

Reconciling TRIPS and CBD

THROUGH DISCLOSURE REQUIREMENT

POLICY BRIEF

INTRODUCTION

Convention on Biological Diversity (CBD), 1992 could be 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, CBD is important on two counts. First, it recognises that the rights over their genetic resources lay with the sovereign states and second, it provides a multilaterally agreed set of rules for access to and sharing of benefits arising out of the commercial use of genetic resources.

However, the emergence of the modern biotechnology industry in the past few decades coupled with the growing interests of the large corporations raised demands for providing protection to the technologies that were being developed by this industry. The formalisation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organisation (WTO) framework was a direct consequence of the efforts that the commercial interests in this frontier technology had made to protect their interests.

Although the two processes, viz, TRIPS and CBD, have been on parallel tracks during the period these were being negotiated, there are at least two compelling reasons why they should be seen in conjunction with one another. First, both are products of the multilateral system, and therefore, any perceived inconsistencies between the two would have to be addressed so that the signatory countries can meet the requirements for complying with both. Second, the WTO, which monitors TRIPS, 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 singularly important because it releases the organisation 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 implementation of CBD and TRIPS in a mutually supportive manner raises several issues that require careful consideration. Such issues can be divided into two broad themes:

- (a) The concerns with the grant of intellectual property rights (IPRs) over products and processes based on



biological resources and traditional knowledge (TK) associated with the same, and how can amendments to the patent regime address some of those concerns.

- (b) The implementation of benefit sharing mechanism under CBD, particularly the one relating to transfer of and sharing of benefits from proprietary technologies based on genetic resources to countries that have been the providers of such resources.

IPRs ON BIOLOGICAL RESOURCES: THE CONCERNS

During the past two decades, the rapid progress made by biotechnology has raised the piquant problem of extending IPRs to products based on genetic resources. In fact, until 1980, when the first patent on a living organism was granted in the United States (US) through the intervention of the country's Supreme Court to a genetically engineered microorganism, the US Patent and Trademark Office (USPTO) followed the broad principle that products of nature are not patentable. Although patents for biological process inventions had been awarded since the 1800's, the USPTO did not permit patents on living products because they were a "product of nature" and

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were, therefore, not subject to the statutory subject matter defined by the Patent Act. In *Diamond vs. Chakrabarty*, the Supreme Court determined that a human-made microorganism is patentable subject matter as a “manufacture” or “composition of matter” and that “anything under the sun that is made by man” could be patented. Since then while the developed world has followed the precedent that was set in the US in respect of patenting of products of nature, many countries in the developing

Box: 1

Concerns about Tangible Physical Resource and Intangible Information Base

The concern with inventions based on biological resources that has been expressed in the developing world is not only about the tangible physical resource but also about the intangible information base associated with that resource. The originators and custodians of such information are local/indigenous communities, who through years of consistent skill, observation and usage have developed a wealth of knowledge base regarding the use and properties of various biological resources. The value of this knowledge base and its key role in the development of the final product have been well documented.

The basic consensus in these writings is that local/indigenous knowledge and use of biological resources play 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. The concern is 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.

world remain steadfastly opposed to extending patents to cover “life forms”.

DISPUTES OVER RECONCILING CBD AND TRIPS

Several developing countries have been arguing for the development of effective linkages between TRIPS and CBD so that the objectives of both can be realised. The principal submissions by these countries have been that TRIPS should be amended thus:

“Members shall require that an applicant for a patent relating to biological materials or TK shall, as a condition to acquiring patent rights, disclose the source of the biological resource and/or TK used in the patent claim; and provide evidence that national laws on prior informed consent (PIC) and benefit sharing have been complied with prior to obtaining the biological resource and/or TK used in the patent claim.”

Developed countries, including the US and Japan, have, however, strenuously opposed these arguments. Their principal contentions have been that: (a) compliance with CBD should be dealt with separately under national

access and benefit sharing (ABS) regimes; (b) the objectives of CBD and TRIPS do not conflict with each other; (c) expanding disclosure norms under TRIPS for products based on biological resources will constitute discrimination based on fields of technology and thereby violate the basic principles of TRIPS; (d) disclosure norms constitute an additional and unnecessary burden on patent applicants and patent offices; and (e) biodiversity rich countries should compile databases of biological resources and TK to enable patent offices worldwide to conduct better searches.

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

ARGUMENTS FOR LINKING TRIPS AND CBD

In view of the above, it is important to look at the arguments that would provide the basis for establishing the linkages between TRIPS and CBD. Besides, it is also important to dwell on what needs to be done beyond developing these linkages.

Why Do We Need Norms of Disclosure ?

It is believed that disclosure of source of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing bio-piracy and misappropriation of TK. A mandatory obligation on the patent applicant as part of the norms of disclosure would, to an extent, be a self-policing provision. This approach would have the following advantages: (a) it would be an additional reason why the patent applicant would be encouraged to comply with the national laws on ABS; (b) the onus would be on the patent applicant, so members cannot raise the objection of higher administrative costs for the patent office; (c) it would enable patent offices to be more vigilant while examining patent applications that deal with a biological resource and associated TK; and (d) it would serve as a critical tool for biodiversity rich countries in tracking down applications based on bio-resources and related TK, and enable adequate challenges to specious patents.

It is but obvious that in the case of inventions based on biological resources and/or associated TK, the source of origin is critical for ascertaining whether or not the applicant has “invented” what he/she claims in the patent, or has just found it in nature or obtained it from traditional cultures. 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 would enable a better assessment by the patent examiner of the novelty and inventive step involved in the invention.

