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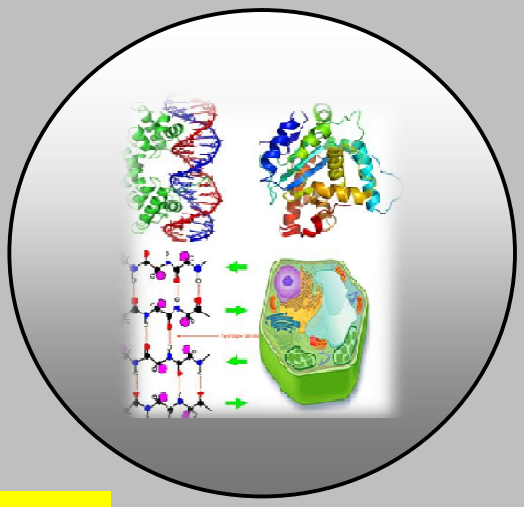

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A Critical Analysis on the Relationship between WTO/TRIPS Agreement and the Convention on Biological Diversity in Context of Genetic Resources and Associated Traditional Knowledge: Issues and Challenges

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ABSTRACT

The issue of "Access to Genetic Resources and Traditional Knowledge and its Benefit Sharing" is one of the most hotly debated topics nowadays in the regime of Intellectual Property Rights. This paper deals with the problems that have aroused because of confrontation between the provisions of WTO/TRIPS agreement (Agreement on Trade related Aspects of Intellectual Property Rights)and Convention on Biological Diversity (CBD) in respect of Access and Benefit Sharing of genetic resources and Associated Traditional Knowledge. A sort of crisis arises in the realm of international law when different treaties and conventions are not in the conformity with each other. For example, if two different international conventions, agreements or multilateral treaties are not compatible with each other or they are in conflict with each other than it directly results in the conflict of interests of member countries and occurrence of the disputes between such member countries are apparent. Same thing is happening due to the conflict between the provisions engulfed in WTO/TRIPS Agreement on one side and Convention on Biological Diversity on the other as the former is putting emphasis on the commercialisation of natural resources while latter is based on the principles of sustainable development. Therefore this paper reflects the position of developed countries on the relationship between WTO/TRIPS agreement and Convention on Biological Diversity and the criticism of such position by developing and least developed countries based on some issues and challenges.

Keywords: WTO/TRIPS Agreement, Biological Diversity and Genetic Resources.

INTRODUCTION

The CBD is having three main goals i.e. conservation of biological diversity or biodiversity, sustainable use of its components and fair and equitable sharing of benefits arising from genetic resources. Whereas WTO/TRIPS agreement in not having any provisions which is in conformity with the aforesaid goals of CBD. On the contrary if an application is filed for the grant of the patent under the provisions of TRIPS Agreement then there is no obligation on the applicant,

- To disclose the source and country of origin of the biological resource used in the invention;
- To provide evidence of prior informed consent through approval of authorities under the relevant national regimes and
- To provide evidence of fair and equitable benefit sharing under relevant national regimes.

Thus the mode of access to genetic resources and associated traditional knowledge without sharing any adequate benefit with the indigenous people who are the main provider thereof and without disclosing adequate information about such access is totally unethical and against natural law. Due to the lack of provisions to prevent such practices in WTO/TRIPS agreement, parties who are making access to genetic resources and associated traditional knowledge are availing undue benefits and also posing a great threat to the sovereignty of a member nation on its own genetic resources.

There are many developing and least-developed countries, including those located between the two tropics, have incredible reserves of Genetic Resources and associated traditional knowledge within their territories.[1] Those Genetic Resources, some of which have been used for centuries by indigenous people in various countries for medicinal purposes, are now proving to be potentially valuable.

The indigenous people have incredible reserves of genetic resources which are very necessary for stability and balance in nature. On the other hand there are some developed industrialised countries which are mainly located globally north and their economy is mainly built on knowledge based industries. These developed countries are having ample of technological and monetary resources. They make access to genetic resources and associated traditional knowledge and make products, say-medicines and lifesaving drugs by using their technology thereon. Subsequently they apply for a patent for the protection of such products which are actually not theirs but belong to those indigenous people who provided them genetic resources and associated traditional knowledge. Thus they acquire monopoly over the use of that particular genetic resource and associated traditional knowledge and which is also against the principles of fair market.

All this injustice is done by developed and industrialised countries who are taking wrong advantage of the ignorance of the indigenous people in the field of intellectual property rights who know all about genetic and biological resources and its values. Such technologically advanced countries are infringing the basic rights of indigenous communities by neither providing them adequate monetary share and nor providing any transfer of technology.

Apart from this they have also posed a great threat of upbringing uniformity which is a direct result of development in biotechnology and genetic engineering and destroying biodiversity which is very necessary for the stability. Thus we can see that all the goals of Convention on Biological Diversity are being violated uninterruptedly and this is not in the favour of future generations.

