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The TRIPS Agreement and access to medicines: who are the main losers?

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"That, as we enjoy great advantages from the inventions of others, we should be glad of an opportunity to serve others by any invention of ours; and this we should do freely and generously." (Benjamin Franklin)

Nowadays, the World Trade Organization exceeds the activity for which it was really established: among other activities, it deals with the regulation of intellectual property rights relating to trade. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has resulted in great influence not only on the competition in the pharmaceutical market, but also on the life and public health in developing countries. However, the reaction of poor countries to the changes caused by the agreement is not the same: there are great differences among the nations, and the heterogeneity of developing countries regarding the TRIPS Agreement can be seen in many fields. This study details these points and shows that the least-developed countries are the main losers, as they are unable to use the potential technical solutions.

Key words: TRIPS Agreement, developing countries, generic medicine, patent
JEL: F13, O34

1. Introduction

The pharmaceutical industry has always been a sensitive area in the economy as access to the essential medicines[1] is an issue of human rights. However, the promotion of further pharmaceutical research needs the provision of patents for new medicines. These two different (ethical and economic) aspects do not meet, and, first of all, developing countries are the losers in it. Several developing countries have had to face with enormous problem since the mid–1990s, but mainly since the early 2000s: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) adopted by the World Trade Organization (WTO) in 1995 prescribes at least 20-years patent protection for all inventions, among others, for pharmaceutical products, as well. This hinders the appearance of cheaper generic

[1] Since 1977, the World Health Organization has issued every two years the list of essential medicines which are needed for the basic health-care system and/or for priority diseases. The last update was in March 2010, see WHO (2010). According to the WTO, essential medicines are to satisfy the health care needs of the majority of the population and they should be available (Smith et al 2009).

drugs on the markets, hurting the right of access to medicines: people living in developing countries can mainly afford only these cheaper drugs.

As a consequence, in some countries and regions, illnesses which have already had treatments developed or can be prevented are still fatal. According to the data of the World Health Organization (WHO), in 2008 there were 247 million cases of malaria, out of which one million were fatal – mainly among African children (WHO 2009a). HIV/AIDS is only treatable and affects, first of all, the low and middle income countries – out of the 33 million AIDS-patients around 30 million live in developing countries. At least 9.7 million patients need antiretroviral, or ARV, therapy, however, only one third is able to receive it (WHO 2009b). Gathii (2007) adds that less than 17 percent of Sub-Saharan African people having infectious diseases can have access to the essential medicines. This problem for public health had become so important by 2000 that the Millennium Development Goals[2] of the United Nations contain the support of developing countries in the access to essential medicines (UN 2000). Furthermore, it can be recognized that the unsolved problem of access to medicines may hinder the poverty reduction, as well (Gathii 2007).

The relatively wide – mainly international and not Hungarian – economic literature analyses the connection between the TRIPS Agreement and public health in relation to developing countries, but there is no distinction made between them. Therefore, *the primary objective of this study is to reflect that the loss arising as a consequence of the TRIPS Agreement is different in both measure and characteristics in the developing countries*. Although the TRIPS Agreement covers a wide range of intellectual property rights, this study emphasizes only its pharmaceutical relations. The paper is structured as follows. As the TRIPS Agreement is not widely known in the Hungarian economic literature, Section 2 gives a short introduction to the TRIPS Agreement and its modifications. Section 3 introduces the recent literature on the effects of the agreement on the developing countries, reflecting the debate among economists. Section 4 details the differences among the developing countries regarding the losses. The study ends with the concluding remarks.

2. The TRIPS Agreement

Regulating the intellectual property rights relating to trade appeared in the mid 1980s at first, when the contracting parties of the GATT[3] during the Uruguay Round

[2] Members of the United Nations adopted eight goals in 2000 to meet the challenges of the developing countries; the deadline for fulfilling these objectives is 2015. For a detailed list of the goals see UN (2000).

[3] The General Agreement on Tariffs and Trade. It regulated the world trade till 1995. The World Trade Organization subsumed the GATT.

negotiated this subject. Finally, the pressure of the advanced countries (mainly of the USA, Japan and the European Union) resulted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Correa 2002, Haakonsson–Richey 2007, Timmermans–Hutadjulu 2000). Although the question of intellectual property rights at the international level is not a new phenomenon, the earlier international or regional agreements[4] lack many things: there are many exemptions from these agreements, and most of them do not determine the length of patent protection (Martin–Winters 1995). On the other hand, the TRIPS Agreement is more comprehensive and does not have any missing areas (Correa 2002). Although the TRIPS Agreement covers a wide range of the intellectual property rights (patents, geographical indicators, copyrights, trademarks, industrial designs, etc.), this study emphasizes only the rules on patents because these affect mostly pharmaceutical products.

