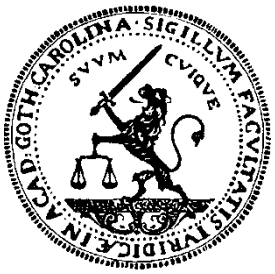

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The Free Trade Agreement between India and European Union and its Implications to Access to HIV/AIDS Medicines

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This thesis is dedicated to my dear parents (Baxodirjon and Fotimaxon) and other family members whose support and kindness made this work possible.

Contents

Summary

This thesis examines how the Free Trade Agreement (FTA) that India is currently negotiating with the European Union (IndEUFTA) may impede the production of Indian generic version of HIV/AIDS medicines and thereby hinder access to HIV/AIDS medicines. The reason for discussing specifically HIV medicines in the context of Indian generic manufacture is important in two ways. First, considering the disasters that HIV pandemic brought while at the same time there are huge cuts in the budget of the major international donors providing access to HIV treatments. Second, Indian generic companies have been contributing their immense role in facilitating access to particularly HIV medicines. The aim is also to show that access to medicines, though subject to some debate, can be claimed as a human right under the umbrella of the right to health and that the IndEUFTA may infringe this right.

The thesis starts with the discussion of approaching access to medicines as a human right under the auspices of the right to health. Then the thesis offers the reader the important role and contribution Indian generic manufacturers have been providing in relation to access to HIV/AIDS medicines by offering low cost good quality generic version of antiretroviral drugs (ARVs). This will help the reader to realize the seriousness of the problem at stake if the Indian generic companies are hindered. Indian pharmaceutical industry has been able to accomplish its advanced generic institutions mainly because from 1970 to 2005 India did not grant patent protection for medicines. This is further explained in detail by looking at the history of Indian pharmaceutical industry.

However, in 2005 India started complying with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and thus was obliged to introduce patent protection for medicines. The introduction of patent rights over pharmaceuticals blocked the production of generics in general and generic version of ARVs in particular to certain extent. The thesis explains how India managed to avoid total obstruction of its generic production by using so called “TRIPS flexibilities”. More importantly for the purpose of this study, the IndEUFTA that India has been negotiating with the EU may bring further hurdle for already constrained Indian generic industry since it contains some provisions which seek even more stringent protection of intellectual property rights (IPRs) than TRIPS. This thesis analyzes strict provisions contained in the IndEUFTA that have been subject to the most of the debates and that may have far reaching impact. Those provisions include data exclusivity, extensions of patent protection term, stringent enforcement of IPRs, and broad scope of investment protection.

The thesis also looks at the experience of other developing countries that entered into FTAs with similar provisions in order to see the impact that those developing countries had on their pharmaceutical industry, particularly in relation to prices of and access to medicines. This will enable to see the real possible effects that the pharmaceutical industry of India may have if such provisions are included in the IndEUFTA. For this purpose, the FTAs that Jordan, Colombia, Peru and Thailand each concluded with the United States of America (U.S.) are discussed.

The IndEUFTA is still under negotiation and there is no clear cut answer as to whether stringent provisions discussed in this thesis will be included in the agreement. However, even assuming that India may not agree for any conditions of the IndEUFTA that may affect its generic production, this study does not lose its value since there are some other even stronger proponents of stricter patent laws, for example like the U.S., that are intending to have an FTA with India. In this sense, this study remains to be helpful so as to aware about the possible implications to access to medicines from FTAs that seek for more rigorous patent protection that India may encounter in the future.

Keywords: access to medicines, free trade agreement, HIV/AIDS, Indian generics, patent tights, stringent IPRs.

Abbreviations

AIDS	Acquired immune deficiency syndrome
ARV	Antiretroviral drug
ColUSFTA	Columbia-US free trade agreement
EU	European Union
FDI	Foreign direct investment
FTA	Free trade agreement
HIV	Human immunodeficiency virus
IndEUFTA	India-EU free trade agreement
IP	Intellectual property
IPO	Indian Patent Office
IPRs	Intellectual property rights
JorUSFTA	Jordan-US free trade agreement
LDC	Least Developed Countries
PerUSFTA	Peru-US free trade agreement
ThaiUSFTA	Thailand-US free trade agreement
TRIPS	Trade related aspects of intellectual property rights
U.S.	United States of America
USD	United States dollar
WTO	World Trade Organization

1 Introduction

"Healing is a matter of time, but it is sometimes also a matter of opportunity"

Hippocrates

1.1 Background

Nobody could expect that several a rare-skin disease, known as *Kaprosi's sarcoma*, that were met in young gay men in New York in 1981 was the start of HIV/AIDS pandemic.[1] Reaching these days there are more than 34 million people currently living with HIV out of which 3.4 million are children under age of 15. Each year at minimum 2 million get the infection while almost similar amount of people die from HIV. For example in 2011 itself 2.5 million people were infected with the disease while 1.7 million people, including 230,000 children being under 15, died in the same year as a result of it. In total the pandemic has taken the souls of 30 million people, almost twice more than the total human death in the World War I, since its start.[2] However, one factor for optimism is that the number of newly infected people has fallen to 21% coming to these days comparing to 1997. One of the main factors for such decline is the increase in the availability of antiretroviral drugs (ARVs)[3][4]. The number of people in low and middle income countries getting HIV treatment has grown from 300,000 in 2002 to more than 6,6 million coming to the end of 2010.[5]

The increase in the availability of ARVs was primarily caused by the global price decrease of ARVs which has taken place owing to the production and provision of low cost good quality generic[6] version of ARVs

[1] Hestermeyer H. P., (2004) *Access to Medications as a Human Right*. Max Planck UNYB 8, p. 103. Last accessed on 19 October 2012, available at: http://www.mpil.de/shared/data/pdf/pdfmpunyb/hestermeyer_8.pdf

[2] amfAR., (2012) *Statistics: Worldwide* [online]. Last accessed on 8 October 2012, available at: http://www.amfar.org/About_HIV_and_AIDS/Facts_and_Stats/Statistics__Worldwide/

[3] UNAIDS., (2010) *2010 Global Report* [online], p.16. Last accessed on 8 October 2012, available at: http://www.unaids.org/documents/20101123_globalreport_chap2_em.pdf

[4] ARVs are medications used for the treatment of HIV. The ARVs do not fully cure the disease but it is essential to keep the level of the virus in the body low and thereby prolong lives and decrease suffering. See, Avert, (2012) *Introduction to HIV and AIDS Drug Treatment* [online]. Last accessed 16 October 2012, available at: http://www.avert.org/treatment.htm#top

[5] UNAIDS, (2012) *The Potential Impact of Free Trade Agreements on Public Health* [online], p. 2. Last accessed on 8 October 2012, available at: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf.

[6] At this stage it is already necessary to understand what a generic medicine means. Usually when a new drug is created, it is further developed, distributed and sold under patent protection and only the patent owner has a right to do this. However, based on several conditions, for example when patent expires, it is possible to copy the branded medicine and produce similar medicine (known as generic version) without investing to a research and development. Therefore, generic version of medicines is comparatively and usually considerably cheaper than branded version. A generic medicine is similar to a brand name in "dosage form, safety, strength, route of administration, quality, performance

by Indian generic companies. In 2001 HIV treatment using patented version of ARVs cost patients USD 10,439 per year and with the introduction of Indian generic version of ARVs the price dropped to USD 350 per annum (*i.e. almost 30 times drop*) in the same year. At the same time, 80% of ARVs bought by low and middle income countries originate from India making it truly be 'the pharmacy of developing world'. Indian local pharmaceutical companies were able to achieve these results primarily because India from 1970 until it implemented TRIPS in 2005 did not recognize patent protection over pharmaceutical products. The absence of patent protection over pharmaceuticals resulted in the foundation of numerous generics based pharmaceutical companies and the escalation of generic production. Even after starting to grant patent protection to medicines from 2005, India was able to some extent retain its local generic production using some particular legislative and policy options towards patent rights. However, for the last five years India has been negotiating a Free Trade Agreement (FTA) with the European Union (EU)[7] and some provisions of the FTA proposed by the EU may have some significant impact to Indian pharmaceutical patenting and by this to production of Indian HIV generics. Such provisions include the extension of patent protection term, data exclusivity, stringent enforcement of patent rights, and broad scope of investment protection.

1.2 Research question

The main research question of this paper which I intend to answer is:

'What legislative changes the Free Trade Agreement between European Union and India may bring to India's patent law and how such changes may hinder India's generic production and thereby access to AIDS medicines?'

I think bearing in mind the vital importance of life saving AIDS generic medicines produced by India that are creating an access huge number of people, especially the poor, it is important to study this question and to be aware of the results that it brings. The conclusion of the FTA has been much delayed than originally planned and both parties intend to finally adopt it by the end 2012. There are several factors causing such delay including rigorous negotiations in the field of IPRs. The EU has been pushing hard to include stronger rules in relation to IPRs, which are discussed later in this thesis, while India has been resisting. Even assuming that India may not agree for some or even any conditions of the FTA that may affect its generic production and which are discussed in this thesis, this study does not lose its value since there are other FTAs that India may face in the future with even stronger proponents of stricter patent laws like, for example, the U.S.. Therefore, this study retains its merit so as to aware about the possible implications to access to medicines created by the FTAs seeking for stronger patent protection, if they especially concern India.

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characteristics and intended use". See, FDA, (2009) *What Are Generic Drugs?* [online]. Last accessed on 27 October 2012, available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm

[7] In later discussions the FTA between India and the EU is referred as IndEUFTA.

1.3 Objective and methodology

Basically, the purpose of the whole thesis is to show how the role of Indian generic manufacturers as facilitator of access to HIV/AIDS medicines through its production of generics is being jeopardized through IndEUFTA and what consequences it might bring to access to HIV medicines. The importance of Indian generic manufacturers is introduced and discussed to expose and highlight the critical important role that Indian generic manufacturers and Indian pharmaceutical industry in general have been playing in facilitating access to HIV/AIDS medicines through its production and provision of generics both in national and international levels. These HIV generics has so far prevented new infections and at the same time prolonged the lives of millions affected by the disease. This has been true especially for those who are not able to afford patented version of the medicines. The thesis also presents a reader the background of Indian pharmaceutical industry. By this it is aimed from to demonstrate how India was able to achieve such sophisticated and highly advanced pharmaceutical industry while still being amounted as "third world country" whereas its other alike partner countries have not attained such progress. In these discussions it is also intended to show how India's production of low cost high quality generics have been already affected due to ratchet up patent laws, mainly since the implementation of TRIPS in 2005. Then the thesis turns the attention of the reader to the main objective of the paper which is to analyze possible changes to Indian patent system from the FTA and its further negative effects on Indian HIV/AIDS generics production and consequent access to such generics. I will involve some empirical analysis through discussing the impacts that some developing countries had to their pharmaceutical sectors and access to medicines within their borders as a result of their free trade agreements. This exercise is done so as to draw some relevant conclusions from the actual experience of other countries for the case of the IndEUFTA. Although the EU has signed FTAs with a number of developing countries, there are no studies available about what consequences in regards to medicines those FTAs brought to those developing countries. On the other hand, there were some comprehensive studies done in relation to implications on access to medicines and pharmaceutical sector as a whole from the FTAs that Jordan, Colombia, Peru and Thailand each signed with the U.S.. The fact that these FTAs contain provisions similar to those contained in the IndEUFTA allows using them as a precedent case for India to demonstrate its possible condition after the conclusion of its FTA with the EU.

In answering my research question my sources will mainly derive from scholarly articles, reports of international organizations and NGOs, interviews and letters of communication with policy makers and other interested groups like pharmaceutical companies.

1.4 Structure

Chapter 1 offers general background of the situation. In particular, it shows the horrifying situation of HIV/AIDS pandemic and briefly describes the role of Indian generic medicines in the fight against the pandemic. Chapter 2 analyzes access to medicines from human rights perspective. In particular,

right to health, internationally recognized fundamental human rights, will be used as the right overarching access to medicines. The aim from this exercise is to show that there can be some strong claims against the impediment for the production of Indian generic for the treatment of HIV. Chapter 3 will present the importance of India's pharmaceutical industry for the purpose mentioned in the previous section. Chapter 4 will study India's pharmaceutical industry for the reason mentioned in the previous section. Chapter 5 analyzes the IndEUFTA in detail. The discussion starts with general background of the IndEUFTA and the main motives for having it (sub-chapter 5.1). By this it will discuss the main benefits sought by each party from having such agreement which will help the reader to understand the reason why India got involved into such agreement even at the possible risk of its generics production. Then in sub-chapter 5.2 the thesis turns its focus to the legislative changes that IndEUFTA may bring to patent system of India and how each change may affect generic production and by this to access to HIV/AIDS medicines. In sub-chapter 5.3 it is intended to use empirical study by looking into already existing FTAs between the U.S and afore mentioned countries for the reasons mentioned in the prior section. In the final part of the Chapter 5, I will discuss what conclusions in terms of India's generic production and access to HIV medicines can be made from all made analysis and other studies in relation to the IndEUFTA. Finally, in Chapter 6 I end up with certain conclusions and recommendations.

2 Defining Access to Medicines - Human Rights Approach

First of all it is necessary to point that there is no explicit right as right to access to medicines. Therefore, in order to approach the access to medicines from human rights perspective it is necessary to address to the right to health as an overarching right. The right to health is both explicitly and implicitly recognized in several international and regional human rights instruments.[8] However, this study will examine right to health as it is enshrined in the ICESCR for two basic reasons. Firstly, considering recognized international solid status of the document as an international human rights document[9] and secondly considering the comprehensive interpretation that the document so far achieved[10]. Right to health is formulated in Article 12 of the ICESCR which specifically reads as following:

> "1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
> …
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

[8] Health is seen in the Universal Declaration of Human Rights (1948), in its Article 25, as a part of the right to an adequate standard of living. Even more, the right to health is explicitly recognized as a human right in Article 12 of International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966). Moreover, right to 'the enjoyment of the highest attainable standard of health' is regarded in the Constitution Preamble of World Health Organization (WHO) as 'one of the fundamental rights of every human being'. The right to health is also accepted as a human right in a number of regional human right treaties such as European Social Charter (1961), African Charter on Human and Peoples' Rights (1981), and Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (the Protocol of San Salvador) (1988).

[9] For the time being 160 countries, which represents 83% of the world, ratified and recognized the rights enshrines in the Covenant as human rights. See, United Nations Treaty Collections at: http://treaties.un.org/Pages/ViewDetails.aspx?chapter=4&lang=en&mtdsg_no=IV-3&src=TREATY Last accessed on:

[10] A treaty body, namely the Committee on Economic, Social and Cultural Rights (CESCR), is appointed to monitor the implementation of the ICESCR. The body is comprised from the group of independent experts that so far issued 21 General Comments which in detail interprets 17 different rights, including right to the highest attainable standard of health, enshrined in the Covenant and clarifies other subject matters. Although General Comments issued by UN treaty bodies do not have binding force upon Member States, many commentators believe that they have 'considerable legal weight'. They argue that treaty bodies are the most authoritative interpreter of the covenants in subject and thus Member States cannot simply ignore their interpretations even if they do not agree with such interpretations. Some commentators even suggest that General Comments are 'authoritative interpretations'. Moreover, General Comments can also serve as a tool to create customary international law by facilitating formation of *opinion juris* and state practice. See, Mechlem K., "Treaty Bodies and the Interpretation of Human Rights", *42 Vand. J. Transnatl L.*, Vol. 42, no. 905 (2009), pp. 929-930.

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

Some implications in relation to medicines can be drawn from the list of steps that the article demands from Member States to take for the realization of the right to health. In particular, Article 12 (2) (c) and 12 (2) (d) demand from a State "[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness". The accomplishment of these tasks obviously points to the necessity and importance of access to medicines. However, the language used in the article is not clear enough to give guidance as to the specific entitlements that the right to health confers to individuals as well as no specification as to the scope of states' obligations under the right. Taking into consideration such vagueness and the need for interpretation of the article, the CESCR adopted General Comment No. 14[11] directed to the clarification of the article.

The General Comment 14, on the other hand, in detail explains the scope and meaning of the right to health. The CESCR interprets the right to health as an inclusive right extending not only to timely and appropriate health care, but also to "the underlying determinants of health".[12] By underlying determinants of heath the CESCR enlist detriments such as "safe and potable drinking water and adequate sanitation facilities … and *essential drugs*[13], as defined by the WHO Action Programme on Essential Drugs" (emphasis added). Moreover, the CESCR mentions that there are four "interrelated and essential elements" of right to health, namely availability, accessibility, acceptability, and quality. These four elements, as defined by the CESCR, relate to (i.e. availability, accessibility, acceptability, and quality of) health facilities, goods and services plus the underlying determinants of health. So in this sense, the essential drugs must, first, be "available in sufficient quantity within the State party". Second, the essential drugs "have to be accessible to everyone without discrimination" at the same time to be physically and economically accessible. Third, the essential drugs "must be respectful of medical ethics and culturally appropriate" and fourthly, they must be "scientifically and medically appropriate and of good quality". [14] Among these four elements, the economic accessibility of essential drugs requires more attention for the purpose of this study. In defining economic accessibility CESCR stated that:

[11] Committee on Economic, Social and Cultural Rights, *General Comment No. 14 on the right to the highest attainable standard of health,* 11 August 2000, UN Doc. E/C.12/2002/11

[12] *Ibid*, para. 4.