A submission was made by some developing countries under paragraphs 12 and 19 of the Doha Ministerial Declaration.[2] This submission was preceded by numerous papers and submissions from developing countries to develop an effective and consistent framework so as to enable the WTO Members to meet their obligations under both the TRIPS and the CBD.[3] The main issues raised in those papers were that the WTO/TRIPS Agreement should be amended in such a manner that the member countries shall require patent applicants for a patent relating to genetic resources or associated traditional knowledge to provide, as a mandatory condition for acquiring patent rights, relevant information about source and country of origin of the genetic resources and associated traditional knowledge used in the invention, evidence of prior informed consent through approval of authorities under the relevant national regime and evidence of fair and equitable benefit sharing under the relevant national regime.

Such amendments in WTO/TRIPS Agreement are critical for ensuring that it can be implemented in a mutually supportive manner with CBD. Other than this such amendment would play a significant role in preventing biopiracy and misappropriation[4] and in some cases, prevent the issue of 'bad patents' which is granted without due regard to the patentability criteria of novelty, that is, prior use and knowledge with regard to the resource. In the absence of rules of disclosure of source of origin of the genetic resources and associated traditional knowledge, country of origin can claim that patent has been granted in a wrong manner, and such country can pursue legal remedies under the patent laws of that other country where the patent has been granted or under its own laws on access to resources. However, pursuing a legal remedy under international laws and in multiple jurisdictions is intricate and expensive, and may not be economically feasible for many aggrieved countries. Apart from this, the unusual patent laws in countries which recognize prior art outside their country only in the form of documents, that is, written and published information, create formidable challenges against legal remedies.

In the case of inventions based on genetic resources or associated traditional knowledge, the information regarding source of origin is important for ascertaining inventorship, that is, whether the applicant has invented, what has been claimed, or whether the applicants have just found it in nature or obtained it from traditional cultures.[5]

Its importance can be ascertained in the case when the traditional knowledge used in the invention is undocumented and exists in oral form, or is documented in a local language. Disclosure of origin of genetic resources and associated traditional knowledge would allow a better assessment to check novelty and inventive step involved in the invention.

Principles of equity and good faith dictate that the international community should create an equitable system for the acquisition, maintenance, and enforcement of intellectual property rights, which should not exclude any section of the society.

It has been acknowledged that the principle of equity dictates that no one should be allowed to benefit from exploiting Intellectual Property Rights based on genetic resources or associated traditional knowledge acquired in contravention of any legislation governing access to the material.[6] This aspect has also 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. The CBD establishes the basic framework for access, prior informed consent and fair and equitable benefit sharing, in recognition of a country's sovereign rights on its genetic resources and associated traditional knowledge. Establishing a link between the frameworks of the CBD with the norms of disclosure of a patent application in the WTO/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 or indigenous communities over their genetic resources or traditional knowledge. It is widely believed that such provisions will be in consonance with, and in pursuance of the CBD as well as the objectives expressed in Article 7[7] of the WTO/TRIPS Agreement, which emphasises on the need for a balance between the monopoly rights granted under the intellectual property regime and the public interest. Thus the disclosure norms should include evidence of Prior Informed Consent through approval of authorities under the relevant national regime in the country of origin of the resource and traditional knowledge, as well as evidence of fair and equitable benefit sharing under the relevant national regime.

It is an established principle of patent law that a false representation of material information could lead to revocation of a patent. For instance, under the Indian patent law, failure to disclose or wrongful disclosure of source of origin of a biological resource and evidence of traditional knowledge, or a false suggestion or representation could result in revocation of the patent. Under U.S. 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 of failure to disclose or wrongful disclosure of origin of the biological resource and associated traditional knowledge, and evidence of prior informed consent and fair and equitable benefit sharing should be addressed within the patent system, in the same manner as consequences of material information have been treated within the patent system.

But there is a conflict between developed and developing nations on the amendment of WTO/TRIPS agreement and bringing it in conformity with CBD. Thus in order to analyse different positions of developed and developing countries and articulate a conclusion a detailed discussion is done following here.

I. Position Of Developed Countries On Relationship Between WTO/TRIPS Agreement And The Convention On Biological Diversity In Context To Disclosure Of Source And Origin, Evidence Of Prior Informed Consent And Benefit Sharing And Criticism Of Such Position:[8]

1. According to developed countries the objectives of WTO/TRIPS Agreement and the CBD are distinct and there is no conflict between them.

CRITICISM

These developed countries compare Article 1 of the CBD and Article 7[9]of the TRIPS, and argue that the objectives of the two documents do not run counter to each other and are mutually supportive. They, however, emphasises its analysis on an excessively narrow interpretation of both treaties, which does not take into account their spirit and objectives. It is well accepted that the CBD does not address the resource depletion issue alone. Instead, it highlights this issue as a result of the extensive piracy of biological and genetic resources of the countries who are rich in it. It is an accepted fact that the gene and biochemical hunt over the components of biological diversity is largely driven by their use, value or the knowledge associated with those resources, without which bio prospecting loses much of its content.

