January 22, 2009

ACCESS AND BENEFIT-SHARING: PEER REVIEW PROCESS FOR ABS STUDIES
COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

The Biotechnology Industry Organization (BIO) would like to express its appreciation to the Secretariat for making the draft studies available for peer review. BIO is pleased to take this opportunity to submit comments on the draft documents. BIO respectfully requests that comments be taken into consideration during revision of the draft studies.

General Comment:

BIO will confine its comments to the draft *Study on the relationship between the ABS International Regime and other international instruments which govern the use of genetic resources: the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), and the Union for the Protection of New Varieties of Plants (UPOV)*.

There is significant focus in the draft study on the relationship between the CBD and intellectual property rights. This topic is of great interest to BIO members. The international organizations mentioned in the study (WTO, WIPO, UPOV) have looked into these matters extensively and BIO has been an active participant in those discussions. We applaud the initial draft of this study and its comprehensive look at the different *fora* in which these matters are addressed.

After years of discussion, consensus is still elusive with respect to ways to address the relationship of intellectual property, genetic resources and associated traditional knowledge. As mentioned in previous comments and submissions of BIO to the CBD ABS Working Group, we continue to oppose proposals for new disclosure requirements in patent applications relating to genetic resources, and believe that such requirements should not be included in the International Regime.

BIO is of the view that these types of requirements (a) will be ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), many of which are examined in the draft study, have confirmed this view. To the extent further discussion is necessary on new patent disclosure requirements and alternative proposals to address the relationship of intellectual property and genetic resources, it should be done at WIPO, which has an intergovernmental committee (IGC) with a specific mandate to discuss matters regarding the relationship of intellectual property and genetic resources, traditional knowledge and folklore.

Nonetheless, we understand the importance of the underlying concerns to many CBD Parties. In that light, we offer the following comments in order to ensure that the entire context of this important debate is reflected in the draft study. BIO continues to support an International Regime that would provide optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing, and will continue to participate in this process to that end.

Specific Comments:

Paragraph 36:
Paragraph 36 identifies three clusters of substantive questions within the WIPO IGC. However, these clusters are more particular recitals of topics within the broader work stream on genetic resources in the IGC.

The same document cited in paragraph 36 (WIPO/GRTKF/IC/13/8(a)) states clearly that the options for work fall into "the areas of [i] the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; [ii] the interface between the patent system and genetic resources; and [iii] the intellectual property aspects of access and benefit-sharing contracts."[1] This language comes directly from the consensus decision of the tenth session of the IGC and should be included in paragraph 36 to give the proper context of the WIPO discussions.

In particular, the reference to "alternatives" to proposals for patent disclosure requirements underscores that patent disclosure proposals continue to be of a highly controversial nature. Paragraph 36 should make specific reference to three categories listed above in order to provide the appropriate context for the IGC discussions.

In addition, drawing from this language, the last sentence of paragraph 36, stating that it is unclear whether the debate will result in the elaboration of new legally binding options for disclosure of origin requirements should be rephrased along the following lines:

> However, it is unclear whether this debate will result in the elaboration of new obligations for disclosure of origin requirements, particularly in light of the WIPO consensus to further consider both proposals for disclosure requirements and alternative proposals to address the issue of the relationship of intellectual property and genetic resources.

Paragraph 41:

Paragraph 41 refers to the development, in WIPO, of the Revised Draft Provisions for the Protection of Traditional Knowledge (TK) as a possible "outline" for an international instrument on TK. While these provisions are certainly part of the work product of the WIPO Secretariat, they have not been agreed by IGC members to be even a basis for work in that organization.[2] Indeed, because of the lack of support for these draft provisions in the IGC by some countries, these provisions have not been further developed, in any way, since the eighth session of the IGC in 2005 and were only identified as one of three streams of work in the IGC at its thirteenth session.[3]

[1] WIPO/GRTKF/IC/13/8(a) at paragraphs 1 and 8. "These discussions have focused on the potential integration of new or expanded disclosure requirements into existing patent systems *as well as multiple alternative measures and proposals* for dealing with the relationship between intellectual property and genetic resources."
[2] WIPO/GRTKF/IC/12/5(c)
[3] WIPO/GRTKF/IC/13/5(a)

In light of the uncertain state of the Draft Provisions, we suggest adding a sentence to paragraph 41 reflecting that the Draft Provisions are controversial and have not been agreed to be a basis of work in WIPO. In that light, while the content appears to be related to the agenda of the ABS Working Group and the Working Group on Article 8(j), it is not clear how viable this approach would be for further work.

