

INDIA'S ATTEMPT TO RECONCILE DIVERSITY AND INTELLECTUAL PROPERTY ISSUES

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I. Introduction

For developing countries, the concept of diversity holds great promises not least because of the protection it promises for the fast depleting natural resources leading to catastrophic effect on the environment. The concept of diversity also holds great promises from a trade perspective. In reality, appropriate protection of diversity can be the solution to balance the effects of the trade regime to achieve sustainable development. The term sustainable development, as opposed to rapid pockets of development, embodies great promises for the socio-political framework in poorer nations, apart from the obvious benefit of sustainability. In fact, sustainable development, if it ensues, would complete the trade regime's agenda by supplying the missing piece of the puzzle. From a practical standpoint, at the very basic level, sustainable development promises a level of inclusiveness, which can facilitate addressing broader national issues.

Similarly, sustainable development is compatible with the larger trade agenda by promising to include newer forms of trading capital – such as biodiversity for biotechnology or traditional knowledge for pharmaceutical innovation - hitherto excluded from the trade regime. The trade regime which traditionally deals with what is typically western properties like goods, services, patents and investments, can, in turn, benefit from the dynamism resulting from say, trade in biodiversity and traditional knowledge. This paper will discuss the issues that impact biodiversity protection as a result of its interaction with the trade regime. Particularly, this paper will focus on India and the issues it faces from embracing the biodiversity and the trade regime.

II. Convention on Biological Diversity

Much has been written about the Convention on Biological Diversity. Hence, after providing a short introduction to the Convention,

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this essay will concentrate on aspects of Convention that are important for developing countries to embrace, not just in principle but in practice.

The Convention on Biological Diversity (CBD), signed at the United Nation's Conference on Environment and Development in 1992, came into force on December 29, 1993¹ with the primary agenda of creating an international framework to beneficially exploit and conserve biodiversity.² At the time of its conception, the Convention on Biological Diversity was meant to complement the UN's efforts in establishing a Conference on Environment and Development (hereinafter "Rio Summit"), which addressed broadly the role of environment, climate, and indigenous communities.³ The CBD was conceived as a global agreement to address all aspects of biological diversity.⁴

Broadly, the CBD streamlined the use of access and sharing of genetic resources to achieve three important objectives: first, conserving biological diversity; second, promoting appropriate access for the sustainable use of biodiversity components; and third, sharing benefits from biodiversity resources in exchange for transfer of technology.⁵ The objectives of the Convention are set in the background of the principle of "fair and equitable sharing" of the benefits from genetic resources, which principle is considered the crux for enabling transfer of technology.⁶ Overall, the CBD's objective is to promote the use of biodiversity resources toward sustainable development. The term *biological diversity* encompasses plants, animals, and microorganisms and their relationship to the overall ecosystems, including the people on earth and the genetic resource in the ecosystem.⁷ The CBD's distinguishing feature is its ability to serve as a

1 Convention on Biological Diversity, June 5, 1992, U.N. Doc. Biodiv.No.92-7807, 31 I.L.M. 818 (1992) [hereinafter "CBD"], *also available at* <http://www.biodiv.org>.

2 *Id.*

3 United Nations Conference on Environment and Development, Rio Declaration on Environment and Development, U.N. Doc. A/CONF.151/5/Rev. 1 (1992), reprinted in 31 I.L.M. 87 (1992) [hereinafter "Rio Declaration"], Chapter 26, Agenda 21; *see also* CBD, *supra* note 1.

4 *Sustaining Life on Earth: How the Convention on Biological Diversity Promotes Nature and Human Well-Being* (May 19, 2005), *available at* <http://www.biodiv.org/doc/publications/guide.asp?id=action>.

5 CBD, *supra* note 1, Art. 1.

6 *Id.*

7 *Id.*

conduit to enable sustainability and thus, it signifies a relative break from the compulsive and one-dimensional developmental perspectives promoted by the trade and intellectual property (IP) agenda.⁸

With the above as the background, the following narrative highlights how the objectives are reflected in the Convention.

2.1 CONSERVATION ON BIOLOGICAL DIVERSITY

Conservation remains the central objectives of the CBD – the main emphasis is to prevent the loss of biodiversity due to bioprospecting and to ensure sustainable use of the diversity materials, each of which is discussed below.

