

**ACCESS, BENEFIT SHARING, INTELLECTUAL PROPERTY RIGHTS:
ESTABLISHING LINKAGES BETWEEN THE AGREEMENT ON TRIPS AND
THE CONVENTION ON BIOLOGICAL DIVERSITY**

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Introduction

When it was formally proposed at the end of the Earth Summit in 1992, the Convention on Biological Diversity (CBD) was seen as the first decisive step taken by the global community to ensure conservation and sustainable use of the world's genetic resources. For the genetic resource rich developing countries, the CBD was particularly important because it recognised that States shall have sovereign rights over the biological and genetic resources within their territories, and can establish laws to regulate access to those resources. Moreover, it provided a multilaterally agreed framework for the development of national laws on access to such resources and the sharing of benefits arising out of the commercial use of these resources.

Another significant development in the past two decades has been the rapid progress made by the biotechnology industry, raising in its stride the critical issue of extending intellectual property rights (IPRs) to products based on genetic resources, and to the technology used for arriving at such products. The formalisation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) at the conclusion of the Uruguay Round of GATT negotiations was a direct consequence of the efforts that the commercial interests in this frontier technology had made.

Although the two processes, viz. the Agreement on TRIPS and the CBD, have been on parallel tracks during the period when these were being negotiated, there are at least two compelling reasons why they should be seen in conjunction with one another. The first is that both TRIPS Agreement and the CBD are products of the multilateral system and

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therefore any points of inconsistency that may arise in the two Agreements would have to be addressed so that the signatory countries can meet the requirements for complying with both the Agreements. The second reason is that the World Trade Organization (WTO), which monitors the TRIPS Agreement, has initiated a process through which attempts are being made to bring the objectives of trade and sustainable development on an even keel. This dimension was added to the WTO work programme after the formal conclusion of the Uruguay Round negotiations, and it is particularly important because it releases the organization from the confines of the narrowly viewed trade perspective and establishes it as one in which the broader concerns of development can be dealt with.

The broadening of the ambit of the WTO was in fact consistent with the foremost objective behind the establishment of the organization. This is reflected in preamble to the Agreement Establishing the WTO which states that the Members of WTO "recognise that their relations in the field of trade and economic endeavour would be conducted with a view to raising the standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand and expanding the production of and trade in goods and services, while allowing for optional use of world's resources with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means of doing as in a manner consistent with their respective needs and concerns at different level of economic development".

This paper has two objectives. In the first place, it aims at raising some of the key issues that arise in the implementation of CBD and the Agreement on TRIPS, particularly for the biodiversity-rich countries where local and indigenous communities have been harnessing the genetic resources using traditional knowledge system over generations. The discussion brings to the fore the possibilities of conflict that have arisen as the two multilaterally concluded treaties are sought to be implemented in a mutually supportive manner. The point that has been brought out in this context is that the existing regime of patent protection is at odds with the two essential elements of the CBD, viz., the rights over their genetic resources that the treaty provides to its Contracting Parties and the

recognition of the rights of the traditional communities over the knowledge relevant for the conservation and sustainable use of biodiversity. In the second part of the paper a possible solution for reconciling the conflicts between the TRIPS and the CBD has been discussed. It may be mentioned here that the solution that has been suggested should be regarded as the first step for the two treaties to be implemented within a consistent framework.

The Issues

This section discusses the basic contours of the CBD and the TRIPS, to enable a better appreciation of their points of convergence and potential conflict.

CBD Principles

The CBD recognizes several broad principles that seek to define the nature of rights of a State over its genetic resources and the legal framework it can establish for regulating access to such resources. CBD's key principles are as follows:

- Every State shall have sovereign rights over the biological and genetic resources within its territory, and can establish laws to regulate access to those resources¹;
- Access to such resources should be on 'mutually agreed terms' and should incorporate the principles of 'prior informed consent' of the resource provider. Moreover, it recognizes an obligation to ensure 'fair and equitable' sharing of benefits arising from access and use of the resources.²
- Every Contracting Party of the CBD shall make efforts to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and to the extent possible, within the countries supplying the genetic material.³
- Contracting Parties should adopt legislative, administrative and policy measures that could ensure effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the

¹ Article 15.

² Id.

³ Article 15.

genetic resources for such research, and where feasible in such Contracting Parties.⁴

- Contracting Parties should "take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property right....".⁵
- Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology for the benefit of both governmental institutions and the private sector of developing countries.⁶
- States should: (i) 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, (ii) promote their wider application with the approval and involvement of the holders of such knowledge, innovation and practices, and (iii) encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.⁷
- Patents and other intellectual property rights (IPRs) may have an influence on its implementation, and urges Parties to ensure that such rights are supportive of and do not run counter to the objectives of the CBD⁸.

TRIPS Principles

The TRIPS Agreement takes a major step towards harmonisation of the norms and standards of intellectual property protection. It requires members to comply with a

⁴ Article 19.

⁵ Article 16.

⁶ Article 16.

⁷ Article 8(j).

⁸ Article 16.5.

defined set of minimum standards for the protection of intellectual property rights covered in it. Its basic principles relevant for the present discussion are as follows:

- It mandates countries to provide patents for products and processes in all fields of technology, subject to the tests of novelty, inventiveness and industrial use.⁹
- It mandates patenting of ‘micro-organisms’ and non-biological and micro-biological processes.¹⁰
- Members are allowed to make limited exclusions from patentability are permitted on the grounds of public order or morality, and in respect of protection extended to human, animal and plant life or health.¹¹ It also gives states the option for protecting new plant varieties through patents or through any other effective sui generis system.¹²
- It recognizes as one of its objective that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation 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.

