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ARE AFFORDABLE PHARMACEUTICALS  
WITHIN REACH FOR DEVELOPING  
COUNTRIES? –  
Clarifying the access situation of today and projecting  
beyond the Paragraph 6-Agreement  
20 points

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Intellectual property rights

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# Summary

The increasing spread of global pandemics such as HIV/AIDS, tuberculosis (TB) and malaria, in particular in developing countries, has forced the engagement of industrialized countries and pharmaceutical companies. Because medicines to cure these diseases are often under patent protection, they are not affordable for people in developing countries where health crises prevail.

In November 2001, WTO Members created the so-called Doha Declaration, which was the result of developing countries' efforts to internationally claim the right to prioritize public health before intellectual property rights. The declaration re-established the available mechanisms for obtaining the lower-priced generic drugs through compulsory licensing, provided by the TRIPS Agreement, and highlighted the importance of supporting health objectives when interpreting the TRIPS provisions. Although the Declaration did not introduce any legal novelty, it represented a benchmark for the developing countries, which had frequently been impeded by pharmaceutical companies and industrialized countries when trying to apply TRIPS compliant compulsory licensing mechanisms. Such mechanisms do, however, have a substantial limitation; namely the export restrictions imposed on a product that is produced under a compulsory license. This pivotal issue was left unresolved at the Doha-round with the paradoxical consequence that the poorest countries lacking medical manufacturing capacities were left with little chance to obtain affordable pharmaceuticals.

The problem, which was recognized in Paragraph 6 of the Declaration, was however not resolved until August 30, 2003, due to much disagreement between Members having contradictory interests. Though not yet implemented into the TRIPS Agreement, the "Paragraph 6-Agreement" has already given rise to much debate. In general, the outcome can be characterized as liberal as it allows unrestricted export of generics produced under compulsory licenses. On the other hand, the outcome can also be seen as restrained since the deal comes with several practical requirements and numerous administrative procedures, which complicate the practice of the system.

Despite its flaws, the Para. 6-Agreement together with the Declaration have overturned the international attitude to developing countries' right to obtain affordable pharmaceuticals. Several options are now available for poor nations, whether concerning the acquisition of generics or brand name pharmaceuticals. In the latter case, parallel import stands as an open alternative but this might deter innovative drug companies from substantially pressing down prices for developing countries, so-called "price-differentiating".

Although at the time of reaching of the Para. 6-Agreement, the aim was to manage the implementation of the text into TRIPS by the end of 2004, that deadline has now been overrun. The expectations are now that this will be achieved in the next year. In the meanwhile, several actions can be taken by all parties – developing and developed countries, pharmaceutical companies, funds organs and health organizations - in order to escalate the processes of making essential medicines accessible for poor people.

# Preface

I would like to express my deep gratitude to my supervisor, Professor Hans-Henrik Lidgard, who has been so encouraging and patient with me.

With this thesis, another chapter in my life comes to an end, and I would like to take this opportunity to thank all of you people whom I am so fortunate to have in my life. I feel that I have been blessed with luck my whole life and you have all contributed to that.

To my parents who have taken me to where I am today with their love and unselfish sacrifices they have made for my sister and me. Your unselfishness is beyond imagination and I can never repay you for having left your comfortable lives behind you so that we could have the best future possible.

To my dearest boyfriend Andreas, who is always in my heart and mind. You always support me, believe in me and encourage me to do what I truly want even if it would be unfavorable for you personally. I feel so fortunate to have you.

To my sister, who is one of my two best friends who has to hear all my problems and who has made it possible for me to be here today.

To Anna-Lisa and Axel, who have been like my Swedish grandmother and uncle. With your love, support and care, which have been given to me since my childhood, you have contributed to many of my achievements and to my being where I am now.

To Arne and Linnéa, two wonderful persons who always are so incredibly kind and supportive and who have helped us in so many ways while I was writing my thesis and also other times when help was needed. I am grateful that you have become a part of my life. I am often thinking about you, Arne. Sadly enough, you did not have the chance to read my thesis that we have discussed, but I hope that you would have liked it.

And last but not least – to my dear friend Alex who always thinks the best of me, and who was there for me when I was on my downside. I know I can always count on you.

Anny Channual, Lund 2004

# Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral
BMS	Bristol Myers Squibb
ddI	Didanosine
DIP	Thai Department of Intellectual Property
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FTA	Free Trade Area Agreement
GSK	GlaxoSmithKline
GPO	Thai Government Pharmaceutical Organization
HIV	Human Immunodeficiency Virus
ICTSD	The International Centre for Trade and Sustainable Development
IPR	Intellectual property rights
LDC	Least developed countries
MSF	Médecins Sans Frontières
NIH	National Institution of Health
NTE	The National Trade Estimate Report on Foreign Trade Barriers
PhRMA	The Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
TB	Tuberculosis
TDRI	Thailand Development Research Institute
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
US	United States
USTR	Office of the United States Trade Representative
WHO	World Health Organisation
WTO	World Trade Organisation

# Introduction

## BACKGROUND

Access to affordable drugs in developing countries has been a frequently debated issue over the years. The struggle has been between, on the one hand, the interest of protecting intellectual property rights (IPR), which promote research and development (R&D) and thus the obtaining of new drugs, and on the other hand, the safeguarding of public health, allowing access to essential drugs in poor societies where health problems are severe and acute. Important events in recent years have triggered new intensified debates. In November 2001, developing countries appeared to have achieved a great victory as they set a historical benchmark in succeeding in evoking a WTO consensus, introducing the Doha Declaration on TRIPS and Public Health (Doha Declaration)<sup>1</sup>. The Declaration clarifies TRIPS compliant rights of Member Countries to protect public health, as it *inter alia* states that "... the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health...", and that "...the Agreement 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."<sup>2</sup> However, the Declaration left behind a burning issue – the so-called Paragraph 6 implication, which concerns export restrictions on compulsory license-produced medicines, with the paradoxical result of practically blocking essential drugs from reaching the poorest countries. Nevertheless, after strenuous negotiation and much disagreement, a consensus was finally reached at the end of August 2003, the so-called Paragraph 6-Agreement or the Agreement of August 30. This agreement allowed, under certain conditions, unrestricted export of generics to least developed countries (LDC) and to certain developing countries.

When I decided to investigate this subject, I thought that I could come to a solution, largely only by observing and examining the practical application of the Para. 6-Agreement. I could not have been more wrong. The issue is so much more complex. It involves the co-existence and co-operation of various parties and sectors. It is now that it becomes obvious that the problem of access to low-cost medicines will not be solved solely on the basis that countries are stated to be legally able and have globally confirmed rights to obtain them. Although ameliorated, the situation of lack of medicines for poor countries remains on a different level. Originator pharmaceutical companies and the US government are often perceived as "the bad guys", trying to lay out obstacles for the introduction of cheap generics. It is undeniable that the efforts of the US government to protect American multinational drug companies by pushing for bilateral trade agreements, inducing stricter IPR in developing countries, has eviscerated the spirit of the Doha Declaration. On the other hand, an interesting and pivotal development in the sector of pharmaceutical companies<sup>3</sup> can now be observed – many of the largest companies are today in one way or another involved with developing country issues and some of them work closely together with local institutes and/or NGOs. We exist in a time of pivotal

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<sup>1</sup> WTO Ministerial Conference, Fourth Session, Doha 9-14 November 2001 - Declaration on the TRIPS Agreement and Public Health

<sup>2</sup> Doha Declaration, §4

<sup>3</sup> "Pharmaceutical companies" in this thesis refers to patent holder companies. Producers of generic medicine are referred to as "generic manufacturers" or "generic companies"



changes when global health crises have compelled collaborations between parties of opposite interests, and the balance between investment interests and public interests are beginning to tip over to the benefit of the latter.

## PURPOSE

The objective of this study is two-fold. It aims on the one hand to clarify and follow up the development of the global situation of access to affordable medicine, and on the other hand, to present suggestions of further steps to be taken in order to supply poor nations with low-cost medicines without undermining IPR.

I would like to state my subjective opinion that the right to access essential medicines should be perceived as a fundamental right to life and health, which is a human right. In this regard, affluent countries have moral obligations to make best efforts to share life saving medical treatments with poor populations. I believe that this view is in the present being supported also by the overwhelming part of wealthy societies.

Because the purpose of this study is to look for a sustainable global solution, notable efforts have been made to assess, review and present the subject in an objective manner. This has in some parts not been so easy. In order to determine the specific implications accurately and meaningfully, this study will illustrate the subject matter from the views of different parties involved. The aim is to find balanced solutions for the conflicting interests.

## METHOD

The methodology applied to conduct this study consists of a descriptive presentation of current international judicial material relevant to the assessment of the access situation.

Given the recently achieved WTO consensus on exportation of compulsory licensed pharmaceuticals, there are now several options for accessing generic drugs. Therefore, it seems called for to disentangle the jungle of international regulations and mechanisms with an over-viewing comparative table.

Further, the impact of the Para. 6-Agreement will be examined by making an observation of country reactions.

A key issue when addressing the problems of supplying developing countries with pharmaceuticals is one of finding means of funding. Important actors in this issue are various funds organizations and the pharmaceutical industry itself. With respect to the latter, it is important to comprehend the economical aspects of the companies if solutions to price reduction are to be found. Therefore, a minor comparison between innovative and generic companies has been conducted with respect to costs of developing a medical product. The study could, however, have been better conducted. Unfortunately I was unable to find other sources of data for this comparison study, than the one of the

frequently quoted by Di Masi at Tufts University<sup>4</sup>, and the one of EFPIA<sup>5</sup>. It was in particular difficult to find data that had been gathered by the medical generics industry, despite searches at the websites of generic associations<sup>6</sup>. Health activists have questioned the data presented by Tufts University, arguing that the fact that it being primarily funded by large pharmaceutical companies may have affected the objectivity of the study. Consequently, there is a risk that the comparison presented in this section may not represent the total picture, taking all aspects in consideration.

The thesis will further examine the situation of developing countries and discuss different possibilities for accessing low-price medicines. Unlike previous parts of the thesis, I have inserted subjective opinions in the two last parts of the chapter, giving analytical discussions around IPR and parallel trade in developing countries.

I have chosen to present major parts of the thesis in a primarily objective manner and to then gather my own thoughts in the final part in the analysis and conclusion. The choice seemed to be a logical approach, but it has occasionally been difficult to adhere to this plan. This was because the subjective views in certain cases could be more naturally presented directly after having treated a certain issue, rather than saving all thoughts for the end. However, the approach of saving all arguments to the last might give a better overview and possibly larger impact.

## SCOPE AND DELIMITATIONS

Attempting to present, assess and conclude a large and complex subject such as global access to essential medicine is indeed an extensive work. The subject comprises a large composition of different areas that each has its significance in forming the total picture. However, trying to examine all these areas would, with the limited scope of this thesis, give a vast study without any depth in the subject.

To get a good compromise between breadth and depth, following questions will be addressed in this thesis:

- What are the disputes really about? (targeting the key questions)
- Which international mechanisms exist for developing countries to access low-cost pharmaceuticals?
- What has happened since 30 August?
- What will happen in 2005 when India and Brazil have to become fully TRIPS compliant?
- Does the “TRIPS-Doha-Paragraph 6-package” constitute a practically feasible solution for access to medicine in developing countries?
- Is the brand-name pharmaceutical industry the “bad guy”? What are the concerns of innovative companies? How are they responding to the health situation today? What has changed?

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<sup>4</sup> Tufts University, Centre of the Study of Drug Development.

<sup>5</sup> EFPIA stands for European Federation of Pharmaceutical Industries and Associations. It is an organization, which represents the research-based pharmaceutical industry operating in Europe.

<sup>6</sup> EGA, European Generic Medicines Association and IGPA, Generic Pharmaceutical Alliance.

- Which other possibilities are available for developing countries to obtain low-cost medicines?
- What is the future tendency?

Affordable drugs certainly represent a major and crucial element when aiming to provide global access to medicine. However, solving this issue alone is not enough to solve the problem because the reason for lack of access depends on several other factors, such as *inter alia* sustainable health care, education and enhanced infrastructure. Assessing and addressing these factors requires profound and extensive research, which the scope of this thesis does not allow.

Discussions about brand-name pharmaceuticals and generics often involve price comparisons. At first I intended to conduct a minor study in this area since I was of the opinion that such a study might be required in order to see whether innovative drug companies in fact have possibilities to lower the prices to the levels of generic drugs prices. However, I soon discovered that such a study would involve assessment and clarification of various comparison methods, which I estimated to require as much space and time as major parts of this thesis. Thus, the price list established by the WHO had to suffice as basic data.

In the part where developing country issues are discussed, I have chosen to dedicate a large section to presenting the situation in Thailand and refrained from conducting a comparative study involving other countries. The reason was that I wanted to carry out an in-depth study instead of making a more brief comparison. Another reason was that it seemed appropriate due to my staying in Thailand at the time of writing, as I had enhanced chances of accessing relevant material. I have however also mentioned India in another part of the thesis in connection with discussions about IPR.

Unfortunately, there has not been much space for a deeper discussion of the situation with generic companies. They are however mentioned in parts of the thesis.

## MATERIAL

Because a vast range of both older and most updated information as publications, articles, press releases, cases and legal texts can conveniently be reached on the Internet, it has become the main source of material for this thesis.

Frequently visited websites were *inter alia* those of WTO, MSF, HealthGap and CPTech

The websites of the US government, the European commission, PhRMA, EFPIA and various pharmaceutical companies provided material representing the views and policy of the innovative pharmaceutical industry and industrialized countries where these companies are mainly situated. Opposite views were gathered from the websites of developing countries and several NGO:s and health organizations.

Sources from the literature in this thesis are scarce, which has its explanation in the subject's novel character. Therefore, major portions of the thesis required the most recent materials, which were available only on the Internet. The use of literature has been limited to those parts concerning more general issues such as the WTO, TRIPS and parallel import and a section concerning India. Another reason for the sparing use of literature was that I was at the time of writing an intern in Thailand, where I did not have the possibility to access such material.

Instead I tried to exploit the situation by taking contact with health officials and the director of the NGO, Health Gap in Thailand, Mr. Nimit Udomkiat, in order to obtain some materials. Unfortunately, all materials were only available in Thai, a language in which I do not have good reading skills.

Due to my internship at the Swedish embassy, I also had the great opportunity to attend EU- and UN-seminars that not only provided me with information, but also gave me real-life insights into the debates as well as the opportunity to personally discuss issues with representatives of the pharmaceutical industry and WHO officials.

## OUTLINE

The reasoning behind the outline was to apply a model of logical order to the presentation of facts throughout this report.

This thesis can be seen as consisting of four parts;

The first and largest part, comprising three chapters, gives the background for the understanding of the contemporary international public health debate. Primarily, this part consists of an introduction of relevant parts of the TRIPS Agreement and the TRIPS related documents concerning health issues that followed. Continuing with a comparative overview of the currently available mechanisms of accessing generic medicines, this part ends with a presentation of actions taken by countries as a result of the recently achieved consensus of 30 August in 2003.

The second part aims to envisage the economical aspects, namely how to finance low-cost pharmaceuticals in developing countries. Here, I also take the opportunity to present the views of innovative pharmaceutical companies. The last part, presenting the various funds organizations might have been unnecessary extensive, but I feel it is still of great interest.

The third part deals with developing country issues. It begins with an in-depth presentation of the situation of accessing medicines in a developing country, which has generic manufacturing capacity for exportation. The country chosen for consideration is Thailand, because of the reason mentioned in the previous. This presentation will give the reader insight of the following:

- the practical ability of a TRIPS-developing country to make use of the TRIPS transitional period to cope with access problems;

- the impact of the introduction of enforced IPR legislation on the economical development and medical prices;
- the effects that could be observed from the introduction of generic drugs;
- the status of the situation today, after the consensus of Doha and Paragraph 6 Agreement.

This part continues and ends with assessment of other options for developing countries to access affordable medicines. The questions discussed are whether developing countries should refrain from introducing IPR and whether they should practice parallel import.

The final part, which is altogether dedicated to my own thoughts and ideas, consists of analyses and final conclusion. Here I express my thoughts on those parts of the thesis I have tried to present in an objective manner. Thereby I attempt to produce suggestions for further steps that can be taken from here and present and my thoughts about future trends and developments.

