

**THE COMMENTS OF THE  
BIOTECHNOLOGY INDUSTRY ORGANIZATION  
ON**

**The List of Options on Genetic Resources for Consideration by  
the Intergovernmental Committee on Genetic Resources,  
Traditional Knowledge and Folklore**

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## **ABOUT BIO**

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,150 members worldwide. Our mission is to be the champion of biotechnology and the advocate for our member organizations—both large and small. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies.

### General Comments:

The decision of the 12<sup>th</sup> session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) called upon Member States and accredited observers to submit comments in respect of documents WIPO/GRTKF/IC/12/8(a) and WIPO/GRTKF/IC/12/8(b), which are reissued for the 13<sup>th</sup> session of the IGC as documents WIPO/GRTKF/IC/13/8(a) and WIPO/GRTKF/IC/13/8(b). The Biotechnology Industry Organization (BIO) hereby expresses its appreciation for the opportunity to submit comments on these issues of central importance to the role of the IGC on these matters. 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. The vast majority of BIO Members are innovative small businesses. BIO Members are involved in the research and development (R&D) of health care, agricultural, industrial and environmental biotechnology products and services. As such, BIO Members have a keen interest in the deliberations of the WIPO IGC.

As recognized since the inception of the Intergovernmental Committee (IGC), the three topics of genetic resources, traditional knowledge and folklore “are closely interrelated, and none can be addressed effectively without considering aspects of the others.” (Document WO/GA/26/6, para. 15). In that light, BIO continues to support a robust discussion of all three of these topics, including genetic resources, in the IGC.

There has been significant progress in the IGC on matters relating to the relationship of intellectual property and genetic resources, as reflected in the documents 13/8(a) and 13/8(b). The IGC should seek to build on that progress through the establishment of pragmatic, concrete outcomes in this area, including:

- the completion of the Intellectual Property Guidelines for Access and Equitable Benefit-sharing (also referred to as the guidelines for contractual practices), contained in document WIPO/GRTKF/IC/7/9
- pragmatic proposals to address the concerns that have been raised with respect to the genetic resources and intellectual property, such as adapting work already agreed for TK to the context of genetic resources (e.g., integration of prior art information sources documenting genetic resources into PCT Minimum Documentation); and
- a fact-based framework for discussions on proposals relating to the relationship of intellectual property and genetic resources that will facilitate a consensus that avoids inherently negative proposals for new patent disclosure requirements, and that will address concerns raised in the IGC regarding “misappropriation,” including inappropriate patenting of genetic resources.

BIO has limited its comments to the options for future work contained in document WIPO/GRTKF/13/8(a). BIO respectfully requests that IGC Members take these views into account in their deliberations.

**Specific Comments on Options Presented in Document WIPO/GRTKF/IC/13/8(a):**

Options

(i) *Development of a mandatory disclosure requirement such as has been tabled in the Committee;*

(iii) *Related analysis of patent disclosure issues making use of the information submitted by Committee Members in the context of questionnaire WIPO/GRTKF/Q.5.;*

(iv) *Guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources;*

Comment: Options (i), (iii) and (iv) relate to the issue of proposals made in the IGC for new disclosure requirements in patent applications in respect of inventions that may relate to genetic resources. The debate in the IGC, similarly as in other organizations where these matters have been discussed, has illustrated a wide range of views on these matters.

In that light, Options (i), (iii) and (iv) do not reflect the deliberations of the IGC as they appear to presume that some type of patent disclosure requirement would be an outcome, or at least likely outcome, of the IGC process. However, many delegations either oppose such proposals outright or favor a broader discussion including alternative proposals. Because these options are clearly inconsistent with the views expressed by a number of Member States, as well as non-governmental organizations (NGO's), including BIO, we do not view these options as a positive way forward.<sup>1</sup> Indeed, for reasons expressed by many before, proposals for new disclosure requirements will not achieve the objectives sought by proponents, but will likely have significant negative consequences on both the incentives of the patent system for innovation as well as the generation of benefits from the utilization of genetic resources that could be shared.