IPRs on Biological Resources: The Basic Issues

Products Based on Biological Resources and Traditional Knowledge

The concern with inventions based on biological resources is not only about the tangible physical resource alone, but also about the intangible information base associated with that resource, referred to commonly as Traditional Knowledge (TK). The growing importance of biotechnology and the increasing number of patents granted to biotechnology-based inventions highlight the potential value of genetic resources and associated TK as source material for biotechnology inventions. A recent OECD study

⁹ Article 27.1.

¹⁰ Article 27.3(b).

¹¹ Article 27.2.

¹² Article 27.3(b).

for instance concludes that the absolute number of USPTO and EPO biotechnology patents has grown substantially in comparison with the total number of patents.¹³

The originators and custodians of much of TK are local and indigenous communities who through years of consistent skill, observation and usage have developed a wealth of a knowledge base regarding the use and properties of various biological resources.

The value of TK and its key role in the development of the final product has been the subject of a variety of literature to date. The basic consensus in these writings is that indigenous knowledge and use of biological resources plays a key role at several stages, ranging from the initial stage of identification of the uses of the biological resource to sometimes information on the precise dosages and preparation of a particular product using the resource.¹⁴ It has been argued that that 'new' products based on these resources and knowledge, are essentially reformulations of existing knowledge, and differ minimally, if at all, from what already exists.¹⁵

Europe and North America have always had a patent system that has been more liberal in its approach towards granting patents, the underlying logic being that patents would promote human ingenuity as well as encourage greater investment into research. With regard to biological material, it is a settled principle in Europe and North America that while it is not possible to claim as an invention something that occurs in nature, patents can be possible if one extracts it from nature and makes it available for industrial

¹³ OECD, *Biotechnology Statistics in OECD Member Countries: Compendium of Existing National Statistics*, STI Working Paper 2001/6.

¹⁴ UNDP Human Development Report, 1999, provides a good overview of the uses of traditional knowledge and resources. *See, also*, Michael J. Huft, 'Indigenous People and Drug Discovery Research: A Question of Intellectual Property Rights', 89 *North Western University Law Review*, 1678, 1995, at 1723; N.R.Farnsworth, 'Screening Plants For New Medicines' in E.O.Wilson(ed.), *Biodiversity*, 1988 pointing out that of 111 commercially useful plant-based drugs, 74 percent were in prior use by indigenous communities; D.M.Lewis, *Millennium: Tribal Wisdom And The Modern World*, 1992, illustrating numerous instances where the folk remedy of tribal people has lead to the pharmacopoeia of modern medicine; UNDP, *Conserving Indigenous Knowledge*, An independent study by the Rural Advancement Foundation International, 1994, where it is explained that indigenous knowledge has made important contributions to agriculture, pharmaceuticals, DNA research and other industrial production; Pat Mooney, 'The Law Of The Seed', *Development Dialogue*, 1983.

¹⁵ *See*, Graham Dutfield, *Protecting Traditional Knowledge and Folklore*, International Centre for Trade and Sustainable Development, 2002. The author argues that as the volume of patent applications rapidly increases and the ability of national and regional patent offices to process them properly becomes an ever more acute concern, the granting of patents for 'inventions' that privatize parts of the public domain has become a huge controversy that has brought the whole patent system into disrepute.

utilization.¹⁶ Such a proposition is explicitly rejected under Indian Patent law for instance, since, discovery of any living thing or non-living substance occurring in nature, are excluded from the purview of patentability.¹⁷

There are various examples regarding the grant of patents in other jurisdictions, commonly in the United States and European countries, over products based on biological resources commonly used in India. Some of these examples are enumerated below:

- i) Use of turmeric in wound healing.
- ii) Composition of jamun, bitter-gourd, gur-mar and eggplant for treatment in diabetes.
- iii) Various products obtained from the neem tree.
- iv) Varieties of basmati which have the characteristics of growing in temperate climate in the absence of sunlight.
- v) Composition of *methi* as a tonic to bring down blood glucose levels.
- vi) Compositions comprising of *kala jeera* or *kalonji* for increasing immune functions, and treatment of diabetes, hepatitis, and asthma.

Other such examples from South America and Africa include patents granted on quinoa and ayahuasca, and on products based on plant material and knowledge developed and used by local communities such as the cases of kava, barbasco and endod.

The premise on which this paper is based is that the conflicts that emerge when patents are granted on products of biological resources, are not simply social, political or economic, but rather, strike at the very root and basis of the patent system.

Patents on Biological Resources: Two Case Studies

The patent granted by the United States Patent and Trademark Office (USPTO) on the ‘Use of Turmeric in Wound Healing’ is a classic example of how an invention was simply a reformulation of knowledge existing in the public domain. This is among the few patents whose grant by the USPTO was challenged by the Government of India.

¹⁶ For example, the European Patent Office Guidelines for Examination state that: ‘.if a substance found in nature has first to be isolated from its surrounding and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it was obtained or by other parameters, and it is ‘new’ in the absolute sense of having no previously recognized existence, then the substance per se may be patentable.’

¹⁷ Section 3(j) of the Patents Act, 1970, as amended in 2002.