This knowledge associated with the biological resources is also a product of the human intellect, which is recognized under the CBD as deserving of protection. Hence, the protection of the components of biodiversity and associated traditional knowledge from bio piracy must be integrated within the framework of WTO/TRIPS Agreement. The WTO/TRIPS Agreement, while promoting the granting of patents to products based on genetic resources and associated traditional knowledge, contains no effective provisions to protect those resources and associated knowledge from misappropriation and theft. It is the absence of such provisions in WTO/TRIPS Agreement that may generate conflicts between its implementation parallel to CBD. On the other hand, amendment in WTO/TRIPS agreement to protect genetic resources and associated traditional knowledge from misappropriation would be in line with the fundamental objectives of itself and will also support fulfilment of the objectives of the CBD.

The lack of safeguards against misappropriation in the WTO/TRIPS agreement has led to a situation where, under the existing intellectual property regime, those genetic resources and associated traditional knowledge are often erroneously dealt with as if they are a part of public domain and open to appropriation by anybody without any duty to ask for permission and pay back the providers. No consideration is given to the fact that genetic resources and associated traditional knowledge constitute fundamental elements of several products and processes and represent both an economic and intellectual contribution to the attainment of the invention. The conflict thus largely relates to the issue of appropriation of benefits arising from the commercialization of products and processes that are based on genetic resources and associated traditional knowledge. The moot point is whether the patent holder should be allowed to appropriate all the benefits arising from the commercialization of a product or whether he/she should share the benefits. This underlying conflict lifts the veil off the balance set by the proposals of developed countries by comparing the objectives of the Convention and WTO/TRIPS agreement.

2. **According to developed countries the provisions regarding disclosure of source of biological resources, evidence of Prior Informed Consent and benefit sharing are neither necessary nor desirable for the reason that it would be unnecessarily burdensome and it is not easy to determine with certainty the origin of genetic resources and associated traditional knowledge.**

CRITICISM

a. Some developed countries argue that the proposed disclosure of origin requirement would lead to uncertainty. They cite examples where the resource is indigenous to one country, but freely available in several other countries. They also cite the degree of relationship between the claimed invention and the relevant genetic resources or traditional knowledge and whether the national courts or national intellectual property offices would have to interpret other nations' laws etc. This cloud of uncertainty, in the view of developed countries and particularly United States of America, would be potentially detrimental to the innovation and technological development, the economic incentives of the patent system and the benefit sharing under the ABS regime. Such an argument of uncertainty, however, is based on a misreading of the proposed disclosure of origin requirement.

b. There are three types of disclosure requirements proposed. As is evident, these disclosure requirements are intended to achieve different yet interrelated objectives of the CBD. The opposing countries try to read these requirements together, which creates confusion. Such unnecessary confusion cannot be a basis to avoid internationally binding solutions to the very real problems of misappropriation and bio piracy. While disclosure of source and origin will lead to ascertain the provider country or nation, and it is also not correct to say that the other two disclosure requirements would create uncertainties and additional burdens for the patent office because the obligation is only to produce evidence issued by the legally recognized authority of the country where access to the relevant material and information takes place. The same applies to the case of the benefit-sharing agreement. Disputes would not arise if the disclosure requirements are complied with the laws of the country providing genetic resources and associated knowledge. Only in cases where the applicant committed fraud could there be an occurrence of dispute. The raising of disputes during the opposition proceeding for failure to satisfy the requirements of the patent law is not new to the patent office. In such cases, parties would provide adequate and convincing evidence to the patent office to establish their claims. The job of the patent office is only to evaluate such evidence and decide the claim. The patent office is not expected to interpret the content of these documents but only to ascertain, through the claims and counterclaims, whether such evidence has been provided where a national regime requires such evidence. It is difficult to appreciate how interpretation of foreign law is involved in such cases.

3. Developed countries are highlighting that obligations of disclosure of origin, prior informed consent and the evidence of benefit sharing would increase costs of acquiring patents. It could also encourage inventors to keep their inventions secret rather than apply for patents and come into public domain.

CRITICISM

To revoke the aforesaid argument it can be said that the procedure for revocation of patents is more expensive and burdensome than merely requiring patent applicants to disclose the source and country of origin of the genetic resources.

The frequent revocation of patents would surely create more uncertainty for the patent system and prevent technological innovation and the facilitated flow of information that may be of great importance for bio prospecting and the biotechnological industry but the disclosure obligation, on the other hand, would only require reasonable efforts on the part of patent applicants to obtain and mentioning of the relevant information. Since such information would normally be part of a larger batch of information collected by the patent applicant for filing an application, it is not correct to argue that disclosure obligation would constitute an expensive and additional and burdensome obligation.

