TRIPS Agreement’s Impact on the Accessibility of Pharmaceuticals in the Developing Countries: Developed Game-Theoretic Model.

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Abstract

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Problem: The problem under consideration is the World Trade Organization’s (WTO) agreement called Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its impact on equal access to essential drugs in the least developed countries. Especially the countries of sub-Saharan Africa lack such access. Moreover, these countries are the ones where severe diseases like AIDS/HIV, tuberculosis and malaria are widely spread over the population. The authors focus also on patents and their obligatory length imposed through the articles of TRIPS agreement.

Purpose: The purpose of the thesis is to describe and analyse the impact of global trade regulations (TRIPS in particular) on the accessibility of essential drugs in developing countries, and to come up with a possible solution as the way of coping with the problem is concerned. The investigation includes detailed description of solutions accomplished by Brazil and India, and their importance for the least developed countries, in terms of importing generic pharmaceuticals from these.

Method: Qualitative method was used in order to obtain data from interviews with citizens of Botswana, Ghana, Ethiopia and South Africa for better understanding of the situation in these countries. Furthermore, the theories included in the theoretical background of this paper were gathered through deep research in the field of studies regarding Intellectual Property protection and World Trade Organization’s agreements and other legal acts.

Results: The result of the analysis is a model developed from the Game-Theoretic Model, and called Developed Game-Theoretic Model. It is a tool which the least developed countries can use while negotiating prices of medicines with pharmaceutical companies, having the possibility of importing the pharmaceuticals from other countries manufacturing the patented product under compulsory licensing.
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“Look to your health; and if you have it, praise God and value it next to conscience; for health is the second blessing that we mortals are capable of; a blessing money can’t buy.”
Izaak Walton (1593 - 1683)

1. Introduction

World Trade Organization (WTO) members have been trying to solve the problem of access to essential drugs in developing countries for many years. Nowadays one-third of the world’s population lacks access to the drugs that satisfy the health need of the majority of people in Africa and Asia\(^1\). The problem is that the most dangerous illnesses in the world such as HIV/AIDS, malaria and tuberculosis are widely spread across the developing countries. At the same time, the overwhelming majority of local population of the least developed countries lives in poverty and cannot afford expensive medicines. There are many causes of the lack of availability of essential drugs such as logistical supply and storage problems, insufficient production. However, the main cause is globalization and international regulation of trade. WTO obliged its member states to protect one’s patents for a minimum term of 20 years. That was stated in Trade-Related Aspects of Intellectual Property (TRIPS), the main international agreement on protection of Intellectual Property (IP). Consequently, the production of cheap analogues of the existing medicines is significantly limited. TRIPS agreement also includes the thorough description of so-called compulsory licensing which is a traditional limitation of patent monopolies.

The paper describes the fact of human right to health and the access to essential medicines in the developing countries. The cases of Brazil and India are given as examples of the developing countries which found ways to supply the domestic markets with antiretroviral drugs, or even export them to these less developed countries which are not capable of domestic production.

\(^1\) Elliott, W. S., 2006
1.1 Problem Discussion

The problem of this paper is the World Trade Organization’s (WTO) agreement called Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its impact on equal access to essential drugs in the least developed countries. Mainly the countries of sub-Saharan Africa lack the access, and the same ones are strongly affected by the severe diseases like AIDS/HIV, tuberculosis and malaria. The unequal access is strappingly affected, if not caused, by legal acts of WTO.

TRIPS agreement affects the access to essential drugs by increasing the length of patent protection (which possibly generates higher prices of pharmaceuticals), which in turn leads to an increase in the gap between developed and developing countries by removing a source of generic drugs. Governments and various global organizations have been trying to solve this problem by compulsory licensing, parallel trading and other methods. Thus new global approaches are needed in order to help developing countries. Compulsory licensing was invented in order to provide the balance between society interests and patent holders and to prevent the situation when society’s needs are not fulfilled because of the limitations from patent holder’s side. TRIPS is a mandatory agreement for all WTO members, which protects their medicines but at the same time sets some norms of compulsory licensing.

The status quo between patents and compulsory licensing that we can see now does not meet the need of developing countries which may not be able to import expensive drugs manufactured by patent holders (or by licensed manufacturers). The threats of global epidemics (including AIDS), which come from these countries, led the developed countries to the thought about the necessity to limit the market authority of pharmaceutical giants based on the patents by compulsory licensing for the delivery of vitally important medicines into these countries. The corresponding recommendations (about the possibility of forced licensing for export purposes) were developed within the WTO framework, which was the essential innovation of TRIPS, that forbade compulsory licensing otherwise as for purposes of saturation of the domestic market.

1.2 Problem Statement

The problem of this thesis is the impact of the TRIPS agreement on the accessibility of essential drugs in the least developed countries.
1.3 Purpose

The purpose of the thesis is to describe and analyse the impact of the global trade regulations (TRIPS in particular) on the accessibility of essential drugs in developing countries, and to come up with a possible solution as the way of coping with the problem is concerned. The investigation includes detailed description of solutions accomplished by Brazil and India, and their importance for the least developed countries, in terms of importing generic pharmaceuticals from these.

1.4 Delimitations

The authors decided to delimitate their study to two major manufacturing countries: Brazil and India. The cases of these were and are extensively discussed in accordance to their solutions to domestic supply of medicines. Moreover, authors interviewed nationals of four developing countries: Ethiopia, Botswana, South Africa and Ghana. The information obtained through these interviews is used to highlight the situation of access to medicines in those countries. Furthermore, the information is of major importance and significance to the statistics about accessibility of essential drugs in poor and developing countries in general.
2. Methodology

In this part we will discuss the methods used while writing the thesis, explain the choice of topic, describe the process of interviews carried out, and discuss the reliability and credibility of the work as a whole.

2.1 Introduction

This bachelor thesis is written by a group of three students of Mälardalens University, Västerås, Sweden. All of the students knew each other personally and have consciously chosen to form a group of three to avoid the obligation of joining unknown people. Two of the group members have the experience of working together, and the last one knows the others’ methods of work from observation on previously completed courses.

In this section we are going to outline our work on this project. First we are going to explain the choice of the topic for research and its type. Secondly we will go through the reasons of choosing this particular type of research and the data that is required for the study. Thirdly our methods of data collection and analysis will be described. Finally we will discuss the reliability of research and critical points will be stressed.

2.2 Choice of Topic

The topic of this thesis is an outcome of long debates between the authors. As all of us are educated in different levels in various fields of business study, we needed to come up with an idea which would not only reflect the common knowledge of ours, but also be interesting and useful for the third persons. Our prime interest was concerning obstacles encountered by pharmaceutical companies during the process of internationalization their products or the companies themselves. The topic was too broad though. Instructed by the tutor, we searched for a captivating way of narrowing the issue of interest. On the 29th of March 2008, while searching the Internet for resolutions, one of the group members came across the
article “Access to Essential Drugs in Poor Countries: A Lost Battle?”\textsuperscript{2} This article was later followed by more findings.

\section*{2.3 Type of Research}

As we needed to get a broad range of information about our subject, we decided to use qualitative approach. As this kind of study is intended to discover and analyse the behaviour or perceptions which drive the target audience in terms of specific topics and issues\textsuperscript{3}. The research depends on opinions and beliefs (about ‘Who’, ‘How’, ‘What’, ‘When’, etc.) of the small sample groups of the target market than the statistical data (it does not answer the question ‘How many’ or ‘How much’), and the results of such research are descriptive rather than predictive. It enables understanding, explanation and interpretation of empirical data and allows researchers to form hypotheses and productive ideas. It originates from social and behavioural sciences: sociology, psychology and anthropology, and is used nowadays also in marketing and management fields of study. Those are the exact questions that our research is meant to answer. In order to conduct our qualitative research we needed to gather the qualitative data.

Qualitative data usually consists of in-depth interviews, direct observations, written documents\textsuperscript{4}. Interviews can include one-on-one interviews as well as group interviews. The answers are usually written down or recorded in order to use it later. Written documents usually include books, web site, articles, magazines and etc. The answers for the interviews gave us our primary data while written documents were used as a secondary data in our research.

\section*{2.4 Primary data}

We decided that we will need primary data in our research. The research supplies the paper with information about the access to pharmaceuticals in developing countries though the eyes of their citizens. In order to obtain that we have conducted a series of interviews. Interviews consisted of both open-end and close-end questions. Most of the interviews were

\begin{thebibliography}{9}
\bibitem{2} Pécoul et al, 1999
\end{thebibliography}
conducted on individual basis. For the rest of the people who agreed to participate in our project but, for different reasons, could not meet us in person, we have created special questionnaire that was later sent by email. One of the in-depth interviews was a group one. That helped us to get way more information than we could get from all three respondents separately because they were able to argue and complete each other’s thoughts. The questions were aimed at gathering the quantitative data, which allowed us to achieve the main attributes of a group interview in this particular situation:

- “Synergy among respondents, as they build on each other’s comments and ideas,
- The dynamic nature of the interview or group discussion process, which engages respondents more actively than is possible in more structured survey.
- The opportunity to probe ("Help me understand why you feel that way") enabling the researcher to reach beyond initial responses and rationales.
- The opportunity to observe, record and interpret non-verbal communication (i.e., body language, voice intonation) as part of a respondent’s feedback, which is valuable during interviews or discussions, and during analysis.
- The opportunity to engage respondents in "play" such as projective techniques and exercises, overcoming the self-consciousness that can inhibit spontaneous reactions and comments”

All of our interviewees are representatives of the developing world countries, in particular from Ghana, RSA, Botswana and Ethiopia. The final number of respondents was 15 people. Most of them were student from Mälardalens University, Västerås, Sweden. The rest, namely two, were citizens of Botswana, whom we contacted through e-mail.