2.1. Main articles of the TRIPS Agreement regarding the pharmaceutical sector

The TRIPS Agreement enables the patenting of any kind of innovation. Patents as a way of intellectual property rights give an exclusive right for an inventor to make, sell, import, or use the invention without authorization within a country during a certain term (Watal 2002). Regarding the pharmaceutical sector and patents, the following articles have to be mentioned from the TRIPS Agreement (WTO 1994, pp. 322–323, 331–332, 334):

- Article 3 and Article 4 oblige Members to provide *national treatment and most-favoured-nation treatment* for other Members.
- Article 7 lays down the objectives for protecting and enforcing intellectual property rights as they *"should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge"*.
- Article 27 (1) says that *"patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"*.
- Article 28 provides the exclusive rights for the patent owner on *"making, using, offering for sale, selling, or importing for these purposes that product"*.
- Article 33 determines the term of protection which *"shall not end before the expiration of a period of twenty years counted from the filing date"*.

Consequently, when the TRIPS Agreement comes into force, the patent protection has to be provided for *both the pharmaceutical products and process,*

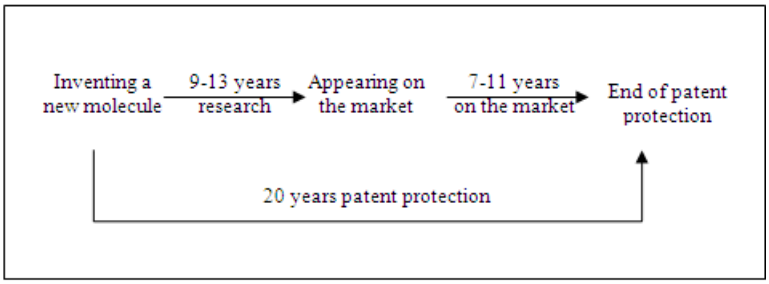
[4] One international agreement is, for example, the Paris Convention signed in 1883. Examples for regional agreements from Africa are the OAPI (African Industrial Property Office) or the ARIPO (African Regional Industrial Property Office).

therefore only the patent holder is eligible for producing and selling the product – that is, there is no right for copying a medicine using other production process. It is important to emphasize that in spite of other regional agreements, TRIPS unambiguously determines *the minimum term of protection giving 20 years for it*.

As for pharmaceutical production, these obligations lead to the following situation. Research in the pharmaceutical sector is a time consuming process: at least 9 or 13 years may pass until a new drug suitable for human consumption is invented from a molecule. Regarding the expenses, inventing a new medicine costs around 802 million USD (containing the costs of unsuccessful research), and this amount is equal to 30 percent of the company's total costs (Moerman–van der Laan 2006).[5]

If there is a possibility for patent protection, the generic producers cannot appear and compete on the market – and the lack of competition (namely the monopoly) leads to higher prices. The TRIPS Agreement provides patent protection for twenty years, and in this case the inventor has 7–11 years to gain revenues for covering their research costs and to continue further research (Figure 1). The monopoly arising due to the patent protection enables the inventor to keep prices at a high level which covers the costs, on one hand, and produces profits, on the other hand.

Figure 1. Linkages between research and patents



Source: own construction

Nowadays, there are 265 nations, dependencies and other entities, out of which 194 areas are independent states (CIA 2009, US Department of State 2009). Since the WTO has 153 Members, the possibility of patenting seems to be universal regarding pharmaceutical products, as well. To meet their WTO obligations, the countries had to change their national legislation, where there were no patent rules earlier, or if the national legislation did not comply with the WTO rules, the national rules had to be changed.

[5] DiMasi et al (2003) – using micro-level data – analysed the innovation costs of a new product in the pharmaceutical sector. Their findings show that the cost of a new drug reaches 403 million USD. Comparing these results with their earlier findings (DiMasi et al 1991), they stated that the innovation costs in this sector have increased above the average inflation rate.

2.2. Flexibilities of the TRIPS Agreement

As a result of the overall patent opportunity, more original and less generic pharmaceutical products will appear on the markets. Not only people in the developing countries could not buy the original products, but the governments themselves also have problems as they are unable to give any subsidy on these pharmaceutical products. Therefore, the linkages between the TRIPS Agreement and public health have appeared: many developing countries cannot afford the essential medicines. In the developed countries, medicines are subsidized by the government to a high extent in order to keep the prices at a lower level. According to the data of the WHO (2004), government assistance exceeded 40% of the pharmaceutical expenses in the developed countries, while this ratio is only around 28% in the developing nations. The reason for it is that the government budget is very narrow in the poor countries and cannot give such large subsidies on medicines. Consequently, the private sector in the underdeveloped nations has to spend more on drugs than in the developed countries.

In the last few years, more transition agreements have been adopted to handle the effects of TRIPS on public health. Barton (2004) and Sonderholm (2010) mention that pharmaceutical companies are obliged to follow differential pricing, and they have to determine lower prices in the developing than in the developed countries. Kremer (2002) adds that differential patent protection in the developed and developing world will lead to beneficial price discrimination. Although price discrimination may have critiques, Kremer (2002) emphasizes that it can enable both access to medicines and further research, but the governments of the developed nations and other international agreements have great responsibility to hamper the imports of cheaper drugs from the developing countries. If cheaper drugs are indeed imported from developing countries, as the author emphasizes, the pharmaceutical companies would increase the prices in the developing countries.