Conservation & Sustainable Use: Conservation is the central tenet around which the CBD is structured. That conservation is uniformly important for all countries that seem to lose biodiversity materials due to lack of adequate programs to conserve existing resources is not lost on the Convention. Consequently, with the objective of furthering the idea of conserving biodiversity materials, Article 8(g) of the CBD,⁹ discusses *in situ* conservation and mandates that countries manage risks that are likely to adversely impact the environment.¹⁰ That is, countries should “[e]stablish or maintain the means to regulate, manage or control risks from biotechnology likely to adversely impact the environment.”¹¹

Tied closely with the concept of conservation is the requirement of sustainable use of biodiversity materials. The underlying objective is that conservation does not take away the right to use biodiversity. Nevertheless, such use should not result in depletion of the biodiversity materials. Thus, Article 3 of the CBD affirms the sovereign right of states to exploit resources “pursuant to their own environmental policies.”¹² It allows governments to take stock of the biological diversity materials and determine the best mechanism to ensure that it is not depleted. Article

8 *Id.*

9 *Id.*

10 *Id.*, Art.8(g).

11 *Id.*, Art.8(g).

12 *Id.*, Art. 3.

15(1) reflects this sentiment by emphasizing the “sovereign rights of States over their natural resources.”¹³

However, although governments may impose restrictions on access to genetic resources using national legislation, arguably the Convention skews towards allowing access. For instance, Article 15(2) specifies that national legislation shall *not* run counter to the objectives of the Convention.¹⁴ One of the objectives of the Convention, outlined in Article 1, is to allow “appropriate” access to genetic resources.¹⁵ In effect, Articles 15(1) and (2), when read in conjunction with Article 1, advocate appropriate restrictions in a manner not stifling access to genetic resources. In all, under the CBD, member states’ have rights to limit and dictate the *manner and mechanism* of allowing access. The Commission on Intellectual Property Rights, a Commission that means to integrate IP rights and developmental policies, reflects this sentiment and notes that:

*... care will be necessary to ensure that legislation and practices that seek to give effect to the CBD do not in fact unnecessarily restrict or discourage the legitimate use of genetic resources, whether with a view to commercialization or in terms of scientific research. There is some evidence that the tightening of restrictions in some countries has hindered the access of biologists studying genetic resources.*¹⁶

Importantly, while the CBD’s legislative objective is to preserve sovereign rights over genetic resources, the criticism remains that operationally those rights are limited by the overall objective of granting access to genetic resources. However, it is important to recognize that development by definition will result in some use of biological diversity. Perhaps, it is in recognition of this that the Convention has attempted to balance use with sustainability. Consequently, countries cannot refuse access but they can carefully impose restrictions to ensure preservation of biodiversity and local communities. Such restrictions can include a mandatory obligation to disclose what is accessed, consent of the

13 *Id.* Art.15(1).

14 *Id.* Art.15 (1) and (2).

15 *Id.*, Art. 1.

16 Report of the Commission on Intellectual Property Rights, *Integrating IP Rights & Development Policy*, 83–84, September (2002) [hereinafter “CIPR Report”], available at http://www.iprcommission.org/graphic/documents/final_report.htm.

indigenous people, disclosure of terms with the indigenous people, limitation of area that can be used for prospecting, restrictions over use of area, and other such obligations.

The Nagoya Protocol¹⁷ has further elaborated on the sovereign rights over the resources as well as the competing interests in generating *fair and equitable* sharing by emphasizing in Article 3 that each signatory party can take appropriate measures to ensure benefit sharing and utilization of traditional knowledge resources. Importantly, Article 3(4) of the Protocol alludes to monetary as well as non-monetary benefits that countries can negotiate as part of the deal. Some of these can be used to work around impediments imposed by the TRIPS agreement.¹⁸ That is, Annex 2 outlines several mechanisms whereby the holder of the genetic resources can collaborate and work with the bioprospector. It provides for non-monetary benefits including agreements that resemble local manufacturing requirements (in exchange for transfer of diversity assets). When IP assets are involved, countries should carefully tailor them to ensure that they fall within the flexibilities outlined under the TRIPS agreement.