After a protracted battle, the patent was revoked. The lessons that emerged from this case are revealing, as will be discussed below.

Another case is that of the Enola bean patent awarded to an American entrepreneur, which has resulted in adverse implications for import of traditional bean varieties on Mexico.

Turmeric Patent

Turmeric has been traditionally used in India for its wound-healing and other properties, as described in the following excerpt¹⁸:

"The turmeric plant (an herb) is a native of South Asia, and is cultivated extensively throughout the warmer parts of the world. In Indian systems of medicine, turmeric is used as a tonic and blood purifier. Mixed with warm milk it is said to be beneficial in treating the common cold. The fresh rhizome is used as an anti-parasitic for many skin infections. Externally it is applied to indolent ulcers, and a paste made from the powdered rhizome along with lime forms a remedy for inflamed joints. A decoction of the rhizome is said to relieve the pain of *purulent ophthalmia*. Oil of turmeric, distilled from the dried rhizomes, has feeble antiseptic properties... Turmeric (rhizomes or powder) is an auspicious article in all religious observances in many Indian households. It is a normal constituent of condiments, curry powders and prepared mustards."

Two US based Indians were granted US Patent 5,401,504 on 28 March 1995 (hereinafter the **Turmeric patent**) on *Use of Turmeric in Wound Healing*, which was assigned to the University of Mississippi Medical Centre, USA. The subject matter of the turmeric patent was as follows:

- It disclosed the use of turmeric to augment the healing process of chronic and acute wounds.
- With regard to 'prior art', it revealed the use of turmeric powder as a food colorant in traditional Indian dishes as also as a traditional medicine for the treatment of various sprains and inflammatory conditions.
- The invention covered under the patent was directed at the use of turmeric at the site of an injury and/or its oral intake to promote the healing of a wound. It was postulated by the patent applicants that turmeric contributes to the treatment of chronic ulcers through the improvement of micro-circulation, stimulation of angiogenesis, promotion of granulation tissue formation and acceleration of re-

¹⁸ R.K.Gupta & Lakshmi Balasubramaniam, 'The turmeric effect', 20 *World Patent Information*, 185 1998.

epithelialization (essentially indicating growth and regeneration of tissue at the wound site).

- The 'inventors' offered an alternative to the conventional therapy based on use of turmeric which is readily available and economic. The inventors addressed the route of drug intake, and found that if turmeric was administered orally in 0.1-2 mg/kg of body weight, and applied topically as well, it could enhance the healing of wound in mammals including humans. The wound could be any wound on the surface of the body, e.g., surgical wound, ulcers or any other injury in which the skin is broken out, pierced, torn, etc.

The media coverage of the patent generated debate and discussion on the issue, and the Centre for Scientific and Industrial Research (CSIR), an autonomous institution under the Department of Science and Technology, Government of India, decided to file for re-examination of the patent. The challenges before them were many. The claimed subject matter was the use of 'turmeric powder and its administration', both oral as well as topical for wound healing. It was therefore necessary to find adequate evidence in the form of printed and published information that would constitute 'anticipation' of the claimed invention. The prosecution history of the case revealed that the examiner had concluded that prior art had disclosed only the use of ointments, paste etc., and did not provide information on the use of turmeric powder and its application routes¹⁹. And that posed the biggest challenge: "[d]espite the fact that the use of turmeric was known to every Indian household for ages, finding published information on the use of turmeric powder per se through oral as well as topical route for wound healing was a difficult task"²⁰.

After an extensive search, 32 references were located, some of which were more than a 100 years old, and in the languages of Sanskrit, Urdu and Hindi. These were then translated, and authenticated as being true translations. These were then filed as part of the re-examination request, which was admitted by the USPTO as raising substantially

¹⁹ See, R.K.Gupta & Lakshmi Balasubramaniam, 'The turmeric effect', 20 *World Patent Information*, 1998.

²⁰ Ibid.

new questions of patentability. Based on the references filed, the examiner rejected the claims as being obvious and anticipated, and concluded that the use of turmeric in powder form was an old art of healing wounds.

Though in effect, the Turmeric case was a 'success story', it also revealed a variety of 'problem areas' in challenging what was obvious to people in India, based on the laws of a foreign jurisdiction. The lessons learnt and problem areas as identified by CSIR after the *turmeric* experience can be summarized thus:

- There is a wide gap in the availability of information for patent examination purposes pertaining to traditional knowledge base from third-world countries. This needs to be documented and put into the public domain to discourage grant of patents based on centuries'-old use of natural products from biodiversity rich regions of the world²¹.
- Although remedy is available in the laws of developed countries, such as the re-examination proceedings in the US, the costs for bringing a case for re-examination are many: identifying the prior art information, translating the same, getting adequate technical and legal expertise, etc. Further, patent such as the turmeric patent, did not in reality have any commercial consequences for a seller or user of turmeric. People could continue to sell or use turmeric in whatever form despite the patent. What was offensive was the very idea that an exclusive right to sell and use turmeric for the purpose of wound healing as claimed in the patent. The CSIR stepped in this instance, more from the point of view of taking it up as a test and trial case.
- To make such an investment (of filing for re-examination) each time an 'invention' is claimed on biological resource and its traditional use, may not be feasible all the time. Challenging a large number of patents would mean wasting money and time. The commercial impetus to take up such case is a gray area. Should it be the responsibility of the state to take up such cases in future, whenever there are no private entities willing initiate action - is a question for

²¹ Ibid.

which there are no clear answers. The CSIR Director General has reportedly stated that if the market of a specific medical product of a corporate entity is threatened, then that entity should take up the challenge²². The ‘affected interest’ may not be easily tracked unless there is a substantial market potential for the patented product.

