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July 16, 2008

Ambassador Susan C. Schwab Office of the U.S. Trade Representative 600 17th Street, N.W. Washington, DC 20508

## Re: Opposition to Proposed TRIPS Amendments on Genetic Resources and Traditional Knowledge Issues

Dear Ambassador Schwab:

I am writing on behalf of the Intellectual Property Owners Association (IPO) to convey the Association's position on proposals to amend the TRIPS Agreement with respect to genetic resources and traditional knowledge issues. We understand that such proposals are currently being discussed in the Doha round negotiations.

IPO is a trade association representing the interests of intellectual property owners. It includes more than 200 companies and 10,000 individuals who are involved in the Association either through their companies or as IPO inventor, author, executive, law firm or attorney members.

IPO recognizes the importance of discussions in appropriate for regarding the use of genetic resources and traditional knowledge, and supports ensuring appropriate benefit-sharing for such use. However, any negotiations aimed at amending the TRIPS agreement with respect to these issues are, at the very least, premature at this time. This is so for a number of reasons, including the following:

(i) There is a lack of consensus on the need for or scope of such amendments. Many fundamental principles relating to such amendments of the TRIPS agreement have not been clearly identified. This is largely due to lack of agreement on the need for such amendments. IPO believes that the attempt to regulate prior informed consent and benefit-sharing via the patent system is misplaced, as such concepts are best regulated at the time of access rather than at the time of filing patent applications. Further, because there is no agreement on the definition of terms used in current proposals, a mandatory disclosure requirement could extend to items that were never intended to be part of the access and benefit-sharing discussions. For example, a proposed amendment to TRIPS could apply to research tools that are used only tangentially in research, or to commodities or other items in trade, or to information that has been available in the public domain for many years.

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- (ii) Discussions in other fora are ongoing. The Convention on Biological Diversity (CBD) has been addressing the issues of access to genetic resources/traditional knowledge and benefit-sharing for many years. At the most recent Conference of the Parties, member states to the CBD agreed to complete work on an International Regime aimed at addressing access and benefit-sharing relating to genetic resources. Similarly, since 2001, an intergovernmental working group of the World Intellectual Property Organization (WIPO) has addressed the inter-relationship between genetic resources/traditional knowledge/traditional cultural expressions and intellectual property. These organizations are still in the process of identifying the best means for achieving the access and benefit-sharing goals related to use of genetic resources -- and practical mechanisms to ensure complete examination of patent applications. Therefore, an amendment to the TRIPS Agreement would undermine the ongoing work of these organizations and would do so in a manner for which there is no consensus.
- (iii) There is a lack of shared national experiences. While those who propose to amend the TRIPS agreement to include a patent disclosure requirement decry the "misappropriation" of genetic resources, many of these same countries have failed to provide meaningful information about their own experience with national regulation of genetic resources. As noted above, discussions have been ongoing in the CBD and WIPO and efforts have been made to conduct gap analyses on national experiences. However, thus far, the claim that greater international oversight is needed has been made without providing practical experience to support that conclusion.
- (iv) Access through facilitating contracts is a better option. Special disclosure requirements in patent systems are not efficient tools for enforcing access and benefit sharing. A more direct path for fulfilling these goals is to facilitate contracting between the holders and users of genetic resources. In fact, IPO supports U.S. ratification of the International Treaty on Plant Genetic Resources for Food and Agriculture, which provides for access to certain plant genetic resources pursuant to a standard material transfer agreement.

IPO strongly urges you to maintain the position that amendment of the TRIPS agreement regarding genetic resources and traditional knowledge is premature and should not be a part of the current Doha round negotiations. I encourage you to contact me or Herbert Wamsley, Executive Director of IPO, if we can be of any assistance on these matters.

Sincerely, Miller

Steven W. Miller

President