2.2 APPROPRIATE ACCESS TO BIODIVERSITY MATERIALS

One of the foremost objectives of the CBD is to preserve sovereign rights over genetic resources. However, granting access to genetic resources remains an equally important aspect of the Convention. The effect of this is that while countries cannot refuse access, they can carefully impose restrictions to ensure preservation of biodiversity and local communities. Such restrictions can include a mandatory obligation to disclose what is accessed, consent of the indigenous people, disclosure of terms with the indigenous people, limitation of area that can be used for prospecting, restrictions over use of area, and other such obligations. One such important formality to access genetic resources is to obtain the “prior

17 Article 6, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity (Oct. 2010), available at <http://www.cbd.int> (last visited July 12, 2011).

18 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS], reprinted in World Trade Organization, The Results Of The Uruguay Round of Multilateral Trade Negotiations 365 (1995), [hereinafter, TRIPS].

informed consent” of the holder. Articles 8(j) and 15(5) treat the community consent requirement as a precondition to accessing biodiversity assets.¹⁹ But, the CBD does not define the term “prior informed consent.” Although the lack of definition allows countries to determine the type, extent, and nature of information required to provide consent, it also leaves a lot of scope for misuse. For instance, generally, in order for consent to be *informed*, resource holders should have adequate knowledge of the proposed use and future financial potential of the resources they would be sharing. Such information is a prerequisite for the *ad idem* required to create a proper “mutual agreement.” In practice, the degree of information to be imparted tends to vary, depending on the bio-pro prospector, the holder, and the genetic material in question.²⁰ This, however, provides an opportunity for information to be withheld, depending on the level of awareness of the indigenous people.

The potential for misuse is tremendous given the inequality in bargaining capacity and sophistication of the parties. The nature of information qualifying the consent as “informed,” the constituents of adequacy of the consent, and the time frame within which the information should be shared are left to the member state to legislate upon depending on the extent of education or knowledge of the community and such other considerations. With a view to addressing this deficiency, the Bonn Guidelines suggested measures that countries can adopt, such as mechanisms that encourage disclosure of information to holders and measures that prevent misuse of the genetic resources.²¹ Similarly, the more recent Nagoya Protocol, discussed later in the paper, provides norms that member states can adopt to ensure “legal certainty, clarity and transparency” in their domestic legislation.²² The protocol suggests that

19 CBD, *supra* note 1, Art. 8(j) and 15(5).

20 See generally Jim Chen, *Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship between Biological Diversity and Intellectual Property*, 31 ELR 10625, 10631 (2001).

21 Article 16(d), Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization, Secretariat of the Convention on Biological Diversity, UNEP/CBD/COP/6/24 (Apr. 2002), available at <http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24>.

22 Article 6, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity (Oct. 2010), available at <http://www.cbd.int> (last visited July 12, 2011).

members establish rules to: (1) streamline access, (b) standardize the process of obtaining prior informed consent, (3) create rules that can allow decisions to be rendered in the event of a dispute, and (4) establish terms relating to benefit sharing and use by third parties, including in relation to intellectual property rights.²³ The Nagoya Protocol gives the impression that related issues that may arise in this regard should be dealt with by individual nations.²⁴ Article 7 of the Protocol provides: “[I]n accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval”²⁵ Thus, the Protocol envisages or guides member states to establish rules that provide for a streamlined application procedure that establishes a fair, non-arbitrary mechanism through a national authority and within a reasonable period of time. Such procedure suggests not only a clear evidence of consent but also notification to a national established clearing house of the consent to access the information. Thus, a dispute settlement clause, a separate clause on benefit sharing and intellectual property rights, including future assignment or division of rights are all required to be part of the consent document.

The issue of prior informed consent has presented many challenges to the member states. For instance, questions like whether the holders of indigenous knowledge retain the right to refuse consent after knowing the “full and fair” circumstances of the case remains unclear and unanswered. Also, what happens in circumstances where an access agreement is violated after the genetic resource has been transferred? The only possible remedy under these circumstances is to invalidate the agreement for breach- but, the question was whether that would violate the access commitment under the CBD.²⁶ Also, considering that the genetic material and knowledge have already been transferred, invalidating the agreement is neither a deterrent to the bioprospector nor a protective mechanism to indigenous societies. Post the Nagoya Protocol, individual member have clearer guidelines to determine these questions. They can fall within the larger ambit of “terms on changes of intent.”²⁷ Alternately, some of these issues can also fall within

23 *Id.*

24 *See* Nagoya Protocol, *supra* note 21.