We presented our findings in two different ways. Even though charts are mostly used for quantitative result representation, we realized that charts could be perfectly used for our “closed-end section” results. Bars on the chart are good way to show the overall tendency in our case. The answers to these questions gave us the general information about the existence of the problem under investigation, and are presented in a form of the already mentioned charts. The answers for the open-end questions were analyzed, interpreted and presented as a summary.

5 http://www.qrca.org/displaycommon.cfm?an=1&subarticlenbr=6
We have also tried to collect primary data from the pharmaceutical companies. In order to do that we decided to use questionnaires which were sent by e-mail. Prior to the sending of actual questionnaires, we wrote emails to the corporate addresses and asked for contact information of a person who is able to answer our questions. Only minor fraction of our requests was fulfilled. Unfortunately, when the actual questionnaires were sent, we have received several, almost identical, responses which stated that the kind of information we asked for is confidential and there is nothing they can help us with. That is why we decided to rely solely on the interviews with people from African countries as our primary data.

2.5 Secondary Data

As stated above, we have used one article as our starting point in a search of our secondary data. The subsequent sources were mainly found in the reference section of that article and the new articles were checked for the appropriate literature again. We searched for the most recent information and, sometimes, preferred more recent article to interesting one if the content was more or less the same. The reason for that was the rapid change in the situation in the modern world. The main database for our search was ELIN@malardalen⁶ and the main search engine was Google⁷. References were also used as a direction to official sources in order to make our research more reliable.

We have also used several books from Mälardalens University library. Some of them were obtained directly in Västerås and some had to be ordered from Eskilstuna.

2.6 Reliability and Validity

In our research we used various types of sources. Articles were mainly chosen from well known publishing houses and we tried to check if the authors were professionals in their field. We found out that a number of sources are used in the majority of publications on our subject, so they are considered to be reliable. The data taken directly from official international organizations is reliable by definition.

⁶ http://elin.lub.lu.se/elin?func=loadTempl&templ=home&lang=en
⁷ www.google.com
The justification of the choice of the target group of respondents to our questions and questionnaires lies in our opinion, that the representatives of the four chosen countries may have the best knowledge about the situation in these countries. Although we are aware of the fact, that the interviewees are not experts in the field of pharmaceuticals or medicine, and that due to usually considerable time spent overseas (in Sweden) the opinions of theirs can base on past memories, they may be the ones who observed and still may be in touch with the current situation (via constant contact with their families back home, newspapers, magazines, TV, and other media) in their countries. Thus, the opinions of our respondents we consider as important, interesting and useful for the specific part of the paper. We also validate the received answers by the fact that none of the received opinions was contradiction the data found through other research method (the official data from World Trade Organization’s and World Health Organization’s web pages).

The research is valid as long as TRIPS agreement exists and the situation in the countries under study remains the same.

2.7 Criticism

Even though qualitative method does not require the amount of respondents to be large, we still think that our approach can be criticized because of the small number of interviewees. Moreover, most of our respondents are currently living in Sweden and, thus, might possibly have different perspectives on situations comparing to people who reside in African countries. The data collected from the interviews may include personal opinions and observations not typical for the whole of the population. We are aware of the facts that contacting national health authorities might have provided us with a more reliable data, but the limitations of time for completing the thesis restricted us from doing so. Moreover, as we approached a report ‘HIV-AIDS in Ghana; Background, Projections, Interventions and Policy’\(^8\), we found numerous data not matching the one gathered from World Trade Organization’s reports. Due to this lack of correspondence we chose WTO’s data over the national one. Nevertheless, the data collected and the survey conducted allowed us to reach our intended goals and base our careful research, analysis and conclusion on it.

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\(^8\) Ministry of Health of Ghana, 2001
In this part of the thesis we will widely discuss the essence of patents, their history and evolution. Furthermore, we present the significant Articles of the TRIPS agreement and the conditions of patentability of pharmaceuticals in selected parts of the World.

3.1 What Is a Patent?

We find it useful to introduce the reader to most important terms which will be used throughout the paper. Stating with detailed description of what a patent is and how its existence affects the pharmaceutical market, we will move further to the brief description of the history of patents and the Trade-Related aspects of Intellectual Property Rights (TRIPS) agreement.

Patent (contraction of 'letters patent', Latin litterae patentes) is a legal document granted by state or government of exclusive rights for a specific period in respect of an invention. However, the patent holder, referred to as a ‘patentee’, by the document itself is not sanctioned to practice the invention\(^9\). This is especially important in the pharmaceutical industry, where a separate permission from the responsible health authority is demanded to market the invented drug. The essence of patenting the yet non-marketable pharmaceutics is preventing others to practice this invention. The rights guaranteed by the document apply to limited territory of the state granting the patent. Thus, a patentee striving for protection in several countries has to obtain separate patents in each of the countries. The document and the exclusive rights guaranteed through it is for a patentee an intangible property, which they can freely manage. That includes the rights to keep it, assign the patent to someone else, grant someone a licence to do something coveted by this patent, mortgage it (use it as security for a loan) or abandon it to the public\(^10\). The last case was and is very common in specific countries, where an annual renewal fee has to be paid in order to keep the patent in

\(^9\) Grubb, P., p. 4
\(^10\) Grubb, P., p. 6
force. In some countries or regions it is usual that the fee increases with the age of the patent. Thus, it is natural that only the patents of real commercial importance are kept alive for all the protective period.

Patents in Britain used to be granted for 14 years, which was changed in 1919 to 16 years. In the US and Canada the case was 17 years from the date of grant. This meant that the longer time it took the Patent Office to grant the patent, the later was the expiry date. The term of 20 years from the filing date was set in Europe by the European Patent Convention in 1978. This later became an international standard set by the General Agreement of Tariffs and Trade (GATT), a treaty set for reduction of tariff barriers, subsidies on trade and quantitative restrictions. The TRIPS (the history of which will be described in the next section) guarantees 20 years of intellectual property rights from the filing date. The difference of counting the protective rights period from the grant day or filing the documents is important for some industries. So is the possibility of prolonging the patent. For innovations which can be rapidly marketed or when the threat of the innovation can be replaced by a newer solution the patentee is more interested in being immediately (from the filing date) granted the protective rights than in prolonging the patent. On the other hand, on the pharmaceutical market, where it takes many years from inventing the drug, obtaining the patent, approval from health authorities and marketing the product, it is vital for a patentee to be granted with as long protective period as it is possible. It is now possible to extend the standard patent duration in the USA, Europe and Japan.

3.2 History and Evolution of Intellectual Property Right Protection

The Paris Convention

On March 20, 1883, in Paris the International Convention for the Protection of Industrial Property was signed by eleven countries: Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, El Salvador, Serbia, Spain and Switzerland. The treaty was revised and improved several times, in Belgium (Brussels, December 14, 1900), United States (Washington, June 2, 1911), the Netherlands (The Hague, November 6, 1925), United

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11 Grubb, P., p. 7
12 Grubb, P., p. 7
13 Grubb, P., p. 25
Kingdom (London, June 2, 1934), Portugal (Lisbon, October 31, 1958) and Sweden (Stockholm, July 14, 1967) and was finally amended on September 28, 1979\textsuperscript{14}. The Convention is now adherent to by 172 countries\textsuperscript{15} from all around the world. It is an important and one of the first treats on intellectual property regulations. The treaty established the ‘Convention priority right’, also called ‘Paris Convention priority right’ or ‘Union priority right’, which stated that applicants from one member country is able to use the first filing date of patent application documents in one contracting state as applicable filing date in any other member country. This works only when another application in other country or countries is filled within 6 (for industrial designs and trademarks) and 12 months (for patents and utility models) from the first filing date\textsuperscript{16}.

**The European Patent Convention**

In 1963 a number of European countries signed in Strasbourg a Convention recommending common standards for patentable novelty, inventiveness and inventions. The result was forming the European Patent Convention (EPC) of 1973, which lead to the establishment of the European Patent Organization. The organization consists of European Patent Office (EPO) granting European Patents, and the Administrative Council supervising The EPO\textsuperscript{17}. The most important issue resulting from the establishment of EPO is that its existence provides a law for the grant of patents in any of the member states through a single application assigned by EPO in Munich. The European patent is like a ‘bundle of national patents’\textsuperscript{18} of the countries chosen by the applicants. The result of EPO is that in some countries, like the Netherlands, the existence of the national Patent Offices was threatened. The Dutch Patent Office used to have one of the most expensive and strict regulations about patents’ examination\textsuperscript{19}. The Dutch innovators preferred to apply for their patents in EPO rather than in the national one. As a result of the decline of applications number, the reductions in the number of employee lead to the situations when there was not enough examiners in all


\textsuperscript{15} [http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2](http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2)

\textsuperscript{16} Grubb, P., p. 26

\textsuperscript{17} Grubb, P., p. 27

\textsuperscript{18} Grubb, P., p. 28

\textsuperscript{19} Grubb, P., p. 29
technical fields, and from one of the world’s strictest examination systems the Dutch changed to almost no substantive examination.

**WTO and TRIPS**

The General Agreement for Tariffs and Trade (GATT) gathered in 1948 to discuss and find solutions to trade issues. The latest round, known as the Uruguay Round, began in 1986 and was concluded eight years later, in April 1994. It resulted in the establishment of World Trade Organization. The organization, operational since 1 January 1995, was designed to supervise and liberalize international trade. One of the core parts of the Final Act of the Uruguay Round, which all the members of WTO must accept, was the agreement on Trade Related Aspects of Intellectual Property Rights. It concerns the various intellectual property issues, like trademarks, industrial designs, geographical indication, integrated circuits, copyrights, trade secrets protection and of course patents. It also covers the core principles, enforcement and dispute resolution. The provisions relating specifically to Patents are presented in the table below included in Appendix 1.

