Comments of **on U.S. Free Trade Agreement with Republic of Korea**

ITAC 3

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FTAs should export the U.S. balance of pharmaceutical innovation and access to affordable medicine in order to ensure the same the same prosperity for Korea as that enjoyed by the U.S. However, recent FTAs and those currently being negotiated are contrary to or exceed U.S. law. In order to produce an agreement that balances the interests of all affected industries, recommends several modifications to the text of the U.S.-Korea FTA:

- **5-year Market Exclusivity**: Throughout Article 9 of the Intellectual Property chapter, with respect to the pharmaceutical marketing exclusivity provisions, the language refers to the application of exclusivity to same or *similar* products. While USTR, in the 5-year exclusivity provision, may intend the

term "*similar product*" to indicate that the exclusivity applies to a product with the same active moiety including any ester or salt, the term, which is also used in the context of the 3-year market exclusivity provision, may be given a far broader interpretation. And given the definition of the term "new pharmaceutical product" as set forth in Article 9 subsection (1)(c) the use of the term is irrelevant and is an area ripe for misinterpretation. In order to clarify precisely to which products the exclusivity applies, so that the agreement is not unintentionally interpreted to exclude the entire drug family or drugs in the same therapeutic class, for the 3-year exclusivity provision we ask that the term stricken from the text so as to limit marketing exclusivity in the same way it is limited in the U.S.

- **3-year Market Exclusivity**: Further under Article 9 subsection (2)(a), the language appears to suggest that the marketing exclusivity awarded on the basis of the submission of new clinical information that is essential to the approval applies to a "pharmaceutical *product*" not to the "new condition of use" of the drug as supported by the new studies which are essential to the approval of that condition, as it is under current U.S. law. Under U.S. law, it is well settled that market exclusivity for new conditions of use does not apply to the entire product per se. Rather, the exclusivity runs to the "new condition of use" which may be a new dosage form, route of administration, indication of use, or a new product. advises that this conflict should be rectified in future drafts of the Korean FTA so that such exclusivity would clearly apply, as it was intended, to the condition of use and not the product. The same issue discussed above with use of the word "*similar*" appears in the 3-year exclusivity section.

- **NCE Patent Extension**: As you know, U.S. law limits one patent extension for each new chemical entity to a maximum of 5 years or 14 years after the date of a drug's approval, whichever occurs sooner. understands that under Korean law, patent extensions are similarly limited to a maximum of 5 years. Given that both country's laws are harmonized to a degree with regard to limits on patent extensions, it is incongruous for the duration of patent extensions to be entirely unrestricted under the text of the free trade agreement. recommends that the Article 8, subsection (7)(a)-(b) limit patent extensions to no more than 5 years, and that the Article 8 limit patent extensions to one per product, just as is mandated in the U.S. U.S. law states that in no event shall more than one patent be extended for the same regulatory review period for any product. Without any limits to the duration of a patent extension, or to the number of patents per product that may be eligible, generic medicines may needlessly be prevented or extensively delayed from entering the market.

- **Definition of NCE**: With reference to Article 8 subsection (7)(b), footnote 14, the definition of new chemical entities should match the definition under Article 9 subsection (1)(c); thus, for the sake of clarity and consistency, recommends striking the term "at least" from the footnote.

- **Sufficient Disclosure**: In the U.S. a patent applicant must disclose the "best mode" of practicing the invention. The disclosure of best mode serves the public's interest in maintaining a strong patent system and encouraging technological progress. When patent and exclusivity protections expire the public may use this information to produce generic versions of the drug, so that scientific resources are not wasted on redundant studies.

  U.S. law states "[t]he specification [containing] a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention" (my emphasis).

  In order to ensure the transfer of this efficiency, the Article 8 subsection 11 should adopt the principle of best mode disclosure. The direct and unintended consequence of not requiring such disclosure would be de facto patent extensions that would place the undue burden of higher cost medicine on consumers, insurers and government healthcare programs.

- **Bolar Provision**: Article 8 subsection 5 includes a permissive Bolar provision. U.S. law mandates that generic companies have the right to research an innovator's drug during the patent term so that a generic version may be developed during the patent term and marketed when the patent expires. The Bolar provision is essential to maintaining a robust generic industry which helps to strike the proper balance between the interests of innovation and access to affordable medicine. understands that Korean law holds a broader exception for research and experimental use of drugs under patent. A mandatory Bolar provision should be included in the terms of the FTA as a minimum requirement, or a "floor" for negotiations, which is consistent with other FTA floor provisions. So long as Korea's current law contains a broader research exception to patent infringement, no conflict should arise.

- Article 9 subsection (4)(a)-(b) requires a form of patent linkage. In other words, the FTA would link the approval of a generic drug to the expiration of patents on the brand drug. Under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) which create the linkage system in the U.S. and the Medicare Modernization Act (MMA) which amended the

Hatch-Waxman Act to close unintended loopholes in the linkage system, Congress provided vital mechanisms for maintaining a balance between access and innovation that the FTA fails to include. The FTA requires linkage, but provides no means to challenge questionable patents, no incentive for the swift resolution of patent disputes, and no limit on the types of brand patents that can be listed for a drug product and block a generic from coming to market. Furthermore, the FTA fails to recognize the cumbersome and protracted process of Korea's judicial system, which takes an average 6 to 12 years to litigate patent dispute claims.

Negotiating an FTA that lacks essential generic access measures amounts to exporting our pre-Hatch-Waxman system which encouraged brand patent evergreening and indefinite monopolies. Moreover, the lessons learned in the U.S. from numerous loopholes prior to MMA—loopholes that were even recognized by President Bush in the Rose Garden—should be recognized and addressed by USTR. An FTA that requires linkage must also include the means to facilitate patent challenges, to ensure timely resolution of patent disputes in Korea's judicial system, and to remove the obstruction of questionable patents that hinder the generic approval pathway. Finally, the FTA should carefully specify the types of patents that are subject to the linkage system.

FTAs that lack the pharmaceutical balance between innovation and access directly undermine the administration's efforts for global R&D sharing, a goal to which this Administration has dedicated considerable resources and time, especially with the OECD countries. strongly endorses and supports the Administration's goal with respect to price controls and global R&D sharing, as well as the protection of intellectual property. Ensuring access to affordable medicine is also needed to promote a balanced, viable health care system. Accordingly our agreements with other nations should foster such a balance. FTAs that fail to promote these interests equitably will result in a less competitive and less productive global generic pharmaceutical industry to the detriment of consumers in Korea and around the world.