25 *Id.* Art. 7.

26 *See* CIPR Report, *supra* note 17, at 91.

27 *Id.*

the scope of special considerations detailed under Article 8 of the Protocol which provides adequate leeway for countries to take emergency, public interest considerations including impact on food and agriculture. Article 10 encourages parties to determine modalities for equitable sharing of resources in transboundary situations where it is impossible to obtain prior informed consent.

Overall, the CBD seeks to empower countries to promote and encourage conducive conditions that not only promote research to protect biodiversity and thus, ensure sustainable development. The overarching benefit of the Guidelines and the Protocols are that they provide clear options for member states to deal with such issues within their legal structure. In all the CBD has made great progress, either directly or through the protocols, to equip countries to seek specific returns to permit prospecting. It is up to the member states to use local legislation to clearly define and subject the access provision to proper consent of the communities by outlining clear and standardized procedures.

a) Access to Technology: Access to biodiversity in exchange for access to technology captures the essence of CBD's vision to promote global equity.²⁸ Thus, the issue of access and benefit sharing needs to be positioned in the light of the CBD provisions for transfer of technology.²⁹ Article 1 of the CBD emphasizes the need for "fair and equitable" sharing of the benefits arising from the use of genetic resources.³⁰ Similarly, Article 15, which discusses access to genetic resources, indicates the expectation of transfer of technology³¹ whereas Article 16 details the access to technology commitments.³² By incorporating the philosophy of exchange of technology and genetic resources, the CBD has raised the awareness level of the value inherent in genetic resources. However, in light of the relatively easy access to genetic resources, the flexibility in the narrative of the CBD has resulted in the issues discussed below.

28 Chen, *supra* note 19, at 10659.

29 See Srividhya Ragavan, *The Global South as the Key to Biodiversity and Biotechnology—A Reply to Professor Chen*, 32 *Envir. L. Rep.* 10358, 10359–61 (2001).

30 CBD, *supra* note 1, art. 1.

31 *Id.* Art. 15.

32 *Id.* Art. 16.

First, the CBD narrative, although encouraging developing countries to provide access to genetic resources, repeatedly conditions transfer of technology commitments on *mutual agreement* of the parties. The emphasis on mutual agreement subjects transfer of technology obligations to the bargaining skills of the parties.³³ For instance, Article 15(4) specifies the expectation for benefit sharing between the providers and users of genetic material, but adds that “such sharing shall be made on mutually agreed terms.”³⁴ Similarly, Article 16(2) specifies the transfer of technology will occur “preferentially” under “fair and most favorable terms.”³⁵ The CBD does not define the terms “fair and most favorable” or “preferential,” presumably to allow nations to effectively define them.³⁶ The article operates on the assumption that “preferential terms” for transfer of technology will be negotiated or facilitated by members. Further, Article 16(3) requires that countries providing genetic material be “provided access to and transfer of [proprietary] technology . . . on mutually agreed terms.”³⁷ Thus, the obligations of transferring technology remains dependent on the bargaining powers of parties, which skews the balance against nations with less bargaining parity. In practice, the relative bargaining power of the parties makes it difficult to negotiate an equitable transfer of technology. In some instances, the local communities that are involved may be unaware of the extent of development or the realm of available technologies, options or possibilities from the accessed materials. Developing or least-developed countries can hardly be expected to bargain and negotiate a meaningful technology transfer agreement under such circumstances. Perhaps, it is in recognition of this impediment that the Nagoya Protocol outlines mechanisms that can be used to improve bargaining exercise. For instance, Article 22 discusses capacity building and encourages member states to identify their national capacity needs and priorities through self-assessment. Such an exercise could greatly enhance the negotiation by informing the diversity holders of their needs and help them exploit their resources towards adding value to existing resources.

Second, the benefit-sharing provision of the CBD does not obligate developed nations to impose statutory transfer requirements in exchange

33 *Id.* Art.15(2) (highlighting that access is also subject to mutually agreed terms).

34 *Id.* Art.15(4).

35 *Id.* Art.16(2).

