and Options for Developing Countries*. Occasional Papers. TRADE. South Centre, October, 2002.

¹⁹ Defensive protection measures have been raised within WIPO as part of the negotiation of the Substantive Patent Law Treaty and the Patent Cooperation Treaty. They have also been discussed (in terms of the role of data bases on TK to support patent searches – within the WIPO Standing Committee on Information Technology (see documents SCTI/3/2 Item 7.2; SCTI/4/2 Annex II, SCTI/4/8), the WIPO Standing Committee on the Law of Patents and the WIPO Committee of Experts of the Special Union for International Patent Classification Union (for details see : WIPO/GRTKF/IGC/3/5).

Section 5) – it already seems necessary to consider the limitations of national jurisdictions in the protection of TK and thereby to discuss possible international options, including an international *sui generis* regime. Just as human inventiveness in arts and sciences is recognised and rewarded through the international IPR system (which sets the basic standards of protection through TRIPs and other international agreements on intellectual property), the informal or indigenous expressions of inventiveness and creativeness require a specific mechanism tailored to their own practical needs and specificities (e.g. a collective created process in many cases; wide ranging distribution of certain knowledge and practices ; isolation and marginalization ; etc).

This international regime will probably, if negotiated, include a combination of defensive protection measures with positive protection principles and rules. Furthermore linkages and synergies with ABS practices should be carefully determined.

If a policy and legislative process is to be undertaken (whether at the national or international level) there are a set of key questions which might need to be responded as the process progresses. These questions could include:

- What is the objective of the protection regime? Protect, compensate, maintain TK ?
- What is the protectable subject matter?
- How will TK in the public domain be reasonably protected?
- What rights are granted and what are their exact scope?
- Who are (or could be) legitimate holders of these rights?
- How will the PIC process (for access to and use of TK) be regulated?
- How will concerns of communities which share TK be taken into account in the context of the granting of rights?
- How can a practical administrative procedure be designed which recognises marginalization (including limited access to technology, urban areas, legal advice, etc.) of many indigenous peoples and their communities?
- How will the right (s) be enforced?

Although among indigenous peoples there are a wide range of views regarding the specific technical content of a protection regime (which the questions mentioned before could help to design), a common and permanently expressed view of indigenous peoples in national, regional and

international forums is *the need to develop legal mechanisms to protect TK including through the use of a sui generis system*²⁰.

4.2 Some advances in national policy and legislation:

Various countries have adopted specific legislation and policies for the protection of TK. Some have included positive and defensive protection within their ABS legislation (Brazil, Medida Provisoria 2,126-8 (2001)); others have used general biodiversity laws (Law 7788, Costa Rica) and others have developed specific legislation on TK (Law 27811, Peru; *Law No. 20 on a Protection Regime for the Collective Knowledge of Indigenous Peoples*, Panama (2002)). The Andean Community has established defensive protection in *Decision 486 on a Common Regime on Industrial Property* (2001). In India, recent PBR legislation (*Protection of Plant Varieties and Farmers Rights Act, 2001*) has incorporated provisions for the protection of native crops and varieties (based on TK and innovation – *Farmers Varieties*). In other cases, it has been *institutions* which have developed tools and mechanisms (usually TK registers or databases) designed to protect indigenous peoples and local communities TK (Biozulua Data Base in Venezuela managed by the Fundación para el Desarrollo de las Ciencias Físicas, Matemáticas y Naturales (FUDECI); Peoples Biodiversity Registers in India managed by the Indian Institute of Science ; Registro Local de Biodiversidad y Conocimientos Locales by Asociación Andes in Peru; among others).

These different regulations and mechanisms serve different purposes according to the meaning and scope given to the concept of “protection”.