Paragraph 43:

This paragraph notes that the extensive work of the IGC could be useful "for the implementation of a potential disclosure provision." This appears to presume that a patent disclosure provision would be a preferred outcome of the either the WIPO or CBD processes. BIO does not believe this represents the current debate in either WIPO or the CBD.

We suggesting replacing this reference with a note that the extensive work of the IGC may be useful for the implementation of "a potential disclosure provision or alternative mechanism to address the relationship of intellectual property and genetic resources developed in other *fora*".

This would better reflect the state of the discussions. For example, completion of the IGC guidelines regarding contractual practices in document WIPO/GRTKF/IC/7/9 would be helpful in better establishing a contract-based approach in the International Regime to remedy many concerns regarding "misappropriation" of genetic resources.

Paragraph 54:

In paragraph 54, the last sentence indicates that no final decision has yet been made on whether to accept a disclosure requirement in the TRIPS Agreement. We fully endorse this statement, but there should be a greater elaboration on the reasoning of those delegations and stakeholders, including BIO, that do not support disclosure requirements.

We suggest adding a sentence along the following lines: "This is because of the view of a number of delegations and stakeholders that new patent disclosure requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts."

Paragraph 55:

A new sentence should similarly be added to paragraph 55:

"However, based on the concerns mentioned above, a number of delegations do not support any proposals for new disclosure requirements in the patent law, and support alternative mechanisms to address concerns regarding misappropriation."

Paragraphs 62:

This paragraph discusses the option of "no disclosure requirement in either [WTO or CBD]". BIO is supportive of this option. However, the option is not fully explained. An additional paragraph along the following lines would help to explain:

> Other countries support this approach because it would avoid the negative consequences of new patent disclosure requirements, i.e., uncertainties introduced into the patent system which have potential to undermine the innovation incentives of that system and, consequently, the potential benefit-sharing therefrom.[4] These countries and stakeholders support other mechanisms to address concerns regarding "misappropriation." For example, proposals regarding improved ABS regimes in national laws as well as an improved global "one-stop-shop" database, as proposed by Japan,[5] to improve patent examination are being examined as means to address concerns regarding misappropriation and improper patenting of genetic resources without the negative consequences of new patent disclosure requirements. In this light, having no patent disclosure requirement, and using alternatives instead to address to root causes of concern, is the best way to ensure mutual supportiveness of the two systems.

Paragraph 68:

As noted above, caution should be taken when referencing the Draft Provisions on TK protection in the context of the IGC. We suggest that two new sentences be added to paragraph 68 after the first sentence:

> However, these provisions have not been agreed even as a basis for work in that organization.[6] In fact, because of the lack of support for these draft provisions in the IGC, these provisions have not been developed, in any way, since the eighth session of the IGC in 2005 and work has since proceeded on other grounds, including consideration of a List of Options and a gap analysis.[7] As a result of this, it is not clear whether significant further work following the model of those provisions is warranted.

Paragraph 72:

As noted above, the last sentence of paragraph 72 should be modified to reflected the lack of further work in the IGC on the draft provisions.

In this light, we suggest deleting the last phrase of that sentence as drafted so that it more simply reads as follows: "The WIPO IGC could continue its work on more detailed provisions for the protection of TK." The reference to the draft provisions is thereby deleted.

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[4] *See, e.g.,* Communication from the United States, *Article 27.3(B), the Relationship of TRIPS and CBD, and the Protection of Traditional Knowledge and Folklore*, IP/C/W/434 (Nov. 26, 2004).
[5] *See* Communication from Japan, *The Patent System and Genetic Resources*, IP/C/W/504 (Oct. 17, 2007).
[6] *See* WIPO/GRTKF/IC/13/5(a)
[7] *Id.*

Paragraph 74:

The last sentence of paragraph 74 only refers to the potential of the WIPO IGC to facilitate implementation of disclosure provisions. However, as noted above, disclosure proposals are highly controversial and it is likely that they will not be included in the outcome of WIPO, CBD or WTO discussions. In that light, the work of the IGC should not be considered so narrowly. This work would also be useful with respect to alternative proposals that would be preferable to new patent disclosure requirements. Indeed, some have argued that, in light of WIPO's expertise in intellectual property matters, the CBD should not intervene in such matters whatsoever.

In that light, we suggest that the last sentence of paragraph 74 be changed along the following lines:

"Whether an outcome of the IR includes a disclosure requirement or not, the IGC work could also facilitate the implementation of disclosure provisions or alternatives to address issues relating to the relationship of intellectual property, if included in the IR negotiations. Some delegations and stakeholders have also expressed the notion that WIPO has the appropriate expertise to address intellectual property-related questions."