Option (ii) *Further examination of issues relating to disclosure requirements **and alternative proposals for dealing with the relationship between intellectual property and genetic resources**, such as the questions addressed or identified in earlier studies and invitations;*

Comment: BIO recognizes the continued concerns expressed by a number of delegations in respect of objectives sought by proponents of new patent disclosure requirements. Option (ii) envisions further examination of these issues. However, to be consistent with terms of the decision of the IGC, and to better facilitate eventual consensus, the terms of this option should reflect not only proposals for “disclosure requirements” but also “alternative proposals” that have been made in the IGC.

As noted by the delegation of Japan, the relationship of the TRIPS and CBD, or more broadly, the relationship of intellectual property and genetic resources, encompasses two issues: (1) the

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<sup>1</sup> See, e.g., statements by Japan (WIPO/GRTKF/IC/12/9 Prov., para. 234), the United States of America (WIPO/GRTKF/IC/12/9, Prov., para. 236), the Republic of Korea (WIPO/GRTKF/IC/11/15, para. 527), Canada (WIPO/GRTKF/IC/12/9 Prov., para. 230), Australia (WIPO/GRTKF/11/15, para. 520), New Zealand (WIPO/GRTKF/11/15, para. 513), the Russian Federation (WIPO/GRTKF/IC/11/15, para. 537), Singapore (WIPO/GRTKF/IC/11/15, para. 529), the Eurasian Patent Office (WIPO/GRTKF/IC/12/9, para. 235), the International Chamber of Commerce (WIPO/GRTKF/IC/11/15, para. 237), the Intellectual Property Owners Association (WIPO/GRTKF/IC/10/7, para. 211), and the American BioIndustry Association (WIPO/GRTKF/IC/10/7, para. 210). BIO has also made statements to this regard. See, e.g., WIPO/GRTKF/IC/7/15, para. 198.

erroneous granting of patents and (2) CBD compliance (in other words, prior informed consent (PIC) and benefit-sharing as set out in the CBD.<sup>2</sup> BIO Members support the objectives of preventing the erroneous granting of patents and in ensuring appropriate access based on PIC and equitable benefit-sharing according to the CBD. In turn, we support concrete proposals to achieve these goals. However, patent disclosure requirements, for reasons expressed at length by various delegations in previous sessions of the IGC, will not accomplish these objectives.<sup>3</sup> Further, such requirements will undermine the incentives of the patent system and the generation of benefits that may be equitably shared, thereby running counter to the objectives of the CBD.

A two-tiered structure to the debate among Member States should be considered that would explicitly address the goals, that are sought to be achieved, as succinctly expressed in the paper by the delegation of Japan:

- (1) Proposals for addressing the prevention of erroneously granted patents; and
- (2) Proposals for regarding activities related to intellectual property rights and compliance with the CBD principles (i.e., compliance with appropriate access and equitable benefit-sharing requirements in national laws).

In respect of item 1, BIO supports initiatives to improve the quality of patent examination in respect of inventions that may relate to genetic resources. In this light, the proposal by Japan for a “one-click database,” articulated in documents 9/13 and 11/11, should be pursued. Other similar proposals that target pragmatic results to achieve this goal should be further considered.

In respect of item 2, some further fact-finding by IGC Members should take place. This could involve a sharing of experiences of existing ABS systems and perceived instances of misappropriation or “biopiracy.” This may help to identify any gaps that may exist in ABS or other relevant laws. Once these “gaps” can be identified, there would be a more credible factual foundation that would assist delegations in making progress on intellectual property-related matters relating to these issues. In addition, increased study of the implementation of the CBD requirement that benefit-sharing be on “mutually agreed terms” should be considered. This could also inform work on the draft guidelines for contractual practices noted in Option (vii) below. In addition, case studies may be pursued. For example, the TRIPS Council has discussed a case involving the patenting of an invention involving turmeric in the United States, which raised significant concerns by many interests. A more thorough study of that case by IGC Members could be useful.

