

PTA's with TRIPS provisions between EU-South Korea and EU-India compared:

Access to essential pharmaceuticals in danger?

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Summary

In recent years the European Union has been forming bilateral preferred trade agreements containing intellectual property articles which go beyond the TRIPS agreement on intellectual property rights. In 2010 an agreement was made with South Korea and currently talks with India for a PTA are ongoing. A PTA with India has been in the works for several years now and has caused commotion. This commotion is due to worries that a PTA will hurt access to essential medication for not only the poor in India but also for the poor in the second and third world. The goal of this thesis was to find out what the relationship is between these two PTA's and the right to health, focusing specifically on access to essential medication. To find out what exactly the relationship was between the EU/India and the EU/South Korea PTA's and the right to health literature research was done of the relevant scientific sources and organizations. Another method that was used was doing law comparative research between the TRIPS agreement and these PTA's to identify possible TRIPS plus articles. The first research step was making an analyses of what these two PTA's exactly entail and to assess what's relevant. Since the EU/India PTA still hasn't been signed information was collected on what's currently on the negotiation table. This was followed by research in the literature to find out what the possible consequences could be of both PTA's regarding pharmaceutical patents and access to essential medication. This was done so that the legal issues could be placed into context. Step three was a search for relevant case law at the WTO and the national courts of India and South Korea to see where possible conflicts could lie with national law and both PTA's in regards to pharmaceuticals. The fourth step was making a comparison between the social and economic situation in India with that of South Korea to put these PTA's into contexts. Specifically focusing on the differences in:

*GDP and life expectancy

*The health care system in India and South Korea

The goal of this was to see where the (legal) issues and consequences of these PTA's are the same and where they differ. The fifth and final step was applying a theoretical model. To help make a founded analyses a theoretical model which offers the possibility to balance economic gains against possible negative effects in the area of human rights has been used. This led to the conclusion that the relationship with the human right to health and more specifically access to essential medication, was different for India and South Korea even though the intellectual property chapters are reasonably similar. This was due to the importance of the context of the country in regards to the effects that a PTA has or in the case of India will have.

1. Background

1.1 Pharmaceutical trade

In the modern day and age trade between countries is a fact of everyday life and pharmaceutical products are no exception to this. This can be clearly seen in figure 1 which details the import and export of pharmaceutical products from several countries back in 2004.

Figure 1. Pharmaceutical trade in the year 2004¹

	Exports (US\$ millions)	Imports (US\$ millions)	Balance (US\$ millions)
Switzerland	22778	12268	10510
France	23251	15143	8108
Germany	37074	29010	8065
UK	23349	16333	7016
Sweden	7715	2841	4874
Netherlands	12347	11518	830
Italy	11480	12644	-1164
Australia	2156	5135	-2979
Spain	5133	9131	-3997
Japan	3170	7237	-4067
Canada	3430	7624	-4194
USA	22659	36097	-13436

The United States alone imported over \$36 billion in pharmaceutical products in a one year time frame. A globalized pharmaceutical trade means that pharmaceutical companies need to compete with foreign competition, competition which doesn't necessarily have to comply to the same rules as they do. The fact that intellectual property wasn't protected by some countries and the large number of different systems used in countries where it was protected, was a reason to undertake action. This is why in 1994 multiple countries pushed for protection of intellectual property through the use of patents at the World Trade Organization (WTO)². The agreement which followed from this is called the agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). Summarized, a patent under TRIPS, as defined under article 27 and 28 of the TRIPS agreement, entails the following. Firstly patents

¹ R.D. Smith et al., 'Trade, TRIPS and pharmaceuticals' (2009) 373 The Lancet 684,685

² R.D. Smith et al., 'Trade, TRIPS and pharmaceuticals' (2009) 373 The Lancet 684

are available for any new invention or innovation on the condition that the invention or innovation has a new part and is useable for application on an industrial scale³.

Secondly a patent gives the holder of the patent certain rights. A patent holder is the only one who can make the patented product, import it or sell it. If other parties want to do any of these things they will have to get consent from the patent holder for the duration of the patent⁴.

1.2 Pharmaceuticals and PTA's

Ever since the agreement on TRIPS was signed in 1995 it has been noted that there's a conflict. A conflict between pharmaceutical patents on the one hand and the right to access of essential medication on the other⁵. The patent protection that TRIPS gives pharmaceuticals makes it more difficult to produce cheap generics. One of the consequences of this is that the poor in third world countries have problems in getting access to essential medication. Essential medication is defined by the World Health Organization (WHO) as:

*"Those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford"*⁶

The TRIPS agreement isn't the only obstacle for making essential medication available to the poor in the third world. The European Union and the United States of America are making preferred trade agreements (PTA's) with individual countries. These PTA's sometimes include provisions that go further than TRIPS and are aptly named as TRIPS plus provisions⁷. In this thesis two different PTA's, between the EU/South Korea and the EU/India, will be compared to see what kind of consequences these PTA's have on access to pharmaceuticals. The focus will be on the legal perspective when analyzing these PTA's, but the economic and social perspective will also be taken into account to put things in context. The choice to compare these two PTA's in this thesis has been made because they are both PTA's with the EU, both have items in them that affect pharmaceutical patents and both are reasonably well documented. Another important factor for why these two PTA's haven been

³ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization (15 April 1994) Annex 1C (TRIPS agreement) art 27 <<http://docsonline.wto.org>>

⁴ TRIPS agreement art 28

⁵ BC Mercurio, 'TRIPs, Patents, and access to Life-Saving Drugs In The Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211 <<http://scholarship.law.marquette.edu/iplr/vol8/iss2/2>> accessed 7 January 2012

⁶ R.D. Smith et al., 'Trade, TRIPS and pharmaceuticals' (2009) 373 The Lancet 684,686

⁷ Valbona Muzaka, 'Preferential Trade Agreements , 'TRIPs-plus' provisions and access to affordable medicines' in A den Exter (ed), *International Trade Law and Health Care: In Search of Good Sense* (Erasmus University Press 2010)

chosen is not the similarity between these two PTA's, but the contextual difference of India and South Korea. By comparing a first world country like South Korea with a relatively poor country like India, we can determine if the consequences of these PTA's in regards to access to essential medication are different. If this is the case the EU should perhaps also make fundamentally different PTA's between these two countries.

1.3 PTA EU/South Korea

Recently the EU has made a preferred trade agreement with South Korea. On October 6 2010, this agreement was signed in Brussels after years of negotiation⁸. The goal of this PTA is to increase trade between the EU and South Korea. This is achieved by removing trade barriers like import duties. Specifically in the area of pharmaceuticals, barriers for trade have been lifted and intellectual property protection has been improved⁹. One example of this is the protection of research data from the development of pharmaceuticals for a period of five years¹⁰. This PTA raises the question what kind of affect there will be or already is on the access to essential pharmaceuticals in South Korea. Does it even have an effect on access in this reasonably rich country or will the poor still be able to get access through insurance or by other means?

1.4 PTA EU/India

Talks between India and the EU for a PTA have been going on for several years that could have severe consequences for India's large generic pharmaceutical industry¹¹. The fear is that with this PTA generic pharmaceutical production will become more difficult, which will mean that the poor in India and elsewhere will not be able to acquire cheap pharmaceuticals¹². India has a history of supporting its pharmaceutical industry dating back to the seventies. During this time India introduced the India patents act which made it

⁸European Commission, 'The EU South-Korea Free trade agreement (fta)' <<http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/korea/>> accessed on 8 January 2012

⁹European Commission, 'The EU Free Trade Agreement in practice' <http://trade.ec.europa.eu/doclib/docs/2011/october/tradoc_148303.pdf > accessed on 8 January 2012

¹⁰ Valbona Muzaka, 'Preferential Trade Agreements , 'TRIPs-plus' provisions and access to affordable medicines' in A den Exter (ed), *International Trade Law and Health Care: In Search of Good Sense* (Erasmus University Press 2010)

¹¹ Kamiike & Sato, 'The TRIPs Agreement and Pharmaceutical Industry: The Indian Experience' (2011) <http://srch.slav.hokudai.ac.jp/rp/group_06/activities/files/20110915_16/20110916_KamiikeSato.pdf> accessed on 9 January 2012

¹² Kamiike & Sato, "The TRIPs Agreement and Pharmaceutical Industry: The Indian Experience" (2011) <http://src-h.slav.hokudai.ac.jp/rp/group_06/activities/files/20110915_16/20110916_KamiikeSato.pdf> accessed on 9 January 2012

impossible to give out patents for pharmaceuticals¹³¹⁴. Since then India has become a member of the world trade organization and was thus forced to accept TRIPS. This meant that India had to allow patents for pharmaceuticals¹⁵. With the PTA between the EU and India possibly nearing its completion, it's important to know if there will be TRIPS plus provisions included in the PTA and if so what they will be. What will be the consequences for India as a producer of generic pharmaceuticals? Will access to essential pharmaceuticals be ensured or will it get worse in India and the third world? These questions need to be answered for this PTA.

1.5 Research questions

There are several legal and non-legal questions that arise from these PTA's in regard to health and more specifically pharmaceuticals. The overarching question has to do with the right to health¹⁶. Will this article be violated in South Korea and/or India, because the poor in South Korea and India will not have access to cheap generics anymore? Could there perhaps be a difference in the way this article should be interpreted between these two countries? The main research question of this thesis is therefore the following:

How do the PTA's between the EU/India and the EU/South Korea relate to the right to health and more specifically, access to essential medication?

Determining if the right to health is getting violated encompasses many different aspects. Another important factor, which will be further explained in chapter three, is that when doing law comparing research it's important to take into account the context of the country where the law is or is going to be applied. To ensure that all the aspects of the right to health and the necessary context is taken into account during the analyses of these PTA's, research will be done to find the answers to the following sub-questions:

- * What is the meaning of the right to health?
- * What does the EU/South Korea PTA encompass in regards to pharmaceuticals?
- * What does the EU/India PTA encompass in regards to pharmaceuticals?
- * How do these PTA's relate to TRIPS?

¹³ India Patents Act 1970 art 3

¹⁴ P Cullet, 'Patents and Medicines: The relationship between TRIPS and the human right to health' (2003) 79 (1) International Affairs 139,141

¹⁵ Radhika Bhattacharya, 'Are developing countries going too far on TRIPS?: A closer look at the new laws in India' (2008) 34 American Journal of Law and Medicine 395

¹⁶ Office of the United Nations High Commissioner on Human Rights & The World Health Organization, 'The right to health: Fact sheet no. 31'

<<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>> accessed 18 September 2012

* What are the main social and economic factors of India and South Korea and how do they differ? By looking at these social and economic factors the PTA's can be put into context and it makes a better assessment of their consequences possible.

* How is the health care politics and policy situation in India and South Korea? The scope will be limited to the amount of the health care system that is public and private, how the health care system is (broadly speaking) set-up and how healthcare is looked at from a political perspective

* What are the possible conflicts with existing law?

*What kind of effect do these PTA's have for India, South Korea and the third world?

The emphasis will be specifically on these questions, because they all play a role in determining how the right to health, which encompasses among other things, items having to do with accessibility, availability, acceptability and quality relates to these PTA's¹⁷. The focus for all these questions will be (mostly) limited to pharmaceuticals, unless otherwise relevant to keep the scope of this thesis feasible.

1.6 Relevance and Goal

The relevance of this thesis is to see what the relationship is between the PTA's made between EU/South-Korea and EU/India and the right to health, with a focus on access to essential medication. With India being a major producer of generic drugs and the talks on this PTA still ongoing, it's important to see from a legal perspective if these PTA's are in violation of basic human rights. If this turns out to be the case, the EU/South Korea PTA should possibly be changed and in the case of the EU/India PTA, reconsidered what is on the negotiation table. Next to this, countries like the European Union and the United States shouldn't be putting pressure on countries to accept a PTA that has a negative effect on human rights. The goal of this thesis is to compare the legal and non-legal effects of these two EU PTA's, one with a relatively rich country, one with a relatively poor country, to see what the legal consequences will be. Especially what the legal effects will be in the area of pharmaceuticals and how this correlates to the right to health. By comparing a relatively rich country with a relatively poor one we can see if there are different legal consequences, because of the difference in wealth and other factors. This knowledge will contribute to strengthening access to essential medication and could help show the importance of the nation specific context when making bilateral PTA's.

¹⁷ UNCHR 'General comment no. 14' in 'The right to the highest attainable standard of health:. 11-08-2000' (2000) UN Doc E/C. 12/2000/4

2. Theoretical framework

2.1 Overview theoretical framework

The legal framework that will be used to compare the PTA's between the EU/India and the EU /South Korea consists of multiple treaties, international laws and case law. One of the treaties that will be used is the treaty on Trade-Related aspects of Intellectual Property rights (TRIPS). The PTA's between the EU/South-Korea and the EU/India will be compared to the relevant part of TRIPS that deals with pharmaceuticals and patents to see which elements of TRIPS they contain and to assess if they go further than TRIPS¹⁸. The right to health will be discussed in paragraph 2.2 and will show the different laws and treaties that give this right "shape". In paragraph 2.3 the link between pharmaceutical patent law and TRIPS is further explored. A short overview of the relevant case law that will be used to analyze the PTA's between the EU/South-Korea and the EU/India will be given in paragraph 2.4.

2.2 The right to health

The right to health and elements of it can be found in multiple international agreements and treaties and creates obligations for the states that have ratified them. These obligations mean that states must do what they can to promote and / or protect the basic human rights of their population¹⁹. In this paragraph the most important international agreements and treaties in regard to the right to health will be named and explained. The right to health is important when looking at the PTA's between EU/South Korea and EU/India, since this right entitles (among other things) people to necessary pharmaceutical products. This might come in danger, because of the measures agreed upon in these PTA's.