# 1 Background

## 1.1 The world situation

The global health problems have in the last decades evolved into epidemic and pandemic crises. Lack of medicine for poor people has resulted in furious acceleration of the spreading of HIV/AIDS, malaria, infectious diseases and tuberculosis (TB), to mention some examples. Not so long ago, TB was a rare disease in modern society. Because of its character as sub-disease to HIV/AIDS and because medicines were unavailable for poor populations, the disease now ravages once again. The World Health Organisation (WHO) produced reports that showed that half of all deaths in the developing countries are caused by HIV/AIDS, TB and malaria. Today, 40 million people around the world are HIV-positive and the death rates are certainly intimidating – just in 2003, 3 million people died of AIDS and reflected in other terms, that makes 8000 victims per day<sup>7</sup>. It is estimated by the WHO that around the world, one child dies every 30<sup>th</sup> second from malaria; that TB kills 2 million people each year, and that it is predicted that between the years 2002 – 2020, approximately 1 billion people will be infected. All these figures are difficult to really comprehend, but they show that providing these people with medical assistance is a matter of extreme urgency. And yes, cures for these diseases are available<sup>8</sup> – but for the poor countries, in which the diseases strike the hardest, this lifeline appears to be far out of reach. Since the first marketing of antiretroviral drugs (ARV) almost ten years ago, 99% of those people, which are able to access them live in the developed countries. The fact is that developing countries represent only 8% of all drug sales in the world. Ten million children under the age of five die yearly and 80% of them could have been saved if they had had access to essential medicines<sup>9</sup>. These are the diseases that have been announced to be of top priority, but there are yet numerous other severe diseases, which ravage rampantly in the developing countries where sanitary conditions are poor. Also diseases that earlier had been considered as “rich-country diseases” now appear in developing countries, as e.g. diabetes. In other words, medical aid should not just be limited to the top-listed diseases, although these are the most critical, which should be dealt with first.

According to the WHO<sup>10</sup>, access to essential drugs depends on several *criteria*, such as rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems. Many countries have, however, expressly declared that lack of access to low-cost medicines is the biggest problem. The high pharmaceutical prices are consequences of patent protection, which on the other hand is needed as incentives for pharmaceutical companies to engage in costly and time-consuming research. The situation thus appears to be caught in an evil circle: in order to obtain new lifesaving medicines, patent protection is needed, something which however raises the prices; at the

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<sup>7</sup> UNAIDS website – [www.unaids.org](http://www.unaids.org) → “Of special interest” → “AIDS epidemic update 2003”

<sup>8</sup> Actually, there are no medicines that can cure AIDS; however, there are effective anti-retroviral drugs (ARV) that slow down the development of AIDS on HIV-infected people, thus allowing them a somewhat sustainable existence.

<sup>9</sup> Velasquez, G – *Drugs should be a common good – Unhealthy profits*, Le monde diplomatique, <http://mondediplo.com>

<sup>10</sup> Globalization, TRIPS and access to pharmaceuticals, WHO Policy Perspectives on Medicines, No. 3 March 2001 World Health Organization Geneva, page 5

same time, people die because they cannot afford the high medical costs. However, there are some possible solutions to this problem, of which one is that by making use of generic manufacturers, which can offer drugs with the same active ingredients<sup>11</sup> for one tenth of the brand name price. This could be possible by using compulsory licenses in cases where voluntary licenses cannot be obtained. But how is this going to work out for the pharmaceutical companies? Does this not undermine the meaning of IP-protection? These questions have been the subject of extensive assessments and negotiations by the World Trade Organisation (WTO) in its special Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).

## 1.2 The WTO

The WTO is an international trade organization that acts as a forum where Member countries negotiate and elaborate different trade-related agreements. Its objective is “to help trade flow smoothly, freely, fairly and predictably”<sup>12</sup>. Some of the other tasks are administering trade agreements, reviewing national trade policies, assisting developing countries in trade policy issues and settling disputes.

In 1995, the WTO became successor to the former international trade organization GATT<sup>13</sup>, and has now nearly 150 Member countries. Its complex is the result of several negotiations (called rounds) under the GATT-period. Each particular round involved a certain trade aspect and at the final round in 1986-94, called the Uruguay round, the WTO was created.

Member countries are obliged to apply the WTO rules, called agreements, and except for some few plurilateral agreements, they cannot chose to be party to only some agreements, but not others. The rationale of WTO:s trading system, which are ***non-discrimination, freer trade, predictability and fair competition***, imply that Member countries can expect that their exported goods will be treated without discrimination and consistently with reached agreements, and that they are as well obliged to give the same treatment towards imported goods from other countries.

The WTO-agreements include six main areas. Of interest for this study are the agreements on intellectual property and dispute settlement, which will now be further examined.

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<sup>11</sup> This is the bulk drug substance in the finished pharmaceutical product. The manufacturing of active ingredients is located to some few producers who sell the substance to different pharmaceutical companies, formulating it to finished pharmaceutical products.

<sup>12</sup> The WTO homepage: [www.wto.org](http://www.wto.org) → ”The WTO in brief” → ”The organisation”

<sup>13</sup> General Agreement on Trade and Tariffs, founded in 1947

## 1.3 The TRIPS Agreement

### 1.3.1 Objectives:

The common vision of achieving a healthy economy is to allow the formation of a competitive and free market. Intellectual property rights, which grant the right holder the right to prevent others from using or making his creation, clearly impose on the general principle of free market. Nevertheless, granting individual creators such exclusive rights is commonly considered to be the prime incentive, which is needed to promote the general public welfare. Innovation and R&D have been shown to be pivotal components to the advancement in national economies<sup>14</sup>.

The objective of TRIPS is to find the proper balance between encouraging researchers so that new inventions can be obtained, and allowing free competition and public welfare. Obviously, this is a delicate and difficult task as the two interests conflict with each other. The instrument for this purpose comprises the carefully elaborated legal texts of the IPR, which allow flexibility in the various upcoming situations.

### 1.3.2 Basic features of TRIPS patent regulations

The right conferred on a patent owner is, with some exceptions, the right to legally prohibit any unauthorized use of the patented invention. As stated in art. 28, this includes acts of making, using, offering for sale, selling or importing the patented product, and products directly obtained from the patented process. Normally, any invention - whether it is a product or a process - can be granted a patent when the basic criteria are fulfilled, namely: novelty, inventive step and industrial applicability, art. 27.1. Nevertheless, some inventions are considered as being inappropriate to patent, and are thus exempted from patentability, article 27.2-3. These three cases are:

- When the commercial exploitation of the invention could prejudice ordre public, or morality, including human, animal or plant life, health or environment.
- Diagnostic, surgical and surgical methods for the treatment of humans or animals
- Certain plants or animal inventions

TRIPS requires a patent protection period of a minimum of 20 years, starting from the filing date, art. 33. However, pharmaceutical products are often granted extension beyond the 20-year period, since they require time-consuming marketing approval procedures, which extremely delay their introduction on the market.

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<sup>14</sup> It is however controversial whether this applies to poorer developing countries, which yet have paramount economical difficulties to tackle.



### 1.3.3 TRIPS and pharmaceuticals

What impact does TRIPS have on the pharmaceutical sector? Firstly, it must be noted that TRIPS was originally written by developed countries and was therefore highly adapted to the standards in those countries. Hence its application, particularly in the pharmaceutical sector, is not always appropriate for the conditions in developing countries. Before TRIPS, over 40 countries did not have any patent protection on pharmaceuticals and many countries had only process- and not product-patents. Further, the duration of the protection period was in many countries much less than 20 years<sup>15</sup>. To a certain extent, TRIPS recognizes this issue and consequently provides special transitional provisions for developing and least developed countries (LDCs)<sup>16</sup>. Still, many other developing countries have to deal with the protection requirements, which can impede the introduction of generic drugs that have much lower prices than brand name pharmaceuticals. TRIPS therefore provides exemption provisions that theoretically should suffice to open the door to cheap (generic) pharmaceuticals, as shall be presented in the following.

#### 1.3.3.1 Exemptions of importance for access to pharmaceuticals

##### PRINCIPLES

TRIPS contains provisions that expressly concern health issues. The preamble, stating the principles of TRIPS, art. 8.1., allows Member countries to formulate or amend their laws in a manner that protects public health. The considerations for health matters are further outlined in the **exemption from patentability**, as mentioned above, art. 27.2-3.

##### COMPULSORY LICENSING

The provision that has been most widely debated in the pharmaceutical discussions is, however, the one concerning compulsory licensing, art. 31, defined as “Other Use Without Authorization of the Right Holder<sup>17</sup>”. Under certain circumstances, the government of a Member State is hereby capable of making use of a patented invention or authorizing the right to third persons without the consent of the patent owner. Situations in which such authorization can be justified can be segmented into two categories - the ***national emergency-case (31.b)*** and the ***anti-competitive practices-case (31.k)***. If read properly and with conformity to the principles of TRIPS, these two paragraphs only imply the possible grounds of compulsory licensing, and do not in anyway constitute an exhaustive list of grounds<sup>18</sup>, as occasionally has been held by some industrialized countries. During the TRIPS negotiations, the parties weighed the options of either setting specific conditions for the grant or defining cases under which a license may be granted. Finally, the decision fell on the first option and it was determined that strict rules of precaution would be applied in combination. This interpretation was later confirmed in the Doha Declaration on

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<sup>15</sup> Globalization, TRIPS and access to pharmaceuticals, see note 10 supra, p. 2

<sup>16</sup> See further below in 1.3.3.4

<sup>17</sup> This term allows a broader application than just compulsory license, as it also comprehends situations of non-voluntary use by governments for its own purposes, *TRIPS and pharmaceutical patents* – WTO Fact Sheet, September 2003, p. 4

<sup>18</sup> Correa, C.M., *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, University of Buenos Aires, June 2002

the demand of developing countries, and a clarifying provision stated that each Member had the right to determine the grounds for issuance of compulsory licenses<sup>19</sup>.

Art. 31 (b) recognizes cases of national emergency or extreme urgency or public non-commercial use by the government. Products derived from compulsory licenses issued under this provision are subject to export restrictions, meaning that a predominant part of such production is due to be consumed in the issuing country, art. 31.f)<sup>20</sup>

Art. 31.k) sets out to remedy anti-competitive practices and it thus allows compulsory licensing when such a situation has arisen. The special feature of this provision is that it is not constrained with the export limitations; generics produced under this provision can thus be exported to an unlimited amount. However, the provision requires that the decision of the presence of an anti-competitive situation had been determined after judicial or administrative process. Because developing countries have been very uncertain about how broadly the provision could be interpreted, this requirement has caused a very restricted use of this option to issue compulsory licenses<sup>21</sup>.

Since compulsory licensing constitutes pivotal infringement of the legitimate rights of the patent holder, the use of such extreme measures has to be carefully conducted. As determined by the TRIPS negotiators and with the view of preventing abuse of the mechanism, a number of conditions must be fulfilled when using compulsory licensing. Prior the grant, the potential user is obliged to have made serious efforts to obtain a voluntary license. However, in emergency cases, etc., this requirement can be waived, but the patent holder has to be notified in reasonable time, art. 31 (b) and (k). Further, the ownership of the patent remains unaffected by the compulsory licensing and the patent holder must be paid an adequate compensation, art. 31(h). Notable is also that authorization must be non-exclusive, 31(d).

## USE FOR RESEARCH WITHOUT THE AUTHORIZATION OF THE RIGHT HOLDER

Another exemption rule of importance for pharmaceutical issues is the so-called “**Bolar**” provision in art. 30<sup>22</sup>. In a WTO dispute settlement, adopted on 7 April 2000, the dispute settlement panel said Canadian law was in conformity with the TRIPS Agreement in

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<sup>19</sup> Doha Declaration, art. 5(b) and 5 (c). The declaration will be presented and explained below in chapter 2

<sup>20</sup> In practice, this means that a generic producer authorized under article 31.b) is allowed to export only less than 49 percent of the production. Naturally this regulation sets out to prevent abusive use of the patent while considering public health interests. Nevertheless, many NGO:s, including the WHO claim this to be discouraging potential generic producers and thus restricting the emergence of a healthy variety of generic pharmaceuticals.

<sup>21</sup> An interesting case in this regard is however the pending South African case, Treatment Action Campaign & others vs. GlaxoSmithKlein South Africa & Boehringer Ingelheim in October 17<sup>th</sup> 2003, where the South African Competition Commission allowed compulsory licenses to generic producers after it had found that both pharmaceutical companies had charged excessive prices for their patented ARV-medicines and unlawfully refused to issue voluntary licenses; thus unreasonably restricted production of these medicines. Although the decisions have been appealed to the Competition Tribunal, they have already caused positive reactions from GSK as it lowered the prices for some essential drugs. See Health Gap, 17 Oct. 2003, [www.healthgap.org](http://www.healthgap.org) → Patents and medicine → Statements and Papers

<sup>22</sup> The name derives from the case Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Federal Circuit 1984). In the case, the Court established that competitor’s use of a patented drug for testing in order to obtain FDA approval once the patent expired was an act of infringement. The case was later overturned by *Canada Pharmaceuticals*.

allowing manufacturers to use a patented invention for research and testing without the permission of the patent owner<sup>23</sup>. In practice, this means that generic producers are allowed to study a patented pharmaceutical product or process and even obtain market approval during the protection period in order to make an immediate market introduction of the generic version the very day the patent expires. However, the *Canada Pharmaceuticals* made clear that manufacturers were prohibited from producing generics and stockpile them while the patent was in force with the view to market them as soon as the patent expires.

### 1.3.3.2 Limitations

#### “DATA PROTECTION”

To obtain marketing approval for a medicine, its safety, quality and efficiency should be demonstrated by submitting data containing pre-clinical studies and clinical trials to the national regulatory authorities. The procedures for obtaining marketing approval require the conduct of elaborate and costly tests and trials, which take many years to carry out. Such test data and clinical trials are confidential. Obviously, companies that have conducted these tests have legitimate interests in keeping obtained data confidential in order to exploit them and retrieve vast investments made. This is being recognized by TRIPS which in art. 39.3 requires Members to provide protection against “unfair competition” for undisclosed test or other data.

The protection is of pivotal importance for pharmaceutical companies in the absence of a patent<sup>24</sup>. However, it is largely recognized that when the authorities already know the characteristics and effects of the product (due to the first registration), it is not rational, from the society's and economic point of view, to require a duplication of these costly tests to recreate existing information. If generics manufacturers are required to repeat long and costly testing, competition will be reduced because of time delays and because local companies in developing countries will not be able to afford such testing. Therefore, it is being recognized that after a certain time period, generic companies should be allowed to rely on such data in order to register a copy of the original product. The burning issue in this matter is therefore at what point of time undisclosed data can be used by generic companies to demonstrate the copied products' bio-equivalency. The answer to this depends on the interpretation of “unfair commercial use”, which varies from one country to another. In April this year (2004), a large EU-ASEAN workshop on Pharmaceutical Data Protection was held in Bangkok where representatives of innovative pharmaceutical companies, generic manufacturers and various experts in the matter from EU and ASEAN countries debated on the question.

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<sup>23</sup> *Canada – Patent Protection for Pharmaceutical Products*, document WT/DS114/R, para. 7.20

<sup>24</sup> The reason for not having a patent can be several – lack of product patent protection in the marketing country, lack of some of the ground criteria for granting a patent, or decisions based on economical market strategy by the pharmaceutical company itself.

## “MAILBOX”-RULES

At the time of entry into force of the WTO in 1995, many developing countries recognized only process patents for pharmaceutical inventions, which purpose was to facilitate access to cheap medicine. Obviously, this was in conflict with the regulations of TRIPS, and the compromise solution reached was to allow these countries to keep the distinction until 2005 under certain conditions. These conditions were to provide a system whereby applications for patents for pharmaceutical inventions can be filed (thereof the name “mail-box”). When the transition period ends in 2005, these applications will have to be examined on the basis of the date of filing and if a patent has been granted, the protection period will start from this date, art. 70.8. The intention of having the mail-box provision is to obtain a priority date, as the assessment of the criteria “newness” is based on the state of technology at the time of filing. Further, if the product that is subject to the patent application is given marketing approval during the transition period, the Member country is obliged to grant that product exclusive marketing rights for five years or until a product patent decision has been taken, whichever comes first, art.70.9<sup>25</sup>.

### 1.3.3.3 Parallel trade and the exhaustion theory

Parallel import is the term used for situations where patented products<sup>26</sup> that have been put on the market with the authorization of the right holder are being imported from one country to another without the patent holder’s consent. Hence, such trade does not concern trade with generic or counterfeit products, but rather trade of brand name products through distribution channels other than those being controlled by the right holder. Because the price settings vary in different countries, the situation opens up attractive opportunities for unauthorized importers to gain significant profits when a product is imported from a low-price nation and sold in a high-price nation. Other beneficiaries might be the governments of countries wishing to lower their medical expenses by importing the same medicines for lower prices compared to those being charged on the domestic market.

