

The TRIPS-CBD Issue in the WTO: A South Asian Perspective

Introduction

1. The Year 2010 has been proclaimed as the International Year of Biodiversity. The United Nations Convention on Biological Diversity (CBD) has the objective of conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of the genetic resources. It recognises the sovereign right of its Contracting Parties to exploit such resources and legislate regarding their access and equitable sharing of the benefits of their exploitation. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the benefits Arising out of their Utilisation invites Contracting Parties to encourage the disclosure of the country of origin of genetic resources used in an invention in applications for intellectual property rights (IPRs) as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted.

2. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allows members to provide patents over biological resources. Patents are private rights. Inventors, therefore, can lay claims to the inventions that use biological resources without any obligation to seek prior informed consent (PIC) or follow any national requirements on access and benefit sharing (ABS) with the source/country of origin of such biological resource or with the traditional knowledge holders in such countries whose knowledge may have been the crucial input in the innovation. Commercial exploitation of such inventions, therefore, need not adhere to any rules relating to equitable sharing of benefits with the source/country of origin or the holders of associated traditional knowledge.

3. To harmonise these different approaches to sustainable use of biological resources, work is on in various inter-governmental organisations, particularly in CBD, WTO and WIPO. The TRIPS-CBD issue is under negotiations as part of the implementation related issues and concerns under the Doha Round¹ of the WTO, apart from the mandate given to the TRIPS Council to examine it as part of the review of Article 27.3 (b) of the TRIPS Agreement². This paper discusses the issue and the stage of negotiations on the issue, taking a South Asian perspective on the way forward.

The TRIPS-CBD Issue

4. The World Conservation Monitoring Centre, an agency of the United Nations Environment Programme, has identified 17 mega-diverse countries, of which 15 are developing countries. Biological resources are a key resource for many inventions, particularly in the field of medicines. Bio-prospectors mine these resources worldwide based on the knowledge of their benefits available in the public domain, conduct research on them and invent medicines, plant varieties and other biotechnological products and patent them with a view to exploit them

¹ Para 12 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1

² Para 19, *ibid.*

commercially. More often than not, they do not disclose in their patent applications the origin of these resources or traditional knowledge used in their research. This has resulted in allegations of bio-piracy against them. If the patents are granted, protagonists of the efforts to seek harmonisation of the different approaches of the TRIPS Agreement and the CBD call these unauthorised patents. Where these patents are granted outside the territories of members owning the genetic resources in question, and since IPRs are limited to the territorial jurisdiction where granted, developing countries, championed by such mega-biodiversity countries, seek an international recognition of the problem and its solution.

5. Many developing countries made a proposal in the WTO, popularly known as the ‘disclosure requirement’ to amend the TRIPS Agreement to require that patent applicants disclose the source/country of origin of a biological resource used in their invention, and inform whether PIC and ABS was obtained under the relevant national law. More particularly, these countries argue that the TRIPS Agreement should be amended in order to require that the 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 and country of origin of the biological resource and of the traditional knowledge used in the invention;
- (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and
- (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.

6. They argue further that it would be more cost-effective to establish an internationally accepted solution to prevent bio-piracy than to divert national resources to expensive judicial processes for revocation of patents that include illegal genetic resources. Developing countries, in particular the least developed countries do not have the resources to follow each patent issued abroad.

7. South Asia comprises of developing and least developed countries and has immense biological diversity.

Swelling Ranks of South Asian support to the WTO proposal

8. One of the first comprehensive proposals seeking such an amendment to the TRIPS Agreement in the Doha negotiations was submitted in June 2002³ by 13 countries of which just two (India and Pakistan) were co-sponsors. A number of them supported the proposal from the floor or as part of the coalitions within the WTO. The proponents of the proposal presented a

³ IP/C/W/356

draft negotiating text in July 2006⁴, which was co-sponsored by all the three developing countries of South Asia and the LDC Group, which represents the balance South Asian Members of the WTO. That proposal has been sponsored by 108 of the 153 WTO members; apart from 15 individual Members, three coalitions also co-sponsored it⁵. The proposal, and the case for negotiations on it, was opposed by some, mostly the 'New World' countries, linking the issue with the one relating to extension of the higher level of protection for geographical indications currently available only to wines and spirits to all products.

9. In preparation for the upcoming Mini-Ministerial conference of the WTO in July 2008, the proponents of all the issues under negotiations relating to the TRIPS Agreement came together almost at the last moment, on 19 July 2009, to propose modalities for adoption by the Ministers of a procedural decision to open a way forward for negotiations⁶. The ranks of individual Members supporting these modalities swelled higher than the July 2006 proposal, and again included all the developing country Members of South Asia. However, perhaps due to the late stage, one coalition, the LDCs Group, did not co-sponsor it. Nevertheless, all South Asian countries are in favour of the disclosure proposal as well as the modalities proposed for all TRIPS issues during their interventions in the WTO negotiating forums.