Summarizing the most important implications of the article, TRIPS demands:

1. Patents to be available under essentially the same criteria of patentability as in the EPC for all fields of technology, including product patents for pharmaceuticals (Article 27),
2. Patent rights to be without discrimination as to whether the products are locally made or imported (Article 27),
3. Provisions defining what constitutes infringement: this includes importation of a patented product (Article 28.1(a)) and using, selling or importing the direct product of a patented process (Article 28.1(b)),
4. Compulsory licences to be allowed only under strict conditions (Article 31),
5. There must be an opportunity for judicial review of any decision to revoke a patent (Article 32),
6. Patent term to be at least 20 years from filing date (Article 33). According to the transitional provisions this should also apply to patents which are already granted.
7. Reversal of onus of proof for process patents (Article 34).\textsuperscript{20}

In 2001, between November 9 and 13, the Fourth Ministerial Conference of the World Trade Organization was held in Doha, Qatar. The main topic discussed at the conference was the issuance of compulsory licensing by WTO Member states in order to ensure better access to medicines under patents in developing countries. According to the Declaration, the least developed countries are not forced to grant patents on pharmaceuticals until 1 January 2016\textsuperscript{21}.

We find it useful to define the terms ‘developing countries’ and ‘the least developed countries’. World Trade Organization groups developing countries (the majority of the WTO Member states) as the developing and least developed ones\textsuperscript{22}. The list of countries classified in both groups is presented in Appendix 5.

Developing countries are those, which by and large ‘lack a high degree of industrialization, infrastructure, and other capital investment, sophisticated technology, widespread literacy, and advanced living standards among their populations as a whole’\textsuperscript{23}. They are usually in a process of change aimed at growth in terms of economy (engrossing more efficient use of natural and human resources) and increase of production, per capita income and consumption. The process of change leads to transformation in the economic, political and social structures of these countries\textsuperscript{24}. Moreover, World Bank defines the countries in terms of 2000 gross national income per capita the following way:

- Low-income - US$755 or less,
- Lower-middle income - from US$756 to US$2,995,
- Upper-middle income - US$2,996 to US$9,265\textsuperscript{25}.

The least developed countries are the world’s poorest countries, usually identified by three criteria. The first one is the low-income criterion, based on a three-year average estimate of the gross national income per capita (under $750 for inclusion, above $900 for graduation).

\textsuperscript{20} Grubb, P., pp. 33-34
\textsuperscript{21} Doha Declaration, paragraph 7, see Appendix 1
\textsuperscript{22} http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm
\textsuperscript{23} http://usinfo.state.gov/products/pubs/trade/glossrl.htm
\textsuperscript{24} http://www.biology-online.org/dictionary/Developing_countries
\textsuperscript{25} http://www.people.hbs.edu/besty/projfinportal/glossary.htm
The second is the so-called human resource weakness criterion, involving indicators of nutrition, health, education and adult literacy. The final is the economic vulnerability criterion, supported by indicators of instability of agricultural production and exports of goods and services, the economic importance of non-traditional activities, merchandise export concentration, and the handicap of economic smallness 26.

3.3 Benefits and Threats of Patents

In this section we are going to discuss different arguments on both pros and cons of intellectual property protection.

In the case of assets being easy to duplicate, intellectual property rights are considered to bring benefits. The reverse engineering of drugs is quite a simple procedure. So patents are especially valuable for pharmaceutical industry. The lack of intellectual property rights can lead to excessive use of new knowledge, which in turn can lead to minimization of the economic value of an innovation and decrease in motivation for other parties to improve the knowledge 27. Therefore intellectual property rights eliminate the incentives for free-riders.

An individual who created something new can feel secure about collecting and appropriate amount of money for his invention when holding a patent. And, thus, is motivated for further research. This also holds for pharmaceutical companies who are encouraged who invest in research and development when holding patents.

However, patents can also limit the availability of drugs for people from third world. The reason is that cross-learning is hardly possible for other firms when one is holding a patent. All the companies have to start from the scratch and that slows down the progress and technology. “Patents produce a loss or ‘dead-weight burden’ in so far as the benefits of the new knowledge to society would have been greater in the absence of a patent regime, and thus reduce the capacity for other firms to exploit the knowledge on a competitive basis.” 28 The direct investments can decrease because of the export of finished goods instead of

26 http://www.nationsonline.org/oneworld/least_developed_countries.htm
27 Cohen, J. C. p. 30
28 Cohen, J. C. p. 32
transferring technology and production is highly concentrated in developed countries. TRIPS agreement gives the possibility for companies to maximize their profits by price discrimination.

Nevertheless patents are considered to be vitally important for pharmaceutical industry; there still exist some significant arguments against them. “Entrenched patent monopolist has weaker incentives then a ‘would-be’ entry firm to initiate and research and development program that would produce substitutes, even superior quality ones, than for goods, which were already profit-generating. This, in turn, results in sub-optimal outcomes for social welfare.”

3.4 Patents and Pharmaceuticals

Sumana Chatterjee gives arguments in favour and against patents in pharmaceutical market, and these are presented in the following table.

<table>
<thead>
<tr>
<th>Arguments in favour of patents</th>
<th>Arguments against patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granting patents stimulates investment for research and innovation because economically meaningful knowledge is expensive to generate. In absence of proper patent protection; the innovator’s ability to recover R&amp;D costs is limited. A delay in imitation through patent protection would stimulate R&amp;D for innovation. An empirical study by Mansfield, and Taylor and Silbertson shows that in comparison to other industries like motor vehicles etc, in absence of patent protection, investment in R&amp;D would be very less in the pharmaceutical industry.</td>
<td>Patent holders can prevent others from using the innovations which may have a negative impact on further technological development in areas like medicine, software, and information technology where innovation is a cumulative and collaborative effort. The evidence received by the Royal Society indicates that ‘patenting hardly delays publication significantly, but it can encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science.’</td>
</tr>
<tr>
<td>Patent protection becomes important for the pharmaceutical industry because a. The cost of developing new drug is high, b. The cost of developing processes for manufacturing a new drug is low.</td>
<td>Patent rights which exclude others from producing and marketing it leads to inhibition of competition and hence high prices. (Affordability Vs Accessibility)</td>
</tr>
</tbody>
</table>

29 Cohen, J. C. p.32.  
30 Chatterjee, S., 2007, pp. 2-3  
31 Mansfield, E., 1986  
32 Taylor and Silbertson, 1973  
33 Royal Society, 2003, p. V
After the Uruguay round of the General Agreement on Tariffs and Trade (GATT) members decided to make several developing countries improve their patent law system. GATT gave a great possibility to pharmaceutical companies to protect the inventions with patents. The problem was that many developing countries hardly ever respected patent protection and after accepting GATT all WTO members are obliged to review their laws and make them US or EU alike.

Due to public’s awareness of HIV/AIDS problem, there were many questions raised on GATT, especially on its intellectual property part – TRIPS. The high price of patented drugs to treat these diseases leads to hot discussions in developing countries. Some countries even rejected the necessity to accept TRIPS and some hardly accepted it.

The unwillingness to accept TRIPS and change the law system is costly and unpredictable and can lead to interference for private sector involvement in drug R&D and concerns about intellectual property system in general.

The discussions lead to two extreme points of view which make a possibility of reaching an agreement suitable for both parties very low. The first group suggests making intellectual property laws the same for all countries at the level the developed countries have right now. The second group suggested exactly opposite solution. Due to the higher prices of patented drugs they claim that the first solution is unacceptable and insist on compulsory licensing or even removing patents for pharmaceuticals at all.

Provision of inventors with intellectual property rights raised the question about the importance of two very important public health goals – access to essential drugs all over the world from one side and motivation to create something new from the other one. Higher prices on drugs, as the consequence of implementing patents, give a way to finance R&D of new drugs but at the same time decrease the amount of people able to afford them.

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34 Chatterjee, S., 2007
Due to the existence of country specific diseases (some are common for developing countries but very rare in developed world), pharmaceutical companies claim that patent rights can bring nothing but good to dealing with this issue. The logic behind this argument is that excessive returns, which companies get exercising monopolistic power, are good motivation for these companies to invest in manufacturing products required by people from the Third World.

As one can see there exist two different types of drug market. This implies that there are, so called, “global disease” and diseases specific for developing countries. It might seem right to implement patent protection for country specific drugs because of the reason stated above. However it is not so obvious in the case of global diseases for which the drugs have been already created and R&D has been made.

Different countries deal with a tradeoff between patents and accessibility of drugs in many different ways. The longer protection, the more motivation there is to invest in research. At the same time people have to wait longer for competitors to enter this market and offer lower prices.

Countries do also understand that patent protection has to differ across different types of inventions. Pharmaceutical and agricultural related innovations usually have very restricted protection due to their importance. Even though food and drug prices are politically sensitive, pharmaceutical protection was slowly implemented in the developed world. The following table represents the development level on adoption of pharmaceutical product patents.

<table>
<thead>
<tr>
<th>Panel A: OECD Adopters</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Year of Adoption</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
</tr>
<tr>
<td>Japan</td>
<td>1976</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1977</td>
</tr>
<tr>
<td>Italy</td>
<td>1978</td>
</tr>
<tr>
<td>Holland</td>
<td>1978</td>
</tr>
<tr>
<td>Sweden</td>
<td>1978</td>
</tr>
<tr>
<td>Canada</td>
<td>1983</td>
</tr>
<tr>
<td>Denmark</td>
<td>1983</td>
</tr>
</tbody>
</table>

### Panel A: Early Adopters

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>GDP per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>1987</td>
<td>39,000</td>
</tr>
<tr>
<td>Spain</td>
<td>1992</td>
<td>33,700</td>
</tr>
<tr>
<td>Portugal</td>
<td>1992</td>
<td>21,800</td>
</tr>
<tr>
<td>Greece</td>
<td>1992</td>
<td>30,500</td>
</tr>
<tr>
<td>Norway</td>
<td>1992</td>
<td>55,600</td>
</tr>
</tbody>
</table>

### Panel B: Recent Adopters

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>GDP per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>1992/3</td>
<td>5,300</td>
</tr>
<tr>
<td>Brazil</td>
<td>1996</td>
<td>9,700</td>
</tr>
<tr>
<td>Argentina</td>
<td>2000</td>
<td>13,000</td>
</tr>
<tr>
<td>Uruguay</td>
<td>2001</td>
<td>10,700</td>
</tr>
<tr>
<td>Guatemala</td>
<td>Future()</td>
<td>5,400</td>
</tr>
<tr>
<td>Egypt</td>
<td>Future()</td>
<td>5,400</td>
</tr>
<tr>
<td>Pakistan</td>
<td>Future</td>
<td>2,600</td>
</tr>
<tr>
<td>India</td>
<td>Future#</td>
<td>2,700</td>
</tr>
<tr>
<td>Malawi</td>
<td>Future</td>
<td>8,000</td>
</tr>
</tbody>
</table>

**Notes:**

‡ China GDP is for 1992. For countries adopting after 1999 the GDP per capita figure is for 1999.

