

TRIPS-CBD Relationship: Why Does it Matter?

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TRIPS-CBD

- Two Main International Instruments:
 - **TRIPS Agreement under the WTO**
 - **Convention on Biological Diversity [CBD]**
- **TRIPS Agreement**: Mandates grant of Patent rights under law for both products and processes.
- **CBD Agreement**: Protection and Conservation of Biological Resources; Recognition of the Importance of Traditional Knowledge for such protection and conservation.

TRIPS Agreement

- National Laws should provide for:
 - Patenting of Products and Processes: For all forms of technology- Article 27, TRIPS
 - Exceptions possible: Plants, Animals, Essentially Biological Processes
 - Plant Varieties have to be eligible for protection through patent protection or through a *sui generis* system of protection.

Objectives and Principles

- **Article 7 Objectives**

- The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

- **Article 8 Principles**

- Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance
- Appropriate measures may be needed to prevent abuse of IPRs by rights holders which unreasonably restrain trade or affect international transfer of technology

Convention on Biological Diversity

Objectives of CBD

1. Conservation of Biological Diversity
 2. Sustainable use of its components
 3. Fair and equitable sharing of benefits arising from the utilization of genetic resources
- Article 8(j), CBD: To **respect, preserve, maintain** Knowledge, Innovations and Practices of Indigenous and local communities and **encourage equitable sharing of benefits**.

Nagoya Protocol to CBD concluded in October 2010- pursuant to Objective 3.

- 40 Signatories, out of 193 CBD Parties. (Needs 50 ratifications for entry into force- has received 25 ratifications)
- Countries yet to sign include: U.S., New Zealand, Philippines.

CBD Principles on Access & Benefit Sharing

- Access to Biological Resources and their Genetic Components should be based on:
 - **Mutually Agreed Terms**
 - **Principle of Prior Informed Consent**
 - **Ensuring Fair and Equitable sharing of Benefits arising from use of the Genetic Resources**

Nagoya Protocol to CBD

Access Obligations w.r.t. GR

Establish Domestic-level access measures to:

Create legal certainty, clarity and transparency

Provide fair and non-arbitrary rules and procedures

Establish clear rules and procedures for prior informed consent and mutually agreed terms

Criteria for PIC; Involvement of local & indigenous communities for Access to GR

Provide for issuance of a permit or equivalent when access is granted (as evidence of PIC & MAT)

Access Obligations w.r.t. TK

Measures aimed at ensuring that TK associated with GR held by local & indigenous communities is accessed after:

Prior Informed Consent has been obtained;

Mutually agreed terms have been established.

“Take into consideration” community customary law, protocols, as applicable while accessing TK associated with GR

Where is the Interface between TRIPS and CBD?

Questions for Consideration

(i) Is there a Conflict between the TRIPS and CBD?

(ii) If so, what should be done for mutual supportiveness?

- Main Interface:
- When Patents are granted on “Inventions” that rely on Biological/Genetic Resources and Associated Traditional Knowledge, without following principles of CBD

- Key Objective
 - Ensure no Erroneous Patents are granted
 - Ensure no misappropriation of the Biological Resource or the associated TK

- How to Resolve the Interface- still being debated

Relevance of this issue

- Emergence of agricultural and pharmaceutical Biotechnology, and processes of 'Inventiveness' involved in these
- Emergence of IPRs for biotech products
- Recognition of the important contribution of genetic resources and 'traditional knowledge' associated with it to growth of agricultural and pharmaceutical biotechnology
- TK however- remains largely unrewarded.
- Debate therefore: How to bridge the gap?

IPRs- A Historical Context

- Emergence of IPRs linked to ‘Industrial Property’
- Applied principally to Mechanical Inventions or Artistic Creations
- IPRs over ‘living’ matter, or things derived from living matter, is of fairly recent origin
- Growth of human ingenuity and creativity: Concept of ‘reward’ & exclusive rights in relation to the same
- IP Regimes: Also reflective of state of economic development and private sector activity
- Similarly, emergence of IPRs over other biotech inventions in agriculture and pharmaceutical spheres, which rely on TK
- But no value was placed on the underlying TK that contributes to an invention.