It is generally agreed that when protecting the right holder’s interest in regaining outlaid investments, there should be a balance to the interests of having free competition market, meaning that the monopoly of the right holder should not exceed what is strictly necessary to provide an incentive to invent. The “**exhaustion theory**” therefore recognizes that once the right holder has commercialized the protected product on the market and thus gained profits and recovered lost investments, the exclusive rights of controlling the distribution should be exhausted. There are two concepts of the exhaustion theory, which determine the extent of the right holder’s chances to exclusively exploit the invention. **International exhaustion theory** gives the patent holder only one opportunity to profit from his invention as, once put on the market anywhere in the world, the patented product can be freely imported to another country where the product exists on the market. The reasoning is that the right holder has enjoyed the opportunity of first sale and is presumed to have obtained sufficient benefits to pursue innovative efforts. A more narrow interpretation of the term “exhaustion” is reflected in the **national exhaustion or territorial exhaustion theory** wherein distribution control of the right holder is exhausted only within a country

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<sup>25</sup> Gervais, D., *The TRIPS Agreement – Drafting History and Analysis, Second Edition*, (Sweet & Maxwell, London 2003) pp. 365

<sup>26</sup> Or other IP protected products.

or certain economic border, e.g. the EU. Any unauthorized distribution from sources outside the territory is thus prohibited.

The question whether to allow parallel trade was subject to intensive discussions and negotiations at the Uruguay Round as TRIPS was being established. Some WTO Members, including the US and Switzerland argued in favor of the national exhaustion doctrine, while other Members as Australia, Brazil, Hong Kong, India and New Zealand contended international exhaustion, or at least, the freedom for each WTO Member to decide<sup>27</sup>. The solution was to exclude the issue of exhaustion from the dispute settlement procedures in the sense that international exhaustion cannot be invoked before a panel as a direct violation of TRIPS, except for cases where the principle of least favored nation has been infringed<sup>28</sup>. Although some countries argued that national exhaustion could be concluded from the Berne Convention, which was incorporated into TRIPS, several opponent nations maintained that in the absence of expressed obligation, they remained free to apply the doctrine that suited them<sup>29</sup>. The common view is therefore that TRIPS leaves it up to Members to adopt the exhaustion theory as they consider appropriate for their own jurisdiction<sup>30</sup>.

The issues of parallel import and exhaustion of rights are of prominent importance for discussions about access to medicine. If countries recognize the international exhaustion theory, there are substantial risks that cheap pharmaceuticals will be diverted from low-price developing countries to industrialized countries. This is one of the key factors in the resistance of pharmaceutical companies to the idea of having differential pricing for developing countries.<sup>31</sup>

#### 1.3.3.4 Transitional period for developing countries

TRIPS provides special transitional arrangements for developing countries and LDCs, which are entitled to an additional period of implementing the agreement beyond the one year limit that applies to all Members<sup>32</sup>.

A transitional period of five years from the entry into force of the agreement is granted not only to developing countries, but also to any other country “in process of transformation from a centrally planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations”<sup>33</sup>. Interesting in this sense is that each Member country can freely determine for itself whether it belongs to the category of “developing country”<sup>34</sup>.

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<sup>27</sup> Gervais, see note 25 supra, p. 112

<sup>28</sup> TRIPS art. 6

<sup>29</sup> Gervais, note 25 supra, p. 113

<sup>30</sup> Bale, Harvey E. Junior, *The conflict between parallel trade and product access and innovation: the case of pharmaceuticals*, Journal of International Economic Law (1998) 637-653, Oxford University Press. Available at: [http://www3.oup.co.uk/jielaw/hdb/Volume\\_01/Issue\\_04/pdf/010637.pdf](http://www3.oup.co.uk/jielaw/hdb/Volume_01/Issue_04/pdf/010637.pdf)

<sup>31</sup> The issue is further discussed below in 5.3

<sup>32</sup> See art. 65-66.

<sup>33</sup> Art. 65.3

<sup>34</sup> See WTO website

In addition, developing countries, which are obliged to introduce product patent protection in areas of technology that previously lacked or had little protection in their jurisdiction, are allowed to postpone the full implementation for another five years. This special exemption is subject to the “mail-box”-rule, mentioned previously in 1.3.3.2. The provisions has a pivotal impact on the supply of generics because major generic manufacturing countries such as India and Brazil can apply these provisions and thus wait until 2005 to become fully TRIPS-compliant. As a response to the special needs of LDCs<sup>35</sup>, the latest date of implementation was in this case set to be 2006. This date was later prolonged with respect to pharmaceutical products, to 2016 in the Doha Declaration on Public Health<sup>36</sup>.

## 1.4 Dispute settlement

As under GATT, the WTO provides dispute settlement processes for disputes occurring between Member States concerning any of the WTO's agreements. The mechanism constitutes one of the most important instruments of the WTO, as it provides enforcement and predictability of the agreement. Disagreements may concern implementation of the provisions or Member's adoption of trade policies, legal texts or other actions that another Member finds being violating, or failure to live up to the WTO agreements. Any other Member state can declare their interest and join the case. The specific rules are set out in a special agreement – the Understanding of Dispute Settlement (DSU)<sup>37</sup>, which aims at settling disputes as much as possible through consultations and mediation and in an equitable, fast and effective manner.

The "court", called **Dispute Settlement Body (DSB)**<sup>38</sup>, establishes a panel of experts, which assesses the information received by the parties. The panel report is then adopted (or rejected) by the DSB. Consultation and mediation are essential elements throughout the procedures. An extraordinary feature of the DSU is that the panel report is automatically adopted by the DSB, unless there is a *consensus to the contrary*. This means that an unsatisfied Member has to persuade every Member Country in order to have the report rejected, which naturally is very difficult.

In order to render the rulings effective, DSU provide enforcement measures, such as trade sanctions, that can be applied against any party which does not comply with the rulings.

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<sup>35</sup> Which however in this case, the determination is based on the UN list of “least developed countries”

<sup>36</sup> See below in chapter 2.

<sup>37</sup> The agreement can be found in Annex 2 of the WTO Agreement.

<sup>38</sup> Which in fact is in essential the same as General Council, hence consisting of all Member Countries.

# 2 The Doha Declaration

## 2.1 Background

For many developing countries, which exempted pharmaceuticals from patentability before adopting TRIPS, the implementation of TRIPS compliant regulations implied considerable restrictions of the supply of inexpensive generic drugs. Aiming to alleviate the impact of the new restrictions, TRIPS thus provided transition provisions, and more importantly, flexibilities that allowed Members to form their own national protection regulations, as the situation varies from one country to another. Prominent among these flexibilities was the freedom to determine the rules of compulsory licensing within the frames set out by TRIPS. Nevertheless, many developing countries were soon facing impediments when trying to implement TRIPS compatible measures in order to manage paramount health crises. Many of the major pharmaceutical companies were US-based, represented by PhRMA<sup>39</sup>, and attempting to protect their interests, they approached the US government for assistance<sup>40</sup>. The latter responded by imposing trade sanctions<sup>41</sup> on countries that were perceived as threatening the interests of American drug companies<sup>42</sup>.

Given the overall spreading health problems, in particular HIV/AIDS crises in sub-Saharan African countries, and the attitude of industrialized countries with strong pharmaceutical industries, developing countries increasingly felt that interests of protecting IPR were prioritized over essential public health objectives. The situation culminated in the turn of the millennium, when 39 pharmaceutical companies challenged the South African to court due to the adoption of a South African Act, allowing TRIPS compatible compulsory licensing and parallel import as an action to fight HIV/AIDS<sup>43, 44</sup>. On the initiative of the African Group, supported by numerous developing countries<sup>45</sup>, the issue of TRIPS and public health was brought up at the imminent WTO Ministerial Conference in Doha, Qatar, 2001. Developing countries had put enormous efforts for the WTO to bring forth a text of statement, and finally, in November 2001, the Declaration on TRIPS and Public Health was adopted.

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<sup>39</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) is an organization, representing the leading research-based pharmaceutical and biotechnology companies in the United States.

<sup>40</sup> Submissions to the Office of the United States Trade Representative (USTR) and The National Trade Estimate Report on Foreign Trade Barriers (NTE) in 1999/2000 only, covered: 9 countries and trade regions in the Americas, 10 countries in Asia-Pacific, 9 countries in Europe, 11 countries in the Middle-East, 2 countries in South Asia and 4 countries in Africa. Excerpts on the submission text for each country can be found on: <http://www.cptech.org/ip/health/phrma/nte-99/nte.html>

<sup>41</sup> Already in 1988, the "Special 301" provision was adopted, empowering the Office of the United States Trade Representative (USTR) the right to impose sanctions on countries with weak patent laws. Even before TRIPS, the provision was frequently used against countries like e.g. Brazil, India and Thailand, as these countries had generic manufacturing industries.

<sup>42</sup> Besides Brazil, India and Thailand, other "threatening" countries were e.g. Egypt, Argentina, Vietnam and the Dominican Republic

<sup>43</sup> Text of the law-suit: The High Court of South Africa (Transvaal Provincial Division), Case number: 4183/98. Can be found on: [www.cptech.org/ip/health/sa/pharmasuit.html](http://www.cptech.org/ip/health/sa/pharmasuit.html)

<sup>44</sup> After enormous international pressure, the pharmaceutical companies dropped their suit on April 19, 2001

<sup>45</sup> Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela. See the submission, IP/C/W/296

## 2.2 The Declaration

It is worth mentioning here that the Doha Declaration does not have the property of a standing agreement – it is a clarification of TRIPS. Although developing countries had to relent to some compromises, the most pivotal points were included in the final text. At the adoption, the declaration represented a historical benchmark and a great victory for poor countries as it clearly defines the rights to protect public health as provided by TRIPS. The key essence of the declaration is the establishment that TRIPS supports measures taken by Members to protect public health; in this view, Members are free to fully apply all flexibilities provided by TRIPS, including compulsory licensing. Pivotal in this essence is that each Member is ensured the right to determine both the circumstances as well as the grounds for authorizing compulsory in their territory.

The Declaration recognizes that, although important for developing new medicines, IP-protection does affect drug prices. It continues by stating that TRIPS should be interpreted and implemented in a manner supportive to health issues, and refers specifically to the promotion of global access to medicines. Furthermore, Members are asserted the freedom to adopt their own exhaustion theory<sup>46</sup> – they are in others words free to use parallel import. The Declaration also admits an extended transitional period for LDCs until 2016.

Even though the declaration may have removed many uncertainties, it left behind a crucial question; how will the poorest countries with insufficient or no local manufacturing capacity be able obtain low-priced medicine with respect to the restricted export of generic drugs produced under compulsory license<sup>47</sup>?

The underlying problem is that many developing countries do not have any capacity to produce their own medicine, as this would require both economical and technological capability as well as and large markets. Not many countries can produce both active ingredients and formulations, and only very few have the capability to research and development. Today, countries like India applying the “mail-box”-rule are able to supply poor countries with new versions of generic medicines without any export restrictions. However, as this possibility ends after the deadline in 2005, extreme difficulties for the poorest countries to acquire medicines at affordable prices is predicted. This issue is recognized in the Para. 6 of the Declaration, which urges for a rapid solution<sup>48</sup>.

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<sup>46</sup> Art. 5(d)

<sup>47</sup> See previously in 1.3.3.1 about TRIPS art. 31(f)

<sup>48</sup> For further reading, see the article about TRIPS, parallel trade, compulsory licensing and Doha Declaration by Lidgard, H-H, *”Löser immaterialrättskonsumtion och tvångslicenser aidsproblemen I världens fattigaste länder”*, Nordiskt ImmaterielltRättsskydd (NIR), 1/2004, pp.1-12



## 3 The Paragraph 6-Agreement

Solving the Para. 6-issue proved to be far more difficult than expected. Several suggestions were submitted, where the EC suggested amendments to art. 31(f) in order to insert an exception that removed the export restriction in certain cases, or an interpretation of art. 30 in a way to allow production for export to certain countries and under certain conditions<sup>49</sup>. Developing countries wished for similar amendments, however with less restriction, while the US proposed a moratorium whereby WTO Members would agree not to bring a WTO complaint against a country that exports medicines to a needing country. This solution came however with a long list of limitations, as *e.g.* application to the three major diseases only, and to countries lacking or having insufficient manufacturing capacity<sup>50</sup>. As negotiations were locked, the former Chairman of TRIPS Council, Perez Motta, suggested a compromised solution, which did not contain any limited list of diseases, but restricted export to countries that had no or insufficient manufacturing capacity. In end of 2002, having overrun several deadlines, WTO Members were prepared to reach a deal by adopting the Motta-text, but was blocked by the US, which prompted on including the limitation of diseases.

In the end, the approaching Cancún Ministerial meeting in late 2003 put pressures on Members to find a solution because they wanted to avoid including the matter in the conference agenda. A team of negotiators was formed, consisting of country representatives of opposing interests<sup>51</sup>. Finally, on August 30, 2003, Members succeeded to reach a consensus. The compromise agreement allowed unlimited scope of diseases, however in return, several countries had to decline from using the possibilities to import generic drugs through the system of the agreement. The solution is however only a temporary waiver; the permanent amendment to the TRIPS was at the time scheduled for this year.

### 3.1 The agreement explained

The deal allows any Member country producing pharmaceuticals to export unlimited quantities of drugs to countries with insufficient or no domestic manufacturing capacity. Certain conditions must however be fulfilled in order to use the system. Firstly, the country in need of generic medicine – the importing country – must be determined as eligible. These include all LDCs, which are WTO Members<sup>52</sup> and any other Member that has notified the Council for TRIPS that it intends to use the system, and which is not one

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<sup>49</sup> See IP/C/W/339, 4 March 2002.

<sup>50</sup> See IP/C/W/304, 14 March 2002.

<sup>51</sup> These were: the US (representing developed countries with pharmaceutical industry), India and Brazil (representing countries with manufacturing capacity), and South Africa and Kenya (representing poor countries which need to import generic drugs).

<sup>52</sup> These include: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Democratic Republic of the Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda and Zambia.

of the countries that has declined from using the system<sup>53</sup>. It is understood that the notifying buyer-country does not need any approval to be able to import; however it has to explain and justify its decision in detail<sup>54</sup> and specify the name and estimated quantities of the pharmaceutical product it wishes to import. The notification also has to include a confirmation from the importing country that it has or intends to issue compulsory license for the products it wishes to import, if these are under patent protection in its country<sup>55</sup>. To clarify – this means that compulsory license is required in both countries (if the product is equally patented in the buyer-country). The system is reciprocal, as the exporting country is prohibited to issue compulsory licenses for more than the products and amounts specified by the importing country<sup>56</sup>. However, remuneration to the patent holder only has to be paid in the exporting country, taking in consideration the possible economic value of the use in the importing country.

One of the greatest concerns by allowing exportation of low-priced drugs to developing countries was the risk of the drugs being re-imported and sold in industrialized countries. The agreement tries to prevent this risk by imposing responsibility on both parties using the system. In this regard, importing country should take all reasonable measures to prevent diversion and re-importation to industrialized countries<sup>57</sup> while exporting country should require generic manufacturers to specify the products as being produced under the system by having specific labeling, packaging and/or special coloring and/or shaping. However, the latter is required only if the procedure is feasible and does not significantly impact on the prices<sup>58</sup>.

In addition, non-importing Members have to provide effective legal measures to prevent diversion of products under the system into their territory. The Council of TRIPS is entitled to make a review at the request of a Member claiming such measures being insufficient<sup>59</sup>.

The deal will permit WTO countries that are Members of regional trade associations to export compulsory licensed-drugs to their developing country neighbors<sup>60</sup>, even if those countries are not WTO Members<sup>61, 62</sup>.

The agreement will not have any prejudice on neither the TRIPS Agreement (save for art. 31 (f) and (h) ) or the Doha Declaration. In addition, it is still free for all Members to export the quantity of drugs, which is lesser than for the domestic supply, in accordance with TRIPS art. 31 (f)<sup>63</sup>.

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<sup>53</sup> The Decision of 30 August, art. 1 (b)

<sup>54</sup> Including *how* it has established the fact of incapacity.

<sup>55</sup> Art. 2 (a)

<sup>56</sup> Art. 2 (b)

<sup>57</sup> Considering the possible difficulties the requirement could impose on poor countries, art. 4 gives the opportunity to developing countries and LDCs to request for technical and financial cooperation from industrialized countries, which shall give it to them.

<sup>58</sup> Art. 2 b (ii)

<sup>59</sup> Art. 5

<sup>60</sup> Whether these drugs are imported or produced domestically.

<sup>61</sup> However, at least half of the members in that regional trade agreement have to be LDCs.

<sup>62</sup> Art. 6 (i)

<sup>63</sup> Thus using the old TRIPS system, which is less complicated.