[13] By essential drugs it refers to, as defined and listed by WHO, 'medicines that satisfy the priority health care needs of a population'. The list of such medicines is created by WHO considering 'disease prevalence, evidence of efficacy, safety, and comparative cost-effectiveness'. See, WHO, (2010) *Medicines: Essential Medicines* [online], fact sheet no.325. Last accessed on 8 October 2012, available at: http://www.who.int/mediacentre/factsheets/fs325/en/index.html

[14] See, para. 12 of the General Comment.

> "health facilities, goods and services[15] must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, *are affordable for all*, including socially disadvantaged groups. Equity demands that *poorer households should not be disproportionately burdened with health expenses as compared to richer households*;" (emphasis added)[16]

In this sense, Member States, India in our case, should make sure that essential drugs are economically accessible and that poorer people are not excessively burdened in order to ensure their general right to health.

Another aspect to be noted in relation to the General Comment 14 is that it places an obligation on Member States to provide only "essential drugs". As explained above WHO defines essential drugs to be those that "satisfy the priority health care needs" of people. Considering the essential and life saving function that HIV medicines carry, it is no doubt that they satisfy this criterion. Besides, the list of essential medicines composed by the WHO itself includes a number of drugs against HIV.[17] So in this way, certain drugs against HIV are regarded as "essential drugs" and thus reference to essential drugs in the General Comment also refers to HIV drugs.

The above discussion shows the essence of access to medicines, including HIV medicines, in the realization of right to health. But question arises, what does this mean for Member States who are the main actors in the realization, or at least facilitation, of the entitlements, including access to medicines, under the right to health? Are Member States under obligation to ensure the access to essential drugs? Well, the CESCR in its General Comment 3 stated that there are certain core obligations upon states to be fulfilled in order to ensure that at least minimum essential levels of rights contained in the ICESCR are realized.[18] In applying this interpretation in conjunction with Programme of Action of the International Conference on Population and Development (the Alma-Ata Declaration) to the right to health, the CESCR found that there are certain core obligations imposed on State Parties emanating from the right to health. In accordance to one of these core obligations, the states are expected to provide with essential drugs.[19] States are also expected to design a reasonable action program and all other appropriate measures, including legislative measures, vectored towards full realization of the right to health. A state can be deemed to be

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[15] By health facilities, goods and services the CESCR also implies essential drugs because the explanatory footnote (no. 6) of the General Comment, it states that 'any reference in this general comment to health facilities, goods and services includes the underlying determinants of health'. As mentioned above, the underlying determinants of health include essential drugs.

[16] See, para. 12 (b) of the General Comment.

[17] The last updated list of such medicines comprises from more than 350 different medicines including medicines against the disease like 'malaria, HIV/AIDS, tuberculosis, reproductive health and also chronic diseases, such as cancer and diabetes'. See, WHO, *supra* note 13.

[18] Committee on Economic, Social and Cultural Rights, *General Comment No. 3 on the nature of States parties obligations (Art. 2, par.1)*, 14 December 1990, UN Doc. E/1991/23, para. 10.

[19] General Comment No. 14, *supra* note 11, para. 43 (d).

under breach of its obligation if it, for example, adopts certain laws and/or policies that would impede the realization of the right to health and its underlying determinants.[20] This implies that the India might be in a violation of its obligations if it allows the impediment to access to medicines, to HIV medicines in the case of this study, by having its FTA with the EU. Furthermore, like with other human rights, the states are under obligation to respect, protect, and fulfill the right to health. Under the obligation to respect the states must not interfere with the right to health and must not allow discriminatory practices in relation to the right.[21] It was claimed that the adoption of, for example, patent laws might be a violation of the obligation to respect since it increases the prices of medicines and thus hinders the economic accessibility of drugs.[22] Analogy can be drawn from this for the case of India and be argued that India would fail its obligation to respect in the case if the prices to HIV drugs rise above economic accessibility as a result of IndEUFTA.

All in all, above discussions demonstrate that access to medicines, though implicitly, is mentioned in Article 12 of ICESCR. Moreover, as described by CESCR essential medicines, including HIV medicines, are deemed to be underlying detriment of the right to health and thus can be deemed as a right and be claimed under auspices of the right to health. Moreover, in order for states to discharge their obligation under Article 12, they must ensure that, at least, essential medicines are economically accessible and that no improper legislative measures impeding the access to medicines are in place.

[20] Hestermeyer H. P., *supra* note 1, p. 133.
[21] General Comment No. 14, *supra* note 11,, para. 34.
[22] Yamin A. E., "Not just a Tragedy: Access to Medications as a Right under International Law", *B.U. Int'l L. J.,* Vol. 21, no. 325 (2003), p. 353.

3 The Importance of Indian Generic Manufacturers

It is important to know both local and global contribution of India's generic manufacturers in facilitating access to HIV/AIDS medicines in order to understand and realize the extent of their importance and possible negative consequences for such access from some stringent provisions of IndEUFTA. The successful development of India's pharmaceutical industry has not only been beneficial for India's economy, but more than that it has been meeting the demands of patients in many developing countries and *ipso facto* stimulating access to medicines to substantial number of people inhabiting in those countries. To begin with, one of the most impressive achievements of Indian produced HIV/AIDS generic medicines is how they caused colossal drop in the prices of ARVs. In 2001 AIDS treatment through patented ARVs cost patients USD 10, 439 per year and with the introduction Indian generic ARVs the price dropped to USD 350 per annum (*i.e. almost 30 times drop*) in the same year. And even more impressive is that coming to 2011 the prices of ARVs dropped to USD 99 per year (*i.e. 100 times drop*) for a patient.[23] The price of the most frequently applied first-line adult regimen decreased from USD 414 per annum in 2003 to USD 74 per annum in 2008 as a result of generics produced in India.[24] Significant price drops owing to Indian generics 'have been instrumental' in the global fight against HIV in the past decade. The number of people in low and middle income countries getting HIV treatment has grown from 300,000 in 2002 to more than 6,6 million coming to the end of 2010.[25]

Furthermore, a study conducted in 2010 revealed that at least 80% of ARVs bought by low and middle income countries originate from India and 91% of global paediatric ARVs were provided similarly by Indian generic manufacturers.[26] The number of Indian generic companies providing with ARVs to low and middle income countries increased from 4 in 2003 to 10 in 2008 and at the same time the variety of ARVs provided by Indian generic firms increased from 14 to 53 during the same period (i.e. 2003 - 2008).[27] Developing countries, especially countries in sub-Saharan Africa where HIV burden is high, including India itself are heavily reliant on the generic ARVs produced in India in order to sustain the national treatment programs that they have.[28] Small examples are national treatment program in

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[23] Selvaraj S. and Nabar V., *Access to Medicines in India: Issues, Challenges and Response* [online], p. 91. Last accessed on 8 October 2012, available at: http://www.hlegphfi.org/uploads/IHR_ch_06.pdf

[24] Waning B., *et al*, "A Lifeline to Treatment - the Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries", *Journal of the International AIDS Society*, Vol. 13, no. 35 (2010), p. 4.

[25] UNAIDS (2012), *supra* note 5.

[26] *Ibid.*

[27] Chakravarty. S., (2010) *India supplies 80% of AIDS medicines to developing countries* [online]. Last accessed on 8 October 2012, available at: http://www.indiapost.com/india-supplies-80-of-aids-medicines-to-developing-countries/

[28] Waning B., *et al*, *supra* note 24, p. 5.

Zimbabwe which gets its 90% of ARVs from Indian generic producers while NDSO, the state procurement agency in Lesotho, gets 95% of its ARVs medicines.[29]

Apart from bringing such revolutionary change in the global price for ARVs, Indian generic manufacturers were also successful in decreasing the prices in the local markets as well. At the beginning of ARVs provision in Indian markets the price of it was USD 8,500 per annum. However, the Cipla's, one of the biggest Indian generic manufacturers, launch of HIV drugs like Zidovudine, Stavudine, Lamivudine and Nevirapine in 1993 boosted competition and caused substantial drops in the prices. In 2001Cipla offered full package of ARVs for USD 600 to Indian consumers.[30] Another interesting feature is that, ironically enough, the US although being one of the strongest proponents of strong patent regimes, largely benefits from Indian produced generics. The US consumers are considered to be the biggest beneficiaries, in value terms, from the generics produced in India.[31]

Furthermore, Indian generics are the main source to the major global treatment programs. United Nations Children's Fund (UNICEF) takes 50% of its essential medicines from Indian generics manufacturers to distribute them in developing countries while 75-80% of generic medicines used by International Dispensary Association (IDA)[32] similarly for distribution in developing countries originate from India as well. Even more, Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund)[33], the major

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[29] MSF, (year of publication is not available) *Examples of the Importance of India as the "Pharmacy for the Developing World".* Last accessed 8 October 2012, available at: http://www.doctorswithoutborders.org/news/access/background_paper_indian_generics.pdf

[30] Gerster R., *People before Patents. The Success Story of the Indian Pharmaceutical Industry* [online], p. 3. Last accessed on 8 October 2012, available at: http://www.medicusmundi.ch/mms/services/bulletin/bulletin200201/kap02/13gerster.html

[31] Kapczynskiti A., "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *Cal. L. Rev.*, Vol. 97, no. 1571 (2009), p. 1582. In 2005, approximately 63% of all dispensed prescriptions in the US were generic drugs and normally the prices of generic drugs were between 30 to 80% cheaper than their branded versions. See, Greene W., (2007) *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market* [online], p. 22. Working Paper No. 2007-05-A, Office of Economics of the U.S. International Trade Commission. Last accessed on 19 October 2012, available at: http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf. Another example of the U.S. consumption of Indian generics is the PEPFAR, the US President's AIDS initiative, which buys ARVs produced by India generic companies for distribution in developing countries. This in its turn enabled PEPFAR to save up to 90% of costs. See, MSF, *supra* note 29.

[32] IDA Foundation was founded in 1972 by a small group of pharmacists and now it became one of the leading global noon-profit organizations supplying affordable pharmaceutical products. Coming to these days, IDA Foundation distributes more than 3000 different kinds of medicines and medical supplies to over 100 countries around the world. This information is available the official website of the IDA Foundation: http://www.idafoundation.org/we-are/our-history.html (Last accessed on 9 October 2012).

[33] The Global Fund is 'public-private partnership and international financing institution dedicated to attracting and disbursing additional resources to prevent and treat HIV and AIDS, TB and malaria… Since its creation in 2002, the Global Fund has become the main financier of programs to fight AIDS, TB and malaria, with approved funding of US$ 22.9 billion for more than 1,000 programs in 151 countries. To date, programs supported by the Global Fund have provided AIDS treatment for 3.6 million people…'The information is

international provider of AIDS treatment, buys 80% of its AIDS medicines from Indian generic suppliers.[34] At the same time, Indian generic account for 80% of ARVs that MSF uses to treat 170,000 people living with HIV around the developing world.[35] UNITAID[36], another major global actor in fighting against HIV, informs that it has been able to provide markets both with pediatric and second-line drugs in 50 countries largely owing to Indian generic suppliers.[37]

Overall, medicines provided by Indian generic suppliers play undeniably significant role in facilitating access to HIV medicines and fighting against the disease. Therefore, any possible curtailment of this role must be avoided. This also explains the reason why IndEUFTA has attracted such considerable attention of different actors. Numerous organizations including civil societies, people living with HIV (PLHIV) networks, HIV & public health organisations, medical organisations, public interest advocates, and individuals joined their effort to raise their concerns in relation to IndEUFTA. One example is that, 240 organizations of the kind mentioned and 38 individuals jointly formed the letter of appeal sent the Indian Prime Minister, Manmohan Singh, urging not trade away the lives of millions by accepting certain intellectual property (IP) provisions, later discussed in this thesis, in the IndEUFTA and to make sure that generic competition is kept.[38]

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taken from the official website of the organization, http://www.theglobalfund.org/en/about/whoweare/ (Last accessed on 9 October 2012).

[34] MSF, (2011) *Access: Indian Prime Minister Must Resist European Pressure to Trade Away Health* [online]. Last accessed on 9 October 2012, available at: http://www.doctorswithoutborders.org/press/release.cfm?id=4965

[35] MSF, *supra* note 29.

[36] UNITAID is a global health initiative founded in 2006 by the governments of Brazil, Norway, Chile, France and the United Kingdom with an to increase access to medicines in 94 low and middle income countries. See, FTA Malaysia, (2012) *UNITAID Warns against Measures to Restrict Access to Medicines in EU-India FTA* [online]. Last accessed on 9 October 2012, available at: http://www.ftamalaysia.org/article.php?aid=265

[37] *Ibid.*

[38] DNP+, (2010) *Re: India's central role in medicines supply is under threat. Don't sign on to intellectual property provisions in the India-EU FTA* [online]. Letter to Dr. Manmohan Singh, Prime Minister's Office. Last accessed on 20 October 2012, available at: http://donttradeourlivesaway.files.wordpress.com/2010/10/letter-to-pmo.pdf .

4 India's Pharmaceutical Industry

Pharmaceutical industry in India plays one of the major roles in Indian economy and at the same time it is one of the fastest developing sectors of manufacturing in India with the growing rate of 14% per year. With such trends India is deemed to have one of the biggest and highly advanced pharmaceutical industries among developing countries.[39] Nowadays India with its massive production of drugs, most of which are generics, is on the fourth place in the world in terms of the volume of production which amounts to 8% of global market share.[40] In terms of sales of drugs India is ranked in fourteenth place in the world, but according to the results of a yearlong study on the future of India's pharmaceutical industry, India is predicted to become among the top ten already by 2015.[41] Furthermore, Price Water House Coopers predicts that in near future, specifically by 2020, Indian sales of medicine will have 163% grow and will reach around US$ 50 billion comparing to only US$ 19 billion in 2009.[42] Furthermore, the pharmaceutical industry is so developed that it offers an employment to five hundred thousand people in around 12,000 pharmacy oriented companies and it is also planned to provide with 2,5 million further employments working in before and after production processes.[43] These all are very astonishing trends and achievements comparing India's pharmaceutical history since before the Second World War "there was virtually no [even] basic drug manufacture" in India.[44] The dramatic change in the story of India's pharmaceutical industry took place starting from 1970s and only during the past 30 years the industry has advanced from "almost nonexistent to a world leader" producing generics with high quality.[45] It is quite interesting, if not surprising, to see achievements of such rapid growth and advancements by India, so-called "third world country", especially in the sector of pharmaceuticals where aggressive competition is present and where major players are mainly comprised from

[39] Corporate Catalyst India, *Report - India's Pharmaceutical Industry* [online], para. 1.2. Last accessed on 8 October 2012, available at: http://www.cci.in/pdf/surveys_reports/indias_pharmaceutical_industry.pdf

[40] Pannu, H.S. *et al*, "Efficiency and Productivity Analysis of Indian Pharmaceutical Industry Using Data Envelopment Analysis", *Int. J. Operational Research*, Vol. 10, No. 1 (2011), p.122.

[41] Kumra G., Mitra P. and Chandrika P., *India Pharma 2015 – Unlocking the Potential of the Indian Pharmaceutical Market* [online], p. 11. Last accessed on 8 October 2012, available at: http://www.mckinsey.com/locations/india/mckinseyonindia/pdf/india_pharma_2015.pdf

[42] Price Water House Coopers (2010), *Global pharma looks to India: Prospects for growth* [online], p.5. Last accessed on 8 October 2012, available at: http://www.pwc.com/en_GX/gx/pharma-life-sciences/pdf/global-pharma-looks-to-india-final.pdf

[43] Gerster R., *supra* note 30, p. 3.

[44] Hamied Y.K., (2005) *Indian Pharma Industry: Decades of Struggle and Achievements* [online], p.3. Last accessed on 8 October 2012, available at: http://www.arvindguptatoys.com/arvindgupta/avra-hamied.pdf

[45] Greene W., *supra* note 31, p. 1.

industrialized countries with advanced economies.[46] In its turn, there arises a question as to how India was able to reach its current position and in such a short period of time whereas its other alike partners have not demonstrated such progress. It is believed that the main locomotive bringing India's pharmaceutical industry to current stage links to the fact that until 2005 India explicitly, specifically by its 1970 Patents Act, used to exclude patent protection over medicines which gave huge boost to the industry through opening up robust competition.[47] So as to understand more on how this legislative alteration benefited India and brought historical change for India's pharmaceutical history, the sub-chapter 4.1 looks at the historical relation of patent protection with and its effects to the Indian pharmaceutical industry. Next, sub-chapter 4.2 examines TRIPS Agreement in Indian context. This sub-chapter further describes how Indian government by using certain "innovative" political and legislative tools was able to avoid its generic industry from being fully blocked. Despite of India's innovativeness, its generics industry has anyway experienced certain barriers and this is explained in more detail section 4.2.2.