Link between Traditional Knowledge and Biological Resources

- Areas of Biological Diversity and Cultural Diversity often co-exist
- Cultural Diversity and Traditional Practices seen as a nurturer and conserver of Biological Diversity
- Significant contribution to Biotech research
- Several pharmaceutical inventions have at their basis the prior knowledge and indigenous use of the substance
 - *One study estimated that out of 111 plant-based drugs, 74% estimated to have been in prior use by indigenous communities*
 - *Another study: By using TK as a 'lead', bio-prospectors can increase success ratio in trials from 1 in 10,000 to 1 in 2!*

India's Experience

- Patent claim over “Use of Turmeric in Wound Healing”
 - Patent was granted by the USPTO. CSIR and GOI decided to oppose it. Challenge- to show documented sources of ‘prior art’.
 - “Despite 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.” Extensive search- lead to 32 references in Sanskrit, Urdu and Hindi.
 - Patent claim over “method for controlling fungi on plants by aid of a hydrophobic extracted from neem oil:
 - European Patent Office granted patent in 1994. Opposition filed by group of Indian and international NGOs- that fungicidal properties of neem were known for centuries and applied by Indian farmers for crop protection. Nothing ‘novel’.
 - EPO concluded that all features in the patent claim were known and disclosed prior to the application; hence patent was revoked.
 - Patent claim by Ricetec over rice lines bearing come characteristics similar to Basmati:
- Most claims rejected after opposition by Indian Govt.

Mexico's Enola Bean

- U.S. Patent No. 5,894,079, the Enola bean, or yellow bean, patent was granted to John Proctor- president of seed company POD-NERS, LLC, in 1999
- Proctor brought the bean seeds to US from Mexico.
- Proctor now 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.
- International Center for Tropical Agriculture (CIAT) challenged the patent, arguing that the patent claims are invalid, failing to meet novelty and non-obviousness requirements and disregarding available prior art.
- USPTO and Federal Court processes- back and forth for close to 10 years. Under US law, pending final proceedings, claimant can enforce; so for 10 years, Proctor enforced his patent.
- Finally, patent claims set aside in July 2009!

Challenges and Lessons learnt

- There is a wide gap between any understanding on the relevance of TK for patent examination purposes
- Costs and Time for challenging/opposing a patent are quite high
- In jurisdictions like the US, the request for re-examination of a patent granted are conducted as *ex parte* proceedings. No scope for oral hearing and explanations to be given. This could act as a limitation.

How can the Challenges be Addressed?

Review of TRIPS Article 27.3(b); Doha Mandate

- The TRIPS Agreement requires a review of Article 27.3(b) which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties.
- **Paragraph 19 of the 2001 Doha Declaration has broadened the discussion. It says the TRIPS Council should also look at the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore.**
- It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account.

What Does TRIPS Provide for

- Minimum standards for protection laid out.
- Does not prescribe what needs to be considered at the Patent office and how procedural aspects are to be managed.
- Article 29: Conditions on Patent Applications:

“Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art...”

India's Proposal at the WTO

Introduce new Article 29bis: WT/GC/W/564- India, Brazil, Thailand, Peru, Pakistan, Tanzania (31 May, 2006)- With a view to enhancing mutual supportiveness of TRIPS and CBD:

Where the subject matter of a patent application is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose:

- Source and/or Country of Origin of such Resources and Knowledge, AND
- Evidence of Compliance with national law requirements on:
 - (i) Prior Informed Consent
 - (ii) Fair and Equitable Benefit sharing from commercial and other use
- Supported by 77 Developing Country Members
- No progress though!