\(\) The Guatemalan government in April 2003 to consent to a TRIPS-plus standard of 5 years of exclusivity on pharmaceutical test data.\(36\)

\(\) Egypt signed the TRIPS Agreement in 1995, therefore pharmaceutical and food products could be filed as “mailbox” applications during the transitional period ending on January 1, 2005.\(37\).

\# In December 2004 the Indian Congress-led UPA government issued a presidential ordinance to bring the country into mandatory compliance with TRIPS by January 1, 2005.\(38\).


**Table 2 Development Level on Adoption of Pharmaceutical Products Patents**

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36 Health Gap, Global Access Project, 2003  
39 Jean O., Lanjouw, W., p. 3.
4. Theoretical Framework

This chapter of the paper concerns the theoretical background for the study. We start from introduction of social responsibility. Further on, we move to detailed descriptions of the original solutions of the problem of accessibility of pharmaceuticals in Brazil and India. The case of Brazil includes the description and explanation of Game-Theoretic Model.

4.1 Three Perspectives and Social Responsibility

The TRIPS agreement is viewed differently from the perspective of the developing countries and the industrial ones. The countries of the second type consider TRIPS as a positive tool which can be used in favour of the developing economies. It is claimed that high IPR protection can help in strengthening developing economies. First, the existence and respect of monopoly rights of the patent holders would and should encourage local innovations. From the pharmaceutical industry’s point of view, the restrictions in copying the protected innovations and probable high prices of the innovative medicines would encourage the local pharmaceutical companies to carry out their own innovations. Second, if any of the developing countries is not able to carry out their own R&D in the pharmaceutical field, the enterprises holding the patent rights on products and technologies would be more willing to transfer these innovations to a country respecting the TRIPS agreement’s regulations. On the other hand, a country violating the regulations will not encourage the enterprises to carry out any operations in the country, because of the threat of the products and technologies being directly copied and possible profits significantly cut down. Third, if the transfer of technologies is not possible in some developing countries, an innovative enterprise can increase the level of their foreign direct investment (FDI) in the countries respecting WTO’s regulations about IPR. The FDI in this particular situation would not only make the medicines accessible, cheaper (local production of pharmaceuticals with the use of the already existing equipment and cheaper labour forces in comparison to these from the US or any European country), but also could create the growth of local economy visualised in the higher GDP deflators. It can be concluded from the above statements, that from the point of view of the

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40 Abbott, F. M., 1998
industrial economies the TRIPS agreement can be a pushing factor of development of local innovation or developed countries’ FDI in the developing countries.

According to Srinivasan\(^{41}\) three major perspectives on intellectual property right (IPR) protection exist in recent papers. The first one is the ‘natural rights’ view, supporters of which claim that each creative act is actually an extension of the identity of an individual, thus should be controlled by its creator. They also claim that IPR should not only rarely or never be finessed by any other values, including social necessity or economic efficiency, but also the rights of control over the innovation should never be taken away by others (including the state) or sold\(^{42}\).

The second perspective, called the ‘communitarian rights’ view, states that only the fundamental creative acts are actually individual, other ones are just ‘one step in a historical continuum’ and cannot be attributed to a specific person\(^{43}\). The monopoly rights over the innovation in this situation should not be granted to a person or an organization thus ought to be commonly accessible. As pharmacological innovations are concerned, the products and technologies should be available for anybody, especially in the situations of economical or societal needs for them occur.

Finally, the view which is widely spread over most Western IPR protection regimes (and TRIPS is based on these) is the utilitarian perspective. According to the supporters of that perspective, ‘the benefit from the positive incentive for creative activity by the grant of temporary monopoly rights through patents and copyrights has to be balanced against the negative aspect of any monopoly, viz. monopolists will charge a higher price for their product compared to competitive producers’\(^{44}\).

David Resnik claims that pharmaceutical companies have a moral obligation to develop drugs affordable and accessible for developing countries\(^{45}\). He states that although there is a popular argument that some private businesses operate ‘outside the bounds of morality and barely within scope of the law’\(^{46}\), and that most of them are only interested in generating

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\(^{41}\) Srinivasan, T. N., 2000
\(^{42}\) Cohen, L. R. and Noll, R.G., 2000
\(^{43}\) Cohen, L. R. and Noll, R.G., 2000, p. 2
\(^{44}\) Srinivasan, 2000, p. 2
\(^{45}\) Resnik, D., 2001
\(^{46}\) Resnik, D., 2001, p. 17
profits, all businesses are ‘shaped by and depend upon social values, such as honesty, integrity, fidelity, diligence, and fairness’. The reasons for social responsibilities of any corporation are:

- Businesses that ignore their social responsibilities may face the public’s wrath (in the sense that polluting companies may in future face problems with additional pollution regulations, or those who market unsafe products may have to deal with lawsuits from harmed clients), and
- Corporations are like moral agents in that they make decisions that have important effects on human beings (and they have moral obligations to avoid causing harm, and to act in order to produce social welfare and justice).

According to the author pharmaceutical companies have two main duties. The first one is beneficence, which stands for promoting the balance between societal benefits and harms. The second is justice, as it is claimed that medical companies should act in order and in the manner that promotes equitable access to medications. If a company operates in a country, it has moral obligation to act responsibly in that country. It can mean that any pharmaceutical company generating profit in a particular country has to give back something more than its products and taxes. This way, although, corporations may choose to do business only in developed parts of the world, for this would mean escaping the economic, social, political and legal challenges involved in conducting business in the developing world. There are more reasons for such a resistance. First, operations in the developing countries bring no guarantee of reasonable profits in the future. Second, such companies often have to conquer or else adapt to an unproductive business climate. Nevertheless, pharmaceutical companies should promote the welfare of humankind.

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47 Resnik, D., 2001, p. 17
48 Resnik, D., 2001, p. 18
49 Resnik, D., 2001, p. 24
4.2 The Brazilian Case: Game-Theoretic Model

4.2.1 General Health Care Information

The Brazilian health care system consists of facilities from basic health care units to complex specialized hospitals, both privately and publically owned. According to Article 169 of the 1988 Brazilian Constitution access to basic medicines and health services is a constitutional right. Quoting after Cohen and Lybecker, the Brazilian Constitution says:

Health is a right of all and a duty of the State and guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and all the universal and equal access to actions and services for its promotion, protection and recovery.

Federal, state, municipal and the national government health system (Sistema Unico da Saude [SUS]) of Brazil share equally the delivery of the health care service delivery in the county. Each of the organs are responsible for different parts of the system; for example the government’s federal level grants technical and financial support to the states and municipal governments, defines policies and regulations and provides some service delivery. Just as in other developing countries, and despite the public provision of medicines, the majority of pharmaceutical expenses are those of the out-of-pocket type. Brazilian Ministry of Health estimates that:

- 50 per cent of the Brazilian population does not have access to basic medicines,
- 20 per cent has partial coverage, and
- 30 per cent is able to satisfy their pharmaceutical demands.

Moreover, the access of the Brazilian society to the drugs, health care services and their quality varies according to geographical areas, the income of the people and the government resources. SUS, although being responsible for providing and financing health care for the

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50 Cohen, J. C., Lybecker, K. M., 2005
whole society of Brazil, serves mostly the 74 per cent (123 millions)\textsuperscript{52} of Brazilians who cannot afford covering their pharmaceutical expenses out-of-pocket.

<table>
<thead>
<tr>
<th>Group</th>
<th>Salary Range (on monthly basis)</th>
<th>Percentage of the Population</th>
<th>Per Cent Market Share Consumed</th>
<th>Per Capita Expenditure on Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>10+ minimum salaries</td>
<td>15</td>
<td>48</td>
<td>US$ 172</td>
</tr>
<tr>
<td>B</td>
<td>4-10 minimum salaries</td>
<td>34</td>
<td>36</td>
<td>US$ 57</td>
</tr>
<tr>
<td>C</td>
<td>0-4 minimum salaries</td>
<td>51</td>
<td>16</td>
<td>US$ 17</td>
</tr>
</tbody>
</table>

Notes: A minimum monthly salary is US$ 100

Table 3 Profile of the Brazilian Pharmaceutical Consumer\textsuperscript{53}

In the above table consumers are divides into three groups: A, B and C. The first, the richest group of people stands for 15 per cent of the Brazilian population, consuming 48 per cent of all pharmaceuticals sold on the Brazilian market. The second group consist of 34 per cent of the society and purchases 36 per cent of the available drugs. The last group, the poorest part of the Brazilian population, represents the 51 per cent of it, and this group consumes 16 per cent of the pharmaceuticals sold in Brazil. The last column presents the expenditure of a member of each of the three groups on pharmaceuticals, and it can be observed that the amount of money scales down with the salary range.

