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October 23, 2006

**To: Members of the TRIPS Council, World Trade Organization**  
**From: The Presidents of the Biotechnology Industry Organization, BIOTECCanada, CropLife International and the Secretary General of EuropaBio**

We write on behalf of the members of the Biotechnology Industry Organization (BIO), EuropaBio, BIOTECCanada, and CropLife International, who together represent more than 2,000 biotechnology enterprises worldwide and are responsible for the hundreds of innovative biotechnology products in healthcare, agriculture, industrial applications and the environment. Our members support the goals of the Convention on Biological Diversity<sup>1</sup> (CBD), which include the sharing of benefits arising out of the utilization of genetic resources. We are concerned however, that mandatory patent disclosure requirements for genetic resources will have the opposite effect than that desired by the CBD. As such we strongly believe that specific proposals recently presented by Brazil, India and others to impose such requirements are not appropriate for consideration at this time or as a basis for future discussions.

These proposals would weaken the patent system by creating additional uncertainty for patent holders. In addition to requirements for disclosure of source/origin in patent applications, many of the proposals would require patent applicants to provide proof of “prior informed consent” from the owner of the genetic resource, and proof that the applicant will share or has shared benefits obtained from use of those resources and traditional knowledge equitably with the providers of the resource or knowledge. Patents would be subject to attack by others for not disclosing the correct or sufficiently complete information about the genetic resource making patent certainty precarious. This uncertainty is further compounded by the current lack of specificity in access requirements in many countries as well as requirements related to prior informed consent and traditional knowledge. We know from experience that these significant risks will discourage capital investment in biotechnology research conducted by our members. Without this capital investment our members cannot undertake vital research on better foods, alternative sources of energy, and medicines. As a result, the owners of genetic resources will stand to lose from this lack of investment. In short, we believe that the burdens and risks of most proposals far outweigh their potentially limited contribution to the fulfillment of the goals of the Convention.

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<sup>1</sup> Convention on Biological Diversity: “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.”

Please be assured that we still recognize the need to conserve the rich biodiversity of genetic resources worldwide and to promote sustainable uses of these existing resources. Indeed, our members believe that benefits arising from the use of genetic resources collected through bioprospecting after the entry into force of the CBD should be shared equitably with the providers of those resources.<sup>2</sup> However, our support for the goals of the Convention does not translate to support for special disclosure requirements. Contrary to assertions made by Brazil and India that unauthorized access of genetic and/or biological materials (“biopiracy”) can successfully be monitored and enforced through patent laws, we believe that patent systems are **not** efficient tools for enforcing access and benefit sharing provisions of the CBD. From experience we know that only a small fraction of the resources accessed will be used in research that results in patentable inventions and, then, only years after accession – regardless of whether the access was authorized or not. Consequently, regulation using patent systems would have no effect on most unauthorized users and would not ensure equitable benefits would be provided to most providers of resources who authorize access to resources.

Moreover, most resources in a biotechnology patent application are not covered by the CBD. Examples are human genetic resources, biological resources that are not genetic resources, and resources accessed legally before the entry into force of the CBD. As a result, this proposal will rarely result in disclosure of CBD-covered resources, but rather, it will only add a significant bureaucratic burden on the applicant to disclose and the government to oversee thousands of resources not covered by the CBD.<sup>3</sup> Our members believe a more direct path for fulfilling the goals of the CBD is through the facilitation of contractual agreements between the holders and users of genetic resources. We understand that there may be many challenges in facilitating contracting, but we will support efforts to build capacity for the effective drafting and enforcing of contracts.

With respect to enforcement of contracts, we are told by proponents of disclosure requirements that holders of genetic resources covered by the CBD find it difficult, if not impossible, to enforce contracts across national borders. Thus, they argue that disclosure requirements are the only available deterrent to unauthorized access to genetic resources. While we have not viewed cross-border enforcement as a significant practical problem, we would support efforts within the Convention on Biological Diversity or the World Intellectual Property Organization to determine if, and to what extent such problems exist.

In conclusion, we believe that special disclosure requirements in patent systems to fulfill the goals of the Convention on Biological Diversity, including the recent proposal to the WTO by Brazil, India, and others, are inappropriate whether they are instituted in World Trade Organization or other organizations. We urge that such proposals are premature and should not be considered as a basis for future TRIPS Council discussions.

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<sup>2</sup> Our organizations have attempted to educate our members on their responsibilities with respect to access of genetic resources after the entry into force of the Convention and the equitable sharing of benefits arising from use of those resources, including through the establishment of guidelines related to access and benefit-sharing in some organizations.

<sup>3</sup> It should be noted that the term “genetic resources” does exclude non-human genetic resources when used within the context of the Convention on Biological Diversity but there is no specific exclusion when used in the World Trade Organization.

We would be pleased to elaborate on these views and hope that you will take them into consideration when you reflect upon proposals to institute special disclosure requirements in patent systems.

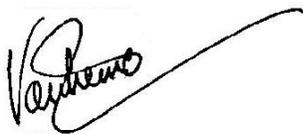
Respectfully Submitted,

A handwritten signature in black ink that reads "James C. Greenwood". The signature is written in a cursive style with a large, looping initial "J".

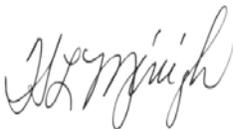
James C. Greenwood  
President and CEO  
Biotechnology Industry Organization

A handwritten signature in black ink that reads "Peter Brenders". The signature is written in a cursive style with a large, looping initial "P".

Peter Brenders  
President and CEO  
BIOTECanada

A handwritten signature in black ink that reads "Johan Vanhemelrijck". The signature is written in a cursive style with a large, looping initial "J".

Johan Vanhemelrijck, DVM  
Secretary General  
EuropaBio

A handwritten signature in black ink that reads "Howard Minigh". The signature is written in a cursive style with a large, looping initial "H".

Howard Minigh  
President and CEO  
CropLife International