5 Developments within the TRIPs Agreement, CBD, and WIPO

²⁰ Some of the most important indigenous peoples forums which have expressed this need and aspiration include but are not limited to : Declaration of Principles of the World Council of Indigenous Peoples (1984), Melaka Accord : Towards the development of legislation to protect biodiversity (1994), Kari Oca Declaration and the Indigenous Peoples’ Earth Charter (1992), Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (1993), Santa Cruz Declaration (1994), Sabah Declaration (UNDP consultation on the protection and conservation of TK)(1995), International Alliance of Indigenous Tribal Peoples’ of the Tropical Forest : te Biodiversity Convention – the Concerns of Indigenous Peoples (1996), Second International Indigenous Forum on Biodiversity (1997), Indigenous Biodiversity Forum (2002). For a detailed review of different issues related to the biodiversity and IPR debate see : Laird, Sarah (Ed.). 2002. *Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice*. WWF, UNESCO, Royal Botanic Gardens Kew. Earthscan Publications Ltd. London, Sterling, VA.

5.1 TRIPs Agreement

The *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPs Agreement) of the *World Trade Organization* (WTO) (1984) establishes minimum international standards for the protection (availability, scope, use and enforcement) of IPRs (including patents) and is backed by the proven effective WTO's dispute resolution mechanism. The TRIPs Council within WTO is, in general terms, responsible for evaluating overall implementation and progress of the TRIPs Agreement.

Key to discussions mentioned in Section a) above, is article 27.1 of TRIPs which provides that “*[...] 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 [...]*”. Article 27.2 on the other hand envisages that certain inventions can be excluded by Members (of WTO) from patentability in order to protect “*[...] ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment [...]*”. In this regard, article 27.3. b permits Members to exclude from patentability “*[...] plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non biological or microbiological processes*”. However, this provision also stipulates that Members “*[...] shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof*”.

Finally, of relevance in regards to disclosure (inclusion of PIC requirements in patent applications, disclosure of origin, etc.) are articles 8 and 29 which address principles under which Members may adopt necessary legal measures (when developing their IPR legislation) in order to promote the public interest in areas which are vital for their social, economic and technological development (as is the sustainable use of biodiversity for many countries) and determine the need for full disclosure of inventions, respectively.

These substantial TRIPs provisions have been at the core of conflicting political positions and views by developing and developed countries. Since the adoption of GATT and the creation of WTO (1994), they have been subject to intense debate and multiple and diverse interpretations have been suggested regarding their exact scope and meaning. National (and regional²¹) IPR legislation

²¹ Decision 486 of the Andean Community (Venezuela, Colombia, Ecuador, Peru and Bolivia) on a Common Regime on Industrial Property (2001) has, for example, determined that parts or the whole of live organisms as they exist in nature, including isolated genes and biological materials, will not be considered inventions for

enacted over the past few years in various countries – to adjust to and conform with TRIPs standards – as well as judicial precedents in others²², have contributed significantly to the varied interpretation of the TRIPs Agreement.

Developed countries (with certain differences between Europe and the US and Japan) have favoured a broad interpretation of patentable subject matter but a narrow interpretation of the TRIPs exceptions, a position which would allow for patents to be granted over biological materials, isolated genes, gene sequences, and biotechnological products and processes in general. In regards to the ongoing but protracted process for the examination and review of the TRIPs Agreement within the TRIPs Council – initiated in 1999 as part of the mandate in article 71.1 of TRIPs – developed countries are basically of the view that an examination should focus mainly on the degree of implementation of TRIPs in countries and not address modifications to the Agreement.

In contrast, developing countries favour a broad interpretation of exemptions in TRIPs in order to ensure the possibility for national legislation to regulate in detail how these exemptions will apply in areas where – in order to protect human and animal health and the environment in general – the national interest might deem it necessary. Furthermore, in regards to the examination process of TRIPs, developing countries propose not only the review of implementation issues, but a detailed review of substantial provisions in order to propose amendments and modifications if necessary²³.

the purpose of patentability (article 15.b). Furthermore, specific disclosure requirements (access to genetic resources and protection of traditional knowledge documentation) are established in order to process patent applications (article 26.h and i) For the text of Decision 486 see: <http://www.comunidadandina.org> Similar provisions have been included in biodiversity legislation in Brazil and Costa Rica.

²² In the US for example, the Supreme Court decision in *Diamond v Chakrabarty* (1980) (hybridized bacterium used in the treatment of oil pollution) laid the foundation for the granting of intellectual property protection for products resulting from modern biotechnology. This 5 to 4, controversial decision of the Supreme Court has blurred the distinction between inventions and discoveries, raising considerable criticism regarding its far reaching consequences.