To start with there's article 12 of the international covenant on Economic, Social and Cultural rights. This article states that everyone has is entitled to the highest attainable standard of health, both mentally and physically²⁰. However what exactly is the highest attainable standard of health for a random person? In General Comment No. 14 the United Nations Economic and Social Council elaborates that this is not only defined by a person's biological aspects, but also by the wealth of the State and a person's social economical position in

¹⁸ TRIPS agreement

¹⁹ Office of the United Nations High Commissioner on Human Rights & The World Health Organization, 'The right to health: Fact sheet no. 31' 22
<<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>> accessed 18 September 2012

²⁰ Office of the United Nations High Commissioner on Human Rights & The World Health Organization, 'The right to health: Fact sheet no. 31' 1
<<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>> accessed 18 September 2012

society. In short article 12 should be interpreted as a right to certain goods and/or services that make it possible to “gain” the highest attainable standard of health²¹.

A second element of the right to health is found in the Universal Declaration of Human Rights art. 25, which specifically defines medical care as a right and states that everyone is entitled to a certain standard of living. In this article this standard of living is further defined by saying it should be high enough to be adequate for the health of the individual and his family²²²³.

There are also regional treaties that incorporate and recognize the right to health. In the European context one could think of the European Social Charter which dates back to 1961²⁴. The current revised version is from 1996 and still contains several articles related to the right to health. Examples of this are article 11 which is about protection the health of the population and article 13 which entails not only the right to social, but also to medical support²⁵.

From General Comment no. 14 of the United Nations Economic and Social Council we can deduct that there are four key aspects that are important in a health care system in regards to the right to health. These four aspects are:

*Availability

*Accessibility

*Acceptability

*Quality

The first aspect of availability is relatively straightforward. It has to do with the fact if the medical goods and services are available to those who need them. This includes things like HIV-programs and essential pharmaceutical products, but also items that are needed to sustain a healthy life, like clean drinking water. Secondly there is the aspect of accessibility, this aspect consist of several different parts. We can divide accessibility into physical, economic and information accessibility. The last important part for accessibility is that of non-discrimination, those who need care should get it. The third aspect of acceptability is about making sure that the provided health care goods and services are acceptable from a social, medical and cultural perspective for those that have to use them.

Aspect number four quality sets a few requirements for what is needed to have good quality. In General Comment no. 14 properly tested pharmaceutical products and trained physicians

²¹ UNCHR ‘General comment no. 14’ in ‘The right to the highest attainable standard of health:.. 11-08-2000’ (2000) UN Doc E/C. 12/2000/4

²² Office of the United Nations High Commissioner on Human Rights & The World Health Organization, ‘The right to health: Fact sheet no. 31’ 1
<<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>> accessed 18 September 2012

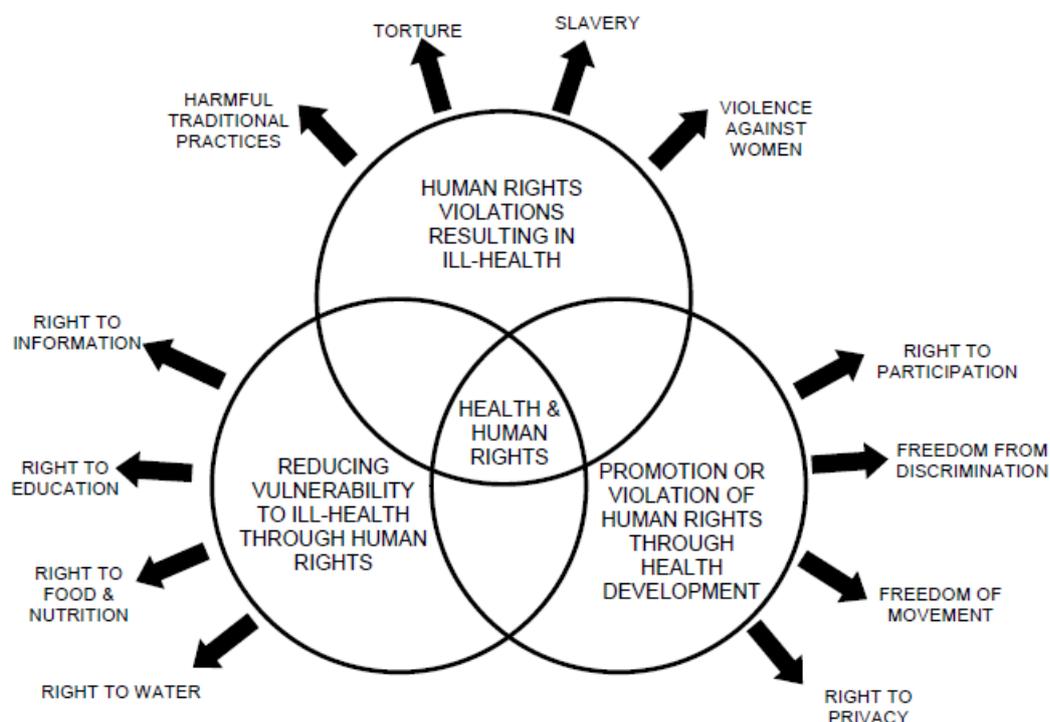
²³ The Universal Declaration of Human Rights art 25

²⁴ UNCHR ‘General comment no. 14’ in ‘The right to the highest attainable standard of health:.. 11-08-2000’ (2000) UN Doc E/C. 12/2000/4

²⁵ European Social Charter (revised) 1996 CETS NO. 163

are specifically named as a requirement for good quality health care²⁶. The WHO has made an overview about the relationship of health with human rights, which also incorporates some of the key aspects which have just been mentioned. This overview can be seen in figure 2.

Figure 2. The linkage between health and human rights²⁷



As we can see from figure 2 there are three different themes that all interact with the right to health and human rights. Things like reducing vulnerability to ill-health can mean in practice that the people also have a right to clean drinking water. Another important aspect in regards to the right to health and access to essential pharmaceuticals are the guidelines made by the United Nations (henceforth UN) for pharmaceutical producers. These guidelines deal with issues like access for the worst off in countries, disclosure of data, quality and transparency. Particularly of interest for this thesis are the following points from the guidelines dealing with TRIPS:

*No lobbying for TRIPS plus measures and respecting the possibilities offered in TRIPS in regards to parallel imports and compulsory licensing.

*Respecting the Doha declaration (will be further explained in paragraph 2.3)

²⁶ UNCHR 'General comment no. 14' in 'The right to the highest attainable standard of health:.. 11-08-2000' (2000) UN Doc E/C. 12/2000/4

²⁷ World Health Organization 2012, 'Linkages between health and human rights', available on < <http://www.who.int/hhr/HHR%20linkages.pdf>> accessed on 9 December 2012

*Pharmaceutical companies should promote access to essential pharmaceuticals by handing out licenses in the countries that are the worst off.

*In low income countries pharmaceutical companies should disregard their rights on data exclusivity for test data.

*Pharmaceutical companies should not try to gain new patents for slightly improved existing pharmaceuticals in low- and middle-income countries²⁸.

In the next paragraph TRIPS and the relationship between TRIPS and the right to health will be further explored.

2.3 TRIPS as a measure of comparison

PTA's can contain measures that could be described as TRIPS or as a TRIPS plus measure. Firstly, a closer look at TRIPS. What is TRIPS and what does it contain in relation to pharmaceutical patents? TRIPS is a treaty that was signed in 1995 and it deals with intellectual property rights. TRIPS obliges states to give patents for pharmaceutical products and processes. In regards to pharmaceuticals the following items from TRIPS are the most relevant for this thesis:

*A patent given out under TRIPS is valid for 20 years, starting from the date the application for a patent was made²⁹.

*Patents are required to be handed out for new inventions or to inventions which incorporate some kind of innovative addition to an already existing product or process. There are however valid reasons to refuse a patent which does not meet this demands. A reason to refuse a patent application can be public health reasons, morality or if it would cause public disorder. Next to this WTO member states are also allowed to exclude "*diagnostic, therapeutic and surgical methods*" for animals and human beings if they want to do so³⁰.

*Compulsory licensing, where the patent is used without the agreement of the owner of the patent, can be allowed under specific circumstances. Summarized, the following criteria (among others) must be met before a compulsory license can be demanded:

- A reasonable effort has to be made to secure authorization from the patent holder, unless there is a situation of national emergency.
- The pharmaceuticals made under the compulsory license are required to be primarily for the relevant state's own market.
- A certain amount of money has to be paid to the patent holder. The exact amount depends on the circumstances, but it should reflect the economic value.

²⁸ UNGA 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' United Nations General Assembly Official Records 63th session Supp No 263 UN Doc A/63/263 (2008)

²⁹ TRIPS agreement art 33

³⁰ TRIPS agreement art 27

These criteria can make it very hard to demand a compulsory license, especially since states need to be able to produce the pharmaceuticals themselves to adhere to the criteria that the pharmaceuticals are primarily for the state's own market³¹³².

*There are exceptions possible to the rights of the patent holder, under the condition that it's not unreasonable to do so and that the reasons of the other party are legitimate³³³⁴.

In 2001 the TRIPS treaty was further specified by the Doha declaration which among other things stated that TRIPS should be supportive to the public health sector. Specifically, access to medication was named as a goal for TRIPS next to helping new pharmaceutical products being developed. This declaration emphasized the possibilities already in TRIPS, like compulsory licensing, to ensure public health wouldn't be comprised by TRIPS³⁵.

Secondly there are TRIPS plus measures; this term means that certain measures go beyond what has been agreed upon in the TRIPS agreement³⁶. The United States and the European Union in general feel that the intellectual property protection that TRIPS gives doesn't go far enough. That's why they try to put regulation in bilateral agreements that go beyond TRIPS. These TRIPS plus measures are generally focused on a few specific areas. When looking specifically at intellectual property and pharmaceutical patents, these TRIPS plus measures can generally be found in the following areas:

*Extension of the maximum patent length

*Exclusivity of clinical trial data

*Linkage between registration of new pharmaceutical products and patents. This linkage means that generic pharmaceutical producers can't gain market approval while the patent is still in effect, unless the patent holder agrees. This causes delays for the generic producer to get the generic product on the market after the patent period has ended, effectively increasing the monopoly of the patent holder³⁷.

³¹ BC Mercurio, 'TRIPs, Patents, and access to Life-Saving Drugs In The Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211

<<http://scholarship.law.marquette.edu/iplr/vol8/iss2/2>> accessed 7 January 2012

³² TRIPS agreement art 31

³³ TRIPS agreement art 30

³⁴ BC Mercurio, 'TRIPs, Patents, and access to Life-Saving Drugs In The Developing World' (2004) 8(2) Marquette Intellectual Property Law Review 211

<<http://scholarship.law.marquette.edu/iplr/vol8/iss2/2>> accessed 7 January 2012

³⁵ WTO OMC, 'FACT SHEET: TRIPS and pharmaceutical patents', (2006) available on

<http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed on 14 January 2013

³⁶ Valbona Muzaka, 'Preferential Trade Agreements, 'TRIPs-plus' provisions and access to affordable medicines' in A den Exter (ed), *International Trade Law and Health Care: In Search of Good Sense* (Erasmus University Press 2010)

³⁷ CM Correa, 'Implications of bilateral free trade agreements on access to medicines' (2006) 84(5) Bull World Health Organ 337,399-404

Now that it's clear what TRIPS and TRIPS plus entail the question is how do TRIPS and TRIPS plus measures interact with the right to health? Phillippe Cullet describes the relationship between the right to health and TRIPS as two types of laws/treaties that have evolved independently, but that have been coming closer together because of the increasing importance of patents for our health needs³⁸. That's why the TRIPS treaty will be used to see how much further both PTA's go in comparison to TRIPS in the area which this thesis will focus upon, namely pharmaceutical patents. This will give an indication of the effects these two PTA's will have upon the human rights of the population in India and South Korea.

2.4 Pharmaceutical patent law in TRIPS and case law

The TRIPS treaty with its articles concerning pharmaceutical patents has not been implemented without a struggle in some countries. In Europe for example, there was the case of *Merck Genéricos v Merck & Co* in 2007 about pharmaceutical patent infringement, which ended up in a discussion to see which court (national or European) was competent in this matter³⁹. Specifically for India there was a lot of discussion if implementing TRIPS wouldn't result in the poor no longer being able to have access to affordable medication⁴⁰. To see what the PTA's with the EU, which contain TRIPS or TRIPS-plus like articles, could mean for India and South Korea research will also be done into the case law of these two countries surrounding TRIPS and the articles it has about pharmaceutical patents and into case law about the right to health. Disputes dealing with TRIPS are reviewed and judged upon by the WTO through its dispute settlement procedure. In this procedure a WTO member country which feels (for example) TRIPS is being violated needs to make a request for consultation, which is the first phase of a procedure which takes on average 1 year and 3 months taking possible appeal into consideration^{41,42}. The body that rules on matters relating to the human right to health however isn't the WTO. As mentioned in paragraph 2.2 the human right to health is can be found in parts at several legal levels and thus relevant case law can originate from different courts. By looking at both the case law from the WTO surrounding TRIPS and the relevant different courts when it comes to issues on the human right to health, we can see if these EU PTA's (which might go further in some areas) are in conflict with the existing case law in India and South Korea.