*Option (v) Other work on provisions for national or regional patent laws to facilitate consistency and synergy between access and benefit-sharing measures for genetic resources and national and international patent law and practice;*

Comment: BIO does not view work on provisions for national or other regional “patent laws” as set forth in Option (v) to be a positive proposal. Such provisions are not necessary and the patent system and the notions of appropriate access and equitable benefit-sharing, as enshrined in the

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<sup>2</sup> Japan, WIPO/GRTKF/IC/11/11. In the World Trade Organization, these objectives have been set forth as (1) ensuring authorized access to genetic resources, i.e., that prior informed consent is obtained; (2) achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources; and (3) preventing the issuance of erroneously issued patents. See United States, World Trade Organization document IP/C/W/434 (Nov. 26, 2004).

<sup>3</sup> See, e.g., description of disclosure requirements and the failure of such proposals to achieve its objectives in WIPO/GRTKF/IC/11/11. See also WIPO/GRTKF/IC/11/11, para. 518, statement of the United States of America.

Convention on Biological Diversity (CBD) are mutually supportive. However, the IGC may want to consider further study of measures outside the patent laws to address concerns that have been raised in the IGC related to intellectual property. In that light, BIO notes how this issue is reflected in Annex I of Document WIPO/GRTKF/12/8(a):

*B. 1 The Committee could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources on the one hand and national and international intellectual property law and practice on the other (emphasis added).*

This work could take a variety of forms. For example, BIO has undertaken a number of initiatives that have relevance to this area. The BIO Guidelines for Bioprospecting are a set of general principles and practices that BIO, as an organization, believes are appropriate to follow when an entity engages in bioprospecting activities. The Guidelines were developed with the goal of educating BIO members as to relevant issues that can arise in the conduct of bioprospecting activities, and in providing assistance to those BIO member companies seeking guidance in this area. In addition, BIO has also developed a Model Material Transfer Agreement (MMTA) to help assist companies involved in these activities. The MMTA provides an outline for a transfer agreement that is consistent with the best practices set forth in the Guidelines.

These types of initiatives could be relevant for consideration by the IGC of national ABS laws and potential gaps therein that are relevant to intellectual property rights that may be developed from the access and utilization of genetic resources.

*Option (vi) Extension of already approved defensive protection mechanisms for traditional knowledge to address genetic resources more specifically, including the review and greater recognition of further sources of already disclosed information about genetic resources*

Comment: The IGC has achieved a number of successful outcomes in its tenure with respect to the defensive protection of traditional knowledge (TK). One of these successes involved the compilation of information sources that document TK and the integration of those sources into the minimum documentation of the PCT. BIO fully supports a similar approach in relation to genetic resources.

It should be noted, in this regard, that the Meeting of the International Authorities (MIA), are still reviewing issues related to a comprehensive review of Minimum Documentation under Rule 34 of the PCT.<sup>4</sup> Proposals relating to genetic resources could be made and considered by the International Authorities pursuant to that agenda item and reported back to the IGC. This would be a concrete outcome that would help to improve patent examination quality.

*Option (vii) Recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources;*

Comment: This option appears to be directed to improving the quality of patent examination for patent applications that contain inventions that may have relevance to prior art documentation involving genetic resources. BIO supports such a pragmatic proposal, with respect to appropriate subject matter, in light of its potential to more concretely benefit the patent system while at the same time addressing concerns relating to the inappropriate patenting of genetic

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<sup>4</sup> See PCT/MIA/15/13, para. 82.

resources. Many options could be considered, including potential agreed recommendations for patent offices. Particular measures could be envisioned for discussion among the MIA as to whether the Searching and Examining Guidelines for International Authorities of the PCT should be amended in light of particular issues that may arise in the context of inventions that relate to genetic resources. However, the focus should remain on searching and examination of the relevant invention at issue and should not address disclosure requirements.