4. **The industrialized countries are also maintaining that the proposed obligations are not consistent with WTO/TRIPS Agreement. Existing disclosure requirement under Article 29 of TRIPS Agreement are directly related to determining whether an invention meets the standards of patentability and disclosure of technology to enable others skilled in the art to reproduce the invention. Proposed obligations would also be contrary to Article 27.1 which provides for non-discrimination in patent availability among fields of technology.**

CRITICISM

Now first of all it is made very clear from the proposals that the disclosure requirements are primarily aimed at preventing the grant of bad patents that do not fulfil the patentability criteria of novelty, utility or non-obviousness. Thus the issue that Article 27.1 is against disclosure requirements is not correct. Additionally if the disclosure requirements are introduced in the WTO/TRIPS Agreement then that would lead to greater legal certainty, as it would ensure that the patent system does not issue bad patents. Similarly Article 29 is in the favour of disclosure obligations as it requires revelation of "invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor".

5. **Another contention of developed and industrialised countries is that intellectual property rights do not aim to regulate the access and use of genetic resources. This could best be done through contracts between the authorities competent for granting access to genetic resources and associated traditional knowledge and those intending to make use thereof.**

CRITICISM

The CBD system, as it exists now, is supplemented by the Bonn Guidelines.[10] Despite this, the number of bad patents and instances of misappropriation are increasing and the objectives of Prior Informed Consent and benefit sharing are not often met. Since the problem is the issue of bad patents and failure to respect the rights and obligations of holders of the genetic resources and associated traditional knowledge on the basis of which the patent is issued, as well as the rights of the countries of origin of the genetic resources, then the solution must also be based on patent law and, in particular, on WTO/TRIPS agreement.

Since the contribution of the custodians and holders of the genetic resources and associated traditional knowledge is not recognized and is clearly manifested in the misappropriation of the knowledge, a TRIPS-based solution is only just and reasonable. It cannot be said that Intellectual property rights do not aim to regulate the access and use of genetic resources and the disclosure obligations can bring to a great extent uniformity and certainty in relation to these concerns. A contract-based system, howsoever perfect it may be, cannot ensure the effectiveness and mandatory enforcement at the international level. Thus, there is a need for a binding international disclosure requirement regarding the source and country of origin (to deal with bad patents) and evidence of Prior Informed Consent and benefit sharing under WTO/TRIPS agreement to enforce national norms. There is no need for opting for a multiple-forum solution or international arbitration when there can be a "one-stop shop" at the WTO. It is much better for the patent system to prevent the issue of bad patents rather than to take a laissez-faire attitude that would shift on to society and aggrieved third-parties the burden of revoking such bad patents after they have been issued.

6. **Developed countries further suggests that in accordance with the provisions of the CBD, countries could incorporate in their national legislation requirements for the conclusion of such contracts and the terms and conditions under which access and use may be granted including provisions for transfer of technology that might result from such use of genetic resources or traditional knowledge to which access is to be granted. Criminal and Civil remedies can also be provided against breach of contract by either party and a contract can be enforced in scheduled jurisdictions and judgments passed thereon could be enforced around the world under international agreements on recognition of judgments.**

CRITICISM

The options contained in a contract-based system as proposed by the developed countries, viz. choice of forum, choice of law, international arbitration provisions, Trans-boundary issues, enforcement issues etc., are concerns of private international law. In this regard, contractual agreements alone cannot ensure compliance with the principles of prior informed consent and benefit sharing, as it is difficult to enforce an obligation that is prohibited by law in other countries. It is an established fact that in enforcement of laws involving multiple jurisdictions, the binding nature and enforceability of foreign judgements and obligations are always controversial. Since the problem of misappropriation of genetic resources and associated traditional knowledge is truly a global one, therefore, international intergovernmental norms and solutions based on private international law are inadequate.

Clearly, the best and most effective way to address the shortcomings of the existing system is through the establishment of an internationally binding obligation rather than the simple use of private international law principles within the national regime. This binding international obligation can easily be achieved by integrating it within WTO/TRIPS agreement. It is this aspect that India and Brazil emphasize when arguing for a binding requirement of disclosure of evidence of prior informed consent and benefit sharing in the patent application.

7. **Developed countries place their view that disclosure requirement in the patent applications with regard to evidence of source and origin will not prevent misappropriation.**

CRITICISM

Some developed countries argue that in the absence of a national regime, the new disclosure requirement of prior informed consent would be of little or no utility and so most important is to establish national regimes. It is submitted that this argument does not take into account the aim of the proposed requirement of disclosing the source and country of origin. This requirement is to ensure that misappropriation of genetic resources and associated traditional knowledge is not encouraged through grant of patents on inventions relating to genetic resources without recognizing the contributions of the holders of traditional knowledge. Disclosure of source and country of origin can surely help the patent office to request more information from the patent applicant during examination of the application to ensure that bad patents are not issued. This can surely prevent bio piracy and misappropriation of traditional knowledge by the patent applicant. This is clearly one of the objectives of the CBD and this can be achieved only if changes are introduced in the global regime governing the patent law and not through national access legislation alone. This also adds to the certainty and legitimacy of the patent system. The disclosure requirement is also not as expensive as the contract-based system envisaged by the United States of America.