4.2.2 The Brazilian Pharmaceutical Industry and AIDS Policy in Brazil

The pharmaceutical industry of Brazil had in past decades benefited from the period of lack of patent protection over pharmaceutical innovations. The legal act known as Law No. 5772 on Industrial Policy (taking effect on 21 December 1971), allows the Brazilian companies to produce on-paten drugs. According to this act, ‘on-patent drugs’ are the pharmaceuticals protected by patents in the markets where such protection exists.

The domestic pharmaceutical industry has a small share of the global market but is the major supplier to the domestic public health system. The table below presents the statistics of the Brazilian pharmaceutical market. It shows clearly that the market is dependent on

\textsuperscript{52} Cohen, J. C., Lybecker, K. M., 2005, p. 215

\textsuperscript{53} Cohen, J. C., 2000
local production, with low international imports and even lower exports of pharmaceuticals. The Brazilian pharmaceutical market is nowadays one of the largest in Latin America, and eight largest in the world\textsuperscript{54}.

<table>
<thead>
<tr>
<th></th>
<th>1997</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Market Size</td>
<td>12.7</td>
<td>10.3</td>
<td>11.0</td>
<td>11.5</td>
</tr>
<tr>
<td>Local Production</td>
<td>11.6</td>
<td>9.5</td>
<td>10.0</td>
<td>10.3</td>
</tr>
<tr>
<td>Imports</td>
<td>1.2</td>
<td>1.0</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Exports</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 4 Brazilian Market Statistics (US$ billion)\textsuperscript{55}

Strong commitment of the Brazilian government to the HIV/AIDS programme is a result of the pressure from civil society. Representative groups of individuals living with HIV/AIDS, gays and lesbians, feminists and faith-based groups demanded the effective respond of Brazilian government to the HIV/AIDS crisis\textsuperscript{56}. The constitutional commitment of the government, mentioned in the previous section, lead the government to turn to domestic pharmaceutical companies for the production of the majority of the medicines demanded for HIV/AIDS treatment. The non-restricted patent law of the country allowed the local producers to supply the domestic market from the mid-1990s with their own nucleoside analogues.

Compulsory licensing, which is important in the case of Brazil, can be described as ‘a license to produce granted by government authorities to a third party to make, use or sell the patented product for a fixed time period during the life of the patent, even without the consent of the patent owner, upon a payment of a reasonable remuneration’\textsuperscript{57}. Point 5(c) of the Doha Declaration on the TRIPS Agreement and Public Health\textsuperscript{58} states that:

\textsuperscript{54} Lybecker, 2000
\textsuperscript{55} Cohen, J. C., Lybecker, K. M., 2005, p. 214
\textsuperscript{56} Galvão, 2002
\textsuperscript{57} Watal, J., 2000, p. 737
\textsuperscript{58} Declaration on the TRIPS Agreement and Public Health – Appendix 1
'Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'

Brazil enforced the ‘national emergency’ clause to enable local production of medicines in this situation. The result was that 47 per cent of antiretroviral drugs, being 19 per cent of expenditure, were obtained from the domestic market, while 81 per cent of expenditure and accounting for the 53 per cent of antiretrovirals were purchased from international companies. The success of the approach is mostly visible in the Brazilian Ministry of Health estimations of cost savings of $1.1 billion between 1997 and 2001.

4.2.3 Game-Theoretic Model of the Brazilian Strategy

The model presented below represents the negotiation between Brazil and Hoffman-La Roche (Roche), and is claimed to be useful and representative for any interaction between a developing country and pharmaceutical company.

![Game-Theoretic Model](image)

**Figure 1 Game-Theoretic Model**

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59 Galvão, 2002
60 Galvão, 2002
61 Cohen, J. C., Lybecker, K. M., 2005
The presented model is a simplified version, as just two players are directly involved in the strategic decisions. This does not mean, as we will present later in this section, that other organizations are not important for the players in the process of decision making.

The game features two players: Brazil and Roche. Roche moves first, offering a discounted price for pharmaceuticals after internal negotiations. It can decide to offer a deep or minimal discount. Brazil has now three options to choose from: accept the offer, reject it and issue a compulsory licence, and reject the offer and renegotiate. (Apparently, the company may choose not to sell to the country and the country does not have to buy for the company, but this situation is ignored here.) The probability of Brazil accepting Roche’s offer is far higher in the case of deep discount than in the minimal discount situation. Moreover, the minimal discount option raises the probability of Brazil issuing a compulsory license for the drug or drugs under negotiation. Moving forewords, if Brazil accepts the offer or rejects it and issues a compulsory license, the game ends. If the country decides to renegotiate the discount offered by Roche, the game is repeated, and the possible outcomes are:

**Outcome 1:** Roche offers a deep discount, which is acceptable for Brazil; Roche produces and sells the drug to Brazil at a price the both players agreed upon; the payoff to Brazil is $A$, and to Roche, $Y$;

**Outcome 2:** Roche offers minimal discount, which Brazil accepts; Roche produces the pharmaceutical and Brazil purchases it at the agreed-upon price; the payoff to Brazil is $B$, and to Roche, $X$;

**Outcome 3:** Brazil rejects Roche’s offer and issues a compulsory license, thus starts production of the patented pharmaceutical; payoff to Brazil is $C$, and to Roche, $Z$ (it is worth noting that in this situation it is possible that Roche would decide to counter with another offer, and the game would repeat);

**Outcome 4:** Brazil rejects Roche’s offer and decides to renegotiate the price; payoffs to both players are zero; the game is repeated.

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Any pharmaceutical company prefers to offer the minimal discount, but in some situations the deep discount may be favourable to the possibility of the loss of market share of the developing country market. The payoffs to Roche are the highest in the case of minimal discount, medium in the deep discount and minimal in the compulsory licensing situation, that is \( X > Y > Z \). The developing country prefers the deep discount to the minimal one, that is \( A > B \). The decision of domestic production of the pharmaceutical will bring higher payoffs than minimal discount, so \( C > B \). As far as comparison between \( A \) and \( C \) is concerned, the need of information about the extent of the deep discount and the cost of domestic production is vital. The deeper the discount, the less favourable the local production becomes. The cheaper the domestic production and the less interesting discount, the more favourable the compulsory license option becomes. This means that apparently three situations can occur: \( A > C \), \( A < C \) or \( A = C \).

Now we will describe the game, the way it was played in practice. On 22 August, 2001, the initial offer of Roche on nelfinavir (also called Viracept is an ‘orally administered protease inhibitor (…) in combination with other antiretroviral drugs (…) produces substantial and sustained reductions in viral load in patients with HIV infection’\(^{63}\)) was claimed to include a minimal discount on non-satisfactory level, and was rejected by Brazil\(^{64}\). Moreover, Jose Serra, the Minister of Health, announced that Brazil had started the domestic production of the pharmaceutical under negotiations, through issuing a compulsory license. (This is where forces of politics should be brought about. At this time Jose Serra was sure that the threat to resort to compulsory licensing would be widely backed by the society. This was of his interest, as it was a means of gaining political capital for the upcoming 2002 Presidential campaign.\(^{65}\)) Roche reconsidered the offer paying attention to two major issues. First, Brazil possessed the manufacturing capacities and capabilities to actually produce the drug under negotiation. Second, as mentioned before, Brazilian pharmaceutical market was one of the top ten in the world. The factors significantly lowered the size of \( Z \), being the payoff to Roche under the compulsory license. The company responded to the Minister’s announcement by lowering the first price by 13 per cent. Again, the price level was unacceptable for Brazil (the

\(^{64}\) Cohen, J. C., Lybecker, K. M., 2005, p. 219  
\(^{65}\) Cohen, J. C., Lybecker, K. M., 2005, p. 220
country’s request was 40 per cent discount\textsuperscript{66}), and preparation were made for production of the drug under patent in a state-owned laboratory, Far-Manguinhos. The drug was claimed to be available to the patients by February 2002. The game continued when Roche offered to cut down the price of nelfinavir by one-third. Yet again, Brazil rejected the offer for not being tough enough to be low. The cost of Roche’s drug was over $88 million, which stood for 28 per cent of government expenses on all antiretrovirals in 2000\textsuperscript{67}. The final decision of the country was to product the drug locally, and the government claimed that domestic production of nelfinavir would stand for $35 million saving a year (the government spent $303 million that year to HIV/AIDS cocktail to roughly 100,000 patients)\textsuperscript{68}. The game got stuck in the point of C payoff to Brazil and Z to Roche.

Other big pharmaceutical companies, which were supplying their antiretrovirals to the Brazilian market, felt insecure. In order to avoid the situation similar to the previously described negotiations between Brazil and Roche, Merck reduced the price of two components of the AIDS cocktail, efavirenz and indinavir (both used in highly active antiretroviral therapy\textsuperscript{69}), offering the deep discounts of 65 and 59 per cent respectively. These discounts cut down the government expenses by about $38 million\textsuperscript{70}. In the beginning of the new century Brazil was importing generic raw materials\textsuperscript{71} and using the existing public manufacturing facilities to produce eight out of twelve drugs used in HIV/AIDS cocktails\textsuperscript{72}.

The game presented above involved examination of the payoffs to and by both players while deciding on the strategic decisions to be made. Brazil’s decision depended on a careful analysis of short-run and long-run implications of the licence. In the short run, the government had to consider the time and expense of the domestic production. As the Brazilian pharmaceutical industry had the capacity and capability of domestic production of antiretrovirals, the financial implications of the final production decisions had to be carefully calculated by the government. It is worth noting that issuing compulsory licensing included

\begin{thebibliography}{99}
\bibitem{66} Jordan, 2001
\bibitem{67} Rich, 2001
\bibitem{68} Rich, 2001
\bibitem{70} Rich, 2001
\bibitem{71} In 1999
\bibitem{72} Cohen, J. C., Lybecker, K. M., 2005, p. 220
\end{thebibliography}
the royalty payment to the patent holder and other administrative costs of it. In the long run, the major factor to investigate was the sufficiency of the capacity to meet the demand on the drug, which could be growing over time. This factor included another important issue, namely the existence of a reliable source of the active pharmaceutical ingredients (APIs) and excipients. (APIs include any substance or mixture of substances that are intended to prove pharmacological effect. Excipients (...) are inactive ingredients and can include fillers, bulking agents, binders, disintegrants, coatings, colorants, slip agents, etc. A pill can contain just one, or more than 20, active and inactive ingredients'.