³⁸ P Cullet, 'Patents and Medicines: The relationship between TRIPS and the human right to health' (2003) 79 (1) *International Affairs* 139

³⁹ C431 / 05 *Merck Genéricos v Merck & Co* [2007] ECR I-7026

⁴⁰ A Kapczynski, 'Harmonizations and Its Discontents: A case study of TRIPS Implementation in India's Pharmaceutical Sector', (2009) 97 *California Law Review* 1571, 1586-1587

⁴¹ WTO, 'Disputes by agreement' (WTO website) <http://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#select_ed_agreement> accessed 16 January 2013

⁴² WTO, 'Understanding the WTO: Settling disputes' (WTO website) <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm> accessed 16 January 2013

3. Methods

3.1 Research steps

The method that will be used to research the issues that arise from these two PTA's will primarily be a research of the scientific literature on this subject. Step one will be researching what these two PTA's exactly entail and what's relevant for pharmaceuticals. This will be followed by step two, which will be a research in the literature to the possible consequences both PTA's could have in the area of pharmaceuticals. This will be done so that the legal issues can be placed into context. Step three will be a search for relevant case law at the WTO and the national courts of India and South Korea to see if there's any precedent that's relevant to the subject of this thesis. The fourth step will be making a comparison between the social and economic situation in India with that of South Korea to put these PTA's into contexts. Specifically focusing on the differences in:

*GDP

*The health care system in these two countries, how it's financed and its effects on, the availability of and access to, essential medication

*Life expectancy.

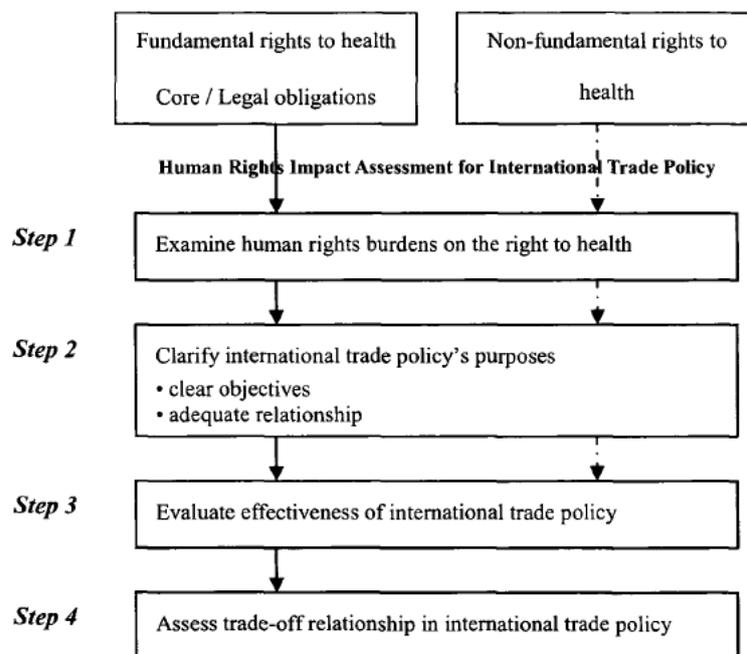
The goal of this would be to see where the (legal) issues and consequences of these PTA's are the same and where they differ. The fifth and final step would be applying a theoretical model to make a well-founded analysis about the impact of these PTA's on access of essential medication.

3.2 Theoretical model for assessing impact of the PTA's

To help make a thorough analysis of the impact of both PTA's a theoretical model has been chosen. The specific theoretical model that will be used in this thesis, was chosen because it makes it possible to balance economic gains against possible losses in regards to the right the health⁴³. Since PTA's are primarily made because of economic reasons this model will be useful to see if the economic gains outweigh losses in regards to the right to health and more specifically in regards to access to essential medication. The model visible in figure 3 is the theoretical model that will be used to make a right to health impact assessment of both PTA's, but the scope will only be limited to pharmaceutical products and access to them. Considering the goal of this thesis to find out if access to essential medication is in danger, a broader view at the right to health is (for this thesis) unnecessary.

⁴³ Chuan-fen Wu, 'Raising the right to health concerns within the framework of international intellectual property law' (2010) 5 Asian Journal WTO & International Health Law and Policy 141,184

Figure 3. Theoretical model for assessing the impact on human rights⁴⁴



In step 1 identification will take place of items in the PTA's that could infringe upon the right to health in the area of pharmaceuticals and access to them. Step 2 will contain the identification of the goals and objectives of both PTA's in the area of pharmaceuticals. The 3rd step is making an assessment if both PTA's are really necessary, reasonable and if there are alternatives. Step 4 is about proportionality. In this final step an assessment will be made if the new PTA rules in the area of pharmaceuticals are an acceptable infringement in regards to the right to health, considering what they offer in return⁴⁵.

3.3 Unanswered questions

If questions remain unanswered after the research of the literature, interviews with health law experts and policy makers will be done to answer these questions and to hear their opinion about the legal issues concerning these PTA's.

⁴⁴ Chuan-fen Wu, 'Raising the right to health concerns within the framework of international intellectual property law' (2010) 5 Asian Journal WTO & International Health Law and Policy 141,185

⁴⁵ Chuan-fen Wu, 'Raising the right to health concerns within the framework of international intellectual property law' (2010) 5 Asian Journal WTO & International Health Law and Policy 141

3.4 Law comparative research

Like stated in paragraph 3.1, the research method will mainly consist of doing law comparative research. Doing comparative law research has several advantages but also some disadvantages that go with it, first a look at the benefits / added value of comparative law research. Comparative law research gives researchers a way to help show that differences among laws in different countries are only perceived differences. One benefit of comparative law research, that is especially relevant for this thesis, is that it can help with the imitation of what Sacco calls foreign legal models⁴⁶. He goes on by saying that one of the aims of comparative research is to see where and in what way laws differ from each other. Although the main goal of law comparative research still is to gain a better understanding of different laws according to Sacco⁴⁷. There are also several disadvantages and possible problems of doing comparative research. One of these problems was described by Montesquieu, who said that comparative researchers shouldn't always expect law to be interchangeable between countries and/or institutions. He explained this by using the metaphor of organ transplantation and that it's more or less a matter of luck when one organ fits into another body⁴⁸. Kahn-Freud argues that if one tries to apply a law into a different social and political context, one runs the risk of rejection. He goes on by emphasizing that to prevent this from happening it's important to know not just what the law in a foreign country is, but that you also need to know its social and political context⁴⁹. That is why in this thesis the social and political aspect will play a role in the analyses of the PTA's between EU/India and EU/South Korea. By also taking into account specific relevant parts of the social and economic context, it should be possible to make a well-founded comparative law analyses.

⁴⁶ R Sacco, 'Legal Formants: A dynamic Approach To Comparative Law' (1991) 39(1) The American Journal of Comparative Law 1,3

⁴⁷ R Sacco, 'Legal Formants: A dynamic Approach To Comparative Law' (1991) 39(1) The American Journal of Comparative Law 1,4-6.

⁴⁸ O Kahn-Freund, 'On uses and misuses of comparative law' (1974) 37(1) The modern law review 1, 6-7

⁴⁹ O Kahn-Freund, 'On uses and misuses of comparative law' (1974) 37(1) The modern law review 1,1-27

4. The EU/South Korea PTA

4.1 Breaking down the EU/South Korea PTA

To fully understand the rules and regulations that have been agreed upon in the EU/South Korea PTA, the treaty will be analyzed from several perspectives. In paragraph 4.2 the history behind this PTA will be given to explain the reasoning and time frame for the forming of this PTA. After this the relevant items in regards to pharmaceuticals will be identified in paragraph 4.3 to show what this PTA entails in regards to protection and production of pharmaceutical products. Next to this it will also give an indication of possible effects on access to essential medication. Paragraph 4.4 will put this PTA in context by using TRIPS as a basis of comparison. In this paragraph the articles relevant to pharmaceuticals will be compared to TRIPS to see if they are equal to or go beyond TRIPS. The next paragraph will look how these articles are enforced and this chapter will be finished by paragraph 4.6 which will be about other relevant items in regards to the right to health in the EU/South Korea PTA.

4.2 History of the EU/South Korea PTA

Back in 2006 the European Union saw in South Korea an ideal opportunity to increase its exports by negotiating a preferred trade agreement. The reasoning behind this was that South Korea was one of the top five export destinations outside the European Union, but European companies still faced numerous obstacles in the form of regulation and tariffs. By getting South Korea to agree to a preferred trade agreement, these obstacles could be lifted or diminished. From 2007 to 2009 talks were held to discuss a PTA, leading to the signing of a preferred trade agreement between the European Union and South Korea in October 2009. Taking approximately two years, this was a much faster process than the negotiations with India, which will be discussed in chapter five⁵⁰⁵¹.

4.3 Relevant items in regards to pharmaceuticals

When looking at the PTA there are four articles which are directly related to pharmaceutical products and patents. In chapter 10 of the PTA, which handles intellectual property, it's made clear through article 10.2 that:

*"The provisions of this Chapter shall complement and specify the rights and obligations between the Parties under the TRIPS Agreement"*⁵²

⁵⁰ CM Brown, "The European Union and Regional Trade Agreements: A Case Study of the EU-Korea FTA" in C Hermann and JP Terhechte (eds), *European Yearbook of International Economic Law 2011*, (Springer-Verslag Berlin Heidelberg 2011), 297-308

⁵¹ Council Decision of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part - International agreements [2011] OJ L127/51 (Council Decision on a FTA with Korea)

⁵² Council Decision on a FTA with Korea art 10.2

Article 10.2 of the EU/South Korea PTA thus signifies that the following articles about intellectual property in chapter 10 come forth from the TRIPS agreement, but might go further and could be more specific. The following articles in this PTA, next to article 10.2, have implications in regards to pharmaceuticals. Firstly there is article 10.34, which emphasizes the importance of the Doha declaration (see paragraph 2.3) when it comes to the interpretation of the articles in the sub-section E of the PTA with the title patents and public health⁵³. This is important, because the Doha declaration further specifies TRIPS and when certain “special” exemptions on patent rights can be used. Next to this the Doha declaration also names access to medication a goal for TRIPS⁵⁴. So by affirming the importance of the Doha declaration, we can conclude that access to medication is still a factor to take into account in regards to interpreting articles in the EU/South Korea PTA when dealing with pharmaceutical patents. The second relevant article in regards to pharmaceuticals is article 10.35, this article deals with patent duration. It stipulates the need for a registration procedure for pharmaceutical products and gives the option for a maximum of five extra years of patent protection. However, these five extra years are only meant as a form of compensation for patent time that was lost because of the registration procedure⁵⁵. Effectively, this means an increase of patent protection from 20 years to a maximum of 25 years for pharmaceutical products. Meaning (a maximum of) five extra years of having to pay premium prices for pharmaceuticals because of no generic pharmaceutical product being available yet. The third article that has consequences for pharmaceutical products is article 10.36, which describes the role of research data and how it should be protected. In order to gain market authorization it is necessary to hand in data to the relevant organizations, so that they can see that it’s a safe, effective etc. pharmaceutical product and are able to make a decision if granting market authorization is justified. Article 10.36 states that in these cases the data given to the relevant organizations is confidential and should not be disclosed. Another important item from this article is the fact that the scientific data used to gain market access can only be used once, unless the patent holder gives explicit permission. The last item from article 10.36 is about the amount of time that this data should be protected. No exact amount of time is given. Just that the minimum is five years, starting from the moment that market authorization is granted. For generic producers this article is an extra burden in the process of getting market authorization for their generic product, because they will have to wait till the data protection has passed, do their own research or buy/negotiate with the original patent holder for use of the data⁵⁶. One can imagine that this drives up the cost of a generic product, causing a higher price when it finally does enter the market. Now that articles 10.2, 10.34,

⁵³ Council Decision on a FTA with Korea art 10.34

⁵⁴ Doha declaration 2001, paras 4

⁵⁵ Council Decision on a FTA with Korea art 10.35

⁵⁶ Council Decision on a FTA with Korea art 10.36

10.35 and 10.36 have been identified as relevant items in regards to pharmaceutical products in the EU/South Korea PTA, a comparison will be made in the following paragraph 4.4. This comparison will be between these articles and the TRIPS treaty. The goal of this is to make an assessment if these articles are less strict, equal to, or go beyond TRIPS.

4.4 TRIPS and TRIPS plus

In the opinion of C.M. Brown, who was the European directorate-general for trade in 2011, this PTA goes beyond what has been stated in the TRIPS treaty in the area of intellectual property rights. The laws made in this PTA in regards to intellectual property rights, are similar to those used by the European Union for its own common market⁵⁷. An example of a law going beyond TRIPS is the in paragraph 4.3 mentioned article 10.36, subsection 2 of the EU/South Korea PTA. Which states that data used for market authorization should not be used by other parties to gain authorization, except in cases where the patent holder gives explicit permission to do so⁵⁸. In contrast TRIPS allows this data being used by the authorities to grant market authorization, since under TRIPS this isn't a violation of the in article 39, subsection 3 stated unfair commercial use⁵⁹. To objectively see if this PTA really does go beyond TRIPS a comparison has been made in figure 4 between relevant items in the PTA regarding pharmaceuticals and/or the right to health and items in TRIPS. After each article, a short summary is given to give an indication what it's about and where it may or may not differ with TRIPS.

