Comments of the Biotechnology Industry Organization (BIO)

on

the Draft Gap Analysis on the Protection of Traditional Knowledge

July 3, 2008

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

July 3, 2008

Sent by electronic mail to the World Intellectual Property Organization

Re*: Comments on the Gap Analysis on the Protection of Traditional Knowledge*

Dear Sir or Madam:

Please find following this letter the comments of the Biotechnology Industry Organization (BIO) on the draft Gap Analysis on the Protection of Traditional Knowledge.

BIO is pleased to have the opportunity to submit these comments as an observer to the Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The comments reflect the views and concerns of BIO Members with respect to the draft document.

BIO respectfully requests that the International Bureau take these comments into account when revising the document.

Regards,

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Managing Director, Intellectual Property
Biotechnology Industry Organization

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General Comments:

The Biotechnology Industry Organization (BIO) represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 32 nations, including both developed and developing economies. BIO Members are involved in the research and development (R&D) of health care, agricultural, industrial and environmental biotechnology products and services. The vast majority of BIO Members are innovative small businesses. BIO is pleased to have the opportunity, as an observer to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge (TK) and Folklore (IGC) of WIPO, to submit comments on the "draft Gap Analysis on the Protection of TK." BIO intends to continue to be actively and constructively engaged as an industry partner in the IGC process.

At the outset, BIO would like to commend the Secretariat of WIPO for providing a comprehensive document in accordance with the decision of the twelfth session of the IGC. As a general matter, we note the point in paragraph 10 of the document that "views are likely to differ as to what is a true 'gap' in protection of traditional knowledge." Indeed, this reflects the greater debate in the IGC, which has included multiple, and widely divergent, points of view as to the definition of traditional knowledge, the identification of appropriate holders of traditional knowledge, etc. In light of these divergences, it remains important to ensure that the views of all stakeholders are represented in an equal and non-prejudicial fashion to enhance open discussion and resolution of differences.

However, BIO has significant concerns that the document appears to single out particular proposals, such as proposals made for specific patent disclosure mechanisms for TK, as "gaps." These proposals remain highly controversial, and the document does not provide any mention of either (1) the different points of view relating to such proposals or (2) alternative proposals to address the same goals. This is not consistent with more typical "gap analyses" that provide factual data relating to building an evidence base for decision-making. It appears that further study would be needed in respect of many of the items mentioned to provide the appropriate factual underpinning for assisting IGC Members to address the different positions on the various proposals.

BIO provides these comments in order to assist the IGC process. A number of "specific comments" are set forth below. These comments are illustrative of the general concerns expressed above.

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Specific Comments:

Pages 11-13, paragraphs 15-17

Paragraphs 15-17 address "defensive protection of traditional knowledge in the patent system." In paragraph 17, proposals for TK-based "disclosure requirements" are specifically explained while other proposals that address this broad topic are not mentioned at all. For example, the "one-stop-shop" database mechanism proposed by the delegation of Japan (in documents WIPO/GRTKF/9/13 and WIPO/GRTKF/11/11) should be listed here as well.

It would also be appropriate to eliminate the specific heading for "TK-specific disclosure requirements" and more aptly discuss both proposals under the general topic of "proposals made with the objective of improving defensive protection."

In addition, paragraph 17 includes specific value judgments which do not reflect any consensus in the IGC. For example, many delegations and observers, including BIO, take the view that the case has not been made that "[t]hese proposals represent significant forms of defensive protection of TK," (page 12, paragraph 17)," and that such proposals have little, if any, significant relevance to defensive protection of TK. These value judgments should be deleted or balanced to reflect different points of view in the IGC.

Page 18, Paragraph 35

In paragraph 35, the citation of the Bonn Guidelines should be expanded to reflect the appropriate context. The paragraph should be amended to list the entirety of paragraph 16(d) of the Bonn Guidelines.

Currently, paragraph 35 cites the *chapeau* of Bonn paragraph 16(d) and then goes on to mention only paragraph 16(d)(ii) relating to consideration of encouraging disclosure of origin of TK associated with genetic resources. This puts undue emphasis on this highly controversial point.