4.1 Historical preview of India's pharmaceutical industry

It is interesting but at the same time helpful to observe history of Indian pharmaceutical industry since it may teach the way India took in accomplishing the status of being one of the dominant countries in the sector of pharmaceuticals. The history of Indian pharmaceutical industry has been highly influenced and colored by the active involvement of the Indian government which aimed to achieve self sufficient pharmaceutical industry through organizing and creating conditions which could best suit India's condition. History rich with intensive changes and interventions can be basically demonstrated in three stages. First is the period when India was under British colony until it got its independence on 1947, second is the post-independence period until the implementation of TRIPS Agreement on 2005 and the last is from 2005 until nowadays.

4.1.1 Pre-independence period

It is necessary to note that India had never had the notion of patent protection throughout its history until it was colonized by Britain. The first introduction of this notion started with the introduction of patent laws enshrined in the Indian patent statue of 1856 which reflected British Patent Law of 1852. The goal from the implementation of the statute was "to

[46] The pharmaceutical industry is a large market with 8% growth rate and with huge capital circulation having around annual turnover of USD 650 billion. The competition is this sector of business is accompanied with rigorous competition especially for pharmaceutical companies from developing countries. The market is mainly dominated by companies established in highly industrialized countries. 48% of the global share is owned by the U.S. companies, 28% by the EU and 12% by Japan and only 20% by the rest of all countries, including India. See, Kiran R. and Mishra S., "Performance of the Indian Pharmaceutical Industry in Post- TRIPS Period: A Firm Level Analysis", *International Review of Business Research Papers*, Vol. 5, no. 6 (2009), p. 1.

[47] Hamied Y.K., *supra* note 44.

enable the English Patent holders to acquire control over Indian markets"[48] whereas some other experts claim that the purpose was just to make the patents granted in England to be enforceable in India.[49] The initial evolution of Indian indigenous pharmaceutical companies started in 1910 with the launch of two local companies, Bengal Chemicals and Pharmaceutical Works and Alembic Chemicals. However, at that period the market was still mainly controlled by multinational companies importing bulk pharmaceutical products from foreign lands.[50] In 1911 Britain enacted Indian Patents and Designs Act (1911 Patent Act) which conferred patent protection for both pharmaceutical products and process of their creation. This Act was seen as a main obstacle confronting Indian local companies from entering the market.[51] At those times India was experiencing development of some industries like steel while pharmaceutical sector was still underdeveloped since multinational companies were able to make successive use of 1911 Patent Act and did not to allow production of foreign drugs by local Indian companies.[52]

4.1.2 Post-independence period

In 1947 India got its independence from Britain which meant that India from then on could prioritize the interest of its own people, companies, market and domestic conditions in general. At the time of independence India did not have even basic pharmaceutical production let alone self sufficient pharmaceutical industry and the local companies were only limited by mere packaging and bottling of drugs.[53] Moreover, despite of the independence the market was still monopolized by foreign drug companies setting unaffordable prices and 99% of Indian drug patents were owned by foreign companies. The government witnessing high prices of drugs and stunned technical possibilities of local drug companies decided to bring changes to the situation. Establishment of two public drug companies, Hindustan Antibiotic Ltd in 1954 and The Indian Drugs and Pharmaceutical Ltd, was the major step undertaken by the government to support the local production of essential drugs with a hope to avoid foreign dependency. Moreover, Indian government tried to make multinational companies to establish their production bases within India itself. However, these attempts turned to be unproductive and India still remained helpless without drugs

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[48] Mueller J. M., "The Tiger Awakens: The Tumultuous Transformation of India 's Patent System and the Rise of Indian Pharmaceutical Innovation", 97 *Cal. L. Rev*. Vol. 68, no. 491 (2007), p. 506.

[49] Pillai M. *et al* (2010), *Patent Procurement in India* [online], p. 2. Last accessed 8 October 2012, available at: http://www.ipoef.org/AM/Template.cfm?Section=Programs&Template=/CM/ContentDisplay.cfm&ContentID=15238

[50] EXIM Bank, (2007) *Indian Pharmaceutical Industry: Surging Globally* [online], p. 47. Occasional Paper No. 119. Last accessed on 19 October 2012, available at: http://www.eximbankindia.com/op/oplast.pdf

[51] *Ibid.*

[52] *Ibid.*

[53] Sahu S. K, (1998) *Technology Transfer, Dependence, and Self-Reliant Development in the Third World: the Pharmaceutical and Machine Tool Industries in India*. India: Praeger, p. 55.

brought from outside.[54] Therefore, Indian government after realizing that it would be impossible to bring effective changes within existing patent law system, the government decided to bring major changes to the whole system which would be reflecting national interests. With this intention there were consecutively appointed two committees of experts mandated to fulfill the task. In 1950 the first committee, headed by Indian Supreme Court Justice Bakshi Chand, composed a report, later named as Chand Report, stating that India's then existing patent system was unable to "stimulate invention and encourage exploitation of new inventions for industrial remedies".[55] As a remedy the report called the government to make effective use of compulsory licenses. Though compulsory license clauses contained in 1911 Patent Act were amended, it did not bring wanted results to some extent because of the fact that patent owners were still able to oppose and appeal the issuance of compulsory licenses. Ineffectiveness of changes that were introduced based on the first report engendered the issuance of the second report in 1959 by the second committee headed by retired Indian Supreme Court Justice Rajagopala Ayyangar (also known as Ayyangar Report). This latter report is seen as "the most important catalyst for [1970] Patents Act" and as "form[ing] the backbone of the Indian patent system".[56] The Ayyangar Report urged to undertake fundamental amendments to the existing patent system and pointed similar views with the first report about the ruling patent system of that time i.e. its failure to stimulate invention and exploitation of new technological inventions. The committee in the report observed that patent could bring benefits only for the system with advanced economy that possesses "a large capital available for investment in industries and a high degree of scientific and technological education" whereas those benefits could not be similarly accomplished in under developed countries like India.[57] Therefore, the report advised that the national patent system "[has] to be designed, with special reference to the economic conditions of the country, the state of its scientific and technological advance, its future needs and other relevant factors … so as to minimize if not eliminate the abuses to which a system of patent monopoly is capable of being put". [58] As a remedy for the situation the report suggested to exclude medicines from patentability so as to create access to medicines for the public at affordable prices. Furthermore, it is also very crucial to highlight that the Ayyangar Report was putting emphasis on the fact that at those times the exclusion of medicines from patentability "was the *accepted practice ... in virtually every* European country" [emphasis added].[59][60]

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[54] EXIM Bank, *supra* 50, p. 47.
[55] Mueller J. M., *supra* note 48, pp. 510-11.
[56] *Ibid*, p. 511
[57] Park C. and Jayadev A., (2009) *Access to Medicines in India: A Review of Recent Concerns* [online], Working Paper, p. 4. Last accessed on 8 October 2012, available at: http://ssrn.com/abstract=1436732
[58] *Ibid.*
[59] *Ibid.*
[60] For instance, Switzerland, one of the strongest supporters of intellectual property rights over medicines in European arena, introduced patent protection over medicines only starting from 1978. See Gerster R., *supra* note 30.

The recommendations of Ayyangar Report, most importantly exclusion of medicines from patentability, were ultimately incorporated in 1970 Patent Act. In particular, the Act stated that patents shall not be granted for "inventions claiming substances intended for use, or capable of being used ... as medicine or drug" and only "claims for the methods or processes of manufacture shall be patentable".[61] In other words, the drugs or medicines as such could not be patented and only the process of making them could be patented. This rule enabled Indian pharmaceutical companies to produce generics of patented medicines by merely changing some steps in production process and by this to outstrip patented production processes without violating them. Initially after implementation of 1970 Patents Act which excluded medicines from patentability, there was a concern that this law would stop multinational companies from offering new molecules to India which may hinder Indians' access to necessary medicines. On contrary, India owing to some factors like the government's initial financial support to the pharmaceutical laboratories, facilitated Indian companies to advance their own technical and technological expertise. As a result Indian pharmaceutical companies started to "successfully reverse engineer virtually every viable drug produced".[62] Moreover, it also engendered reduction of Indian market share of multinational companies from over 60% in 1970 to around 25% in the early 2000s.[63] Furthermore, coming to 1999 70% of active pharmaceutical ingredients and 80% of formulations were locally produced which titled India as "possibly the only developing country in the world that has come this close to achieving so-called self-sufficiency in medicines".[64] In addition to the benefits brought to India itself such successful "generics-friendly patent system" of India in the long term "has become far-and-away the developing world's primary supplier of inexpensive, life-saving medicines, including first-generation ARV treatments".[65]

All in all, starting from 1970s the pharmaceutical history of India experienced impressive breakthrough firstly by fulfilling major part of local needs for medicine, which is itself sufficiently remarkable achievement considering huge population of India and secondly by meeting medical needs of third countries.

4.1.3 Implementation of TRIPS - from 2005 onwards

Prosperous status of Indian pharmaceutical sector, in particular its generics production, was jeopardized in 2005 through India's introduction of patent protection over pharmaceuticals due to the obligation under TRIPS agreement. Considering that this issue opened a new chapter in pharmaceutical history of India and that this issue was considerably important in relation to generics supply in both domestic and international

[61] Section 5 in the 1970 Patents Act.
[62] Park C. and Jayadev A., *supra* note 57, p. 5.
[63] *Ibid,* p. 6.
[64] *Ibid.*
[65] Bazzle T., "Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: Trips, India's Patent System and Essential Medicines", *Georgetown Journal of International Law*, Vol. 42 (2011), p. 800.

level, next section deals with it separately. The next section in particular looks at how Indian government approached its obligation under TRIPS, what tactics it took trying to outstrip the agreement leaving the doors for generic production open without breaching the agreement and finally what were the anyway effects to generic production and supply of India.

4.2 TRIPS agreement in the context of India's pharmaceutical industry

In January 1, 1995 India joined World Trade Organization (WTO) and along with it joined WTO agreements that were obligatory to join including TRIPS Agreement.[66] No doubt that Indian government was aware of the fact the accession to TRIPS could impede India's generic production, but it seems that joining WTO outweighed this concern. A transition period that was allowed under TRIPS agreement for developing and least-developed countries[67] gave India ten years of delay after its membership to WTO for the implementation of TRIPS. During this transition period the Indian patent law, in particular 1970 Patent Act, underwent three main changes in 1999, 2002 and 2005. The amendment done in 1999 introduced "mailbox" provision based on which patent applicants could start their applications already from the India's transition period (i.e. 1995-2005) so that to get a patent protection after the end of the transition period. This amendment also introduced "Exclusive Marketing Rights" for patent applicants as a compensation for the time spent for reviewing patent application. The amendment of 2002 used the UK Patent Act as a model and brought even more far reaching changes to 1970 Patent Act. Finally, the amendments made in 2005 introduced product patent for medicines and shaped 1970 Indian Patent Act to make it in full compliance with TRIPS requirements.[68] On December 26, 2004 the Indian government adopted the Patents (Amendment) Ordinance in order to give effect to aforementioned amendments and to launch the compliance with the terms of TRIPS agreement.[69]

Y.K. Hamied[70] described the changes brought to 1970 Patent Act especially through the above mentioned Ordinance as the beginning of "one

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[66] There are around 60 WTO Agreements, including TRIPS, created at 1986–94 Uruguay Round negotiations. Any new member wishing to join the WTO must sign and ratify all these agreements. See the official website of the WTO, available at: http://www.wto.org/english/docs_e/legal_e/legal_e.htm (Last accessed on 13 October 2012)

[67] Articles 65 and 66 of TRIPS.

[68] Yalamanchili V., "State of India's TRIPS-Compliant Patent Regime", *Biotechnology Law Report*, Vol. 26, no. 3 (2007), p. 215.

[69] *Ibid.*

[70] He is the Chairman of one the biggest and one of the main Indian generics producing company known as Cipla. He is described as being "[the most] closely associated [industry leader] with the goal of seeding the globe with low-cost generics". See, Ghaswalla A., (2011) *Y. K Hamied: Changing the Dialogue* [online]. Last accessed 8 October 2012, available at: http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=744321. His company, Cipla, made immense contribution in producing low-cost life-saving generics against HIV/AIDS and considerably lowering down the prices of those drugs. This will be more elaborated in upcoming sections.

of the greatest predictable tragedies the world [had] witnessed".[71] He further stated that "no right-thinking person" was able to claim that India had gone so far in ensuring standard of living for Indians so as to justify the changes made to pharmaceutical legislation to launch patent rights.[72] In addition many other interested groups similar to generic pharmaceutical companies, international organizations, NGOs and society of people leaving with HIV/AIDS showed strong counter reactions towards the changing patent laws. The Indian Pharmaceutical Alliance (IPA), an organization being comprised from the largest Indian generic producers, persisted on the Patent Act to exclude new uses and new forms of already known substances from patentability. Delhi Network of Positive People (DNP), an Indian organization representing people with HIV/AIDS, through the cooperation with foreign activists demonstrated protests against the changes. Moreover, the representatives from the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) submitted letters of concern to Indian government to encourage the government to design the laws so as to facilitate access to medicines and remain within the minimum requirements of TRIPS.[73] Consequently, the Indian Parliament was pushed to consider these raised concerns raised by "exceptionally globalized advocacy efforts" and bring several changes in new patent laws.[74] As a result India "mapped out an extraordinary array of TRIPS flexibilities, some of which are unknown elsewhere in the world".[75] Moreover, India was seen as "the best placed to implement the TRIPS flexibilities" among developing countries which similarly had to comply with TRIPS starting from 2005.[76] Through these flexibilities the Indian government was able to keep the generic production to certain extent. Even though there were certain effects on the volume and possibility of Indian generic production, which will be further discussed below, these flexibilities, at least, allowed to outstrip the full side effects of TRIPS agreement that otherwise could even fully impede Indian generic production. More on how India utilized TRIPS flexibilities and by this, at least partially, kept its generic productions is discussed in the next section.

4.2.1 India's use of TRIPS flexibilities

As mentioned before, up until 2005 Indian pharmaceutical companies were freely able to produce generic version of patented drugs since no patent was granted to pharmaceutical products under Indian patent laws. However, after grace period given to India to implement TRIPS Agreement into its domestic laws expired in 2005, India was expected to, and actually did, start complying with TRIPS Agreement and thereby introduced patent protection for pharmaceutical products. A reasonable question arises, as to how India has been able to still continue its production of generics relatively in large scale even if from 2005 pharmaceutical companies could protect their

[71] *Ibid.*
[72] *Idid.*
[73] Kapczynskiti A., *supra* note 31, pp. 1586-87.
[74] *Ibid*, p. 1587.
[75] *Ibid*, p. 1573.
[76] Gopakumar K.M. "Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime", *The Law and Development Review*, Vol. 3, no. 2 (2010), p. 328.

products from copying by having them patented. To begin with, it is necessary to mention that TRIPS Agreement contains certain so called "flexibilities". The aim from incorporating such flexibilities into the Agreement was to allow developing and least developed countries (LDCs) to adopt TRIPS rules that would leave them space to "pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development".[77]WIPO together with its Member States classified TRIPS flexibilities into four[78]:

a) Flexibilities as to the method of implementing TRIPS obligations;[79]
b) Flexibilities as to substantive standards of protection;[80]
c) Flexibilities as to mechanisms of enforcement;[81]
d) Flexibilities as to areas not-covered by the TRIPS Agreement.[82]

In its turn Indian generic producers were partially able to retain their generic production owing to skillful use of TRIPS flexibilities. There are several tactics that Indian government used to leave the room for generic production while not trespassing the boundaries of TRIPS flexibilities. However, it is not within the scope of this thesis to discuss each of them, but rather the thesis will discuss the major mechanisms that India has been using in order to keep its generic production. There are five such major mechanisms that have been more constantly used and they are, first, novel patentable subject matter limitations, second, more demanding rules for passing obviousness requirement, third, procedural limitations such as oppositions and disclosures, fourth, limitations for injunctive remedies[83] and finally compulsory licensing. Upcoming paragraphs will discuss each of them in more detail.

First, to start with discussing novel subject matter limitations one should first understand what the subject matter in relation to patents itself mean. Patentable subject matter relates to an invention which is acceptable to be patented and any invention must fall under the scope of this subject matter in order to be granted a patent protection. Generally speaking,

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[77] WIPO, (2012) *Advice on Flexibilities under the TRIPS Agreement* [online]. Last accessed on 8 October 2012, available at: http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html

[78] *Ibid.*

[79] This flexibility takes its origin from Article 1.1 of TRIPS Agreement. According to this provision, Member States are free to choose a corresponding way of implementing TRIPS Agreement in their legal system and practice.

[80] This flexibility may enable to reduce or limit the rights conferred. The examples of the use of this flexibility include 'experimental use and the "Bolar" exceptions; and the limitation to the use of trademarks in packages and advertisement of products considered prejudicial to health, like alcohol and tobacco'. See, WIPO, *supra* note 7777.