Figure 4. The EU/South Korea PTA articles relevant to pharmaceuticals and the right to health compared to TRIPS		
EU/South Korea PTA	TRIPS	Less than TRIPS / Equal to TRIPS / Beyond TRIPS
Art. 10.2: The parties agree to implement TRIPS.	--_--	Equal
Art. 10.34 subsection 1: Recognition of the Doha declaration by the EU and	--_--	Equal

⁵⁷ CM Brown, "The European Union and Regional Trade Agreements: A Case Study of the EU-Korea FTA" in C Hermann and JP Terhect, *European Yearbook of International Economic Law 2011*, (Springer-Verslag Berlin Heidelberg 2011) 297-304

⁵⁸ Council Decision on a FTA with Korea art 10.36

⁵⁹ S Adamini et al., 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009) 34(6) *Journal of Health Politics, Policy and Law* 980, 986

South Korea and its importance.		
Art. 10.34 subsection 2: Implementation of the in 2005 amended TRIPS treaty as well as the Doha declaration.	--_--	Equal
Art. 10.35 subsection 1: A registration procedure for patented pharmaceutical products is necessary.	Not mentioned in TRIPS.	Beyond TRIPS
Art 10.35 subsection 2: A maximum of five years of extra patent protection as a form of compensation for effective patent time lost.	Not mentioned in TRIPS.	Beyond TRIPS
Art. 10.36 subsection 1: Data confidentiality of data used for market authorization.	TRIPS Art. 39 subsection 3: Data should be protected against unfair commercial use. Except in cases where it is to protect the public or measures are in place to prevent unfair commercial use.	Beyond TRIPS, since there are more exceptions in TRIPS.
Art. 10.36 subsection 2: Unless the patent holder agrees, data used for first time market authorization can't be used again by other parties.	Doesn't fall under "unfair commercial use" if done by the authorities and thus doesn't apply in a TRIPS perspective ⁶⁰ .	Beyond TRIPS
Art. 10.36 subsection 3: Data is protected for a minimum of five years.	No minimum amount of data protection time is specified in TRIPS ⁶¹	Beyond TRIPS

⁶⁰ S Adamini et al., 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009) 34 (6) Journal of Health Politics, Policy and Law 980, 986

⁶¹ S Adamini et al., 'Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities' (2009) 34 (6) Journal of Health Politics, Policy and Law 980, 987

4.5 Enforcement of TRIPS and the EU/South Korea PTA

In chapter two the WTO dispute settlement procedure was already briefly discussed. In this paragraph it will be explained in greater detail as well as the dispute settlement methods of the EU/South Korea PTA. This will be done to make comparing them possible, with the intent to find out in which aspect(s) they differ. First let's take a look at TRIPS. The dispute settlement procedure for TRIPS consists of multiple phases in which both parties can have their say, as well as possible experts if deemed necessary by the dispute settlement body. If in the end it becomes clear that a country keeps violating the TRIPS agreement, the penalty would be to implement trade sanctions against the guilty party. This however, is something that is only done as a last resort, when it's clear that the guilty party won't comply with the ruling made by the settlement body⁶². Dispute settlement of the EU/South Korea PTA is different in regards to that of TRIPS. Instead of going to the WTO dispute settlement body, disputes regarding this PTA fall under the authority of a separate arbitration panel. If the EU and South Korea have a dispute, the complaining party can demand the forming of an arbitration panel under art. 14.4 of the PTA⁶³. This arbitration panel consists of 3 arbiters⁶⁴. The panel has to give its ruling after a maximum of 150 days, starting from the moment the panel was established⁶⁵. If either the EU or South Korea is found in violation by this panel and refuses to comply with the ruling given by the panel, the party whose rights have been violated has the right to take measures equal in size to the violation. An option that this PTA offers to achieve this is by allowing the party whose rights have been violated to insert tariffs at WTO levels to off-set possible losses⁶⁶.

4.6 Other items relevant for the right to health

It's imported to note that, although this PTA does increase pharmaceutical patent protection in several ways and therefore could damage access to essential medication; it also has items about protecting the labor force in South Korea and Europe. Specifically in annex 13 article 1, subsections a, b and k there is a reference to the International Labor Organization (henceforth ILO) Conventions. Stating that ratification of the ILO conventions is one of the things that should be promoted by South Korea and the European Union⁶⁷. Although it would go beyond the scope of this thesis to list all ILO conventions and their relationship with health

⁶² WTO, 'Understanding the WTO: Settling disputes' (WTO website) available on: http://www.wto.org/english/thewto_e/whatise/tif_e/disp1_e.htm accessed 16 January 2013

⁶³ Council Decision on a FTA with Korea art 14.4

⁶⁴ Council Decision on a FTA with Korea art 14.5

⁶⁵ Council Decision on a FTA with Korea art 14.7

⁶⁶ Council Decision on a FTA with Korea art 14.11

⁶⁷ Council Decision of 16 September 2010 on the signing, on behalf of the European Union, and provisional application of the Free Trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part - International agreements [2011] OJ L127/1335

and health care, concretely one could think about the occupational health services convention of 1985 as an example of an ILO convention which has an effect on health care and access to it. In article 3 of this convention on occupational health services, it's stated that the development of progressive health care services is required for workers occupational health risks/problems⁶⁸. Another relevant ILO convention is ILO C102, which in article 10 gives an indication on the maximum amount of payment for morbid diseases. It states that the exact rules which deal with cost sharing in such a situation need to "avoid hardship"⁶⁹. By specifically naming these conventions in the EU/South Korea PTA they become a factor to be taken into account in chapter 9, when assessing the impact on the right to health by this PTA.

⁶⁸ International Labor Organization, C161 Occupational Health Services Convention 1985, art 3

⁶⁹ International Labor Organization, C102 Social Security (Minimum Standards) Convention 1952, art 10

5. The EU/India PTA

5.1 Breaking down the EU/India PTA

Since the EU/India PTA hasn't been signed yet and thus a final version isn't available, the method for analyzing this PTA will be slightly different compared to the EU/South Korea PTA discussed in chapter 4. Instead of comparing the PTA directly with TRIPS and analyzing if the relevant articles are less strict, equal to or go beyond TRIPS expert views will be combined with the information that is already available on the PTA to make an assessment of what could end up in this PTA. To achieve this paragraph 5.2 will describe the history of the EU/India PTA and describe the issues that the parties want to resolve by signing on to a trade agreement between these two countries. In 5.3 this will be followed up by the views of several scientific experts on what they think and/or fear will be in the EU/India PTA regarding pharmaceuticals. Based on the assessment made in paragraphs 5.2 and 5.3, paragraph 5.4 will compare the items that could end up in the EU/India PTA to the TRIPS agreement. After it's clear what items could end up in the PTA, the chapter will be summarized in paragraph 5.5 with a short analyses of the current situation in regards to this PTA.

5.2 History of the EU/India PTA

The last few years' extensive talks have been held between the European Union and India in order to reach an agreement for a new PTA. India was designated as a potential partner for a PTA by the European Union, because it fulfilled two criteria which are part of the EU's global Europe program. The first one is market potential, which is large with a population of 1.1 billion inhabitants and an economy that's growing rapidly. Secondly there's the criteria of how protected the market is. Currently, access to India's market place is restricted through multiple barriers of varying sorts⁷⁰. This is why since 2007 a total of thirteen negotiation rounds have been held, in order to come to an agreement. Up till now however, this hasn't led to the signing of a treaty. Europe and India want to resolve several issues with this PTA, issues concerning (among others):

- *Access to the European market place by India and vice versa
- *Government procurement
- *Intellectual property
- *Competition⁷¹

⁷⁰ S Khorana & N Perdakis, 'EU-India Free Trade Agreement: Deal or no Deal?' (2010) 11(2) South Asia Economic Journal 181,186-7

⁷¹ The High Level Trade Group 'Report of the EU-India High Level Trade Group to The EU-India Summit' (2006) <<http://trade.ec.europa.eu/doclib/html/130306.htm>> accessed on the 10 October 2012

Currently there are several issues which have caused these talks to take so long without leading to a treaty. The main differences are found in the areas of tariffs, agriculture and the scope of services and manufacturing that should be included in the PTA⁷².

5.3 Relevant items in regards to pharmaceuticals

Negotiations over the EU/India PTA are still ongoing and no concept of the current proposed PTA has been published by any trustworthy source. That's why assessing which items could end up in this PTA will be done by looking at expert sources and relevant documents. In May 2010 an official response gave some insight into what was then the situation in the negotiations between the European Union and India. Several scientists, organizations and commentators fear that this new PTA will contain items about pharmaceuticals patents, which could have negative consequences for the access to essential medication. One of these organizations with concerns about the EU/India PTA is doctors without borders, who wrote a letter to the European Commission. In response to this, Karle de Gucht who is the trade commissioner of the European Union, wrote a letter back to Mr. von Schoen-Angerer. Von Schoen-Angerer, who works for doctors without borders, had raised his concerns to the commissioner about the proposed PTA with India and the consequences it could have for access to essential medication⁷³. This fear by doctors without borders was and is partly justified when looking at the High Level Trade Group (HLTG) report. The HLTG was given the task in 2005 of exploring the possibilities of making a PTA between the EU and India and to report their findings to the India-EU 2006 summit. In this report the high level trade group already states that intellectual property provisions, which would be complementary to those of the WTO, would need to be in any future trade agreement between India and the EU⁷⁴. Summarized, the commissioner's response in May 2010 was that there wasn't any need to be worried that this PTA would prevent the poor in India or in other countries from having access to essential medication. To support this claim he sums up the current state of the negotiations with India, giving a clearer view of what could end up in the final draft. The following items from his letter are noteworthy in order to get an idea of what the final draft could entail in regards to pharmaceuticals and pharmaceutical patents:

*Europe has already proposed that there should be a legally binding article in the PTA referring to the Doha declaration (see paragraph 2.3 for explanation of the Doha declaration).

⁷² S Khorana & N Perdakis, 'EU-India Free Trade Agreement: Deal or no Deal?' (2010) 11(2) South Asia Economic Journal 181,181-206

⁷³ Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010 available on: <http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf> accessed on 16 March 2013

⁷⁴ The High Level Trade Group 'Report of the EU-India High Level Trade Group to The EU-India Summit' (2006) 1-11 <<http://trade.ec.europa.eu/doclib/html/130306.htm>> accessed on the 10 October 2012

*Europe wants to incorporate an article that the ability of the EU and India to promote access to essential medication won't be harmed by anything stated in the PTA.

*There will be no interference with generic medication which is in transit through the EU. If necessary, the commission is willing to propose changes to existing regulation to achieve this. De Gucht makes the explicit point that this will be noted in the intellectual property chapter of the PTA.

*The system for market authorization in India seems to be reasonably fast, so Europe might not further pursue extension of the patent duration. In Europe this was used as a form of compensation for long market authorization procedures, which could significantly reduce effective patent time. Since this might not be the case in India, the wish for patent extension by Europe could be dropped.

*It was still unclear on how data exclusivity was going to take shape in the PTA (back in 2010).

*For Europe limiting data exclusivity is acceptable in some cases. In case of a public health need, data exclusivity could be limited and use of the original data by another party to gain market access could be accepted⁷⁵.

However, James Arkininstall and his colleagues from doctors without borders, disagree with the assessment that Karel de Gucht makes in regards to access to essential medication. In their article "The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries" they state that Europe is introducing new policies that go beyond what is required by the WTO. By doing this, the European Union is creating a threat for the access to essential medication by the poor in the developing countries. They name the following items that could be harmful for access to essential medication and that could end up in the EU/India PTA:

*Even though the European Commission has agreed with India that generic pharmaceutical products will no longer be detained if patents aren't violated in both the producing as well as the importing nation, detaining would still be possible in cases of similar labeling. This means that when a generic and a patented pharmaceutical product have similar appearances, the generic could be detained while in transit through the European Union.

*Data exclusivity, meaning a generic pharmaceutical product can't use the original research data for market authorization, has been on the wish list of the EU in several PTA's and is also on the wish list for the EU-India PTA.

*An increase of the penalties for patent and/or trademark violation

⁷⁵ Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010 available on: <http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf> accessed on 16 March 2013

*The European Union wants to create a new sort of dispute around civil trademarks. This would entail cases where generic products would look too similar in comparison to patented products. For the generic pharmaceutical industry this could cause possible counterfeit judicial challenges.

* Seizure in cases of civil trademark infringement is on the EU wish list, even when the pharmaceutical product is just in transit.

* Earlier action against patent infringement through granting injunctions sooner, which could cause destruction of generic pharmaceuticals before a court has judged on the case⁷⁶.

Next to these points that have been mentioned by the European Commissioner and Doctors without borders, there is at least one other import item on the negotiation table that is being mentioned by experts. This item is third party liability, which would give governments the power to hand out penalties to anyone in the generic pharmaceutical chain in cases of patent infringement⁷⁷. Now that several items have been identified that could end up in the EU/India PTA by looking at the opinion of experts and already known information a comparison with TRIPS will be made in the next paragraph.