²³ As an example, for the June 2003 meeting of the Council for TRIPs, the Permanent Mission of Morocco, on behalf of the African Group, submitted for discussion the document “*Taking Forward the Review of Article 27.3.b of the TRIPs Agreement* with specific recommendations for the modification of article 27.3.b (WTO. IP/C/W/404 26 June 2003. (03 – 3410 Council for TRIPs)). During this same Council for TRIPs meeting, delegations of Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela submitted a text for discussion entitled “*The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*” which proposes specific modifications to patent disclosure requirements of the TRIPs Agreement (WTO. IP/C/W/403 26 June 2003. Council for TRIPs).

One often discussed issue is the reference to the protection of plant varieties in article 27.3.b. Considerable attention has been given to what exactly is an effective *sui generis* system of protection. Many developed countries consider that the UPOV Convention or a “UPOV like” system of Plant Breeders Rights - PBRs) are an effective *sui generis* system to protect plant varieties. Developing countries favor a more flexible interpretation to allow for legal systems that include elements such as protection of TK, recognition of Farmers Rights²⁴, and protection of native crops that do not necessarily comply with protection requirements under UPOV – which covers only novel, homogenous, stable and distinct varieties.

5.2 Convention on Biological Diversity

Within the CBD, COP Decisions related to IPRs have focused on compiling information and data regarding the impacts of IPRs on the objectives of the CBD and in analysing the relationship between CBD and the TRIPs Agreement provisions.

COP 2 adopted Decision II/12 on IPRs. It requested the CBD Secretariat to liaise with the WTO and undertake a preliminary study on the impacts of the IPR system on conservation and sustainable use of biodiversity and the equitable sharing of benefits derived from its use (in the context of the analysis of article 16(5), Access to and Transfer of Technology). COP 3 (Decision III/17) called for the preparation of cases studies regarding the impacts of IPRs on the CBD objectives and stressed the need for cooperation among the CBD, WTO and WIPO. Decision IV / 15 of COP 4 also addressed relationships between CBD and WTO Agreements, including TRIPs. Consistency between agreements, how to achieve technology transfer , etc. were also part of this Decision. Through Decision IV/8 a Panel of Experts on Access and Benefit Sharing was established to explore and analyze in detail ABS options, mechanisms, principles, etc. Decision V/27 of COP 5 reaffirmed the importance of traditional knowledge, *sui generis* systems and continued for calls to

²⁴ Sometimes, Farmers Rights are mistaken for the Farmers Privilege under PBR UPOV regimes. The Farmers Privilege is basically the right of farmers to use and consume the seeds from protected varieties after these have been sown. UPOV 91 leaves countries the option on whether to implement this exceptional right. Many analysts question how a historical right of farmers now becomes a privilege under PBR systems. Farmers Rights are – in terms of the FAO International Treaty – a set of rights which could include – according to how national legislation implements them – protection of TK and compensation for the use of TK or farmers varieties. See : The Crucible Group. *Seedling Solutions . Volume 1. Policy Options for Genetic Resources. People, Plants and Patents revisited*. IDRC, IPGRI, Dag Hammarskjöld Foundation. Printed in Rome, Italy, 2000. Chapter II.

assess relationships between CBD and TRIPs. COP 6 adopted Decision VI/24 (Bonn Guidelines) which include detailed elements and proposals linking ABS with IPRs (see Section 3.2)²⁵.

5.3 World Intellectual Property Organization

WIPO began its work on ABS and TK in 2000 through the Intergovernmental Committee on GRTKF (see footnote 15) . During its five sessions, Member States – including indigenous peoples representative organizations – have discussed legal, policy, economic and scientific aspects related to TK, including TK related case studies on TK protection, analysis of IPR principles, *sui generis* alternatives for TK protection, revision of national legislation and draft policies, among others. The Fifth Session of the Intergovernmental Committee signified the end of the Committee’s mandate, therefore forcing Members States to decide on the future existence and work of the Committee. Positions among Members have been extremely varied ranging from the need to launch within WIPO (and the Committee) negotiations for the development of an international *sui generis* regime for the protection of TK to stressing the need for the continued work in analysing options and alternatives for TK protection. Due to the lack of consensus on how to continue work within the Committee, the Committee will leave the next General Assembly of WIPO (meeting in September, 2003) to decide on the way forward.