Disclosure of source and country of origin also facilitates realization of the CBD objectives of prior informed consent and benefit sharing and Production of their evidence along with the patent application are proposed specifically to achieve this. It is in this context that the proposal from India and Brazil emphasized the need for national systems to support the international obligation in this regard. Thus, it is incorrect to state that the object of the new disclosure requirement of source and country of origin is of "little or no utility" if national regimes on prior informed consent and benefit sharing is not in place. Even in the absence of a national access and benefit sharing regime, disclosure of source and country of origin could surely help prevent bio piracy and misappropriation of traditional knowledge associated with genetic resources by preventing the issue of bad patents.

8. **Developed countries emphasizes that disclosure requirement with regard to evidence of benefit sharing cannot transfer benefits because such requirement would only convey the information required. It will not have mechanism to transfer benefits to the parties. That is, if the country of origin has no benefit sharing infrastructure, then any compensation to the custodians of genetic resources and traditional knowledge would not be possible. So, first a mechanism to transfer benefits must be established. Thus developed countries affirms that establishing national access and benefit-sharing systems is essential before engaging in discussion of supplemental patent disclosure requirements with regard to evidence of benefit sharing.**

CRITICISM

Of course, a national access and benefit sharing regime is necessary for the proper running of the benefit sharing aspects of the system. But it is not correct to argue that establishment of national access systems is a pre-requisite for discussing an international framework for the disclosure requirement. There are many instances where international norms are set before national systems are put in place. This is all the more true with new and emerging areas, including in the field of intellectual property. An example is the Treaty on Intellectual Property in Respect of Integrated Circuits (the Washington Treaty), which was adopted in 1989 and has never entered into force. No Member states of World Intellectual Property Organization at the time had national legislation or experience in implementing that Treaty during the negotiations of the WTO/TRIPS Agreement, but its provisions were nevertheless adopted as minimum standards of protection within national legislations as part of those negotiations. Another example is the protection of copyright in the digital environment. The issue was internationally discussed and the so-called "WIPO Internet Treaties" (WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty) adopted at a Diplomatic Conference in 1996 before many countries, particularly developing and least-developed countries, could even experience and understand the full extent of the problem, let alone establish an appropriate legal framework to find solutions. The justification for that normative effort had been the need to prevent violation of rights and misappropriation of profits. The international framework once established, led to the introduction of national systems, including in the United States, where legislation to implement the "Internet Treaties" came into operation only in 2000. Similarly, to prevent violation of rights over genetic resources and associated traditional knowledge, national regimes, howsoever effective they may be, can only require that the evidence of prior informed consent and benefit sharing should be linked to the grant of access. The effective enforcement of such national regimes will be very weak, unless they are supported by an international legally binding obligation, or else such national regimes will fail in preventing the grant of bad patents also involving genetic resources and associated traditional knowledge. But if disclosure is made obligatory at the international level, all the concerns will be properly addressed. So the establishment of an international obligation assumes primacy.

9. **Developed countries also showed their concern that a new disclosure requirement could have significant, unintended consequences. For example, if improper disclosure results in revocation of a patent due to a legal action by a third party which is not affiliated with a genetic resource or an associated traditional knowledge, then this could actually upset the benefit-sharing agreement arrived at before grant of the patent. This would clearly fail to meet the shared objective of ensuring the equitable sharing of benefits arising out of the utilization of genetic resources and associated traditional knowledge.**

CRITICISM

The goal of the disclosure requirement primarily is to prevent misappropriation of genetic resources and associated traditional knowledge.

Disclosure of origin, coupled with disclosure of evidence of benefit sharing and prior informed consent, promotes the equitable sharing of benefits. When there is patent protection involved in the commercialization of genetic resources and associated traditional knowledge, an enforcement mechanism within the patent framework will be more effective in ensuring that fair and equitable benefit sharing takes place. The disclosure requirement will ensure that prior informed consent and fair and equitable benefit sharing agreements are obtained in compliance with the national law of the country of origin of the genetic resources. The consequences of non-disclosure, such as invalidation of patent rights, will flow only in cases of fraudulent claims, not bona fide ones. The intention is to protect the legal rights of the custodians and holders of the knowledge or the resources. The nature of the benefit shared, the mode of its sharing etc., are concerns to be addressed under the national regime. For example, if the person providing the genetic resources is giving only the raw material and he does not have any knowledge of its use value, he can claim benefit sharing for the mere supply of the resources. It is a wrong notion that patent monopoly is essential for the sharing of benefits and that if there is no patent, no benefits can be shared. Furthermore, remedies for non-compliance with disclosure are not limited to invalidation, as they may include other possibilities, such as the full or partial transfer of rights.