Moreover, the payoff to the local market is also dependent on the experience gained by the domestic production, the experience from learning-by-doing. This experience may lead to future domestic innovations in the area of atiretirovirals and other pharmaceuticals.

Roche also had to weight the short-run and long-run consequences of its offers to Brazil. As mentioned before, the company would obviously prefer minimal discount to the deep one, although the first increased the possibility of the offer being rejected or Brazil’s issuance a compulsory licensing. The company had to investigate the local market’s capacities and capabilities to produce the drug. The domestic production of the drug under patent and through compulsory licence would deliver royalties to Roche, while at the same the company would lose significant market share of one of the biggest Latin America’s markets. Furthermore, the licence would effect in bad press to Roche. The inability of the company reaching the point of agreement with Brazilian government about the price level could bring effects in the long run, when negotiations with any other country would take place. In this situation the company had to weight the cost of probable licenses following the prime issuance, and the loss from those. Nevertheless, Roche could offer deep discount on the drug under patent, which would mean a significant market share in Brazil, and reduction of profits generated in that country. The company had to decide on the importance of either the market share or the profits. Another important factor to consider in the long run here is the possibility of other countries demanding comparable depth of discounts on Roche’s retrovirals, thus considerable loss in the global market.

73 Watal, 2000
74 GlobalOptions Inc., 2003
75 Cohen, J. C., Lybecker, K. M., 2005, p. 222
The game involves two major players, Roche and the government of Brazil, but is affected by and affects third parties (and political situations as upcoming Presidential Elections in Brazil). As already mentioned, Merck reacted to the interaction between the players reducing its prices on two antiretrovirals. The third parties affecting the decisions of the main players are mostly the press (also mentioned already) and the network of health activists. This network, consisting of non-governmental organizations (NGOs) like Oxfam (‘a confederation of 13 organizations working together with over 3,000 partners in more than 100 countries to find lasting solutions to poverty and injustice’\(^{76}\)) and Médicins Sans Frontières/Doctors without Borders (‘is an international humanitarian aid organisation that provides emergency medical assistance to populations in danger in more than 70 countries’\(^{77}\)). These two companies are strongly involved in the discussions about the TRIPS agreement’s effects on access of the developing countries to essential drugs, and fight for insurance of such access to the poorest members of the globe. The constant cry from these NGOs about pharmaceutical companies placing profits over people significantly assisted Brazil’s government in successful issuance of compulsory license.

There is one more important issue connected with compulsory licensing under TRIPS agreement. And this issue is of great importance for the countries, where local production is impossible due to lack of existence of needed facilities. The document states in Article 31(f) that compulsory licensing shall be ‘predominantly for the supply of the domestic market’. Point 4 of the Doha Declaration on the TRIPS Agreement and Public Health states:

*We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.*

Thus, wide interpretation of Article 32(f) enables the companies to supply other than domestic markets with licensed drugs. In this light, Brazil will be able export the domestically manufactured antiretrovirals to less developed countries, like Zambia, after Zambia issued a compulsory licence for the drug.

\(^{76}\) [http://www.oxfam.org/en/about](http://www.oxfam.org/en/about)

\(^{77}\) [http://www.msf.org/msfinternational/aboutmsf](http://www.msf.org/msfinternational/aboutmsf)
4.3 The Case of India

India is a developing country with well established pharmaceutical industry. The development of this sector in the country is mostly an outcome of the fact that since 1970 the India’s Paten Act allowed the local manufacturers to produce generic versions of medicines under patents in other countries. In this country the lack of patent protection not only did not stop the industry from growing, but encouraged it to become the number one source of medicines for the domestic market’s demand and a main exporter to less developed countries (with two-thirds of the domestic pharmaceutical output exported to other developing countries78). India was one of the main opponents of the TRIPS agreement and one of the strongest leaders of discussions in Doha. As far as the price of antiretroviral drugs is concerned, the India’s generic AIDS triple therapy is extremely an offer in comparison to the price level of patent holders for the drugs. The original therapy is available at a cost of $10,000 per patient per year, whereas the Indian generic mode of the same therapy is offered at less than $200 per year79. The price level was and is interesting enough to encourage some of the NGOs to purchase the generic antiretroviral drugs in India and offer them to the patients under treatment in other, less developed countries. According to the 2005 statistics of Médecins Sans Frontières, 70 per cent of the 25,000 AIDS patients treated by the NGO in 27 countries were receiving Indian generics80. Different sources say that of ‘700,000 people receiving antiretroviral treatment in developing countries, half rely on India-made drugs’81. But that is not all. Indian pharmaceutical companies do not only ‘copy’ the drugs. The manufacturers combined several AIDS pills originally produced by different companies into one pill, a fixed-dose combination of drugs. This simplified the AIDS treatment programmes in poor countries, by cutting the price and making the treatment easier under difficult circumstances.

Until 2005, January 1, India was able to produce the generic drugs as the TRIPS agreement was not applying to the country’s law. Nevertheless, on December 26, 2004, the eleventh President of India, Abul Pakir Jainulabdeen Abdul Kalam, issued the Patents Amendment

78 Aslam, 2005
79 Médecins Sans Frontières, 2005
80 Médecins Sans Frontières, 2005, p. 2
81 Aslam, 2005
Ordinance to comply with the terms of the TRIPS agreement. The Ordinance requires that patents are granted on new medicines from January 1, 2005. This constituted a problem for the countries previously supplied by India with the antiretroviral treatment substances. As mentioned before, countries can use compulsory licensing ‘predominantly for the supply of the domestic market’. This can be interpreted in two manners:

a. Countries can export the drugs under license (if a compulsory license for the drug is granted by the importing country), and

b. Countries cannot issue compulsory license in order to produce for export only.

The 2003 August 30th meeting regarding Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health made available the import of drugs under patent by the least developed countries. Although 5.1 million of people in India are infected with HIV virus (and it’s the second largest number after South Africa), it is not seen as a national emergency, one of the predominant for compulsory licensing. Therefore, Indian companies will not be able to copy those inventions under patent which were developed after January 1, 2005. Nevertheless, the company named Cipla Ltd. India, the pharmaceutical company manufacturing the generics, is still allowed to manufacture the old inventions and deliver them to its clients in 170 countries of North America, South America, Western Europe, Eastern Europe, Eastern Asia, Southeast Asia, Mid East, Africa and Oceania.

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82 See: Appendix 3, Paragraph 1(b)
83 See: Appendix 3
84 http://www.cipla.com/globalpresence/globalpresence.htm
85 http://www.alibaba.com/member/ajayw.html
5. Empirical Findings

We will now present the current situation in the world, as long as HIV/AIDS, malaria and tuberculosis are concerned. In the later part we will introduce the information gathered through interviews with the citizens of Ghana, South Africa, Ethiopia and Botswana.

5.1 Current situation

The current situation of HIV/AIDS, malaria and tuberculosis is dramatic. Below we can see the world maps which describe the spread of these diseases.

![Figure 2 People Living with HIV/AIDS (Adults and Children)](http://www.globalhealthfacts.org/topic.jsp?i=1)

As one can see, South Africa, Nigeria, India, Mozambique, Zimbabwe, Tanzania, Kenya, Zambia, Congo and Uganda have from one to fine millions of people living with HIV/AIDS.

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86 [http://www.globalhealthfacts.org/topic.jsp?i=1](http://www.globalhealthfacts.org/topic.jsp?i=1)
We can see that most of these counties are African ones. AIDS/HIV is truly one of their major problems. Regions that lie on the south of Sahara are mostly influenced by this disease.

In contrast to other regions of the world, AIDS in Africa receives the widest use through the heterosexual contacts and through the transfer of virus from the mother to the child, while in Eastern Europe, Russia and the countries of Asia an increase in the number of virus carriers is connected with the infection of those, who use narcotics. A similar method of propagation of HIV explains those proportions, which exist in the distribution of the number of those infected in different social groups. Thus, women mostly suffer from AIDS in Africa while on a global scale we can observe the reverse tendency. AIDS is “getting younger” in the entire world, and in particular in Africa, leads to the fact that the disease strikes the most productive part of the society.

The next two maps show the malaria and tuberculosis cases worldwide.

Figure 3 Malaria Cases\(^{87}\)

\(^{87}\) http://www.globalhealthfacts.org/topic.jsp?i=23
As is visible on the two figures presented above, the countries where malaria and tuberculosis are most common are the poor countries of Africa.

5.2 The Interviews

As it can be seen from the previous section of the paper, mostly African countries experience the problems with diseases under our study. Thus we have conducted a series of short interviews with people from Africa. The purpose of those interviews was getting the up-to-date information from people who actually live or lived in Africa. They have the most reliable information about the real situation in their countries and what is being done in order to ease the access to essential drugs and prevent further spread of the diseases. We have interviewed citizens of Ghana, South Africa, Ethiopia, and Botswana. This helped us to gather both country specific information and facts about the situation in the whole Africa in general.

Below we present the charts illustrating the answers gathered through the interview. The charts will be discussed in the following part of the paper. The open-end questions, and the answers received, could not be presented in the form of charts. Thus, we describe them.

http://www.globalhealthfacts.org/topic.jsp?id=16
13 of 15 respondents (86,67%) answered positively when asked if they have ever heard about the TRIPS agreement. Two answers (13,33%) were negative.