36 *Id.*

37 *Id.* Art.16(3).

for benefits derived from genetic resources. For instance, Article 19 of the CBD states that countries shall “take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities.”³⁸ Article 19(2) stresses the need for developing countries to participate in efforts to further research and development.³⁹ The local participation requirement is another form of the local working requirement rendered as a barrier to trade under the TRIPS agreement. Unlike clause 1, however, clause 2 operates only if the parties arrive at “mutually agreeable” terms.

Third, the CBD’s contemplated objective is an exchange of genetic and technological resources “taking into account all rights over those resources and to technologies.” The rights over biodiversity resources are unclear because ownership remains unresolved. The government, one or more indigenous societies (which need not be a cohesive group), or other locals can all either share or retain specific rights of ownership. Consequently, what amounts to effective protection of rights over biodiversity resources—whether it is right to royalties, sharing IP rights, or merely a requirement to grant “prior informed consent”—is left for individual member states to determine. The Nagoya Protocol in the Annex lists monetary and non-monetary benefits that can serve as a guidepost to member countries.

The flexibility and the opportunity to create mutually beneficial agreements offered by the CBD is a great asset. Recognizing that in practice, there is a tendency to acquire as much of the genetic resources as possible with minimal transfer of technology, the Nagoya Protocol has attempted to address how the CBD’s flexibilities can be best exploited. In all, CBD provides a great opportunity for biodiversity-rich members to statutorily structure access to technology requirements as a precondition for appropriate access.

b) Access and IP Rights: The biggest criticism of the CBD is perhaps its emphasis on accommodating IP rights that will interfere with transfer of technology to the poorest regions of the world. For instance, Article 16(2) of the CBD specifies that technology subject to IP rights shall

38 *See id.*, Art. 19.

39 *Id.* Art.19(2) (mandating access to technology by developing countries “on a fair and equitable basis”).

be transferred “on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.”⁴⁰ In practice, arguably there will be no access to technology under the CBD unless IP is adequately protected and respected by an agreement defining the contours of the technology.

Further, unlike rights over resources discussed earlier, the IP regime clearly allocates rights over technologies. Consequently, the process of granting access to biodiversity recurses while accounting for the “rights over the technology” results in positing IP rights ahead of rights over the biodiversity resources. Ideally, access to genetic resources should be made in exchange for a transfer of technology that leads toward sustainable development “notwithstanding intervening IP rights.” This way, indigenous communities can, for instance, seek access to sophisticated technologies or patented medications in return for access to genetic resources. Although the language in Article 16 (5) highlights that IP rights should not run counter to the working of the CBD, so far very few negotiations have actually used Article 16(5) to ensure access by indigenous people to the technologies. The Nagoya Protocol has attempted to address some of these issues through their guidelines like laying out clear terms over ownership of intellectual properties, joint ownership etc. Even though the success of these terms unfortunately depends on bargaining parities, the increased awareness has resulted in conscious efforts in several countries towards protection of biodiversity assets. Similarly, many developing countries, including India, have attempted to provide different types of protection to prevent depletion of traditional knowledge assets.

III. India's Standing in the Diversity and Trade Complex

India's standing on biodiversity issues remains important on account of several reasons. First, as one of the leaders of emerging economies and a member of the BRIC group of nations, the steps that a country like India takes to protect biodiversity becomes a trend setter to other developing countries. Second, protection of environment and its related assets is a Constitutional issue in India.⁴¹ Third, India is a documented mega-diversity country. The National Biodiversity Authority in

40 See CBD, *supra* note 1, Art. 16(2).

41 Constitution of India, (India) (1950), Directive Principles of State Policy, Part IV Art 48A.

India accounts for 7-8% of the recorded species of the world with a documented 45,968 species of plants and 91,364 species of animals.⁴² Fourth, the country houses 4 of the 34 global biodiversity hotspots and is recognized as a Vavilovian Center for diversity of crops.⁴³ These are the geographic regions where crops exhibit maximum diversity in terms of number of races and botanical varieties.⁴⁴ Fifth, India also houses several tribal and indigenous communities within the country and hence, protection of their knowledge is important. Last, notwithstanding all of the above, India's status as an emerging economy, its rate of real estate development, the extent of corruption and the extent of pollution has resulted in the depletion of biodiversity at alarming levels. Hence, efforts to conserve biodiversity and develop sustainably are important paradigms of India's development agenda.

India has taken steps to preserve its biological diversity and associated assets. The following narrative examines some of these steps and its adequacy to address the problems. The narrative below examines whether these are adequate and if so, to what extent?