[81] This means that Member States are able to 'resort to their own legal system and practices' while implementing their enforcement obligations under TRIPS Agreement. See, *ibid.*

[82] There are certain IP related areas that are not covered by TRIPS Agreement and Member States are free in dealing with those areas. The examples of such IP areas that are not addressed in the TRIPS Agreement are traditional knowledge, utility models, and handicrafts. See, *ibid.*

[83] Kapczynskiti A., *supra* note 31, pp. 1575-76.

according to Article 27.1 of the TRIPS Agreement patentable subject matters are "any inventions, whether products or processes, in all fields of technology". However, there are certain areas which fall outside the patentable subject matter even though they are within "a field of technology" and these expectations are set out by statute.[84] Furthermore, Article 27.2 of the Agreement specifies that Member States can further exclude certain subject matters from patentability if their commercial exploitation would be against "*ordre public* or morality". India in its Patent Amendment Act, No. 15 of 2005, went beyond what is excluded in TRIPS Agreement from patentability and added additional subject matters that cannot obtain patent protection clearly. Those "unpatentable" subject matters are enlisted in a separate chapter of Patent Amendment Act (2005).[85] The most noteworthy among these new additions is the exclusion enshrined in paragraph 3(d) of the Act which specifically states that an act cannot be called an invention and thereby cannot be granted patent if it is:

> "(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

In other words, an act cannot be called an invention if it is a mere repetition of a known substance just only with some changes in its form or is a new form of use of that substance and does not improve the efficacy of the known substance. This clause was essentially aimed to avoid "evergreening"[86] of patents. Indian Patent Office (IPO) has already rejected to grant patents to several applications on the basis that there were mere amendments or extensions of known substances.[87]

Second strategy that India uses is a high threshold of obviousness. One of the standard criteria for an invention to qualify for patent grant is

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[84] In international level, these exceptions are established in Article 27.3 of the TRIPS Agreement and they are:
'(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof ...'

[85] In particular, Chapter II of the Act, titled as 'inventions not patentable', sets out several clauses which specifies what cannot be called as invention and thus cannot be patented and what inventions are not patentable.

[86] Evergreening of patents is a term used to describe tactic that many patent holders use in order to prolong their patent protection for the same product. This is done through some modifications of different aspects of the same product which already has patent protection and by this to prolong its patent protection term. The evergreening of patents is primarily used in pharmaceutical industry. See, Thomas J. R. (2009), *Patent "Evergreening": Issues in Innovation and Competition* [online], p. summary. Congressional Research Service Report. Last accessed on 19 October 2012, available at: http://ipmall.info/hosted_resources/crs/R40917_091113.pdf

[87] The pharmaceutical companies which got such rejections were giants like Pfizer for its Caduet, GlaxoSmithKline for its rosiglitazone salt, and Gilead Science for its Tamiflu and Hepsera. See, Kumar S. *et al*, (2009) *Evergreening of Patents and the Indian Patent Law* [online], p. 3. Last accessed on 8 October 2012, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1420003

non-obviousness, also known as inventive step, which means that an invention must not be so obvious as to be easily identifiable by a person with common knowledge in the field.[88] Unlike this standard requirement, paragraph 2(ja) of Indian Patent Amendment Act (2005) puts some further requirements for an invention to be regarded as non-obvious. In particular, as an addition for an invention not being obvious for a person with average knowledge in the field, the invention must show that it technically advances the existing knowledge or that it has economic significance or both. In this way, a new form of a known invention with some advancement in its efficacy could get around with the clause 3 (d) Patent Amendment Act (2005), discussed in the previous paragraph, 'but fail a robust inventive step requirement'.[89]

Third mechanism that India has been using is a procedural limitation such as patent oppositions. Paragraph 64 of Indian Patent Amendment Act (2005) provides three stages where an opposition to a patent application or to patent itself can be made. These stages are: pre-grant and post-grant oppositions while the application is still before a patent office and an appeal before Intellectual Property Appeal Board or a regular court suit to revoke granted patent.[90] An interesting attribute of paragraph 64 is that it states that an opposition can be made by "any person interested". The IPO office interpreted this as embracing not only generic producers but also any organization acting in the interest of patients. By the mid-2007 around 200 pre-grant oppositions were filed in India among which "substantial number of cases" were initiated by the organizations acting in the interest of the public.[91] This implies that a patent application is not only under scrutiny and challenge of the Patent Office and generic competitors but also NGOs promoting the interest of people with different disease[92] and the latter sometimes can be even more careful and vigilant to make sure that the price and production of medicines for the treatment of the people whom they represent do not become inaccessible.

Fourth way that India uses as flexibility to its patents laws is limits on injunctive remedies. This means that Indian courts consider different issues, for example public health, while deciding whether to grant an injunction remedy for a patent holder claiming his or her patent being infringed. The precedent of such considerations by the courts was established in *Roche vs. Cipla* case where Roche, the patent holder, brought Cipla, Indian generic manufacturer, before the court in order to stop it from manufacturing patented drug owned by Roche. Cipla, in its turn, argued that the Court should not confer preliminary injunction since "overwhelming interest of society" in access to affordable and life saving drugs was at stake. To underpin its argument Cipla provided price difference between the patented and generic version of the drug in subject where the former cost

[88] WIPO, (2009) *Understanding Industrial Property* [online], publication no. 895(E), p. 6. Last accessed on 8 October 2012, available at: http://www.wipo.int/freepublications/en/intproperty/895/wipo_pub_895.pdf
[89] Kapczynskiti A., *supra* note 31, p. 1593.
[90] *Ibid*, p. 1598.
[91] *Ibid*, pp. 1599-1600
[92] For example, there are at least 30 NGOs established in India working on HIV/AIDS in India. See, http://cnls.lanl.gov/~rajan/AIDS-india/invngo.html

around USD 110 per month whereas the latter was around USD 36. After consideration of different aspects of the case, including price difference of the drugs in subject, the Court held that:

> "[It would] be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted [and that] [t]he degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if [an] injunction were granted. Such injuries to third parties are un-compensatable."[93]

This signifies that Indian courts take into consideration the interest of public rather than considering only technicalities of patent and relevant laws in cases related to pharmaceutical patents.

Last but not least, India like some other developing countries has been using more traditional flexibility allowed by TRIPS Agreement which is a possibility of TRIPS Member States to issue compulsory licensing.[94] In addition to what is enshrined in TRIPS Agreement, the Indian Patent Amendment Act (2005) deals with compulsory licensing even more expansively and embraces some additional "innovative" rules. Accordingly, thus Indian rules relating to compulsory license were even named as "undoubtedly the broadest and most comprehensive of all the world's patent systems".[95] Based on some rules in relation to compulsory licensing that the Act contains, the Indian government can import medicines that have patent protection in India (also known as parallel importation) "for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government".[96] Another remarkable clause of the Act provides that once three years of patent life of a patented medicine is over, "any person interested" is entitled to apply to a patent controller asking to grant a compulsorily license in relation to the patented medicine based on any of following three grounds. First ground for such application is that a patent holder has not fulfilled "the reasonable requirements" of the public in relation to the patented medicine.

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[93] Kapczynskiti A., *supra* note 31, p. 1606.

[94] Generally speaking a compulsory license is a document issued by a government that allows the use (including manufacturing, producing, and selling) of patented product without the authorization of the patent owner. However, there are certain requirements to be met by the government to be able to grant such document. Basic requirements under the Article 31(a) of the TRIPS Agreement are that a Member must examine each case separately and exclusively on its own merits before bringing a compulsory license. Moreover, Article 31(b) states that prior to issuance of a compulsory licensing, a Member should try to build negotiations with the right holder offering 'reasonable commercial terms and conditions'. However, the same Article further states that if such negotiations has not reached successful conclusion within a reasonable time or if the Member was under the condition of public emergency or aimed to make public non-commercial use of the subject, the Member is released from seeking the authorization of the right holder assuring that the right holder is notified about the decision as soon as possible. The imposition of compulsory licensing must also be followed with adequate monetary compensation to the right holder and the validity of both, authorization and compensation, shall be subject to judicial appeal (see Article 31(h, i and j) of the Agreement). These requirements are not only ones and there are some other conditions enlisted in the Article 31 of the Agreement.

[95] Mueller J. M., *supra* note 4848, p. 580.

[96] See paragraph 47 (4) of the Indian Patent Amendment Act (2005)

Second, and more striking, is that the patented medicine is not offered to the public at a "reasonably affordable price". Third condition for a compulsory license application is that the patented medicine is not worked in India. It is suggested that such "ambiguity of the compulsory licensing provisions and the broad discretion they confer on the Controller is a source of much discomfort to MNC patent holders".[97] At least hypothetically, it is no doubt such conditions and the possibility to apply for a compulsory license under such grounds will make the pharmaceutical companies to be more alarmed to ensure that they do not give a justification a compulsory license to be issued. This in turn means that pharmaceutical companies will set "reasonably affordable price[s]" to their drugs.

All in all, these all flexibilities formulated by India have been enabling the country to deploy patents in a way suiting its economic and social conditions. Patentable subject matter being limited only to new compounds avoids evergeening of patents and prevents pharmaceutical companies from extending their monopolies merely with some changes and modifications of the same product. Moreover, high threshold of obviousness set by Indian patent system will further encourage pharmaceutical companies to be more innovative and bring technical advancements to existing knowledge. Possibility of patent oppositions is another challenge for pharmaceutical companies and a line of attack for generic competitors and health concerned organizations. Lastly, compulsory licensing is a tool to "convince" pharmaceutical companies to set the prices in an affordable amount and avoid other misuses of patents.

4.2.2 Anyway effects on Indian generic production from TRIPS

No matter how good India designs its flexibilities in relation to pharmaceutical patenting, TRIPS Agreement has anyway affected Indian pharmaceutical industry and the accessibility, affordability and availability of medicines produced therein. Therefore it is deemed that "the post-TRIPS era is one in which access has unquestionably been curtailed"[98]. This is inevitable especially for a country like India which for 35 years did not have patent protection over medicines[99] and where pharmaceutical companies, their way of production, R&D spending, and competition within each other was adjusted to an environment without patent protection. In the absence of patent protection the Indian pharmaceutical companies, mainly generic producers, tried to set the prices as low as possible in order to survive the rigorous competition. However, after implementation of TRIPS Agreement India "has been subjected to numerous threats to its ability to manufacture and supply affordable generic finished products and active pharmaceutical ingredients (APIs)".[100] Moreover, India has been experiencing notable

[97] Mueller J. M., *supra* note 48, p. 583.
[98] Clayden P., *et al* (2011), 2011 *Pipeline Report* [online], the report prepared for i-Base and Treatment Action Group, p. 61. Last accessed on 8 October 2012, available at: http://www.treatmentactiongroup.org/pipeline-report/2011
[99] As mentioned before, India in accordance with its 1970 Patent Act excluded medicines from patentability until the implementation of TRIPS Agreement in 2005.
[100] Clayden P., *et al*, *supra* note 98, p. 61.

changes in the nature of its generic industry along with increasing number of product patents including many ARV drugs.[101] In 2008 the Indian Parliament was informed that from January 2005 to 30 August 2007 IPO issued 460 product patents for pharmaceutical inventions. Out of these patents 392 (representing 85%) belonged to foreign applicants whereas only 68 (representing 15%) belonged to Indian applicants. These patents were granted to medicines against life threatening and serious diseases like HIV, cancer, renal failure and neurological disorders.[102]

Another impact that TRIPS Agreement had on India was substantial increase in patent applications. Currently IPO has huge backlogs in examining patent applications. By 2010 there were nearly 79,000 pending applications, out of which 6,322 were for pharmaceuticals, before IPO waiting for their examination. India's start of full compliance with TRIPS Agreement has undoubtedly some contribution in relation to this. Commerce and Industry Minister Anand Sharma while explaining the cause for such backlog noted that IPO experienced substantial increase in patent application after 2003-04[103] which coincides to the time right before India implemented TRIPS Agreement. This shows that patent applicants were reserving a place in the queue awaiting the rights, including patentability of medicines, which TRIPS Agreement would confer. By February 2012 IPO already hired 150 new examiners with a hope to handle the excessive number of applications.[104] Due to the increase of pending patent applications India even may need to bring some reforms to its patents system because it is believed that the mere increase in the number of patent examiners will not bring out from the problem.[105] Another noteworthy factor in relation to patent grants by the IPO is that the study of 2,339 patents granted to medicines showed that 67 of the 86 granted patents were not in compliance with Section 3 (d) of the Indian Patent Amendment Act (2005). As a result, India's well designed flexibilities are not being fully benefited "because either the regulators or the executing agency do not have the skill, interest or wherewithal to ensure that the law is implemented in spirit and letter".[106] The increased work load of IPO might be another main cause why inventions that are not eligible for patent protection are being granted patents.

It is believed that the full impact of TRIPS agreement, in particular patent protection over medicines, has not yet been fully experienced since Indian generic companies are still in control over 80% of India's pharmaceutical market. In terms of HIV medicines, the fact that treatment

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[101] *Ibid.*
[102] Gopakumar K., *supra* note 76, p. 360.
[103] Indian Institute of Patent and Trademark Attorney (IIPTA), (2010) *79,000 patent applications are pending at India Patent Office!* [online]. Last accessed on 8 October 2012, available at: http://www.iipta.com/ipr/79000-patent-applications-are-pending-india-patent-office
[104] IndiaMART, (2012), *Indian Patent Office straining to clear huge backlog of 1 lakh pending patent applications by 2016* [online]. Last accessed on 8 October 2012, available at: http://news.indiamart.com/story/indian-patent-office-straining-clear-huge-backlog-1-lakh-pending-patent-applicat-155585.html
[105] IIPTA, *supra* note 103.
[106] *Ibid.*

against the disease using different medicines is offered freely in India, the real impact of patented HIV/AIDS medicines in India will be experienced in the future when people affected by the disease will become resistant to currently offered treatments.[107]

[107] Gopakumar, *supra* note 76, p. 361.

5 Analysis of the Free Trade Agreement between India and the EU

5.1 General background

In 2006 the European Commission introduced a new trade policy agenda known as Global Europe strategy (GES) with an aim of bringing new jobs and economic growths. This strategy caused the Europe to refocus its bilateral agreements through new FTAs with Asian markets and moved forward its focus in the areas like IP and access to raw materials.[108] The EU aimed to play a leading role in advancing global rules and standards mainly through international and bilateral cooperation. Seeing the suspension of the Doha negotiations in the WTO as "a missed opportunity for global growth and development", the EU deemed FTAs as an appropriate tool to address the issues like "investment, public procurement, competition, other regulatory issues and IPR enforcement". It was considered that in order for FTAs to bring positive effect, they "must be comprehensive in scope, provide for liberalization of substantially all trade and *go beyond WTO disciplines*" (emphasis added). By this, the EU intended to introduce "stronger provisions for IPR and competition, including for example provisions on enforcement of IP rights along the lines of the EC Enforcement Directive" in its FTAs.[109] The GES was also an aim to start a second stage of the EU IPR enforcement strategy.[110] From 2006 to 2010 the EU initiated several actions as a result of the GES including launch of FTAs with several developed and developing countries among which was India. Consequently, at the annual India-EU summit held in Helsinki in 2006 leaders of both parties called for "an expansion and deepening of trade and investment linkages" and thus they decided to press forward their bilateral trade by formation of bilateral trade and investment agreement.[111] This resulted in the launch of negotiations in 2007 of the FTA between the EU

[108] European Commission, (2008) *European Competitiveness* [online]. Last accessed on 9 October 2012, available at: http://ec.europa.eu/trade/creating-opportunities/trade-topics/european-competitiveness/index_en.htm

[109] European Commission, (2006) *Global Europe – competing in the world. A Contribution to the EU's Growth and Jobs Strategy* [online], p. 11. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2006/october/tradoc_130376.pdf

[110] *Ibid.* The EU has established 'strategy for the enforcement of intellectual property rights in third countries' through different actions including multilateral and bilateral agreements. These agreements usually include IP chapter which 'establishes that a very high standard of protection of IP (including the enforcement thereof) must be achieved'. The EU considered that the EU's role in monitoring of the adoption of general IP legislation within WTO members was not enough itself and thus found it 'essential that the EC increasingly focuses on vigorous and effective implementation of the (IPRs) enforcement legislation'. See, European Commission, "Strategy for the enforcement of intellectual property rights in third countries". *Official Journal of the European Union*, 2005/C 129/03, 129/03-129/16.

[111] ITP (2007), *India-EU Joint Statement* [online]. Last accessed on 9 October 2012, available at: http://www.indiainbusiness.nic.in/business-news/speeches_statements/pm_oct13(a)_06.htm

and India (already known in this paper as IndEUFTA) the conclusion of which "remains a key priority" since India is deemed as the "most important trading partner"[112] of the EU. [113]

It is worthwhile to see what factors, mainly economic, caused India to come to the table of negotiations with the EU, what are the benefits sought by the FTA and what are the positions of the parties. However, it should be noted that the views in relation to these differ. The main aim sought from having the Agreement is considered, first, "to gain preferential and additional market access to the negotiating partners market". Second is to achieve "leverage tariff concessions into more substantial gains".[114] The Centre for the Analysis of Regional Integration at Sussex (UK), funded by the European Commission, made a qualitative analysis of the IndEUFTA and its potential benefits. It was believed that the Agreement would be "relatively easy to negotiate" since "[t]here appears to be comparatively little sectoral overlap on trade structures or measures of revealed comparative advantage on goods between the EU and India". This in turn implies that both sides "have somewhat different offensive and defensive interests" which ultimately should make the negotiations easier. Moreover, it was believed that the IndEUFTA could increase the EU's foreign direct investment (FDI) to India by 27% while FDI stocks would increase to 18%.

