EU-India TRIPS-plus Agreement: A Real Threat for the Developing World?*

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Abstract: *Issuing the Global Policy Report in 2006, the EU approached a new generation of north-south FTAs. Among others, India fulfilled the main criteria of market size, economic growth, trade barriers and trade negotiations with EU competitors. The EU, being one of the main trade partners of India, enhanced the mutual FTA negotiations, which have been on going since 2007. Various areas such as trade in goods, liberalization of services, investments, intellectual property rights and Singapore issues are being covered in EU-India FTA. This paper focuses on one of the widely discussed issues — Intellectual Property Rights (TRIPS-plus Agreement). While IPR protection is normally included under TRIPS provisions for all WTO members, TRIPS-plus, proposed by the EU, goes further in measures. The aim of this paper is to provide a better understanding of the political, economic and social consequences resulting from such an agreement.*

Keywords: *EU, India, TRIPS (-plus), FTA, pharmaceuticals*

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Introduction

Failure of the multilateral Doha Development Agenda in 2006 and active approaches from the USA towards new free trade areas (FTA) launched impetus towards EU bilateral negotiations. In response to the situation the European Union published a Global Policy Report, where it stated its strategy of a new generation of north-south FTAs where developing countries are playing the key role. Even though the EU still endeavors to foster its foreign trade policies in accordance to multilateralism, bilateral negotiations currently lead towards greater success in a gradual removal of trade barriers (EC 2006a: 10). In contrast to the USA there is no defined template for FTAs in the EU (Woolcock 2007: 2). Moreover, each FTA is negotiated based on mutual agreements and needs. But the EU's goal for a new FTA is to tackle not only general areas but also far reaching comprehensive Singapore issues and intellectual property rights (EC 2006a: 10).

In 2007 the EU and India launched their FTA negotiations, which have been on going since then. The progress has been very slow and the date of conclusion was postponed several times currently being set for the year 2012 (Dogra 2011). This paper focuses on one of the widely discussed issues — Intellectual Property Rights (IPR) (TRIPS-plus Agreement). While IPR protection is normally included under TRIPS provisions for all WTO members, TRIPS-plus, proposed by the EU, goes further in measures. The aim of this paper is to provide a better understanding of the political, economical and social consequences resulting from such an agreement, as public health is a key issue for economic stability, growth, and the enhancement of mutual trade. The paper assesses intellectual property rights and their incorporation of international law and agreements, particularly to TRIPS/TRIPS-plus, and their implications to India's generic production and public health in developing countries. In general FTA negotiations are usually less transparent than those on a multilateral level. A lack of access to information and non-transparency in negotiations regarding FTA between EU-India may cause profound concerns mainly among the general public and non-governmental organizations (NGOs) pointing out in-depth consequences for the livelihood of people.

This paper reviews IPR law, trade policy, and international relations in order to provide a complex overview of current IPR issues between the EU and India. The following section two provides an overview of the evolution of the international IPR laws. Further on, in section three the paper reviews EU's common commercial policy with a focus on new FTAs. The historical and current EU-India trade relations are elaborated in section four followed by a closer insight into the TRIPS-plus negotiations on pharmaceuticals between the EU and India in section five. The last section presents an overview of Indian pharmaceutical production and depicts the second-line drugs price issue.

1 IPR Protection Overview

The need for IPR protection arose together with industrial revolution. The legal predecessors of today's TRIPS were the Paris Convention for the Protection of Industrial Property from 1883 and the Berne Convention on Copyrights from 1986. In 1967, the World Intellectual Property Organization (WIPO) was established in Stockholm, which administers the two treaties mentioned above. However, the IPR regulations covered under WIPO do not include trade related aspects or a sufficient enforcement system (Pastor: 2). In the 1980s the process of globalization resulted in the necessity to change the current legal framework due to major changes in the world. New electronically based technologies and products became easily copied, competition of newly industrialized developing countries was growing and the IPR protection was perceived as a key asset by developed countries (Yusuf 2008: 4). IPR issues were finally encompassed to the GATT Uruguay Round (1986–1994) resulting to the establishment of the World Trade Organization, which also included an annex regarding Trade-Related Aspects of Intellectual Property Rights (TRIPS). The aim of TRIPS is as follows:

> "desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights and ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" (WTO 2011a: 320).

