
Looking beyond the Global Pharma Horizon

CPhI Annual Industry Report 2015

Industry Expert Panel Submissions

Part 3.

Push-pull factors on growth



PANEL MEMBER

Dilip G Shah CEO, Vision Consulting Group

Mega Trade Pacts and Their Impact On the Pharmaceutical Markets

Introduction

The passage of the Trade Promotion Authority (TPA-2015) Bill by the US Congress gives powers to the President, for the first time after 2007, to fast track the mega trade deals: a trade deal among 12 pacific rim countries and a trade and investment agreement with the European Union. After the Bill was passed, the US Trade Representative (USTR) Michael Froman, in a statement, said that the Bipartisan Trade Priorities and Accountability Act (TPA-2015) represents “the most significant upgrade to our approach to trade in over four decades, including the requirement that labour and environmental protections be fully enforceable; new requirements for taking on unfairly subsidized foreign state owned enterprises; strong and balanced intellectual property protections; and new consultations and transparency requirements.” He further claimed that “TPA will move us one step closer to delivering trade agreements like the Trans-Pacific Partnership (TPP) and the Trans-Atlantic Trade and Investment Partnership (T-TIP) which will open growing markets to “Made in America” exports, protect our workers, and ensure that America, not our competitors, sets the rules of the road on trade.”¹ The pacific rim countries negotiating the trade deal are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, U.S.A. and Vietnam. The “companion agreement”

to TPPA is TTIP. President Obama is aiming to conclude the trans pacific deal in 2015 and the trans atlantic deal in 2016.

As both these deals are being negotiated in secrecy, their draft texts are not in the public domain. Whatever is written and discussed about these deals is based mostly on “leaked” texts; the 11 May 2015 version of the intellectual property (IP) chapter of the TPPA, and the proposed draft text of the TTIP leaked in March 2014. The European Commission disclosed some clauses in January 2015 for public consultation.

The academia, civil society, media and political commentators have all raised concerns about the impact of the TPPA on the public health and the TTIP on the inability of the governments to regulate the big corporations. This article seeks to assess effects of these mega deals on the pharmaceutical market by 2020.

TPPA-Key IP Provisions

The US negotiators want:

- Patent Law changes to make it easier to obtain “secondary” patent
- Regulatory Harmonization to fast track drug registration

¹ Third World Network, 20 April 2015

- 12-year Data Exclusivity to prevent generic competition
- Patent Linkage to prevent drug regulators from approving generic versions
- Patent Term Extension to keep the competition at bay
- Weakening of the early working provision (Bolar Exception) to delay entry of generics
- Empowering customs authorities to decide on “confusingly similar” trademarks

The deal would favour big companies like Pfizer, Roche, and Novartis if the 11 nations were to concede these demands. It would slow down and delay entry of generics in their markets. It would also force these countries to bear the burden of U.S. drug prices and create lucrative markets for patented drugs. No wonder that the Pharmaceutical Research and Manufacturers of America (PhRMA) has been lobbying for the TPPA.²

It is a different matter that the US domestic laws do not have some of these provisions.³ It is of even lesser importance that the Obama Administration wants to reduce drug costs for its citizens. It does not matter that it wants to dilute the patent monopoly for the benefit of its public. The contradiction between the demands on the Pacific Rim countries and the US domestic law could lead to one or more of three potential outcomes.

1. It could increase the cost of healthcare for 11 Pacific Rim countries
2. It could deny the U.S. citizens benefits of reduction in data exclusivity period for follow on biologics and higher standards of patentability
3. It could result in 11 Pacific Rim countries paying more for the medicines and providing justification to reverse policies of Obama Administration

The third and the last is the most likely outcome of the TPPA.

TTIP – Five Key Provisions

The US and the EU represent 60% of world GDP. They share 33% of world trade in goods and 42% of world trade in services,⁴ and yet they are home to only 20% of world population. A free trade agreement between the two,

covering 46% of world GDP, will potentially be the largest regional free-trade agreement.⁵

The free-trade agreements generally focus on tariff barriers to improve trade flows. Impact assessment of such agreements is relatively easy. The TTIP, on the other hand, aims to remove non-tariff barriers. Its societal impact on labour, employment, public health, markets, financial stability and governance are very deep and widespread but difficult to assess. Nevertheless, many have tried to assess and caution the negotiators based on whatever little is in the public domain.

The TTIP could also lead to harmonisation of North American Free Trade Agreement (NAFTA) and European Free Trade Agreement (EFTA) with the TTIP. The first will affect Canada and Mexico; and the second will affect Iceland, Norway, Switzerland and Leichtenstein in Europe and Canada and Mexico in North America.

