



May 13, 2011

The Honorable Gary Locke
Secretary
Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Dear Secretary Locke:

On behalf of the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA), we write to express our appreciation and support for your continued leadership in promoting robust intellectual property standards and policies.

We wish to commend the efforts of the Department and the Patent and Trademark Office (PTO) during meetings earlier this year at the World Intellectual Property Organization (WIPO). At a recent meeting, held from February 28 – March 4, the U.S. Delegation effectively resisted demands from certain countries to commence negotiations on ill-advised and harmful changes to the global patent system relating to “genetic resources” and “traditional knowledge.” Such changes would undermine the ability of U.S.-based innovative companies to protect their inventions and their ability to thrive, create jobs and compete fairly in global markets. The U.S. Delegation to this meeting presented a well-reasoned and persuasive opposition to these demands, while maintaining a positive and constructive tone during the meetings. We believe this posture of principled opposition and constructive engagement is essential, and will continue to best serve the interests of the United States in these discussions at WIPO and elsewhere.

BIO and PhRMA have long supported the principles embodied in the Convention on Biological Diversity (CBD) and the Nagoya Protocol concerning appropriate access to genetic resources and the fair and equitable sharing of benefits from their use. We recognize that the utilization of these resources and knowledge hold promise to benefit all people, including the holders of these resources and knowledge, through the development of new crops, new industrial uses, and new cures and treatments. However, the proposals for new patent disclosure requirements concerning genetic resources and traditional knowledge being advanced in WIPO ignore these principles, despite being cast as a means for ensuring compliance with the CBD and preventing “biopiracy” (which we understand to mean the unauthorized collection and use of genetic resources).

The proposals have many practical and conceptual flaws. Most fundamentally, they would introduce uncertainties in the patent system that would undermine entire patent portfolios for companies that use natural materials, particularly for those in the life sciences. In many cases, it will not be possible for a patent applicant to knowingly comply with such requirements, yet

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failure to comply could result in denial of a patent or render a granted patent invalid. Moreover, no attempt has been made to show how the proposed disclosure requirements could actually remedy the concerns that motivate these proposals – i.e., the unauthorized collection and use of genetic resources. This is because it is not possible to meaningfully monitor or enforce conditions concerning the use of genetic resources through such proposed measures. In the attached Appendix, we explain in greater detail some of the background and concerns regarding these important matters. We hope that this will be helpful to you and your staff.

Our members remain open to discussions, in WIPO and other fora, to identify mechanisms that would provide for meaningful monitoring of the collection and use of genetic resources as well as safeguards against illegal uses of such genetic resources. Examples of constructive proposals under consideration in WIPO include: a “one-stop-shop” database to improve the quality of patent examination, model material transfer agreements that contain enforceable cross-border provisions and guidelines for contractual practices relating to managing intellectual property in ABS agreements.

We are confident that, with the continued leadership of the United States and other like-minded countries, such mechanisms can be further developed. We urge you, therefore, to continue to oppose ill-advised patent disclosure proposals and, in doing so, encourage a global, pro-innovation solution that benefits developed and developing countries alike while achieving a level-playing field where our innovation-based companies can compete fairly to “win the future.”

Sincerely,



James C. Greenwood
President and Chief Executive Officer
Biotechnology Industry Organization



John J. Castellani
President and Chief Executive Officer
Pharmaceutical Research and Manufacturers of America

Attachment

cc: The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office