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[112] European Commission (2010), *Report on progress achieved on the Global Europe strategy, 2006-2010* [online], p. 7. Commission Staff Working Document, Brussels, SEC(2010) 1268/2. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2010/november/tradoc_146941.pdf

[113] India's contemporary trade relations with the EU are rooted back to older times of India's colonialism. From those times India's main trading countries were Commonwealth countries amounting to 54% of India's exports out of which 34% was directed to the UK. At the same time the UK was also the highest exporter for India which constituted 30% of India's imports. In general terms even after independence India kept the Western Europe, largely the European Common Market (ECM), as one of the main trading partners having 18.2% of its imported products from it in 1955-56. The trade relationship between India and the ECM witnessed a decline with 8% decrease of Indian imports from the ECM due to the rise of a trade partnership with East European Socialist Countries representing 18% of Indian imports. However, after the collapse of the communist countries, the Western Europe recovered its economic partnership with India. See, Ruddar D. and Sundharam K.P.M., (2006) *Indian Economy.* New Delhi: Rajendra Ravindra Printers (Pvt.) Ltd., pp. 741-743 quoted in De Castro T., "EU-India TRIPS-plus Agreement: A Real Threat for the Developing World?", *Contemporary European Studies 1/2011*, pp. 27-28. In 2004 the EU gave India the status of "strategic partner" and in 2005 it formed an EU-India Joint Action Plan aiming since then to accomplish 'the full potential of this partnership'. See the official website of the European Commission, available at: http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/india/. Nowadays, the EU remains to be the biggest trading partner of India. This partnership already reached more than €100 billion in trade of goods and services in 2011 comparing to €86 billion in 2010. In 2010 India's 19% of exports were directed to the EU whereas 14% of its imports derived from the EU. In contrast, only 2.6% of EU's exports were forwarded to India while 2.2% of its imports were originated from India. However, the economic importance of India for the EU is growing. In 2002 India was amounted as the EU's 15th main trading partner whereas India became 8th in 2010. See, Johnson J., (2012) *Trading with the New India* [online], Business for New Europe, p. 19. Last accessed on 9 October 2012, available at: http://www.bnegroup.org/images/uploads/publications/files/Trading_with_the_New_India_-_Jo_Johnson.pdf

[114] Khorana S. and Perdikis N., "EU-India Free Trade Agreement : Deal or No Deal?", *South Asia Economic Journal*, Vol. 11, no. 181 (2010), p. 186.

Another forecasted benefit of the Agreement was that it could make India to become more convergent with international rules since India's standards in their current form were not always compatible with international norms. The central findings of the report suggested that forecasted benefits from the Agreement would largely depend on "the extent to which such an FTA adequately identifies and deals with issues of deeper integration in areas such as government procurement, services, investment, trade facilitation, trade defence, standards, intellectual property and competition policy". On the other hand the study acknowledged that there are some possible drawbacks and costs from the Agreement. In particular, for past couple of decades India has relatively diverged its economy from the EU markets to third countries (40% in the early 1990s against 25% in current days). In this sense, the Agreement could imply that India would be growing its imports from the EU "but at the expense of more efficient suppliers from third countries". [115] Another study initiated by the EC suggested that, from economical perspective, India could gain €4.9 and €17.7 billion in the short and long terms respectively whereas gains for the EU would be €4.4 and €1.6 billion in the short and long terms respectively.[116] The overall results of the study found that:

> "Even though the overall effects are positive for the EU and positive for India, it is clear that some sectors gain and some lose, and within the sectors, some people gain and some lose."[117]

Some experts further believe that "there is a compelling case to take the trade and investment relationship between the EU and India to a higher plane"[118] and that overall impacts on India from the Agreement would be positive and India's exports to the EU would rise in all sectors.[119] On the contrary, some skeptics consider that the real outcomes of the Agreement "could be dire" for India's economy[120], that the Agreement could curb India's national policy space which "risks stripping away the very tools that India could use to re-balance the gains from growth and to ensure that the

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[115] Gasiorek M. et al, (2007) *Qualitative analysis of a potential Free Trade Agreement between the European Union and India* [online], Centre for the Analysis of Regional Integration at Sussex, pp. 2-8. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2007/june/tradoc_135112.pdf

[116] ECORYS Netherlands, CUTS and CENTAD, (2009) *Trade Sustainability Impact Assessment for the FTA between the EU and the Republic of India* [online], p. 16. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2009/june/tradoc_143372.pdf

[117] *Ibid.*

[118] EU-India High Level Trade Group, (2006) *Report to the EU-India Summit* [online], p. 11. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_130306.pdf

[119] Decreux Y. and Mitaritonna C., (2007) *The Report on Economic Impact of a Potential Free Trade Agreement (FTA) between the European Union and India* [online], CEPII – CIREM, p. 26. Last accessed on 9 October 2012, available at: http://trade.ec.europa.eu/doclib/docs/2007/may/tradoc_134682.pdf

[120] Rivera J. D., (2011) *The Alarmingly Uneven Deal of the India-EU FTA* [online], p. 1. Last accessed on 9 October 2012, available at: http://www.bilaterals.org/IMG/pdf/The_alarmingly_uneven_deal_of_the_India-EU_FTA._By_Javier_Delgado_Rivera.pdf

poor are not further marginalized".[121] It is further suggested that the "potential gains [from IndEUFTA] are modest and the risks are not insignificant".[122]

Although, as mentioned before, it was predicted that it would be "relatively easy" to negotiate the agreement, in practice, however, it does not seem to be true. Initially the parties planned to conclude the negotiations by the end of 2008. However, the negotiations have been delayed till these days. There are many factors and obstacles causing these delays. The EU officials considered that these delays were mainly caused "by bureaucracy, divergent interests among its member countries and slow progress on key issues like access to India's legal and financial service sectors and the protection of intellectual property".[123] Divergent interest of the parties were in relation to, on one hand, India seeing the Agreement as an opportunity to improve market access to the EU market for its goods and services and at the same time expecting from the EU to abolish its non-tariff barriers for agricultural products imported from India. On the other hand, the EU wants to achieve from the Agreement its objectives set in its GES as well as get access to India's protected areas like banking, retail and government procurement areas.[124] Despite of all these hurdles Jose Manuel Barroso, president of the European Commission, on the EU-India Summit held on February 2012 stated that until that point both parties were able to bring the positions "closer in all areas and [that] the contours of the final agreement [were] emerging" and he expressed their commitment to intensify the talks with an aim to conclude it by the end of 2012.[125]

5.2 Potential changes to Indian patent system from the IndEUFTA

It is no doubt that the IndEUFTA will result in certain legislative changes in India. What worries more, at least in the context of this study, is how those legislative changes, particularly in relations to IPRs, will look like and what would be their implications to Indian production of generics. It is already predicted that if the IndEUFTA is concluded in the way the EU has been proposing, it will greatly undermine the possibility of India to provide with

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[121] Powell S., (2008) *The EU-India FTA: Initial Observations from a Development Perspective* [online], the report prepared for the Traidcraft Exchange, p. 37. Last accessed on 9 October 2012, available at: http://www.indianet.nl/pdf/EU-IndiaFTAInitialObservations.pdf

[122] Polaski S. et al, (2008) *India's Trade Policy Challenges* [online], the report prepared for Carnegie Endowment for International Peace, p. ix. Last accessed on 9 October 2012, available at: http://www.carnegieendowment.org/files/india's_trade_policy_choices_final.pdf

[123] Nelson D., (2011) *EU-India Free Trade Deal Delayed* [online]. Last accessed on 9 October 2012, available at: http://www.telegraph.co.uk/finance/globalbusiness/8408748/EU-India-free-trade-deal-delayed.html

[124] Khorana S. and Perdikis N., *supra* note 114114, p. 192.

[125] Barroso J. M. D. (2012), *Statement by President Barroso following the signing ceremony of agreements in the India-EU Summit* [online]. Speech/12/82. Last accessed 20 October 2012, available at: http://europa.eu/rapid/press-release_SPEECH-12-82_en.htm

affordable medicines.[126] In particular, the proposals of the EU that may have substantial effect on the generic production in India and which have been subject to most of the discussions include data exclusivity, extensions of patent protection terms, and seizure of generics through border enforcement measures. These measures may have significant effect on generic medicines by delaying and/or restricting their production.[127] More detailed analysis of each provision is done in the upcoming sections.

5.2.1 Data exclusivity

Data exclusivity is a term used in relation to a registration data used to get regulatory approval from an authority responsible for granting such approval, also known as Drug Regulatory Authorities (DRA), for a medicine. The registration data is obtained through testing and trials in order show that the produced drug passed the necessary tests and proves to have standard quality, safety and efficacy for consumption of human beings. Only after approval of DRA, the new drug can be freely distributed on the markets.[128] Data exclusivity protects the registration data from unfair commercial use and from the revelation to the third parties without the permission of the originator. The data exclusivity lasts for a certain term depending on different jurisdictions which usually ranges from 5 (US) to 10 (EU) years.[129] Under data exclusivity, a DRA has two responsibilities upon receiving the data needed to grant a marketing approval. First is to keep the data in secret from other parties. Second is not to rely on the registration data of a drug provided by an originator to approve the production of similar drug by other parties. In other words, if for example a generic company creates a generic version of an original medicine, the DRA cannot authorize the marketing of that generic medicine based on the registration data of the original one without the permission of the owner of the original medicine. Consequently, the generic company has to create its own registration data. However, this responsibility is treated and interpreted with some disparity in different jurisdictions. For example, in the US and EU any kind of reliance is prohibited whereas in Canada it is argued that this responsibility should be subject to interpretation.[130]

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[126] Hoen E. et al., "Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All", *Journal of the International AIDS Society*, Vol. 14, no. 15 (2011).
[127] Waning B., *et al*, *supra* note 24, p. 2.
[128] Clift C., (2007) *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals* [online]. Last accessed on 9 October 2012, available at: http://www.iphandbook.org/handbook/ch04/p09/
[129] *Ibid.*
[130] Pugatch M.P., (2004) *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access* [online], p. 7. Last accessed on 9 October 2012, available at: http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf
Some even argue that regulatory authorities does not have obligation not to rely on the already submitted registration because such reliance cannot be called as unfair commercial use but merely it is use for the interest of public to insure access to affordable medicine. Srinivas K.R. (2006), *Test Data Protection, Data Exclusivity and TRIPS: What Options for India?* Last accessed on 9 October 2012, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=935847

In international level data exclusivity, although ambiguously, is mentioned and protected under article 39.3 of TRIPS agreement which reads as follows:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which *involves a considerable effort*, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use." [Emphasis added]

This ambiguity has left some important questions without an answer. First of all, the article does not indicate for how long the protection should last. Therefore, different jurisdictions apply a different period which generally ranges between 5 to 10 years, but in most jurisdictions the period is either 5 or 10 years.[131] Secondly, the article does not specify as to whether the authorities can rely on a successful registration data of a medicine and authorize other producers to produce similar products. As described above this is very important factor for other, especially generic, producers of the same kind of a medicine. Thirdly, it is not definite as what is meant by data "invlov[ing] considerable effort" so as to define the extent of effort, should it be economic or technical, to be put to registration data to be qualified for a protection.[132] Consequently, such ambiguity in relation to very basic and important conditions left wide discretion for countries to apply their own way of application which sometimes can go far beyond what is sought in TRIPS agreement.

One of the main arguments that is used to support data exclusivity is that in order to develop a registration data pharmaceutical companies in industrialized countries spend around USD 500 million and it can take on average 10 years to bring such data.[133] Accordingly, pharmaceutical companies claim that it should be impermissible to share the data, which involved such considerable costs, with the third parties without the consent of the originator or else there would be no incentive for pharmaceutical companies to create new drugs at such expanses.

In its turn, a relevant question arises as to what is added value of data exclusivity in comparison to patents, what is the relationship between both and how does it further effect generic production. It is claimed that data exclusivity is "an expression of trade-secrets, and that as such, data exclusivity should be independent of patents".[134] By this it is meant that data

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[131] 10 years mostly apply in the EU countries whereas in majority other countries it is 5 years. In exceptional countries, like in Croatia, Turkey, China, South Korea it can be either 6 years or 8 years, like in Japan, Canada. For reference and more information about other countries see, IFPMA (2011), *Data Exclusivity: Encouraging Development of New Medicines* [online]. Last accessed on 9 October 2012, available at: http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf

[132] Pugatch M. P., *supra* note 130, p. 8.

[133] IFPMA, (2000) *Encouragement of New Clinical Drug Development: the Role of Data Exclusivity* [online], p.1. Last accessed on 9 October 2012, available at: http://www.eldis.org/assets/Docs/29224.html

[134] Pugatch M.P., *supra* note 130, p. 1.

exclusivity is a separate protection mechanism with its own protection conditions and terms different from that of patents.[135] Therefore, data exclusivity is becoming more popular as means of protection and its economic significance is growing. The reasons for this is "(i) the lengthy and costly process of clinical trials; (ii) the ongoing innovative productivity challenges (some would use the word crisis) the pharmaceutical industry now faces, and; (iii) the fierce legal patent disputes between research-based and generics-based pharmaceutical companies".[136] Theoretically, data exclusivity is not as restrictive as patent rights. Because unlike patents, where third parties are not allowed to produce a product similar to patented one, data exclusivity does not prevent others from generating similar data. However, in practice data exclusivity appears to be more limiting, especially for generic-based companies, since as mentioned above the significant portion of R&D is invested to produce the data protected under data exclusivity and third parties consider it to be ineffective or in most cases are unable to invest similar amount of resources to produce similar data.[137] Consequently, the data exclusivity can be considered as well thought protection tool by the rivals of the generic-based companies. Because, even if generic producers are able to overcome patent barrier through legal means, for example through compulsory licenses, and they will still face impediment when it will come to registering data to obtain an authorization for marketing. The registering data of the medicine subject to compulsory licensing will be protected under data exclusivity and thus such registering data can neither be used by generic producer nor the relevant authority can rely on it. Consequently, generic producers will have to produce their own registering data, which requires huge resources that in most cases cannot be afforded by generic producers.

Another interesting aspect of data exclusivity which should be noted is that the protection period of data exclusivity (between 5 to 10 years) is shorter than that of patents (at least 20 years). So a logical question arises as to what is the added value of the data exclusivity if its protection does not anyway extend the protection period of the patents and anyway expires within the protection period of patents. In this context, the significance of data exclusivity usually comes into play in cases when a drug is not patented[138] in a certain country or when it is possible to challenge or

[135] At this stage it is also necessary not to confuse between the data involved in getting patent rights and the data protected by data exclusivity. It is well known that one of the main conditions for a patent grant is that the information, or data, about how the product was developed and brought must be revealed by the originator for the exchange of receiving the patent protection. The data protected by data exclusivity is generated as a result of testing and trials needed to get a marketing authorization whereas the data, which is obligatory to be revealed upon the grant of a patent, is about how the product was invented to teach others the way of producing the product.

[136] Pugatch M.P., *supra* note 130, p. 9.

[137] *Ibid*, p. 6.

[138] Pharmaceutical companies may consider that it is not reasonable to apply for a patent protection due to the considerable costs, time and effort put in getting a patent protection. Therefore, pharmaceutical companies sometimes may prefer to rather opt in to a protection provided by data exclusivity which, although grants shorter protection period, is much easier to obtain.

circumvent[139] patents.[140] Another scenario for the use of data exclusivity is when a new indication or use is designed for a patent expired medicine. Although it is usually not possible to get a patent extension for a medicine based on its new indication or use, it is allowed to grant a data exclusivity for a new indication.[141] It can be very regular way of extending market monopoly by preventing generic competition since it is claimed that now pharmaceutical companies accustomed to find a new disease to treat with already existing medicines rather than creating a new medicine.[142] Last but not least, for the reasons explained in previous paragraph, data exclusivity can keep effective use of compulsory licensing at bay.

According to the report provided by the British Medical Journal (BMJ), European delegates have been pushing hard on India during the negotiations of the FTA to accept the data exclusivity protection.[143] Like for other least developed and developing countries data exclusivity is a sensitive issue in India's context, but it may have even farer reaching effects for India than for other countries. There are at least two general reasons for this. First, as discussed in Chapter 3, India is the world's largest producer of life saving antiretroviral drugs against HIV and data exclusivity may additional hinder already constrained production of such drugs with the possibility of delaying their production at least till their data exclusivity expires. Secondly, unlike many other countries, India has been successfully and persistently taking the benefit of compulsory licensing, although argued by proponents of patent rights, in a way allowed in TRIPS agreement. However, if India opts to the data exclusivity protection then it may delay the production of drugs even under compulsory license.[144] Moreover, as

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[139] For example, in China it is possible to circumvent one of the main first line antiretroviral drugs against HIV/AIDS since it is protected under process patents and not product patent. Accordingly, Chinese local producers are manufacturing and exporting the raw material of the mentioned drug. Even though it is possible to produce the medicine itself by circumvention, the Chinese manufactures are limited for producing only raw material for it because of the data exclusivity protection of the drug. See, Grace C., (2005) *Update on China and India and access to medicines* [online], the report prepared for the British Government's Department for International Development. Last accessed on 15 October, available online at: http://hdrc.dfid.gov.uk/wp-content/uploads/2012/09/Update-on-China-an-India-and-Access-to-Medicines.pdf

[140] Timmermans K., "Monopolizing Clinical Trial Data: Implications and Trends", *Journal of PLoS Medicine*, Vol. 4, no. 2 (2007), p. 0207.