- The *ex parte* nature of the proceedings throws up further challenges in that the re-examination filed for should be self-explanatory and clear. There is no scope for an oral hearing or clarifications when the process of re-examination is on-going.

Enola Bean Patent

U.S. Patent No. 5,894,079, the Enola bean, or yellow bean, patent was granted to John Proctor, the president of seed company POD-NERS, LLC, after he brought the bean seeds back from Mexico. With the patent granted, Proctor has an exclusive monopoly on yellow beans and can exclude the importation or sale of any yellow bean exhibiting the yellow shade of the Enola beans. The International Center for Tropical Agriculture (CIAT) is legally challenging the patent, arguing that the patent claims are invalid, failing to meet novelty and non-obviousness requirements and disregarding available prior art. The United States Patent and Trademark Office (USPTO) has yet to rule on the re-examination.

Proctor planted the yellow beans in Colorado and allowed them to self-pollinate. By selecting yellow beans in several generations, a segregating population resulted in which the colour of the beans is uniform, stable and changes little by season. Proctor openly admits the Mexican origin of the beans. However, he believes that his seeds are patentable because a new yellow shade was obtained, and this shade coupled with the bean being grown in the United States for the first time, is sufficient to satisfy the novelty requirement. It is difficult for many to understand how this patent could have been granted when its novelty appears to be based solely on its colour and that it was previously never grown in the United States. It raises serious issues such as: Can a

²² Dr.R.A.Mashelkar, Director General, CSIR, as quoted in *Frontline*, August 27, 1999.

colour be patented? How is the novelty requirement satisfied when these beans, that Proctor bought while vacationing in Mexico, have been grown for centuries? Customs officials at the US-Mexico border are reportedly inspecting beans, searching for any patent infringing beans being imported into the United States. Because of this bean alone and the threat of infringement, some export sales have dropped over 90%, also affecting the market for other non-yellow beans.²³

Overview of IPR & TK debate in International Negotiations

There are three principal forums where the issues pertaining to protection of TK, access to biological resources and IPRs have figured prominently. These include the Conference of Parties to the CBD, the TRIPS Council of the WTO, and the World Intellectual Property Organization (WIPO). This section will attempt to summarize the status of debate and discussion in these forums.

Developments at the CBD Conference of Parties

The Conference of Parties (COP) to the CBD meets every two years to review the national and international implementation of the CBD. It has also addressed itself to issues regarding interface with the TRIPS Agreement. The debate on IPRs is specifically addressed in the context of the CBD provisions on access to genetic resources and the traditional knowledge associated with the same, benefit sharing, and prior informed consent.

For instance, the COP has requested the CBD Secretariat to *inter alia* liaise with the Secretariat of the WTO to inform it of the goals and the ongoing work of the CBD.²⁴ It has also asked the CBD Secretariat to invite the Secretariat of the WTO for assistance in preparing a paper that identifies the synergies and relationship between the objectives of the CBD and the TRIPS Agreement.²⁵ The COP has also recognized the need to develop a common appreciation of the relationship between IPRs under the TRIPS Agreement and the CBD, in particular the impact of such relationship on provisions pertaining to technology transfer, and to the three-fold

²³ *Enola Bean Patent Challenged*, available at <http://www.etcgroup.org/article.asp?newsid=96>

²⁴ Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information, UNEP/CBD/COP/2/13, November 1995.

²⁵ *Id.*

objectives of the CBD, viz., conservation and sustainable use of biodiversity and the equitable sharing of benefits arising from such use.²⁶ It has further stressed the need to ensure consistency in implementing the CBD and the WTO agreements, including the TRIPS Agreement, with a view to promoting increased mutual supportiveness and integration of biological diversity concerns and the protection of intellectual property rights.²⁷ Yet another decision of the COP has invited the WTO to acknowledge relevant provisions of the CBD and to take into account the fact that the provisions of the TRIPS and the CBD are interrelated and to further explore this relationship.²⁸ The Executive Secretary of the CBD has an observer status in the WTO Committee on Trade and Environment (CTE) for representing the CBD in meetings whose agendas have relevance to the CBD. However, its efforts to obtain an observer status at the TRIPS Council of the WTO have yet been unsuccessful.²⁹

At the sixth meeting of the CBD COP, which took place in May 2002, the Bonn Guidelines on Access to genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, were officially adopted. The Guidelines encourage parties to “adopt measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovation and practices of indigenous and local communities in applications for intellectual property rights.” The Guidelines also refer to a ‘legally recognized certification of origin system as evidence of prior informed consent and mutually agreed terms.’ This refers to a possible harmonization of procedures and requirements for certificates of origin that all member states would recognize and implement, and which patent offices of member states would recognize.

The decision at COP VI incorporating the Bonn Guidelines also asks for information gathering and analysis of several aspects, including: (i) the efficacy of country or origin and prior informed consent disclosures in assisting examination of IPR application and re-examination of IPRs granted; (ii) role of oral evidence of prior art in the examination, granting, and maintenance of IPRs.

²⁶ CBD, Access to Genetic Resources, UNEP/CBD/COP/3/20, October 1996.