5.4 TRIPS and TRIPS plus

In 2005 India had to accept patent laws as described under TRIPS by the WTO. According to professor R.D. Smith of the London School of Hygiene and Tropical Medicine and his co-writers access to essential medication for the poor in India and elsewhere could be under threat because of this implementation. They argued that India has a large amount of generic pharmaceutical producers which (back in 2005) exported two thirds of their production to other countries, which helped to keep generic prices low. Now these low prices are under possible threat, because of TRIPS in 2005 and TRIPS plus provisions that could end up in the PTA between the EU and India. Seeing that low prices for medication is in the interest of the population of India, why would they accept regulation causing prices to go up? Smith et al. point out that some governments accept TRIPS plus provisions in regards to patent protection, because they get (among other things) market access to developed countries in return. An often used route by Europe and the United States to make developing countries accept TRIPS plus provisions is through free trade agreements⁷⁸. This is exactly what is currently happening in the negotiations between the EU and India, where the EU is trying to get TRIPS plus provisions on intellectual property protection accepted into the PTA (as mentioned in paragraph 5.2). We can conclude from this that some countries are willing to

⁷⁶ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

⁷⁷ A Sengupta, 'Do not trade away our lives' (2012) 9 Indian Journal of Medical Ethics 81,82 <<http://ijme.in/pdfs/issue202.html.pdf#page=8>> accessed 22 March 2013

⁷⁸ R.D. Smith et al., 'Trade, TRIPS and pharmaceuticals' (2009) 373 The Lancet 684, 684-91

sacrifice access to essential medications, in order to make an economic leap in other areas. As of yet it remains to be seen how much India will be willing to give up in the area of patent protection with regards to the PTA with the EU. However, since India did agree to implement TRIPS in compliance with WTO regulation, it has already shown that it's willing to make some sacrifices in regards to access to essential medication if it means economic gain in other areas. The implementation of TRIPS in India has not been an entirely smooth process, as the following case shows. Recently a dispute in regards to TRIPS and pharmaceutical patents arose between the Netherlands and India. The dispute was about the fact that the Netherlands had seized several different transports of generic pharmaceutical products. This was done by the Netherlands because they believed that these pharmaceuticals had infringed upon existing pharmaceutical patents. To resolve this issue India made a request in 2010 for consultation with the EU and the Netherlands⁷⁹. This example shows that there are currently still problems with India and respecting pharmaceutical patent law, raising the question if a PTA between India and the European Union won't lead to similar issues.

Taking into account the goals that have been set out for this EU/India PTA, the information that is already known and expert opinions, a comparison has been made in figure 5. This comparison is between what will likely end up in the EU/India PTA compared to the current TRIPS treaty.

Figure 5. The EU/India PTA articles relevant to pharmaceuticals that could end up in the PTA compared to TRIPS

EU/India PTA	TRIPS	Less than TRIPS Equal to TRIPS / Beyond TRIPS
No patent extension beyond what has been stated in TRIPS ⁸⁰ .	TRIPS Art. 33: 20 years, counting from the moment that an application was filled ⁸¹ .	Equal to TRIPS
Reference to the Doha agreement ⁸² .	--_--	Equal to TRIPS

⁷⁹ WTO, 'European Union and a Member State: Seizure of Generic Drugs in Transit' http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm

⁸⁰ Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010 available on: <http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf> accessed on 16 March 2013

⁸¹ TRIPS agreement art 33

⁸² Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010 available on: <http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf> accessed on 16 March 2013

No harm can be done in regards to access to essential medication, because of the EU/India PTA ⁸³ .	--_--	Equal to TRIPS
Introduction of civil trademark disputes for pharmaceutical products ⁸⁴ .	Pharmaceutical products are not specifically mentioned in TRIPS in regards to trademark disputes.	Beyond TRIPS
Seizure in case of civil trademark infringement for in transit pharmaceuticals ⁸⁵ .	Not mentioned in TRIPS.	Beyond TRIPS
Third party liability ⁸⁶ .	Not mentioned in TRIPS.	Beyond TRIPS
An increase of the penalties in cases of patent and/or trademark violation ⁸⁷ .	TRIPS Art. 61: Possibilities for penalties include criminal procedures against the producer. Next to that destruction, seizure or forfeiture of the product is also a possibility ⁸⁸ .	Beyond TRIPS
Data exclusivity, this would mean that third parties would not be allowed to use the original research data to gain	TRIPS Art. 39 subsection 3: Data should be protected against unfair commercial use. Except in cases where it is to protect the public or measures are in place to	Beyond TRIPS

⁸³ Letter by EC Commissioner Karel de Gucht to Tido von Schoen-Angerer, MSF, 25 May 2010 available on: <http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146192.pdf> accessed on 16 March 2013

⁸⁴ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

⁸⁵ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

⁸⁶ A Sengupta, 'Do not trade away our lives' (2012) 9 Indian Journal of Medical Ethics 81,82 <<http://ijme.in/pdfs/issue202.html.pdf#page=8>> accessed 22 March 2013

⁸⁷ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

⁸⁸ TRIPS agreement art 61

market authorization after the patent has expired ⁸⁹ .	prevent unfair commercial use ⁹⁰ .	
Possibility to destroy possible infringing pharmaceuticals even before the court has decided if this is justified or not ⁹¹ .	--_--	Beyond TRIPS

5.5 A clash between access and patent protection?

In this chapter we have seen that a lot of the EU-India PTA is still unclear, because of the ongoing negotiations. This is the reason why, unlike in chapter four for the EU/South Korea PTA, no dispute settlement method was discussed. What is clear however is that there are several items on the negotiation table that are TRIPS plus measures in nature and that there could be a potential damage done to access to essential pharmaceutical products. There is also a distinct clash noticeable between what the European Commissioner for trade is saying in regards to safeguarding access to essential medication and what is on the negotiation table. Now that both the EU/South Korea and EU/India PTA's have been researched the following chapters 6 and 7 will aim to put these PTA's into context by looking more closely at these two countries and their social economic status, instead of just at the PTA's.

⁸⁹ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

⁹⁰ TRIPS agreement art 39 subsection 3

⁹¹ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8(1) Journal of Generic Medicines 14

6. Social and economic differences between India and South Korea

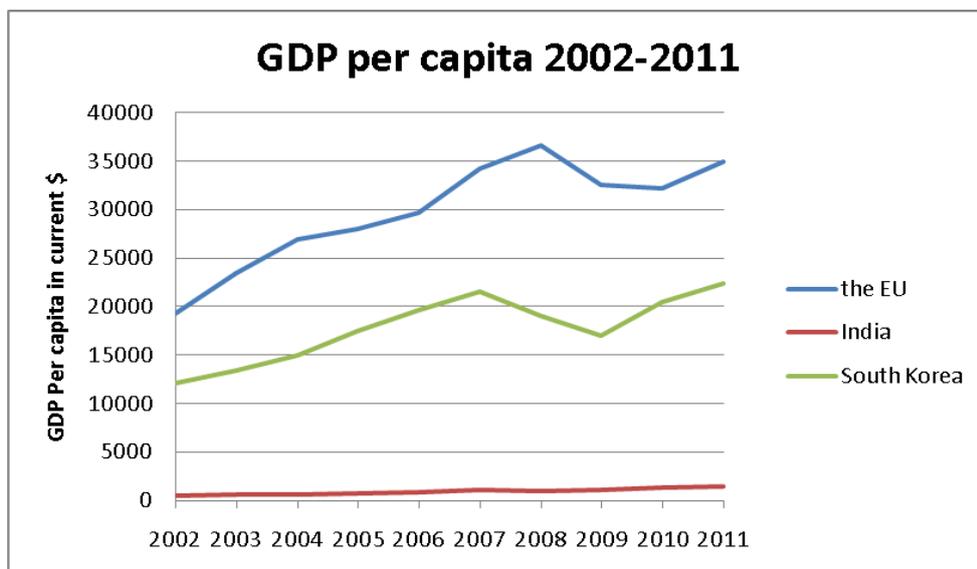
6.1 Indicators

As discussed in paragraph 3.4, it's necessary to take into account the social economic and political context when doing law comparative research. That's why this chapter will give an overview of several social economic indicators as well as show some indicators that say something about the way the health care systems in India and South Korea work. In paragraph 6.2 a comparison will be made between the GDP between India and South Korea and what this means in regards to health care. Paragraph 6.3 will follow up on this by showing the life expectancy in both India and South Korea. Several indicators that show something about the health care systems will be shown in paragraph 6.4. Lastly in paragraph 6.5 the access to essential medication between these two countries will be compared by giving a summary of all the indicators shown in the previous paragraphs and by summing up which of the two countries performs better on each indicator from an access to essential medication perspective.

6.2 GDP per capita and income inequality

To help assess what the people in South Korea and India could afford to pay for pharmaceuticals, the graph below (figure 6) shows the GDP per capita of the inhabitants of South Korea, India and (for comparison purposes) the European Union.

Figure 6. GDP per capita in current US \$⁹²



⁹² The graph is based on data from The World Bank's database. Dataset name: GDP per capita (current US \$). Dataset source: World Bank national accounts data and OECD national accounts data files. Available on: <<http://data.worldbank.org/indicator?display=graph>> accessed on 5 April 2013. Terms of use available on: <<http://web.worldbank.org/WBSITE/EXTERNAL/0,,contentMDK:22547097~pagePK:50016803~piPK:50016805~theSitePK:13,00.html>>

The GDP per capita shows a big difference between the European Union, South Korea and India. Where the GDP in 2011 for the EU was \$35000 in current \$, that of South Korea is around \$22500 and India is below \$1500 per capita. This means that the average person in India has far less means to acquire essential medication, when these are not provided by the state or health insurance, in comparison with the European Union and South Korea.

6.3 Life expectancy

Life expectancy is an important indicator in regards to the context of a country. By looking at the life expectancy one can get an idea of the level of the health and social services in a country. In figure 7 there's a table with the figures on life expectancy in 2010 for males, females and the total life expectancy for those two categories combined. The best scores in each category are marked green and the worst scores are marked red.

Figure 7. Life expectancy at birth in years in 2010⁹³

Nation	Life expectancy at birth females	Life expectancy at birth males	Total life expectancy at birth
The European Union	82.60	76.85	79.65
South Korea	84.25	77.44	80.76
India	66.71	63.63	65.13

With a total life expectancy at birth of around 65 years, compared to the almost 81 years in South Korea and the almost 80 years in the European Union, India really stands out in a negative way. In every country females have a better life expectancy at birth compared to males.

6.4 The health care system

A relevant question in regards to access to essential medication is how the health care system functions, is it mostly privately or is it more publicly funded? How much money is

⁹³ This table is based on data from The World Bank's database. Datasets names: Life expectancy at birth females, Life expectancy at birth males, Total life expectancy at birth. Datasets sources: (1) United Nations Population Division. World Population Prospects, (2) United Nations Statistical Division. Population and Vital Statistics Report (various years), (3) Census reports and other statistical publications from national statistical offices, (4) Eurostat: Demographic Statistics, (5) Secretariat of the Pacific Community: Statistics and Demography Programme, and (6) U.S. Census Bureau: International Database. Available on: <<http://data.worldbank.org/indicator?display=graph>> accessed on 5 April 2013. Terms of use available on: <<http://web.worldbank.org/WBSITE/EXTERNAL/0,,contentMDK:22547097~pagePK:50016803~piPK:50016805~theSitePK:13,00.html>>

spent on health? What do people need to pay out of pocket? To answer these questions the indicators that will be shown in this paragraph are:

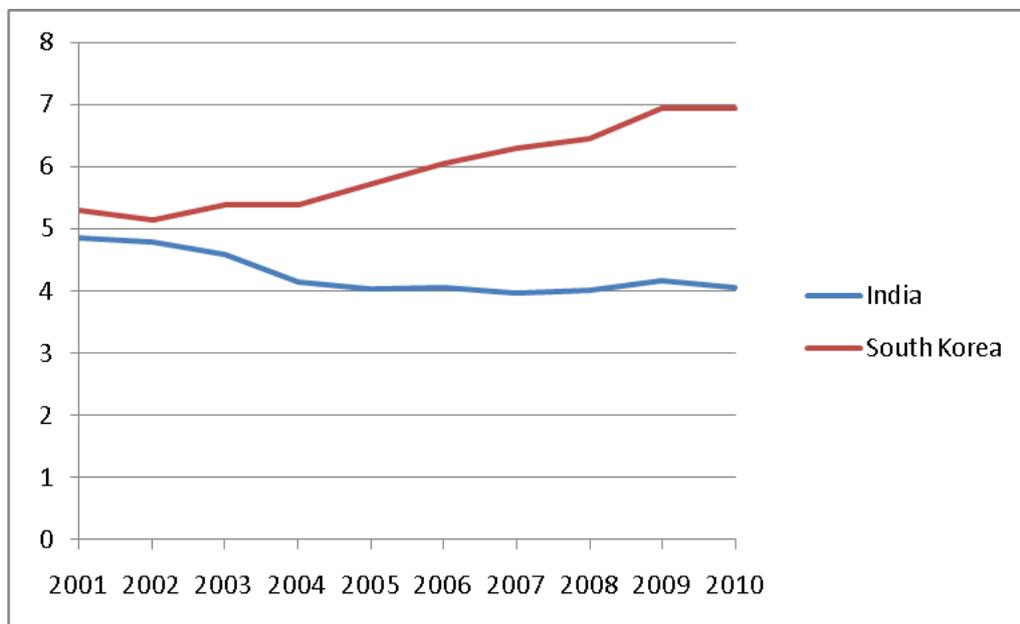
*the total health expenditure as a % of GDP

*the amount of money that is spend publicly versus privately in health care

*the % that needs to be paid out of pocket

The total expenditure on health as a % of GDP can be found in figure 8. From 2001 onwards the % of GDP India has spent on health care has dropped, from 4.8% in 2001 to just over 4.0% in 2010. In contrast South Korea has seen its total health expenditure as a % of GDP increase from 5.3% in 2001 to 6.9% in 2010.

