

# INTERFACE OF IPR WITH GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE: INTERNATIONAL PROVISIONS

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## ABSTRACT

*Traditional knowledge, developed and passed on generation to generation by indigenous and native (aboriginal) communities, is an integral part and an identity mark of the ethos and cultural existence of a community. Existent in diverse fields such as food, medicine, tools, yoga, etc., traditional knowledge must be protected and safeguarded in order to ensure sustainable development practices.*

*In light of the same, this paper is an honest attempt to explore varying issues and challenges that exist in recognition of IPR in the area of traditional knowledge. This paper provides an insight into the established norms and principles, national as well as international, that govern this complex yet extremely important interface. An overview of the recent developments, including the misappropriation of genetic resources, the strengths, weaknesses and inherent contradictions in provisions of the TRIPS agreement and the CBD mechanism along with RTAs, and the role of the WTO, etc. is provided as a necessary background and discussed in detail, so as to present a comprehensive view of the debates surrounding the extension of IPR protection to traditional knowledge. The present research, through anthropological, biological and economic reasoning and rationale, argues for the establishment of an IPR regime that aims to balance the rights of local people with the obligation to preserve viable ecosystems for posterity.*

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## INTRODUCTION

With the dawn of civilization several thousand years ago, human beings have over time used their intellect to understand the need and usage of genetic materials available in their surroundings. The knowledge they acquired by means of these genetic resources was nurtured carefully, passed on from generation to generation, and thus began the evolution of traditional knowledge. Genetic resources provide food crops, cash crops, clothes, medicines, toiletries and cosmetics, beverages, paper, and several other products. The processing of genetic resources by traditional communities creates traditional knowledge, which is quite vast in nature. It includes knowledge related to genetic resources, traditional medicine, agricultural practice, and traditional cultural expression and folklore, and has evolved by experimentation for survival of life. Genetic resources and associated traditional knowledge, as stated previously, have an immense potential to be translated into economically profitable commodities. With the globalisation and promotion of trade, these commodities are of interest in national as well as international markets. Modern science and technology, if coupled with the genetic resources and associated traditional knowledge, can provide scientific backing to traditional practices, and in turn can generate enormous economic benefits.

It is unfortunate that various multinational companies are trying to access and undertake research and development activities with the motive of earning a good amount of financial profit, without the involvement of the original holders. By doing so, not only are the companies failing to include the traditional community in commercialisation and benefit sharing, but are also trying to protect their own input by utilizing the existing intellectual property rights, specifically patents. When such monopolisation turns into reality, traditional knowledge holders find themselves out of reach of their own knowledge. Hence, it is necessary that they are provided with a uniform protection regime for genetic resources and associated traditional knowledge with a minimum standard of protection which will be available in legal regimes across the globe. Such a protection regime has to be consolidated at the international level, and implemented at the national level by the State Governments as they can best assess the needs of the traditional and indigenous communities within the State and can accordingly provide the requisite protection.

## I. TRIPS AGREEMENT: PROVISIONS RELATED TO GENETIC RESOURCES

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) forms the international legal regime providing the minimum standards for intellectual property protection. Intellectual property rights are essentially private rights, with patents being most used for the misappropriation of genetic resources and associated traditional knowledge. According to Article 27.3(b) of the TRIPS Agreement, a Member State may exclude plants (except microorganisms) from patentable subject matter. While provisions for plant variety protection also relate to the genetic resources, the criteria for protection of plant varieties are quite specific and unique, being only for the protection of new plant varieties and not for misappropriation of genetic resources and associated traditional knowledge. The TRIPS Agreement is silent about the protection of genetic resources and associated traditional knowledge as its aim was to provide the minimum standard for intellectual property rights, which are private rights. Conversely, States have sovereignty over their genetic resources and associated traditional knowledge, usually held by the traditional or local communities. Hence, the mechanism for protection of both genetic resources and traditional knowledge requires the establishment of community rights, which is not included within the purview of the TRIPS Agreement.

## II. CBD: ABS MECHANISM FOR GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

For the commercialization and utilization of genetic resources and associated traditional knowledge, the Convention on Biological Diversity (CBD) provided the Nagoya Protocol in 2011, which suggested a framework for fair and equitable benefit sharing. This benefit sharing mechanism is based on mutually agreed term (MAT) and thus assists both the parties to develop legislative, administrative, or policy measures to ensure fair and equitable benefit sharing. It includes awareness on implementation, promotes capacity building, and strengthens the clearing house mechanism for co-operation between parties and stakeholders. A competent national authority is to be made responsible for advising on MAT in terms of implementation, evaluation, and monitoring of the benefit sharing arrangement. According to the Protocol, access to genetic resources and/or associated traditional

knowledge for their utilization is subject to the prior informed consent (PIC) of the country of origin of the resource. The process of PIC or approval should include involvement of indigenous and local communities;<sup>1</sup> benefits may include monetary and non-monetary benefits, and the competent national authority shall be held responsible for implementing the procedure of obtaining PIC and establishing MAT including benefit sharing clauses.<sup>2</sup>

### III. TRIPS AND CBD: IN CONVERGENCE OR DIVERGENCE?

The World Trade Organisation (WTO) implemented the TRIPS Agreement in order to provide a minimum standard of protection for all possible intellectual property rights. Owing to its binding nature, the TRIPS Agreement imposes a legal obligation on all Member States to abide by it in matters of drafting and implementation of intellectual property right regimes. However, the issue of sovereignty of States over their biodiversity and plant genetic resources and special provisions regarding sustainability and fair and equitable benefit sharing is not at all addressed in the TRIPS Agreement. On the other hand, the CBD is based on the objectives of conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits arising from the use of genetic resources. The CBD does not focus on the intellectual property regime as such. Instead, its objective is to protect the genetic resources and associated knowledge by their proper utilization through regulated access. Further, as both genetic resources and associated traditional knowledge have immense potential to be transformed into economically valuable products, the CBD seeks to establish a benefit sharing mechanism in cases of commercial utilization of genetic resources and associated knowledge. Hence, it is obvious that the basic objective of TRIPS and CBD is different and cannot converge with each other. Their aims are different, their approach of protection is different, and rights provided through TRIPS and CBD are also completely different.

The relation between the objectives of the CBD and the TRIPS Agreement has been subject to continuous debate at the WTO, especially within the TRIPS Council and Committee on Trade and Environment (CTE). The core element of this discussion is the lack of recognition of the objectives of the CBD and the need to incorporate those objectives into the text of the

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<sup>1</sup> 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 art.6,7, Oct. 29, 2010, 1760 U.N.T.S 79 [hereinafter, Nagoya Protocol].

<sup>2</sup> Nagoya Protocol, *supra* note 1. art. 13.

TRIPS Agreement. According to Article 16(5) of the CBD *“the Contracting Parties, recognizing that patents and other IP rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives”*. In view of the binding nature of the TRIPS Agreement, it is well understood that the essence of non-compliance between the TRIPS and the CBD objective is included in this way in the text of Article 16(5).