[141] *Ibid.*

[142] Thompson N., (2002) *Drug Abuse: Where Have All the New Meds Gone?* [online]. Last accessed on 15 October 2012, available at: http://business.highbeam.com/4776/article-1G1-92378115/drug-abuse-have-all-new-meds-gone

[143] Janodia M. D. et al., "Data Exclusivity Provisions in India: Impact on Public Health", *Journal of Intellectual Property Rights*, Vol. 13 (2008), p. 445.

[144] Similar concern was raised in the EU and the Directorate General of the European Commission's Enterprise and Industry was asked as to whether according to European pharmaceutical legislation it would be possible to waive data exclusivity in case of marketing Tamiflu subjected to compulsory licensing. The answer was that there is no "any exception … [for] data exclusivity… [*even*] *in case of emergency situation* or in case a compulsory patent license has been granted by an EU Member State"(emphasis added). See, European Commission's Enterprise and Industry Directorate-General, (2006) *Tamiflu application and data exclusivity in an emmergency compulsary situation* [online]. The response letter no. ENTR/F/2CSK/ISD/35236(2005). Last accessed on 20 October 2012, available at: http://www.cptech.org/ip/health/dataexcl/ec-de-tamiflu.pdf

described in Chapter 4 India imposes special requirements for patents to be granted and this, even after implementation of TRIPS, makes it more challenging for pharmaceutical companies to get patents for their drugs comparing in most other developing countries. This in turn has been keeping the doors for generic production open and avoided ever greening of patents. However, data exclusivity may grant monopoly for a drug much easier than patents since unlike patents, data exclusivity does not have burdensome requirements to comply with. Some experts support the idea that if India brings in data exclusivity protection it may negatively affect India's generic industry which may result in price increases confronting with public health interest.[145] In 2007 Indian government requested the Committee comprising from Department of Chemicals and Petrochemicals (DCPC) and Ministry of Chemicals and Fertilizers to look at the data exclusivity in the context of Article 39.3 of TRIPS agreement and to make recommendations in relation to appropriate measures to be taken. The Committee noted that there should a balance be kept between the ability of public to have access to affordable medicines and opportunity for pharmaceutical companies to earn revenues to cover their R&D. The Committee concluded that registration data could be protected under data exclusivity for a fixed protection period of five years. However, the Committee suggested that if such protection is provided, a number of safeguards should be adopted to avoid any negative impact on public health or in the cases of health emergencies. The most noteworthy of suggested safeguards included:

- Making sure that in cases where a data protection was provided for patent drugs such protection does not in any way prolong the patented drugs protection period of 20 years;
- To terminate data protection of the patented drugs subjected to compulsory licensing;
- Allowing generic companies to start the application procedures and required studies even during the data protection period to enable them immediate commercialization after expiration of data protection;
- Allowing Indian government to fully or partially forgo any provisions of data protection in a situation of public health related emergency;
- Allowing India government to design its mechanism for negotiation the price in order to guarantee affordability and accessibility of new drugs for public.

The most notably and importantly, the Committee suggested that data protection shall not apply for the drugs against life threatening disease like HIV/AIDS. It implies that even in the case of data protection Indian DRA could rely on the data submitted by the originator to approve marketing of the same drug for subsequent applicants. These safeguards and exemptions in cases of providing data exclusivity can avoid the impediment of generic production of HIV/AIDS drugs and comparatively ease the production of other generics. However, not less important question is whether data

[145] Janodia M. D. et al., *supra* note 143, p. 445.

exclusivity with these conditions would satisfy the EU and, especially, the influential multinational pharmaceutical companies that have been sturdily lobbying. It would be more logical to expect that the EU would not agree to such conditions.

Nevertheless, Indian Commerce Minister Anand Sharma before the meetings for further negotiations on the EU-India FTA in 2011 stated that:

> "[t]here is no question that we will accept data exclusivity in any agreement with any country. On [the] intellectual property rights issue, whatever is discussed has to be in compliance with the TRIPS commitment."

At the beginning it seemed that the EU gave away its position in relation to data exclusivity but "in a spectacular turnaround… [the EU] seems determined to stand firmly by its position" in regard to data exclusivity.[146] Therefore, it is too early to conclude that the data exclusivity is put aside of round table negotiations and it would be more correct to rather expect that the subject of data exclusivity will be continued with rigorous discussions and negotiations until the final dot. However, if India gives up its position and accepts to adopt data exclusivity in the way it is proposed by the EU, then all consequences mentioned in this section might become inevitable.

5.2.2 Extension of patent protection term

In an international arena Article 33 of TRIPS Agreement sets the minimum protection term for patents to be twenty years starting from filing date and thus the standard protection term for many countries is twenty years. For medicines this means that for twenty years a third party is not allowed, unless the patent holder consents, to make, use, offer for sale, or sell the patented medicine.[147] Such long protection term is justified due to large expanses incurred by pharmaceutical companies for R&D in creating new medicine and by having patent protection patent holder can repel other competitors and be able to sell the product in considerably higher price than the marginal cost to recoup invested money. Any regulations seeking longer protection term than twenty years can be deemed to be going beyond the requirements of TRIPS and it will be up to the will of any country to adopt such longer protection term.[148] However, proponents of patent protection, mainly pharmaceutical companies, afterwards started to claim and still claiming that even twenty years are not sufficient due to certain procedures

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[146] Agazzi I., (2012) *FTA: India Fights Back Over Its Generics* [online]. Last accessed 15 October 2012, available at: http://www.alliancesud.ch/en/policy/trade/fta-india-fights-back-over-its-generics

[147] Article 28 of TRIPS Agreement.

[148] However, practice shows that some countries, especially with weaker negotiating, political and economic power, often do not willingly opt to longer protection period but rather are pushed to do so through bilateral international agreements having 'TRIPS plus' provisions. Besides, creation of international agreements with such character is systematically increasing. A study conducted in 2001 revealed that there were already 23 bilateral or regional agreements which had provisions more stringent than TRIPS Agreement and thus being considered as TRIPS plus agreements. These agreements have an effect on 150 developing countries which also implies that such agreements were systematically created. GRAIN, (2001) *"TRIPS-plus" through the back door. How bilateral treaties impose much stronger rules for IPRs on life than the WTO* [online]. Last accessed on 15 October 2012, available at: http://www.grain.org/article/entries/5-trips-plus-through-the-back-door

and laws that pharmaceutical industry must undergo in order to get a marketing approval from DRAs. Because, the patent application is done before the procedures to get marketing approval start and thus patent keeps running until a marketing approval is granted which shortens the effective patent term of a medicine. Accordingly, it is claimed that shortening of effective patent term of a medicine in this way "may result in diminishing profits, decreased R&D expenditures, and an eventual decline in the introduction of new drugs".[149] This is the main rationale behind for proponents of patent rights to claim for a longer patent term. In contrary, some argue that such extension is not needed and justified due to several reasons. Firstly, it can take not years but even only several months for "a commercially successful medicines" to earn the cost spent for R&D. Secondly, the usual time required for getting market approval has declined in nowadays. Thirdly, there are only few new active ingredients protected by patents and "the great majority [of other patents] cover logical extensions of existing knowledge or developments that are patented with the deliberate aim of delaying competition".[150]

Both sides have the strengths and weaknesses of their argument in relation to patent extension. However, when it comes to the ultimate effect on access to medicines, the negative effect of the patent extension is more obvious. Patent extension, even for administrative delays, levies additional burden on the public. It makes those who can afford higher prices to pay for a longer term and leaves those who cannot afford costs of patented medicine without access to medicines for a longer term. Moreover, patent holder might be reluctant to advance the patented medicine until patent expires and thus improved version of the medicine will reach the consumer later. In addition to such consequences that the public may encounter, there are other parties that may also have negative impact from extended patent terms. In particular, production-intensive companies in some cases develop new formulations or components from the existing medicine that are therapeutically beneficial. If patents have longer life, such developments will be postponed to the extent of the additional protection term that medicines have. Furthermore, extended patent term will boost revenues of only a few companies that have managed to create financially successful medicines. These additional revenues may enable such companies to perpetuate their domination in certain research areas whereas other companies that lack capacity may become discouraged to be involved in those research areas. And not to mention about research intensive companies based on generic production that will naturally also face less revenue and less production of generics.[151]

The EU in its proposed FTA put forward to extend the patent term. In particular, referring to Article 9.3 of the proposed FTA patent term should

[149] Greenberger M. *et al,* (1982) *Patent Term Extension and the Pharmaceutical Industry* [online], p. 3. Last accessed 15 October 2012, available at: http://www.fas.org/ota/reports/8119.pdf

[150] Correa C. M., (2006) *Implications of bilateral free trade agreements on access to medicines* [online]. World Health Organization Bulletin 84, p. 401. Last accessed 15 October 2012, available at: http://www.who.int/bulletin/volumes/84/5/correa0506abstract/en/index.html

[151] Greenberger M. *et al, supra* note 149, pp. 6-7 and 44-45.

be extended for additionally five years in order to cover up the time spent to get marketing approval.[152] The acceptance of such terms would mean for India acceptance of the possible consequences for the public and pharmaceutical industry discussed in the previous paragraph. More worryingly, patent term extension in Indian context has more wide ranging impact and chain effect than it would have in other countries. Apart from possible delay of access to affordable HIV/AIDS medicines for additional five years for Indian public, millions leaving abroad may also be indirectly delayed for similar terms considering their dependency on HIV/AIDS medicines provided specifically by Indian generic manufacturers. However, positive and calming news in relation to this matter is that referring to Daniele Smadja who serves as the EU's ambassador and head of delegation to India, the issue of patent term extension was already put off from the table of negotiations at the beginning of 2011.[153]

5.2.3 Enforcement of IPRs

Another debated issue around IndEUFTA is the enforcement measures that the EU is seeking to tighten in relation. More stringent enforcement measures are sought in order to make sure that IPRs of companies established in both the EU and India are not breached and in cases of infringements of IPRs proper, which is usually harsh, actions are undertaken. Such stringent enforcement measures are aimed to be realized through courts, executive authorities, private parties and customs authorities. It is considered that strict enforcement rules and regulations that are sought to be accomplished may result in "wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines" and may "[undermine] the legitimate interests of poor patients and Indian generic manufacturers".[154]

TRIPS Agreement demands strict enforcement rules only in relation to trademark counterfeiting and copyright piracy and not for patent rights because in practice it is harder to confirm the infringements of the patent rights due to their complexity and necessity for technical analysis. Therefore, enforcement measures in this form are deemed to be more than what is required in TRIPS Agreement and thus are seen as TRIPS Plus. Nevertheless, the IndEUFTA aims to apply enforcements rules, similar to copyright and trademark, to the patent rights as well. For a generic

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[152] Correa C. M., (2009) *Negotiation of a Free Trade Agreement European Union-India: Will India Accept Trips-Plus Protection?* [online], p. 10. Last accessed 15 October 2012, available at: http://www.oxfam.de/files/20090609_negotiationofafreetradeaggrementeuindia_218kb.pdf

[153] The information that patent term extension, as officials claim, was no longer relevant subject matter in the IndEUFTA was already known while writing this thesis. Despite of this it was decided to keep the discussion of possible effects of patent term extension, mainly because, as stated above, the patent term extension may have the most far reaching and direct impact on access to medicines and thus it would be crucial to be aware of this in future negotiations as well.

[154] Medicines Sans Frontiers, (2012) *The Enforcement Provisions of the EU-India FTA: Implications for Access to Medicines* [online], pp.1-2. Last accessed on 15 October 2012, available at: http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_FTAEnforcementProvisions_ENG_2012.pdf

production industry this could mean that generics would be under "excessive and unwarranted enforcement measures" in cases when they are even suspected of patent infringement.[155]

One of the worrisome enforcement mechanisms the EU is intending to have in the IndEUFTA is the possibility to involve third parties suspected in a patent infringement into litigation. In other words, a patent holder might have a right to sue all parties engaged in the circulation of suspected generics which may include from manufacturer to the supply chain of the generic in subject. By this, important actors in the distribution of affordable medicines can be dragged into litigation even though they were not directly involved in the manufacture of the drug.[156] For example, even an NGO or philanthropic organisation getting a generic medicine for a non commercial use and supplying it to those in need may be also brought under the court if the generic medicine in subject is later found or even suspected in patent infringement. This may ultimately discourage third parties like humanitarian and philanthropic organizations that play crucial role[157] in supplying life saving and affordable HIV/AIDS medicines from dealing with generics. Moreover, the EU wants to empower courts to issue an order to temporarily stop the circulation of generics, including manufacture, selling, and distribution by third parties, even based on a suspicion that generic might be infringing patent rights until the suspicion becomes clear.[158] This may inevitably delay the on time circulation of HIV/AIDS generics even based on suspicions whereas the time plays vital role in particular in relation to such life saving drugs. In addition to issuing such orders, the EU wants to empower the courts to issue orders that allow physical seizure of "goods, materials and implements used in the production and/or distribution of such goods and the freezing of bank accounts [of parties involved], even in cases where infringement has not yet been proved".[159]

Another issue at stake is border enforcement measures. The IndEUFTA in its current form demands India to have border measures not only to imported products but also to exported ones. However, it should be noted that patented products are excluded from the scope of border enforcement measures. But even so, the border enforcement measures for trademarks can become a reason for a disruption of provision of generics. One example for this is the an antibiotic generic amoxicillin originating from India which was prevented from reaching its destination by custom officials of Frankfurt airport on the suspicion that it breached GlaxoSmithKline's trademark name "Amoxil". However, the customs officials were later informed by the GlaxoSmithKline that the drug did not

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[155] *Ibid.*
[156] *Ibid.*
[157] One of such organizations is Medicines Sans Frontiers (MSF). The MSF is an international medical humanitarian organization initiated by doctors and journalists in France in 1971. It currently provides comprehensive care to more than 200,000 people affected by HIV/AIDS in 19 countries. It also provides ARV treatment to over 170,000 people. See, See official web site of the organization, available at: http://www.msfaccess.org/our-work/hiv-aids/article/1345 (last accessed on 15 October 2012).
[158] Medicines Sans Frontiers (2012), *supra* note 154, p. 2.
[159] *Ibid.*

violate the trademark name since the amoxicillin was in the public domain as an international non-proprietary name. Yet, the drug had to reach its destination, which was a least developed country Vanuatu, late.[160] Another aspect of border enforcement measures in relation to trademarks is that, if applied as the EU wants, a trademark holder will not need to have judicial determination of infringement or declaration of a court in relation to trademark infringements, but rather the trade mark holder can directly request custom officials to seize and detain a consignment of generic drugs in the cases of suspicion of trademark violation. Therefore, it is considered that "unnecessary and harmful interruptions" to the supply of medicines may take place if trademark protection is not also taken away from the scope of border enforcement measures enshrined in the IndEUFTA.[161]

On the other hand, patent holders also have their legitimate claim to ask for enforceable and realizable IPRs so that to protect their interests that required considerable effort and resources. Therefore, it would not be rational to demand total loosening of IP border enforcement measures, which is not also the claim of this thesis, which may ultimately result in deliberate and abusive IPRs infringements. However, from above analysis it is evident that the EU is pushing forward stringent enforcement measures that may go beyond mere protection and enforcement of rights of patent holders and instead may, as mentioned above, undermine the legitimate interest of poor people and Indian generic industry.

5.2.4 Wide scope of investment protection

The EU is using different tactics in the IndEUFTA to anyway ensure that IPRs, including patents, are vigorously protected as in the way the EU would want. While the issues of intellectual property logically should be dealt under IP chapter of the IndEUFTA, the EU achieved to launch front of intellectual property negotiations under "investment chapter" as well. This was achieved through wide and open-ended definition of investment that includes "almost every of asset owned or controlled by an investor of both parties". In particular, the term investment is defined to be covering "foreign direct investment, shares, debentures, loans, interests, business concessions, movable and immovable property, *intellectual property rights*, goodwill,

[160] This was not the only case where Indian generics were detained while being in transit through the EU. There were several other similar cases. For example, generics from India destined towards South America were stopped in the territory of the EU, particularly in the Netherlands. This in its turn induced India on 11 May 2010 to call for a dispute settlement consultations with the EU at the WTO claiming that such measures were not in compliance with Article V of General Agreement on Tariffs and Trade (known as GATT) guaranteeing freedom of transit of goods and with Articles 41 and 42 of the TRIPS Agreement. Brazil also joined India in the consultations on the basis of similar claims. The series of negotiations led to the conclusion of 'Understanding' between parties enshrining guidelines for border enforcement measures of IPRs. See, Ministry of Commerce and Industry's Department of Commerce, (2011) *India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit* [online]. Last accessed on 15 October 2012, available at: http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=2807

[161] Medicines Sans Frontiers (2012), *supra* note 154, p. 2

technical processes and know-how" (emphasis added).[162] By having patent rights under the investment chapter, patent holders will enjoy protection granted for investments as an addition to the protection measures provided under IP chapter in the ways explained below.