The TRIPS agreement defines the minimum IPR standards and enables member countries to implement more extensive protection. The minimum standards are however viewed differently by developed and developing countries. While advanced economies (the EU, USA and Japan) perceive the TRIPS agreement as a basic provision for further expansion, it constitutes a ceiling in IPR matters for less developed countries (Pastor: 1).

The TRIPS agreement covers various IPR areas such as patents, copyrights, designs, trademarks, plant varieties and geographical indicators. Pharmaceutical Paragraph 4 of the Declaration on the TRIPS Agreement and Public Health states:

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose" (WTO 2001: 1).

In order to safeguard public health countries are allowed to use the instrument of compulsory licensing. Again the TRIPS agreement reflects flexibilities in the matter as each country can determine its own grounds for granting compulsory licenses. Under this provision the government allows the production of patented drugs without the consent of the owner. This situation is usually in the case of emergency when there is need for fast response and the process of getting approval might be lengthy (WTO 2001: 1).

2 EU Common Commercial Policy

EU trade policy aimed towards third countries differs according to their trade preferential classification. The classification stems from a pyramid structure, where countries on the top are closely linked to the EU, such as accession candidates, who enjoy larger trade preferences rather than countries classified in the lower structure of the pyramid whose trade is based only on the Most Favored Nation (MFN) treatment. Free Trade Areas agreements are situated right in the middle of the pyramid followed by countries granted by the General System of Preferences as in the case of India (Leal-Arcas 2008: 240).

Even though the EU claims to support multilateralism under the WTO as its main objective it also exerts bilateralism. There were two main reasons for this shift in the European trade policy. Firstly, failure of the Doha Development Agenda (DDA) in 2006 halted subsequent multilateral negotiations. Secondly, an active approach of the USA towards a new FTA spurred the EU towards a new strategy embraced in the Global Europe policy report (2006). Global Europe defined a strategy of how to obtain the EU's global competitiveness and set goals for economic policy for the years 2006 through 2010. Hence, new potential partners for FTA are being carefully selected under key criteria including the size of the market, economic growth, existing trade barriers and their negotiations with EU competitors (EC 2006a: 11). With India being one of the countries to have fulfilled the criteria mentioned above, this could be one of the reasons to look at this more in depth. It is a sign of changes, which could help expand the European-Indian market. As a result we are witnessing a shift towards a new generation of north-south FTAs with a focus on developing countries that provide large markets for EU products. The positive effect of bilateral FTAs is supported by Leal-Arcas (2008: 241) who refers to bilateral FTAs as an instrument for liberalizing trade with a "carrot" function providing preferential market access.

The EU's goal for new FTAs is to tackle general areas such as trade in goods and services but also far reaching comprehensive Singapore issues (trade and investment, competition policy, transparency in government procurement and trade facilitation) that were refused at the Doha negotiations by developing countries; requirements

for other non-tariff measures and intellectual property rights (EC 2006a: 10). The importance of strengthening IPR enforcement in future bilateral agreements is specified in section 4.2 of Global Europe. The IPR enforcement strategy reflecting the new challenges is further incorporated in Trade, Growth and World Affairs reports issued by the European Commission in 2010. The EC report is part of the EU's 2020 Strategy, which defines trade policy as its core component. The IPR section stresses the importance of identical IPR protection for FTA partners as in the EU; nevertheless, it also reflects on the development level of a partner country (EC 2010a: 13). According to Karel De Gucht, European Commissioner for Trade, this is the EU's approach to promote itself as a knowledge-based economy. The IPR protection is a tool used to eliminate infringements and to protect its own producers while at the same time maintain its competitiveness. In addition this approach is supported by the European Parliament who also views IPR enforcements as the biggest challenge for EU's internal market (De Gucht 2011: 1–2).

3 EU-India Relations

Modern trade relations between the EU and India have a long tradition, which dates back to the era of colonialism. In its pre-independent period India's main trade partners were Commonwealth countries (54 % of all exports) lead by the United Kingdom (U.K.) constituting 34 % of Indian exports. The U.K. alone also held the highest number of Indian imports at about 30 %. In general, after independence, India remained closely linked to Western Europe, mainly to the European Common Market (ECM) covering 18.2 % of total Indian imports in 1955–56 and at the beginning of the 1960's India tied its diplomatic relations with this regional group (Datt and Sundharam 2006: 741–742). However, with the aim of industrialization, and in order to protect its market, India imposed import duties, import quotas, import licensing and import substitution policies.