In a similar vein, document WIPO/GRTKF/13/7 envisions “recommendations” in respect of searching and examining related to traditional knowledge. To the extent the document focuses on particular searching and examining provisions relating to traditional knowledge, the document identifies helpful issues for further deliberation. However, the document then discusses issues relating to examining patent disclosure requirements (see para 64 *et seq.*). BIO asserts that such disclosure requirements are a highly controversial topic that is not appropriate when considering recommendations related to searching and examination of inventions. As explained thoroughly by the delegation of Japan in WIPO/GRTKF/IC/9/13, information requested in disclosure requirements (e.g., relating to source or origin, to evidence of prior-informed consent, etc.) would generally not be relevant to patentability determinations.

Further, while the draft document states that the recommendation is suggested “without prejudging policy choices in this area,” the document endorses a study of implementation of details of disclosure requirements that are directly opposed by a number of delegations and observers and is thereby prejudicial to the views of these delegations. In that light, draft recommendation XVII of document 13/7 should be rejected. Similarly, any work with respect to searching and examining guidelines or defensive protection of genetic resources, should also avoid this approach. If disagreement persists in this area, further deliberations within the fact-based framework suggested earlier should be considered to try to resolve concerns of different delegations instead of adding that discussion to a more pragmatic agenda item.

*Option (viii) Considering options for the expanded use, scope and accessibility of the Online Database of IP clauses in mutually agreed terms for access and equitable benefit sharing;*

Comment: BIO can support this initiative as a pragmatic process to expand the reach of the Online Database. The database itself is one of the concrete outcomes of the IGC and is helpful in providing guidance on “best practices” as they are occurring in the field of biodiversity-related transactions.

*Option (ix) Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9*

Comment: BIO strongly supports this option. As recognized in document 7/9, the development, and subsequent implementation of the draft guidelines for contractual practices would play both a capacity building and normative role in addressing issues relating to the relationship of patents and genetic resources.

This work program, as suggested in document WIPO/GRTKF/IC/7/9 should proceed on three levels:

- i. Developing the operational principles;

- ii. Developing model intellectual property clauses which may be considered for inclusion in contractual arrangements; and
- iii. Revising and further elaborating the text of the draft guidelines for contractual practices.

The guidelines, if agreed, would represent a landmark international instrument that would help both providers and recipients of genetic resources when engaging in decisions relating to intellectual property matters that are relevant to ability to come to mutually agreed terms as envisioned in the CBD.

*Option (x) Development of case studies, describing licensing practices in the field of genetic resources which extend the concepts of distributive innovation or open source from the copyright field, drawing on experiences such as the Global Public License and other similar experiences in the copyright field.*

Comment: As currently worded, this proposal does not appear to be a positive way forward. There is no reason to single out or focus on concepts of “distributive innovation” or “open source” in respect of licensing practices in the field of genetic resources. However, it may be helpful to develop case studies on licensing practices in the field of genetic resources that have developed over the years. By considering the different practices in use in ABS agreements, as well as tools such as the BIO MMTA, the IGC could perhaps develop “best practices” that could be incorporated into an outcome for the organizations – *e.g.*, within the context of the draft guidelines for contractual practices.

### **Conclusion**

BIO notes that the IGC discussions, while fruitful, have not been able to coalesce around a particular Option for further work on genetic resources in recent sessions. As noted by the delegation of Brazil at the previous session, there is “very little convergence” on the issues related to Genetic Resources in the IGC (WIPO/GRTKF/12/9 prov. para. 255). Nonetheless, the current divergence of views is evidence of a need for further work in this area. In that light, BIO intends to continue its positive engagement in the IGC and its deliberations with respect to genetic resources.