First, the investment chapter prohibits the governments from, both explicit and implicit, expropriation of foreign investment. The implicit expropriation in this context means to be any regulatory or policy actions undertaken by the government that could obstacle the enjoyment of investment by foreign investors. In this sense Indian government can be challenged, for example, where it tries to support domestic generic producers by advancing domestic flexibilities for IPRs or even in other instances where it aims to adopt regulations or policies for the support of public health which could interfere with the patent rights, equally treated as investment, of foreign companies. In addition to this, even the court decisions and judgments in relation to patent rights can be subject to opposition and challenges in the international arbitration by patent holders.

However, it should be noted that investment chapter states that the rules of expropriation shall not apply for cases of compulsory license if those were issued in compliance with TRIPS Agreement. So in this way a state can apply compulsory license on a medicine and allow generic production of it without being deemed as "expropriating investment" of foreign pharmaceutical company. Nevertheless, the safeguard against expropriation clause relates only to compulsory licensing which means that other regulatory and policy actions for the promotion of access to affordable medicines can be still challenged.[163]

Second, the EU wants to insert in the investment chapter "a fair and equitable treatment" standard. This standard requires the state to provide minimum standards to foreign investors no matter how the state treats its own domestic investors. Strictly speaking, this means that, for example, if the state has a special treatment of domestic pharmaceutical companies, it should not apply such treatment to foreign pharmaceutical companies if foreign pharmaceuticals companies regard the treatment not to be "fair and equitable".[164] The standard of fair and equitable treatment is a new breakthrough in international agreements and thus usually does not follow with a concrete definition which leaves it uncertain as to what exact obligations must a state fulfill under this standard.[165] Consequently, this usual uncertainty has left wide discretion for arbitral tribunals to define what is meant by "fair" and "equitable" treatment. In some cases arbitral tribunals enjoying this wide discretion decided against the governments' decisions or policies created for the interest of public.[166]

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[162] Madhyam, (2011) *India-EU FTA: Policy Implications of Unfettered Investment Flows* [online], p. 2. Briefing paper no. 2. Last accessed on 15 October 2012, available at: http://www.madhyam.org.in/admin/tender/MadhyamPaper2.pdf

[163] MSF, (2011) *The Intellectual Property and Investment Chapters of the EU-India FTA: Implications for Health* [online], p. 3. Last accessed on 15 October 2012, available at: http://ec.europa.eu/health/eu_world/docs/ev_20110616_rd01_en.pdf

[164] *Ibid*, pp. 4-5.

[165] *Ibid*, p. 5.

[166] See for example the case *Metalclad Corporation vs. The United Mexican States*, ICSID Case No. ARB(AB)/97/1, the full text of the case available at:

Third, the EU in its investment chapter is seeking to involve "national treatment" and "most favored nation" (MFN) treatment in accessing India's markets. This would mean that India will not be able to treat its own domestic investors in more privileged way than foreign investors since according to MFN treatment India would have to give the same privileges and benefits to European investors as it gives to any other foreign investors. These factors, consequently, limits the India's capacity to design its market in a way so as to boost and keep the production of affordable medicines by supporting domestic generic manufactures.[167] In addition to the mentioned two kinds of treatment, the EU in its draft IndEUFTA put forward to confer foreign investors "pre-establishment" protection which could mean that investors would be able to have legal action even before having their investment in India.[168] This increases potentiality of legal challenges to India by outsiders, especially by large pharmaceutical companies, to curb India's generic production.

Fourth, the IndEUFTA in the form put forward by the EU allows foreign investors to have arbitration directly against the state. This feature of the investment chapter of the draft IndEUFTA is regarded as "the most problematic" since it enables foreign investors to directly bring India to a secret arbitration tribunal and claim for a compensation for any regulations, policies, court decisions or any other actions of the government that could impede foreign investors in enjoying their investments. By this, foreign investors would be able to avoid domestic courts and procedures and have their case being heard by an arbitral tribunal.[169] This can be problematic for India's ability to generate affordable medicines at least in two ways. First, as described above, tribunals sometimes rule against government actions even though those actions were undertaken to benefit public interest. This implies that it would be harder for India to win the cases related to compulsory licenses or patent challenges done by domestic generic manufacturers when the case is brought before arbitral tribunal. Second, Indian courts while deciding cases in relation to pharmaceuticals gives special care to life saving pharmaceuticals and they treat such pharmaceuticals different from others basing the cases also on human rights. The case of Roche, a Swiss pharmaceutical company, against Cipla, an Indian generic manufacturer, over the patent rights of the anticancer drug "erlotinib" sold and owned by Roche under the name "Tarceva" could be an example. In this case the Delhi High Court stated that an injunction to stop a manufacture of generic version of the drug could violate Article 21 of the India Constitution which provides with right to life. The Court noted the seriousness of the issue of having the right to access to life saving drugs and the necessity of having long term supply of them in India. Ultimately, the Court considered that the possibility of having damage to general public from not having generic version of such life saving drug can serve as a basis

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http://jay.law.ou.edu/faculty/Gismondi/NAFTA/Metalclad%20Corporation%20v%20Mexico.pdf

[167] MSF (2011), *supra* note 163, p. 5.

[168] *Ibid.*

[169] *Ibid*, p. 2.

for a refusal to grant an injunction.[170] However, if the cases are heard before arbitral tribunals, foreign pharmaceutical companies will be able to circumvent Indian national courts which, as explained, take into account human rights and public interest while deciding cases rather than treating all cases similarly. The practice has showed that it was extremely challenging for governments to justify their actions based on public interest safeguards while having their cases heard before arbitral tribunals.[171]

The possible risk caused by drafted investment chapter is not based on just hypothetical predictions. There have been several cases observed where companies relying on the rules contained in the investment chapter were able to sue governments for carrying out actions for public health interest. For example, the Swiss based multinational company Philip Morris sued Uruguay for measures undertaken for the benefit of public health by requiring the company to enlarge the size of warnings on the cigarette. The dispute was launched in accordance with 1991 Switzerland - Uruguay Bilateral Investment Treaty which enabled foreign investors, like in the current investment chapter of the EU-India FTA, to directly bring the case against the government before an arbitral tribunal. Philip Morris based its claim, among others, on "expropriation" of company's trademark and impediment with its investment rights. Another similar case, but involving a pharmaceutical company, was noted in the case of Brazil issuing a compulsory license for efavirenz, an anti retroviral medicine, belonging to Merck. The company made a press release similarly naming this action of the government as "expropriation" of IP.[172] The investment chapter is seen to be bringing new "TRIPS-plus-plus" rules that could limit the government's ability to implement measures to boost public health and especially access to affordable medicines.[173]

5.3 Consequent impact on access to medicines – lessons learnt from other FTAs

The before sections made the analysis of possible legislative changes and their potential effects on affordable medicines that India may encounter after having signed the IndEUFTA in the form proposed by the EU. However, it is necessary to go beyond probabilities and rather to see actual effects on access to medicines by looking at the experience of other developing countries that already signed FTAs with similar character and learn what kind of impacts brought to the medicines. Even though the EU has signed FTAs with number of developing countries[174], there are no studies available

[170] Ranjan Narula Associates, (2010) *Cipla v Roche – Generics Industry Rejoices!* [online], p. 2. Last accessed on 15 October 2012, available at: http://www.indiaiprights.com/new-pdfs/3616144202news.pdf

[171] MSF, (2011) *EU-India Free Trade Agreement: Investment and Intellectual Property Chapters Threaten Access to Medicines* [online], p. 2. Last accessed on 15 October 2012, available at: http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_Investment%26IPChapters_FTA_ENG_2011.pdf

[172] *Ibid.*

[173] *Ibid,* p.1.

[174] The EU has already formed FTAs with following developing countries: Algeria (2005), Chile (2005), Egypt (2004), Jordan (2002), Lebanon (2003), Mexico (2000), Morocco

about how an FTA specifically signed with the EU affected access to medicines in partner developing country. However, as mentioned before there are instead some studies available instead in relation to the FTAs between Jordan, Colombia, Peru and Thailand each having with the U.S.. Considering that these FTAs have similar characteristics and provisions to that of the IndEUFTA, it is possible to come up with relevant conclusions for the case of IndEUFTA and thus this will be the main aim of upcoming two sections. The study of the Jordanian FTA with the U.S. provides more thorough analysis and thus merits a discussion in a separate section.

5.3.1 Lessons learnt from Jordan-U.S FTA

Jordan signed its FTA with the U.S on October 24, 2000 and it entered into force in December 17, 2001. By this Jordan became in general the third country and the first Arab country signing an FTA with the U.S. (hereinafter JorUSFTA). The Agreement aimed at creating a free trade zone between both partners by involving their certain commitments in different areas including intellectual property rights. The aim was to be achieved by steady removal of duties and commercial barriers during upcoming 10 years and to have full free trade area starting from January 1, 2010.[175]

One of the similar attributes that JorUSFTA may have with IndEUFTA is the introduction of data exclusivity. However, unlike in the IndEUFTA, the conditions of data exclusivity are not explicitly mentioned in the JorUSFTA. Rather, Jordan had to introduce data exclusivity under national law, in particular Article 8 of 2000 Unfair Competition Law and Trade Secrets Law No. 15, as a precondition to have the FTA with the US.[176] Accordingly, it was not possible anymore for Jordanian generic manufacturers to get a marketing approval relying on the data submitted by the originator. In practice, pharmaceutical companies in Jordan are making more regular use of market monopoly granted by data exclusivity rather than addressing the issue to patent rights. Based on studies of 103 medicines registered and produced starting from 2001that did not have a patent protection, it was found that even though these drugs did not have patent protection, 79% of them enjoyed monopoly because of data exclusivity. Another study showed that total sales of 81 drugs out of 108 that did not have a generic version because of data exclusivity and this gave extra cost of USD31.49 million from mid 2002 to 2006 which represented 68% of the total sales of all new drugs that does not have generic version.[177]

(2000), Palestinian Authority (1997), South Africa (2000), Syria (1977), and Tunisia (1998), available at: http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/agreements/#_europe (last accessed on 15 October 2012).

[175] The American Chamber of Commerce in Jordan, (2009) *Jordan – U.S. Free Trade Agreement (JUSFTA)* [online]. Last accessed on 15 October 2012, available at: http://www.amchammena.org/Jordan/Free%20Trade%20Agreement.pdf

[176] Ryan M. and Shanebrook J., (2004) *Establishing Globally Competitive Pharmaceutical and Bio-Medical Technology Industries in Jordan*, International Intellectual Property Institute and AMIR, p. 19.

[177] Oxfam, (2007) *All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines* [online], p. 9. Last accessed on 15 October 2012, available at: http://www.oxfam.org/en/policy/bp102_jordan_us_fta

The best illustrative example of how data exclusivity affected the price of medicines can be captured by the comparison made between the price of medicine having protection under data exclusivity in Jordan and the price of its generic equivalent. The price of five best selling drugs used for diabetes and cardiovascular disease in Jordan and Egypt was compared to see the difference between the prices of those drugs produced in Jordan having data exclusivity protection and the prices of their generics version produced in Egypt where no data exclusivity protection was available (see Table 1).[178]

Table 1: Comparison between prices of drugs with no generic competition in Jordan due to having data exclusivity protection and the prices of their generic equivalent in Egypt

Active Pharmaceutical Ingredient (dosage)	Medical use	Country (company)	Price per Unit (in Jordanian dinars at prevailing exchange rate)	Jordan price compared to Egyptian price
Metformin (800 mg vs. 500 mg)	Anti-diabetic	Egypt (local generic company)	.02	800%
		Jordan (Merck)	.16	
Atenolol (100 mg)	Anti-hypertensive	Egypt (local generic company)	.03	367%
		Jordan (Kleva)	.11	
Rosiglitazone maleate (4 mg vs. 2 mg)	Anti-diabetic	Egypt (local generic company)	.40	167%
		Jordan (Glaxo SmithKline)	.67	
Simvastatin (20 mg)	Anti-hyperlipidemic	Egypt (local generic company)	.452	498%
		Jordan (Merck)	2.25	
Ramipril	Anti-hypertensive	Egypt (local generic company)	.14	557%
		Jordan (Sanofi-Aventis)	.78	

The table above demonstrates enormous difference of the prices of the drugs even though having similar content and medical use. This price difference is generated by not having generic competition in the market due to the monopoly granted by data exclusivity. The studies identified that the government of Jordan and consumers "could have saved between [USD 6,3 million] and [USD 22,04 million] on the 81 medicines that have no generic equivalent due to data exclusivity".[179] This is considerable amount of health spending for a country like Jordan where "chronic high rates of poverty,

[178] The data is taken from, *ibid*, p.10.
[179] *Ibid*, p. 14.

unemployment, inflation, and a large budget deficit" exists[180] along with poverty rate anywhere between 15 to 30%.[181] Moreover, 40% of Jordanians are not covered by health insurance which implies that the cost for the drugs is paid from the pocket of such high percentage of people.[182]

The JorUSFTA, in general, caused a sudden and notable increase in the prices of medicines. By 2006 medicines in Jordan got 20% more expensive after the enforcement of the JorUSFTA in 2001. Considerable number of therapeutic classes of medicines[183] underwent price increases. From 2001 to 2006, the price of 91 therapeutic classes rose for more than 20% whereas 88 other therapeutic classes had increase in the price up until 20%.[184] Similarly, Jordanian hospitals observed "an alarming surge" in spending for pharmaceuticals starting from 2002. The Royal Jordanian Hospital calculated that between 2002 to 2006 pharmaceutical expenditure rose up to *six-fold* which indicated increase in spending from two million to twelve million Jordanian Dinars annually.[185] In 2006 patients were regularly complaining about sudden increase of essential drugs in the previous few years and were informing that they were not being able to afford high prices of drugs sold in private pharmacies.[186] These price increases for essential drugs were also acknowledged by top officials and raised their serious concern for impeding access to life saving medicines to a large number of people living in Jordan. The National Health Strategy (2006-2010) stated that the "surge in the spending on medicines in the public and private sectors" poses one of the major risks "to the continuity of health programmes and sustainability of their financial resources".[187] JorUSFTA also has been directly contributing to the delays in the Jordanian generic production and thereby production of affordable drugs. Local companies stated that the possibility to produce generic version of original drugs had been delayed from 6 to 9 years.[188]

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[180] CIA Factbook, (2012) *Jordan*, available at: https://www.cia.gov/library/publications/the-world-factbook/geos/jo.html [last accessed on 15 October 2012].

[181] Ministry of Social Development, (2002) *Poverty Alleviation for a Stronger Jordan: A Comprehensive National Survey*, Amman, JPAP, pp. 14-15.

[182] Oxfam, *supra* note 177, p. 5.

[183] The term therapeutic class of medicines is 'used to classify similar medications used to treat a specific condition or disease'. The definition is available at: http://coventry-medicare.coventryhealthcare.com/glossary/index.htm

[184] Oxfam, *supra* note 177, p. 12.

[185] *Ibid*, p. 19.

[186] El-Said H. and El-Said M., "TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan–United States Free Trade Agreement", *The Journal of World Intellectual Property*, Vol. 10, no. 6 (2007), p. 461.

[187] *Ibid*, p. 465.

[188] The reason for a delay from 6 to 9 years is explained by the fact that according to Jordanian Patent Law a pharmaceutical company can not get a marketing approval for one year for a drug for which originator already got an approval. In other words, once original producer of the drug got a marketing approval, it is automatically granted one year monopoly since other companies are not allowed to get an approval for the same drug for one year. After, the original owner of the drug can get additional five years of protection term through data exclusivity protection which implies that the original producer already can have six years of possible monopoly. In addition to this, the original producer may get additional three years of data exclusivity protection if new use or new indication for the drug is found. See, ibid, p. 463.