It was clarified at the Doha Ministerial Conference (in 2001) that the original TRIPS Agreement (Article 31) contained the provision that in case of a public health emergency, a certain country was allowed to produce the necessary medicines with its own capacities and without the permission of the patent holder in order to prevent further epidemics (Fink 2006, Sun 2004, Watal 2002). This facility is known as compulsory licensing.[6] To avoid the re-export of cheaper generic drugs to the developed countries, the production is allowed only for their own use and the new products must not appear in international markets (Barton 2004). However, several developing countries are unable to produce medicines with their own capacities. The solution for this problem appeared in August 2003. This decision contains the provision that if a country could not use the opportunities of compulsory licensing, it is allowed to import necessary generic drugs from other countries producing them

[6] For more detailed information on compulsory licensing, see, for instance, Chien (2002) or Feldman (2009).

but the country has to do everything so that these drugs will not appear on the markets of developed countries (Fink 2006). This facility is called *parallel importation*.

2.3. A new phenomenon: the TRIPS-Plus

Although the decisions regarding the TRIPS Agreement provide flexibilities, protecting intellectual property remains a problem for the developing nations. Recently, a new phenomenon is influencing the TRIPS Agreement because the industrialized countries and pharmaceutical companies (mainly in the US) are trying to extend the TRIPS Agreement and make the protection of intellectual property rights (IPRs) much stricter. Their solution is to involve intellectual property rights into bilateral or regional trade agreements (Boring 2010, Gallagher 2008, Sell 2007, Smith et al 2009). This is the so-called "TRIPS-Plus" effect, and El Said (2007, p. 158.) defines it as when *"a country implements more extensive levels and standards of IPRs protection than of those required under the TRIPS Agreement, or undertakes the elimination of an option which was awarded to it under the agreement"*. That is, the TRIPS-Plus provisions exceed the requirements of the TRIPS Agreement or reject the flexibilities of it (Sell 2007). Because of this, the TRIPS-Plus is a good example how the large pharmaceutical (multinational) companies are able to influence the international economic processes for their own profit interests.

The United States has TRIPS-Plus agreements with Korea, Sri Lanka and the Philippines (Smith et al 2009). But El Said (2007) claims that the European Union has had such kind of agreement long before the US agreements, and the EU has built up this kind of relationship with countries in the Arab world.[7]

The TRIPS Agreement has a significant influential power both on the pharmaceutical companies and on the situation of the public health in the developing countries. Analysing the potential impact on public health is relevant in our study, as it can help us determine where there could be differentiation points among the developing countries. Furthermore, we can see that recent literature does not make differences among these nations.

3. TRIPS and public health

Although the economic (and law) literature on the effects of the TRIPS Agreement in the developing countries is very rich, its real effects on the access to essential medicines in the developing countries and on trade in patented products are still unclear. The debate over the TRIPS Agreement and public health raises both social and economic issues (Abbott 2002). Furthermore, Malhotra (2003) emphasizes that

[7] For more detailed analysis of the TRIPS-Plus see, for instance, Boring (2010), El Said (2007) and Sell (2007).

the TRIPS Agreement itself restricts trade and decreases competition by providing a monopoly for new products. Consequently, the TRIPS Agreement is in contradiction with the overall objective of the WTO of promoting economic development through increased trade. In the following we emphasize the most important literature on the access to medicines dividing it into two groups: one accepting and one rejecting the TRIPS-effects.

3.1. TRIPS as a reason for lack access to medicines

There are authors saying that the TRIPS Agreement is disadvantageous to the trade of generic drugs and access to medicines in the developing countries. For instance, Abbott (2002) strengthens the importance of patents from the point of view of pharmaceutical companies, adding that it results in higher consumer prices of pharmaceutical products and less generic drugs on the market. Besides this, developing countries cannot offer purchasing power for the more expensive medicines, and they can afford only cheaper generic drugs. Sonderholm (2010) emphasizes that owing to the TRIPS Agreement, *sales determine the profits* of the pharmaceutical company: the higher a price is acceptable on the market, the higher return the company can gain. Consequently, prices for pharmaceutical products will be higher.

Chaudhuri et al (2006) empirically investigated the *welfare effects* of the TRIPS Agreement using the example of India. The results of their econometric analysis show that the TRIPS Agreement may have adverse welfare effects, and the decrease in welfare is mainly the loss of consumer welfare. Although there is the possibility of parallel importation and compulsory licensing, Haakonsson–Richey (2007) focus attention on *a new phenomenon*: many African countries do not use these additional tools for access to medicines but try to develop their own generic pharmaceutical production using their donor relations and their support.