Moreover, by the end of the 1960's the share of imports from ECM declined by 8 % in favor of East European Socialist Countries that accounted 18 % of all imports (Datt and Sundharam 2006: 743). Nevertheless, since the 1970's, India has also benefited from the Generalized System of Preferences (GCM) applied by ECM. The very first bilateral agreement between India and ECM dates back to 1973 and resulted in the establishment of the Indian Business Centre in Brussels in 1980 (Giri 2001: 89). Within the next two decades the EU and India concluded several cooperation agreements aiming towards the reduction of duties for particular products, deepening trade relations and simplifying access to India into European market. However, tariffs for sensitive goods still remained considerably high (Woolcock 2007: 5–6, WTO 2010).

Since the collapse of the communist bloc, territories like Western Europe and North America regained their positions among Indian trade partners. The Cooperation Agreement between the European Community and the Republic of India, on partnership and development, played a significant role in trade liberalization and the elimination of trade barriers, which set up a legal base for mutual relations, between the two parties (Datt and Sundharam 2006: 755).

The EU and India have also held yearly summits since the year 2000. One of the two most important summits resulting in further integration was the 5th Summit in the Haag (2004) promoting a mutual relationship to Strategic Partnership. An authorized High Level Trade Group created an FTA study between the EU and India. As a result both counter parties agreed on negotiations regarding a FTA as of 2007 at the Helsinki Summit in 2006 (EC 2006b: 1–2). An end period for conclusion of the EU-India FTA was set for 2009. However, there have still been several open topics such as discussions regarding IPRs, non-tariff barriers (NTB), technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) and others, therefore conclusions were postponed to 2011. Nonetheless, it seems that further delay for 2012 is very likely to occur.

4 TRIPS-plus Negotiations on Pharmaceuticals

As mentioned in section three new EU FTAs incorporate a wider range of topics contrary to former standard FTAs. Proposal of the TRIPS-plus agreement, unacceptable for discussion at multilateral level negotiations, is one of them. Interestingly, Correa (2008: 2) highlights that the European Parliament's Resolution in 2007 on the TRIPS Agreement, and access to medicines, was against the position of the European Commission to seek further TRIPS-plus standards protection for developing countries. Furthermore, article 2.1 of the EU-India draft FTA, as he comments, does not meet the commitments of the Doha Declaration, hence the TRIPS-plus provisions, such as data exclusivity, patent extensions, and limitations on grounds of a compulsory licenses, should be prevented. IPRs for pharmaceuticals belong to the most controversial areas of negotiations. This stems from the EU strategy, included in Global Europe, requiring stronger IPR protection for its trade partners.

There have been two particular areas discussed. First, the extension of the patent period and second the data exclusivity issue. Regarding the patent period, its role is very specific in the pharmaceutical industry due to high research and development costs, a long testing period and associated risks. The TRIPS agreement has set the duration of patents for 20 years from the filing date of the patent application. High costs in research, regulation, commercialization and brand importance are named by Hasenclever and Paranhos (2008: 49) as the main factors contributing to high drug

prices. The EU proposed an extension of 5 years to the granted patent period particularly for the reason of a long testing period (increasing from 20 to 25 years). Thus, on one hand this extension may help pharmaceutical producers generate greater profits from their inputs; on the other hand it would hinder the cheaper generic production. According to Daniele Smadja, the EU's ambassador and head of delegation to India, the patent extension debate was resolved at the beginning of 2011 and the protection of the patent period will remain unchanged (Chatterjee 2011: 1306).

Since the interpretations of Indian patent laws are rather vague and unclear the EU proposed the use of data exclusivity as a precautionary tool to prevent generic drug production in India and thus protect its own producers. Data exclusivity has been one of the thorniest issues negotiated under TRIPS-plus (covering period of approximately 10 years). Data exclusivity provides a protection of clinical test data and results, which are submitted to regulatory authorities in order to provide the safety and efficacy of pharmaceutical products. Therefore, if generic producers wished to produce generic drugs, they would not only have to provide bioequivalence tests and bioavailability tests but also conduct clinical tests. Most likely, this would result to increasing production costs hence higher generic drug prices (Hasenclever and Paranhos 2008: 49). The negative side of proposed data exclusivity may incorporate the inability to use compulsory licenses for drug production in the case of urgent situations with public health, as opposed to patents. Furthermore, this would most likely lead to reduced investments in local generic firms from foreign multinational corporations (MNC) as in Jordan after signing FTA with the USA, according to the Oxfam study (Chatterjee 2011: 1306). Proposed data exclusivity may result in delay or prevention of the registration of generic drugs with a consequence of low drug and price competition. Therefore, firms would have to either carry out their own research and/or wait until the data exclusivity period passes. Nonetheless, negotiations during 2011 have also revealed signs of opposition towards data exclusivity in EU-India FTA.