²⁷ CBD, Report on the activities of the Global Environment Facility, UNEP/CBD/COP/4/15.

²⁸ CBD, Access to Genetic Resources, UNEP/CBD/COP/5/26.

²⁹ See, CBD, Conference of the Parties to the Convention on Biological Diversity, Access and Benefit-sharing as Related to Genetic Resources, UNEP/CBD/6/19, January 9, 2002.

Developments at the WIPO

The Standing Committee on Law of Patents (SCP) of the WIPO has been reviewing various aspects of patent laws for the purposes of harmonization. The initial focus on harmonizing procedural aspects of patent laws led to the conclusion of the Patent Law Treaty (PLT) in June 2000. Prior to the conclusion of the PLT, the Columbian delegation in 1999 submitted a paper on ‘Protection of Biological and Genetic Resources’ which argued that the PLT should comprise of provisions linking filing of patent applications with access and benefit sharing regulations. The basic demands made in the proposal were that: (i) ‘All industrial property protection shall guarantee the protection of the country’s biological and genetic heritage. Consequently, the grant of patents or registrations that relate to the elements of that heritage shall be subject to their having been acquired legally; ‘ and (ii) Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources or products thereof, of which one of the member countries is the country of origin.’³⁰

This proposal was supported by several developing countries, but was staunchly opposed by United States, European Union and Japan, on the ground that this was an element of substantive patent law and had no place under the PLT. As it turned out, the PLT was concluded without any reference to the Columbian proposal. However, this led to further meetings within the WIPO and consensus was reached that the ‘WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies and through the setting up of an appropriate forum within WIPO for future work.’³¹

The WIPO Secretariat invited member states to consider the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources,

³⁰ WIPO, Standing Committee on Law of Patents, Protection of Biological and Genetic Resources: Proposal by the Delegation of Columbia, SCP/33/10, 1999.

³¹ WIPO, Matters concerning the Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WO/GA/16/6, 2000.

Traditional Knowledge and Folklore (IGC) in the year 2000. The WIPO Secretariat suggested three themes that the IGC could focus on in its consultations. These were ‘intellectual property rights issues that arise in the context of: (i) access to genetic resources and benefit sharing; (ii) protection of TK, whether or not associated with these resources; and (iii) the protection of expression of folklore.’³²

In the sessions of the IGC that were held between 2001-2002, the discussion has revolved around how patent law could prevent misappropriation of TK and promote benefit sharing.

A parallel development at the Standing Committee on Law of Patents (SCP) was to consider the “deep harmonization of a number of issues relating to the grant of patent rights as well as the validity of patents” through the adoption of the Substantial Patent Law Treaty (SPLT). The SCP decided that the provisions of the SPLT should address a number of issues relevant to the grant and validity of patents, such as the definitions of prior art, novelty, inventive step/non-obviousness and industrial applicability/utility, the issue of sufficiency of disclosure and the drafting and interpretation of claims.³³

Each of the international processes discussed above has a valuable role to play in clarifying how inventions based on biological resources and TK should be treated in international law. Some developed countries, like the US and Japan, have argued that the process relegated to the CBD related developments and that it is not the domain of IP laws to address these issues. Others like Switzerland have argued that the WIPO is more competent to address the IP linkages of TK and biodiversity. There is a perception that some developed countries, by relegating TK issues to the WIPO’s IGC are attempting to exclude this from the debate under the TRIPS Agreement. While developing countries like India and others have been active in both the CBD and WIPO meetings, their emphasis has been on a TRIPS related amendment to address the issue.

The reasons for emphasis on a WTO process rather than the WIPO are basically to do with the stronger enforcement mechanisms under the WTO. The WIPO processes, although of considerable complimentary value to the WTO processes, are limited because WIPO does not have a strong enforcement mechanism that the WTO does. India and several other countries have been relentless in pushing the issue of effective linkages between the TRIPS and the CBD,

³² Ibid.

³³ WIPO, Report adopted by the Standing Committee on Law of Patents, SCP/4/6, December 7, 2000.

and attempting to ensure that the WIPO processes are not used as an excuse to sideline the TRIPS processes.

Assuming that the TRIPs were amended to reflect this proposition, then it would be a welcome development to have the same reflected through relevant changes in WIPO's Substantive Patent Law Treaty (SPLT) and the Patent Cooperation Treaty (PCT). However, the latter should not be used as an excuse not to introduce the clarification in the TRIPS itself.³⁴

Developments at the World Trade Organization

Developing countries from Asia, Latin America and Africa, have been active at the WTO, particularly at the General Council and the TRIPS Council in order to focus attention on the issue of TRIPS-CBD relationship. Papers submitted to the General Council have highlighted the various implementation issues that developing countries seek solution to.³⁵

At the TRIPS Council under the WTO, developing countries have made several submissions³⁶ aimed at developing an effective and consistent framework so that the WTO Members can meet their obligations under both the TRIPS and the CBD.

An important culmination of these submissions was their recognition in the Doha Ministerial Declaration (DMD) issued at the conclusion of the fourth session of the WTO Ministerial Conference, held in November 2001. While setting out the post-Doha work programme on the TRIPS Agreement, the Ministers instructed that the Council for TRIPS should examine, inter alia, the relationship between the TRIPS Agreement and the CBD.³⁷ Pursuant to paragraphs 12 and 19 of the DMD, Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and

³⁴ See for instance, Switzerland's proposal to the TRIPS Council, which proposes an enabling clause under the PCT and not the TRIPS, Article 27.3(B), the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge: Communication from Switzerland, IP/C/W/400/Rev.1, June 2003.