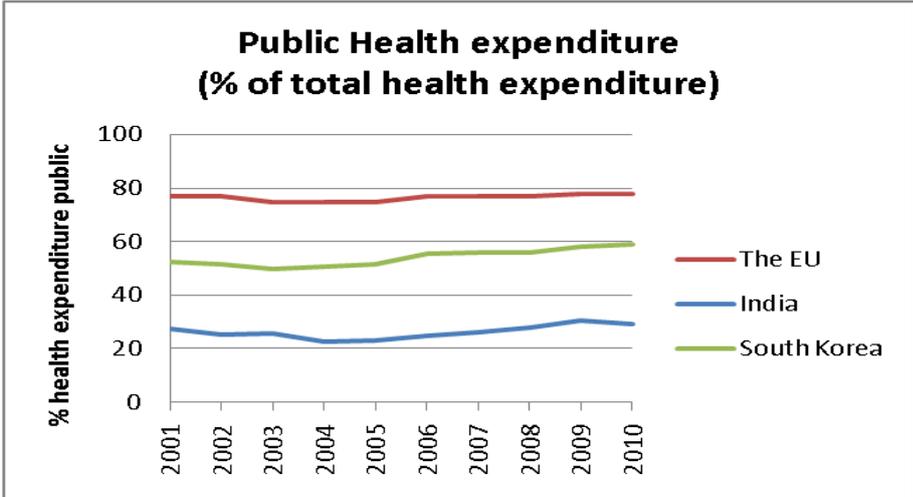
Figure 8. Total health expenditure as a % of GDP⁹⁴



In figure 9 we can see what percentage of the public health expenditure was spent publicly on health care in Europe, India and South Korea.

⁹⁴ The graph is based on data from The World Bank's database. Dataset name: Health expenditure, total (% of GDP). Dataset source: World Health Organization National Health Account Database. Available on: <<http://data.worldbank.org/indicator?display=graph>> accessed on 24 March 2013. Terms of use available on: <<http://web.worldbank.org/WBSITE/EXTERNAL/0,,contentMDK:22547097~pagePK:50016803~piPK:50016805~theSitePK:13,00.html>>

Figure 9. Public health expenditure as a % of total health expenditure⁹⁵



The division between what’s spent privately and what is spent publicly has been reasonably stable for the European Union, India and South Korea. In South Korea there was a slight rise from 52.3% to 59.0% for the public health expenditure compared to 2001. As can be seen in this graph, the European Union has a public health expenditure as percentage of total health expenditure of 77% (and thus 23% is spent privately). South Korea has 59% spent publicly and India 29%, showing significant differences in the way these three organize their health care systems. Knowing the percentage that is spent privately, it’s also interesting to see what percentage needs to be paid out of pocket. The percentage that needs to be spent out of pocket by the people of the European Union, South Korea and India can be seen in figure 10, over a three year period.

Figure 10. The amount spent out of pocket as a % of total expenditure on health⁹⁶

Nation	Year 2008	Year 2009	Year 2010
The European Union	14.5%	14.1%	14.2%
South Korea	34.2%	32.4%	31.4%
India	62.9%	60.2%	61.2%

⁹⁵ The graph is based on data from The World Bank’s database. Dataset name: Health expenditure, public (% of total health expenditure). Dataset source: World Health Organization National Health Account Database. Available on: <<http://data.worldbank.org/indicator?display=graph>> accessed on 5 April 2013. Terms of use available on: <<http://web.worldbank.org/WBSITE/EXTERNAL/0,,contentMDK:22547097~pagePK:50016803~piPK:50016805~theSitePK:13,00.html>>

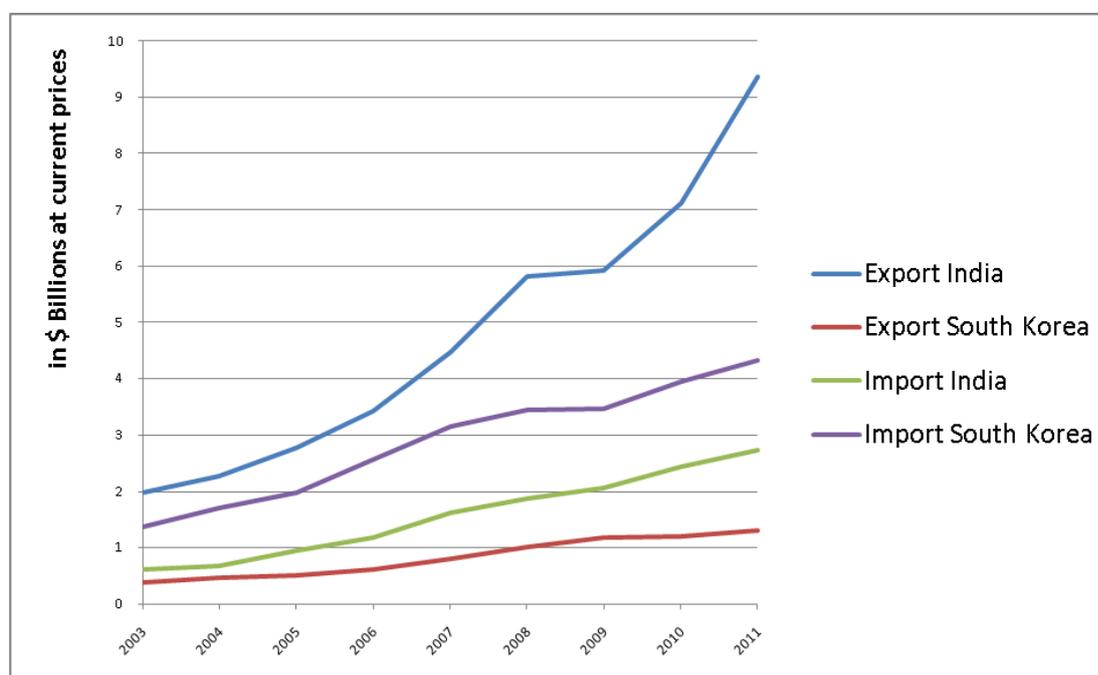
⁹⁶ The table is based on data from The World Bank’s database. Dataset name: Out-of-pocket Health expenditure (% of private expenditure on health). Dataset source: World Health Organization National Health Account Database. Available on: <<http://data.worldbank.org/indicator?display=graph>> accessed on 5 April 2013. Terms of use available on: <<http://web.worldbank.org/WBSITE/EXTERNAL/0,,contentMDK:22547097~pagePK:50016803~piPK:50016805~theSitePK:13,00.html>>

Looking at these numbers it seems that there is a correlation between the GDP per capita of a country and the amount spent out of pocket as a % of total expenditure on health. In Europe only 14.2% was spend out of pocket in 2010, compared to 31.4% in South Korea and 61.2% in India. These numbers show that a price raise for medication, which could happen because of both PTA's, would hit the poor in India the most. The reason for this is that they pay the highest amount out of pocket out of these three countries. So where someone in the European Union gets most of a price raise back because it's provided by the government or through insurance, someone in India could end up paying (on average) 61.2% of a price raise on pharmaceuticals by him- or herself.

6.5 Access to essential medication

India has a history of being a large producer of generics for the third world and has a significant pharmaceutical sector to produce these generics. If a country has a large pharmaceutical sector it should (in theory) be better able to provide its subjects with access to essential pharmaceuticals. So how does India relate to South Korea in the area of export and import of pharmaceuticals? In figure 11 the data for import and export of these two countries has been plotted into a graph.

Figure 11. Import and export figures between 2003-2011 of pharmaceuticals by India and South Korea, based on WTO data⁹⁷



⁹⁷ This graph is based on WTO statistics available on <http://stat.wto.org/StatisticalProgram/WSDDBViewData.aspx?Language=E> accessed on 18 March 2013, see <http://stat.wto.org/Home/WSDDBHome.aspx?Language=E> for terms of use

From this graph it's noticeable that India has had an enormous increase of its exports of pharmaceuticals, from \$2 billion in 2003 to \$9.4 billion in 2011. In the area of imports there was also significant growth from \$0.6 billion in 2003 to \$2.7 billion in 2011, a more than quadrupling of the import of pharmaceuticals in an 8 year time-frame. South Korea has also seen an increase of both import and export in the 2003-2011 time-frame. In 2011 it exported for \$1.3 billion and imported for \$4.3 billion. This shows a fundamental difference between the pharmaceutical industry in South Korea and India. India exported in 2011 3.5 times more than it imported, in contrast South Korea imported around 3.3 times more than what it had exported.

As we have seen in this chapter there are multiple differences between India and South Korea which are relevant in regards to access to essential medication. In the table in figure 12 a summary is given by using the data per indicator from the most recent year available.

Figure 12. Indicators for South Korea and India

Indicator	South Korea	India	Difference (South Korea – India)
GDP per capita	\$22424	\$1488	-\$20936
Life Expectancy	80.76 years	65.13 years	-15.63 years
Total health expenditure as a % of GDP	6.9%	4.0%	-2.9%
Public health expenditure as a % of total health expenditure	59%	29%	-30%
% out of pocket from total health expenditure	31.4%	61.2%	+29.8%
Trade balance: export minus import of pharmaceuticals in 2011	-\$3 billion	\$6.7 billion	-\$9.7 billion

When looking specifically at access to essential medication for the poor the indicator where India performs better is:

+ Trade balance in the area of pharmaceuticals

South Korea performs better on:

- + GDP per capita
- + Total health expenditure as a % of GDP
- + Public health expenditure as a % of total health expenditure
- + % out of pocket from total health expenditure

In this chapter several key indicators relating to access to essential medication of both these countries have been shown. In the next chapter, chapter seven, the healthcare policies and politics will be explored to give more insight in how the health care systems of South Korea and India have evolved and work with a focus on pharmaceuticals.

7 Health care policy and politics explored

7.1 Scope and goal

To better understand the consequences of both PTA's and how this relates to national health care policy and politics, this chapter will explore the recent history surrounding health care policy and politics in India and South Korea. Like mentioned in paragraph 1.5 the scope will be limited to the amount of the health care system that is public and private, how the health care system is (broadly speaking) set-up and how healthcare is looked at from a political perspective. A brief explanation on how both health care systems currently function will be given in paragraphs 7.2 and 7.3. After having examined how the health care system functions, paragraph 7.4 will be about the pharmaceutical policy and politics in South Korea. In paragraph 7.5 the same will be done for India. The scope of this will be limited to the relevant parts for access to essential medication to stay in line with the goals of this thesis. By looking at how the health care system functions a better assessment can be made of the possible consequences that the EU/India and the EU/South Korea might have (for the poor) in both these countries.

7.2 Functioning of the health care system in India

When India gained its independence from Great Britain it set out to make a public health care system and abolishing the the Indian Medical Service which was a remnant of India's colonial history. They did keep part of the British system in the sense that they continued the principle that the state level (and not the national level) was the primary body responsible for providing health care. Currently however the part of the health system which is funded publicly is facing shortages of trained staff. Most illustrative for this shortage is the fact that 18% of the primary health centers don't even have a single doctor. Quality is low in the public sector and this is one of the reasons people prefer to go to privately owned health care providers⁹⁸. Currently India doesn't have mandatory health insurance and thus insurance is limited to those who can afford it⁹⁹. It was already mentioned in paragraph 6.4 that the people of India need to pay 61.2% (2010 level) out of pocket for their health care. These out of pocket payments for pharmaceuticals hit the poor relatively harder than the rich. Next to this fact, pharmaceutical out of pocket payments are a larger part of the total out of pocket payment for the poor than they are for the rich¹⁰⁰.

⁹⁸ M Rao et al. , 'Human resources for health in India' (2011) 377 The Lancet 587

⁹⁹ WHO, 'Devolved power: key for health care in India' (2008) 86 Bulletin of the World Health Organization 817,829 <<http://www.who.int/bulletin/volumes/86/11/08-071108.pdf>> accessed on 19 April 2013

¹⁰⁰ Y Balarjan et al. , 'Health care and equity in India' (2011) 377 The Lancet 505

7.3 Functioning of the health care system in South Korea

South Korea has had universal health care for its entire population since 1989. In 2000 the health care system underwent a significant overhaul by merging all health care funds into one. This system is funded through proportional taxes which are split 50/50 between the employer and employee. For the people who are self-employed, property is also taken into account when setting the taxation level. Next to this single health care fund there is a government run program called Medicaid, which provides coverage to the poor (<5% of the population) and is paid for from taxes raised by the governments on both the local and the national level. The health care providers are for 90% under private control and the insurer doesn't differentiate in the way it deals with health care providers between public and private¹⁰¹. In regards to access to essential medication it was already noted in paragraph 6.4 figure 10 that the population has to pay, on average, 31.4% out of pocket of total health expenses (2010 level). For pharmaceutical prescriptions specifically, the number is slightly lower with a 30% coinsurance since august 2007, although the deductible has to be added to this number to see the real amount that needs to be paid out of pocket on average for pharmaceuticals¹⁰².

7.4 Pharmaceutical policy and politics in India

Before having to implement TRIPS in 2005 to meet its WTO obligations the country had a very soft stance regarding pharmaceutical patents, allowing India to develop a large generic producing industry. TRIPS threatened this industry as it would mean that under TRIPS certain pharmaceutical producers would be in violation by producing generics of pharmaceuticals that were still under patent. To (partly) counter this threat imposed by the implementation of TRIPS, India set out to make patent eligibility criteria. This meant that the risk of ever greening (the slightly changing of an existing pharmaceutical product and then re-applying for a patent) has been made a lot harder. Only in cases of proven added efficacy a patent is given for pharmaceuticals which are modified "old" pharmaceutical substances¹⁰³. TRIPS also forced pharmaceutical companies in India to invent more pharmaceuticals themselves and as a result a clear increase in the number of patent applications can be seen in India after TRIPS implementation¹⁰⁴. Like many countries in the west, India is also

¹⁰¹ S Kwon, 'Thirty years of national health insurance in South Korea: lessons for achieving universal health care coverage' (2008) 24 Health Policy and Planning 63

¹⁰² LH Lee et al., 'The effects of new pricing and copayment schemes for pharmaceuticals in South Korea' (2012) 104 Health Policy 40,41

¹⁰³ A Grover & B Citro, 'India: access to affordable drugs and the right to health' (2011) 377 The Lancet 976

¹⁰⁴ N Bedi et al., 'Patenting and R&D in Indian Pharmaceutical Industry: Post TRIPS Scenario' (2013) 18 Journal of Intellectual Property Rights 105

experiencing a rise in cost of pharmaceuticals. To counter this several different policies have been developed. One of these policies is regulation of the prices of pharmaceuticals, although so far this is only limited to the pharmaceuticals that are seen as essential. Other methods that have been used are standardization and reduction of taxes on pharmaceuticals and the opening by the government of stores that sell pharmaceuticals with a significantly reduced price¹⁰⁵.