5 Indian Pharmaceutical Production

The statutes at large of Patent Act 1970 guaranteed the patent process of medicines and pharmaceuticals, among others (Colin 2007: 877). Moreover, the patent period protection was reduced to 5–7 years from the former 16-year patent period. As a result, Patent Act 1970 eliminated India's own research and development of pharmaceuticals but spurred generic production (Colin 2007: 882). India's pharmaceutical exports grew rapidly in the following decades. Between 1970 and 1998 its share in the world's pharmaceutical exports more than doubled (Mukhopadhayal et al. 2010: 341). Nevertheless, the TRIPS agreement from 1995 grants product

patents 20 years. Therefore, India as a signatory to the treaty had to change its law accordingly in effect from 2005. This ten-year delay was tolerated for developing countries, including India, to adjust legislative changes in accordance to TRIPS.

Despite the EU-India FTA negotiations for IPR proposals represented in section five, the major problems in the Indian pharmaceutical industry are second-line drugs that have been protected under the longer TRIPS patent time period (20 years) (AVERT 2010). This approach could eliminate the competition of generic drug producers to that of original drug producers, hence, consequently increase the price of drugs. Such a policy may negatively impact affordable drug availability for poor people in developing countries Even though the WTO introduced voluntary licensing and compulsory licensing methods to avoid the elimination of generic drug production, it might be unlikely that India will adopt these strategies. The reason for this assumption can be seen in the Thai compulsory license policy example which was viewed by foreign pharmaceutical producers as breaching IPR's (AVERT 2010). As a consequence there might be a threat to India stemming from foreign pharmaceutical companies/states who, as a result, may not release newer drugs to the Indian market.

Furthermore, Article 8 in Annex 1c of the TRIPS agreement (WTO 2011b: 5) grants member countries a rather broad spectrum for defining their own rules for the disclosure of patents. India, particularly, actively applies a strict approach when considering the novelty of drugs (Cohen 2007:1). Thereafter, it provides India with a useful tool for the elimination of a number of granted patents subsequently promoting its own generic production.

Today, India's pharmaceutical market is the third largest in the world covering 8 % of global production and supplies India's market with about 70 % of its own pharmaceutical products (PDM 2011). The market is quite well developed and highly fragmented. None of the biggest producer's amount to more than 7 % of the market share (Datamonitor 2010: 12). The market is constituted of 270 large R&D based pharmaceutical companies, 5,600 smaller licensed generics manufacturers and 3,000 companies involved in pharmaceutical production (Market Publishers 2010: 2). This reflects in a low price of generics enabling to cut their prices 40–60 % off the original drug price (Bakthavathsalam 2006: 17). Thus, India is accounted among major drug exporters to developing countries. Table 1 shows the top ten developing countries where India exports pharmaceuticals.