Sonderholm (2010) claims that beside the access problem, there exists the *"availability problem"* as there are illnesses from which people mainly in low-income countries are suffering (such as malaria, and leishmaniasis). For the for-profit pharmaceutical companies it is not worth spending on R&D for drugs on these diseases as the return on investment is uncertain (Troullier et al 2001). In numbers it means that less than 1% of 1223 new drugs appeared on the world market between 1975 and 1997 were specifically for tropical diseases (Kremer 2002, Troullier et al 2001). A reason for this could be that the market for pharmaceuticals in the least-developed countries is quite tiny (Kremer 2002).[8] Kyle and McGahan (2009) analysed the *effects of patents on research and development* in both developed and developing countries. They found that patents positively affect the research in the

[8] A solution for the problem of neglected diseases may be advance purchase agreements, where the sponsors *"commit, in advance of product development, to financing the purchases of vaccines for low-income countries, at a fixed price specified in advance"* (Berndt–Huvitz 2005, p. 2.).

developed nations, while in the developing world there is no strong correlation. Therefore, they think that *patents cannot be the best incentives for developing new medicines for the neglected diseases.*

3.2. Rejecting the negative effects of the TRIPS Agreement

Some authors (e.g. Attaran 2004, Watal 2000) argue that *patent protection does not influence the access to medicines in the developing countries* but that deep poverty is the main reason for the lack access. Boring (2010) claims in her analysis that the level of intellectual protection does not influence the access to medicines in the developing countries, but the government activity in health care or the improvement of infrastructure are more important factors in this field. Attaran and Gillespie-White (2001) analysed whether the patents would have any effects on access to AIDS-drugs in Africa. They received a surprising result: patents do not affect access to medicines as there is no correlation between the geographic patent coverage and the access to treatment in Africa. Instead of patents, the authors – similarly to the researches mentioned above – assume that poverty, the high costs of treatment, national rules regarding medicines, and tariffs and taxes are the main barriers of access to medicines.

There are also some country analyses – both from the developed and developing side. For instance, Islam (2009) gives an interesting review on the effects of the TRIPS Agreement in several sectors in Bangladesh. As for the pharmaceutical sector, he strengthens the view that though there are some unfavourable effects of the agreement, the country seems to be in a good position owing to the generic drug producers, and it even can utilize the amendments of the Doha Declaration for producing and exporting generic drugs. Boring (2010) analysed the impacts of the TRIPS-rules on the US pharmaceutical trade using a gravity model, and she found there was no evidence that the TRIPS Agreement promoted the US pharmaceutical exports.

Some studies analysed how the TRIPS Agreement influences the patent-sensitive trade and innovation process in the underdeveloped nations. Ivus (2010) studied how the TRIPS-rules and patent rights affected the patent-sensitive exports from developed to developing countries over the 1962–2000 period. The author gave great emphasis on the colonial past, and investigated and compared the pre- and post-period of the TRIPS Agreement. The results are favourable as there was an increase in the export of these products, which is equal to an almost 9% increase in the developing countries' patent-sensitive imports.

Chen and Puttitanun (2005) analysed the effects of intellectual property rights on the innovation in the developing countries. Their model consisted of two sectors in a developing country: one of them was the import (foreign – North) sector, the other was a local one. Both sectors had two firms, out of which one had a patented technology, while the other could imitate the more developed technology. The authors reached a surprising conclusion about the TRIPS and innovation effects in

the developing countries: their empirical results involving 64 developing countries show that intellectual property rights have a positive impact on the innovation activity in the developing countries. Furthermore, they experienced a U-shaped relationship between intellectual property rights and economic development. Schneider (2005) analysed the innovation changes between 1970 and 1990 in 47 developed and developing countries preparing different regression models. She received a similar result to that of Chen and Puttitanun (2005), though she strengthens the view that the impact of IPRs on innovation is much stronger in developed than in developing countries.

Although there is still a dispute among researchers regarding the TRIPS Agreement, this agreement has intervened into pharmaceutical competition, and it has impact on the access to medicines in the developing world, as well.[9] The TRIPS Agreement seems to hurt one of the principles of the WTO, namely the principle of encouraging development. Looking through the most important literature about the effects of TRIPS Agreement, we could see that the literature emphasizes the impacts either on developing countries as a whole group, or on one or two countries as case studies. It is unambiguous that there is a great gap between advanced and developing regions, as the largest pharmaceutical companies are concentrated in the developed countries (Roth 2010). Furthermore, majority of the R&D activity is in the advanced countries, consequently, they are the main exporters of highly innovated and patented pharmaceuticals, while developing countries can be only importers and users of these products or of their generic versions (Smith et al 2009, WHO 2004).

This study does not investigate the differences between the developed and developing regions, but it tries to reflect that the developing countries are heterogeneous and "their pain" as a consequence of the TRIPS Agreement is different. Consequently, *our objective is to show that when analysing the impact of the TRIPS, we should make differences among the developing countries.* This study's aim is not to offer resolutions for the problem which arise due to the TRIPS Agreement[10], but to show that the developing countries are faced with different problems.

[9] There are several international organizations, programs and NGOs (for instance, the UNAIDS, the WHO, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Medicines Sans Frontiers) which aim to provide the essential medicines to the poor. However, analysing their activity is not the subject of this paper – see, for instance, the studies of Aziz (2009), Brousselle and Champagne (2004) or Triponel (2009).

[10] For detailed solutions and the role of other international institutions and civil societies, see, for instance, Gathii (2007), Sonderholm (2010) and Sun (2004).