The main vehicle used by developing countries in the DOHA negotiation for promoting recognition and incorporation of the CBD objective is the review of Article 27.3(b) in the CTE. The implementation of the TRIPS Agreement is affecting the fulfilment of CBD objectives in multiple areas. These include the dominance of private rights over public rights, recognition of patent and other intellectual property rights using genetic resources and associated traditional knowledge without PIC and benefit sharing arrangements, and the lack of acknowledgement over alternative knowledge and innovation system (of which traditional knowledge is a part) along with a lack of respect for the holders of that knowledge.

#### IV. DIFFERENT VIEWS

These views pertaining to the TRIPS Agreement and the CBD can be divided into four broad categories:

- a) The first view suggests that there is no conflict between these two instruments and they can be implemented in a mutually supportive way. This is the view of most

developed countries like the USA,<sup>3</sup> Australia,<sup>4</sup> Japan,<sup>5</sup> and Canada.<sup>6</sup> According to this view, the scope and the subject matter of these two Agreements are different and implementation of both can be pursued in separate frameworks. No reference of specific clash has been cited, and the sovereignty of States over biodiversity and genetic resources, and access and benefit sharing (ABS) mechanism is not influenced by the patent system. Further, this view postulates that the existing patentability criteria is fool-proof even for granting of patents on inventions related to biodiversity and genetic resources. It has been suggested that the conservation of biodiversity and the implementation of benefit sharing mechanism can be carried out on a voluntary contractual basis, and protection of undisclosed information will be of help to this.<sup>7</sup>

- b) According to the second view, there is no conflict and they can be used in a mutually supportive way in national regimes, but, further discussion is needed to decide

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<sup>3</sup> Further Views of the United States, *United States - Review of the Provisions of Article 27.3(b)*, IP/C/W/209 (Oct. 3, 2000); Communication from the United States, *United States - Review of the Provisions of Article 27.3(b)*, IP/C/W/162 (Oct. 29, 1999); Communication from the United States, *United States – Article 27.3(B), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, IP/C/W/434 (Nov.26, 2004); Communication from the United States, *United States - Views of the United States on the Relationship between the Convention on Biological Diversity and the TRIPS Agreement*, IP/C/W/257 (June 13, 2001); Minutes of Meeting, *Held in the Centre William Rappard on 8 March, 2004*, IP/C/M/43 (May 7 2004); Minutes of Meeting, *Held in the Centre William Rappard on 18 November 2003*, IP/C/M/42 (Feb. 4, 2004); Minutes of Meeting, *Held in the Centre William Rappard on 1-2 December 2004*, IP/C/M/46 (Jan.11, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 20-21 October 1999*, IP/C/M/25 (Dec. 22, 1999).

<sup>4</sup> Communication from Australia, *Australia - Review of 27.3(b)*, IP/C/W/310 (Oct. 2, 2001); Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, IP/C/M/47 (June 3, 2005); , Minutes of Meeting, *Held in the Centre William Rappard on 1-2 December 2004*, IP/C/M/46 (Jan.11, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 4-5 June 2003*, IP/C/M/40 (Aug. 22, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 and 29 November, and 20 December 2002*, IP/C/M/38 (Feb. 5, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, IP/C/M/36/Add.1. (Sept. 10, 2002).

<sup>5</sup> Communication from Japan, *Japan – Review of the Provisions of Article 27.3(b) – Japan’s View*, IP/C/W/236 (Dec.11, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, IP/C/M/47 (June 2, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 18-19 February 2003*, IP/C/M/39 (Mar.21, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 21 March 2000*, IP/C/M/26 (May 24, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 20-21 October 1999*, IP/C/M/25 (Dec.22, 1999).

<sup>6</sup> Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, IP/C/M/47 (June 2, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 4-5 June 2003*, IP/C/M/40 (Aug. 22, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 17-19 September 2002*, IP/C/M/37/Add.1 (Nov. 8, 2002); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, IP/C/M/36/Add.1. (Sept. 10, 2002).

<sup>7</sup> Communication from the United States, *United States – Article 27.3(B), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, IP/C/W/434 (Nov.26, 2004); Communication from the United States, *United States - Views of the United States on the Relationship between the Convention on Biological Diversity and the TRIPS Agreement*, IP/C/W/257 (June 13, 2001); Minutes of Meeting, *Held in the Centre William Rappard from 2 to 5 April 2001*, IP/C/M/30 (June 1, 2001).

whether any international action is required for the patent system. This view, much like the first one, emanates from some developed countries such as the USA, Japan, Korea, Australia, and Canada.<sup>8</sup> As per their communication to the WTO, minimal material evidence has been put forward from the national level to prove that ABS system is not providing proper protection from misappropriation of genetic resources.<sup>9</sup> Further, if problems do exist, they can be addressed through administrative measures such as information sharing between patent offices and establishment of database,<sup>10</sup> instead of IP rules. According to Australia, Canada and New Zealand,<sup>11</sup> if Member States share national experiences more often with each other, the analysis on a particular matter can be more comprehensive and will help enhance the understanding of the legal and conceptual aspects, which will in turn ensure the mutual supportiveness of two agreements. Another option can be to strengthen the legal and administrative regimes outside intellectual property rights, such as sharing of information between patent offices or by disclosing relevant information or by establishment of a database.

- c) The third view suggests that there is no inherent conflict between these two instruments; but during their implementation, international action is needed for increasing mutual supportiveness and to reduce chances of potential conflict between them. This view is expressed by a number of developing countries and a few

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<sup>8</sup> *Supra* note 3, 5, 6.

<sup>9</sup> Minutes of Meeting, *Held in the Centre William Rappard on 1-2 December 2004*, ¶¶55, 61, 65, IP/C/M/46 (Jan.11, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 4-5 June 2003*, ¶¶101, 115, IP/C/M/40 (Aug. 22, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶¶54, 66, IP/C/M/47 (June 3, 2005);.

<sup>10</sup> *Id.*

<sup>11</sup> *Supra* note 9,

developed countries, including Andean Community,<sup>12</sup> Brazil,<sup>13</sup> China,<sup>14</sup> Colombia,<sup>15</sup> Ecuador,<sup>16</sup> EC,<sup>17</sup> Egypt,<sup>18</sup> India,<sup>19</sup> Indonesia,<sup>20</sup> Kenya,<sup>21</sup> Norway,<sup>22</sup> Pakistan,<sup>23</sup> Peru,<sup>24</sup>

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<sup>12</sup> Minutes of Meeting, *Held in the Centre William Rappard on 17-19 September 2002*, ¶231, IP/C/M/37/Add.1 (Nov.8, 2002).

<sup>13</sup> Communication from Brazil, *Brazil - Review of Article 27.3(b)*, IP/C/W/228 (Nov. 24, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June 2005*, ¶35, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Held in the Centre William Rappard from 18 to 22 June 2001*, ¶128, IP/C/M/32 (Aug.23, 2001); Minutes of Meeting, *Held in the Centre William Rappard from 27 to 30 November and 6 December 2000*, ¶¶ 146,148,234, IP/C/M/29 (Mar.26, 2001); Minutes of Meeting, *Held in the Centre William Rappard on 21 and 22 September 2000*, ¶135, IP/C/M/28 (Nov.23, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 26-29 June 2000*, ¶122, IP/C/M/27 (Aug.14, 2000).

<sup>14</sup> Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶57, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 18 November 2003*, ¶119, IP/C/M/42 (Feb.4, 2004); Minutes of Meeting, *Held in the Centre William Rappard on 18-19 February 2003*, ¶132, IP/C/M/39 (Mar.21, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 and 29 November, and 20 December 2002*, ¶239, IP/C/M/38 (Feb. 5, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 17-19 September 2002*, ¶229, IP/C/M/37/Add.1 (Nov. 8, 2002); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, ¶¶227, 228, IP/C/M/36/Add.1. (Sept. 10, 2002).

<sup>15</sup> Minutes of Meeting, *Held in the Centre William Rappard on 1-2 December 2004*, ¶57, IP/C/M/46 (Jan.11, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, ¶209, IP/C/M/36/Add.1. (Sept. 10, 2002).

<sup>16</sup> Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶49, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 20-21 October 1999*, ¶87, IP/C/M/25 (Dec. 22, 1999).

<sup>17</sup> Communication from the European Communities And their Member States, *Review of Article 27.3(B) of The TRIPS Agreement, and the Relationship Between The TRIPS Agreement and The Convention On Biological Diversity (CBD) and The Protection of Traditional Knowledge and Folklore*, IP/C/W/383 (Oct.17, 2002); Communication from the European Communities and their Member States, *Review of the Provisions of Article 27.3(b) of the TRIPS Agreement*, IP/C/W/254 (June 13, 2001); *supra* note 13,14; Minutes of Meeting, *Held in the Centre William Rappard on 5-7 March 2002*, ¶233, IP/C/M/35 (Mar.22, 2002).

<sup>18</sup> *Supra* note 6.

<sup>19</sup> Submission by India, *India - Protection of Biodiversity and Traditional Knowledge - The Indian Experience*, IP/C/W/198 (July 14, 2000); Communication from India, *India - Proposals on Intellectual Property Rights Issues*, IP/C/W/195 (July 12, 2000); *supra* note 4, 7, 13; Minutes of Meeting, *Held in the Centre William Rappard on 7-8 July 1999*, ¶81, IP/C/M/24 (Aug.17, 1999).

<sup>20</sup> *Supra* note 4, 13.

<sup>21</sup> *Id.*

<sup>22</sup> Communication from Norway, *Norway - Review of Article 27.3(b) of the TRIPS Agreement: The Relationship between the TRIPS Agreement and the Convention on Biological Diversity*, IP/C/W/293 (June 29, 2001); *supra* note 4, 13.

<sup>23</sup> Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, ¶211, IP/C/M/36/Add.1. (Sept. 10, 2002).

<sup>24</sup> Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June 2005*, ¶¶92, 93, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, ¶203, IP/C/M/36/Add.1. (Sept. 10, 2002).

Philippines,<sup>25</sup> Switzerland,<sup>26</sup> Thailand,<sup>27</sup> Turkey,<sup>28</sup> and Venezuela.<sup>29</sup> They suggested the inclusion of the 'disclosure of origin' in the patent application, especially when the invention is related to genetic resources and associated traditional knowledge. Further, it was suggested that along with the disclosure of origin of such an invention, the PIC obtained from a competent national authority has to be furnished, and there ought to be fair and equitable benefit sharing arrangements.<sup>30</sup> Accordingly, they called for international action in this regard. Switzerland proposed to include the disclosure of origin criteria into international patent application for invention on genetic resources and associated traditional knowledge in PCT of WIPO<sup>31</sup> at the earliest possible time. The EC suggested that the origin or source of the genetic material must be made mandatory for all patent applications at all three levels - national, regional and international, and penalties must be imposed for non-compliance with the legal

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<sup>25</sup> Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶¶79, 80, IP/C/M/47 (June 3, 2005).

<sup>26</sup> Further Observations by Switzerland on its Proposals, *Switzerland - Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, IP/C/W/433 (Nov.25, 2004); Additional Comments by Switzerland on its Proposal, *Switzerland - Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, IP/C/W/423 (June 14, 2004); Communication from Switzerland, *Switzerland - Article 27.3(b), the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge*, IP/C/W/400/Rev.1 (June 18, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June 2005*, ¶16, IP/C/M/48 (Sept.15, 2005).

<sup>27</sup> Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June 2005*, ¶61, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 18 November 2003*, ¶105, IP/C/M/42 (Feb. 4, 2004); Minutes of Meeting, *Held in the Centre William Rappard on 20-21 October 1999*, ¶78, IP/C/M/25 (Dec. 22, 1999).

<sup>28</sup> Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶63, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 26-29 June, 2000*, ¶132, IP/C/M/27 (Aug.14, 2000)

<sup>29</sup> Minutes of Meeting, *Held in the Centre William Rappard on 4-5 June 2003*, ¶102, IP/C/M/40 (Aug. 22, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 25-27 June 2002*, ¶208, IP/C/M/36/Add.1. (Sept. 10, 2002); Minutes of Meeting, *Held in the Centre William Rappard from 18 to 22 June 2001*, ¶136, IP/C/M/32 (Aug.23, 2001); Minutes of Meeting, *Held in the Centre William Rappard on 21 and 22 September 2000*, ¶165, IP/C/M/28 (Nov.23, 2000).

<sup>30</sup> Note by the Secretariat, *Summary of Issues and Points Raised and Points Made – The Relationship between the TRIPS Agreement and The Convention on Biological Diversity*, ¶14, IP/C/W/368/Rev.1 (Feb.8, 2006).

<sup>31</sup> Further Observations by Switzerland, *Switzerland - Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, IP/C/W/433 (Nov.24, 2004); Additional Comments by Switzerland on its Proposal, *Switzerland - Declaration of Source of Genetic Resources and Traditional Knowledge in Patent Applications*, IP/C/W/423 (June 14, 2004); Revised version of document IP/C/W/400 – Article 27.3(b), *Switzerland - The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and Traditional Knowledge – Revision*, IP/C/W/400/Rev.1 (June 18, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 25-26 and 28 October, 29 November and 6 December 2005*, ¶115, IP/C/M/49 (Jan.31, 2006);, Minutes of Meeting, *Held in the Centre William Rappard on 21 September 2004*, ¶¶47,48, IP/C/M/45 (Oct.27, 2004); Minutes of Meeting, *Held in the Centre William Rappard on 16 June 2004*, ¶25, IP/C/M/44 (July 19, 2004).

provisions.<sup>32</sup> In case of international applications, if a patent application were to have the disclosure of source of origin, regulations of the PCT would need to be amended to incorporate that requirement. Moreover, in that case, it is necessary that declaration of the source is to be made publicly available at the earliest possible time.<sup>33</sup> It can be implemented only by the co-operation of the CBD, the WTO, the WIPO, and the Food and Agriculture Organization (FAO).

- d) The fourth view suggests that there is an inherent conflict between the two and that the TRIPS Agreement needs to be amended to minimize this conflict. This is reflected in some communications by developing countries. Among the developed countries, the EC is supportive of this view.<sup>34</sup> In furtherance of this view, they remarked that patenting of certain genetic resources is possible as per the TRIPS Agreement, and this is contrary to the principle of States' sovereignty over genetic resources, traditional knowledge and the access and benefit sharing mechanism proposed by CBD.<sup>35</sup> Two proposals were put forward to address this ambiguity; first, that Article 27.3(b) of TRIPS be amended to make all life forms or their parts non-

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<sup>32</sup> Review, *European Communities and Member States - Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, IP/C/W/383 (Oct.17, 2002); Communication from the European Communities and their Member States, *European Communities and Member States - Review of Article 27.3(b) of the TRIPS Agreement*, IP/C/W/254 (June 13, 2001); Minutes of Meeting, *Held in the Centre William Rappard on 5-7 March 2002*, ¶234, IP/C/M/35 (Mar.22, 2002); ; Minutes of Meeting, *Held in the Centre William Rappard from 2 to 5 April 2001*, ¶¶144,146, IP/C/M/30 (June 1, 2001).

<sup>33</sup> *Supra* note 31.

<sup>34</sup> *Supra* note 32.

<sup>35</sup> Joint Communication from the African Group, *Morocco on behalf of the African Group - Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, IP/C/W/404 (June 26, 2003); Communication from Mauritius, *Mauritius on behalf of the African Group*, IP/C/W/206 (Sept.20, 2000); Communication from Kenya, *Kenya on behalf of the African Group - Review of the Provisions of Article 27.3(b)*, IP/C/W/163 (Nov.8, 1999); Communication from Brazil, *Brazil - Review of Article 27.3(b)*, IP/C/W/228 (Nov.24, 2000); *supra* note 13, 17, 19; Minutes of Meeting, *Indonesia - Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶51, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Indonesia - Held in the Centre William Rappard on 25-27 June 2002*, ¶217, IP/C/M/36/Add.1. (Sept. 10, 2002); Communication from Peru, *Peru - Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, IP/C/W/447 (June 8, 2005); Minutes of Meeting, *Thailand - Held in the Centre William Rappard on 14-15 June, 2005*, ¶¶18, 19, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Peru - Held in the Centre William Rappard on 14-15 June, 2005*, ¶61, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Thailand - Held in the Centre William Rappard on 20-21 October 1999*, ¶78, IP/C/M/25 (Dec. 22, 1999); Minutes of Meeting, *Turkey - Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶63, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Turkey - Held in the Centre William Rappard on 26-29 June, 2000*, ¶132, IP/C/M/27 (Aug.14, 2000); Minutes of Meeting, *Venezuela - Held in the Centre William Rappard on 4-5 June 2003*, ¶102, IP/C/M/40 (Aug. 22, 2003) .

patentable.<sup>36</sup> However, this proposal did not accommodate the genetic resources and associated traditional knowledge protection. On the other hand, the second proposal was directly beneficial to genetic resources and associated traditional knowledge. It proposed the amendment of the TRIPS Agreement in such a way that an invention based on traditional knowledge or its products or processes related to its derivatives be excluded from patenting and that any application inconsistent with Article 15 of CBD would not be granted.<sup>37</sup> Concerns were raised about erroneously granted patents, which was justified by stating that post-grant opposition and re-examination is a necessarily lengthy and costly procedure which could possibly be avoided by adopting a stricter patentability criteria<sup>38</sup> and by a “*searchable database of knowledge, innovation and practices of local and indigenous community*”.<sup>39</sup> Further discussion on a stricter patentability criteria is relevant, as this was a topic of continuous debate in the WTO. In the Doha Ministerial Declaration, developing countries demanded urgent negotiation regarding implementation issues which are called for in the Paragraph 12 of the Ministerial Declaration.<sup>40</sup> Among the Tires and proposals relating to biodiversity issues, Tiret 15 is the most important provision pertaining to stricter patentability criteria. Tiret 15 asks for non-granting of a patent if the application is not in consonance with Article 15 of the CBD.<sup>41</sup> Article 15 of the CBD provides for recognition of sovereign rights over genetic resources, an ABS system based on PIC and MAT, and collaborative research activities between different countries. As such, Tiret 15 proposed for a patent application to undergo a ‘consistency examination’ in order to be in conformity with Article 15 of the CBD. This ‘consistency examination’ would be a new and added criteria for patent

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<sup>36</sup> *Id.*

<sup>37</sup> Communication from India, IP/C/W/196 (July 12, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 17-19 September 2002*, ¶ 224, IP/C/M/37/Add.1 (Nov. 8, 2002); Minutes of Meeting, *Held in the Centre William Rappard on 20-21 October 1999*, ¶70, IP/C/M/25 (Dec. 22, 1999).

<sup>38</sup> Minutes of Meeting, *Switzerland - Held in the Centre William Rappard from 2 to 5 April 2001*, IP/C/M/30 (June 1, 2001).

<sup>39</sup> *Id.*

<sup>40</sup> According to Paragraph 12, Members..... “*agree that negotiations on outstanding implementations shall be an integral part of the Work Programme*” ..... *In this regard we shall proceed as follows: (a) where we provide a specific negotiating mandate in this Declaration, the relevant implementation issues shall be addressed under the mandate; (b) the other outstanding implementation issues shall be addressed as a matter of priority by the relevant WTO bodies, which shall report to the Trade Negotiations Committee, .....*”

<sup>41</sup> Text of Tiret 15 “*A clear understanding in the interim that patents inconsistent with Article 15 of CBD shall not be granted.*”

applications.<sup>42</sup> However, this issue is still under debate and a decision is yet to be reached.

Two approaches talk about the solution of the issue in conflict: one being a national based approach, and the other being to include the ‘disclosure’ requirement in patent applications. The USA, being the primary voice behind ‘National Based Approach’, suggested the use of contract system in national legislation for authorised access by PIC, access permits, and the imposition of civil or criminal penalties. A contract system, as per the USA, can also be effectively used for establishment of rights and obligations of both parties, transfer and sharing of benefits and monitoring of the same, and the inclusion of mandatory disclosure of source or origin to a competent authority.<sup>43</sup> According to this view, the advantages would be: (i) it is easily adaptable to a country’s national legal regime as every country has its contract law therein; (ii) valuable time and cost will be saved if a new legal regime is not enforced and ABS system for the protection of genetic resources and associated traditional knowledge can commence immediately; (iii) it can provide criminal or civil remedies for non-compliance with the legal obligations. As such, a contract system can provide necessary flexibility in ensuring benefit sharing arising out of commercialization of genetic resources and associated traditional knowledge.<sup>44</sup>

Wrongly granted patents can be taken care of with the help of post-grant opposition and re-examination. Further, enhancing information on prior art and formation of a relevant database on traditional knowledge can stop erroneous patents from being granted. Two examples cited by the US in favour of the contract based approach are the policy and programme of US National Cancer Institute's Departmental Therapeutics Programme (NCI-DTP), and policies of the US National Institutes of Health-Office of Technology Transfer (NIH-OTT).<sup>45</sup> However, as stated previously, the key concern regarding the use of genetic resources and associated traditional knowledge is its trans-boundary nature of use. National or regional measures alone will not be adequate when one country’s genetic resources and

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<sup>42</sup> David Vivas Eugui, *Issues linked to Convention on Biological Diversity in the WTO negotiations: Implementing Doha Mandates* CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (Apr. 19, 2020, 9:44PM), [https://www.ciel.org/wp-content/uploads/2015/03/Doha\\_CBD-10oct02.pdf](https://www.ciel.org/wp-content/uploads/2015/03/Doha_CBD-10oct02.pdf).

<sup>43</sup> *Supra* note 3.

<sup>44</sup> *Id.*

<sup>45</sup> Communication from the United States, *United States - Technology transfer practices of the US National Cancer Institute's departmental therapeutics programme*, IP/C/W/341 (Mar.25, 2002).

associated traditional knowledge are misappropriated in another country. Although reliance on the contract system is necessary at some point for acquiring MAT (as required by para 4 and 7 of Article 15 of CBD), it will not be enough if it is not obligatory and enforceable across borders.<sup>46</sup> Limited bargaining power would be a serious concern for provider countries.<sup>47</sup> By an analysis of biopiracy cases relating to genetic resources and associated traditional knowledge and the free trade agreement (FTA) between developing and developed countries (USA and others), it can be easily concluded that countries who have stronger bargaining power always get preferences from contract based approaches so that they can channel its benefits to their favour. It is evident that traditional and indigenous communities are not empowered enough to negotiate equitable and beneficial contractual terms. In fact, even national governments and authorities lack proper training and orientation with respect to genetic resources and associated traditional knowledge protection to some extent.<sup>48</sup> Hence, the advantages highlighted by USA for this approach are inaccurate in practice.

The second approach as a solution is the 'Disclosure Approach,' relating to which, three different proposals have been given.

- a) The TRIPS disclosure proposal - Amendment of the TRIPS Agreement to include source and country of origin of genetic resources and associated traditional knowledge, evidence of PIC from the competent national authority of the source or origin country, and evidence of fair and equitable benefit sharing arrangement should be made available in the patent application.<sup>49</sup> Member countries need to make it mandatory<sup>50</sup> in their national legal regimes and ensure implementation of the same by providing evidence. Even in case a national legal regime is not available, the applicant should at least obtain consent from the community or the capable authority. Documents have to be handed over within the stipulated time period and non-

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<sup>46</sup> *Supra* note 35.

<sup>47</sup> Minutes of Meeting, *Pakistan - Held in the Centre William Rappard on 21 and 22 September 2000*, ¶158, IP/C/M/28 (Nov.23, 2000).

<sup>48</sup> Minutes of Meeting, *Kenya - Held in the Centre William Rappard on 1-2 December 2004*, ¶67, IP/C/M/46 (Jan.11, 2005).

<sup>49</sup> *Supra* note 35.

<sup>50</sup> Minutes of Meeting, *Brazil - Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶25, IP/C/M/47 (June 3, 2005).

disclosure or wrong disclosure will be penalised.<sup>51</sup> In terms of the legal effect of this amendment, the suggestions of developing countries provided as follows:

1. Amendment of Article 27 of the TRIPS Agreement to include another exception of patentability<sup>52</sup> by virtue of the following text:

*“[Members may also exclude from patentability]:*

*(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.*

*Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity.”*

2. Another proposal is an amendment of Article 29,<sup>53</sup> with the alternative text proposed as follows:

*“Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.”<sup>54</sup> or*

*“Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted.”<sup>55</sup>*

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<sup>51</sup> Submission from Brazil et. al, *Brazil - The Relationship Between the TRIPS Agreement and the Convention On Biological Diversity (CBD) and The Protection of Traditional Knowledge - Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, IP/C/W/438 (Dec.10, 2004); Submission from Brazil et. al, *Brazil - Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, IP/C/W/429/Rev.1 (Sept.27, 2004); Submission from India et. al, *India - The Relationship between the TRIPS Agreement and the Convention On Biological Diversity and the Protection of Traditional Knowledge*, IP/C/W/403 (June 24, 2003); Minutes of Meeting, *India - Held in the Centre William Rappard on 1-2 December 2004*, ¶40, IP/C/M/46 (Jan.11, 2005); Minutes of Meeting, *India - Held in the Centre William Rappard on 21 September 2004*, ¶¶22, 23, IP/C/M/45 (Oct.27, 2004).

<sup>52</sup> Communication from Brazil, *Brazil - Review of Article 27.3(b)*, IP/C/W/228 (Nov. 24, 2000); Minutes of Meeting, *Held in the Centre William Rappard on 19 and 20 September 2001*, ¶121, IP/C/M/33 (Nov.2, 2001); Minutes of Meeting, *Held in the Centre William Rappard from 18 to 22 June 2001*, ¶128, IP/C/M/32 (Aug.23, 2001).

<sup>53</sup> *Supra* note 35.

<sup>54</sup> Joint Communication from the African Group, *Morocco on behalf of the African Group - Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, IP/C/W/404 (June 26, 2003).

<sup>55</sup> Communication from Peru, *Peru - Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, IP/C/W/447 (June 8, 2005).

3. Introduction of a new Article in TRIPS Agreement.<sup>56</sup>

4. Proper interpretation of Article 29.<sup>57</sup>

b) PCT disclosure proposal: The PCT of WIPO regulates international patent applications and Switzerland proposed the requirement of disclosure of origin and the source to be included in PCT applications relating to genetic resources and associated traditional knowledge.<sup>58</sup> The declaration of source of origin is to be incorporated in the application, which, according to Swiss suggestion, will not be mandatory but will depend upon the discretion of the Member Country's Government to incorporate it into the national legal regime. Once included in the national regime, it will be made compulsory for that country to provide declaration of source of used genetic resources and associated traditional knowledge in its patent applications. The voluntary nature of this proposal helps to gain insights on the implementation of this new requirement without further deliberations on obligations. Once it is submitted within the stipulated time period, it has to be finalised; provided it is reasonably and unambiguously worded. Post grant, if it is found that no disclosure document exists, or more importantly, incorrect information has been submitted, then the validity of that patent can be reviewed by the Member country and can be revoked.<sup>59</sup> Patent offices, on receiving patent applications having declaration of source, will in turn inform the relevant competent national authority so that national authorities need not keep an eye on patent applications worldwide.<sup>60</sup> The advantages claimed are, the formation of a legal base at international level to converge to the ABS system, the provision of flexible and effective national law and mutual supportiveness between related international agreements such as the TRIPS Agreement, the Nagoya Protocol to the CBD and International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA) of FAO.

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<sup>56</sup> Submission from Brazil et. al, *Brazil - The Relationship between the TRIPS Agreement and the Convention On Biological Diversity and the Protection of Traditional Knowledge*, IP/C/W/403 (June 24, 2003).

<sup>57</sup> Minutes of Meeting, *Cuba - Held in the Centre William Rappard on 4-5 June 2003*, ¶117, IP/C/M/40 (Aug. 22, 2003).

<sup>58</sup> *Supra* note 26.

<sup>59</sup> The Patent Law Treaty art. 10, June 1, 2000, 2340 U.N.T.S. 3.

<sup>60</sup> *Supra* note 26.

c) Mandatory disclosure proposal: The EC suggested<sup>61</sup> this proposal in the WIPO Inter-governmental Committee on Intellectual Property & Genetic Resources (WIPO IGC). This proposal calls for all national governments to include the requirement of disclosure of country of origin or source of genetic resources and associated traditional knowledge in all patent applications, if such genetic resources and associated traditional knowledge are used in that invention. Addition, emphasis was also laid on the following: (i) traditional knowledge has to be defined properly; (ii) this requirement should be binding in nature and should be applied to all national, regional and international applications; and (iii) the disclosure of origin and source is to be made as early as possible in the procedure of patent application. Submission of wrong information is to be associated with civil or administrative remedies as available in that national legal set up. PIC and other ABS measures are to be followed strictly in the application. The patent office will notify a central body about the receipt of an application. Further, either that central body will work in co-ordination with relevant competent national authorities (list of such authorities would be maintained in WIPO and CBD) or a clearing house mechanism can be started by the central body for the purposes of dissemination of information.<sup>62</sup>

For instance, Norway amended some provisions of its existing Patent Act to incorporate CBD guidelines of ABS measures. Consequently, all applications for patents based on genetic resources and associated traditional knowledge require the country of origin of the material to be provided. It also requires PIC to be submitted along with the patent application under the amended Act.<sup>63</sup> Similarly, the common legal regime of the Andean Community has regulation for protection of plant varieties. Peru follows this legal regime in its national territory, and under this rule, plant breeders have to obtain the certificate from INDECOPI.

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<sup>61</sup> Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June, 2005*, ¶62, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶58, IP/C/M/47 (June 3, 2005).

<sup>62</sup> *Supra* note 17.

<sup>63</sup> Minutes of Meeting, *Norway - Held in the Centre William Rappard on 14-15 June 2005*, ¶81, IP/C/M/48 (Sept.15, 2005); Minutes of Meeting, *Norway - Held in the Centre William Rappard on 8-9 and 31 March 2005*, ¶65, IP/C/M/47 (June 3, 2005); Minutes of Meeting, *Norway - Held in the Centre William Rappard on 8 March, 2004*, ¶54, IP/C/M/43 (May 7 2004); Minutes of Meeting, *Held in the Centre William Rappard on 4-5 June 2003*, ¶¶87, 88, IP/C/M/40 (Aug. 22, 2003); Minutes of Meeting, *Held in the Centre William Rappard on 18-19 February 2003*, ¶121, IP/C/M/39 (Mar.21, 2003).

For this, it is a must to submit the geographical origin of the plant genetic resources and access certificate issued by the competent national authority.<sup>64</sup>

After judging the international position and discussions on different proposals, it is evident that there is a need of a minimum legal standard of protection which is binding in nature. The national legislation needs to be enhanced for best protection of genetic resources and associated traditional knowledge, which will provide proper protection for traditional knowledge, and also provide recognition and legal certainty to the original traditional knowledge holder community.

## V. DISCLOSURE OF ORIGIN: DEVELOPING COUNTRIES'

### PROPOSITION FOR ARTICLE 29BIS

A group of developing countries in 2011 proposed introduction of Article 29*bis* into the TRIPS Agreement to enhance the mutual supportiveness between the CBD and the TRIPS. Accordingly, a communication was circulated by WTO among all Member States on a request by Brazil, India, China, Colombia, Ecuador, Indonesia, Peru, Thailand, the African Group and the ACP (African, Caribbean & Pacific) Group on 15<sup>th</sup> April 2011.<sup>65</sup> The communication states that, to ensure fair and equitable sharing of benefits arising from the utilization of genetic resources and/or associated knowledge, which is one of the core objective of the CBD, every Member State must comply with the access and benefit sharing legislation of the country of origin of such resource or knowledge. It also recognized that the disclosure requirement in Article 29 of the TRIPS Agreement remains incomplete without the disclosure of origin of genetic resources and associated traditional knowledge. Hence, it mentioned that a legal obligation of a mandatory disclosure requirement in patent applications should be established so as to prevent misappropriation of genetic resources and associated traditional knowledge and the grant of erroneous patents.<sup>66</sup> Accordingly, these developing countries suggested an amendment to the TRIPS Agreement by insertion of

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<sup>64</sup> Communication from Peru, *Peru – Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, IP/C/W/447 (June 8, 2005); Minutes of Meeting, *Held in the Centre William Rappard on 14-15 June 2005*, ¶93, IP/C/M/48 (Sept.15, 2005).

<sup>65</sup> Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, *Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement And The Convention On Biological Diversity by the Trade Negotiations Committee*, WTO Doc. TN/C/W/59 (Apr.19, 2011).

<sup>66</sup> *Id.*

Article 29*bis*, which will ensure the disclosure of country of origin of the genetic resources for any patent application, whenever the subject matter of such invention includes genetic resources or associated traditional knowledge.<sup>67</sup> Article 29*bis* also requires Member States to mandate the applicant to provide a copy of Internationally Recognised Certificate of Compliance (IRCC) or the compliance with PIC and access and benefit sharing.<sup>68</sup> However, this issue is still pending in the WTO Ministry. If the suggested amendment is approved by WTO, it will certainly be a welcome change in the TRIPS Agreement as it will ensure fair and equitable benefit sharing by Member states upon utilization of genetic resources and associated traditional knowledge.

## VI. RELATION OF FREE TRADE AGREEMENTS WITH MISAPPROPRIATION

Across the world, almost all countries are engaged in negotiating different bilateral and multilateral free trade agreements (FTAs). The main problem is that every country is trying to negotiate according to its own needs and benefits. In order to address this topic, we first need to understand the relation between genetic resources and/or associated traditional knowledge and FTAs. This relation depends upon each country's point of view. For countries which are trying to exploit genetic resources and associated traditional knowledge solely for economic benefit, genetic resources and associated traditional knowledge are nothing but a means to make commodities. They seek to misappropriate genetic resources and associated traditional knowledge by using FTAs. The fallacy is that governments try to insert genetic resources and associated traditional knowledge into bilateral or multilateral FTAs to prevent biopiracy. This can be best understood in a scenario where the USA is the negotiating party across the table, in which case, the opposite would happen. For example, the Andean proposal of insertion of Disclosure of Origin, PIC and Benefit Sharing for biodiversity related patents was rejected by the USA. Peru accepted the US-Peru Trade Promotion Agreement in 2005.<sup>69</sup> There are certain clauses in it which demand a change in Peruvian Law for genetic resources and associated traditional knowledge, and also to abolish the obligation of the USPTO to search Peruvian database of genetic resources and associated

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<sup>67</sup> See *supra* text accompanying note 65.

<sup>68</sup> *Id.*

<sup>69</sup> *United States – Peru Trade Promotion Agreement (Feb.1, 2009)*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, <https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa..>

traditional knowledge before granting of patents. In 2006, Colombia negotiated its own FTA with the US which resulted in a similar situation like Peru. Another example is the US - Dominican Republic - Central America FTA (CAFTA),<sup>70</sup> signed in 2004. It is drafted in such a way that the signatory countries can never add conditions like disclosure of origin and PIC for indigenous communities even if their genetic resources and associated traditional knowledge are misappropriated in any invention. Thailand is also negotiating an FTA with the US. According to Thai academics, the US will force Thailand to change its patent laws so as to ensure monopoly over their genetic resources and associated traditional knowledge. The US has previously rejected their proposal of disclosure of origin and PIC criteria in patent (when genetic resources and associated traditional knowledge is involved) during the sixth round of talks in 2006.