Table 1: India's Pharmaceutical Exports to Developing Countries

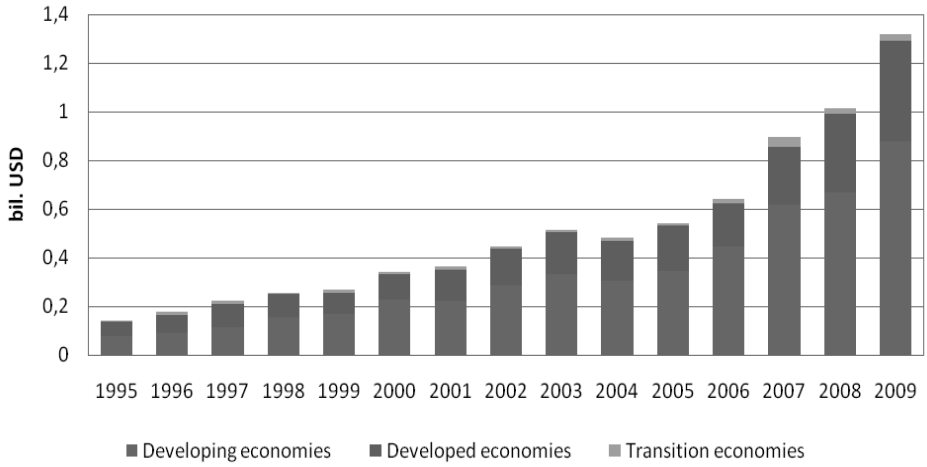
1.	Brazil	5.7%
2.	Turkey	3.3%
3.	China	3.2%
4.	Bangladesh	3.1%
5.	Egypt	3.0%
6.	Thailand	2.7%
7.	Congo	2.7%
8.	Nigeria	2.6%
9.	Viet Nam	2.2%
10.	Iran (Islamic Republic of)	2.2%

Source: UNCTAD database (2010)

As Thach et al. (2009: 251) points out, the Doha Declaration enables developing countries to export products, under compulsory licenses, to the least developed countries which do not have sufficient, or own, drug production and thus cannot solve problems with public health. This may be preceded according to the Indian law even if the compulsory license is granted only to the Indian market. Thus, the Indian legislation can enable quite easily drugs catering to developing countries.

According to the PWC report (PWC 2010: 9), from a global perspective, India is responsible for 20 % of global generic production. India produces 80 % of drugs for HIV/AIDS as well as drugs for cancer and heart disease. The study reveals that 70 % of patients who received medicines from India belong to 87 developing countries (Doctors without borders 2007: 1). Only in Africa, are there more than 2.5 million AIDS patients who rely on generic drug production from India for their treatment. Table 2 represents the evolution of India's exports of medicinal and pharmaceutical products from 1995 to 2009. It is obvious that total exports are rapidly increasing but the increments for developing countries are surpassing those of developed countries, which indicate the increasing importance of Indian drug production and export to developing markets.

Table 2: India's Exports of Medicinal and Pharmaceutical products (1995–2009)



Source: UNCTAD database (2010)

6 Concluding Remarks

The TRIPS-plus agreement negotiations may raise large concerns among the general public both in developing and developed countries. On the one hand, there is the European Commission and some of India's policy makers who support strengthening of the IPR regime and, on the other hand, there is the general public led by public health advocates, civil society groups, non-governmental organizations etc. (Chatterjee 2011: 1305) who are strongly against the agreement. Moreover, negotiations are accompanied by a strong lobby of pharmaceutical MNCs who fight for stronger IPR in order to prolong and maintain payoffs for research and marketing costs. Hence, these negotiations might affect millions of people in the developing world; therefore, they should be clear and transparent. So far negotiations seem to be rather overshadowed by secrecy and held behind closed doors to the public. This non-transparency may cause distrust in EU and Indian politics and negatively impact the role of India as a "cheap pharmacy." Consequently, the effects may result in further legislative and policy changes in India causing unavailability and rising prices for critical drugs. Furthermore, any change under the TRIPS-plus should also be extended to other WTO members under the principal of Most Favored Nations (MFN).

Whilst the aim of WTO is to promote trade liberalization the effect of TRIPS-plus might seem rather contradictory. Implementation of stronger IPRs within new FTAs usually stem from trade-offs in other areas that are important to developing

countries. The unanswered question still remains, whether or not it is justifiable to trade-off strictly trade issues to the "public health." In the case of India, trade-off areas can be technological transfers, geographical indications, or migration issues (Mode 4 of GATS). However, it is also important to note that on the contrary India's strengthening IPR regime would lead to better relations not only with the EU but also with other developed countries. From the TRIPS experience it is proven that such provisions attract more foreign investments and lead towards a more willingness to enable access to these products in regulated markets of the "west." In contrast, there might be a possible threat of Indian pharmaceutical production diversion towards "western lifestyle" drugs. However, there is a big chance that this might not result in a negative supply trend for developing countries since India belongs to them and its aim will most likely be to ensure healthcare for its public which will most likely impact the Indian economy in the future as a whole. Nevertheless, there is no doubt that currently negotiated TRIPS-plus or general EU-India FTA is most likely to be a leading case for other future FTAs between the EU and developing countries, as well as a precedent that can help to push frozen multilateral agreements.

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