A. BIODIVERSITY ACT, 2002

India has embraced the mandate of conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources by enacting the Biological Diversity Act, 2003. The statute's conduit to lead towards conservation of biological diversity and sustainable use of its components is to facilitate fair and equitable sharing of the benefits arising from the use of biological resources or traditional knowledge. Consequently, the enactment establishes a National Biodiversity Authority (NBA) with powers to address the broad objectives of the enactment. For instance, the scope of the responsibilities of the NBA includes to ensure joint ownership with the knowledge holders to facilitate transfer of technology and oversee research and development activities with the local people. Among other things, the NBA will also deal with issues of "agro-biodiversity" which relates to

42 Policy Issues on Biodiversity (PPT), National Biodiversity Authority of India, Chennai (2003) *available at* www.nba.nic.in

43 *Id.* Vavilovian Centers are areas around the world where most life originated from.

44 K. Venkatraman, India's Biodiversity Act 2002 and its Role in Conservation, *Tropical Ecology* 50(1): 23-30, 2009.

biological diversity of agriculture related species and their wild relatives. Functionally, the NBA is required to streamline access to biological resources by instituting an approval process. Thus, the concentration seems to be to ensure that no biological resource is transferred out of India especially by non-Indians (or non-resident Indians) or foreign corporations. The extensive approval process creates an oversight except in the case of institutional research which is exempted from the permission requirement provided such research falls within the scope of the Central Government policies. Importantly, any patent obtained using information relating to biodiversity is subject to benefit sharing and other comparable conditions like royalty sharing arrangements.

In terms of its structure, the NBA consists of a Chairperson and three *exofficio* members one of whom will represent Ministry of Tribal Affairs and the other two representing the Ministry of Environment and Forests of whom one shall be the Additional Director General of Forests or the Director General of Forests. Additionally, the Central Government will also appoint seven other members (also termed as *ex officio* members) representing different ministries including agriculture, biotechnology, Ocean Development, Indian Systems of Medicine and Homeopathy, etc. These members will be guided by five non-official members who will serve as specialists with special knowledge of biological diversity. The NBA will also be assisted and advised by the State Biological Diversity Board (SDB) which is similarly structured like the NBA. In turn, local bodies can have biodiversity management committees which will oversee conservation and sustainable use issues within the area.

B. TRADITIONAL KNOWLEDGE BILL⁴⁵

Amidst all of this, India is also attempting to legislate a Traditional Knowledge Bill with the objective of protecting traditional knowledge and “the rights of the traditional communities to practice, use, share and sell the products of the use of traditional knowledge as per their customary practice.” The Bill’s objectives include “sustainability of resources on which the traditional knowledge are based, as well as to ensure the continuum of the customary practices of the traditional knowledge.” This Bill also establishes a governing mechanism – the Traditional Knowledge Board –

45 Draft Traditional Knowledge Bill, 2009, Circulated during the 2nd National Consultation on IPR & TK, New Delhi, July 4th and 5th 2009.

with zonal several offices. The more egregious portions of the Bill adds that this office will receive applications for access to the traditional knowledge in the prescribed format along with the details of the prior informed consent, evaluate the impact on the environmental, conduct social impact assessments, and oversee the traditional knowledge and resource management plans submitted by the acesor. Further, before approving access and license to use the traditional knowledge, the board will evaluate to determine whether the bioprospecting will affect public order and morality. Additionally, the Board will also facilitate the traditional communities to negotiate the terms and conditions of benefit sharing upon access to use the traditional knowledge.

C. INDIAN PATENT OFFICE GUIDELINES ON TRADITIONAL KNOWLEDGE⁴⁶

With a view to further bolster legislative and regulatory protection in this area, the Indian patent office has also issued guidelines for the processing of traditional knowledge related applications. The Guidelines mandate examiners to include the Traditional Knowledge Digital Library (TKDL) as part of its prior art search process and to ensure that any material taken from the database is duly accounted for. Thus, the source of the biological materials, a declaration as to whether that the material originated from India or abroad and due permission from the competent authority should all be appended with the application. In addition to all of these, separate permission is required from the NBA in order for the application to be prosecuted for patentability analysis. Under the Guidelines, the following materials would be considered patent defeating:

- a) Extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants,
- b) Combination of one or more plants with same known-therapeutic effect for treating the same disease would be treated as an obvious combination (even if increased therapeutic efficacy is seen),
- c) Use of an ingredient known for the treatment of a disease will create a presumption of obviousness when any combination using the same active ingredient is used, and

46 Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material, Office of Controller General of Patents, Designs and Trademarks, India (2013) *available at ipindia.nic.in*.