4. The different characteristics of the developing countries regarding the TRIPS

For determining and reflecting the different characteristics of the developing countries, the actions of the TRIPS and tools for solving the public health problems may be the basic points. Although the points for the differentiation are based on the effects, consequences and provisions of the TRIPS Agreement, they are even in relation with the development level of the country. We use the following points for differentiation:

- whether there was a patent protection law for pharmaceuticals and what it covered: only processes or products;
- whether there is a company producing generic drugs in the country;
- what kind of epidemics there are in the country;
- possibilities for using parallel importation and compulsory licensing;
- transitional periods for implementing the TRIPS Agreement.

In the following, we detail these points. We try to make strict differences between them, but in some cases there are strong relationships between these points. Consequently, in some cases there will be overlaps between the subsections.

4.1. Existence of patent protection law for pharmaceutical products before the TRIPS

The effects of the TRIPS Agreement are influenced by the fact of whether the country implemented a patent law earlier. The type of patent protection (process or product) also has an influential power. If the process was the only object for patent protection, the country was allowed to produce the same product but with another kind of process (Li 2008, Timmermans–Hutadjulu 2000), therefore the possibility of producing generic drugs was given. On the other hand, the product patent means a higher level of protection as the patent owner holds the exclusive right for production and selling – other companies are allowed to sell only with the permission of the patent holder (Li 2008, Timmermans–Hutadjulu 2000). As a result of the product patent, there are more original medicines on the market, and producers of generic drugs must wait for the expiration of the patent.

In general, most developing countries did not have any kind of patent law in the pharmaceutical sector before the Uruguay Round. If there was even some, pharmaceutical products were excluded or only the process could have been patented[11] (Barton 2004, Chaudhuri et al 2006, Cullet 2003, Lanjouw 1997).

[11] Islam (2009) claims that some developed countries, such as Portugal or Spain, did not have any product patent for pharmaceutical products before the Uruguay Round.

Consequently, three groups of the developing countries can be determined based on the patent law in the country before the TRIPS Agreement:

- countries not having any patent protection for pharmaceuticals;
- countries having patent protection law only for process in the pharmaceutical industry (most developing countries belong here);
- countries ensuring the highest level protection in the pharmaceutical industry with product patent law (e.g. China and Thailand).

The majority of the developing countries belong to the first two groups, however, there are a few states which ensured product patents before the TRIPS Agreement. Analysing the case of India and China, we can see the importance of the patent type as India and China granted protection in a different way.

Although India as a low-income country had had a patent law for products, since 1970 the country has excluded pharmaceutical products from the patent law – only process patents could be obtained for these goods and only for a seven-year period (Barton 2004, Chaudhuri et al 2006, Cullet 2003).[12] As a result of this, the production of generic drugs became important in the country – which, by the way, was a direct aim of this law, beside providing cheap drugs for the inhabitants (Chaundhuri et al 2006, Lanjouw 1997, Temmerman 2008).[13] In the 1970s, multinational companies dominated the Indian pharmaceutical industry; while by 2000 the Indian-owned enterprises became important actors not only on the domestic, but on foreign markets, as well (Chaudhuri et al 2006).[14]

Since the protection in India could be obtained only for production process, drug prices remained at a low level in the country in international comparison (Li 2008, Smith et al 2009). However, since 2005 India has had to comply with the rules of the TRIPS Agreement, and the country is obliged to ensure patents for products. Consequently, the companies producing generic drugs lost their foreign markets, for instance, in the Commonwealth of Independent States, in Africa and also in Europe and America (Kale 2005). As a result of this, decreasing potentials of producing generic drugs in India caused problems not only for the domestic companies, but the country itself lost. As these companies could not enter into foreign markets and sell their products, the Indian government lost a huge amount of income resulting a decreasing level of tax revenues.

On the other hand, China has been providing patents for pharmaceutical goods since the 1993 revision of the earlier 1985 patent law (Li 2008), which shows China as a special country in the developing world. Li (2008) details that the domestic

[12] Ganguli (2003) gives a relatively detailed introduction to the earlier history of patent law in India.
[13] Bangladesh has similar characteristics, and for a deeper analysis, see, for instance, the study of Islam (2009).
[14] Timmerman (2008) claims that in the 1970s the multinational companies' market share reached 70% in India; today it is less than 35%.

pharmaceutical industry was not concentrated before the product patents: there were several small companies with small market shares. As a consequence, they could not spend a lot on research and development. Perhaps this was also a reason to introduce the product patent law in the country. Although this experience helped China adjust to the new WTO-rules, there are still problems in the country. Empirical studies show that access to medicines in China is still a problem, and the effects of the product patent and the following monopoly is unambiguous: prices for the medicines are relatively high in the country (Li 2008). This means a great problem as social differences are large within the country and the rate of people living under poverty line is high (Csanádi et al 2009).

The cases of India and China reflect how important it is whether a country had experiences with patents. Both countries had the aim to help the pharmaceutical sector develop and they seem to be successful in this field. In spite of fact that they had patent laws, the TRIPS-rules affect them differently: China could adjust to the new rules more easily, while India's development process is hindered.

It has to be emphasized that the existence of intellectual property rights does not mean that the country is able to provide protection for intellectual property without any problem, because in many countries there are problems with the enforcement of these rules. Kusumadara (2010) mentions Indonesia as an example: although the country had experience in the field of intellectual property rights, the country faces difficulties in complying with the TRIPS-rules. One of the reasons may be the low level of law development in Indonesia or the different cultural background of the country. Beside Indonesia, China is also criticised because of the low level of IPRs enforcement (Athanasakou 2007).