7.5 Pharmaceutical policy and politics in South Korea

South Korea, like India, has been facing increasing pharmaceutical expenditures for several years, especially when compared to other developed countries. To counter these rising pharmaceutical costs policy was made in regards to the separation of prescribing and dispensing, an expenditure rationalization plan was made and a 30% coinsurance was implemented for outpatient pharmaceuticals. Figure 13 shows the exact amount of out of pocket payments that need to be paid for different kinds of care in 2010.

Figure 13. Co-payment in South Korea 2010¹⁰⁶

Classification		Copayments
Inpatients		20% of total treatment cost
Outpatient	Tertiary hospital	60% of treatment cost + per visit consultation fee
	General hospital	50% of treatment cost + per visit consultation fee
	Hospital	40% of treatment cost + per visit consultation fee
	Clinic	30% of treatment cost
	Pharmacy	30% of total cost

There is a ceiling on the maximum amount of co-payments since 2004. Generics also have had specific policy made for them in 2001. In figure 14 these policy changes can be seen in order with a short explanation for each policy.

¹⁰⁵ AK Shiva Kumar et al., 'Financing health care for all: challenges and opportunities' (2011) 377 The Lancet 668,674

¹⁰⁶ Taken from table 6 in W Chung, 'Social Protection in Korea: Current State and Challenges', in MG Asher & S. Oum & F Parulian (eds), *Social Protection in East Asia – Current State and Challenges*.(ERIA Jakarta 2010) 55,73

Figure 14. Pharmaceutical policy in South Korea¹⁰⁷

Date	Policy	Synopsis
July 2000	Separation of prescribing and dispensing of drugs.	Preventing doctors from dispensing and pharmacists from prescribing by law.
November 2001	Regulation in regards to generics reimbursement.	The first five generics: -20% compared to the original. The sixth generic: -10% compared to the cheapest version.
January 2007	Pharmaceutical expenditure rationalization plan.	Introducing (1) price cut after patent expiry by 20%; (2) price agreement; (3) positive list system.
August 2007	30% coinsurance for outpatient prescription drugs.	Converting fixed copayments per prescription to 30% coinsurance system for non-senior patients.

As can be seen from figure 14 the maximum price of generics has been regulated twice, causing the maximum price of generics to be 64% of that of the original branded pharmaceutical. This is because after patent expiration the maximum reimbursement is 80% and a generic gets a maximum of 80% reimbursed compared to the original product, so that makes the maximum price $100 \times 0.8 \times 0.8 = 64\%$ of the original branded pharmaceutical, if it would still be patented. These policies in regards to pharmaceuticals have had an interesting effect on the generic pharmaceutical market in South Korea. Studies have suggested that there is only a <5% difference between the value and the volume of the generic market in South Korea. In contrast, several Western-European countries like the Netherlands and the UK have a generics market with 2 to 3 times the volume share compared to the value share. For South Korea this implies that:

- a. Prices for generics are too high when compared to non-generics
and/or
- b. South Korean medical providers are more inclined to prescribe the latest medication which are still under patent
and/or

¹⁰⁷ Taken from table 1 and the article of LH Lee et al., 'The effects of new pricing and copayment schemes for pharmaceuticals in South Korea' (2012) 104 Health Policy 40,41

- c. The people of South Korea don't trust "cheap" generics. A reason for this could be the perception that the quality of generics is lower compared to the branded original pharmaceutical.

Since prices are so close to still patented pharmaceuticals and combined with the fact that generics aren't that often prescribed leads to the conclusion that a drop in the volume of generic pharmaceuticals wouldn't necessarily lead to an increase of pharmaceutical cost¹⁰⁸. One has to realize of course that the reason for this is the current pharmaceutical market situation made by the South Korean government. The question arises how these pharmaceutical policies relate to the EU/South Korea PTA. Since the pricing of generics is so close to that of branded pharmaceuticals in other pharmaceutical classes, the consequences of the PTA would be limited. The later availability of generics through data exclusivity and the extension of patent time would mean a direct loss of 20% of the price of the branded pharmaceutical. Since the 20% cut is only applied after the patent has expired. If the South Korean government would decide, at a later time, to change the way its pharmaceutical market functions to a situation where generics are much cheaper than the effects of the PTA might be greater. If South Korea would promote price competition between generics, the cost of having generics later available would obviously increase compared to the current situation.

¹⁰⁸ LH Lee et al., 'The effects of new pricing and copayment schemes for pharmaceuticals in South Korea' (2012) 104 Health Policy 40,47

8. Possible conflicts with existing law

8.1 Legal perspectives

This chapter's goal is to find out where possible legal conflicts in the area of pharmaceuticals can be found from three different legal perspectives in regards to the EU/South Korea PTA and the EU/India PTA. Paragraph 8.2 will show the legal conflicts from the perspective of the national law of South Korea. In paragraph 8.3 the same will be done from the perspective of India. Having seen the legal conflicts from the perspective of India and South Korea, paragraph 8.4 will be from the legal perspective of the European Union and TRIPS. There will also be an explanation under what article(s) of TRIPS these PTA's are being made and what argument could be made against the use of this "method".

8.2 National judicial perspective of South Korea and India

As of yet, South Korea hasn't filed a complaint at the WTO in regards to a conflict with the European Union in the area of pharmaceuticals¹⁰⁹. During research of the literature no direct conflicts with national South Korean Law were found. This isn't the case for India however where there are several possible conflicts if the EU/India PTA is signed. A direct conflict can be found in India's constitution in regards to article 21 which is explained by the courts in India as an article that entitles everyone to timely medical treatment if this offers the possibility to save lives. The case with the pharmaceutical producer Roche is a clear example of article 21 of the constitution in effect. Roche had a patented pharmaceutical on the market for cancer treatment, which was (in their view) unrightfully being produced by another manufacturer. To stop this Roche asked for an injunction, but in the end the Delhi High Court rejected the injunction. This ruling was based on the fact that an injunction would lead to the shortening of people's lives, because they wouldn't have access anymore to this cancer pharmaceutical¹¹⁰. As this case shows India's patent laws are reasonably flexible when comparing them to other countries. These flexibilities could come under threat because of the EU/India PTA. In chapter five it was noted that one of the things that could end up in the PTA is the destruction of infringing pharmaceuticals even before a court has made a decision. This would threaten the flexibility now offered by the law in India. Data exclusivity is another point in the PTA that could come in conflict with article 21 of the constitution. By allowing data exclusivity, and as a consequence the later introduction of generic pharmaceuticals, it would limit the government's resources to ensure a decent level of public

¹⁰⁹ This can be seen on the WTO dispute settlement page available on http://www.wto.org/english/tratop_e/dispu_e/dispu_by_country_e.htm accessed on April 22th 2013

¹¹⁰ C Marotta, 'Licensing in the public interest: Limits on patent property rights in China and India' (2013) 8 Journal of Intellectual Property Law & Practices 213, 224

health¹¹¹. Other conflicts with India's national law could perhaps be found, but at the core of this, the conflict between the EU/India PTA and India's national law from a pharmaceutical perspective comes down primarily on article 22 of the constitution.

8.3 Both PTA's from an EU and TRIPS perspective

In paragraph 5.4 it was already mentioned that the Netherlands had seized a load of generic pharmaceuticals in transit, originating from India. The Netherlands wasn't the only European Union country who detained a load of pharmaceuticals in transit. This was done under EU border regulation BMR 1383/2003 which says that when judging a possible violation of patent for pharmaceuticals which are in transit, one should refer to the countries own criteria to make a decision on whether there is a violation of patent. In reaction India started a dispute settlement procedure at the WTO. Eventually an understanding between the European Union and India was reached and action was taken by the European Union to change BMR 1383/2003. In return India has said it wouldn't be asking the WTO to form a dispute settlement panel¹¹². The aforementioned of course, all has to do with TRIPS and the WTO so how does it relate to the EU/India and (to a lesser extent) the EU/South Korea PTA's? In the analyses of the EU/India PTA made in chapter five we saw that the European Union wanted to introduce civil trade mark disputes. It was feared by doctors without borders that this would cause possible counterfeit judicial challenges for, in principle, legal generic pharmaceutical products¹¹³. In short, the relation between the actions taken under TRIPS and primarily the EU/India PTA is that this PTA could offer new possibilities to detain pharmaceutical products in transit. The fear of using civil trade mark disputes to detain generic shipments is not unjustified when looking at the recent history. In one case the German custom authorities detained a shipment of generics because the name resembled a by GSK trademarked pharmaceutical product (amoxicillin <====> Amoxcil). However, there was nothing wrong with the naming of the generic, since amoxicillin was just the nonproprietary name of the pharmaceutical. The legal reasons for why seizure of pharmaceuticals in transit is unlawful, and a future civil trade mark dispute for in transit pharmaceuticals under the EU/India PTA will also be, comes down to the point that border measures should only be used against products that are imported. Products that are in transit shouldn't be exposed to border measures under TRIPS art 51¹¹⁴. By doing so the European Union is in violation of the

¹¹¹ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8 Journal of Generic Medicines 14

¹¹² BK Baker, 'Settlement of India/EU WTO Dispute re Seizures of in-transit Medicines: Why the proposed EU border regulation isn't good enough' (2012) PIJIP research paper 2012-02, 1 <<http://digitalcommons.wcl.american.edu/research/24/>> accessed on 05-04-2013

¹¹³ J Arkinstall et al., 'The reality behind the rhetoric: How European policies risk harming access to generic medicines in developing countries' (2011) 8 Journal of Generic Medicines 14

¹¹⁴ TRIPS agreement art 51

TRIPS agreement according to the reasoning of India and Brazil to the WTO¹¹⁵. Another possible legal conflict forthcoming from these PTA's has to do with their relationship with TRIPS. Both the EU/South Korea and the EU/India PTA are allowed under TRIPS by the so called article 4 Most Favored Nation Treatment (henceforth MFN)¹¹⁶. MFN gives the possibility to make bilateral trade agreements with higher standards of intellectual property protection than described in TRIPS. Although it is (currently) allowed to make use of this "method" to make preferred trade agreements there is an argument to be made that this is in fact not in line with TRIPS. Since the MFN is now mainly used to increase intellectual property rights, one could argue that this goes against the goals and purposes set out in TRIPS and could be seen as a violation of the TRIPS-agreement¹¹⁷. Thus far however, no clear signal has been given by the WTO that this practice of bilateral trade agreements with an emphasis on increasing intellectual property protection should end.

¹¹⁵ HG Ruse-Khan, 'A Trade Agreement Creating Barriers to International Trade?: ACTA Border Measures and Goods in Transit' (2011) 26 Am. U. Int'l L. Rev. 644

¹¹⁶ TRIPS agreement art 4

¹¹⁷ S Frankel, "The Legitimacy and Purpose of Intellectual Property Chapters in FTAs" in Ross Buckley, Vai lo Lo and Laurence Boule (eds), *Challenges to Multilateral Trade The Impact of Bilateral, Preferential and Regional Agreements* (Wolters Kluwer The Netherlands 2008)

9. Assessing the impact on the right to health

9.1 Applying a theoretical model

In paragraph 3.2 a theoretical model for making a human rights impact assessment was discussed. This theoretical model will be used in this chapter to make human rights impact analyses of both PTA's, while keeping possible economic gains in mind. Through this theoretical model an answer will be given to the question what the effects of these PTA's will be for India, South Korea and the third world in relation to the right to health and access to essential medication. In paragraph 9.2 step 1 will be done to identify the items in the PTA's that could infringe upon the right to health in the area of pharmaceuticals and access to them. Step 2 in paragraph 9.3 will contain the identification of the goals and objectives of both PTA's in the area of pharmaceuticals. This will be followed with paragraph 9.4 in which step 3, an assessment, will be made if both PTA's are really necessary, reasonable and if there are alternatives. Paragraph 9.5 will be about step 4 which deals with proportionality. In this final step an assessment will be made if the new PTA rules in the area of pharmaceuticals are an acceptable infringement in regards to the right to health, considering what they offer in return¹¹⁸.

9.2 Step 1: identification

In chapters 4 and 5 several items in the EU/South Korea and the still to be signed EU/India PTA have been identified as TRIPS plus measures. In this paragraph all these items will be put next to each other with a short explanation how they (could) affect the right to health. First the TRIPS plus measures and their effect for the EU/South Korea PTA will be shown in figure 15.

Figure 15. TRIPS plus measures in the EU/ South Korea PTA and their effect on the right to health.