The Intergovernmental Committee has contributed significantly to the policy (and conceptual) discussion of TK related issues. Key elements analysed through information documents, parallel workshops during sessions, country submissions, etc., *inter alia*: the role of registers and data bases in the protection of TK; the role of contracts in protecting TK; incorporating new requirements into IPR legislation to ensure appropriate disclosure; current examples of TK protected through IPR instruments; national drafts and legislation on TK; relationships between TRIPs and CBD; TK in the public domain.

²⁵ For a detailed review of the substantial content of CBD COP Decisions and SBSTTA Recommendations, as well as to further understand the “ABS and IPR process” within the CBD see : Secretariat of the Convention on Biological Diversity. *Handbook of the Convention on Biological Diversity*. CBD, UNEP. Earthscan Publications Ltd. London and Sterling, VA, 2001 .

6 Other negotiating forums: WSSD, the Doha Declaration and the Like Minded Group of Megadiverse Countries.

6.1 World Summit on Sustainable Development

Paragraph 44(o) of the Johannesburg Plan of Implementation (World Summit on Sustainable Development, 2002) recognised the need for countries to negotiate *“[...] within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”*.

Furthermore, paragraph 42 (j) of the Plan of Implementation calls for, subject to national legislation, the recognition of *“[...] the rights of local and indigenous communities who are holders of traditional knowledge, innovations and practices, and, with the approval and involvement of the holders of such knowledge, innovations and practices, develop and implement benefit sharing mechanisms on mutually agree terms for the use of such knowledge, innovations and practices”*.

These policy goals set important objectives related to biodiversity, ABS and IPRs. Paragraph 44, refers to an international regime oriented at ensuring that the benefits derived from access to and use of genetic resources are adequately shared. This declaration recognises the limitations national efforts in themselves have in ensuring realisation of the CBD objectives. Although Paragraph 42 includes a qualifier (subject to national legislation) it constitutes another important international recognition of the importance of TK and of the need recognise specific rights over TK and of the need to ensure that if TK is used, benefit sharing effectively takes place with holders of this TK.

6.2 Doha Declaration

The Ministerial Declaration of Doha (Doha Declaration) is the only relevant ministerial level text specifically addressing the review of the TRIPs Agreement. Paragraph 19 reads:

“We [Ministers of Members of WTO] instruct the TRIPs Council, in pursuing its work program included under the review of article 27.3.b, the review of the implementation of the TRIPs Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1.

In undertaking this work, the TRIPs Council shall be guided by the objectives set out in Articles 7 and 8 of the TRIPs Agreement and shall take fully into account the development dimension.

This mandate determines that the examination by the TRIPs Council²⁶ of the relationship between the CBD and the protection of traditional knowledge and folklore and the TRIPs Agreement will take place: a) during the review of article 27.3.b *per se*, b) during the review of implementation of TRIPs under article 71.1 and c) during the review process established under paragraph 12 of the Doha Declaration²⁷.

So far, the initial review of article 27.3.b has been oriented towards the analysis of exceptions to patentability, development of *sui generis* options for the protection of plant varieties, conditions for processing of patent applications, among others. This debate has opened the possibility to reconsider TRIPs in general and assess how to balance this Agreement with developing countries environmental, health and social concerns. The reference to article 27.3.b in Paragraph 19 is an important recognition of the pressing need to undertake a detailed analysis of potential synergies, complementarity and contradictions among TRIPs and the CBD.

Positions are clearly marked between developing countries – which seek a substantial review of TRIPs – and that of developed countries who would much rather focus on implementation issues and deter or prevent any modification to this Agreement. Furthermore, the negotiations within WIPO on the *Substantive Patent Law Treaty* opens up yet another battlefield where developing countries need to ensure their interests are not further affected by the patent system.