4.2. The existence of companies producing generic drugs

The existence of generic drug companies has strict linkages with the patent rules. It often arises that patent rules miss some areas and there are no rules on intellectual property rights in order to support the development of a sector – or to obtain goods at a lower price level. In a simple way, many countries are said to have no patent rules or only process patents in order to ensure the establishment of companies producing generic drugs (see, for instance, the case of India). For implementing the TRIPS Agreement, there are differences among countries whether there are generic drug companies in the country and whether they can use compulsory licensing. Consequently, countries can be divided into two main groups:

- countries having companies producing generic drugs;
- countries which do not have these companies
    - but have the physical and human capacity for producing generic drugs;

- and do not have capacities for producing generic drugs either[15].

However, if there was a generic drug producing company in the country, the country unambiguously lost by implementing the TRIPS Agreement. These companies are not allowed to copy the original medicines sparing the R&D costs as they have to wait for the expiration of the patent protection. These cause significant time- and income-loss for the companies, which influence the development process of the country, as well. Consequently, regarding the capacities of producing generic drugs, the TRIPS Agreement influences whether the country can impose compulsory licensing and parallel importation, on one hand, and it jeopardises the existence of companies producing generic drugs, on the other hand.

Among the developing countries, for instance, India, China, Brazil, Thailand and Bangladesh have pharmaceutical companies producing generic drugs. Analysing the differences of the patent laws, we mentioned that India did not have product patents for pharmaceutical goods, and it ensured the development of the generic industry (Barton 2004, Cullet 2003, Gerster 2000, Temmerman 2008, Tulasi–Rao 2008). As a result of the development, nowadays this sector employs more than 500,000 workers (Gerster 2000), India became the main supplier of generic drugs for the poorest countries (Barton 2004, Timmermans 2006), and India was said to be the greatest producer of generic drugs in the world[16] (Chaudhuri et al 2006). Consequently, the TRIPS Agreement does not effect exclusively only the public health and economy of a country, but other countries also may feel the negative consequences due to the mutual interdependence appearing through international trade. However, interdependence can occur with countries outside of the WTO, therefore countries with no WTO-membership can feel the negative impact as well.

4.3. Transition periods

The WTO provided transition periods for implementing the TRIPS Agreement: developing countries obtained a moratorium for adjusting to the new rules. However, the length of the transition period is not the same for all countries: it depends mainly on both the development level of the country and on the earlier patent rules. Advanced countries were obliged to implement the TRIPS Agreement by 1 January 1996, and compared to this date three groups of developing countries appear (Correa 2002, Sonderholm 2010, Sun 2004, Temmerman 2008, WTO 1994):

- The *first group* contains the relatively developed developing countries except the least developed ones. They received an additional four years to comply with the TRIPS-rules. This means that the relatively developed developing countries had to implement them by 1 January 2000, and this transition period is also called *general transition period.*

[15] The least developed countries must belong to this last group.
[16] Recently, India's market share reached 30% on the global generic market (Temmerman 2008).

- The *second group* consists of countries which did not have product patent laws and protected only the processes before the TRIPS Agreement. They received a so-called *special transition period* with an additional 10 years compared to the developed countries: they had to implement the TRIPS rules by 1 January 2005. Countries like India, Egypt, Argentina and Arab countries belong to this group.
- The *third group* contains the least developed countries.[17] At first, they received an additional one year compared to the previous group (deadline: 1 January 2006), but regarding the pharmaceutical products, the deadline could be extended by 10 years, and at the Doha Ministerial Conference (in 2001), the Member States adopted it.[18] Consequently, the least developed countries must implement the TRIPS-rules by 2016.

The transition period gives an important opportunity to the generic drugs producers. Islam (2009) argues in the case of Bangladesh that the country can benefit from the transition period because during this time the country is allowed to produce generic versions of the patented life saving pharmaceuticals. Consequently, the transition period is not only a preferential implementation date, but gives also opportunity for some generic producer countries.

It is important to note that though most developing countries may enjoy a transition period, they have obligations as well in this field. During the transition period, they must ensure the principles of national treatment and most favoured nations for all WTO-members. However, it is not clear how much the transition period can solve the problems of developing countries. Regarding the least developed countries, it is not the national implementation, but the background institutions for the final implementation which mean the greatest problem, because if there is no or only a small level of research and development, the appropriate institutions lack in these countries. To establish these essential serving institutions would be the primary task for the country – but in a poor country, satisfying the basic human needs is also problematic, therefore the government is unable to finance the infrastructure-question.