Attached to the legal text of the decision is also the text of **General Council Chairperson's statement**, which often is perceived as a part of the agreement. According to the WTO, the purpose of the statement was to “provide comfort to those who feared that the decision might be abused and undermine the patent protection<sup>64</sup>”. Members are urged to use the system under the agreement “in good faith to protect public health”, and not as “an instrument to pursue industrial or commercial policy objectives<sup>65</sup>”. Further, the statement addresses the diversion problem and re-establishes that Members should apply all reasonable measures of prevention, adding that clear identification of the products also applies to active ingredients and products using those active ingredients. In this regard, the Chairperson incites producers to apply the attached “Best practices” guidelines, which are examples of anti-diversion procedures, developed by pharmaceutical companies<sup>66</sup>. Such procedures include *inter alia* different markings, shaping and coloring on the tablets, distinctive packaging and different trademark names. Another feature introduced by the statement involves the right of any Member to request a review, followed by appropriate action, by the TRIPS Council regarding the interpretation or implementation of the agreement. A Member may also address WTO bodies if it finds that the agreement has not been complied with.

### 3.2 The reactions

At the reaching of the comprise agreement, many of the WTO Members, including US, EU, India and Brazil welcomed the deal as a success. The positive reactions were, however not shared by everyone. For many developing countries, LDCs and activists that had put high expectations for the agreement to come as a rescue to the acute global health crises, the final outcome came as a great disappointment.

Many activists in both developed and developing countries considered the deal to be a step back from the victory in Doha and claimed the reason to be US threats- and promises-tactics. The US is further being to accused to have inserted clauses, creating new barriers, which undermine agreed patent exemptions.

Mainly, critics point out the following flaws:

The administrative procedures set out in the provisions are unnecessarily burdensome for developing countries as these in general already have difficulties with bureaucratic and undeveloped administrative systems. The deal forces importing nations to undertake comprehensive process of proving they cannot manufacture the drugs themselves, creating costly delays in the extremely urgent health need situation.

Because countries probably will have to issue compulsory licenses for every purchase, the system impedes rather than facilitates the process of urgently distributing medicines to countries in need of help. It is unclear if global procurement mechanisms, as those planned by WHO, also will have to apply compulsory licensing procedures for each country they

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<sup>64</sup> *The general council Chairperson's statement, 30 August 2003*, WTO news: 2003 NEWS ITEMS - Intellectual Property.

<sup>65</sup> The statement p. 1, part 2

<sup>66</sup> Here, by the dominating companies Bristol Myers Squibb, Novartis, GlaxoSmithKline, Merck and Pfizer.

will assist. Furthermore, the requirement of two compulsory licenses will impose additional delay and administrative difficulty to the procuring processes.

The possibility for other countries to require a WTO review of an importing country's decision to use the mechanism in addition with the onerous administrative procedures mentioned above, are condemned to deter poor nations from exploiting the system.

The deal also imposes constraints on the business practices of generic manufacturers. These constraints, not clear in advance, could hinder generic manufacturers from achieving large-scale production, resulting in higher drug prices. For example, allowing production only on a case-by-case basis and having requirements for differentiation which vary from country to country, could prove significant impediments for the generic manufacturers. In the long term, many generic companies could disappear, leaving the ground free for patent holder companies to set the prices. Furthermore, since generic producers naturally have to make profit in order to be willing to engage in their business, the agreement implanted more uncertainty and interpreting loopholes by stating that the system should not be an instrument to pursue industrial or commercial policy objectives.

Indeed, there are many possible barriers that could arise with the new system, but the fact is that the new system has not yet been employed and so it is unknown as of yet what barriers could actually arise. The assumption of health activists - that purchase and production will be allowed on case-by-case basis only - is not actually grounded in any of the wordings in the Agreement, and is in fact nothing more than a prediction of the worst-case scenario. It is also dubious whether generic companies will be much disturbed in their business practices by requiring different appearance of pills, as this is already a normal practice.

The WHO has expressed that the full impact of the deal will depend on how effectively it can be implemented in countries. Countries will also need to review the full range of medicines required from multiple suppliers when making the purchasing decision, if the agreement is going to reach its intended impact on public health. In this regard, the WHO will work closely with countries wishing to make use of the system and assist them to reach low price medicines.

### **3.3 Summary of available mechanisms for accessing generic medicines.**

Given the presented WTO solutions for global access to medicines through low-cost generic products, it now feels necessary to clarify and summarize the whole range of available mechanisms for accessing them.

Currently, there are now four international texts covering patent exemption for pharmaceuticals – the original TRIPS Agreement, the following Doha Declaration and the recent Paragraph 6 Agreement with the attached text of Chairman's Statement. However, it is important to take into consideration that national legal texts or concluded bilateral or regional trade agreements in the specific country may further limit the possibilities given in the international mechanisms.

Other possibilities for accessing generic medicines are naturally through countries where there is no patent protection on the product. These so-called “off-patent” countries include five different categories:

Non-WTO Members are for obvious reasons not limited by the patent protection set out in the TRIPS system (including the subsequent agreements). These countries are therefore in this regard free to produce, export and import generic drugs. However, national intellectual property regulations might impose limitations to these possibilities.

LDCs are granted exemption from introducing patent protection for pharmaceutical products and processes until 2016.

Some countries, such as Brazil, did not provide *any* patent protection in the pharmaceutical sector before becoming WTO Members; they are thus allowed to produce generic copies of medicines that were patented before the entering into force of the WTO regulations in 1995.

The same applies on countries like India, which only had patent protection for *pharmaceutical processes* and not for products, save that copies are not allowed if they involve a patented process. In addition, for post-1995 medicines the “mail-box” rule<sup>67</sup> applies and India may therefore legally make copies of pharmaceutical products until 2005/2006<sup>68</sup>

Other countries where the pharmaceutical company for one reason or another chooses not to file for patent are of course free to exploit the product.

Presented below is a table for over-viewing all mechanisms available for accessing generic medicines and the requirements for using them.

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<sup>67</sup> Presented previously in chapter 1.3.3.2

<sup>68</sup> This is however practically possible only with respect to inventions filed in the mail-box before 2000/2001 as that invention will be granted five years market exclusivity once given market approval.

Mechanism	Eligible importing countries	Compulsory license requirements	Procedure	Export restriction	Other comments
<p><b>WTO Paragraph 6 Agreement</b></p>	<p>WTO Members including all LDCs and countries with insufficient or no manufacturing capacity that is not on the list of voluntarily excluded countries.</p>	<p>Yes, in both importing and exporting country if the product is patented in both countries.</p> <p>In both cases efforts must have been made to obtain voluntary licenses.</p> <p>Compensation to the patent holder is required only in the exporting country.</p>	<p>The importing country has to:</p> <ul style="list-style-type: none"> <li>- notify the WTO that it wishes to use the system to import generic pharmaceuticals and specify product names and quantity,</li> <li>- assess and establish the situation of manufacturing incapacity and present this in its notification (not required if it concerns a LDC),</li> <li>- issue compulsory license,</li> <li>- take measures to prevent diversion.</li> </ul> <p>The exporting company has to:</p> <ul style="list-style-type: none"> <li>- obtain compulsory license,</li> <li>- distinct the product for being produced under the system; special packaging, labeling, shaping and coloring.</li> </ul>	<p>NO</p>	<p>The success of exploiting the system depends to great extent on the implementation into national laws in both importing and exporting countries.</p> <p>Another condition is that poor countries refrain from concluding bilateral agreements that exclude the possibilities of using of the system.</p>

Mechanism	Eligible importing countries	Compulsory license requirements	Procedure	Export restriction	Other comments
<p><b>TRIPS art. 31 k</b></p> <p>+</p> <p><b>Doha Declaration</b></p> <p>Anti-competitive measures</p>	All countries	<p>Yes, in the exporting country.</p> <p>In the case the product is patented in both countries, the requirement in the importing country depends on its national legislation on exhaustion rules.</p> <p>Efforts must have been made to obtain voluntary licenses.</p> <p>Compensation to the patent holder is required in each case.</p>	The issuance of compulsory license in the exporting country has to be preceded by a judicial or administrative decision stating that an anti-competitive situation is beforehand.	NO	Reference to the Doha Declaration is not necessary, but it provides developing countries more courage and resolve in evaluating whether an anti-competitive situation exists and, if so, issuing the appropriate compulsory licenses.
<p><b>TRIPS art. 31 b</b></p> <p>+</p> <p><b>Doha Declaration</b></p> <p>Cases of national emergency, extreme urgency, public non-commercial use and other cases to protect public health</p>	All countries	<p>Yes, in the exporting country.</p> <p>In the case the product is patented in both countries, the requirement in the importing country depends on its national legislation on exhaustion rules.</p> <p>In the cases of national emergency, extreme urgency or public non-commercial use, the obligatory attempt to obtain voluntary license may be waived. The patent holder must however be notified.</p> <p>Compensation to the patent holder is required in each case.</p>	Compulsory license can be issued whenever the government itself finds the country to be in a situation of national emergency or extreme urgency or wishes to use the invention for public and non-commercial purposes. However, these are only examples of possible uses, and the government is free to issue compulsory licenses in order to protect public health. This is re-established by the Doha Declaration.	YES, a predominant part of the production must be used for domestic consumption, meaning at least 51%.	Reference to the Doha Declaration is not necessary, but it removes interpretational ambiguities, providing developing countries more certainty in using the mechanism.

Mechanism	Eligible importing countries	Compulsory license requirements	Procedure	Export restriction	Other comments
<b>Purchase from a country with no pharmaceutical patent protection before entering the WTO. (i.e. Brazil)</b>	All countries	Non in the exporting country.  In the case the product is patented in the importing country, the requirement depends on its national legislation on exhaustion rules.		NO	Availability is restricted to pharmaceutical products patented before 1995.
<b>Purchase from a country with no pharmaceutical product patent protection before entering the WTO. (i.e. India)</b>	All countries	Non in the exporting country.  In the case the product is patented in the importing country, the requirement depends on its national legislation on exhaustion rules.		NO	Availability is restricted to pharmaceutical products not covered by any process patent or market exclusivity, according to the "mail-box" rule. Copies of "mail-box" products are allowed only to 2005/2006
<b>Purchase from a country where patent has not been filed, whether or not WTO Member.</b>	All countries	Non in the exporting country.  In the case the product is patented in the importing country, the requirement depends on its national legislation on exhaustion rules.		NO	
<b>Purchase from a non-WTO Member.</b>	All countries	The requirement depends on whether that country provides patent protection and if the product is patented there.		Depends on national regulations.	In general, non-WTO Members are poor countries. They are therefore not likely to provide any patent protection.



### 3.4 The situation post-paragraph 6-agreement

After the reaching of the Agreement, there were expectations that an amendment of the TRIPS could be ready by June this year. However, the process appears to still be controversy and Members have agreed to the Chairman's proposition to postpone the deadline until the end of March 2005<sup>69</sup>.

According to AIDS activists, significant conflicts over which countries that can qualify to use the Agreement emerged only a few weeks after the compromise<sup>70</sup>. The US view is a narrow interpretation of the term "insufficient manufacturing capacity", implicating that countries with some capacity of domestic production should be excluded from the possibility to import low-price generics. Developing countries have been induced to exclude themselves from making use of the Agreement although their manufacturing capacities are insufficient to gain lowest-priced drugs. One of these countries is the Philippines, which has been pressured not to import generics.

The EU commissioner Lamy, has however declared that he did not agree with the US on this point<sup>71</sup>. The conflict between the two biggest territories hosting inventive drug companies, strengthens the opinion of health activists that the deal was just an illusion of consensus because countries wished to clear off the issue before the Cancún Ministerial Conference.

At this point, it is yet too early to tell the full implication of the Para. 6-Agreement. However, certain countries have already started to show some reactions.

#### 3.4.1 The US FTAs

Subject to much attention and criticism from activists and health organizations are the US bilateral and regional free trade agreements (FTA), which have been concluded with several countries globally<sup>72</sup>. The FTA:s contain without exception IPR clauses, which in many cases provide stronger IP-protection than what is required by TRIPS (so-called TRIPS-plus provision) and remarkably many of the countries that have signed FTA:s are either countries with generic manufacturing capacities or countries dependent on generic drugs.

In return for slightly ameliorated trade agreements in the agriculture and textile industry and promises of financial aid, developing countries agree to introduce stronger IP-protection and give up their rights to protect public health, as established in the TRIPS, and in the recent Doha-declaration and Para. 6-Agreement.

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<sup>69</sup> *Quiet TRIPS Council focuses on Health, Biodiversity-related issues*, Bridges Weekly Trade News Digest, Vol. 8, No. 22, 23 June 2004. Available at: <http://www.ictsd.org/weekly/04-06-23/story3.htm>

<sup>70</sup> *Lamy and Zoellick clash over terms of new WTO medicines deal*, Health Gap Press release, September 13, 2003

<sup>71</sup> This statement was made during an NGO briefing on September 12, 2003

<sup>72</sup> These countries are the following: Australia, the CAFTA-countries: Costa Rica El Slavador, Guatemala, Honduras and Dominican Republic, Chile, Jordan, Morocco, Vietnam and Singapore.

Developing countries entering the deals are forced to prematurely introduce stronger IP protection and give up their right to use the TRIPS transitional period, something that critics contend to be of paramount importance for poor countries facing severe health crises.

Still today, after the signing of the Para. 6-Agreement, the US approach of seeking bilateral renouncement of TRIPS protections continues. Activists and health organizations contend that the US government is intentionally undermining the meaning and spirit of the Doha Declaration by selecting countries one by one after being forced to agree to the paragraph 6-agreement. The direct impact of this action is said to be remarkably restricted access to medicines in developing countries.

The recently concluded US – Singapore FTA, including *inter alia* terms, such as five years of data exclusivity, restricted use of compulsory licensing and possibility of blocking parallel import, is anticipated to serve as a model for FTA:s in the Asian-region<sup>73</sup>. On-going FTA negotiations appear in Thailand, Panama, the Andean countries (Bolivia, Colombia, Ecuador and Peru) and the countries of Southern African Custom Union, SACU (Botswana, Lesotho, Namibia, South Africa and Swaziland).

### **3.4.2 EU Anti-diversion regulation**

Hosting several of the largest pharmaceutical companies, the EU, along with many industrialized countries, has emphasized a similar policy as the US regarding low-priced generic drugs. The recent development has, however, been a turn to a more open approach.

The strongest indication for this approach is the adoption of the anti-diversion regulation in May, 2003<sup>74</sup>, which sets out to challenge diversion problems as low-priced drugs, intended for poor nations, enter the market of industrialized countries through parallel imports. The regulation gives a practical solution on how to provide poor countries with price-differentiated drugs at the same time as the original prices of the drugs are kept within the EU by providing the so-called “requirement list”, which will block drugs, intended for developing countries, from entering the EU-territory. Both original and generic pharmaceutical manufacturers are invited to introduce products they wish to export on the list, which will serve as a reference for custom authorities to take measures in the case of re-importation. Listed products will also bear a special logo, which will facilitate for customs to recognize them.

In order to be on the list, the price of the pharmaceutical product is required to be either 75% lower than the average “ex-factory” price in OECD countries, or at the production cost plus 15%. Products that can be distributed under the Regulation are limited to those related to the prevention, diagnosis and treatment of HIV/AIDS, TB and malaria. Furthermore, the system is applicable only for sales in certain developing countries, which comprises a total of 76 countries, including LDCs, countries with high HIV/AIDS-prevalence and countries with lowest per-capita income<sup>75</sup>.

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<sup>73</sup> See further in appendix 5, the terms of agreement for each country that have entered into FTAs.

<sup>74</sup> Council Regulation (EC) No. 953/2003 of 26 May 2003

<sup>75</sup> These countries are listed in Annex II of the Regulation

As pointed out by professor Lidgard, the necessity of the Regulation might be questionable, as the EU already applies a territorial exhaustion theory that prohibits parallel import of products from countries outside the community borders<sup>76</sup>. Nevertheless, at a time when there is an acute need for medicines to stop global pandemics and much dispute and confusion paralyse action, the EU initiative sets out clear and tangible rules of procedure, which might have effect in a substantial number of countries. As concluded by the professor: "...the Regulation makes perfect sense. It highlights a problem and reinforces a prohibition. There can be no doubt about the state of the law after the Regulation. General public is made aware and enforcing authorities must be prepared to take action".

The most important implication of the Regulation may however be the incitement to pharmaceutical companies to show more willingness and engagement in providing low-priced medicine to poor countries.

So far only one producer has taken the step of placing its products on the list. The application was filed by GSK in February 2004 and introduced on the list, seven ARVs at 25% of the current prices in Europe.

### **3.4.3 Canadian patent act**

Being one of the generic manufacturing nations with exporting capacity, Canada was the first country to initiate reforms in its national legislation to permit the supply of essential generic medicines to developing countries

The initiative received much positive attention from all over the world and created great expectations by health organizations and NGO:s. However, in spite of the positive start, the introduced government proposal, Bill C-56 of November 2003, was shown to contain several barriers to the production and delivery of low cost drugs. The most controversial of these was the "right of first refusal"-clause, permitting brand name drug companies to take over a contract that originally were concluded between generic drug companies and the purchaser. By doing this, the patent holder could thereby block compulsory licensing from being issued. Critics contend that generic manufacturers would soon be deterred from initiating negotiations, thus leaving the ground free for brand name drug companies to set the prices. This would severely impede medicines to reach poor people.

