



INTERNATIONAL GENERIC
PHARMACEUTICAL ALLIANCE

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IGPA Statement on the Trans-Pacific Partnership (TPP) Negotiations

The Asia-Pacific Region is of key importance to the generic pharmaceutical industry. It is the location of hundreds of generic manufacturing facilities and strategic export opportunities. It is also an important source of pharmaceutical ingredients and other raw material inputs for our high-quality, low-cost medicines. As such, IGPA strongly supports efforts to expand trade in the region through the Trans-Pacific Partnership (TPP) negotiations.

While the TPP currently includes 12 member countries (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam) covering almost 40% of the global economy, IGPA encourages the expansion of the TPP to other countries in the region in order to increase the overall coverage of this agreement.

The TPP presents an opportunity for enhanced regulatory cooperation and collaboration in the life sciences sector in the areas of drug submission requirements and inspection compliance programmes.

In addition, the TPP provides an opportunity to promote well functioning pharmaceutical patent systems for all TPP members in a manner that respects the WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS).

We are aware of the “leaked intellectual property text” that shows a series of pharmaceutical IP proposals by the United States that include mandatory measures that go beyond the requirements of the WTO TRIPS Agreement, such as patent term extensions and patent linkage. The effect of these proposals would be to expand the length of market monopoly provided to brand-name pharmaceutical products by several years through provisions that exceed the existing laws of most TPP member countries.

The timing of entry of new products is critically important in the highly competitive global generic industry. Domestic patent protection and other intellectual property provisions in a given country have a direct bearing on when generic manufacturers develop, manufacture and export new generic medicines. Trade agreements that include requirements that go beyond the WTO TRIPS agreement create barriers to trade for generic pharmaceutical companies. These companies must be able to access global markets as soon as they open up in order to compete effectively.

Our concerns over trade and investment in generic pharmaceuticals are in addition to the access to affordable medicine concerns. The US proposals would create significant delays in the ability of generic



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manufacturers in TPP member countries to develop, and export new generic medicines. These proposals would undermine public health policies for TPP countries while also undermining industrial investments and economies where generic pharmaceutical manufacturing facilities are present. The IGPA does not support them.

IGPA supports fair and reasonable lengths and coverage of intellectual property protection. A properly functioning patent and intellectual property system is crucial for the generic pharmaceutical industry to develop and bring its lower cost equivalent products to market with business certainty.

To this end, IGPA supports the WTO TRIPS Agreement as the basis for IP provisions in the TPP. In addition, the following provisions are among those that should be adopted in the TPP and other trade agreements to ensure a well functioning pharmaceutical intellectual property system:

- A requirement for a strong “Bolar Provision” early working exception, to permit market entry by generic medicines at the earliest possible opportunity after patent issues are cleared.
- A requirement for the patentee to disclose in a patent the “Best Mode” of creating the invention, as a quid pro quo for the monopoly that is granted.
- A requirement for safeguards against abuse/misuse by intellectual property rights holders
- A requirement for IP opposition/review procedures to ensure only quality patents are granted, and only products that meet the criteria for data protection receive it.
- Maintain current TRIPS flexibilities on patentable subject matter and exports for humanitarian purposes.

The IGPA also recommends that the following provisions not be included in any intellectual property chapter on pharmaceuticals:

- Patent Term Extensions
- Data Protection provisions that go beyond the requirements of TRIPS Agreement
- Special/additional measures for biologic molecules
- Differential IPR requirements between countries within bilateral, plurilateral or multilateral treaty text
- Patent Linkage

The IGPA and its member Associations look forward to continuing to work with TPP negotiators to achieve intellectual property provisions that reflect the public health needs of TPP countries and the industrial needs of generic pharmaceutical manufacturers in TPP countries.