²⁶ It should be noted that discussions on relationships between IPRs and the CBD have also taken place within the context of the WTO Committee on Trade and the Environment

²⁷ Paragraph 12 is important because it determines that “outstanding implementation issues” are under negotiation and are an integral part of the work programme. These issues are divided into immediate actions (contained in the Decision on Implementation Related Issues and Concerns – WTO Document. WT/MIN(01)/DEC/November 20, paragraph 12), which would require no modification to WTO Agreements and make no references to biodiversity and future actions (contained in the Compilation of Outstanding Implementation Issues) which could require new negotiations (including of TRIPs). This latter document – whose political value and weight is often questioned, especially by developed countries – is, precisely, where specific references to biodiversity and direct linkages to IPRs (TRIPs) are made (Tiret 88, 95 and Proposal by Least Developed Countries). For further analysis see : Vivas, D. Issues linked to Convention on Biological Diversity in the WTO negotiations : implementing Doha mandates. CIEL at [www. http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf](http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf)

6.3 Like Minded Group of Megadiverse Countries

The Like Minded Group of Megadiverse Countries²⁸ is a consultation and cooperation bloc of megadiverse countries which seeks to promote common policy interests in different forums regarding the conservation and sustainable use of biodiversity. Initial interests have focused on issues related to access to genetic resources and the protection of traditional knowledge. Through its different public statements (Cancun Declaration, COP VI, Declaration for WSSD, Cusco Declaration) and its draft Action Plan for the Group (Kuala Lumpur meeting, 2003), the Group has highlighted and promoted the need to consider the development of an international regime on access to genetic resources, as well as an international *sui generis* system to ensure the protection of traditional knowledge.

These identified needs are the result of a reaction to current operation of IPR systems in developed countries (where most direct and indirect misappropriation of resources and traditional knowledge takes place) and multiple cases where unjust, inequitable, unlawful or outright illegal access to and use of the natural heritage of megadiverse countries and the traditional knowledge of indigenous peoples have been verified²⁹, thus affecting their rights under the CBD.

7 Final comments

Determining positive synergies between IPRs, *vis a vis*, biodiversity, is a politically and technically complex and challenging endeavour. Considerable progress has nevertheless been made over the past few years. However, as has been demonstrated by briefly addressing some of the key issues under discussion and some of the most important processes where this discussion takes place, achieving the CBD objectives, particularly in regards to benefit sharing still remains a goal and is far from fulfilled.

²⁸ The Like Minded Group of Megadiverse Countries was established in February 2002 in Cancun, Mexico (Cancun Declaration) . The Group is currently formed by : Bolivia, Brazil, China, Colombia, Costa Rica, Ecuador, Filipinas, India, Indonesia, Kenya, Malaysia, Mexico, Peru, South Africa and Venezuela. For additional information on the Groups see : <http://www.megadiverse.org>

²⁹ Group of Like Minded Megadiverse Countries. Expert Meeting on Institutional Building. Action Plan for the Group. Background note prepared by the Secretariat. Kuala Lumpur, Malaysia, July 2003, GMC/2003/KL/REF/013.

Whether it be developing positive legal protection for TK, entering into a substantial review process of the TRIPs Agreement, designing an international ABS regime, among others, policy and law will need to create and develop new tools and instruments to

- a) effectively ensure countries of origin assert their rights over their genetic resources,
- b) guarantee benefits for the use of these resources are equitably shared, and
- c) indigenous peoples' intellectual efforts are adequately protected.

These efforts will require work in many of the mentioned processes and furthermore assess how best to link different legal regimes (e.g. IPR, biodiversity, ABS, TK).

Finally it is clear there are a series of ongoing, parallel processes where many of these issues are under consideration. This in itself is an important result ten years after the CBD entered into force. WIPO, Council of TRIPs, CBD and numerous other national and regional processes are very much engaged in finding ways to establish positive synergies and complementarity among IPR and biodiversity related issues, including the protection of TK.

8 Table of acronyms

ABS	Access and benefit sharing
CBD	Convention on Biological Diversity
GRTKF	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IUCN	The World Conservation Union
IPRs	Intellectual Property Rights
MAT	Mutually agreed terms
PBRs	Plant Breeders Rights
PIC	Prior informed consent
SPLT	Substantive Patent Law Treaty
TK	Traditional knowledge
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization