

Developing countries propose TRIPS amendment to fight biopiracy

Beijing, 1 June (Chee Yoke Ling) – As governments gear up for the first preparatory meeting next week in Montreal to lay the ground for the entry into force of the new Nagoya Protocol on Access and Benefit Sharing, a large group of developing countries have submitted a proposal to amend the World Trade Organisation’s intellectual property agreement to require the disclosure of origin of genetic resources and/or associated traditional knowledge in patent applications.

On 15 April 2011, the WTO delegations of Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of the African-Caribbean-Pacific Group), Peru, and Thailand circulated a communication (TN/C/W/59) entitled: “Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity” to the Trade Negotiations Committee as part of the ongoing Doha talks. The draft decision proposes to add a new Article 29bis on “Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge” in the WTO Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement.

The proponents call for recognition that the disclosure requirement in Article 29 of the TRIPS Agreement is incomplete without the disclosure of origin of genetic resources and/or associated traditional knowledge.

They stress the need to ensure that the utilization of genetic resources and/or associated traditional knowledge must comply with the access and benefit-sharing legislation of the Member providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a Member that has acquired the genetic resources in accordance with the Convention on Biological Diversity (CBD).

They call for acknowledgement that a legal obligation establishing such a mandatory disclosure requirement in patent applications will contribute to prevent both misappropriation of genetic resources and the grant of erroneous patents and also enhance transparency about the utilization of genetic resources and/or associated traditional knowledge

[Article 16(5) of the CBD states that Parties shall ensure that intellectual property rights “are supportive of and do not run counter to the objectives of the Convention”.]

The relationship between the TRIPS Agreement and the CBD is part of the ongoing work programme and a large number of developing countries had earlier submitted a proposal to amend the TRIPS Agreement to require the mandatory disclosure of origin of a genetic resource and/or associated traditional knowledge; evidence of prior informed consent from the party that provides the resource; and evidence of a fair and equitable benefit sharing arrangement.

There have been years of discussions at the TRIPS Council and informal consultations by the WTO Director-General (the latter is limited to a mandatory requirement for the disclosure of origin of genetic resources and/or associated traditional knowledge used in inventions for which IPRs are applied for). The developing country-developed country impasse remains.

The proposed addition in the 15 April communication focuses on the mandatory disclosure of origin (country and source in the country). However it also obliges Members to require that applicants provide a copy of an Internationally Recognized Certificate of Compliance. This

refers to Article 17.3 of the Nagoya Protocol that states that "An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent".

According to the proposed Article 29bis, if such a certificate is not applicable in the providing country the applicant should still provide equivalent information regarding compliance with prior informed consent and benefit sharing in national laws.

In cases of violation of Article 29bis Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the disclosure obligations.

In a parallel process, Parties to the CBD adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in October 2010. This came after years of difficult negotiations as developing countries press to stop biopiracy of their biodiversity and traditional knowledge, and to have a legally binding system to implement the CBD's third objective of fair and equitable benefit sharing.

One of the most contentious issues that remained unresolved till the end, due to strong resistance from developed countries (except Norway), was the requirement that patent offices be a mandatory checkpoint to capture non-compliance with the domestic laws or requirements of countries providing genetic resources and/or associated traditional knowledge.

Developed countries argue that the selection of checkpoints should be discretionary while developing countries contend that to be "effective" (as agreed by all CBD Parties) certain check points must be mandatory, patent offices being one of them, and these should be explicitly listed in the Protocol.

Due to the manner in which the Nagoya Protocol was in the final hours "foisted, primarily upon developing countries" (in the words of a lead developing country negotiator) the most critical provisions including on the compliance measures were not actually negotiated in the usual open, transparent and inclusive UN process.

One of these was Article 17 where the list of mandatory checkpoints that included IPR offices was removed. It now provides in very qualified language that, "To support compliance each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources" including the designation of checkpoints "to collect or receive, as appropriate, relevant information related prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate".

The checkpoints "must be effective" and "should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization."

The proposed TRIPS Agreement addition by the developing countries appears to build on the Nagoya Protocol momentum. This move will be of great interest for the delegations and participants at the first meeting of the Intergovernmental Committee for the Nagoya Protocol on 6-10 June in Montreal.

There are 5 paragraphs in the proposed Article 29bis as follows:

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Convention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing.

2. Where the subject matter of a patent application involves utilization of genetic resources and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source (including details of whom in the providing country such resources were obtained from) in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that applicants provide a copy of an Internationally Recognized Certificate of Compliance (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD.

3. Members shall publish the information disclosed in accordance with paragraph 2 of this Article jointly with the publication of the application or the grant of patent, whichever is made first.

4. Members shall put in place appropriate, effective and proportionate measures so as to permit effective action against the non-compliance with the obligations set out in paragraph 2 of this Article. Patent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article.

5. If it is discovered after the grant of a patent that the applicant failed to disclose the information set out in paragraph 2 of this Article, or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD, Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2.

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