However, if the USA is not a negotiating party, the scenario is different. In the Panama - Taiwan FTA signed in 2003, both the countries committed to protect genetic resources and associated traditional knowledge. They also agreed to stop unauthorized third-party access to genetic resources and associated traditional knowledge.

New Zealand's government includes genetic resources and associated traditional knowledge in all FTAs to affirm that each country can develop its own domestic law of protection. The Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC) and the South Asian Association for Regional Cooperation (SAARC) are trying to adopt their own regional FTA and also seeking to harmonize their domestic law to cover genetic resources and associated traditional knowledge protection. Hence, it is evident that if an FTA is negotiated with the right intentions, it can be fruitful for genetic resources and associated traditional knowledge protection. However, if one of the signatory countries uses its higher bargaining power at the time of negotiation, then genetic resources and associated traditional knowledge protection can be misappropriated. After analyzing the entire scenario, it seems that FTAs cannot give effective protection for genetic resources and associated traditional knowledge for every country. Thus, FTAs are not a solution for genetic resources and associated traditional knowledge, and should instead be considered as a threat to them.

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<sup>70</sup> *The Dominican Republic-Central America FTA (CAFTA-DR)*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, <https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta>.

## VII. INDIAN PATENT ACT: PROVISIONS RELATED TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

India is a WTO Member State, and has implemented the minimum standards of intellectual property rights as per the TRIPS mandate. The Indian Patent Act, 1970 is the domestic legislation concerning patent protection in India. Section 3 of the Act enlists the non-patentable inventions, and some of them can be used directly or indirectly to prohibit patenting of inventions using biodiversity or genetic resource. The following are the provisions:

- i) An invention is non-patentable if it pertains to the discovery of any living thing occurring in nature<sup>71</sup> - any species of living plant or animal are thus non-patentable;
- ii) An invention is non-patentable if it is about a new form of a known substance or the mere discovery of any new property or new use of a known substance<sup>72</sup> - a new mannose binding insecticidal lectin isolated from seeds of *Annona* was recently granted patent in India. It was a mere discovery of a known substance as *Annona* is known for its insecticidal property since ages and is used by traditional farmers;
- iii) An invention is non-patentable if it is obtained by a mere admixture resulting only in the aggregation of properties of the components of a genetic resource<sup>73</sup> - herbal and medicinal plants of India are known and used for various therapeutic and cosmetic purposes, and any new product or process of their making should not be patentable;
- iv) An invention is non-patentable if it is about mere arrangement or re-arrangement or duplication of known devices<sup>74</sup> - Vaidis and Hakims are using many devices for extraction, purification and preparation of traditional Ayurvedic medicine, and those should not be the part of patentable inventions;
- v) An invention is non-patentable if it is a method of agriculture or horticulture<sup>75</sup> - any traditional methods of agriculture or horticulture should not be patentable as that will hamper the traditional agricultural activity and will have a detrimental impact on the sustainable use and conservation of biodiversity;

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<sup>71</sup> The Patents (Amendment Act) 2005, §3(c), No. 15, Acts of Parliament, 2005.

<sup>72</sup> The Patents (Amendment Act) 2005, §3(d), No. 15, Acts of Parliament, 2005.

<sup>73</sup> The Patents (Amendment Act) 2005, §3(e), No. 15, Acts of Parliament, 2005.

<sup>74</sup> The Patents (Amendment Act) 2005, §3(f), No. 15, Acts of Parliament, 2005.

<sup>75</sup> The Patents (Amendment Act) 2005, §3(h), No. 15, Acts of Parliament, 2005.

- vi) An invention is non-patentable if it is about a method of treatment of human or animals<sup>76</sup> - traditional methods of treatment are thus non-patentable which includes a huge number of plant and animal genetic resources;
- vii) An invention is non-patentable if it involves plants or animals (whole or their part) including seeds, varieties, species, and essentially biological processes, for production or propagation of plant and animals;<sup>77</sup>
- viii) An invention is non-patentable if it involves a traditional knowledge or involves aggregation or duplication of traditionally known components of genetic resources<sup>78</sup> - wound healing property of turmeric or pesticidal extracts of neem components were not patentable and were revoked abroad.

Components of genetic resources or their known characteristics are in public domain. Hence, it would be difficult to fulfil the novelty requirement<sup>79</sup> of patentability. The Controller has the power to refuse to proceed with the application, or may ask for an amendment to the application or the specification or other documents, if the application is not in compliance with the requirements of the Patent Act.<sup>80</sup> Pre-grant and post-grant opposition is allowed for any invention using genetic resources and traditional knowledge,<sup>81</sup> or for any application wherein the complete specification is not disclosing or wrongfully disclosing the geographical origin of the used biological material.<sup>82</sup> Post-grant opposition on these grounds may cause revocation of such faulty patents.<sup>83</sup> These provisions make the Indian standards stronger for prevention of biopiracy and misappropriation of genetic resources and associated traditional knowledge.

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<sup>76</sup> The Patents (Amendment Act) 2005, §3(i), No. 15, Acts of Parliament,2005.

<sup>77</sup> The Patents (Amendment Act) 2005, §3(j), No. 15, Acts of Parliament,2005.

<sup>78</sup> The Patents (Amendment Act) 2005, §3(p), No. 15, Acts of Parliament,2005.

<sup>79</sup> The Patents (Amendment Act) 2005, §2(1)(j), No. 15, Acts of Parliament,2005.

<sup>80</sup> The Patents (Amendment Act) 2005, §15, No. 15, Acts of Parliament,2005.

<sup>81</sup> The Patents (Amendment Act) 2005, §25(1)(k), No. 15, Acts of Parliament,2005.

<sup>82</sup> The Patents (Amendment Act) 2005, §§25(1)(j), 25(2)(j), No. 15, Acts of Parliament,2005.

<sup>83</sup> The Patents (Amendment Act) 2005, §§64(1)(p), 64(1)(q), No. 15, Acts of Parliament,2005.

## VIII. BIOLOGICAL DIVERSITY ACT: PROVISIONS TO PREVENT MISAPPROPRIATION OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

The Biological Diversity Act, 2002 (BDA) is India's sole attempt to operationalize the provisions of the CBD. In order to discuss proper conservation and sustainable development, there is a need to analyse the BDA in depth. It is to be analysed whether some parts of this Act are ambiguous and consist of lacunae, which may lead to misappropriation of Indian genetic resources and associated traditional knowledge. Further, the role of the BDA in prevention of misappropriation of Indian genetic resources and associated traditional knowledge by using intellectual property rights, and the mechanism to address the ambiguity regarding patentability/non-patentability of such patents need to be examined.

The BDA provides for strict rules regarding the application for any form of intellectual property right concerning inventions based on Indian biological resources. This is evident from Section 6 of the BDA which prevents Indian citizens as well as foreign nationals from applying for any form of intellectual property right in India or abroad unless the applicant gets the prior approval from National Biodiversity Authority (NBA).<sup>84</sup> The proviso to Section 6 states that the applicant can get the approval even after acceptance of the patent but before sealing of the patent by the patent authority. As per the requirement in Form 1, the applicant has to provide a declaration that he/she will submit the necessary approval from the NBA before the grant of the patent.<sup>85</sup>

Approval from the NBA is a necessary requirement to stop the misappropriation of genetic resources of Indian origin. It is the duty of the NBA to make proper enquiry regarding the application of any form of intellectual property right<sup>86</sup> and to consult with an 'expert committee' regarding the issue.<sup>87</sup> The application fee needs to be collected by the NBA, and it can also collect necessary additional information to judge the merit of the application. The NBA is required to make a decision within a 3 month time period.<sup>88</sup> The NBA can reject the

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<sup>84</sup> The Biological Diversity Act, 2002, §6(1), No. 18, Acts of Parliament, 2003; Rule 18, Biological Diversity Rules, 2004, Gazette of India, pt.II sec. 3 (Apr.15, 2004).