All of the elements contained in paragraph 16(d) of the Guidelines are relevant considerations with respect to traditional knowledge, including, e.g., measures to prevent use with prior informed consent 16(d)(iii), cooperation to address infringement of ABS agreements 16(d)(iv), and measures discouraging unfair trade practices 16(d)(vi)) among others. These are all equally within the mandate of the IGC for consideration. All of these items should be listed.

Page 23, Paragraphs 46-47

Paragraph 47 states that a "gap can clearly be identified" for TK that is "excluded from conventional forms of IP." However, the "indicative list" given continues to define this "gap" in the negative, e.g., "subject matter not covered under existing IP law," rather than defining the gap as to what needs to be addressed. It is clear that more work needs to be done to better

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identify how TK may be protected, preserved, and promoted under existing intellectual property laws before such a gap can effectively be identified.

Page 24

On page 24, both the comment and the identified "gap" state that "protection does not extend to cumulative, collectively held and intergenerational traditional knowledge, unless it meets criteria for undisclosed or confidential information." This should be revised or deleted.

This characterization appears to be incomplete and misleading. For example, protection in the form of trademarks or geographical indications may be collectively held and may protect intergenerational traditional knowledge in effective ways without the TK meeting criteria for undisclosed or confidential information. It may be that particular types of protection are not available for every aspect of TK, but that does not, in and of itself, identify a "gap" in "protection." This is illustrative of the need for further empirical study.

In addition, the assertion in the second "gap" identified on page 24 that protection does not extend to an "integrated TK system as such" and may only extend to certain "isolated elements" is not clear. The IGC has discussed many ways in which IP protection does extend to different "TK systems" and is not limited to "isolated" elements. A more appropriate "gap" may be lack of studies available to determine extent of TK that is protected and in what manner. Nonetheless, it has been demonstrated that mechanisms to preserve, promote and protect TK exist in the current IP system and extend widely to many different forms or expressions of this knowledge.

Page 25

The document, on page 25, identifies an "express norm against illegitimate patenting of TK" as a gap in the international system. This should be deleted or clarified.

The suggested "gap" raises significant concerns, as it is not clear if this is advocating additional or different patentability criteria specific to TK that would not apply in other areas. Such a proposal or concept would add great uncertainty to the patent system and should be avoided. According to existing norms, it is not permitted to "illegitimately patent" any invention regardless of an invention's relationship to TK. Although some erroneous patents may be granted, there are methods to correct this, such as oppositions, reexaminations, and other remedial practices.

In addition, the term "illegitimate" is not clear and appears to be prejudicial. The document seems to be directed toward situations in which patents are granted in error that do not conform to patentability criteria of novelty, inventive step and industrial applicability. If this is what is intended, a better articulation of a "gap" would be the need for an exchange of views on best practices in addressing mistaken granting of patents.

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Page 26

On page 26, the document identifies "a specific requirement for applicants for patents to disclose the source or origin of TK used in the claimed invention, as well as potentially information of prior informed consent and equitable benefit sharing" as a "gap." This should be deleted.

A disclosure requirement of this type is currently the subject of highly controversial proposals made in the IGC with respect to the objectives of preventing misappropriation and preventing erroneously granted patents on TK. The lack of agreement to a particular proposal should not be considered a "gap."

The discussion, if retained at all, would be characterized more accurately as discussion of a particular proposal to address the broader goals relating to concerns of unjust enrichment or misappropriation as the proposal is intended for those objectives. However, many delegations disagree with these proposals because such requirements would be ineffective with respect to their asserted goals and, more importantly, would be harmful to the patent system and the goals of encouraging innovation and benefit-sharing more broadly.

In a similar vein, alternative proposals directed toward the same goal, such as the "one-stop-shop" database proposed by the delegation of Japan, should also be reflected here. Other proposals made relating to implementation of effective ABS systems, such as that presented by the United States in document WIPO/GRTKF/4/13, should also be reflected here as these proposals also aim to remedy concerns relating to "misappropriation."

Page 28

A gap is identified on page 28 to be lack of a "collective right to entitlement to equitable remuneration or other equitable benefit-sharing." In the commentary, this is described as a community being "entitled" to a share of benefits from commercial activity.