³⁵ See for example, WTO, General Council, Implementation Issues to be Addressed Before/At Seattle: Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, WT/GC/W/354.

³⁶ See, for instance, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Review of Article 27.3(B): Communication from Brazil, IP/C/W/228, November 2000; WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India, IP/C/W/195, July 2000; WTO, Council for Trade-Related Aspects of Intellectual Property Rights China, IP/C/M/36/Add.1, para 228.

³⁷ *Doha WTO Ministerial 2001: Ministerial Declaration*, WT/MIN(01)/DEC/1, Para 19, available online

Zimbabwe had given a submission to the TRIPS Council on the relationship between the TRIPS Agreement and the CBD and the protection of Traditional Knowledge in June 2002³⁸. These countries had contended that 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 traditional knowledge shall provide, as a condition to acquiring patent rights:

- (i) disclosure of the source of the biological resource and/or the traditional knowledge used in the invention
- (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes where applicable; and
- (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin where applicable.

The argument underlying the above submission is that this framework for linkages is essential for implementing the TRIPS Agreement and the CBD in a mutually supportive manner.

The primary objections to the above have been raised by the United States and Japan. These countries have argued that there is no need for any clarification or amendment to the TRIPS Agreement. Their principal arguments have been that:

- (i) Compliance with the CBD should be dealt with separately under national ABS regimes and bilateral contractual arrangements;
- (ii) The objectives of the CBD and Agreement on TRIPS do not conflict with each other;
- (iii) Expanding disclosure norms under TRIPS Agreement for products based on biological resources will violate the principles of non-discrimination based on fields of technology and thereby the basic principles of the Agreement³⁹;
- (iv) Disclosure norms constitute an additional and unnecessary burden on patent applicants and patent offices and would affect compliance with reasonable procedures and formalities as laid down in Article 62.1 of the TRIPS Agreement⁴⁰;

at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (Visited April 19, 2002).

³⁸ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge: Submission by Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, June 2002.

³⁹ Statement by Japan on the review of Article 27.3(b), WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting IP/C/M/29, March 2001, para 155.

- (v) Biodiversity rich countries should compile databases of biological resources and TK to enable patent offices worldwide to conduct better searches.

The European Communities (EC) has interestingly been far more sensitive to developing country concerns. Their main position has been that the TRIPS Agreement does not preclude members from requiring disclosure of origin or production of evidence on access and benefit sharing⁴¹. However, the EC argues that the legal consequences of non-disclosure should be left outside the purview of patent laws.

Rationale and Arguments for linking TRIPS and CBD

The following section provides an elaboration of the developing country positions advocated through their submissions to the TRIPS Council. These have been elaborated in a recent submission to the TRIPS Council.⁴²

(i) Why we need Norms of Disclosure

Several developing countries have been arguing for effective norms of disclosure revealing source of origin of the resource and TK used in the invention, as well as provide evidence of prior informed consent and benefit sharing. It is believed that disclosure of source of origin and evidence of prior informed consent and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation.⁴³ A mandatory obligation on the patent

⁴⁰Statement by Japan on the review of Article 27.3(b), WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting IP/C/M/29, March 2001, para 155. The United States has held the view that a system that requires patent applicants to disclose “the source of any genetic materials or traditional knowledge used in developing their claimed inventions ... would be a legal and administrative nightmare for all involved and would not ensure that those contributing such resources or knowledge would share in any benefits that might flow from commercialization of any product or process that might be developed from the resource or knowledge” (emphasis added). See WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Review of the Provisions of Article 27.3(b): Further Views of the United States, IP/C/W/209, October 2000.

⁴¹ This view of the EU is consistent with its position taken in Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions (the Biotechnology Directive) which states the following: “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known ...”.

⁴² WTO, Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge: Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, June 2003.

⁴³Statement made by Brazil in the TRIPS Council Meeting, WTO, Council for Trade-Related Aspects of

applicant as part of the norms of disclosure would, to an extent, be a self-policing provision. This approach would have the following advantages: (i) it would be an additional reason why the patent applicant would be encouraged to comply with the national laws on ABS; (ii) the onus would be on the patent applicant, so member countries cannot raise the objection of higher administrative costs for the patent office; (iii) it would enable patent offices to be more vigilant while examining patent applications that deal with a biological resource and associated TK; and (iv) it would serve as a critical tool for biodiversity rich countries like India in tracking down applications based on bioresources and related TK, and enable adequate challenges to specious patents.

In the absence of norms for disclosure of source of origin, it can be said that a country of origin claiming that the ‘invention’ is not genuine, can pursue legal remedies under the patent laws of the country which has granted a patent; or its own laws on access to resources. This, for instance, was the case when the Indian Government opposed the turmeric patent and won the case. However, as discussed in the context of the turmeric case above, the peculiar nature of the patent laws in countries which recognize prior art outside their country only in the form of written and published information, make legal challenges formidable and cumbersome. Moreover, pursuing a legal remedy under international laws and in multiple jurisdictions is complicated and expensive, and may not be economically feasible for many aggrieved countries.