Other Steps at the National Level and Going Beyond the WTO

10. South Asian countries have a considerable stake in the TRIPS-CBD issue. Not only will the disclosure proposal prevent bio-piracy and grant of erroneous patents, it can lead to traditional knowledge holders in the region availing benefits from use of their knowledge in commercialised patents. Hence these countries are working together in the WTO negotiations to support the disclosure proposal. India has also developed a Traditional Knowledge Digital Library⁷ to supplement these international efforts aimed at preventing erroneous patents and bio-piracy. TKDL lists more than 200,000 traditional medicines formulations and makes it available as prior art to patent offices to determine the novelty, one of the three criteria of patentability. TKDL is available in five languages, thus increasing its reach to many patent offices of the world.

11. South Asian countries participate in the ongoing initiatives in the CBD on access and benefit sharing and in WIPO on traditional knowledge. The CBD Working Group on Access and Benefit Sharing has drafted a Protocol to prevent misappropriation of genetic resources in March 2010. This could be finalised at the CBD Conference of Parties in October 2010. In addition, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) also obtained a renewed mandate⁸ in the WIPO General Assemblies in October 2009 to undertake text-based negotiations that will eventually become an

⁴ TN/C/W/41/Rev.2

⁵ The ACP Group, the African Group and the LDC Group

⁶ TN/C/W/52

⁷ See <http://www.tkdil.res.in/tkdil/LangDefault/Common/Home.asp>

⁸ See http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_15/wipo_grtkf_ic_15_ref_decision_28.pdf

international legal instrument (or instruments) to ensure the effective protection of traditional knowledge, genetic resources and traditional cultural expressions (folklore). The IGC meets on 3-7 May 2010 to discuss, *inter alia* a list of options⁹ compiled by the WIPO Secretariat based on earlier documents and feedback from Members. The list contains options on how to undertake future work in the IGC on (a) defensive protection of genetic resources, (b) disclosure requirement, and (c) IP issues in mutually agreed terms for fair and equitable benefit sharing. UNCTAD has published¹⁰ a well researched paper containing elements of an International Regime for the Recognition of National Regulations on Access to Genetic Resources. All these efforts will need to be complemented by national access and benefit sharing regimes so as to put such international agreements and elements into operation.

12. The notifications of South Asian countries in the CBD show a range of preparedness at the national level. Seven of them have national biodiversity action plans. Afghanistan has plans to embed related legislation in its Environment Act. In some cases the preparedness has advanced to the stage of having legislation, while in others national executive action aims to protect biological diversity and provide for access and benefit sharing procedures. Details culled out of the most recent national reports from the South Asian countries to the CBD are listed in the Annex.

Suggestions for Way Forward

13. South Asian delegations may like to discuss the following possible ways to advance their objective of having an amendment to the TRIPS Agreement to provide for the disclosure requirement and to prepare the countries to benefit from such a provision:

- a. South Asian countries could make a joint submission to the WTO Trade Negotiations Committee supporting the modalities for adoption of a procedural decision to open a way forward for negotiations, and work as a group in these negotiations.
- b. Where not done already, they could take expeditious steps to develop legislation necessary to protect biological diversity and an access and benefit sharing regime at the national level.
- c. They could increase regional efforts through the aegis of SAARC to assist each other with experiences of fighting bio-piracy and in developing legislation and procedures for access and benefit sharing.
- d. South Asian countries could benefit from the experience of TKDL in India in preventing erroneous patenting.

⁹ See http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_16/wipo_grtkf_ic_16_6.pdf

¹⁰ See http://www.unctad.org/trade_env/test1/publications/UNCTAD_DITC_TED_2007_9.pdf

South Asian countries' laws or action plans notified to CBD

Bangladesh

- *3rd National Report 2005*
 - No laws or national policies that address the role of intellectual property rights in access and benefit-sharing arrangements. Potential policies have been identified, there are relevant provisions identified in the Biodiversity and Community Knowledge Protection Act (draft)
- *Biodiversity and Community Knowledge Protection Act (draft) 1998*
 - Bangladesh wishes to model a potential law or act on this draft
 - Upholds the common property regimes as against any private claim over the biological and genetic resources and intellectual and cultural knowledge and practice related to these resources in case of legal conflicts
 - Recognize a 'community' as having legal persona and their rights are inscribed in article 5 of this act
 - All biological and genetic resources within the territory of Bangladesh belong to the people of Bangladesh and all biological and genetic resources are declared common