On May 14, 2004, the final text was amended (now under the name Bill C-9) in which the right of first refusal was removed, probably as a result of pressures from NGO-campaigns. Some barriers from the initial proposal had however remained, as the Bill introduced a short-list of pharmaceuticals permitted for production and countries that were eligible of using the system, and moreover - rigorous proceedings if any new drugs would be added to the list. Nevertheless, Bill C-9 finally allowed export of compulsory licensed pharmaceuticals to other developing countries than LDCs and WTO Members, although only in cases of "national emergency" or "circumstances of extreme urgency". A developing country is also qualified as importing country if it is eligible for "official

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<sup>76</sup> Lidgard, H-H., *Is there a legal solutions to the AIDS crises in developing countries? – A European viewpoint*, 2004, p. 16

development assistance”<sup>77</sup>.

Furthermore, the government resisted pressures to introduce limitations as exportation under emergency and urgency cases only to LDCs and eligible Members. It also permitted NGOs to act as a purchaser and contract directly with a Canadian generic manufacturer for use in another country<sup>78, 79</sup>.

The outcome of the Canadian initiative received mixed reactions by civil society organizations and health organizations. On the one hand, the legislation has been much criticized for containing several unnecessary barriers to the issuing of compulsory licenses, which was neither required by the WTO decision nor the TRIPS. According to Oxfam Canada, the limitation undermines the intention of the WTO agreement and sets a poor international precedent<sup>80</sup>.

On the other hand, only the initiative itself and the experiences of addressing the issues along the way could constitute a useful lesson for other countries and NGOs as they assay to implement the WTO decision of 30 August. The bill is scheduled to enter into force in late 2004. It remains thus to be seen, the effectiveness of the legislation to supply low-cost medicines in developing countries.

#### **3.4.4 Norwegian consultations on March 2004 to implement §6-agreement.**

Another country that has sought to amend its patent regulations is Norway, which has initiated consultations for the implementation of the Para. 6-Agreement into its patent regulations.

As the current Patent Act<sup>81</sup> requires compulsory licensed pharmaceuticals to be mainly supplying the domestic market<sup>82</sup>, a draft proposal suggesting the implementation was circulated for comments on January 16, 2004. Evaluation of the public consultation showed a widespread positivism to the proposal; in fact all commenting bodies supported such amendment, including The Association of Pharmaceutical Manufacturers<sup>83</sup>.

The unopposed draft regulation text is in comparison with the new Canadian patent act, considerably more generous, adopting the WTO decision generally word by word and adding all non-WTO Members as eligible importing countries on same conditions as Members.

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<sup>77</sup> As in the requirements of the Organization for Economic Cooperation and Development.

<sup>78</sup> In order to do this, the NGO must however receive permission from the government of the importing country in question; yet, the clause in whole should be seen as a substantial improvement compared with the former Bill C-56, which prohibited such deals.

<sup>79</sup> Canadian HIV/AIDS Legal Network, *Global Access to Treatment: Canada's Bill C-9 Compulsory Licensing of Pharmaceuticals for Export to Countries in Need – A synopsis of Bill C-9*, 30 June 2004

<sup>80</sup> *OxfamCanada welcomes affordable medicines law*, May 20, 2004. Available at: [www.oxfam.ca/news/AIDS\\_Drugs/Bill-C9-final.htm](http://www.oxfam.ca/news/AIDS_Drugs/Bill-C9-final.htm)

<sup>81</sup> As last amended on February 1, 2004

<sup>82</sup> In compliance with art. 31(f) of the TRIPS provisions.

<sup>83</sup> Comments were received from *inter alia*, the following institutions: The Ministry of Health, the Biotechnology Advisory Board, the Association of Pharmaceutical Manufacturers, Intellectual Property Law Association and the Patent Office.

### **3.4.5** **Zambian grant of compulsory licence**

Recently, on September 3, 2004, the government of Zambia has declared the AIDS epidemic a national emergency. The country is using TRIPS compliant measures to issue compulsory licenses for ARVs (patented by BMS and Boehringer Ingelheim) to local generic manufacturers<sup>84</sup>. The event is in particularly interesting as it might serve as a model for developing countries facing AIDS-crises.

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<sup>84</sup> See CPTech, <http://www.cptech.org/ip/health/c/zambia/>

# 4 Economical aspects – how to finance affordable drugs for developing countries

Financing of pharmaceuticals to developing countries calls for enormous amounts of money. The major actors in this aspect are the innovative pharmaceutical companies and fund organizations.

## 4.1 Pharmaceutical companies

### 4.1.1 Why is IP-protection important for the pharmaceutical industry?

The pharmaceutical industry is the sector relying most heavily on strong IPR. There are three main reasons for this:

- Research process of developing a new medicine require exorbitant and risky investments,
- The development of a new medicine takes very long time, much due to clinical trials and processes of authority approval,
- The production of medicines is cheap and in general easily copied.

As the candidate drug<sup>85</sup> eventually passes all the costly stages of trials and development, a demonstration of its safety and efficacy (clinical trials-based) has to be presented to regulatory authorities before being permitted to reach the market<sup>86</sup>. With respect to the first mentioned, a study<sup>87</sup> shows that the cost of bringing a new chemical or biological entity into the market has increased considerably within the last 10 years - 187 million Euros in 1991, compared to 895 million Euros in 2001. Of the candidate drugs, only 1 out of 10 actually reaches the market. Further, it is estimated that it takes in average 10 years from idea to the first marketing of the pharmaceutical product, meaning that the company has somewhat 10 years left of the patent term to retrieve its vast investments.

Comparing these facts with the situation of generics manufacturers, the study envisages that the respective cost of developing a single new medicine is less than 1 million Euros, and that it takes about 2-3 years to develop and register a bio-equivalent generic copy of the original drug. The level of risk for generic companies to develop a new product is also substantially lower as they can choose to produce only successful drugs.

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<sup>85</sup> Candidate drugs are drugs tested on humans.

<sup>86</sup> See previously in 1.3.3.2 – “Data protection”

<sup>87</sup> Di Masi J, Tufts University – Centre of the Study of Drug Development, 2001 and Efpia. Available at: [www.efpia.org/3\\_press/FMLgenericvsinnov.pdf](http://www.efpia.org/3_press/FMLgenericvsinnov.pdf)

## 4.1.2 Change of policies

Having the facts presented, it is not difficult to comprehend the protective attitude of the innovative pharmaceutical industry and why these companies are not so keen of licensing out the product of their hard work to generic manufacturers. Nevertheless, health advocates have constantly been arguing that the companies in any case do not gain any substantial income from sales in developing countries, as these cannot afford high prices. Consequently, pharmaceutical companies could without prejudice contribute much more to relief health problems in poor areas.

The argument is to some extent sustained by the industries' own figures. A study conducted by Astra Zeneca reveals that the global distribution of their sales is 50% in US and Canada, 20% in EU, 10% in Japan, 10% in Asia-Pacific and 10% in South America. This makes a total of 80% in developed countries<sup>88</sup>.

Increasing public awareness over health problems and lack of access to medicines for poor countries has consequently compelled pharmaceutical companies to new approaches. Today, most of the largest drug companies have in one way or another introduced philanthropy programs in developing countries, including *inter alia* differential pricing, donations and partnerships with governments and NGOs in developing countries<sup>89</sup>.

Although the initiatives are much commended, health advocates such as MSF, Oxfam and Global Aids Program contend that donation programs and time-limited funds do not comprise sustainable long-term solutions for solving the health problems. Considering that 40 million people die yearly due to preventable diseases, distributing medicines on a donation basis is not realistic. Instead, the solutions need to be found in the trade areas. The programs have also been criticized for delays and for protecting patent rights, causing the feeling that drug companies are trying to divert focus from the important issues of compulsory licensing while at the same time attracting good public relations<sup>90</sup>.

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<sup>88</sup> Walan, L., *Creation and Development of a Medicinal Product*, hand outs from Astra Zeneca at EU-ASEAN workshop on Data Protection (Pharmaceuticals), Bangkok, 29-30 April, 2004

<sup>89</sup> Examples of such programs are those provided by Pfizer, GlaxoSmithKline (GSK), Bristol Myers Squibb (BMS), each being producers to essential HIV/AIDS, TB and malarial medicines.

Pfizer has partnership programs with both governmental organizations and NGOs, donating medicines and providing education and training of health care workers. Of these, the prime example is its "Diflucan partnership program", treating opportunistic infections associated with HIV/AIDS. The program offers free treatments without time limits in 21 developing countries. In 2001, Pfizer founded a center in Uganda to train African doctors in administering the most advanced AIDS drugs available. See: [www.pfizer.com](http://www.pfizer.com)  
→ Access to medicines → Philanthropy programs and K.Vick: *Pfizer to train doctors in use of new medicine*, Washington Post Foreign Service, June 12, 2001. Available at: <http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&contentId=A52959-2001Jun11&notFound=true>

GSK offers non-for-profit prices of all of its ARV and anti-malarials to 63 LDCs in the sub-Saharan region and to all projects fully funded by Global Fund to Fight AIDS, TB and Malaria. In addition, it offers preferentially priced drugs in 56 countries. GSK is also engaged with partnership with several public health institutions in developing countries. See further: [www.gsk.com](http://www.gsk.com) Recently in 2003, a collaboration on drugs discovery and development was initiated between GSK and India's largest generic manufacturer, Ranbaxy.

BMS has introduced a "Four Point Program to fight HIV/AIDS in Africa", which *inter alia* supplies DDI and Stavudine.

<sup>90</sup> Boseley, S., Pratley N.: *In the time it takes you to read this article Pfizer will make \$250,000. So does it have a duty to provide cheap drugs to the poor?* The Guardian, April 24, 2003. Available at: <http://www.guardian.co.uk/g2/story/0,942281,00.html>

Apparently, drug companies are reluctant to license out their products to generic manufacturer, according to themselves, some of the reasons being that they have to be assured that the licensee will be able to supply safe quality products and protect them against diversion. Having their own programs, drug companies are assured of being able to control the product quality and diversion risks. The drug industry also point out that, 95% of the drugs listed on the WHO Essential Drugs List actually are not patent protected and reason that it is therefore misleading to claim IP protection to be a significant barrier to access in developing countries<sup>91</sup>. According to them, the real causes lie *inter alia* in undeveloped infrastructure, lack of literacy and trained medical staff. Undermining patent rights would have the fatal consequence of diminished R&D, which is crucial as diseases are increasingly becoming immune to existing treatments.

Despite the factual accurateness of the argument, the circumstance that most of the essential drugs are off patents does not display the real picture of patent barriers to medical access. As contended by the pharmaceutical industry, problems of disease immunity are augmenting; in the developing countries, much due to the fact that infected people only take cures partially as they cannot afford the whole treatment. The situation thus invokes the need of the newest, patented drugs. The argument is neither applicable on the crucial HIV/AIDS drugs, as these have been developed rather recently and are therefore still being patent protected.<sup>92</sup> Another specific problem is the fact that off-patent drugs are often granted patents for secondary inventions, as formulations, crystalline forms and isomers<sup>93</sup>. Although the product as such is no longer being patent protected, numerous patents may be developed around this secondary product. This may, in practice, prevent others (generic companies) from entering that particular market. An example of such a situation was the ddI-case in Thailand. In the case, ddI, owned by the US government was not under patent protection in Thailand. It was, however licensed to BMS, which used it to make new formulations, for which the company was granted patent in Thailand. As a consequence, the company obtained monopoly for ddI under several years, blocking generic manufacturers to produce lower priced ARVs containing the substance. Later, civil AIDS activists legally challenged BMS, accusing the company for applying anti-competitive practices<sup>94</sup>.

As frustrated health advocates pressure them for taking responsibility, drug firms feel that focus should be on global responsibility, where every part take their role; wealthy nations must give more, middle income countries should resist seeking the lowest prices intended for poor nations and developing countries need to show genuine engagement and take political actions.

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<sup>91</sup> *GlaxoSmithKline's contribution to fighting HIV/AIDS & improving healthcare in the developing world*, April 2004, p. 4

<sup>92</sup> Lidgard, H-H., see note 76 supra

<sup>93</sup> Isomers is an isomeric entity, defined by Webster's Revised Unabridged Dictionary as the following: **“Isomeric :** (...) having the same elements united in the same proportions by weight, and with the same molecular weight, but with a different structure or arrangement of the ultimate parts (...)

<sup>94</sup> See further about the case in chapter 5.3 below.



## 4.2 Funds organizations

In 2001, UN secretary General Kofi Annan and world health experts announced that US\$ 10.5 billion a year was needed to carry out massive prevention programs, reduce mother to child transmission and care for the 40 million people living with AIDS. For the prevalent diseases HIV/AIDS, TB and malaria, acute solutions needed to be found and there are now some main funds organization to tackle the problems. Besides those which only make grants, such as the Global Fund to Fight AIDS, TB and Malaria (Global Fund), there are also organizations combining grants with technical assistance (Bush's Global Access Foundation) and those which only focus on providing help to self-assistance for developing countries (Clinton Foundation, UNAIDS).

The funds organizations obtain financial contributions from governments, the World Bank and private foundations, as in the cases of the Global Fund<sup>95</sup> and UNAIDS<sup>96</sup>.

Given the negative US-policy of lowest medical prices for developing countries, it seems ironic that the US at the same time actually is the largest single donator. From 2001 to date, it has donated approximately US \$980 millions to the Global Fund<sup>97</sup> and additionally US \$137 millions to UNAIDS in 1995-2004<sup>98</sup>. In 2003, President Bush launched the Emergency Plan for AIDS relief, pledging US \$15 billion over five years to fight the global AIDS pandemic.

In spite of these contributions, health advocates are criticizing the US for giving too little. They argue that the figures should be seen relatively to national economy. The EU countries, which together have an economy smaller than the US, have donated almost twice as much to Global Fund. Donations to UNAIDS made by the Netherlands totaled US \$136 millions, only slightly lower than the US \$137 US contribution for the same period<sup>99</sup>.

Bush's Emergency Plan has been denounced for being the President's tactic to derail a larger sum to the Global Fund, as voted by certain senators.

The program is further condemned for refusing to procure generic ARVs, which cost at least one third of the price of the cheapest brand name drug, and which have been approved by the WHO. The program will provide countries with technical assistance,

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<sup>95</sup> The Global Fund to fight AIDS, TB and Malaria, launched in 2001 by the UN and G8 countries on the initiative of Kofi Annan, is an independent, public-private partnership created to mobilize new resources to fight the three major diseases. Receiving financing from over 50 governments and private donors, the organization works as a financial instrument, distributing grants to existing programs in developing countries. The fund encourages in particular local operation and ownership. From its start in 2001 to date, the fund has received about US\$ 3 billion, and has granted funds to support 154 programs in 93 countries worldwide.

<sup>96</sup> Joint United Nations Programme on HIV/AIDS, UNAIDS, is an initiative governed by a joint-venture of the UN-branches and co-sponsored by the WHO and the World Bank.

<sup>97</sup> See [www.globalfund.org](http://www.globalfund.org) → Fund Raised and Spent → Pledges and Contributions

<sup>98</sup> See [www.unaids.org](http://www.unaids.org) → About UNAIDS → Donors → Table

<sup>99</sup> Small countries as Norway and Sweden were third and fourth biggest contributors, donating approx. US\$ 78,5 and 56,3 millions respectively during 1995-2004. See previous reference to UNAIDS' homepage.

which is positively greeted, but it allows at the same time the American ambassador in each receiving country to set priorities, which activists say could be in conflict with that country's own intentions<sup>100</sup>. With regard to the latter, one could ask if it would be in the benefit and best interest of the country receiving assistance to be in a depending position to the donating country.

Another US-based program is the Clinton Foundation HIV/AIDS Initiative, established by the former US president. It is an independent non-governmental organization, which does not provide funds, but aims to assist developing countries with bringing into force and run treatment and prevention programs, applying for funds and negotiating and procuring low-price medical treatments and equipments. The Foundation is working in partnership with governments, organizations and corporations in Africa, the Caribbean and Asia. It is also working in close cooperation with WHO and UNAIDS on "The 3 by 5 Initiative" and other organizations as the World Bank and The Global Fund.

In contrast to Bush's Emergency Plan, health activists are applauding the achievements of the Clinton Foundation, of which the most recently has been the reaching of an agreement with five prominent medical technology companies on substantial price reduction of HIV/AIDS testing for infected people in Africa and the Caribbean. Together with the previous success in securing a deal with generic manufacturers, allowing nearly 50% price-reduction of today's cheapest ARV treatments for developing countries<sup>101</sup>, the Foundation has achieved a price cut of nearly 70% of the current cost of testing and treatment in countries such as South Africa.