It is but obvious that in the case of inventions based on biological resources and/or associated TK, the source of origin of the resources and of the traditional knowledge, are critical for ascertaining whether or not the applicant has “invented” what he claims in the patent, or has just found it in nature or obtained it from traditional cultures.⁴⁴ This is especially important when the TK used in the invention is undocumented and exists in oral form, or is documented in a local language. Disclosure of origin of the resource and TK would enable a better assessment by the patent examiner of the novelty and inventive step involved in the invention.

Intellectual Property Rights, Minutes of Meeting , IP/C/M/39, March 2003, para 126.

⁴⁴ Statement made by India in the TRIPS Council Meeting, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting , IP/C/M/37/Add.1, November 2002, para 253. See also, Statement made by India in the TRIPS Council Meeting, WTO, Council for Trade-Related Aspects

Disclosure of origin of the resource and TK will therefore serve the following purposes. These are: (a) reducing instances of bad patents; (b) enabling the patent office to ascertain more effectively the ‘inventive step’ claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on prior informed consent and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge. This would also increase the credibility of the patent system, as well as contribute to achieving the principal objectives of the TRIPS Agreement. Placing the onus on a patent applicant to disclose the basis of its claims is a step that can pre-empt any misuse of patent laws and thereby prevent misappropriation of knowledge and resources.

(ii) Notions of Equity and Good Faith

India and several other countries have also consistently argued for notions of equity and good faith behind the proposal for clarifying the TRIPs Agreement. Equity and Good Faith are principles recognized under most jurisdictions. There are no strict definitions for these terms. They essentially connote a situation of fair play and justice.

It has been argued that notions of equity and good faith mandate that the international community create an equitable system for the acquisition, maintenance, and enforcement of intellectual property rights, which does not *a priori* exclude any section of the society.⁴⁵ It has been acknowledged that the principle of equity dictates that a person should not be able to benefit from exploiting IPRs based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to

of Intellectual Property Rights, Minutes of Meeting , IP/C/M/39, March 2003, paras 122-123

⁴⁵ Statement made by India in the TRIPS Council Meeting, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, IP/C/M/28, November 2000, para 128. See also, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities: Communication from Bolivia, Colombia, Ecuador, Nicaragua, and Peru, IP/C/W/165, November 1999; WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Proposal on Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities: Communication from Cuba, Honduras, Paraguay and Venezuela, IP/C/W/166, November 1999.

the material.⁴⁶ This aspect can also be said to have been recognized under the CBD, Article 16 (5) of which states that countries should cooperate to ensure that patents and other intellectual property rights *are supportive of and do not run counter to the objectives of the CBD*. Among the principal objectives of the CBD are to put in place the basic framework for access, prior informed consent (PIC) and fair and equitable benefit sharing, in recognition of a country's sovereign rights to its biological resources. Establishing a link between these objectives of the CBD with the norms of disclosure of a patent application in the TRIPS Agreement is aimed at putting in place a mechanism for ensuring that patents are not granted, or are invalidated if granted in violation of the rights of the countries/ communities over their resources/knowledge. Such a provision, it is believed, will be in consonance with, and in pursuance of the CBD as well as the objectives articulated in Article 7 of the TRIPS Agreement, which emphasize that the *'protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation... 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'*.

(ii) Compliance with basic tenor of TRIPS Agreement

One of the arguments against the proposal for expanding the norms of disclosure has been that the amendments would not be consistent with the TRIPS Agreement and would violate the principle of non-discrimination between fields of technology.⁴⁷ This however, is not the case when adequate distinctions can be drawn between fields of technology.

As pointed out earlier in this paper, the basis for the invention in the case of a product based on a biological resource can often be the existing knowledge and use by a local or indigenous community pertaining to the biological resource, a fact that has been

⁴⁶ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, September 2002, http://www.iprcommission.org/papers/text/final_report.

⁴⁷ WTO, Council for Trade-Related Aspects of Intellectual Property Rights United States, Communication from the United States, IP/C/W/257, June 2001.

recognized.⁴⁸ Before a patent is granted, it would therefore be important to verify the extent of the prior existing knowledge that it utilizes and the ‘inventiveness’ involved in the invention. Procedures adopted for granting patents often have to be different depending on the ‘field of technology’. For instance, in the case of micro-organisms, the nature of the invention demands that the micro-organisms that are used are deposited prior to grant of the patent. In a similar vein, where the field of technology involves bioresources, the special circumstances surrounding bioresources and associated knowledge, should require additional norms for disclosure to enable, *inter alia*, adequate assessment of the tests of patentability. It is an established principle of interpretation that treating dissimilar fields of technologies differently will not be contrary to the non-discrimination principle.⁴⁹

(iii) Disclosure norms are a reasonable demand on the patent applicant

The logic behind placing the onus of disclosure on a patent applicant is that it is the patent applicant who is involved in the research and finding out of the products based on such research. The applicant would also have information on whether there has been compliance with the national legal regime of the country of origin with regard to PIC and fair and equitable benefit sharing. Requiring such disclosure is a 'reasonable procedure' based on knowledge readily available with a patent applicant.

Expanding the norms of disclosure would therefore not amount to a legal and administrative nightmare or an unnecessary burden on either the patent applicant or the patent office, contrary to what has been suggested.⁵⁰ Such a requirement would also pave the way for a comprehensive international solution, so that countries that are victims of biopiracy do not need to divert their precious national resources to expensive

⁴⁸ UNDP, Human Development Report, 1999.