Proposal on How to Enforce such requirement

- Effective enforcement procedures to ensure compliance
- Administrative and/or judicial authorities should have the authority to prevent the further processing of an application or the grant of a patent and to revoke, or render unenforceable, a patent when the applicant has:
 - knowingly or with reasonable grounds to know, failed to comply with the obligations or
 - provided false or fraudulent information.
- New Proposal on 15 April 2011: Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of the African-Caribbean-Pacific Group), Peru, and Thailand circulated TN/C/W/59: Building on earlier Proposal, and linking to Nagoya Protocol

Opposition to India's Proposal

- **Disclosure under WIPO:** Switzerland's proposal that Disclosure should be addressed under WIPO's PCT
- **Disclosure under TRIPS, but remedies outside TRIPS:** EU's proposal to examine a requirement that all patent applicants disclose the source or origin of genetic material, with legal consequences of not meeting this requirement lying outside the scope of patent law.
- **Disclosure and Remedies under National Laws:** US position that CBD obligations should be addressed under National Legislation and Bilateral Contracts. TRIPS should not be touched.

Parallel Developments at WIPO

- Broad Mandate of WIPO: Promote Cooperation worldwide on Patent Law Procedures and Enforcement
- 2000: Patent Law Treaty was signed- Aim to Harmonize and Streamline Patent Law Procedures:
 - Intervention by India and other developing countries on need for Disclosure norms
- Inter Governmental Committee on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions (IGC) at WIPO was established by the WIPO General Assembly in October 2000.
- IGC Mandate: Develop legal mechanisms & practical tools for:
 - *Protection of traditional knowledge (TK) and traditional cultural expressions (TCEs) against misappropriation and misuse*
 - *Intellectual property issues relating to genetic resources (GR).*

WIPO- 13 years on...

- **Endless rounds of meetings and discussions:**

 - 3 Legal Texts on TK, TCE and GR**

- **On Traditional Knowledge:**

- Should the protection under the treaty be in respect of only TK held closely by the communities, or should there be inclusion of diffused TK?
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- What should be the terminology that is used to identify beneficiaries: “indigenous peoples” or “indigenous communities”? Should families, nations and individuals be considered as beneficiaries? How should “local communities” and “traditional communities” be defined? Who would be the beneficiary, where TK is not specifically attributable or confined to an indigenous people or local community, or it is not possible to identify the community that generated it?
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- Scope of protection: discussions have focused on the issue of mandatory disclosure of the TK holders, the country of origin, as well as evidence of compliance with prior informed consent and benefit-sharing requirements. The key issues are:
 - Should the treaty list out positive rights?; or
 - Should the treaty provide freedom for countries to decide the nature of protection;
 - Should prior informed consent be required in respect of use of all forms of TK?
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WIPO- 13 years on...

Approach to GR: Same Issues as Under WTO; Same principles as Article 29bis

- **Mandate and Ambit of Disclosure Norms in Patent Applications**
- **Consequences of Non-Disclosure or Incorrect Disclosure**
- **.....**
- **No Resolution in sight**

India's Own Experience

Legal Framework

- India does not have a law on Traditional Knowledge
- However, legislative innovations in past decade provide some basis for protecting TK:
 - Protection of TK against Misappropriation
 - Fair and Equitable Benefit Sharing
 - Rights of TK holders

TK Interface

- **National Biological Diversity Act**
- **Patents Act**
- **Protection of Plant Varieties and Farmers Rights Act**
- **Geographical Indications Act**
- **Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006**

India's Patent Act

- Section 3: What are NOT Inventions:
 - (p): an invention which in effect, is TK or which is an aggregation or duplication of known properties of traditionally known component/s
- Section 10: Disclosure Norm
 - Applications pertaining to Biological Material should disclose Source and Geographical Origin of Biological Material
- Form 1 under Patent Rules
 - Declaration by Applicant that Biological Material used from India has been obtained after permissions from relevant authority

Traditional Knowledge Digital Library (TKDL)

- Database on the codified knowledge for the Indian Systems of Medicine -Ayurveda, Siddha, Unani and Yoga
- NOT a diagnostic or usage database
- Main Objective: To Help Patent Examiners to determine Prior Art

TKDL Experience

- Pilot project- not a comprehensive documentation of TK
- Access MoUs signed with EPO, JPO, USPTO
- Effective mechanisms to prevent leakage are yet to be perfected
- In any case, it is only to supplement Disclosure Norms
- US View: Document all your knowledge and give us access to TKDL!

THANK YOU!