10. **If an inventor fails to get patent on an invention based on genetic resources and associated traditional knowledge because of inability to fulfil disclosure requirements properly or even if a patent is granted but later it is revoked owing to wrongful disclosure, the inventor may still be able to commercialize the invention outside the patent system without any obligation to share benefits. In either case, the invention having been disclosed to the public, third parties are most likely to use and commercialize the genetic resources or associated traditional knowledge without any obligation of sharing benefits. It is argued by the developed countries that a more suitable solution would be strengthening national regimes outside the patent systems in order to take a comprehensive approach and address all instances of commercialisation of misappropriated genetic resources and associated traditional knowledge that need to be addressed outside the patent system in any event.**

CRITICISM

It is true that misappropriation of traditional knowledge and genetic resources may or may not include patent protection. The new patent disclosure requirement can only deal with situations where there is misappropriation through patents. The instances of other forms of commercialization are dealt with under the national access and benefit sharing regimes. But it is erroneous to argue that since the patent disclosure requirement does not cover all instances of commercialization, such a requirement is not necessary. The fact that misappropriation may not always involve the granting of patents does not mean that, when patents are actually involved, disclosure of origin may not make a significant contribution to preventing misappropriation. Moreover, when there is a patent, it is only through the disclosure requirement that we can better assess the novelty and inventive step in the claimed invention and thereby prevent the grant of patents to ineligible claims.

It is clear, therefore, that we cannot undermine the significance of the new patent disclosure requirement on the ground that it does not cover all instances of commercialization.

11. According to developed and industrialized countries the disclosure requirements will be ineffective in having a better assessment by patent examiners of novelty and inventive step; rather these would only complicate an already overburdened patent system. New patent disclosure requirement may lead to significant administrative burdens on the patent offices of member countries that would in turn create additional costs, with regard to those requirements which demand compliance with foreign laws.

CRITICISM

It is to be noted that the applicant is required to submit only information of which he or she in any case should be, well aware of. In most countries having national regimes, the evidence relating to prior informed consent and benefit sharing are conditions precedent for the grant of access. So the new patent disclosure requirement does not impose on the applicant any cost or administrative burden while proceeding for a patent. Likewise, the patent office is also not asked to test the authenticity of the evidence furnished in relation to Prior Informed Consent or benefit sharing. These serve as prima facie evidence of compliance. Disclosure of source and country of origin of the genetic material or associated traditional knowledge enhances the capacity of the patent office in examining the patent applications involving genetic resources or associated traditional knowledge and serves as a critical tool in tracking down applications involving them. This gives the patent office useful hints to enquire into the novelty and inventiveness claimed in the invention.

12. Developed countries also contends that it does not appear possible that patent examiners could examine, those decisions involving interpretations of foreign laws to determine the validity of Prior Informed Consent or benefit sharing, with legal certainty. This would only compound the uncertainties both in granted patent rights and in the process of granting patents.

CRITICISM

The proposed disclosure requirement would in fact introduce much needed certainty and preserve the balance in the patent system in consonance with the objectives and principles of the WTO/TRIPS Agreements enshrined in Articles 7 and 8 and the conditions on patent applicants that have been established by other relevant Articles of WTO/TRIPS agreement. In this regard, it is important to remember that facilitated access to genetic resources and associated traditional knowledge, as acknowledged by the developed countries, is of significant importance to researchers and bio prospectors that use the patent system. By establishing clear internationally agreed rules on disclosure, prior informed consent and benefit-sharing, the proposed requirement would go a long way in establishing certainty in these matters, not uncertainty.

13. **Developed and industrialised countries also took the view that additional conditions will violate the principle of non-discrimination.**

CRITICISM

One of the arguments of developed countries against the proposal of requiring the norms of disclosure to include source of origin of the genetic resources and associated traditional knowledge, as well as evidence of Prior Informed Consent and benefit sharing, has been that the amendments would not be consistent with the WTO/TRIPS agreement and would violate the principle of non-discrimination between fields of technology.[11] There would be discrimination only if the three criteria of patentability i.e. novelty, inventiveness and usefulness are applied differently to different fields of technology. For the reasons discussed below, it is submitted that different norms of disclosure for inventions based on genetic resources and associated traditional knowledge, would not constitute discrimination between fields of technology. The basis for the invention, claimed in the patent application, can often be the existing knowledge and use by a local or indigenous community pertaining to the biological resource, a fact that has been recognized.[12] 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 manner, where the field of technology involves genetic resources, the special circumstances surrounding genetic resources and associated knowledge, should require norms for disclosure of source of origin, and evidence of prior informed consent and fair and equitable benefit sharing 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.[13]