The impact of the TTIP on the pharmaceutical sector has to be seen in the larger context and with reference to five key provisions being negotiated by the U.S. and the EU. They are:⁶

- Changes in intellectual property regulations
- Limits on pricing and reimbursement policies
- Attempts to limit transparency of clinical trials
- Increased corporate involvement in policy making + Dispute resolution mechanisms
- Setting a global standard

As is obvious, the intention is to push the EU to adopt the US standards and in return, the U.S. to raise its own barriers in the domestic market – “America sets the rules of the road on trade.” The most likely outcome of this trade deal is promotion of interests of the brand-name industry by delaying generic competition. The impact will not be limited to the U.S. and 28 Member States of the EU. It will extend not only to Canada, Iceland, Leichtenstein, Mexico, Norway and Switzerland but also to the developing countries and their generic industry. The new “standards” of IP, Drug Registration, Protection and Enforcement will hit the generic industry across the world.

²William New, ip-watch.org on 05/06/2015

³Frederick Abbott, Bloomberg, 10/07/2015

⁴Wikipedia, the free encyclopedia

⁵World Economic Outlook Database October 2013

⁶TTIP – A Civil Society Response to the Big Pharma Wish List. Joint Position by commonsnetwork.eu

Future of the Pharmaceutical Market

The chronology of events indicates that the U.S. will first conclude the TPPA and use it as a benchmark to negotiate the TTIP. The 11 Pacific Rim countries, looking for access to the US market, are more vulnerable and prone to giving in to the USTR pressure than the EU. Among them, only three countries namely, Australia, Canada and New Zealand are known to evaluate trade-offs between the public health and other sectors. Japan has been a moot supporter of the US for pharmaceuticals in various trade forums. It is already practising most of what is being negotiated. This leaves seven countries. They may be lured by the preferential treatment in sectors like textiles, minerals, leather footwear, coffee, rice, rubber, wood and wood products, palm oil, fruits, fish and fish products, paper and pulp, etc. Consequently, the pharmaceutical industry will face disruptions across all major markets.

The brand name industry will be a major beneficiary of the trade pacts. It will be able to improve its price realization in the low-priced markets. It will be able to delay generic competition in all markets, including the US. and the EU. This would however be not without a certain cost. Its consumers (the patients) will be unhappy. Its customers (the doctors) will complain of unwarranted high prices of medicines, as they did for Novartis' Glivec.⁷ Businesses and corporations will be concerned for rapid rises in the healthcare cost of their employees. The law makers (parliamentarians), feeling cheated by the trade negotiators, will target the brand name industry for rise in medicine prices. The civil society and health activists will raise their banners for denying access to affordable medicines. The net outcome would be a poorer image of the brand-name industry.

The generic industry will suffer on several counts slowing down its growth and earnings.

- A major driver of growth for generics is new product introductions. As data exclusivity period and patent protection get longer, the new product introductions will suffer
- As the new product launches become scarce, generic companies will focus on a slice of the pie of older products. The resultant competition will lead to price

- erosion of even mature products, affecting their earnings
- Thus, two major drivers of growth, viz. new introductions and value, could have negative impact
- The remaining two drivers of growth, viz. new markets and volume, could provide opportunity to efficient manufacturers as they would drive volume and enter “new markets”, but it would be at the cost of existing players, as they will eat into their share
- As the patent linkage kicks-in in EU and other trading partners, the generics will face delays in obtaining marketing approvals
- Dilution of the early working provision (Bolar Exception) for marketing approval in other countries would require a generic company to manufacture the medicine locally in every country where it wishes to seek early marketing approval
- Not only patents, data exclusivity, and patent linkage, the TRIPs-Plus provisions related to protection of trademarks could question prominent display of international non-proprietary name (INN) or generic name of a product. It could prevent generics from using colours or shapes identical or similar to those of the original products⁸
- The fear of costly and lengthy infringement proceedings will keep generic companies at bay and limit them challenging even poor quality patents⁹
- The US proposal envisages empowering patent-holders to seek information of the entire supply and distribution chain in case of alleged infringement. The information so obtained could be used effectively to block the supply chain – transporters, warehousing agents and distributors
- The proposed border measures in the deal revive the fear of detention of goods in transit for alleged violations of patents and trademarks. The application of “confusingly similar” trademarks by the customs officials would most likely lead to seizure or detention of many generic consignments as it happened in case of a shipment of amoxicillin from India to Vanutan. The use of INN appeared confusingly similar to GlaxoSmithKline's brand Amoxil¹⁰

Thus, generic industry and the public health will be severely impacted. The generics decline will be discernible from the end 2017, if the TPPA is signed in 2015. It would begin from 11 Pacific Rim countries and accelerate with the

⁷ <http://bloodjournal.hematologylibrary.org/content/early/2013/04/23/blood-2013-03-490003.full.pdf>

⁸ UNITAID – The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health March 2014

⁹ Ibid.

¹⁰ Ibid.

conclusion of TTIP in 2016. The decline will extend to the US and 28 EU countries, besides members of NAFTA (2) and EFTA (4). The full blown impact of these mega trade deals will be felt by 2020.

Encouraged by its success, the brand-name industry will be ready by 2020 to push the USTR to seek amendments to the TRIPs Agreement. Backed by some 50 signatories to TPPA and TTIP, the USTR will push for maximalist standards of protection and enforcement in the TRIPs Agreement. The moot question is if BRICS or any other new alignment of the developing countries would be able to thwart this grand design.

DGS:lf:27VII15