4.4. Illnesses, epidemics

Regarding illnesses and epidemics, developing countries seem to be the most homogeneous. However, Kremer (2002) explains that the developing countries have to face with different diseases than the developed nations because of poverty and geographic features. Ito and Yagmata (2005) make a distinction between two types of infectious illnesses as follows: one of them affects both the low and high income

[17] Out of the 49 least developed countries (UN 2009), 32 states are members of the WTO.
[18] The reason for it is mainly the public pressure regarding the pricing features of the AIDS medicines (Kremer 2002).

countries, i.e. they are said to be global epidemics (e.g. HIV/AIDS, tuberculosis), while the other affects exclusively the developing countries – they are the so-called neglected illnesses (e.g. malaria). Both types have impact on the developing countries – and they appear when analysing the effects of the TRIPS on public health: beside the WTO documents, researchers analyze these illnesses, as well. The reason for it is that these epidemics belong to national emergencies when compulsory licensing or parallel importation may be used. However, these are not the most important and most serious epidemics in all countries; therefore other pharmaceuticals may be needed.

Pharmaceutical companies do not spend much on the development of pharmaceutical products which are for treating tropical diseases (Opderbeck 2005, Sterckx 2004, Smith et al 2009). According to the WHO (2004), only one-tenth of the R&D expenses is spent on development of medicines for epidemics, which cause 90% of the health damages (it is the so-called "10/90 gap"). This suggests that countries which suffer from epidemics affecting many countries (i.e. illnesses of the first type) are in a much better position. Where there is a rare illness and low-level of purchasing power, pharmaceutical companies do not have the interest to develop medicines these countries really need.

4.5. Using parallel importation and compulsory licensing

Whether parallel importation or compulsory licensing may be used strongly depends on the previous points. Only those countries can impose compulsory licensing which have their own production capacity and are able to produce pharmaceuticals. Among others, South Africa, Thailand, India, Brazil, China and Argentina belong to them, as these countries have relatively developed pharmaceutical capacities (Fink 2006). However, in the previous years, Malaysia, Mozambique and Zambia issued the compulsory licensing to handle the HIV/AIDS crisis (Feldman 2009, Fink 2006). Feldman (2009) argues that high-income developed countries (such as the United States[19] or Germany and Italy) also issued compulsory licenses.[20]

Chien (2003) and Feldman (2009) argue that only a few compulsory licenses were given during the TRIPS-era, because of the fear of decreasing research and innovation. Furthermore, Correa (2004) emphasizes that not general capacity and knowledge is needed, but specialized knowledge is required for producing a certain pharmaceutical product which is needed under compulsory licensing. It makes the situation more complicated. Special skills, knowledge, and experience do have an important role, and if they are missed – even in a country with company producing generic drugs – the needs will not be satisfied. Analysing the heterogeneity of

[19] It happened after the September 2001 terrorist attack. The agreement was between the US government and Bayer German pharmaceutical company to provide access to treatment for anthrax (Feldman 2009).

[20] For more health-related compulsory licensing examples, see: http://www.cptech.org/ip/health/cl/recent-examples.html.

developing countries, these facts have to be taken into consideration. As a result of this, the underdeveloped African countries will be unable to use compulsory licensing because beside the infrastructure, the skilled labour is missing.

As for the parallel importation, the epidemics a county face have a great importance. This point connects to the question of compulsory licensing: at first, the country without any producing capacity but with a huge epidemic has to find a company producing generic drugs which are relevant to the epidemic of the country. Another question is whether the generic drugs would really be cheaper enough for people living on only a few dollars to afford them. For instance, Malaysia and Indonesia could import generic drugs from India to handle the HIV/AIDS epidemic (Feldman 2009).

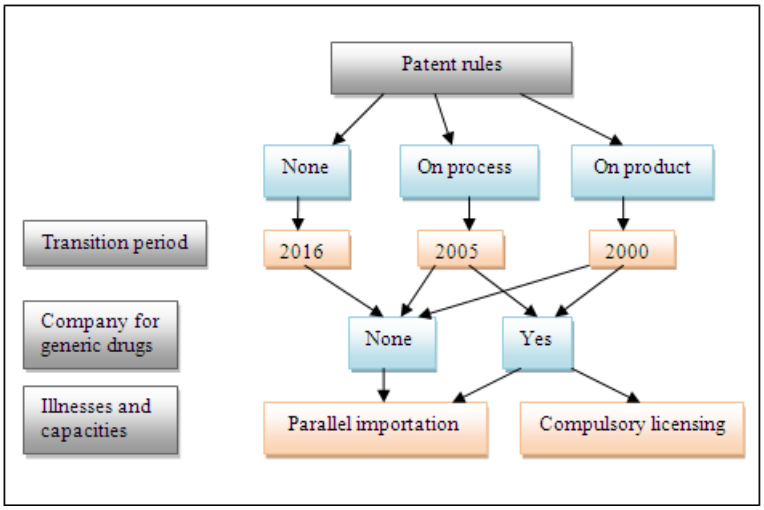
But there is also misuse of compulsory licensing when some developing countries use it as bargaining power as Feldman (2009) points out. As examples, he mentions Thailand and Brazil. The Thai government issued a compulsory license for heart disease medication, or Brazil, instead of accepting the lower prices offered by the pharmaceutical company Merck, issued compulsory licenses on AIDS-drugs. These examples show that several middle-income developing countries issue compulsory licensing, and the developing countries tend to recognize the negotiation potentials of this opportunity.