With the view of accelerating access to treatment of HIV/AIDS, the WHO launched the "3 by 5 initiative" in 2003. The program aims to provide treatment to 3 million HIV/AIDS infected people in developing countries by year 2005<sup>102</sup>.

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<sup>100</sup> See: *Bush's AIDS initiative*, New York Times, 16 February, 2004, *Global AIDS: State of the Union Backgrounder – The Bush Administration and AIDS Funding – A Health GAP Briefing Paper*, Health GAP, January 29, 2004. Available at Health GAP's website, Fact Sheet: *The President's Emergency Plan for AIDS Relief, the White House*, January 28, 2003. Available at [www.whitehouse.gov/news/releases/2003/01/20030129-1.html](http://www.whitehouse.gov/news/releases/2003/01/20030129-1.html)

<sup>101</sup> *AIDS Drugs Now Available for 36 US Cents a Day Under Clinton Foundation Deal*, MSF Access to Essential Medicines, October 23, 2003. Available at: <http://www.accessmed-msf.org/> → Press Releases, *Clinton Program Would Help Poor Nations Get AIDS Drugs*, Wall Street Journal, October 23, 2003

<sup>102</sup> See further: [www.who.org](http://www.who.org) → WHO sites → 3 by 5 Initiative

# 5 Developing country aspects

## 5.1 A country's development regarding access to pharmaceuticals - Thailand

### EVOLUTION OF THE PATENT REGULATIONS

Thailand is regarded as a middle-income developing country with a population of 63.5 million, of which about 1 million are infected with HIV/AIDS. Being a Member of the WTO, it entered into the TRIPS Agreement in 1995.

With the objectives of promoting innovation in Thailand and inciting foreign technology transfer, the first patent act was promulgated in 1979, recognizing *inter alia* process patents for pharmaceutical inventions. However, not having previous traditions of IP-protections, and because IPR was perceived as creating monopoly, the act was paid little attention. As a respond to the concerns of American drug companies in Thailand<sup>103</sup>, the US government started in an early stage to work for a stronger patent protection. The Thai government argued that considering the social, economical and industrial development situation of Thailand, it was not possible to apply the same level of protection as in the US, where development was fare more advanced<sup>104</sup>. Following negotiations resulted in the placing of Thailand on the "Priority Watch List" under the "Special 301" provision of the US 1988 Trade Act, largely due to requests of PhRMA. Subject to trade sanctions worth US\$165 millions<sup>105</sup>, the Thai government submitted to the pressures, and in 1992, the Patent Act was amended, allowing pharmaceutical product patents, extended patent term (from 15 to 20 years) and prohibiting parallel import and previous provisions that facilitated compulsory licensing<sup>106</sup>. However, the US soon expressed renewed concerns over the Thai patent protection. One of the reasons was because of the lack of transitional protection, which would have also protected pre 1991 inventions. Once again, Thailand was placed on the "Watch List" and was removed from the "Priority Foreign Country List". The Thai government responded by allowing pipeline protection for foreign

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<sup>103</sup> In 1985, Pfizer submits to the American Chamber of Commerce in Thailand a paper, in which it stresses that "lacking patent protection (...) American pharmaceutical firms (...) are being intentionally deprived of a free market", Markandya, S. (July 23, 2001) *Timeline of Trade Disputes involving Thailand and access to medicines*, p. 1, 3<sup>rd</sup> passage.

<sup>104</sup> Markandya, S., ut supra, p. 1, 8<sup>th</sup> passage.

<sup>105</sup> Limpananont, J. (2002) *Thailand: The impact of pressure from the US. Patents, pills and public health: Can TRIPS deliver?*, Panos, London, pp. 41-43. Available at: [www.panos.org.uk/PDF/reports/TRIPS\\_low\\_res.pdf](http://www.panos.org.uk/PDF/reports/TRIPS_low_res.pdf)

<sup>106</sup> Just before the entry into force of the 1992 Patent Act, The Thai Supreme Court states in a report that "Thailand is not ready to change and improve the level of (pharmaceutical) patent protection (...), which intends to protect the public to a new Act which (...) aims to protect the inventors." Further, that Thailand, however, had been forced by "(...) countries who own technologies of producing pharmaceutical products to improve patent law for the exchange of trade benefits." *National Experience on Judiciary and Intellectual Property Systems, September 1992*

patents<sup>107</sup> and restricting the use of compulsory licensing. The placement on the "Watch List" remained. Meanwhile, in 1997, Thailand entered a period of economic crises, which forced the amendment of the Patent Act in 1998, establishing major parts of the US demands.

## IMPACT

As early as in the 1960s, the Thai government established a generic pharmaceutical organization – the Government Pharmaceutical Organisation (GPO), which formulates and packages drugs from imported raw materials. Before 1989, generic producers were more successful than originator companies. Due to the reluctant attitude of the Thai government to allow generics, and the new amendments in the Patent Act, the situation became rapidly reversed. After the amendment of the Patent Act in 1992, the share of originator companies in the Thai market made an annually augmentation<sup>108</sup>. So what was the impact of these circumstances? Studies show that there has not been strong evidence of technology transfer, or any substantial foreign direct investments to the Thai pharmaceutical industry since 1992<sup>109</sup>, which had been the arguments for stricter protection. When some of the generic drugs finally were granted market entry in 1998, the substantial price drop of the drug flucanazole was striking – from US\$6.10 to US\$0.60 per 200 mg capsule. A few years later, the price of stavudine fell from US\$2.20 to US\$0.34 per 40 mg capsule. Possibly due to these events, the Thai government decided to suspend the market exclusivity for drugs benefiting from the 1992 patent law (but pipeline protection remained)<sup>110</sup>.

## A CASE STUDY

In 2001, two people living with HIV in Thailand, supported by AIDS Access Foundation, an NGO, and two PLWHA<sup>111</sup> support groups, filed a lawsuit against the drug company Bristol Myers Squibb (BMS). The allegation was that BMS and the Thai Department of Intellectual Property (DIP) had cooperated to unlawfully issue the ARV<sup>112</sup> didanosine (ddI) without specifying any dosage limits, thus giving BMS unrestricted exclusive rights.

DdI was originally developed in the US by the governmental funded National Institution of Health (NIH), which licensed it to BMS for marketing in certain countries. The drug needed to be taken along with an antacid buffer as the acidity in the stomach reduced the efficiency of ddI. BMS later introduced a combination formulation, containing ddI with built in antacid buffer, for which it finally received a patent in the US. When BMS first filed for patent on ddI in Thailand, 1992, the patent application was restricted to cover a drug dosage of 5-100mg of ddI. However, when the application came up for examination

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<sup>107</sup> This meant that pharmaceuticals, patented abroad between 1986 – 1991, would be protected by market exclusivity in Thailand for 5-6 years. This was the solution to the lack of protection for pharmaceutical product patents prior 1992.

<sup>108</sup> The peak was reached in 1997, when the share of generic producers were 33 % and originator companies 66%

<sup>109</sup> Supakankunti, S., Janjaroen, W. S. *et al.* - *Impact of the World Trade Organization TRIPS Agreement for the pharmaceutical industry in Thailand*, Bulletin of the World Health Organization, 2001, 79 p. 463

<sup>110</sup> Limpananont, J., see note 104 *supra*.

<sup>111</sup> People Living With HIV/AIDS

<sup>112</sup> Antiretroviral drugs are used to inhibit the growth of the HIV, and with the right combinations, they can postpone AIDS considerably and allow a quite acceptable existence for the HIV infected.

in 1997, BMS applied for a removal of the dosage limitation. This had been rejected in BMS' original US patent application, but was now granted by DIP, which issued a patent that covered all ddI doses.

DdI (sold under the name Videx) and Zidovudine were the two most commonly available ARV in Thailand. In 1996, a generic equivalent to Zidovudine became available to an affordable price, while the production of ddI remained the exclusive rights of BMS. Although discounted in comparison to the international prices, the cost of one Videx tablet ranged between 2.56 US\$– 4.11 US\$ and the required dosage was normally two tablets per day. Consequently, according to the Thai Communicable Disease Control Department, only 5% of HIV/AIDS patients could afford the combination use of ddI and Zidovudine<sup>113</sup>.

The implication of the unlimited patent was that GPO could not produce the drug in any dosage even though it had developed the know-how for this. The exorbitant prices of ddI caused NGO:s campaigns to issue compulsory license to GPO for the manufacture of ddI-drugs. Alerted by this, the US government warned that Thailand would face trade sanctions if compulsory license was issued for the BMS ddI<sup>114</sup>. The Thai government thus refrained from making use of the compulsory licensing provisions.

This provoked the suit against BMS in 2001 at the Thai Central Intellectual Property and International Trade Court. In the final verdict the court stated *inter alia* that "*Medicine is one of the fundamental factors necessary for human beings, as distinct from other products or other inventions that consumers may or may not choose for consumption*" and that "*(...) lack of access to medicines due to high price prejudices the human rights of patients to proper medical treatment.*"<sup>115</sup> In addition, the court reminded of the priority of human life in trade agreements as internationally recognized in the Doha Declaration, and further, that injured parties could consist of others than manufacturers and sellers as people in need of medicine also had an interest in the granting of a patent<sup>116</sup>. Finally, the court concluded that the alteration of the patent application to remove the dosage indication extended the initially scope of application and ruled that the act was unlawful.

The decision was appealed by the defendants, but was withdrawn in January 2004.

According to various sources<sup>117</sup>, this ruling had in many ways set a benchmark and had paved ways for generic production of medicines. It had stated that **essential drugs are not**

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<sup>113</sup> Ramachandran, R., *A patent war in Thailand*, Frontline Vol. 20 – Issue 22, October 25 – November 07, 2003

<sup>114</sup> Markandya, S., note 103, supra, p. 7

<sup>115</sup> AIDS Access Foundation, Mrs Wanida C and Mr Hurn, vs Bristol-Myers Squibb company and the Department of Intellectual Property. The Central Intellectual Property and International Trade Court, 2002 (10). BC Tor Por 34/2544, RC Tor Por 93/2545

<sup>116</sup> BMS and DIP had argued that individuals did not have right to challenge a patent as they were not manufacturers and also could chose other medicines. Therefore, they were not to be accounted as injured or interested parties.

<sup>117</sup> Ford, N., Wilson D., Bunjumong, O., Angerer, T. and others, *The role of civil society in protecting public health over commercial interests: lessons from Thailand*, Viewpoint, The Lancet, Vol. 363, February 14, 2004, pp. 561-562. Can be found on: [www.thelancet.com](http://www.thelancet.com), *Two people with HIV/AIDS overturn AIDS drug patent*, Médicines Sans Frontières, Foundation for Consumers, Thai Network for people living with HIV/AIDS, 13 February, 2004. Available at: [www.accessmed-msf.org/prod/publications](http://www.accessmed-msf.org/prod/publications)

**just another consumer product, but a human right, and that patients could be injured by patents, thus having a standing right to sue.** In addition, it is believed to be the first time that a court had made direct use of the Doha Declaration.

A cautious tendency to return to a more open view towards generic drugs can be noticed in the launching of governmental HIV/AIDS treatment programs. The GPO is currently producing generic ARVs that are between 2 to 25 times cheaper than the cheapest brand drug.

## CURRENT FTA-NEGOTIATIONS

In the present (2004), Thailand and the US are in negotiations for a bilateral FTA, which is scheduled to be launched later this year. Many concerns have been raised that the Thai patent regulations would be targeted to stricter protection, beyond what is required by TRIPS and out of reach from Doha application. Health organizations contend that the US proposal will follow the model of the recently signed U.S.-Singapore FTA, which applies a much more extensive protection than TRIPS compliant<sup>118</sup>.

Not only activists, but also senators, academics and civil groups have urged the government to exclude the IPR out of the trade negotiations. If not, the agreement should at least be in consistence with TRIPS. Further, they demand that the Health Ministry be involved in all negotiations<sup>119</sup>.

A report made by an IP researcher at the Thailand Development Research Institute (TDRI)<sup>120</sup>,<sup>121</sup> recommends that the Thai government revise and clarify some IPR issues when negotiating the terms of the FTA and that the government should negotiate for a delay of 10-12 years to implement the IP-conditions set forth in the FTA, which is estimated to be the transitional period required for the country to adjust itself. The report further states that notice should be given to the differences in technological capacities, and claims that Thailand would lose its freedom to develop its own IPR system, as enjoyed by the industrialized countries in their early stages of development, should the US-Singapore FTA be applied. The conclusion was that Thailand was not yet ready to apply a high standard IPR with respect to its technological and economical developments and that "Benefits for Thailand from the high standards of IPR regime are, at best, long-term, while cost of adopting them are real and immediate<sup>122</sup>".

So far, it appears that a clear picture of the negotiations is unavailable. There are concerns that Thai finance ministers involved in the negotiations do not really comprehend the total impact of an FTA on US terms and that they have gotten the wrong idea of the scope of

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<sup>118</sup> See previously in 3.4.1

<sup>119</sup> *Keep Intellectual Property out of the (US-Thailand) FTA*, The Nation (Thailand), 28 February, 2004.

Available at: [www.accessmed-msf.org/prod/publications](http://www.accessmed-msf.org/prod/publications)

<sup>120</sup> *Intellectual property focus of FTA – Researcher finds deal with US is "different"*, Bangkok Post, 13 Feb, 2004. Available at: [www.bangkokpost.com/Business/13Feb2004\\_biz59.php](http://www.bangkokpost.com/Business/13Feb2004_biz59.php)

<sup>121</sup> The author, Tangkijvanich, S is in fact hired by the American Chamber of Commerce in Bangkok as part of a TDRI research group, set to study Thailand's competitiveness in key sectors and the commitments the country could offer under the FTA.

<sup>122</sup> *Intellectual property focus of FTA (...)*, see note 120 supra

the free trade. Activists demand that there be greater transparency in the process and that civil society should be included before the agreement is finalized.

## 5.2 Should patents on pharmaceuticals be enforced in developing countries?

Especially in discussions about access to medicines, there are flourishing arguments on whether intellectual property are evolving or deteriorating developing countries. Some believe that IPR should not be applied in these countries. Intellectual property rights may indeed give rise to increased innovation and national welfare, but since countries find themselves in different stages of development, it is not at all obvious that this fact is applicable to all countries. The poorest countries may not profit from the benefits of an IPR system, as a certain level of development is needed before IPR can yield efficiency to the country. Primary needs such as access to food and medicine and a certain level of education should be satisfied before introducing IPR. Otherwise, there is a risk that wealthy countries will abuse poor countries by using their resources and imposing a system from which the inhabitants themselves cannot benefit.

India, which represents a special case, is often taken as an example by opponents to IP-protection in developing countries. In 1970 India adopted a new Patent Act, abolishing the colonial Patent Act from the British era. The new Act excluded product patent on medicine and food, as legislators believed that there should not be any “profiteering from life and death”. After the 1970 Act was enacted, the number of registered pharmaceutical producers increased from 5000 to 24 000. The production of pharmaceuticals also grew 48-fold from INR250 million in 1971 to over INR1.2 billion in 1997-98<sup>123</sup>. The increased exports that followed lead to dramatically drop of pharmaceutical prices. Today, India is one of the world’s largest exporters of generic drugs. Pharmaceutical prices in India are also considerably lower than in many other countries, taking the example of the drug Ranitidine, produced by Glaxo, which costs INR7.16 in India, INR739 in the US and INR127 in Pakistan<sup>124</sup>. The latter country is an example of a developing country that lacks manufacturing capacity; it is thus heavily dependent on imports, which causes high medical prices.

Although the Indian case clearly displays the advantages of abolishing IP-protection, it is also an exceptional case and it is doubtful whether the same model would be successfully applied in other developing countries. The success of India may include various factors, as *inter alia*, historical, social and cultural components - factors that substantially dispartate from one country to another. However, the main reason should lie in the country’s tactic of allowing free availability to western know-how (by removing product patenting) in order to achieve a rapid upswing on the economy and level of know-how. By achieving these goals, the country were able to produce new inventions of its own and finance them too. At this point, introducing full IP-protection will yield all the positive effects of having such protection, such as encouraging innovation, which in turn will be a step in advancing the society.

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<sup>123</sup> Shiva, V. – *Protect or Plunder – Understanding Intellectual Property Rights*, Global Issues 2001, p. 88

<sup>124</sup> Shiva, V., ut supra p. 89. With the current rate (August, 2004), the prices would be approx. US \$ 0.14, US \$ 14.76 and US \$ 2.54 respectively.