South Korea	
TRIPS plus measure	Effect
Art. 10.35 A registration procedure for patented pharmaceutical products is necessary and a maximum of five years of extra patent protection can be	An extra five years of patent protection would delay to arrival of cheap generics on the market. Causing increased cost directly and indirectly for the people in South Korea. At the very least it would mean that they would have to pay 100% instead of 80% for the same pharmaceutical for a period of up to five years. 30% of the cost for this would end up

¹¹⁸ Chuan-fen Wu, 'Raising the right to health concerns within the framework of international intellectual property law' (2010) 5 Asian Journal WTO & International Health Law and Policy 141

granted as a form of compensation for effective patent time lost.	directly at the population through the coinsurance. This could cause problems in regards to access to essential medication for specific groups (too rich for Medicate but too poor to be able to afford them) in South Korea.
Art. 10.36 Data confidentiality of data used for market authorization. Unless the patent holder agrees, data used for first time market authorization can't be used again by other parties. This data is protected for a minimum of five years.	This won't increase the cost of generic pharmaceuticals since the maximum price is already regulated, but it could mean that generics would be available at a later time. This later availability could however raise pharmaceutical cost, possibly negatively effecting access to essential medication. It could also lead to the ethically debatable practice of doing unnecessary clinical trials to recreate the same clinical data, but this time for a generic.

Figure 16 shows the same for the yet to be signed EU/India PTA.

Figure 16. TRIPS plus measures in the EU/India PTA and their effect on the right to health.

India	
TRIPS plus measure	Effect
Introduction of civil trademark disputes for pharmaceutical products and seizure in case of civil trademark infringement for in transit pharmaceuticals	Generics in transit could be detained in Europe, causing people in for example South America to be without affordable essential medication.
Third party liability	This could cause people and organizations to avoid generic pharmaceuticals in fear of being liable to patent infringement.
An increase of the penalties in cases of patent and/or trademark violation	Pharmaceutical companies might be daunted by these increased penalties and might stop making generics unless they are absolutely sure they are not in violation. This could cause access to essential medication to be negatively affected, especially for the poor in India.
Data exclusivity	Generics will be more expensive, since the cost of research data has to be earned back and it will take longer before generics can enter the market. This will hurt access to

	essential medication for the poor in India.
Possibility to destroy possible infringing pharmaceuticals even before the court has decided if this is justified or not.	Perfectly legal generic pharmaceuticals could end up being unjustly destroyed, causing delays and extra cost to deliver generics to the countries which need them. Possibly this could lead to pharmaceuticals being temporarily unavailable.

9.3 Step 2: goals and objectives of both PTA's

Step 2 of Chuan-fen Wu's theoretical model for making human rights impact assessment is about naming the goals and objectives, because of the scope of this thesis this will be limited to the area of pharmaceuticals. First the goals and objectives set-out in the EU/South Korea PTA will be given and secondly the goals and objectives of the EU/India PTA. The goal and objective for the EU/South Korea PTA can be found in article 1.1 of the PTA. The most relevant in regards to pharmaceuticals are:

- *Protection of intellectual property rights
- *Promote trade
- *Promote competition
- *Promote investment, without damaging health¹¹⁹

Since the EU/India PTA hasn't been signed yet, the goals and objectives are less clear. In the original perspective of the European Union in 2006 however, a PTA with India should be made with the goals in mind to resolve the following issues (as identified in paragraph 5.2):

- *Access to the European market place by India and vice versa
- *Government procurement
- *Intellectual property
- *Competition¹²⁰

9.4 Step 3: necessary, reasonable and possible alternatives

In step 3 both PTA's are examined with the question in mind if the proposed/agreed upon regulation is really the best method to achieve these goals. An examination of the EU/South Korea has shown that one of the main goals of this PTA is to better protect intellectual property rights. In step two we saw that this is primarily done through extending the maximum patent time and data confidentiality. One could argue that extending the maximum patent time as a form of compensation for time lost during a market authorization procedure

¹¹⁹ Council Decision on a FTA with Korea art 1.1

¹²⁰ The High Level Trade Group 'Report of the EU-India High Level Trade Group to The EU-India Summit' (2006) <<http://trade.ec.europa.eu/doclib/html/130306.htm>> accessed on the 10th of October 2012

is reasonable, seeing as the patent holder otherwise has no chance of enjoying the full patent time of his or her invention. Data confidentiality is another matter however. In my opinion it is not reasonable that a generic producer has to do clinical trials again to produce data, possibly causing unnecessary health damage (for example in the placebo group). An option would be to add in article in the PTA that a generics producer has the option to pay a certain percentage of the research cost to get access to this data. Research and development would get a boost by this and ethical issues surrounding re-doing clinical trials could be avoided. When looking at the proposed EU-India PTA, one of the goals of the European Union was to resolve issues concerning intellectual property. To achieve this, new regulations like higher penalties, data exclusivity and third party liability have been proposed. India has been using its own constitution and TRIPS flexibilities to protect public health and has been the producer of generics for several developing countries. A possible alternative to the intellectual property chapter in this PTA is a further evolution of the TRIPS treaty and Doha declaration. Although it would be very hard for the European Union to convince developing countries of the necessity of stricter intellectual property rules, it would create a level playing field for all and wouldn't cause conflict between treaties.

9.5 Step 4: proportionality

In this final step an assessment will be made if the new PTA rules in the area of pharmaceuticals are an acceptable infringement in regards to the right to health, considering what they offer in return. The EU/South Korea PTA has been in effect for several years now. In the area of human rights and specifically access to essential medication this PTA seems to have little effect. As was shown in chapter seven, the value and volume of generics in the South Korean market place are very close to each other suggesting that generics don't play a big role in the pharmaceutical expenditure of South Korea compared to branded pharmaceuticals. South Korea also has a system in place for the poorest called Medicaid and is a reasonably wealth country with a GDP per capita of around \$22400 in 2011. In return it promotes the ILO-conventions, offers new trade and economic growth possibilities and emphasizes the importance of the Doha declaration. In summary this PTA seems to be proportional when looking at the human right to health, balanced against economic gains.

Given the fact that a lot of the EU/India PTA is still unknown, both in the manner of what is exactly going to be in it and what it's effects will be, my opinion (given what is known) is that the EU/India proposed PTA could end up not being proportional. The poor in India and elsewhere in the developing countries are set to lose their access to essential pharmaceuticals through the limiting of TRIPS flexibilities, the introduction of third party liability and through the increase of penalties in cases of patent and/or trademark violation.

When one looks at the GDP per capita and the amount that the people in India need to pay out of pocket, it becomes apparent that any price raise because of this PTA will have serious effects for the poor. This could be partially off-set by a boost to the economy because of this PTA. Through an economic boost that a PTA could give, the poor would perhaps have better chances at getting work and a better chance to improve their prosperity. However, there is no proof that the EU/India PTA would directly improve the situation for the poorest in India. Next to this there are serious consequences for other countries which make use of the generic producing industry in India. Allowing foreign governments to destroy shipments of generics in transit, even before a court has made a ruling, could lead to serious problems in regards to access of essential medication and therefore the right to health. This all leads me to conclude that this proposed PTA is disproportional when balancing the economic benefits to the harm it would cause to human rights and more specifically to access of essential pharmaceuticals.

10. Conclusion and discussion

10.1 Research goals of this thesis, main- and sub-questions

In this thesis the EU/India and the EU/South Korea PTA have been analyzed and compared from several different angles through the answering of multiple sub-questions. These sub-questions were:

- * What is the meaning of the right to health?
- * What does the EU/South Korea PTA encompass in regards to pharmaceuticals?
- * What does the EU/India PTA encompass in regards to pharmaceuticals?
- * How do these PTA's relate to TRIPS?
- * What are the main social and economic factors of India and South Korea and how do they differ?
- * How is the health care politics and policy situation in India and South Korea?
- * What are the possible conflicts with existing law?
- * What kind of effect do these PTA's have for India, South Korea and the third world?

In this final chapter the main question of this thesis:

How do the PTA's between the EU/India and the EU/South Korea relate to the right to health and more specifically, access to essential medication?

will be answered in paragraph 10.2. This will be followed by a discussion of what the results implicate for future bilateral PTA's in paragraph 10.3. This thesis will be concluded in paragraph 10.4 with suggestions for further research to better understand the both legal and socioeconomic consequences that these PTA's have.

10.2 Relationship with the human right to health

After having analyzed both PTA's it has become apparent that the EU/South Korea PTA does not have a serious effect on access to essential medication. Although people need to pay 30% of medication out of pocket, there is a fund for the poor and the other 70% is paid through universal health care. With an average GDP per capita of \$22500 in 2011, it should be possible for the average Korean citizen to acquire additional health insurance to limit the risk of the 30% co-insurance that the National Health Insurance has. Added to the fact that a decrease in the volume of generic pharmaceuticals wouldn't have that much of an effect leads to the conclusion that this PTA, in the area of pharmaceuticals, is on a decent standing with the right to health. Though it should be noted that the lower middle class which doesn't have Medicaid entitlements could be affected negatively in their access to essential medication. For India the assessment is very different from South Korea. Unlike South Korea,

India doesn't have universal healthcare and there isn't a special fund for the poor. With a much lower GDP, higher amounts of out of pocket payments for health care and a pharmaceutical industry that produces generics not only for India but also for the second and third world, the relationship of a possible PTA with the human right to health would be a lot more strained. Access to essential medication could be in serious danger, as the cases in the Netherlands and Germany showed. The stopping of generic medication in transit through Europe under the guise of a trademark dispute at the very least delays delivery of pharmaceuticals that possibly people can't do without. This PTA would offer new possibilities to do the same thing again, but on a different basis. On the positive side these PTA's do offer new potential for economic development, economic development which could cause added growth and an opportunity for primarily the poor in India to improve their social economic status. By having more money they would have better access to essential medication. Although there is no proof that the poor in India will prosper significantly enough, and fast enough, to off-set the possible negative effects to access of essential medication. In summary the relationship between the right to health from the perspective of access to essential medication doesn't seem to be that negative for the EU/South Korea PTA, but the proposed EU/India PTA offers serious questions on how the human right to health can be guaranteed. Not only in India but also in the second and third world.

10.3 Discussion

Given the result of this research that the proposed EU/India PTA could have a strained relationship with the human right to health in the form of access to essential medication, the European Union should reconsider their goals and how they want to achieve them with this PTA. If the European Union really stands behind TRIPS and the human right to health there should be several changes made in this PTA. Especially in regards to pharmaceuticals that are in transit, third party liability and data exclusivity. Till these items have been addressed India shouldn't sign this PTA, even though it could cost India in the form of economic growth. The EU/South Korea PTA that was already signed is in comparison on a far better footing with the human right to health in the form of access to essential medication. Partly because of how the Korean health system works and partly for other reasons like the GDP per capita. Showing that it's very important to not just look at what is in a PTA, seeing that there is a lot of overlap with the EU/India PTA in the area of pharmaceuticals, but also to the specific context of a country. In a reasonably wealthy country like South Korea it can be perfectly acceptable to have data exclusivity, because the population can either afford higher pharmaceutical prices or have insurance to limit the impact of price raises. When you don't have a Medicaid like program to help the poorest people in a country, no universal health care and a low GDP per capita the effects of the same law will be much more severe. If the

country is also one of the biggest producers of generics for the second and third world this effect becomes even greater. Next to the importance of context when looking at these PTA's there is also a conflict visible. A conflict between what the EU/South Korea and EU/India PTA says/could say and what it in effect does/ will do. In both PTA's the Doha declaration and TRIPS is mentioned / will most likely be mentioned but both PTA's introduce measures that go beyond what has been stated in TRIPS. This is possible in bilateral trade agreements under TRIPS regulations. However, when TRIPS flexibilities, further specified in the Doha declaration, are undermined through these TRIPS plus measures one should consider a revision or reconsideration of these PTA's. A revision or reconsideration could bring these PTA's more in line with TRIPS and also with themselves. It would be very strange that the importance of TRIPS and Doha is underlined, but that in the same document articles are named which undermine it.

It should be noted that during the literature research it was very hard to find information of what is exactly going to end up in the proposed EU/India PTA. Currently a lot of rumors are going around, rumors which can't be substantiated by scientific or trustworthy sources. The analyses made is therefore done on the information that is known through communication of the European Union in the form of the commissioner for trade or by scientific sources who in some cases had seen draft versions. Although something is on a draft version there is absolutely no guarantee that it will end up in the final version and this should be realized when interpreting the results of this research.

10.4 Further research

The effects these PTA's will have will need to be analyzed over a longer period of time to see what exactly their effects have been or in the case of India will be. Keeping the scope of this thesis feasible caused the focus to be primarily on pharmaceuticals and access to essential medication. The human right to health is of course much wider than just access to essential medication and in this thesis I "stumbled" on two subjects that could warrant further research. In the EU/South Korea PTA the promotion of the ILO-conventions is specifically named. It would be interesting to see what effect(s) this PTA has in relation to these ILO-conventions for occupational health. Especially the ILO C102 convention in the form of article 10, which says that cost sharing in cases for morbid diseases should avoid hardship, could be in conflict with the high percentage of out of pocket payment for pharmaceuticals in South Korea. Another subject is the guidelines made by the Special Rapporteur for pharmaceutical companies. One of the guidelines is that in low income countries pharmaceutical companies should disregard their rights on data exclusivity for test data. It would be interesting to see how often pharmaceutical companies disregard their rights on data exclusivity in low income countries. During my literature research I also came across several authors who suggested

that TRIPS is also a ceiling for intellectual property protection and thus does not only offer a minimum level of intellectual property protection for all the WTO members. It would be very interesting to see if this train of thought would gain more support in the future and what effects it would have on both the EU/South Korea PTA and a future EU/India PTA. Possibly it could lead to the conclusion that certain intellectual property provisions in these bilateral PTA's need to be changed in order to comply to TRIPS.

Enclosure 1. Schedule

Literature research: March 2012 – February 2013

Answering the sub questions: January/February/March/April

Interviews if necessary: February / March

Conclusion and discussion: March/April

Improving the thesis after feedback: April/May

Defense: June