CONCLUSION

Intellectual property rights are important under both The Convention on Biological Diversity and The WTO/TRIPS Agreement, but the two agreements approach them from very different perspectives. A large and growing number of countries are both Parties to the CBD[14] and WTO. Thus, this fact creates a powerful motivation to develop a mutually supportive relationship and to avoid conflicts. Both the conference of parties to CBD and the World Trade Organization are trying to explore the complex interrelationships between Intellectual Property Rights and biological diversity. At this stage, the most critical issue for the relationship between the Convention on Biological Diversity and the WTO/TRIPS agreement appears to be whether and how to establish procedures for consultation and cooperation between the bodies associated with the two agreements. Therefore the answer is that, amendments in the WTO/TRIPS agreement to include an responsibility to disclose the source and origin of genetic resources and associated traditional knowledge and to provide evidence of Prior Informed Consent and fair and equitable benefit sharing are

imperative to implement the TRIPS Agreement and the CBD in a mutually supportive and complementary way.[15] This obligation would ensure transparency as regards the origin of biological materials that are used in the patent claim, as well as make the CBD provisions on Prior Informed Consent and fair and equitable benefit sharing more effective.[16]

Both the Convention on Biological Diversity and the WTO/TRIPS agreement allow a significant degree of flexibility in national implementation. This suggests that there is potential for complementary and perhaps synergistic implementation. Because both agreements entered into force recently and discussions of the relationships between Intellectual Property Rights and Biological Diversity are at an earlier stage. Specific legal or policy mechanisms that would create synergies between the two agreements or their implementing measures have yet to be identified. Nevertheless, some general areas for complementary have been noted. For example, mutually agreed-upon terms for access to genetic resources could allocate intellectual property rights as part of the benefits to be shared among parties to an agreement on genetic resources, as noted previously. Such Intellectual Property Right could be defined under TRIPS-compatible IPR systems.

Another possibility is for the CBD and the WTO/TRIPS agreement to develop procedures for exchanging relevant information. Articles 16[17] of the Convention on Biological Diversity prescribe obligations in context to intellectual property rights for the Parties. The implementation of these obligations would likely to be fall within the scope of the notification requirement found in Article 63[18] of the WTO/TRIPS Agreement. Countries implementing measures that implicate both agreements such as rules requiring patent applications to disclose the country of origin might report them to the TRIPS Council while at the same time disclosing the same information to the clearing-house mechanism for scientific and technical cooperation established under Article 18(3) of the Convention, or including information regarding the measures in the national reports required under Article 26 of the Convention. It may be useful to note that the WTO and the World Intellectual Property Organization (WIPO) recently concluded an agreement formalising arrangements for the exchange of information, in particular copies of intellectual property right laws and regulations received by the two organisations.[19]

Other policies and legal schemes involving interrelated implementation of both the Convention on Biological Diversity and the WTO/TRIPS agreement may permit further examination. For example, there was a proposal, to require or encourage disclosure in patent applications of the country and community of origin for genetic resources and informal knowledge used to develop the invention. This has been proposed by a number of analysts.[20] Some evidence suggests that such disclosures are already common practice in filing patent applications. Possible elements of such a requirement, which could help to encourage the implementation of both Article 15 and Article 8(j), are outlined in the Executive Secretary's background paper on Article 8(j)[21].

Further looking to the provisions of the agreements regarding conflicts, Article 22(1) of the CBD provides that its provisions "shall not affect [a Party's] rights and obligations ... deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity".

It is not clear how this Article would apply in the case of conflicts with the WTO/TRIPS agreement because it does not contain any reference to its relationship with the CBD or any other environmental agreement.

If WTO members cannot resolve disagreements regarding the implementation of the WTO/TRIPS agreement through consultations, one member may bring a complaint against another for failure to meet its obligations, using the dispute resolution procedures generally applicable for WTO members.[22] In certain circumstances, a member prevailing in a dispute may be authorised to take measures for compensation and suspension of concessions. While decisions in such dispute-resolution proceedings do not establish legal precedents, as a practical matter members may look to them when interpreting terms of the Agreement in the future. To date, there have been five cases in which the dispute-settlement mechanism has been initiated regarding disputes in respect of WTO/TRIPS agreement; none of these cases has reached the panel stage as yet. On the other hand if Parties to CBD have a dispute about its interpretation or application, they may seek solution by negotiation, by the mediation of a third party, by conciliation, or if they agree to be bound by such a means of dispute settlement by arbitration or submission of the dispute to the International Court of Justice.[23] These procedures have not yet been invoked by a Convention Party. Unlike WTO procedures, dispute-resolution procedures of CBDemphasises avoidance of direct conflict by requiring other steps, such as negotiation.

Here there are several possible scenarios for conflict. A dispute might arise between countries that are parties to both CBD and WTO or between a country that is a party to CBD and a country that is a WTO member. A conflict concerning the two agreements would presumably involve a claim, in a forum associated with one of the instruments, that a country had violated its obligations, countered by a defence that the alleged violation constituted implementation of the other instrument, and was obligated or authorised by it. In such disputes, it is likely that a forum associated with one instrument would need an interpretation of the other agreement. In such a case, it is unclear how a dispute-resolution proceeding would reach such a determination, neither instrument provides for such an eventuality. The absence of a clear mechanism for reconciling perceived differences further emphasises the value of cooperation to avoid such differences. In order to bring this cooperation there is a need to amend WTO/TRIPS agreement so that both the agreements can be interpreted to support each other's objectives.

