Intervention of BIO
Agenda Item 7

Patent Disclosure Requirements relating to Genetic Resources

Thank you Mr. Chairman.

The Biotechnology Industry Organization (BIO) commends the effort of the Committee to engage in a constructive discussion of measures that will improve the transparency and accountability in the collection and use of genetic resources.

BIO is an international association representing more than 1000 companies, academic institutions and biotechnology centers in over 33 countries. Our members conduct a diverse range of research and development in the fields of agriculture, healthcare, industrial engineering and environmental remediation. Innovations from the biotechnology industry are producing dramatic new improvements in agriculture, industrial processes, and most importantly, human health.

The vast majority of biotechnology companies are small and medium sized businesses. More than 90% of these companies have no products, and no revenue. What they have are innovations and hope. Since most of our Members have no products and no revenue, they must attract funding from private investors to exist and continue their operations. Our companies do this by demonstrating that they have made a significant technological innovation that has a promising commercial application. But they also must demonstrate that they can deliver a strong return on an investment because of the very high risk of failure. Effective and certain patent exclusivity for their inventions is essential for these ventures.

There is also intense competition for research and development investments. A venture that has a high degree of uncertainty, such as a possible loss of patent exclusivity, simply will not be funded.

I would like to now address the topic of use of the patent system to provide greater transparency in the collection and use of genetic resources, and to enforce obligations under the Convention on Biological Diversity.

BIO has consistently expressed its support for the principles set forth in the Convention on Biological Diversity. These include, in particular, that before any genetic resource is collected, prior informed consent must be obtained from the

country providing access, and that mutually agreed terms are reached concerning, *inter alia*, the sharing of benefits arising from use of that resource. Although our members do not engage in bioprospecting activities, BIO nonetheless recognizes the importance of these principles, and our Members subscribe to them. For example, BIO has supported the effort to conclude access and benefit sharing provisions in the FAO International Treaty on Plant Genetic Resources.

The Convention on Biological Diversity, which many delegations have observed is the motivation and justification for a patent disclosure requirement. The Convention embraces and incorporates several key concepts.

First, it recognizes the importance of providers and users of genetic resources working together in a cooperative and mutually beneficial manner. As we all appreciate, cooperation is essential to create the commercial and non-commercial benefits that the Convention envisions. If the private sector does not invest in the research and development of genetic resources, these resources will not yield any of the benefits that the Convention envisions.

This is why the Convention repeatedly emphasizes that mutual agreement between the provider of a genetic resource and the user of that resource must be reached. The Convention protects the right of a country of origin to condition access to its genetic resources on obtaining prior informed consent and agreement regarding use and exploitation of those resources. The Convention also, however, makes it clear that obligations cannot be imposed unilaterally or retroactively on users of genetic resources. Instead, obligations to share benefits arise when a user makes a decision to obtain access and when it agrees to conditions for being providing that access.

Second, the Convention plainly applies to non-human genetic resources. This cannot be seriously questioned. Indeed, in CBD Decision II/11, the Conference of Parties of the Convention expressly provided that the Convention does not apply to human genetic resources.

As a general matter, we question whether use of the patent system is the most viable or effective way of promoting the goal of greater transparency and accountability under the Convention. As I noted earlier, BIO supports the principles of the Convention. We also would support an effective mechanism for improving transparency in bioprospecting activities and in ensuring that commitments undertaken by users of genetic resources can be enforced. BIO believes this can be done most effectively by a system that directly regulates bioprospecting activities. In this respect, we encourage the International Bureau

to solicit comments on other measures for monitoring access to and use of genetic resources that are not incorporated into the patent system. By doing so, the relative merits of the various approaches could be compared and the most effective system identified.

We are also concerned that many of the proposals being made regarding patent disclosure requirements do not reflect the essential features and conditions of the Convention, and do not take into account the practical impact of these measures. For examples, many of these proposals would require disclosures to be made for uses of human genetic resources, and for materials that were not collected or which are not governed by the Convention. Indeed, many of these proposals would impose obligations entirely unrelated to situations that are actually governed by the Convention. We find this troubling and unacceptable.

In our view, a special patent disclosure requirement would not improve transparency and accountability in bioprospecting activities governed by the Convention. One reason is that a patent disclosure requirement would only provide information when the use of a genetic resource has led to a potentially patentable invention, and would exclude all other situations where access to a genetic resource has been provided or used. A patent-based monitoring system would thus ignore the vast majority of collection activities that we are aware of that occur today – namely, those done for non-commercially motivated research by academic researchers.

The disclosure requirement proposals we have reviewed also would run counter to a central goal of the Convention to encourage uses of genetic resources that result in benefits that can be shared. As I noted before, biotechnology companies must be able to count on patent exclusivity to justify taking risks and spending money to discover and develop inventions. A disclosure requirement that could block the grant of a patent for an otherwise eligible invention, or could be used to invalidate that patent, will create unacceptable risks for our Members. Companies facing these risks will simply choose to avoid engaging in bioprospecting activities or using genetic resources that are governed by the Convention. This will plainly frustrate one of the goals of the Convention to promote these uses and the sharing of benefits derived from such uses. In this regard, we encourage the Committee to assess as part of its continuing work the likely impact of disclosure requirements on the interest and use of genetic resources by the private sector.

With respect to Document 7/9, we support the effort to develop model guidelines. We also encourage the IB to include experiences not only in the form of provisions

suitable for these contracts, but also the experiences of collaborators in activities conducted under such contracts. For example, we think it would be helpful to obtain information on how frequently success is realized in developing new products out of research on genetic resources. Such information might inform parties about the relative merits of the various types of economic and non-economic benefits that might be covered by an agreement. It would also be useful to get a better understanding of the non-economic priorities of stakeholders and how those may be effectively protected through these types of agreements.

We also think it is important to understand and appreciate the value of contributions of the private sector through their research and development activities. For example, an important form of benefit sharing identified in the Convention is the transfer of research results and other information, along with technology know how. This comes about through dissemination of information, training, joint research and joint technology development efforts. Cooperation between the public and private sector is essential to realize these benefits. Indeed, the biotechnology industry exists as a result of its strong tradition of collaboration and publication. We are therefore troubled by the suggestions that the industry cannot be trusted to live up to its obligations or is not a reliable partner.

In conclusion, as I noted earlier, BIO believes the most appropriate path is one that does not seek to use the patent system to police the provisions of the Convention on Biological Diversity. We appreciate the importance that the global community places on devising an effective regime to govern bioprospecting activities, and the valuable insights and expressions of concern of the various delegations that have spoken eloquently on this issue. We are confident that these discussions will lead to productive outcomes, and are committed to working with this community to devise an effective system for improving transparency and enforceability of the Convention's provisions.