5.3.2 Lessons learnt from other FTAs

Beginning from May 2004 Columbia started negotiations with the US on an FTA (hereinafter ColUSFTA) between both countries. One of the main focuses of the negotiations was the IPRs. In February 2006 both parties were able to end the negotiations and agree on the text of the ColUSFTA. Based on this available text, a study was done using a method developed by the World Health Organization and Pan American Health Organization[189] to estimate the impacts on pharmaceutical spending and access to medicines in Columbia. The studies concluded that if no measures were taken to lessen the impact of the ColUSFTA, by 2020 the ColUSFTA with its intellectual property chapter would enable to achieve a market monopoly in the level of around 63% as a result of both patent and data exclusivity. Consequently, this would enormously curb generic competition, large portion of domestic pharmaceutical market would experience monopoly prices, and domestic pharmaceutical industry would face severe constraints by possibility of losing up to 57% of its current market share value. Price index for medicines would also rise to around 40%. In addition, by 2020 Columbia could experience an increase of USD 919 million in spending on pharmaceuticals, or which equals to health care expenditure of 5.2 million Columbians contributing in the social security system that year. If spending on pharmaceuticals was not increased by public health care in accordance to price increases, this could result in 40% drop in medicine consumption which inevitably implies impediment for access to medicines, especially, for those who cannot meet the expense of higher prices.[190]

On April 12, 2006 Peru signed Trade Promotion Agreement, equal to an FTA, with the US (hereinafter PerUSFTA) and consequently the Agreement entered into force on February 1, 2009.[191] On April 2005, the Ministry of Health of Peru conducted a study to examine potential impacts of this agreement to access to medicines in Peru. The studies found that already in the first year after the enforcement of the Agreement, the average price of the drugs would increase to 9.6% whereas original drugs would increase to 12.5% and branded generics to 4.3%. The average prices would increase between 55% to 100% whereas original medicines would increase between 72% to 132% most probably in the period from 2011 to 2017. In the extreme case where generic copies would be driven out of the market, the price of original medicines could rise up until 225% in the same period. Already in 10 years Peru would experience USD 199.3 million additional costs for medicines out of which USD 110 million would need to be covered

[189] These two bodies in collaboration introduced 'Guide to estimate the impact on access to medicines of changes in intellectual property rights'. See, Rovira J. et. al., (2005) *Guía para estimar el impacto sobre el acceso a los medicamentos de cambios en los derechos de propiedad intelectual (DPI)* [online]. Last accessed on 15 October 2012, available at: http://www.ops.org.bo/textocompleto/prensa/estimacion-impacto-tlc-bol-usa/1.pdf

[190] For more details about how the study was made and how the results were derived see Gamba C. M., (2006) *Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia* [original in Spanish] [online]. Last accessed on 15 October 2012, available at: http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf

[191] See the official website of the Office of the United States Trade Representative (USTR), available at: http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa

by Peruvian households. Data exclusivity protection would engender USD 34.4 million additional costs for medicines already in one year after the enforcement of the Agreement. Of this total, USD 29 million would need to be borne by private Peruvian households and the remaining by Ministry of Health of Peru. Between the seventh and thirteenth years after enforcement, the additional costs were estimated to reach from USD 130 to 170 million.

With regards to access to medicines, the foremost effect would be experienced in the first five years after the enforcement of the PerUSFTA. In this period it was forecasted that the drug consumption could fall between 2.4 to 3.1%s or which alternatively means that from 700,000 to 90,000 people would be unable to have access to medicines if the budget of Peruvian Ministry of Health and income of poor people would not be increased. Moreover, traditional medicines in Peru are becoming less effective for the diseases such as HIV/AIDS, malaria, tuberculoses and thus people affected by these diseases are in need to switch to new pharmacological breakthroughs. However, as an impact of PerUSFTA access to such new breakthroughs might be delayed or even not occur due to price increases.

Another noteworthy factor is how market composition would change as a result of the PerUSFTA. As a result of market deregulation at the beginning of the 1990s in Peru, the Peruvian pharmaceutical market structure in 2004 became comprising of 83% generic drugs against 17% of original ones. After the enforcement of the intellectual property rules contained in the PerUSFTA, the market would experience considerable change in its composition. In particular, in thirteen years after the enforcement, the original drugs would take over 69% of the market leaving only 31% to generic versions. According to predictions these original drugs would focus only on the demand of people with medium to high purchasing power leaving the demand of poor people unmet. [192]

In 2004 Thailand and the US started talks on drafting an FTA (hereinafter ThaiUSFTA) between both countries. The negotiations were focused on the matters like intellectual property rights, customs and ways of pushing forward WTO Doha negotiations.[193] The issues at stake in the ThaiUSFTA that went beyond TRIPS Agreement were, first, extension of patent term for unreasonable delays caused by procedures required for patent grant or marketing approval. Second, the ThaiUSFTA required linkage of marketing approval process and patent status of a drug.[194] Third, it introduced data exclusivity protection for the period of five years. [195]

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[192] All information about PerUSFTA was taken from the study conducted by the Ministry of Health of Peru in 2005. See, Valladares Alcalde G. et al., (2005) *Evaluacion de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de America* [online], pp. 7-21. Last accessed on 15 October 2012, availale at: http://www.minsa.gob.pe/portada/Especiales/TLC-MINSA/EstudioTLCSalud_ResumenEjecutivo.pdf (last accessed on 15 October 2012)

[193] See the official website of the USTR, available at: http://www.ustr.gov/about-us (last accessed on 15 October 2012)

[194] This means that Thai DRA will have to make sure that a generic drug that is submitted to get a marketing approval does not infringe patent rights of exiting drugs if the marketing approval is granted for that generic. This, in turn, imposes an extra task to the DRA which, in fact, is not responsible for policing patents. Subsequently it can take longer time for the

A study funded by the Thai FDA and Ministry of Health was launched to evaluate the impact that afore mentioned three changes in Thai patent system would have on access to medicines in Thailand. The results of the study indicated that 10 year patent term extension due to delays, a 5 year postponement due to linkage of marketing approval process and patent status of a drug, and a 10 year delay resulting from data exclusivity would cause 67 percent increase of drug prices bringing additional spending of USD 23,595 million in following 20 years after the enforcement of the ThaiUSFTA. The domestic industry would also lose USD 9,000 million from such scenario.[196] In the conducted study an investigation of 35 different cases for patents that may affect access to medicines due to ThaiUSFTA suggested that patent term extension would have the greatest negative effect on access to medicines. The investigation presented that in subsequent 20 years after enforcement of the ThaiUSFTA a patent term extensions for 10 years, for example, would result in the rise of spending on medicines for around USD 11,191 million and there would be loss of USD 3,370 million for domestic pharmaceutical industry mainly because many domestic companies are based on generic production. Alternatively this could imply 32% increase in the price index for medicines by 2027. It was further shown that in shorter term, negative economic impact of data exclusivity would be more than a 5 year patent term extension whereas the positions would change in longer term (i.e. patent term extension would be more economically damaging than data exclusivity). Moreover, it was suggested that data exclusivity would have more negative impact especially in a situation where a medicine did not have a patent protection.[197]

5.4 Conclusions to be drawn in relation to the IndEUFTA

The analysis made in the previous chapter indicate, through the actual experiences of Jordan, Colombia, Peru, Thailand, how an FTA containing TRIPS Plus provisions may hinder availability of cheap medicines and by doing so hinder access to medicines of, especially poor, people leaving in those developing countries. Consequently, India should make corresponding conclusions from the experience of those countries. Especially the case of Jordan is more concrete since Jordan has already felt the actual impact on both availability of affordable medicines and access to medicines in reality rather than just hypothetically anticipating them.

On contrast, the case of India may even have even farer reaching results and negative impact on access to HIV/AIDS medicines and other medicines in general. Because, as demonstrated in the Chapter 3 India, first,

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DRA to approve application of a generic drug. See, MSF, (2011) *How the Trans-Pacific Partnership Agreement Threatens Access to Medicines* [online]. Last accessed on 15 October 2012, available at: http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf

[195] Kessomboon N. *et al.*, "Impact On Access to Medicines from Trips-Plus: a Case Study of Thai-US FTA", *Journal of Southeast Asian J Trop. Med Public Health*, Vol. 41, no. 3 (2010), pp. 670-671

[196] *Ibid*, p. 674.

[197] *Ibid*, pp. 673-74.

have been massively supporting and promoting access to medicines to its local people and at the same time to the extensive number of, mostly financially vulnerable and dependant, people outside its borders owing to its large scale of generic production. Oxfam, one of the leading charity organizations, estimates that the number of people being prevented from access to affordable to medicines due to IndEUFTA could be hundreds of millions.[198] Another very particularity and importance of the IndEUFTA from other FTAs lie on the fact that, as noted by Philippe Douste-Blazy, Chair of UNITAID's Board[199], "[IndEUFTA] coincides with a delicate time for access to treatment efforts" when the grants by the Global Fund are being suspended and resources for health and development are decreasing.[200] In other words, the global price for HIV/AIDS medicines can be on rise due to IndEUFTA whereas the funds for the facilitation of access to HIV/AIDS medicines in contrary are dropping. This will logically bring distressing situation for access to medicines of especially poor people residing in developing and least developed countries. The seriousness of the situations particularly around IndEUFTA is acknowledged in an international level by numerous leading NGOs, funds, and experts in the field.[201] The United Nations Special Rapporteur on the right to health, Anand Grover, acknowledged that draft of IndEUFTA "could prevent people from all over the world from gaining access to life saving and life prolonging medicines" and "have a devastating public health impact and affect the right to health for millions of people" by hindering generics production. These give the

[198] Banks M. (2012), *EU Urged to Avoid 'Pressurising' India at Summit* [online]. Last accessed on 16 October 2012, available at: http://www.theparliament.com/latest-news/article/newsarticle/eu-urged-to-avoid-pressurising-india-at-summit/

[199] "In 2006, Brazil, Chile, France, Norway and the United Kingdom decided to create an international drug purchase facility financed with resources that would be both sustainable and predictable. The initiative was given the name UNITAID, and a tax on airline tickets was chosen as the most appropriate means of providing sustainable funding.
UNITAID was officially launched on 19 September 2006 in New York at the opening session of the United Nations General Assembly. Today, UNITAID fills a critical gap in global health financing. It provides a sustained and strategic market intervention that aims both to decrease the price of medicines for priority diseases and to increase the supply of drugs and diagnostics". The information is taken from the official website of UNITAID, available at: http://www.unitaid.eu/who/background?id=159

[200] The Global Fund to Fight Aids, TB and Malaria is becoming unable to issue new grants to countries due to the considerable cuts in the funding of the Fund by donors. This is mainly due to the financial crisis that the world has been experiencing. In the 2010 New York Meeting the Fund was able to manage only USD 11.7 billion out of sought USD 20 billion. The Guardian, (2011) *Crisis Looms as Global Fund Forced to Cut Back on Aids, Malaria and TB Grants* [online]. Last accessed on 15 October 2012, available at: http://www.guardian.co.uk/society/sarah-boseley-global-health/2011/nov/23/aids-tuberculosis

[201] Among them are: MSF, UNITAID, IDA Foundation, Oxfam, Delhi Network of Positive People, European Parliament Working Group on Innovation, Access to Medicines and Poverty-Related Diseases, and Elton John AIDS Foundation. The majority of these organizations have been actively involved in scrutinizing the IndUSFTA by organizing different campaigns including public demonstrations, publications and information awareness. Some of them also have sent official letters to relevant bodies condemning dangerous provisions of the FTA and calling for their reconsideration. The copies of these official letters are available at: https://donttradeourlivesaway.wordpress.com/letters-to-officials/

scenario and possible outcome from the realization of the draft of IndUSFTA being dressed with the provisions discussed before.

On other hand, it would not be reasonable and objective to claim that only "badness" emanates from IndEUFTA and that is all about harm. As described in sub-chapter 5.1 there are certain economic benefits sought and expected from the IndEUFTA benefiting both sides and people inhabiting there. At the same time it is essential to note and acknowledge the important role that IP plays for the economy of a country 'by providing the freedom to innovate, allowing incentives to encourage innovation and protecting those innovations".[202] Pharmaceutical industry especially needs IPRs more than any other industry since it is the main tool that pharmaceutical companies use to enable them to recoup considerable investments they make in bringing up a new product to the market. The importance of the IPRs in this sense is undeniable but more important questions remains as to whether IPRs rules being sought in the form proposed in the draft IndUSFTA can be beneficial for developing country like India. As pointed out by Carlos Correa, one of the leading experts in IPRs in the context of developing countries, "uncontestable and solid set of studies . . . that consistently indicate . . . that developing countries are going to suffer from substantial price increases and other costs" from tighter IP rules.[203] More than that, the US Congressman Henry Waxman, strong proponent of IPRs who used to be one of the main players for introduction of stronger IPRs in the US through commented on how stronger IPRs practiced in the developed countries may affect developing countries if applied similarly. In particular, he criticized the attempts of the US to apply IP rules similar to its own to other developing countries. He expressed these strong words:

> "[Such stricter IP rules exercised in the US] delay market entry of low-cost generic drugs for years after a life-saving drug becomes available . . . [The] system works in this country because most people … in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment. But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical."[204]

In addition to this, a report prepared by the Commission on IPRs205 in 2002 underpinned the actuality of the claim that it might not be in the interest of developing countries to incorporate stricter IPRs because it may result in the

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[202] Matthews M. and Giovanetti T., (2002)*Why Intellectual Property is Important?* [online], p. 2. Last accessed on 16 October 2012, available at: http://www.ipi.org/docLib/II-CaseForIP-2.pdf-OpenElement.pdf

[203] Correa C., (2000) *Intellectual Property Rights, the WTO and Developing Countries.* London: Zed
Books, pp. 36-37.

[204] El-Said H., *supra* note 186, p. 444.

[205] The Commission was established by the initiative of the government of the UK and tasked "…to look at the ways that intellectual property rules need to develop in the future in order to take greater account of the interests of developing countries and poor people". The Commission is composed from six Commissioners from range of expertise including professors, barrister in IP, a senior official of the pharmaceutical company Pfizer, and other experts in the field. For more information see the official website of the Commission, available at: http://www.iprcommission.org/graphic/about.htm [last accessed on 16 October 2012]

increase of prices of medicines and thus hinder access to medicines. The report stated that "[d]eveloping countries should not be coerced into adopting stronger IP rights without regard to the impact this has on their development and poor people". The report further suggested that IPRs should rather be adopted in accordance to the development status and specific situations existing in a country.[206]

These expressed views the experts in the field of IPRs and afore made analysis of other FTAs imply that it would not be in the benefit of India in the context of production and access to medicines to conclude IndEUFTA in the form proposed by the EU (i.e. having stringent IPRs going beyond TRIPS Agreement). In this sense, when the strict IPRs prove their obvious side effects to India's ability of generic production and access to the medicines of millions dependant on that production, it will be up to the political will of India to resist such provisions. Of course one important issue to be underlined in relation to this is that, unlike other discussed developing countries that ratified FTAs, India has stronger political status and negotiation power which leaves a room for optimism.

[206] El-Said H., *supra* note 186, p. 444.

6 Conclusions and Recommendations

The HIV pandemic has already demonstrated its horrifying picture and it does not seem to step back in the coming future. Therefore, the role of HIV medicines remains to be vital. The HIV medicines are not medications against headache or stomachache, but they are medications which can mean life or death for the people affected or who may potentially be affected by the disease. Besides this material significance of HIV medicines, the accesses to such medicines can also be important from human rights perspective. As described before, there are certain bases to see access to, at least, essential medicines, which include ARVs, as a human right under the umbrella of the right to health. Therefore, an access to HIV medicines is undeniably important from both material and rights perspectives. It is true that HIV medicines cannot fully cure the contemporary plague of the world HIV, but, not less importantly, HIV medicines have so far engendered remarkable decrease in the newly infected people, have prolonged the lives of millions of people already infected with the disease and have been pushing the disease back from further escalation. Indian generic producers, in their turn, have been an instrumental player in accomplishing this task by providing with majority of low cost good quality generic version of ARVs worldwide. Taking into account this mutual importance of HIV medicines and Indian generic manufacturers, parties, especially the EU, of the IndEUFTA must make sure that this importance is not sacrificed for mere economic benefits.

On the other hand, one should acknowledge the benefits that IndEUFTA and IPRs in general may bring to the people. And it is not also the purpose of this thesis to claim that both IndEUFTA and IPRs must be totally avoided or else they may bring only detriments. It is also necessary to understand the rivalry position of multinational pharmaceutical companies towards generic production and their attempt to push forward stronger IPRs. The pharmaceutical companies invest considerable effort and money to come up with new drugs whereas generic companies can easily copy and produce those drugs for almost next to nothing. However, the case of particularly Indian generic manufacturers can be exceptional for, at least, two main reasons. First, as explained before, Indian generic manufacturers mainly target their products to local producers and to developing countries. Therefore, this does not bring much loss to original drug producers since the most of the consumers of Indian generics cannot anyway afford to buy the original product from its original producers. Second, generics manufactured in India may not bring some fatal consequences for multinational pharmaceutical companies whereas it might be so for human beings. Indian generics can at the best mean for original pharmaceutical companies some loss of the revenue. We can let the annual net income of original pharmaceutical companies to be, let’s say, USD 2 billion instead of 2.5 billon for the expanse of millions of saved lives.

The provisions of, especially, the IndEUFTA must be designed with special care considering all factors discussed in this thesis. The thesis does not limit itself with just encouragement of special care, but instead offers some modest recommendations. These recommendations are:

- Any provisions of the IndEUFTA, including those discussed in this thesis, that have negative impact on access to affordable medicines, particularly HIV medicines for the purpose of this study, must be avoided;
- In all negotiations and in the final draft of the IndEUFTA, public health must be prioritized and placed at the heart of decision making when the subject concerns IPRs and other regulations that may have an effect on access to medicines;
- Considering the crucial importance of Indian generics in terms of access to medicines in both domestic and international level, Indian generic manufacturers must be left enough space to keep their production of low cost high quality generics;
- Provisions of the IndEUFTA must not compromise India's ability of using TRIPS flexibilities and similarly must not impede the currently used flexibilities in India;
- The fact that IndEUFTA may hamper access to affordable HIV medicines and other lifesaving medicines not only to Indian local consumers but millions, mostly poor, leaving in other developing countries must be given due consideration;
- Parties to the IndEUFTA must be aware that along with lives of millions, their human right to health might be also at stake and that certain provisions of the IndEUFTA might infringe this right.

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