There are some additional purposes that can be served by the amendment in the WTO/TRIPS agreement in context of disclosure requirements as discussed below:

a. Preventing the grant of bad patents,
b. Supporting the patent offices to determine more effectively the inventive step claimed in a particular patent application,
c. Improving the ability of countries to track bad patents in the instances where they are granted and challenge the same,
d. Improving compliance with national laws on Prior Informed Consent and fair and equitable benefit sharing prior to access of genetic resources and associated traditional knowledge.

This would also increase the credibility of the patent system, as well as contribute to achieving the principal objectives of the WTO/TRIPS Agreement. Placing the onus on a patent applicant to disclose the basis of its claims is a step that can obstruct any misuse of patent laws and thereby prevent misappropriation of knowledge and resources.

It was therefore submitted that adequate amendments be introduced into the WTO/TRIPS agreement to ensure its harmonious and mutually supportive implementation along with the provisions of the Convention on Biological Diversity.

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REFERENCES

1. Robert P. Merges et al., Intellectual Property in the New Technological Age 380 (2007)

2. A submission was made in the TRIPS council (Council for Trade-Related Aspects of Intellectual Property Rights) by some developing countries viz. Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe on the relationship between the TRIPS Agreement and Convention on Biological Diversity and the protection of Traditional Knowledge in June 2002. (IP/C/W/356)

3. See Brazil, IP/C/W/228; India, IP/C/W/195; China, IP/C/M/36/Add.1, Para 228, available at http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf (Last visited on January 26, 2013).

4. See Brazil, IP/C/M/39, Para 126, available at http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf (Last Visited on January 26, 2013).

5. See India, IP/C/M/37/Add.1, Para 253; India, IP/C/M/39, Para 122-123, available at http://www.iprsonline.org/ictsd/docs/wto_IPCW403.pdf (Last Visited on January 26, 2013).

6. Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (September 2002), available at http://www.iprcommission.org/papers/text/final_report (Last visited on January 26, 2013).

7. The protection and enforcement of intellectual property rights shouldcontribute to the promotion of technological innovation..... to the mutual advantage of producersand users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

8. The reports on the meetings of the TRIPS Council held during the period January 1999 to October 2005 (IP/C/M/21-35, 36/Add.1, 37/Add.1, 38-40 and 42-49) reflect the work done so far in the TRIPS Council with respect to three agenda items, namely, the review of the provisions of Article 27.3

(b); the relationship between the WTO/TRIPS Agreement and the Convention on Biological Diversity; and the protection of traditional knowledge and folklore (List A). The substantive discussions in the TRIPS Council on these issues have been recorded in the reports of the meetings held from August 1999 to October 2005 (IP/C/M/24-35, 36/Add.1, 37/Add.1, 38-40 and 42-49), available at www.commerce.nic.in. (Last visited oh January 26, 2013).

9. Supra Note 7

10. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization is one of the significant outcome of conference of parties to the CBD at the meeting of the Ad-hoc Open-ended Working Group on Access and Benefit Sharing held in October 2001 at Bonn, which were adopted at the Sixth Meeting of the Conference of Parties held in April 2002 in the Hague. COP Decision VI/24, available at http://www.cbd.int/decision/cop/?id=7198 (Last Visited on January 6, 2013).

11. United States, IP/C/W/257, available at http://commerce.gov.in/trade/wtopdfs/ip-c-w-449.pdf (Last Visited on January 26, 2013).

12. UNDP, Human Development Report 1999, available at http://hdr.undp.org/en/media/HDR_1999_EN.pdf (Last Visited on January 26, 2013)

13. See India, IP/C/M/37 Add.1, Para 224 available at http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/6_ipcw349rev2_e.pdf (Last visited on January 26, 2013).

14. There were 156 Parties to the Convention on Biological Diversity as of 4 November 1996 and 125 members of the WTO as of 23 October 1996.

15. See Brazil, IP/C/W/228; India, IP/C/W/195; Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356; China, IP/C/M/38, Para 238, available at http://www.iprsonline.org/ictsd/docs/wto_IPCW403.pdf (Last Visited on January 26, 2013).

16. See Norway, IP/C/W/293, available at wtocentre.iift.ac.in/Folder/IP-C-W403.doc (Last Visited on January 26, 2013).

17. Access to and Transfer of technology:

18. COP 3 Decision III/17 available at http://www.cbd.int/decision/cop/?id=7113 (Last Visited on January 26, 2013).

19. WIPO/WTO 1995

20. For e.g., Gadgil and Devasia 1995, Hendrickx et al. 1994 andGollin 1993.

21. UNEP/CBD/COP/3/19, available at http://www.cbd.int/doc/meetings/cop/cop-03/official/cop-03-19-en.pdf (Last Visited on January 26, 2013).

22. Article 64 of WTO/TRIPS agreement.

23. Settlement of Disputes

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