August 9, 2007

Addendum to the Reports of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) on the The U.S. –Peru, U.S.–Colombia, and U.S.–Panama Free Trade Agreements The Intellectual Property Provisions

Submitted on February 1, 2006; September 20, 2006; and April 25, 2007, respectively

Following a closed meeting of ITAC 15 members on August 9, 2007, ITAC 15 approved the submission of an Addendum to the Korea FTA report representing the views of five of its members. This addendum addresses revisions to the text of the Agreement that were made subsequent to the deadline for the submission of the previous ITAC 15 report.

We would like to recall that, in the introduction to the Patents section in each of the original ITAC 15 reports on the Colombia, Panama and Peru FTAs, "ITAC 15 [had] note[d] that, as a general rule, the level of patent protection found in the industrial countries, and especially the level of patent protection found in the United States, provides an appropriate level of incentives for innovation." ITAC 15 went on to reiterate "its view that it should continue to be the U.S. objective in all FTA negotiations to ensure that our negotiating partners adopt a level of patent protection comparable to that found in key developed countries, including the United States." It was in light of these objectives that ITAC 15 provided its comments in its original reports on the provisions relating to patents and to measures related to certain regulated products and that it does so once again.

Unfortunately, while the changes that were made in the amended intellectual property provisions are not inconsistent with U.S. law, the changes would permit our FTA partners to provide patent and data protection for pharmaceutical products at a level that would be inferior to that found in the United States. Provisions that had been mandatory in the previous FTA Agreements, such as those with respect to patent term extension for pharmaceutical patents (revised Article 16.9.6) and patent linkage (revised Article 16.10.4), are no longer mandatory, while the period of non-reliance (Data Exclusivity), which, in the previous FTA Agreements, had been counted, as in the United States, from the first registration in the host country, now begins, in certain cases, with the marketing of the originator's pharmaceutical product in the United States (revised Article 16.10.2).

While ITAC 15 appreciates the additional procedures that are aimed at facilitating and expediting the resolution of pre-marketing approval disputes related to pharmaceutical patents that are now included in Article 16.10.3, these measures cannot substitute for the previous obligation that our FTA partner had to "implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent …"

The undersigned are especially troubled by the signal to our trading partners that will be sent by the discrimination against patents in one technological field—pharmaceuticals—found in the

revised intellectual property provisions of the three FTAs. One of the most significant achievements of the TRIPS Agreement was the prohibition contained in TRIPS Article 27.1 of any discrimination with respect to the availability of patents and the enjoyment of patent rights by field of technology. Until now, this obligation was viewed as essentially requiring equal treatment for all patents with respect to the enjoyment of patent rights. While the revised intellectual property provisions may not violate the "letter" of the TRIPS Agreement, their differentiation between the mandatory patent term extension for non-pharmaceutical patents for general patent office administrative delays and the optional extension for similar delays for pharmaceutical products violates the "spirit" of the TRIPS Agreement. That is indeed unfortunate.

We thus oppose the changes to the intellectual property provisions that are included in these revised Agreements. We believe that the changes substantially diminish the level of intellectual property protection in the Agreements. Most importantly, we do not believe that these changes will advance the claimed objectives of fostering access to medicines in the partner countries, and in fact are more likely to be counter-productive to that goal. Furthermore, these changes will almost certainly undermine U.S. jobs and companies in one of the most innovative sectors of the American economy. As a result, the undersigned do not support the Free Trade Agreements with Peru, Colombia and Panama.

Jacques J. Gorlin
President, The Gorlin Group

J. Anthony Imler
Director, Public Policy, Latin America,
Merck & Co., Inc.

Herbert C. Wamsley
Executive Director, Intellectual Property
Owners Association

Jeffrey P. Kushan
Sidley, Austin, Brown & Wood LLP
Representing Biotechnology Industry
Organizations

Douglas T. Nelson
Executive Vice President, General Counsel,
CropLife America