Nevertheless, the reality for most developing countries is that other factors and circumstances might effect larger benefits in providing an IPR system than if they would have refrained from it. An exclusion from international trade communities, as the WTO, may cause more prejudice to the economic and social development than the choice of not providing IP-protection. There are possibilities for developing countries to provide IP-protection without prejudice to pursuing primary needs, such as public health. It cannot be repeated enough that there need to be more focus on how to efficiently make use of the instruments provided for in TRIPS, as exceptions, compulsory licensing and the recent agreements supporting measures that protect public interests. This is actually exactly the circumstance that could turn the situation more to the favour of poor countries. Instead of just focusing on the negative implications of an IP-protection system, governments of poor countries should realize that they have considerable margins within the limits of TRIPS to design their own patent protection system in order to meet the needs of their own situation. They should resist outside pressures to adopt patent systems that largely only serves foreign interests and that are not appropriate for their own country. Real efforts must be made to use all favourable loopholes that the system offers. By doing this, developing countries will have good chances of participating in the global economical, social and technological development as well as protecting public health.

### **5.3 Parallel trade – an option for developing countries?**

In relation to the spreading of HIV/AIDS pandemic, a frequently debated question is whether developing countries should practice parallel importation of pharmaceuticals as a way to approach public health issues. As earlier presented in 1.3.3.3, the TRIPS Agreement allows each Member to freely determine the exhaustion regime they consider appropriate.

However, before proceeding any further, it has to be made clear that this is not about investigating whether parallel trade should be practiced in general. As has been repeatedly stressed in this thesis, parallel trade of pharmaceutical products from low-cost markets to industrialized countries seriously impairs access to medicine, as it diverts differential priced or donated drugs intended for poor countries and violates on the market where drug companies can retrieve their investments and afford differentiated prices to developing countries.

Obviously, such trade is highly profitable for importers in high-income countries because prices are generally set at a lower level in developing countries. But is it then possible for poor countries to find lower prices elsewhere, which they can afford, than those being charged on their own market?<sup>125</sup>

To answer this question, it is necessary to look at the causes for the price variations across countries. In principle, pharmaceutical firms will try to set prices as high as people in a certain country can possibly afford. There are however several other factors that are not always easy to separate. Of immediate significance are the national price regulations,

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<sup>125</sup> It is worth reminding that, when discussing parallel import, the products referred to are brand-name products stemming from the same manufacturer.



which control that price settings of a certain product, national tax levels, regulatory systems and liability laws. The IPRs status of a product also varies in different countries – e.g. the patent may be current in a country, but expired in another, or the presence of generic competitors, which pressure down prices. Furthermore, prices also need to be adjusted to per-capita income, local taste and labour and advertisement costs. Other possible influences are changes in exchange rates and procurements in wholesales<sup>126</sup>,<sup>127</sup>.

Hence, from this point of view, developing countries may also have possibilities to benefit from parallel trade. The question is, however, which effect this will have on access and prices in the long run and whether it in the end of the line really would benefit public health from an international point of view.

In particular, the scale of the AIDS crises in Africa has led to calls for developing countries to be allowed importation of cheaper drugs from other countries. This has expanded the debate about drug pricing from just a financial one to a moral one. Notwithstanding the art. 6 of the TRIPS Agreement, many developing countries have encountered several impediments from the pharmaceutical industry and governments supporting them whilst trying to apply such imports, and many have subsequently been forced to amend their patent laws to prohibit parallel importation. In the submission of the developing countries group to the Council for TRIPS at the upcoming Doha Ministerial meeting, it was stressed that parallel imports could be an effective tool ensure adequate access to medications and thus in the light of art. 6 of the TRIPS Agreement, the Council should confirm the unconditional right of each Member to determine the exhaustion regime they deem appropriate<sup>128</sup>.

Theoretically, when it comes to the pharmaceutical industry where a fixed amount of costs has to be recovered, prices should be set at a high level in high-income markets, where people afford to pay. In low-income countries, pharmaceutical companies may consider it preferable to set prices as low as feasibly possible, since small revenues after all are better than none at all. However, when the market of a less affluent country can be segmented to two (or more) groups - a predominant mass of poor people, and a small minority of rich people, pharmaceutical companies may find it more profitable to supply only the latter group, as feasibly lowest prices might anyway not be affordable for many of the poor majority<sup>129</sup>. In such cases, prices will be much higher than in the preferred theoretical situation, and parallel import of cheaper pharmaceuticals could play a determinant role for the public health.

Advocates of parallel trade argue that such measures may be beneficial to prevent anti-competitive practices on behalf of patent owners who offer their patented products at unreasonably high prices in the domestic market. In this case, patent owners would

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<sup>126</sup> Bale, Harvey E. Junior, *The conflict between parallel trade and product access and innovation: the case of pharmaceuticals*, Journal of International Economic Law (1998) 637-653, Oxford University Press.

Available at: [http://www3.oup.co.uk/jielaw/hdb/Volume\\_01/Issue\\_04/pdf/010637.pdf](http://www3.oup.co.uk/jielaw/hdb/Volume_01/Issue_04/pdf/010637.pdf)

<sup>127</sup> Barrett, M., *The United States Doctrine of Exhaustion – Parallel Imports of Patented Goods*, 27 N. Ky. L. Rev. 911 (2000 Northern Kentucky University Law Review)

<sup>128</sup> Council for TRIPS - Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ec[...] Lanka, Thailand and Venezuela, IP/C/W/296. Available at WTO homepage: [www.wto.org](http://www.wto.org)

<sup>129</sup> Scherer, F.M., Watal, J., *-The Economics of Parallel Trade in Pharmaceutical Products - Revised Summary for WTO-WHO Workshop April 2001* Available at: [http://www.who.int/medicines/library/edm\\_general/who-wto-hosbjor/19Scherer.doc](http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/19Scherer.doc)

compete with other legitimate products; and in accordance with the international exhaustion theory, the interests of the patent owner would not be damaged, as he has been given the chance of retrieving the investments and thus exhausted his exclusive rights<sup>130</sup>.

It is also argued that the trade mechanism would be a significant way of increasing access to medicine in developing countries and LDCs that lack domestic medical manufacturing capacities. This argument has however lost a bit of its essence by the emergence of the Para. 6-Agreement. Nevertheless, developing countries might find parallel importation to be a more rapid answer to the need of solving raging health crises in comparison to the more complex mechanisms of Para. 6-solution, which may require substantial procedures of amendments to the national patent law in order to become applicable.

However, many believe that that international parallel trade could be dangerous as it will stifle the ability of pharmaceutical companies to invest in R&D and dissuade them from investing in developing countries. What incentive would they have to invest in a certain developing region, when their products could be bought up at a cheap price and resold at a higher price elsewhere in the world?

Because parallel trade aims to exploit price differences by diverting products from low-price to high-price markets, it threatens attempts to maintain a system of discriminating prices. This induces two adverse consequences. First, it will erode profits in the higher-price markets, lessening the contribution those markets make to the recovery of fixed R&D costs. Consequently, it will likely discourage companies to be engaging with ongoing donation programs and co-operations with health organizations. Second, profit-maximizing firms might react to the diversion of products from low-price markets by reducing their supply to those markets, raising prices there and perhaps - in the worst scenario - by choosing not to supply them at all<sup>131</sup>.

Beyond the aspects of economics and supply, there are also concerns about health and safety issues that are connected with parallel importation. Many cases show substantial risk of the widespread of counterfeited products that have been re-packed and re-labelled before reaching the importing country.

Faked ingredients have resulted in fatalities in many countries and inadequate amounts of active ingredients in counterfeited drugs have also increased the cases of human resistance to treatments<sup>132</sup>.

The US has adopted neither the international exhaustion nor the national exhaustion theory to its fullest extent. The specific application of the doctrine of exhaustion in each of the three primary intellectual property regimes has varied. Save for some exceptions, it can very generally be said that international exhaustion is applied on trademark and copyright and that the situation is unclear when it comes to patent right. The US Patent Act is quiet in this area, and leaves it for the case law to establish the doctrine of exhaustion. Prior to *Jazz Camera Photo v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), and in some cases in other circuits following that decision, the general rule in the U.S. was

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<sup>130</sup> Council for TRIPS, see note 128 supra.

<sup>131</sup> This matter is also discussed by Lidgard, H-H in *Parallellhandel – konsumtion av immaterialrätt i Europa och USA*, pp. 313-315

<sup>132</sup> Bale, see note 126 supra.

perceived by many to be an international exhaustion rule<sup>133</sup>. In the case *Adams v. Burke*, 84 U.S. 453 (1873) as several other early Supreme Court decisions<sup>134</sup>, it was established that once the patented products have been lawfully sold and the patentee having in the act of sale received all compensation for the invention, the article is “open for the use of the purchaser without further restrictions”<sup>135</sup>. *Jazz Camera* overturned the previous trend that advocated international exhaustion doctrine, as the Federal Circuit noted that the sale of products by a patent holder in another country did not exhaust the US patent rights. Some legal experts were of the opinion that the ruling was questionable and although it cannot be clearly stated that the case law has been reversed by the case, it has nevertheless created a legal uncertainty around the parallel trade of patented products<sup>136</sup>.

However, in the case of patented pharmaceutical products, the legal status is very clear. Because unauthorized distribution channels substantially narrow down chances for government control, threatening the sustainability of adequate safety standards, the doctrine of exhaustion for patented pharmaceuticals is established in the US Prescription Drug Marketing Act of 1987, which prohibits the re-importation of prescription drugs that is not controlled by the manufacturer<sup>137</sup>.

Finally, there are several problems of regulatory character arising with the practice of parallel import, which often have been overlooked in the discussions. Illustrative in this context is the case of Kenya, where parallel importation was introduced to cope with the HIV/AIDS-crises that claimed 600 lives daily<sup>138</sup>. Since the mechanism became legal, parallel imported medicines have flourished on the Kenyan market. An assessment of the distribution of drugs made by the National Drug Quality Control Laboratory showed alarming evidence of sub-potent and counterfeiting products in high volumes. A letter from a Kenyan drug regulatory official to her counterpart in South Africa expresses the concerns of the situation:

“... the reality of parallel imports raises a number of additional problems from a regulatory standpoint: (1) the application of double standards for approved packaging and labeling; (2) required cooperation of manufacturers and distributors in determining counterfeit products; (3) patient confusion due to multiple presentations of the same product; (4) the persistent threat of intellectual property infringement challenges; (5) the inability of the Pharmacy and Poisons Board to ascertain that the parallel import was manufactured with good GMP (Good Manufacturing Practice) standards and; (6) in the event of quality control problems there was an inability to implement necessary product recall policies.”<sup>139</sup>

Parallel trade might certainly benefit developing countries by cutting down prices, but the practice of it comes with great risks, which governments must be aware of before introducing such a system. There are few possibilities to manage the control of “wealthier” developing countries importing from poor developing countries, depleting these from

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<sup>133</sup> Love, J., Flynn, S, *Legal and Policy Issues Concerning Parallel Trade (aka Re-Importation) Of Pharmaceutical Drugs in the United States*, CPTEch, March 31, 2004. Available at: <http://www.cptech.org/ip/fsd/love03312004.pdf>

<sup>134</sup> See also *Curtiss Aeroplane v. United Aircraft*, 266 F. 71 (2d. Cir. 1920)

<sup>135</sup> *Adams v. Burke* (17 Wall.)

<sup>136</sup> Love, see note 133 supra

<sup>137</sup> Exemptions are allowed only in cases of emergency with the authorization of the government.

<sup>138</sup> Blomfield, A., *Kenya Will Import Cheap Generic AIDS Drugs*, Reuters NewMedia, March 6, 2001. Available at: <http://www.aegis.com/news/re/2001/RE010310.html>

<sup>139</sup> Letter from Dr. Elizabeth Ominde-Ogaja, Director of National Quality Control Laboratory in Kenya to Peter Foib, Director of Medicines Control Council in South Africa, 14 October 1997.

medicines. The concerns are particularly called for in countries where medicines are being donated or price differentiated. In order to draw benefits from the system, several regulatory measures will have to be applied; prevention of drug diversion, means of blocking the entering of counterfeited and sub-potent drugs, expanded drug quality controls, to mention a few. In addition, solutions would have to be found on how to practice parallel trade without discouraging the pharmaceutical industry to engage in price differentiating and donation programs, something that might not be so easily done. All these measures are remarkably difficult to administer, which also is recognized even by a country with as highly advanced regulatory system as the US.

In the end, it is immensely difficult to envision all possible consequences that the practice of parallel importation may entail, and with the changes of Para. 6-Agreement and increasing engagement of multinational drug firms, parallel trade might involve unnecessarily high risks.

## 6 Taking the next step

Finding a balanced solution for achieving access to medicines in developing countries is indeed an immensely difficult task. Unfortunately, the Para. 6-Agreement does not provide a rapid solution to the acute need of pharmaceuticals due to the technically complex set of rules that were needed to prevent abuse of the mechanism and the collapse of the IPR system. Therefore, despite the fact that poor developing countries now theoretically have possibilities to procure low-cost generic medicines, many practical steps remain yet to be taken. Besides the importance of a rapid implementation of the agreement by governments in both exporting and importing nations, the national regulations that come as a result must be free from another layer of restrictions, learning from the case of Canada<sup>140</sup>. Preferably the national rules should be designed so as to the largest extent facilitate the practice of the mechanisms. However, the experience from the Canadian implementation shows a clear tendency for new conflicts to arise. If this was the case for a highly developed country, how will it then be for developing countries? The problems facing developing countries are, however, of another character than those, which faced Canada. Often, poor countries have to deal with corruption that impedes the functioning of administrative procedures. Having to additionally deal with such problems, importation of life-saving drugs through the WTO-Agreement may be far from reach unless governments react directly and definitely, as in the case of Zambia<sup>141</sup>. Developing countries should be aware that many of the practical questions in the rules, such as *e.g.* procurement procedures and comparing the lowest prices offered by different generic companies, could be facilitated by the assistance of the WHO and other health organizations. All these possibilities are available and should be exploited regularly. Finally, it is of paramount importance that developing countries resist pressures of adopting TRIPS-plus regulations that deprive them of use of the exemptions they are entitled to, and which they will need in order to address public health problems.

The outcome of the Para. 6-Agreement was the result of delicately negotiated compromises, in which all Members to some extent had to refrain from their demands. In particular, poor developing countries felt that they were deprived of the solution they had hoped to be the answer to their health problems. Now in the wake of both Doha and August 30, the behavior of the US of going from country to country with their FTAs that eviscerate the arduously achieved WTO-consensus, clearly shows bad intentions. Because of the US position as a powerful nation, small countries can easily be pressured into agreements that prioritize economic views before public interests. The world community cannot regard these kinds of acts as acceptable. Even though TRIPS only sets minimum requirements and implementation of stricter conditions do not constitute breach of obligations, the behavior of the US of intentionally undermining recent consensus by using its superior position must be regarded as violations of reached agreements. Consequently - although it might not be likely - the possibilities of bringing the US before the DSB should be examined.

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<sup>140</sup> See above in 3.4.3

<sup>141</sup> See above in 3.4.5

It is not unthinkable, however, that the US policy eventually would change along with the new approaches of multinational pharmaceutical companies. Before the outbreak of the HIV/AIDS-crises, pharmaceutical companies had large freedoms of setting their conditions and controlling the markets. Surely, generic manufacturers have always been disturbing competitors, but never have they been playing such a pivotal role as now when major parts of the world are in desperate need of medicine. The situation forces governments to take actions they may have refrained from or neglected before, as scarcities become obvious. At the same time, civil organizations and health activists get media and civil support, which in turn also engages affluent nations.

As constantly being argued by health activists, pharmaceutical companies would actually not be substantially injured economically by cutting prices or by licensing patents to generic manufacturers in developing countries. However, the real worries of the pharmaceutical companies are basically the one of losing control of the market, which may yield more profits in the future and the one of drug diversion to lucrative affluent markets. The new changes compel companies to change of policies in order to retain goodwill while preventing the loss of control. The balance of giving and taking is delicate and companies have likely found the smallest loss to be time-limited philanthropy programs. Although they do not in any way constitute sustainable solutions, they may certainly meet the need of acute efforts and function as complements during the processes of implementation of the Para. 6-Agreement.<sup>142</sup> Still, companies will have to take further steps in order to not exclude themselves from the ongoing development of the new situation. A company that has recognized this is GSK that already has initiated collaboration with the Indian generic company Ranbaxy.

There are concerns that the supply of generic drugs will decrease dramatically in 2005, when major generic producing countries such as India and Brazil will have to become fully TRIPS compliant. The feared scenario is that now that countries are being allowed to import generics, there will not be any to for them to buy. Theoretically countries are free to produce copies of brand-name drugs, but the solution does not lie in promoting local manufacturing for each country since it is neither feasible nor cost-efficient. The reason is that generic manufacturing requires technical know-how, efficient infrastructure, investments and processes of drug safety controls<sup>143</sup>.