⁴⁹Statement made by India in the TRIPS Council Meeting. See, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting , IP/C/M/37/Add.1, para 224 [In the Canada-Pharmaceutical products case, the panel also elaborated about the possible “differentiation” between fields of technology]

⁵⁰WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, IP/C/W/257, June 2001.

judicial procedures for the revocation of patents based on illegally obtained resources and associated knowledge.⁵¹

(iv) Role of TK Databases & limitations of relying only on databases

Compiling databases of traditional knowledge at the national level is an important aspect being addressed at the national level in several countries, including India, through efforts at compiling a Traditional Knowledge Digital Library. Such databases would play a key role in facilitating a patent examiner's check against patent requests relating to unauthorised use of the knowledge of traditional communities.⁵² It was, however, recognised that given the vast breadth and depth of such knowledge, there was an inherent limitation of such documentation which was that it cannot be completely comprehensive and exhaustive of all the traditional knowledge available in a country.⁵³ This would be particularly true when traditional knowledge used in a particular invention was undocumented, based on oral traditions or documented in the local languages.⁵⁴ In such cases, reliance on the documented source itself may not be sufficient. Disclosure of the source and nature of the knowledge and location of the material, however, would play a significant role in determining inventorship, as was stated in an earlier discussion.

It has been suggested that the use of databases documenting the knowledge, innovations and practices of traditional communities which can be made widely accessible over the internet, to enable their use by patent examiners, will be an adequate solution to redress the problem of biopiracy.⁵⁵ For the reasons discussed above, use of databases is fraught

⁵¹Statement made by Brazil in the TRIPS Council Meeting. See, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, IP/C/M/39, para 126.

⁵² Statement made by Brazil in the TRIPS Council Meeting. See, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting , IP/C/M/37/Add.1, November 2002, para 255.

⁵³ Statement made by India in the TRIPS Council Meeting. See, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting , IP/C/M/37/Add.1, November 2002, para 253

⁵⁴ Statement made by India in the TRIPS Council Meeting. See, WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting , IP/C/M/39, March 2003, para 123.

⁵⁵ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, IP/C/W/257, June 2001.

with certain limitations. While use of databases can complement the purpose of expanded disclosure norms, they cannot substitute the same.

(v) ***Limitations of National laws or Contracts***

It has been suggested that there should be a separate law for governing aspects of biopiracy, and that PIC and benefit sharing can be done through contracts as well.⁵⁶ The CBD mandates its member states to enact national laws that would facilitate PIC and benefit sharing in a fair and equitable manner, prior to access and use of biological resources and traditional knowledge. It is acknowledged that these mechanisms can and should be used, and several countries have already enacted laws to put in place an Access and Benefit Sharing (ABS) regime. However, this in itself is insufficient to arrest biopiracy and misappropriation of resources. It also does not achieve the central objective of disclosure norms- that is to stall the reward of a patent for knowledge or information misappropriated from another country.

For the same reasons, relying on contracts will be insufficient as well. Contracts being voluntary in nature would be ineffective if the parties to the contract are of vastly unequal bargaining strengths, as would be the case involving traditional communities and the commercial interests.

National systems by themselves would not be adequate to fully protect and preserve traditional knowledge. For example, the ability of patent offices in national jurisdictions to prevent biopiracy as well as to establish informed consent mechanisms to ensure reward to TK holders, does not *ipso facto* lead to a similar action on the patent applications in other countries. Similarly, benefit sharing mechanisms established through national legislations would need to be recognized in user countries.⁵⁷ The remedies that can be sought under national laws for access and benefit sharing will also inevitably have only territorial application within the country whose laws are violated.

⁵⁶ *ibid*

⁵⁷ WTO, Council for Trade-Related Aspects of Intellectual Property Rights, Seminar on Systems for the Protection and Commercialization of Traditional Knowledge: Communication from UNCTAD, IP/C/350, June 2002, summarises the views and discussions of an international seminar convened with the participation of Brazil, Cambodia, Chile, China, Cambodia, Cuba, Egypt, Kenya, Peru, Philippines, Sri Lanka, Thailand, Venezuela and India at New Delhi, April, 2002.

It is not our submission that patent law should be the mechanism to ensure compliance with other international obligations, or that patent law should fill in where other national laws prove ineffective. It is also not our submission that patent laws should facilitate 'benefit sharing' with country/community of origin of the biological resource and knowledge. What is being sought is a simple mechanism whereby patent laws in different countries through the world make an effective determination of 'inventorship' and 'prior art', and further, do not reward a patent applicant for violating the source countries laws on access and benefit sharing.

Towards a Conclusion

This paper tried to argue that implementation of the Agreement on TRIPS and the Convention on Biological Diversity (CBD) in a mutually supportive manner has become imperative at the present juncture from the point of view of protecting the interests of developing countries. Initiatives for realising this objective have been taken in the WTO where a number of developing countries have coordinated their efforts in this regard. But although examination of the relationship between the TRIPS Agreement and the CBD figures prominently in the Doha Ministerial Declaration, which has set out the current work programme of the WTO, little progress has been visible. Issues that will have to be resolved in the discussions will be: the form and content of the actual clarification/amendment to the TRIPS Agreement; the nature of obligation that is placed on the patent applicant; the form of evidence for PIC and benefit sharing that can be regarded as acceptable; and the related issue of the legal remedies that should accompany non-disclosure of origin, or lack of evidence of PIC and benefit sharing, in patent applications. In other words, developing countries should look for a solution to the vexed problem that the present paper dealt with, which can be effectively enforced.