Bhutan

- *4th National Report 2009*
 - Goal 2.1: to promote equity and benefit sharing
 - Target: established by 2008 mechanisms for the equitable sharing of both costs and benefits arising from the establishment and management of protected areas
 - Progress: assess and benefit sharing modules being developed and the provisions incorporated in Biodiversity Act 2003, in the framework for fair and equitable benefit sharing outlined in BAP III
 - Obstacle encountered: issues are complex with various stakeholders, new ideas/concept is difficult for people to accept
- *Biodiversity Act 2003*
 - Asserts sovereignty of the country over its genetic resources, the need to promote conservation and sustainable use of biodiversity resources as well as equitable sharing of benefits arising. Lays down the conditions for grant access, benefit sharing, and describes various rights, offences and penalties.
 - Access to Bhutan's biodiversity now requires prior informed consent (PIC). PIC is obtained and access authorized through an access permit
 - Benefit sharing is required as a condition of access (determined by a case-by-case basis)
 - Cannot collect biological specimen without the permit, however there are exceptions.
- *Biodiversity Action Plan from 2002*
 - Part 6 states the need to have guidelines for regulating plant genome resources (PGR).

India

- *Fourth National Report to CBD 2009*
 - *The Biodiversity Act (BDA) of 2002* provides for regulating access to biological resources and associated traditional knowledge so as to ensure equitable sharing of benefits arising out of their use, in accordance with the provision of the CBD.
 - *The PPV&FR Act 2001* and the *PPV&FR Rules 2003*, provide measures to protect plant breeder's rights over new varieties developed by them and the entitlement of farmers to register new varieties and also to save, breed, use, exchange or sell the plant varieties.
- *The Patent Second Amendment Act 2002* and *Patent Third Amendment Act 2005*
 - Provide for exclusion of plants and animals from the purview of patentability (Section 4e); exclusion of an invention which in effect is traditional knowledge from patentability (Section 4p); mandatory disclosure of the source and geographical origin of the biological material in the specification when used in an invention (Section 8d); and the provision for opposition to grant of patent or revocation of patent in case of non-disclosure or wrongful disclosure of the source of biological material and any associated knowledge.
- *Biodiversity Act 2002*
 - Section 19 and 20 show how to get the approval of the National Biodiversity Authority to obtain any biological resource coming from India or to apply for a patent.
 - The National Biodiversity Authority shall while granting approvals under section 19 or section 20 details the terms and conditions subject to which approval is granted so as to secure equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.
 - Benefit sharing can be given in any of the following manners:
 - (a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
 - (b) transfer of technology;
 - (c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
 - (d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
 - (e) setting up of venture capital fund for aiding the cause of benefit claimers; and
 - (f) payment of monetary compensation and non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.
- *National Biodiversity Action Plan 2008*
 - Issues relating to benefit sharing and protection of traditional knowledge are rather complex and still evolving. Being a megadiverse country rich in associated traditional

knowledge, effective implementation of the Biological Diversity Act and Rules is in the interest of the country and its people, and therefore needs to be strengthened. Experience gained in implementation of the national legislation on Access and Benefit Sharing (ABS) would be of much value in strengthening and effectively articulating the developing country perspective for an international regime on ABS presently being negotiated under the CBD.

- Acknowledges that even though access and benefit sharing is subject to national legislations, national action alone is not sufficient to ensure benefits to the country that provides the resources, particularly when the genetic resource is utilized in another country for developing processes and products on which protection is obtained.

- Solution? – international regime on ABS being negotiated by a working group on ABS

Maldives

- *First National Report 2002*
 - Access to genetic resources of the Maldives is at present only regulated with respect to marine resources. Fisheries Law stipulates that no marine research activity can be undertaken without the prior consent of the Ministry of Fisheries, Agriculture, and Marine resources (MOFAMR).
 - The Marine Research Regulation stipulates conditions for access for research into marine genetic resources. Benefit sharing mechanisms for the use of marine resources for research have been developed and imposed by MOFAMR on an *ad hoc* basis. Hence, while some research programmes have resulted in benefits to the country, many programmes have been carried out to show components of Maldivian biodiversity exported without legally binding agreements with the Government for equitable benefit sharing measures on the use of the country's genetic resources. Furthermore, end of research results are rarely made available to the public or non-government parties. This is a gap that must be addressed through the management framework.
- *National Biodiversity Strategy and Action Plan (NBSAP) 2002*
 - (Actions 44 and 45) strategies have been recommended to establish regulations for access to both terrestrial and marine genetic resources, and the mechanism for equitable benefit sharing measures for communities for the use of their resources. Activities would include strengthening system for screening research proposals made by foreigners entering into contract with parties whose research proposals are accepted, so the IPR are protected; monitoring the activities of parties who have been awarded contracts to use such material; introduce appropriate legislation setting out terms of access to genetic materials of/in the Maldives to control access to genetic resources and ensure that Maldivians gets their fair share of any benefits derived from the utilization of these resources; establishing appropriate forms of IPR protection to ensure that local/indigenous knowledge about living organism and their use are protected.
- *Second National Environment Action Plan (NEAP II)*
 - Identify and analyses options to meet the objectives of the CBD, including strategies for conservation, sustainable use and benefit sharing.