Box-2

Purposes of Disclosure of Source of Origin

Disclosure of source of origin serve different purposes: (a) reducing instances of the so-called “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; and (d) improving compliance with their national laws on PIC and fair and equitable benefit sharing prior to accessing a biological resource/associated TK. This would also increase the credibility of the patent system as well as contribute to achieving the principal objectives of TRIPS. Placing the onus on a patent applicant to disclose the basis of the claims is a step that can pre-empt any misuse of patent laws and thereby prevent misappropriation of genetic resources and TK.

Notions of equity and good faith mandate that the international community create an equitable system for the acquisition, maintenance and enforcement of IPRs, which does not *a priori* exclude any section of the society. 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 TK acquired in contravention of any legislation governing access to the material. This aspect has also been recognised under CBD, which provides in Article 16(5) that countries should cooperate to ensure that patents and other IPRs are supportive of and do not run counter to the objectives of CBD. As stated at the outset, CBD principally seeks to establish the basic framework for access, 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 CBD with the norms of disclosure of a patent application in TRIPS 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 CBD as well as the objectives articulated in Article 7 of TRIPS, which emphasises 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”.

Compliance with Basic Tenor of TRIPS

One of the arguments against the proposal for expanding the norms of disclosure has been that the amendments would not be consistent with TRIPS and would violate the principle of non-discrimination between fields

of technology. This, however, is not the case when adequate distinctions can be drawn between fields of technology.

It may be stated in this context that the basis for the invention in the case of a product based on a biological resource can often be the existing knowledge used by a local or indigenous community pertaining to the biological resource, a fact that has been recognised. Before a patent is granted, it would, therefore, be important to verify the extent of the prior existing knowledge that it utilises and the “inventiveness” involved. Procedures adopted for granting patents often have to be different depending on the “field of technology”. For instance, in the case of microorganisms, the nature of invention demands that the microorganisms that are used are deposited prior to grant of the patent in order to effectively fulfil the requirements of disclosure of the invention. In a similar vein, where the field of technology involves bio-genetic resources, the special circumstances surrounding bio-genetic resources and associated TK 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.

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 “invention” 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. Such a requirement would also pave the way for a comprehensive international solution so that countries that are victims of bio-piracy do not need to divert their precious national resources to expensive judicial procedures for the revocation of patents based on illegally obtained resources and associated TK.

Consequences of Non-disclosure

One of the critical issues to be addressed is the following: assuming there is an in-principle agreement over the inclusion of the norms of disclosure as discussed above, what would be the consequences of non-disclosure?

As discussed above, the EC has supported the inclusion of disclosure of origin as part of the patent application but would want the consequences of non-dis-

closure to be dealt with outside the patent system. This raises the question: would we not be diluting the nature of the provision itself by leaving consequences outside of the patent system?

It is an established principle of patent law in most jurisdictions that inadequate disclosure is an offence, which could lead to revocation of a patent. Under current Indian law governing patents, for instance, failure to disclose or wrongful disclosure could result in revocation of the patent. The Indian Patents Act, as amended



in 2002, provides in Section 25 the following grounds for revocation of patents owing to non-disclosure: (a) the complete specification does not disclose or wrongly mentions the source or geographical origin of

the biological material used in the invention; and (b) the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

Under the US law, when a patent is marked by a failure to disclose material information or submission of false material information, with intent to mislead, the patent becomes unenforceable. This is also called the doctrine of inequitable conduct. The consequences for non-disclosure have thus been dealt with within the patent system, and should continue to be done so, despite suggestions to the contrary.

Information on origin of a biological resource and knowledge pertaining to the resource used for a patentable invention are material to determining the nov-

elty and innovation involved in the patent claim, and hence should be treated as "material information". This would be an inevitable outcome of recognising the centrality of such disclosure in assessing "novelty" and "inventiveness", elements necessary to grant a patent. Consequences for non-disclosure would, therefore, have to be built into the patent system, since any departure from this would strike at the very root and logic of the patent system. Wrongful or inadequate disclosure can defeat the entire objective of the patent system.

CONCLUSION

The functioning of the IPR regime has, in recent years, raised a number of concerns arising primarily from the growing evidence of misappropriation of TK and unauthorised exploitation of genetic resources through the grant of "bad" patents. These issues are of particular concern to the biodiversity rich developing countries where local communities have traditionally used the bio-resources as well as the associated TK for sustaining their livelihood.

These concerns have been adequately reflected in discussions that have been held in several multilateral forums, where developing countries have emphasised the need to put in place a legal regime that could help address the concerns referred to above. Developing countries have proposed that TRIPS should be amended so as to provide for mandatory disclosure of source of origin of biological resources and/or associated TK in any patent application containing an invention that uses these resources and/or knowledge. It has been argued that inclusion of such provisions would help both countries that have been given the rights over their biological resources by CBD and the local communities, who have been using associated TK for sustaining their livelihood. This would also complement measures taken to ensure benefit sharing in a fair and equitable manner with commercial interests exploiting the resources and knowledge. ■

Launched in December 1994 at Nagarkot, Nepal by a consortium of South Asian NGOs, South Asia Watch on Trade, Economics & Environment (SAWTEE) is a regional network that operates through its secretariat in Kathmandu and 11 member institutions from five South Asian countries, namely Bangladesh, India, Nepal, Pakistan and Sri Lanka. Registered in Kathmandu in 1999, the overall objective of SAWTEE is to build the capacity of concerned stakeholders in South Asia in the context of liberalisation and globalisation.



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