The vast majority of the respondents – 10 – admitted that in the last 10 years the situation of epidemics in their countries improved slightly. Only one person noticed significant improvements, two described the situation as stable, and the last two claimed that the situation became worse in that period of time.
When asked about the organizations and other bodies on which citizens of their countries rely, nine respondents picked NGOs, four claimed that both NGOs and the government provide help. One person claimed that citizens of their country depend only on the help from the government, and one said that people cannot depend on any of the organizations and bodies.

86.67 per cent of the interviewees (13 out of 15) answered positively to the question about differential pricing of drugs in accordance to the specific country. The rest, being the 13.33 per cent (2 out of 15) replied negatively.
Most of the people, 12 out of 15 (standing for 80 per cent of the respondents) should have the moral obligation to develop country specific drugs regardless to existence or non-existence of respect of intellectual property rights. Three respondents disagreed.

14 respondents, over 90 per cent, gave a positive answer to the question about allowance of national prices regulations in cases of them being kept high by pharmaceutical companies, and just one person disagreed with such regulations.

The above answers and the investigation of their visualized version enabled us to conclude that the nationals of Ghana, Botswana, South Africa and Ethiopia are aware of the size and importance of the epidemics. Although most of them claim that the situation in their
countries has slightly improved over the last decade, they still claim to be highly dependent on Non Governmental Organizations as far as help is concerned. Most of the respondents find differential pricing appropriate for pharmaceuticals in Africa. Also the majority believes that companies have the moral obligation of developing country specific medications and that the governments are allowed to regulate prices of overpriced medicines.

**General Information**

Even though HIV/AIDS, malaria and tuberculosis are all considered to be the diseases that have a huge impact on African countries, most of our respondents where only concerned with AIDS/HIV problem.

All our respondents stressed that the situation differs significantly between different African countries. While such in countries as Somalia and Senegal the percentage of people infected is minor, the amount of people with HIV/AIDS in countries like South Africa, Zimbabwe, Zambia, Botswana, Lesotho and Swaziland is huge and estimated to be more that twenty percent of the population. The patterns of AIDS epidemics also differ from country to country. In some countries the HIV prevalence is still growing as fast as it was before. Some countries managed to get it stable and only Kenya and a few other countries experience a decline.

Interviewees stated the following impacts of AIDS on their countries:

1. In many countries from sub-Saharan Africa governments have been trying to increase the life expectancy for many years. With a current AIDS situation all the efforts they've made during last decades became worthless.
2. AIDS also affects households in a way that many families loose children and relatives who were intended to provide for their families. The people in their labour years are sometimes forced to abandon their jobs in order to be able to take care of their family members infected by any of the epidemics.
3. The increase in amount of people infected leads to an increase in demand of care for that people which in turn affect medical workers.
4. Schools are considered to play a vital role in further reduction of HIV/AIDS spread through education. Prevention of the evolution of the epidemics on even larger scale may be crucial, and schools’ role in this process essential.

5. HIV/AIDS has a huge impact on the labor force as well. The majority of those living with aids are between 18 and 50. That basically means that the majority of people who are supposed to be working are ill. Public sector and other employers have nothing else to do than train newcomers continuously in order to replace those who are ill.

6. Respondents have told us that all the facts stated above lead in turn to the slowdown in economic growth and development. And this in turn leads to decreasing ability to deal with epidemic.

**Treatment issues**

While all of the aspects of coping with epidemics are important, the crucial one is still the access to the required drugs. Antiretroviral drugs are used in case of HIV/AIDS. The distribution of these drugs requires:

1. Funding
2. Good healthcare system
3. Appropriate amount of doctors

The majority of third-world countries experience the absence of all the things listed above.

Even though international public organizations often report about their huge progress in dealing with this problem, all of our interviewees clearly stated that for most people living in Africa antiretroviral pharmaceuticals are not available. Furthermore, millions of people do not receive any help when they have other infections, which have huge effect on those whose immune system was influenced by HIV.

Nevertheless one of our respondents from Botswana stated that his country succeeded in supplying antiretroviral drugs. The country was the first ones which started their own national program several years ago and now almost every person in need of antiretroviral pharmaceuticals receives them (by governmental organizations). The rest of the respondents
confirmed that Botswana is the only country which has great success with their program, but the situation in their countries is also improving, although very slowly.

Another major concern is continuous supply of drugs. It is extremely important because if a person starts to take antiretrovirals, they have to keep doing that for the rest of his life, otherwise they will become resistant to this treatment.

There were two more problems that all of our respondents were concerned about:

1. Discrimination problem

   Discrimination is still a big obstacle in a battle with AIDS. People often resist to get tested and hide the fact that they are ill from everyone else, because of the possible discrimination. Therefore, all our interviewees agreed that the education plays a vital role because it prevents ignorance which, in term, is the main cause of discrimination.

2. Funding

   The increasing funding could definitely improve the overall situation in Africa. Most of our respondents stated that they do not really rely on governmental funding and programmes; their only hope lies on various non-governmental organizations (NGO). There are many NGOs which provide people with treatment and education. Though, getting money from international organizations can be a major difficulty itself. As our respondent from Ethiopia said: “corrupted politicians exist in every poor country in Africa”.

**Special Case of Ghana**

Even though our respondents believe that Ghana made big improvements in the health care system over the last years, they admit that there are still many problems to be solved. From one side the life expectancy has increased, from the other big fraction of ill people do not receive appropriate treatment.

Drugs are available in many different institutions in the country; however, most of the people cannot afford them. Ghana’s public health system works under such a model that assumes co-payments (patients pay 10%). The idea behind this model is co-payments can help funding and improve the health care system in general. Thus, on the one hand, patients are partially financed by Global Fund, on the other hand, these 10% that have to be paid are much more than average patient can afford.
Respondents also mentioned big mark-ups that exist in their country. On every stage of the product supply chain (from customs to retail) a significant mark-up is added which leads to substantial increase in price.

Interviewees state that Ghana has a big potential in drug production. However all the mark-ups that exist in the country bring this potential nearly to zero. The government tries to help industry by limiting the import of certain pharmaceutical products. This creates additional working places however the problem with skilled labour and advanced technology has to be solved first.

In general people in Ghana rely mostly on NGOs, which are present in this region in huge amount. Furthermore Ghana’s government cooperates with these organizations in order to help financing treatment. They are also concerned about people’s education because many people, especially in the rural areas, are not even aware of basic hygienic principles. This in term leads to the spread of such diseases as tuberculosis and HIV.
6. Conclusions

As we presented above, in the empirical findings and their analysis, citizens of the poor or developing countries of Africa have the perfect recognition of the existing problems of access to essential drugs. Although it is not possible to change the world in just one day, it seems to be the moral obligation of corporations originating from the developed countries to deliver the best way to develop worldwide welfare step by step. At this stage, especially the interplay between pharmaceutical companies’ responsibility and governments’ care of citizens’ health plays an important role. The lack of access to essential drugs in the developing countries is not to be blamed upon pharmaceutical companies’ profit orientation, neither upon helpless governments or unawareness of the developed parts of the world, but it is the joined forces of the three actors what can change the situation.

The existence of patents, and the three different perceptions of them, is crucial for the pharmacological sector. The supporters of the ‘natural rights’ view would probably not succeed in transforming their points of view to the wider public. Patenting every innovative or creative act would just produce more discussion, or even more, create more obstacles for developing countries to access such innovations. It may be claimed that the strong patent protection works for the development of R&D, but even scholars do not find common ground for the interrelation between incentives from patents and the actual level of innovativeness. It is true, that they increase the level of competitiveness between companies, but does it really have a strong impact on the pharmaceutical market? The process of developing and marketing a new drug is not only very time consuming, but also demanding in terms of financial and non-financial investments. An assumption can be made, that none pharmacological company is interested just in obtaining plentiful of patents, even if the financial and non-financial outcomes of them seem profitable.

The ‘communitarian rights’ view, perceiving an innovation patentable only if it is a major step in the process of development, shows totally reverse view point on patents in the pharmaceutical industry. According to this perspective, all improvements should be commonly available. Combining this with the moral obligation of the drug developers, and their social responsibility, indicates the corporations devoting their resources (financial and
non-financial) to the creation of welfare. As it seems reasonable for the developing countries, it may constitute major expenses and minor benefits for the companies themselves. Such an approach to business making may mean that resources would be significantly diminished, if not extensively exploited, in the short run and in the long run effect of such utilization may not give birth to the resources needed for future needs for development of the industry.

The third approach to patents, namely the utilitarian one, provides the point of view where the benefits and threats of such patents have to be taken into account before actual granting. As any monopoly, even the temporal one, produces high prices of the unique products, it may also provide access to such products controlled by responsible authorities. It should lie in the responsibilities of such authorities to act in favour of equal distribution of the products under patents, especially in the case of pharmaceutical products. The TRIPS agreement, evolving over time, supports this point of view, and only the way that countries, governments and societies are dealing with the Articles of the agreement will bring either cost or profits to them.

The cases of Brazil and India show the direct connection between the governments’ perception of patentability of pharmaceutical products and the possible cost and profits of their existence or non-existence. The lesson learned from the Brazilian example, the way the government played the ‘game’ with Roche, provides a path to follow for other countries. We find hereby, that the difference lies in the characteristics of the pharmaceutical industry in the specific country. As far as one can have the industry well established, and the Brazil-Roche game can be repeated in the same manner, there are far more problems for those poor and developing countries where the pharmaceutical industry is either weak or non-existent.

In our mind, the difference between the situations of issuance of compulsory licensing of a drug under patent for domestic production and import form countries like India is too colossal to be considered only in the way Cohen and Lybecker did. Coming back to the model and the claim of its authors that the game played by Brazil and Roche can be applicable to any other developing country and a pharmaceutical company, we add one more factor: the existence or level of development of the domestic pharmaceutical market. The authors claim
that the payoffs to Brazil, or any other country finding itself in such a situation, is $A>B$, and $C>B$, ($A$ being the payoff from acceptance of the deep discount, $B$ being the payoff of acceptance of the minimal discount, and $C$ the payoff of issuance of compulsory licensing).