4.6. Linkages between the different points

Although we investigated the heterogeneity of the developing countries according to these points separately, summarising them we can give a general picture. Looking through the differentiating points, we could see the linkages between them, as well: problems in one field caused problems in other field. Consequently, we can determine in general, how the TRIPS Agreement affected the different developing countries and we can determine the relatively homogeneous country blocks. This may mean a basis for analysing the TRIPS Agreement further.

In principle, the type of the patent law the county had before the TRIPS Agreement influences the effects and consequences of the Agreement in the largest extent (Figure 2). Therefore, we can determine the so called *"countries in a cumulative underprivileged situation"*, where everything is missing: both the patent law and generic drug companies, therefore the possibility for using compulsory licensing is rejected. Consequently, countries where there is no opportunity for producing generic drugs by their own capacities belong to the least developed countries. In these states, providing parallel importation is not enough, as people here cannot purchase the generic drugs, either, and the supplying infrastructure is also in bad circumstances. Although there are some developing countries with productive capacities for generic drugs, it could arise that they cannot produce the required medicines because of the lack special knowledge – so, they need to use parallel importation, as well. This means that illnesses and epidemics also have an influential power.

Figure 2. Linkages between the differentiating points



Source: own construction

The facts mentioned above show that the developing countries – independent from the starting conditions – became losers. However, the starting conditions determine the areas where the damaging effects appear and the extent of the loss, as well. The least developed countries (or countries in cumulative underprivileged situation) must face the greatest loss as no opportunity seems to be there for them for access to essential medicines. On the other hand, the relatively developed developing countries – such as India or Brazil – feel that the TRIPS Agreement hinders their own development. These countries possess their own generic drug producers based on a small research base and are able to supply generic drugs to their domestic markets. Their opportunities decreased after the implementation of the TRIPS Agreement, and the country and economy themselves may suffer from its bad consequences.

It must be emphasized that the problems of the least developed countries cannot be solved by providing them medicines. Should the essential medicines be available in the country to prevent and treat certain epidemics, there would be still unsolved questions remaining because the human and physical infrastructure (hospitals, doctors, roads, equipments, etc.) are missing for using the medicines effectively. To produce generic drugs with compulsory licensing, a suitable system for quality assurance is also required. Analysing the economics of AIDS, Canning (2006) argues that prevention is a better solution than treatment, therefore more assistance should be spent on prevention than, for instance, access to medicines.

In the developed countries – as it was mentioned earlier – there is a relatively low level of research on medicines for diseases which are typical illnesses in developing countries. Because of the unfavourable purchasing power potentials, the

pharmaceutical companies cannot be inspired to continue research in these fields (Fink 2006). The appropriate consequence of this situation would be if researches in the more developed developing countries with pharmaceutical producing capacities were specialized in these diseases. However, if they developed a new drug, would not it be their own interest to patent these products? Would they be more human(itarian)? The situation seems to be a vicious circle where somebody must lose.

5. Conclusions

The World Trade Organization has intervened into the pharmaceutical competition and into the international pharmaceutical markets since the TRIPS Agreement came into effect. Although the multilateral trading system should ensure higher welfare and development in all member countries of the WTO, the TRIPS Agreement has different impact on the members. Beside the pharmaceutical companies, some countries can gain or lose while complying with the obligations of the agreement: the developed countries can follow their own interests, but access to medicines as a human right is hurt in the developing countries.

As the TRIPS Agreement made obligatory and general the overall patenting and protecting intellectual property rights, many countries are faced with several problems. Most of the developing countries could not finance the original pharmaceuticals, since, as yet, the poorest people in these countries cannot afford them. Consequently, the public health situation in the least developed countries seems to become worse. It is not only a health and ethical problem: as the lack access to medicines has negative economic effects, as well, so the TRIPS Agreement is opposite to the WTO-principle of economic development.

This study argues that the losses of the developing countries are not the same. Somewhere public health is the greatest loser, because complying with the TRIPS-rules, the country cannot afford and finance the essential medicines. However, there are countries with companies producing and selling generic drugs: they have losses because of the minimal length of the patent protection. Furthermore, when there was a patent law in a country, it could comply with the new rules more easily. On the other hand, countries which did not provide any patent protection at national level before the TRIPS Agreement are faced with huge costs of building the appropriate human and physical infrastructure for providing the provisions of the TRIPS. This means a great resource loss for the least developed countries from other areas, therefore the TRIPS Agreement eventually influences their own development possibilities. In addition, their public health problems still remain. This study also reflected that the TRIPS Agreement does have effects on the access to medicines, and although poverty may be one reason, the situation is worsened by this binding agreement. Not only the access to medicines is hindered, but some countries may

lose, as well, because the important generic drug companies have to stay in the background.

Consequently, if we try to analyze (especially with empirical methods) and handle the negative effects of the TRIPS Agreement, it is important to make differences between the developing countries – it is not worth using the same approach for India and Chad. Distinguishing the developing countries is not sufficient according to their income level (e.g. GDP per capita), and the factors analysed in this study (e.g. type of patent law, their own capacity for pharmaceutical production, illnesses) need to be also considered. Whether the solutions of this problem start either from the supply side (developed countries, international organizations, aid organizations), or from the demand side (developing countries), we have to take them into consideration.

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