<sup>85</sup> Clause 9(iii) of Form 1 for Application for Grant of Patent

<sup>86</sup> The Biological Diversity Act, 2002, §19(2), No. 18, Acts of Parliament, 2003.

<sup>87</sup> The Biological Diversity Act, 2002, §19(3), No. 18, Acts of Parliament, 2003.

<sup>88</sup> *Supra* note 84.

application if the applicant failed to furnish necessary information to judge the merit, in which case, the reasons have to be recorded and the applicant has to be provided with a chance to defend himself in a hearing in front of the Authority prior to rejection.<sup>89</sup> It is also the duty of the NBA to supervise the intellectual property applications filed abroad regarding misappropriation of Indian biological resources and associated traditional knowledge obtained from India in an illegal manner and to take necessary measures to oppose those applications.<sup>90</sup>

Any person applying for the protection of plant variety shall not take any permission from the NBA. This means that breeders applying for the protection of a new plant variety will not come under the purview of Section 6 of the BDA.<sup>91</sup>

According to Section 6 of the BDA, the applicant has to obtain the approval of the NBA before applying for intellectual property in India or outside. The Act or the Rules do not specify the criteria that the NBA adopts for approving or rejecting an application. The website of the NBA mentions that to date, NBA has received 709 different kinds of applications for approval, among which, 476 are for obtaining intellectual property rights. The Annual Report of 2009-2010 tells us that until 31<sup>st</sup> March 2010, eleven patents were granted based on approval of the NBA. No detailed information is available either in the Report or on the website regarding the criteria on which the applications were accepted or judged. The Report provides the Application number, the Applicant's name and a one-line description of every such invention. It is difficult to understand on what basis those approvals had been given. All these inventions supposedly involve commonly used biological materials of Indian origin like fenugreek seed, annona, pineapple leaf, etc. Despite the above-mentioned provisions in the Patents Act and the BDA, a large number of patents are granted in India for inventions primarily using Indian biological resources. This points to the need for proper implementation.

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<sup>89</sup> The Biological Diversity Act, 2002, §19(3), No. 18, Acts of Parliament, 2003; Rule 18(6), Biological Diversity Rules, 2004, Gazette of India, pt.II sec. 3 (Apr.15, 2004).

<sup>90</sup> Rule 12(xix) Biological Diversity Rules, 2004, Gazette of India, pt.II sec. 3 (Apr.15, 2004).

<sup>91</sup> The Biological Diversity Act, 2002, §6(3), No. 18, Acts of Parliament, 2003.

## CONCLUSION

It is evident from the discussion above that the question of protection arises only when there are chances of misappropriation. Threats of misappropriation can come from within the country as well as from outside. This article thoroughly discussed the difference in approaches of the TRIPS Agreement and the CBD. When misappropriation occurs between two WTO Member States, i.e. one Member state applying for the patent for an invention based on genetic resources and associated traditional knowledge originating from another Member State, the existing system provides the option for pre-grant and post-grant opposition to stop such misappropriation. However, this is a tedious process and involves huge amounts time and money. This can be avoided by reducing the grant of erroneous patents. All WTO Member States follow the TRIPS mandate of minimum standard of intellectual property rights. The issue of protection of genetic resources and associated traditional knowledge and thereby minimising their misappropriation has been subject to debate for a long time. This issue is intricately related to patent protection, which is by far the main vehicle for misappropriation of genetic resources and associated traditional knowledge. This is also a pending issue in the Doha Ministerial Conference of the WTO. Hence, everyone is trying to look for a solution.

The probable way out is the insertion of two new Articles in the TRIPS Agreement, i.e. Article 27.3(c) and Article 29*bis*, suggested by the group of developing countries led by India and Brazil. If this amendment is accepted, these clauses will be denoted as the minimum standard and all Member States will have to follow them as a TRIPS mandate. The Doha Declaration tries to resolve major public health issues through an amendment to Article 31. The issue of protection of genetic resources and associated traditional knowledge can also be resolved in the same manner by the aforesaid amendment. In this way, the misappropriation can be minimised by a significant percentage.

The Traditional Knowledge Digital Library (TKDL) is a well-known defensive mechanism of protection of genetic resources and associated traditional knowledge. It is considered by the European Union as a dependable database for prior art search during examination of patent applications, and they reject patents based on TKDL. The updation of the TKDL is an ongoing process and emphasizes only on medicinal knowledge. As such, commonly used commodities like Bhojpatra (used to make utensils for community food or Prasad in

gatherings since ancient age), or Brahmi juice (used for enhancement of memory since ages), which are now used as the basis of invention for patent can be taken care of. At the same time, the difference in approach between TRIPS and CBD can be minimised significantly in this manner.

Additionally, when FTAs between two or more countries come into the picture, the country with a high bargaining power can overpower the country with a low bargaining power. The latter would be compelled to accept the terms and conditions proposed by the former. Practical experiences suggest that when countries with similar bargaining power (for instance New Zealand and India or India and Malaysia) enter into an FTA, the situation is much better as no one can compel the other to accept any unusual terms or conditions.

If new Articles are included in the TRIPS Agreement, then Member countries have to abide by the new standard and it will minimise the chance of misappropriation of genetic resources and associated traditional knowledge by using FTAs. During negotiations, the exploitation of country with a low bargaining power by a country with high bargaining power will also be reduced to minimum. The WIPO is also working on providing draft guidelines for protection of genetic resources and associated traditional knowledge, but, due to its non-binding nature, it may not be implemented by most countries. The agenda of the WIPO has always been the development and dissemination of intellectual property. Hence, the mechanism they have propagated may be useful as guidance for any country, even if it is not mandatorily implemented owing to an absence of enforcement mechanism. Further, the WTO's specific mechanism for dispute resolution is also missing in the WIPO draft guidelines. Therefore, without inclusion of these aforesaid amendments in the TRIPS Agreement, it is very difficult to stop erroneous patents and to handle the misappropriation of genetic resources and associated traditional knowledge.

Countries in the Indian sub-continent and the south-east Asian countries have a common culture, common civilization, migration and knowledge sharing. Hence, they also share common traditional knowledge and genetic resources. Different associations of countries are present in Asia (like BIMSTEC or SAARC), but they are not politically successful and a common regional legal regime does not exist either. Without any regional understanding and strong legal regime, it is difficult to handle the common problems. It may also happen that one country of this region may unintentionally misappropriate genetic resources and

associated traditional knowledge of another country. Therefore, a regional mechanism needs to be developed, which can provide a common platform to all those countries having similar genetic resources and associated traditional knowledge.

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