On the other hand the payoffs to Roche, or any other pharmaceutical company discussing supply of drugs to a developing country, are $X>Y>Z$ ($X$ being the payoff from minimal discount, $Y$ the payoff from deep discount, and $Z$ the payoff from the royalties is a country decides to issue compulsory license for the drug under patent).

Basing on our research, we deduct that not all countries have the same choice, and more factors have to be taken into consideration while playing the game. Most countries of the sub-Saharan Africa or other poor developing countries either lack the pharmaceutical industry or the industry is very weakly developed. As mentioned in the empirical findings, the prevention of evolvement of epidemics of our concern is not well developed as well. Prevention involves teaching the society about the causes of the illnesses and their consequences. But education may also mean encouraging people to learn more about HIV/AIDS, tuberculosis or malaria in a professional manner. These professionals, educated in the field of medicine or pharmaceutics might one day develop country-specific drugs. Nevertheless, for them to do so the evolvement and development of the pharmaceutical industry must have started long time ago, or may bring effects in far future if started now.
As most countries lack of such industry, our model, presented as Figure 5, concerns the two types of compulsory licensing. One of them is legally possible due to the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health regulations and agreements: import. The second is the domestic production. The least developed countries can measure which option would be more profitable for them:

- Accepting the minimal discount; with payoffs at \( B \)
- Accepting the deep discount; with payoffs at \( A \)
- Renegotiating deep or minimal discount, and renegotiation; with payoffs at \( 0 \)
- Reject either of the offers and start domestic production of the drug under patent after issuance of compulsory licensing, with payoffs at \( C \)
- Reject either of the offers and import the drug from a country where the drug is already manufactured under conditions of compulsory licensing, with payoffs at \( I \).

Payoffs in the first cases, are still \( A > B \) and \( C > B \). The rules of the games are the same, until the moment when a country decides to issue compulsory licensing. The second player is almost irrelevant. The decision has to be made internally by the government or other authoritative
organizations. Nevertheless, the decision can still be affected by the pharmaceutical company, due to possibility of another offers or strong opposition to importing. The important issue is the difference in the payoffs I and C. The size of the difference depends on the costs which would be involved in development or establishment of the pharmaceutical industry in comparison to the cost of importing the drug. It can be speculated that in the case of least developed countries C>I. Thus, our study may allow to speculate that countries may prefer to choose importing via issuance of compulsory licensing to domestic production, on the condition that either of the offers of price levels supplied by pharmaceutical companies are unacceptable for financial or non-financial reasons.

The second player of the game, the company, is also strongly affected by the acts of the first one in our model. The company, or generalizing – the companies, have the same number of variables to investigate:

- Offering the minimal discount; X
- Offering the deep discount; Y
- Both types of discount being rejected; O
- Payoffs from the country issuing compulsory licensing and domestic production of the drug; Z
- Payoffs from the country issuing compulsory licensing and importing the drug; I.

The payoffs are still X>Y>Z in the ‘original’ version of the game, but we deliver one new: I, which stands for the payoffs to the company or companies when the country decides to import under issuance of compulsory licensing. It can be considered that the option I, will be even less profitable than Z. This is due to the fact that only the issuance of compulsory licensing for domestic production includes payment of royalties to the original patent holder. The exporting country will be paying the royalties, but no law exists about increasing them if the drug is intended to be exported. The company loses also the market share, good press and international image, which, although non-financial per se, bring huge financial consequences.

The model presented and described above, and developed from our study, may be a guideline for the least developed countries while negotiating with pharmaceutical companies
7. Recommendations

As we presented in the analysis part, the utilitarian view on patentability of pharmaceutical drugs may be the best one for the developing countries. The pros and cons of temporal monopolistic rights, and their actual existence in the Western world, encouraged the World Trade Organization to be established, and the TRIPS agreement to be accepted and respected by all the Members of the organization. Moreover, the Member states continuously and constantly fight for their rights of equal accessibility of essential drugs, which give them more incentives to actually obtain such access. The Doha Declaration and the 2003 comment on TRIPS secure the least developed countries in a clear way. It appears from our investigation that the way the countries’ government will use the agreement and the declarations as a tool for protection depends only on the path they will choose in the situation of negotiations with companies.

The model we came up with, or more accurately, the model which we developed from already existing one (proposed by Cohen and Lybecker) is just a guideline for these countries, where the pharmaceutical industry is either weak or totally non-existent.

The most important thing to be mentioned in this moment is that in the occasion of the lack of pharmaceutical industry in the particular country, the drugs under patent have to be imported from another country, which issued the compulsory licensing in the past. The country from which the drugs can be imported is for example India. It has to be buried in mind, that the potentially importable products are those which were developed before January 1, 2005. That means that the most recent inventions and innovations may still not be available for the least developed country. Nevertheless, the drugs invented and developed before January 1, 2005 are being recently used in both developed and developing countries recently. They appear to be sufficient and efficient enough to secure, protect and control the growth of the size of the epidemics (especially in the countries, where the access to those antiretrovirals is common).

Although changes may appear in all fields: WTO’s legal acts, pharmaceutical industry’s R&D and the situations of the poor countries as long as the size of epidemics is concerned, we consider our model to be appropriate in the current situation. Nowadays it seems to be
more profitable for a country with weak or non-existent pharmaceutical industry, to import the drugs under patent from countries like Brazil or India. Although, according to our findings and the original Game-Theoretic Model, the companies’ profitability may in this situation decrease significantly. This fact may in turn have a negative effect in their lack of interest in R&D, especially in the antiretroviral drugs’ field.

Basing on our research, the best recommendation that can be given is for the pharmaceutical companies to offer the discount on the optimal level. Optimal level does not mean the deepest discount possible, but the one which would be acceptable for the country and still profitable for the company. The option of the ‘game’ finishing like this will save time (so important in the case of endangered health) and money invested in weighting pros and cons of other options.

We recommend, for the further study, deeper investigation of the situation in the particular developing countries in terms of epidemics evolution, political, economical, sociological and social changes, as well as the level of development of the local pharmaceutical industry. We find it also useful to advise future scanning of the actual paths taken by the least developed countries in accordance to the Developed Game-Theoretic Model in search of indicators in favour and against the variable paths to be followed.
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9. Appendix

9.1 Appendix 1 – TRIPS Agreement’s Selected Articles

<table>
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<th>Article number</th>
<th>Rules</th>
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| 27             | **Patentable Subject Matter**  
|                | 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.  
|                | 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.  
|                | 3. Members may also exclude from patentability:  
|                | (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;  
|                | (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. |
| 28             | **Rights Conferred**  
|                | 1. A patent shall confer on its owner the following exclusive rights:  
|                | (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product;  
|                | (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.  
|                | 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. |
| 31             | **Other Use Without Authorization of the Right Holder**  
|                | Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following |
provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
(i) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Table 5 TRIPS Provisions Relating to Patents

www.wto.org
1. We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

    In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country Members pursuant to Article 66.2. We also agree that the least developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

_________
Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

Decision of the General Council of 30 August 2003

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;
Decides as follows:

1. For the purposes of this Decision:

   (a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)

   (b) “eligible importing Member” means any least developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

   (c) “exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

   (a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

      (i) specifies the names and expected quantities of the product(s) needed (5);

      (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

      (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

   (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

      (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

      (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

      (iii) before shipment begins, the licensee shall post on a website (7) the following information:
- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.
7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member’s needs, the system shall no longer apply.
# Antiretroviral generic drugs offered by Cipla Ltd. India

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<thead>
<tr>
<th>Active Ingredients</th>
<th>Product Type</th>
<th>Product Brand</th>
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<td>96KITS + REAGENTS</td>
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</tr>
</tbody>
</table>

Table 1 The List of the Antiretroviral Generic Drugs Offered by Cipla Ltd. India
### 9.5 Appendix 5 - The Interview Form

1. Have you ever heard about TRIPS?

   - YES
   - NO

2. How would you describe the situation in your country, as long as the above diseases are concerned?

   ..............................................................................................................................................................
   ..............................................................................................................................................................
   ..............................................................................................................................................................

3. How did the situation in your country change during the last 10 years?

   Improved a lot | Slightly improved | Stable | Became worse

4. Should pharmaceutical companies price the drugs with respect to purchasing power of population and the overall situation in the country?

   - YES
   - NO

5. Should pharmaceutical companies have moral obligations to develop country specific drugs even though some of these countries do not respect intellectual property rights?

   - YES
   - NO

6. Should governments regulate the prices on drugs if they are kept high by pharmaceutical companies?

   - YES
   - NO

7. On whose help people mostly rely on in your country?

   Government | NGOs | Both equally | Neither

8. What are the authorities of your country doing in order to solve the problem? Is the problem discussed in your country?

   ..............................................................................................................................................................
   ..............................................................................................................................................................
   ..............................................................................................................................................................

9. How would you change the existing situation?

   ..............................................................................................................................................................
   ..............................................................................................................................................................

9. Comments
### 9.6 Appendix 6 - The Lists of Developing and Least Developed Countries

#### a. The Developing Countries

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### Table 2 The List of Developing Countries

99 http://www.ams.org/membership/develop.html
b. The Least Developed Countries

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| Asia            |          |          |          |          |
| Afghanistan     | Bangladesh | Bhutan    | Cambodia |          |
| Lao PDR         | Maldives  | Myanmar   | Nepal    |          |
| Timor-Leste     | Yemen     |          |          |          |

| Australia and the Pacific |          |          |          |          |
| Kiribati          | Samoa    | Solomon Islands | Tuvalu |          |
| Vanuatu           |          |          |          |          |

| Caribbean        |          |          |          |          |
| Haiti            |          |          |          |          |

Table 3 The List of the Least Developed Countries

91 [http://www.nationsonline.org/oneorld/least_developed_countries.htm](http://www.nationsonline.org/oneorld/least_developed_countries.htm)