- d) Isolation of a single component from multiple ingredients with known to therapeutic activity (as per traditional knowledge).

Interestingly, that materials isolated from its natural state should not patented is a point vigorously argued in the United States over the dispute involving the Myriad gene patents issue that is currently being considered by the Supreme Court of the United States.⁴⁷

d. A NOTE ON INDIA'S EFFORTS – WHAT A MESS!

In gist, the various legislative framework in India that caters to this area of law seems over-lapping, unclear and poorly drafted. The good intentions to provide protection for biodiversity materials have not fully translated into appropriate legislative mechanisms. Instead, the over lapping legislative efforts seemingly covers the same issues while leaving out gaping loopholes.

The Biodiversity Act widely covers sustainable development. Yet, the notion of “sustainability of resources” is discussed under the Traditional Knowledge Bill and reflects the same principles. Having two legislations discuss the exact same components is confusing and unnecessary. Further, each of these legislations establishes central and state authorities to perform similar functions. In essence, areas where communities practice traditional knowledge are also areas that are rich in diversity. Hence, the oversight under the biodiversity statute should be more than sufficient without the need for duplicative efforts under the traditional knowledge legislation.

With respect to traditional knowledge, several of the documents in India discuss “protection.” And, many of the models that seem to be discussed are styled akin to the intellectual property style of protection. It seems lame that a country that objects to patent protection would jump towards protection of traditional knowledge using intellectual property as a framework. Importantly, one has to recognize the regulatory & implementation costs associated in creating such an IP based model

⁴⁷ Association of Molecular Pathology, *et al*, v. Myriad Genetics Inc, *et al*, No. 12-398 (On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit).

reduces efficiency – thus, establishing such a model should be avoided at all costs. Arguably, these efforts do not fully appreciate the important differences between beneficially exploiting the resources versus creating a protection regime for traditional knowledge. Mere protection regime does not necessarily mean that there will be beneficial exploitation of resources unless the plan for the latter is carefully delineated.

With respect to protection of traditional knowledge, there seems to be no research or on-going study on the question of underlying differences between the nature of the property in traditional knowledge and other intellectual properties. Such understanding is critical to structuring a regime to ensure protection for traditional knowledge by taking into account the important differences with the intellectual property regime.

The over populated bureaucratic regimes that the biodiversity act and the traditional knowledge bill together imposes will merely increase the burdens which can impede realistic attempts to conserve biodiversity, or protect traditional knowledge materials appropriately. The amount of public money that would be required to fund and maintain these institutions will eat into finances that should rightfully belong to the traditional communities from benefit sharing. Further, the interaction of these two bureaucracies with other government institutions will create more burden and overly complicated mechanisms to deal with this area.

With respect to a patent, if a patent covers part of traditional knowledge materials, it will be cleared by the National Biodiversity Board, the authorities under the traditional knowledge statute (if passed) and will also be subject to the oversight of the patent examiner. If India feels that new discoveries in Ayurveda and Herbal medicines should be subjected to patent protection, such overly burdensome procedures involving several statutory authorizes is the best way to kill it.

The traditional knowledge bill provides for the authorities under the enactment to conduct “social impact assessments” and evaluate whether the access of traditional knowledge affects public order, morality and the environment.” It is unclear how these authorities, who are typically administrative or service officers, will transform to perform the role of arbiters or specialists of morality, environment impact studies and public order all at the same time and without appropriate guidelines is unclear.

Presumably, each of these are subjects require independent specialists to evaluate the outcome appropriately.