Afghanistan

- *Third National Report to the CBD 2007*

- There are no national policies or measures which address the role of intellectual property rights in access and benefit sharing. At present, access and benefit sharing is a new and untested phenomenon in Afghanistan. At a later stage, it is likely that regulations will be developed to flesh out the access and benefit sharing provisions in the Environment Act, 2005. This reports states that the ABS is a new and alien concept to Afghanistan.
- Has no measures to prevent and mitigate the negative impacts of key threats to mountain diversity
- It has also not developed any legal, policy, and institutional framework for conservation and sustainable use of mountain biodiversity and for implementing this program of work.
- No action has been taken to identify and assess the mountain biological diversity
- Still need to develop a national biodiversity strategy and action plan

Pakistan

- *Fourth National Report 2009*
 - Access and benefit sharing legislation drafted, but national and regional consultations not completed.
 - IUCN Pakistan – In order to demonstrate the contribution of healthy ecosystems and natural resources on reducing poverty and improving livelihoods needs sustainable harvest and equitable benefit sharing of edible pine nut seeds; sustainable community forest and management and benefit sharing; and benefiting community from cold water fisheries.
 - The protected areas in Pakistan are generally established on state lands where there are no indigenous or local communities within the protected area itself. However, the communities living around the protected areas have always depended on the protected areas for some of their subsistence needs. The economic and socio-cultural costs of protected areas are now being increasingly taken into consideration. The protected areas are presently being managed under the wildlife laws that were made in early 1970s. These laws are now under revision, and participatory approaches are being incorporated.
- *Biodiversity Action Plan 1999*
 - One of the issues still needed to be addressed is access and benefit sharing
 - To develop access legislation as a matter of priority to comply with Article 15 (genetic resources), Article 16 (technology) and Article 19 (handling of biotechnology and distribution of its benefits (Section 4.11).
 - To develop policies and laws to regulate access to genetic resources and promote the equitable sharing of benefits between resource owners and users (objective 22)

Sri Lanka

- *Fourth National Report to the CBD 2009*
 - Benefit sharing has not been addressed in depth in the Biodiversity Conservation Action Plan (BCAP), developed in 1999 when such issues were at a very incipient stage in the global arena and considerably new at the national level. However many of its recommendations are still relevant particularly pertaining to access and benefit sharing.
 - In the Addendum to the BCAP access and benefit sharing and biotechnology was suggested as possible themes for the proposed task force and as a link to the 2010 target

- Goal 10 to ensure the fair and equitable sharing of benefits arising out of the use of genetic resources, to put a system in place that precludes provision of the country's genetic resources to external parties without PIC and MTA.
- The need to ensure fair and equitable benefit-sharing and secure farmers' rights are currently being discussed
- A national policy on access to genetic resources and benefit sharing is proposed. An act on plant breeders' right to cover fair and equitable benefit-sharing is also proposed
- *Biodiversity Conservation: A framework for Action 1999*
 - Does not address the issues of disclosure, PIC, or benefit sharing, though does state that actions must be taken.

Nepal

- *Fourth National Report 2009*
 - Target 9.1- Ensure protection of traditional knowledge through access to genetic resources and benefit sharing (AGRBS) legislation.
 - Target 9.2 – Protect IPRs through *sui generis* system.
 - Target 10.1- Access to genetic resources is in line with the CBD and its relevant provisions. Access to AGRBS drafted per guidelines of CBD Articles.
 - Target 10.2- Benefits arising from the commercial and other utilization of genetic resources shared in a fair and equitable way with the countries providing such resources in line with CBD and its relevant provisions. Make an attempt to develop a regional AGRBS framework and policy. *This target is achievable, but depends on political will.*
- *Nepal Biodiversity Strategy Implementation Plan (NBSIP) 2006*
 - Framework to materialize the vision of the Nepal Biodiversity Strategy (NBS) into practical actions of effective conservation of biodiversity and sustainable use of its resources.
 - One of the objectives for 2006-2010 is to develop legislation on access and benefit sharing of genetic resources.
- *Nepal Biodiversity Strategy (NBS) 2002*
 - No practical measures have been taken to integrate conservation, sustainable use of biological resources, and equitable and fair sharing of the benefits arising out of these into district level decision-making in Nepal.
 - A major achievement- Humla Oil Pvt. Ltd. has been established to ensure the sustainable management of Jatamansi and equitable sharing of benefits amongst the local people in Humla district, who are benefiting from the local processing
 - On the section for securing intellectual property and farmer property rights (section 5.1.11) it states that Nepal will ensure the IPRs of farmers and local communities through appropriate strategies and legislation. However it never goes into detail of what these strategies and legislation will be and encompass.