This also does not appear to be a gap, *per se*, but instead, a proposal to address certain objectives, such as effective benefit-sharing mechanisms for traditional knowledge. Further, this should be clarified to be understood in the context of "mutually agreed terms," similarly as provisions in the Convention on Biological Diversity (CBD) relating to equitable benefit-sharing with respect to genetic resources and associated traditional knowledge in that context.

The Gap Analysis Matrix

As the matrix summarizes the issues raised in the body of the document, similar issues arise. The following are a number of specific examples given that raise concerns.

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Annex, Page 3:

In the Annex, on page 3, lack of an agreed international norm for "specific disclosure mechanism for TK" is mentioned as a "gap identified" relating to defensive patent protection. As discussed above with respect to page 12, paragraphs 15-17 of the body of the document, this should be deleted.

Many delegations and observers to the IGC, including BIO, note that such proposals for disclosure mechanisms have little, if any, relevance to the goals of either defensive protection or preventing "misappropriation. Further such proposals would have negative consequences for innovation and benefit-sharing. If retained at all, this should be mentioned as one of the "options" in the last column. However, the options should also reflect alternative proposals to address defensive protection of TK, including the "one-stop-shop" database proposed by Japan.

Annex, Page 4:

See comments above with respect to page 23, paragraphs 46-47 in the body of the document. The same concerns apply.

Annex, Page 9:

Similarly as above, the use of the term "illegitimate patenting" should be reconsidered as unclear and prejudicial. It should be replaced by a more apt description of what is intended, e.g., "mistaken" or "erroneous" granting of patents.

In the section relating to "illegitimate patenting of TK" on page 9 of the Annex, one gap is identified relating to "patenting of invention made possible by the misappropriation of traditional knowledge." BIO is unaware of any patent law that permits patenting due to the "misappropriation" of TK. This should be recast as a concern that underlies issues relating to mistaken patent grants or misappropriation of TK.

In addition, page 9 of the Annex refers to "specific disclosure requirements" under the category of "existing measures." While certain national laws have implemented such requirements, this is still a highly controversial matter within the IGC. The reference on page 9 of the Annex relates to the identified gap of "prior informed consent over TK". However, many delegations that oppose disclosure requirements have made other proposals to meet this goal which should be reflected.

For example, proposals have been made by the delegation of the United States of America, with respect to particular access and benefit-sharing (ABS) schemes that would address this "gap."

In that light, under "existing measures" – the term "national ABS systems" should be added. In addition, in the "considerations and options" box, the references to "specific amendments to patent law" should be replaced by "specific amendments to national laws" to accommodate the

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view that patent laws should not be amended, but that other national laws, such as ABS laws, may need to be reconsidered.

Annex, Page 11:

In the Annex, page 11, TK-specific patent disclosure mechanisms are listed as part of the "extent of coverage." However, there is no provision for any such disclosure mechanism that "already exists" in the international level. While some national laws provide for certain disclosure requirements, many delegations and observers consider such requirements ineffective and therefore they remain highly controversial. This reference to disclosure mechanisms should be deleted. It could be noted that there are proposals for such mechanisms in the "factors considered" section, but this should only be done if other proposals that are made to address similar goals, such as the "one-stop-shop" database proposal from Japan, are also noted.

Annex, Page 14:

The indication on page 14 of the Annex that classifies the lack of a TK-specific disclosure requirement as a "gap" should be deleted.

It could be identified as a particular proposal to meet the broader gaps, such as "protection against unjust enrichment or misappropriation" or "proposals made with respect to mistaken granting of patents relating to TK," along with other such proposals addressing the same objectives, such as the Japanese proposal for a "one-stop-shop" database.

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Conclusion

While specific comments have been provided, these should be viewed as illustrative, not exhaustive, of concerns with the approach taken in this document. Other "gaps" noted in the document, but not identified specifically above, also appear to reflect individual proposals without appropriate context being given in the document. Similar to the suggestions made above, further modifications to provide different points of view expressed in the IGC and to address alternative proposals and views would help better flesh out these concepts and provide a more meaningful analysis.

BIO respectfully submits these comments in the interest of facilitating progress in the work of the IGC.

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