

# OPINION: Impact Of The TPP On The Pharma Industry

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## Executive Summary

**The final text of the Trans-Pacific Partnership confirms beyond doubt the apprehensions expressed by civil society, academia and the generic industry about new barriers to access to medicines. The TPP has done away with several flexibilities provided under the TRIPS Agreement and the Doha Declaration on Public Health. Though the text mentions “nothing in this [IPR] Chapter limits a Party’s rights and obligations under Article 31 of the TRIPS Agreement,” the TPP Investment Chapter overrides these flexibilities, says D G Shah.**

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*By D G Shah, CEO, Vision Consulting Group and Secretary General, Indian Pharmaceutical Alliance.*

The final full text of the recently concluded negotiations on the 12-country Trans-Pacific Partnership trade agreement was recently released (["Contentious TPP Details On Patent Linkage, Reimbursement Revealed"](#) — PharmAsia News, Nov. 9, 2015 12:21 AM GMT).

The key elements in the TPP and their likely impact on pharmaceutical industry - both innovative and generic - are noted below:

## Patentability Criteria

The TPP member states have surrendered their sovereign right to define ‘patentability’ criteria. Not only have they have surrendered their right, they have agreed to grant patents for:

- a) new uses of a known product;
- b) new methods of using a known product, or;
- c) new processes of using a known product.

This would lead to the “evergreening” of patents and result in an average extension of monopoly by at least five years. Some can stretch it beyond five years, as was done by [Novartis AG](#) for *Gleevec* (imatinib). This would encourage innovators to go for low-hanging fruits at the cost of

more difficult-to-succeed efforts. Generics will slow down and patients will have to wait longer for affordable treatments.

## **Patent Term Extension**

The TPP member states have agreed to adjust the term of the patent for “unreasonable” delays in the issuance of patents. The “unreasonable” period is defined as “more than five years from the date of filing of the patent application”. Likewise, any delay in granting marketing approval for a drug will entitle the rights holder to extension of the patent term.

The patent term adjustment provision has several implications. First, it would enable the rights holder to delay launch of the product in relatively low-priced markets, particularly developing countries. Secondly, to delay the launch, the innovators may furnish even incomplete data to the drug regulator to show the approval process look tardy and inefficient.

Thirdly, it would thus deny access to a new medicine in the lower priced markets. Fourthly, even after the expiry of a patent in the developed countries, the product would retain monopoly status in the developing countries. This could on an average give at least two years of extended monopoly, further impacting generic growth and patient access.

## **Protection of Undisclosed Test Data**

Commonly known as “data exclusivity”, the protection ensures that a drug regulator cannot rely on the innovator’s data for approval of second and subsequent manufacturer’s application for a specified period from the date of marketing approval to the innovator.

This would ensure extended monopoly for innovators in developing countries, though the patent may have expired in developed countries.

This is because innovators launch their new drugs in low-priced countries years after their launch in the developed economies. As regards biologic drugs, the TPP member states are required to either grant eight years of exclusivity or deliver a “comparable outcome in the market” through “other measures”. This would add to the period of monopoly for innovators and delay the launch of generics.

## **Patent Linkage**

“Patent linkage” means linking marketing approval by the drug regulator to the patent status of the drug. The Orange Book system as it operates in the US generally provides a 30-month time frame to the drug regulator for approval of a generic (Abbreviated New Drug Application) product.

The proposed obligation could effectively lead to three to four years of additional monopoly in other markets, as they do not have a formal system, similar to the Orange Book, which binds the drug regulator to approve a generic product within the stipulated time frame.

This would benefit innovators and delay launch of generics, depriving patients of an affordable alternative.

## **Compulsory Licenses**

The intellectual property provision in the TPP Investment Chapter will curtail governments' ability to use a compulsory license as a tool to negotiate price with the rights holder, as was done by Brazil for antiretroviral medicines. It provides that the meaning of the World Trade Organization's TRIPS Agreement can be subject to review and arbitration led by the private rights holders.

The review extends to "adequate" or "reasonable" compensation or remuneration for non-voluntary use of intellectual property rights; the standards of patentability; and other issues to determine "to the extent" an action of policy is "consistent" with the TPP Intellectual Property Chapter.

This would not only lead to "forum shopping" between the WTO Dispute Settlement Body and the TPP's Investor-State Dispute Settlement (ISDS) mechanism, but also empower the private rights holder investors (and not end consumers) to bring cases against governments and benefit from sanctions.

[Eli Lilly & Co.](#)'s \$500m NAFTA (North American Free Trade Agreement) suit against Canada for its Federal Court's invalidation of the *Zypprexa* (olanzapine) patent is a testimony to the shape of things to come. Not only the government but also the judiciary of a country will be subject to arbitration proceedings by a private investor.

## **Border Measures**

The TPP member states have agreed to empower certain "competent authorities" such as Customs to initiate border measures. This includes goods in transit also.

Thus, goods originating in a non-member state and destined for a non-member state, if transiting through a TPP member state, could be seized for "alleged" violation of intellectual property rights *as determined* by the customs authorities, and not through the judicial process. This would certainly curtail generic companies' reach to many markets.

## **Dispute Settlement Mechanism**

The inclusion of intellectual property as a covered asset in the TPP Investment Chapter is potentially more consequential than anything in the TPP IP Chapter itself. It enables private investors to use the ISDS mechanism to interpret the IP Chapter as well as the TRIPS Agreement.

This will provide the arbitrators in the ISDS mechanism with discretion to interpret and decide on compliance with the TRIPS Agreement, even though the WTO has its own dispute settlement mechanism.

This would change the dynamics, as private parties would have less restraint than the States regarding policy space, so also the perspective of seeing intellectual property rights as innovation stimulants rather than as assets.

## **Collective Impact**

Thus, the collective impact of the TPP on the pharmaceutical industry will be to grant at least 10 years of additional monopoly to innovators in various ways. This may reduce pressure on innovators for researching new drugs and developing new remedies. Consequently, the society at large will suffer.

This would also mean that patients in TPP countries would have to continue to pay higher prices for 10 more years. Those who can't afford these will have to suffer without medicines that could have cured them.

This will in turn slow down the development and commercialization of generics elsewhere in the world, depriving people of access to affordable medicines.

(Mr. Shah can be contacted at [dgshah@vision-india.com](mailto:dgshah@vision-india.com).)