In addition to all of the above, India has also enacted a Protection of Plant Varieties and Farmer's Rights Act, 2001.⁴⁸ This enactment also discusses benefit sharing and outlines a detailed set of statutory procedures relating to benefit sharing. Interestingly, this enactment also creates an extant *variety* typology which was introduced to protect traditional knowledge and indigenous farmers.⁴⁹ The extant variety register serves as a compilation of matters known and existing in the public domain. In essence, an extant variety encompasses a farmers' variety, or a variety about which there is common knowledge, or a variety in the public domain and any variety notified under section 5 of the Seeds Act.⁵⁰

By making *farmers' variety* a subset of *extant variety*, the PPVFA facilitates farmers to register varieties they have cultivated for years to ensure that it cannot be appropriated. The most important benefit is that registration or compilation of extant varieties creates a higher standard for distinctness/non-obviousness for registering "new" varieties. Thus, it prevents protection of miniscule innovations by breeders. The interesting aspect is that the Biodiversity Rules, 2004 mandates in Rule 22 that every local body constitute the Biodiversity Management Committee (BMC).⁵¹ The main function of these committees is to prepare People's Biodiversity Register in consultation with local people. Such registers are conceived to "contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them."⁵²

Interestingly, these registers perform the exact same function like the extant variety register, perhaps with more information. It would be natural for both of these registers to contain overlapping information –and, they would both perform the same function of creating a log of existing

48 The Protection of Plant Varieties and Farmers' Rights Act, No. 53 of 2001; India Code (2001) available at <http://indiacode.nic.in/fullact1.asp?tfnm=200153>. (Hereinafter, PPVFA). The President of India assented to the PPVFA but the enactment came into force as of Jan, 2007.

49 *Id.* §14(b).

50 *Id.* § 2(j).

51 Biodiversity Rules, 2004 available at nbaindia.org

52 *Id.* at Rule 22(6).

materials. Perhaps creating one log that will record the extant varieties, existing traditional knowledge and biological resources would be a more efficient idea than having similar data spread over materials several statutory registers controlled by different authorities.

Similarly, the PPVFA's registration regime also recognizes the role of local farmers and their traditional knowledge. In doing so, the application requirements under this enactment (which is a *sui generis* regime for the protection of innovation in plant breeding) must include a denomination to the variety and describe (1) the geographical origin of the material and (2) all information regarding the contribution of the farmer, community, or organization in the development of the variety.⁵³ Further, the application must state that all genetic or parental material used to develop the variety has been lawfully acquired.⁵⁴

Moreover, section 40 necessitates the breeder to disclose information "regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such [new] variety."⁵⁵ The information in the application is meant to facilitate benefit sharing – which is very similar to the system described in the Biodiversity Act, 2002 – yet, these two mechanisms not been reconciled well. That is, whether there will be one benefit sharing mechanism into which all of the recourses generated from the various enactments will flow or whether these will all function as different benefit sharing systems within the scope of different bureaucracies set up under different statutes. This issue remains unclear.

India's biggest problem is the depletion of valuable bio-diversity assets on account of urbanization. Unfortunately, this aspect is completely left uncovered. Thus, whether conservation efforts should include having adequate parks and green areas in the city has not been addressed. If so, that the biodiversity authorities and town planning authorities need to work together towards sustainable development and conservation is a concept that seems to be untouched in India. Instead, there is an overly egregious and misplaced fetish on traditional knowledge protection falling into the framework of several legislations. That traditional knowledge should be

53 *Id.* § 18(1)(c).

54 *Id.* § 18(1)(h).

55 PPVFA, *supra* note **Error! Bookmark not defined.**, § 40.

protected appropriately is not denied, but, the mechanism in India is unfortunately, not well-thought of.

Similarly, depletion of valuable agricultural land to real estate and buildings is an on-going concern in India. Amidst this, the country also faces woeful infrastructure making it impossible to ignore the requirements of building roads. Yet, these efforts have to be balanced with biodiversity protection as well as sustainable development – a paradigm that the Biodiversity Act, 2002 unfortunately, does not address. Notably, India also has an Environment Protection Act, which can also address some of these issues. Perhaps, the hype and the excitement surrounding the Biodiversity Act and traditional knowledge Bill has caused India to diminish the role of the Environment legislation.

IV. CONCLUSION

India's interest to protect traditional knowledge, beneficially prevent undue exploitation of such knowledge while conserving biodiversity and its related assets is highly commendable. But, the exercise has to be more thoughtful from the point of view of outcome and objectives that needs to be achieved. An efficient and integrated system that helps achieve the objectives of protection, conservation and sustainable development needs to be a by-product of careful research and not a piece-meal approach.