Joint Position Statement on the Trans Pacific Partnership (TPP) Negotiations

May 10, 2012

- Asociacion Industrial de Laboratorios Farmaceuticos (ASILFA) - Chile
- Asociacion Mexicana de Fabricantes de Genericos Intercambiables (AMEGI) – Mexico
- Asociacion Nacional de Fabricantes de Medicamentos (ANAFAM) – Mexico
- Asociación de Industrias Farmacéuticas Nacionales (ADIFAN) - Peru
- Canadian Generic Pharmaceutical Association (CGPA) – Canada
- Generic Pharmaceutical Association (GPhA) – United States
- Generic Medicines Industry Association (GMiA) – Australia
- Japan Generic Medicines Association (JGA) – Japan
- Malaysian Organisation of Pharmaceutical Industries (MOPI) - Malaysia

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The generic pharmaceutical trade associations of Australia, Canada, Chile, Japan, Malaysia, Mexico, Peru and the US represent a large majority of the generic manufacturers doing business in the Trans-Pacific Partnership countries, and within those countries expressing interest in joining the negotiations. Our members provide access to affordable medicine for millions of people. The competition brought to the pharmaceutical market by our member companies and their high quality, bioequivalent products is essential to the sustainability of domestic and global public health systems and to ensuring timely patient access to affordable medicines.

The Trans Pacific Partnership (TPP) is a set of plurilateral trade negotiations that is currently comprised of nine countries – Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States and Vietnam. In early 2012, three additional countries – Canada, Mexico and Japan – formally applied to join the TPP negotiations. The Philippines, South Korea and Taiwan have also expressed interest in joining the TPP negotiations. While enhancing trade between countries in the Asia-Pacific Region is a laudable objective, it is critical that parties to the TPP negotiations ensure the measures and procedures to enforce intellectual property rights for pharmaceuticals do not themselves become barriers to legitimate trade. As such, the TPP must reflect a balance between protecting IP rights and encouraging competition that will ensure access to affordable medicine.

In September 2011, the United States tabled several pharmaceutical IP proposals in the TPP negotiations, which were subsequently "leaked" to the public online in September, 2011. These proposals were met with great disappointment and concern by our Associations and the generic pharmaceutical companies we represent. The US TPP proposals on IP are excessive and in direct conflict with the May 10, 2007 Bipartisan Agreement on Trade Policy (the "New Trade Policy"), which has been adopted in the US-Peru Free Trade Agreement (FTA). The bipartisan agreement had represented a significant improvement to US trade policy, and was supported by GPhA and generic pharmaceutical companies. The key features of the Bipartisan Agreement include:

1. Elimination of the requirement to provide patent extensions for pharmaceuticals
2. Elimination of the requirement to provide patent linkage
3. Significant improvements on data exclusivity
4. Provisions allowing for the granting of effective rewards for the successful challenge of the validity or applicability of a patent.

The following discussion outlines the specific concerns of our associations and our member companies with respect to the September 2011 leaked text of the pharmaceutical IP proposals tabled by the US in the TPP negotiations:

Patent Linkage

This term refers to a link between the patent status of a product and the application for marketing authorization, which prevents the registration and authorization of generic medicines until after the expiry of patents, and has the consequence of considerably delaying generic market entry. This forced "link" creates a difficult situation, as regulatory authorities lack resources and expertise to assess the validity of each patent.

Position: Patent linkage is a complex and costly system, which is uncommon outside of Japan, Canada and the United States. It is also contrary to E.U. law (illegal). Such an onerous and costly system must not be imposed on other jurisdictions, as proposed by the US in the TPP negotiations.[1] In addition, this provision has been the source of many abuses.

Data Exclusivity or Equivalent (Similar) Regulatory Measures

[1] It should be noted that while Australia technically has a patent linkage regime on paper, it is a notification system that does not provide automatic injunctions to patentees and bears no resemblance to U.S. or Canadian patent linkage.

Data exclusivity operates independently of the patent system. It prevents regulators from accepting and/or approving an application for a marketing authorization from a generic manufacturer during a defined period. In the case of Japan the same kind of limitation of generic entry is given through the requirement of a post-marketing survey of newly approved innovative drugs or additional features such as new indications, formulations, etc. This system is called the "Re-examination System" which effectively protects data exclusivity of innovative drugs in addition to patents.

Position: The TPP should restrict data protection to only truly innovative products and in those cases allow parties the flexibility to implement exclusivity measures similar to those adopted in the US-Peru FTA under the New Trade Policy[2]. The possibility of granting exclusivity periods to medicines was debated during the development of the TRIPS agreement, and parties determined to exclude such provisions. If an exclusivity provision is established at all in the TPP it should be only for truly innovative drugs that cannot be protected by a patent. Otherwise, patent protection should be enough to compensate the investments that were made. In addition, if and when an exclusivity period is granted to data in the TPP it should be only be for new chemical entities. Biopharmaceuticals should not yet be protected by an exclusivity period as it is still too premature to know how this market will develop. Based on IMS information and the US Federal Trade Commission Report on Follow-on Biologics, this additional protection does not seem to be necessary as innovator companies retain most of their market share even after the expiration of the patents.

Patent Term Extensions

Patent term extension provisions generally extend the term of patent protection for medicinal (human or veterinary) or plant products beyond the international standard of a 20-year patent. The aim of such an extension is to compensate the patent holder for the time lost in exploiting the patent due to the requirement to first obtain regulatory approval.

Position: Patent extensions are not a requirement of the TRIPS agreement, are not mandated under the New Trade Policy and should not be mandated in the TPP.

Early-Working Exception (Bolar)

Bolar provisions allow generic companies to conduct research prior to the expiration of a patent. This provides consumers with access to generic drugs almost immediately after the patent ends in that jurisdiction.

Position: Eight of the nine countries that are currently party to the TPP negotiations have a Bolar provision. A strong Bolar provision should be mandated in the TPP and in every FTA.

Best Mode

'Best mode' refers to the requirement that the inventor disclose in the patent application the most efficient known method of producing the invention. Without a best mode requirement, an inventor or patent holder could gain a further monopoly as the public would have to spend time reinventing the best way to make the product after the patent has expired.

Position: Disclosure of best mode is fundamental to the patent system, and is especially important for biopharmaceuticals. Disclosure of best mode should be a requirement included in the TPP text.

Patentable Subject Matter

Article 27.3 of TRIPS allows for restrictions of patentability. Countries can ban patents for plants and animals other than micro-organisms. This is one of the flexibilities of the Doha Declaration and should not be limited. Requiring the patentability of plants and animals in a trade agreement could have serious implications to bringing biosimilar products into the market as it could create additional undue layers of patents.

Position: TPP should respect and not undermine the restrictions of patentability of TRIPs.

Abuse or Misuse of intellectual Property Rights

Consistent with Article 8.2 of the TRIPS Agreement, Parties should include similar penalties for those that infringe patents as for those that abuse or misuse an intellectual property right. The TPP should not give carte blanche to the misuse of IP rights. Both abusers and infringers should be equally penalized.