It is likely that India and Brazil will continue to supply the global market with generics, which would be the most rational and cost-efficient solution from the global point of view. There are reasons to believe that compulsory licenses will be issued to keep the production going in these countries; the fact that generic manufacturing represent a major part of the national industry; the governments of India and Brazil have previously not refrained from taking actions and the fact that TRIPS compliant compulsory licensing will be increasingly accepted for protecting public health.

From a global cost-efficiency point of view, the originator pharmaceutical company is in fact the one most likely to produce the cheapest medicines, since the cost of producing an additional volume of a product, which already is in mass production, will be lower than the cost of producing a newly developed product in lower volume. The generic manufacturer will have to spend time and money in repeating the procedures already done

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<sup>142</sup> However, in this regard, it is important that governments do not neglect the implementation!

<sup>143</sup> See Kaplan, W., *Local Production of Pharmaceuticals and Vaccines*, Boston University School of Public Health. Available at: [www1.worldbank.org/hnp/hsd/documents/lpofpav.pdf](http://www1.worldbank.org/hnp/hsd/documents/lpofpav.pdf)

by the originator drug company; develop a formulation which has characteristics similar to those of the original drug, evaluate the product's stability, conduct clinical trials in order to establish bio-equivalency to the original product, apply for market approval and produce packaging and labelling for the product.

Therefore, a strategy on the part of pharmaceutical companies could be to drop prices to the levels of generic products in developing countries, once they have profited from the product and retrieved their investments. Developing countries would benefit from such market strategy since procedures of issuing compulsory licensing would be unnecessary and cheap medicines would be immediately accessible.

Unfortunately, this solution contains flaws. In such a situation, it is likely that generic companies will be competed out of existence and once the market is free from these competitors, brand name pharmaceutical companies will be able to demand the prices that suit them.

The EU Regulation offers a good and balanced solution, addressing both the need of solving health problems and the interests of protecting IPRs. Though the system primarily promotes IPR, it does not discriminate against generic producers. Besides, it introduces a "safe" distribution channel for price-differentiated medicines. By substantially reducing the risk of diversions while at the same time as setting price limits, the Regulation positively provides incentives for companies to offer low-price products to needy countries. The system is easily applied and the numerous administrative processes required when applying compulsory licensing can be avoided both in exporting and importing countries. Inevitably, the Regulation offers a more rapid solution to the health crises than the Para. 6-Agreement. Thereby, it is not implied that the Agreement would be superfluous. Because it is likely that the Regulation will be predominantly used by originator companies, the mechanism of compulsory licensing will be needed to assure that prices will be kept at a low level. In addition, the use of the system is limited, both with respect to the number of beneficiary countries and to products related to the three major diseases only.

In the end, solving health problems in developing countries is a matter of balance of constant negotiations and reciprocal understanding. Health advocates have to realize that although pharmaceutical companies, from the moral point of view, should take responsibility, they still are not charity organizations. In turn, companies cannot longer remain unaffected by the urgent needs of developing countries, where they are capable of making substantial contributions. Neither party can afford to push their demands too far, as both in fact are depending on each other; should health advocates and developing countries infringe the exclusive rights beyond the limit and substantially injure inventive companies, they would also decrease the investments to the development of new medicines. On the other hand, if drug companies behave too badly, the use of compulsory licensing and the practice of parallel trade will increase, possibly in the end also supported by rich nations (in particular nations as Norway, which lack pharmaceutical industry).

# 7 Conclusions

Having achieved a legal framework, characterized by adequate documents, the next step is to make use of them in practice. In this respect, there are yet many issues to be resolved and a number of barriers to be overcome. This will require that all parties involved be willing to take the appropriate level of responsibility.

The obligations of governments of developing countries will first and foremost be in making real efforts to incorporate the Agreement into their national laws. This will be a difficult task as several barriers stand in the way, most notably corruption and bureaucracy, which pose the most serious threats. Governments cannot allow these threats to undermine progress in achieving advancement in public health. Now that international measures are in place and available, developing countries cannot passively regard themselves as victims and expect to be served aid solutions by the rich countries. In this respect, developing countries are also obliged to their nationals to persist the trading away of these means to protect public health for trade bargains with the US. Additionally, other insufficiencies that impede access to medicines, such as lack of infrastructure and a dearth of medically skilled officials, will have to be solved; *e.g.* with the help of funding programs, education and other strategy measures.

Developing countries should also be careful in deciding whether or not they will practice parallel import as an option to obtain low-cost medicines. As has been discussed above, parallel import may seem to be a rapid solution, but in practice, the strategy contains several risks that are difficult to control.

Obviously developed countries also need to rapidly implement the Agreement in order to be able to supply developing countries. They are further obliged to take measures to block drug diversion into their own territories. Here, the EU initiative of introducing anti-diversion measures sets a good example, which should be followed in other developed regions.

Further, industrialized countries should make the best effort to assist developing countries by allowing them to make use of TRIPS compliant mechanisms without threats or pressure and condemn the US policy in this respect that is clearly an act of bad faith.

A long-term, but maybe one of the most significant ways of solving health problems is to promote transfer of technical know-how<sup>144</sup> and health education. Though some developed countries provide different forms of technical assistance on IPR-related issues, LDCs have repeatedly noticed that little or no action has been taken by industrialized countries to comply with their obligations in the TRIPS Agreement.

Finally, to overcome health problems, key actors need to create mutual awareness and reciprocal understanding. Health advocates have to consider that what innovative drug companies aim to do is to make money by developing and selling pharmaceuticals, and

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<sup>144</sup> As industrialized countries have obliged themselves to do according to art. 66.2 of the TRIPS-Agreement, and which has been reaffirmed in para. 7 of the Doha Declaration.



that they are not charity organs that have to take the main responsibility for supplying drugs for non-profit prices. However, drug companies should take moral (if not tactical) aspects into consideration and make real engagements, now that safe distribution channels are becoming available. Drug companies should realize that their strong position is now being challenged in the sense that ongoing health pandemics along with increasing negative public opinion and the new Agreement are limiting their freedom of action. Probably, drug firms will start cutting prices more substantially terms in the near future, as they come to the conclusion that this will be the best way of securing their position in the developing country markets.

Still, it is important for developing countries to bear in mind that, despite the eventual price drops by originator companies, they should not neglect the implementation of the compulsory licensing mechanisms, as these may come in handy should drug companies eventually resume policies of higher pricing. In this respect, measures should be taken to ensure the survival of the generics industry, so that when the need comes, there will be manufacturers to which compulsory licenses issued.

As we now have seen, remarkable changes on the global level are ongoing. The full outbreak and expansion of global health pandemics have finally engaged individuals and forced authorities, corrupted governments and profit-based multinational pharmaceutical companies to react. The finally reached WTO consensus supporting public health in the balance with IPR could easily be perceived as the end of a long story. However, on the contrary, together with the Doha Declaration, these events mark the beginning of a new era. Despite intrinsic procedural flaws, they certainly represent a development in the right direction. In addition, the two agreements seem to be timely, coming at a moment when the transitional period for major generic-supplying nations is running out.

In conclusion, the future situation with global access to medicines appears to be bright. The EU Regulation will most likely come in frequent use and perhaps this example will be followed by other parts of the industrialized communities. Although the full use of the Para. 6-Agreement will require some time to be realized, it has already, with the Declaration, strengthened the position of developing countries and implemented positive psychological effects, inducing them to make use of their rights. More countries will surely follow the examples of Thailand and Zambia<sup>145</sup>.

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<sup>145</sup> Referring to the Court ruling in the dDI-case, where the Court specifically referred to the Doha Declaration, see above in 5.1 and the recent Zambian grant of compulsory licensing.

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# Appendix

## I. EXCERPT FROM TRIPS AGREEMENT

### **Article 6** *Exhaustion*

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

### **Article 7** *Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

### **Article 8** *Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

### **Section 5: patents**

### **Article 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.

### **Article 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.

### **Article 29** *Conditions on Patent Applicants*

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

**Article 30**  
*Exceptions to Rights Conferred*

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

**Article 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;
- (l) 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.

**Article 32**  
*Revocation/Forfeiture*



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

#### **Article 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 (8)

#### **Article 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.

### **Section 7: protection of undisclosed information**

#### **Article 39**

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (10) so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

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

#### **Article 65**

##### *Transitional Arrangements*

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

**Article 66**  
*Least-Developed Country Members*

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

**Article 70**  
*Protection of Existing Subject Matter*

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

## II. DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

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:

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.

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

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.

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.

### III. 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.

#### **Notes:**

- 1.** This subparagraph is without prejudice to subparagraph 1(b).
- 2.** It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
- 3.** Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.
- 4.** Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.
- 5.** The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.
- 6.** This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.
- 7.** The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.
- 8.** It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
- 9.** The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

## IV. THE GENERAL COUNCIL CHAIRPERSON'S STATEMENT 30 August 2003

On 30 August 2003, the General Council approved a decision to make it easier for countries in need to import cheaper generic medicines made under compulsory licensing if they are unable to manufacture the medicines themselves. A separate statement by General Council chairperson Carlos Pérez del Castillo, Uruguay's ambassador, was designed to provide comfort to those who feared that the decision might be abused and undermine patent protection. Below is the statement:

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

### Attachment

"Best practices" guidelines

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.
- Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.



# V. Table of selected provisions related to health care in the FTA-texts that have been made public.

IP Provision	TRIPS Agreement	US-Jordan FTA	FTAA	US-Singapore FTA	US-Chile FTA	CAFTA	US-Australia FTA	US-Morocco FTA
Compulsory Licenses (CLs)	Governments may issue CLs for any reason, though a certain number of conditions must be met. These conditions include prior negotiations for a voluntary license, and that "adequate" royalties be paid to the patent holder. In some situations, conditions may be waived. For instance, CLs issued to address national emergencies and licenses issued for government use do not require prior negotiation. <a href="#">Article 31.</a>	Governments may only issue CLs under the following conditions: 1) as an antitrust remedy, 2) public non-commercial use or in cases of national emergency, and only for the government or parties authorized by it can use licenses under these terms 3) non-working of the patent, with importation counting as working. When CLs are issued, the TRIPS conditions must be met. <a href="#">Article 4(20)</a>	There are two versions of Article 6.1, concerning CLs. The less restrictive says TRIPS Article 31 will guide the rules. The more restrictive includes these limits: 1) only for public, non-commercial use or in cases of national emergency 2) only the government can purchase goods produced under license 3) no exports of CL goods 4) patentee gets "reasonable and entire" compensation. Also under article 6 – CLs can be used for antitrust remedies. They can not be issued until 4 years after the patent is applied for or 3 years after it is granted and no sub-licenses of CLs can be granted. <a href="#">Subsection B.2.e, Article 6</a>	CLs only allowed 1) as an antitrust remedy 2) public non-commercial use or in cases of national emergency, in which case only the government or parties authorized by it can use licenses under these terms, and the patentee must get "reasonable and entire" compensation CLs issued under these circumstances must meet the conditions outlined in Article 31 of the TRIPS. <a href="#">Article 16.7.6.</a>	No language relating particularly to compulsory licenses, but each country must abide by the TRIPS Agreement. <a href="#">Article 17.1(5)</a>	No language relating particularly to compulsory licenses, but each country must abide by the TRIPS Agreement. <a href="#">Article 15.1(7)</a>	CLs only allowed 1) as an antitrust remedy 2) public non-commercial use or in cases of national emergency, in which case only the government or parties authorized by it can use licenses under these terms, and the patentee must get reasonable compensation CLs issued under these circumstances must meet the conditions outlined in Article 31 of the TRIPS. <a href="#">Article 17.9(7)</a>	No language relating particularly to compulsory licenses.
General Exceptions to Rights Conferred	Governments can provide limited exceptions to the rights conferred by a patent as long as they don't "unreasonably conflict with the normal exploitation of the patent." (Bolar and other research exceptions are examples of such limited exceptions, though can/could be others.) <a href="#">Article 30.</a>	Bolar provision specifically permitted, but no open-ended general exceptions as in the TRIPS. <a href="#">Article 4(19).</a>	Two bracketed versions of Article 5.1 both use TRIPS Article 30 as the standard for exceptions to rights conferred. Article 5.2 would limit exceptions to patentability to private non-commercial use, research or experimentation, teaching, or on biological inventions excluding plants. Article 5.3 would protect users of an invention who could prove they were using it before the patent was applied for. Two versions of Article 5.4 specifically authorize Bolar provisions, though one of the versions mandates patent extensions when Bolar provisions are used. <a href="#">Subsection B.2.e, Article 5.</a>	Language in the text copied exactly from TRIPS Article 30. <a href="#">Article 16.7.3.</a>	Governments can provide limited exceptions to the rights conferred by a patent as long as they don't "unreasonably conflict with the normal exploitation of the patent." This the same language as Article 30 of the TRIPS Agreement. (Bolar and other research exceptions are examples of such limited exceptions, though can/could be others.) <a href="#">Article 17.9(3)</a>	Language in the text based on TRIPS Article 30 to provide for limited exceptions that do not "unreasonably conflict with the normal exploitation of the patent." The draft specifies that when a good is produced under a Bolar provision, it can only be made, used or sold for that purpose. <a href="#">Article 15.9(3,5)</a>	Language in the text based on TRIPS Article 30 to provide for limited exceptions that do not "unreasonably conflict with the normal exploitation of the patent." <a href="#">Article 17.9(3)</a> The draft specifies that when a good is produced under a Bolar provision, it can only be made, used or sold for that purpose. <a href="#">Article 17.9(6)</a>	Language in the text based on TRIPS Article 30 to provide for limited exceptions that do not "unreasonably conflict with the normal exploitation of the patent." <a href="#">Article 15.9(3)</a> The draft specifies that when a good is produced under a Bolar provision, it can only be made, used or sold for that purpose. <a href="#">Article 15.9(6)</a>
Protection of Test Data	When data has been submitted to a regulatory agency, it must be protected against "unfair commercial use." ( <a href="#">Carlos Correa's explanation of this term</a> ) No period of time mandated for which data exclusivity must belong to originator. <a href="#">Article 39(3)</a>	TRIPS Article 39.3 applies. Furthermore, in cases where a generic firm seeks regulatory approval based on originator data submitted to regulatory authorities in another country, the Government must provide exclusivity of the data for the same period as granted by the country where the data was originally filed. (This is typically 5-10 years in industrialized countries.) <a href="#">Article 4(22).</a>	Five years of data exclusivity from the date of the originator's approval mandated. In cases where a generic supplier seeks regulatory approval based on data submitted in another country, the five-year period begins on the date of approval in whichever country is later. If the patent expires before the term of data exclusivity, the data will still be kept confidential for the rest of the period. <a href="#">Subsection B.2.j, Article 1</a>	Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). In cases where a generic supplier seeks regulatory approval based on data submitted in another country, the period begins on the date of approval in whichever country is later. If the patent expires before the term of data exclusivity, the data will still be kept confidential for the rest of the period <a href="#">Article 16.8(1-3).</a>	Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). <a href="#">Article 17.10(1)</a>	Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If data is used to gain marketing approval in one CAFTA country, the data exclusivity must be honored in all of the CAFTA countries, regardless of whether the data is submitted in the other countries or not. <a href="#">Article 15.10(1)(a,b)</a>	Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If data is used to gain approval in another territory that provides up to five years of data exclusivity for drugs, the data exclusivity in that territory must be honored in each party. <a href="#">Article 17.10(1)</a> . If a drug's patent expires before the period of data exclusivity, the data exclusivity remains in tact. <a href="#">Article 17.10(3).</a>	Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If a drug's patent expires before the data exclusivity remains in tact. <a href="#">Article 15.10(1)</a>
Linkage of IP And Regulatory Authorities	No mention of linkage in the text.	A patent owner must be notified if another party seeks marketing approval for a generic version of a drug while it is still under patent. <a href="#">Article 4(23).</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent – essentially giving it the role of another layer of IP enforcement. In addition, if the drug is under patent in more than one country, the patent in the second country must at least last as long as the patent in the first country. <a href="#">Subsection B.2.j, Article 1-4.</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent, unless the patent holder permits it – essentially giving the regulatory authority the role of another layer of IP enforcement. <a href="#">Article 16.8(4)(c).</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of for a generic version of a drug while it is still under patent. <a href="#">Article 17.10(2)(b-c)</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of for a generic version of a drug while it is still under patent. <a href="#">Article 15.10(3)</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of for a generic version of a drug while it is still under patent. <a href="#">Article 17.10(5)</a>	A country's drug regulatory authority may not approve a generic drug for marketing while the brand name drug is under patent (unless the patent holder permits it). A patent owner must be notified if another party seeks marketing approval of for a generic version of a drug while it is still under patent. <a href="#">Article 15.10(4)</a> Possible further restriction – only for Bolar Exemptions.
Patent Extensions	No mention of patent term extensions beyond the 20-year minimum.	Extensions given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable not defined.") <a href="#">Article 4(23).</a>	Extensions given when a delay in the granting of a patent exceeds 4 years from the filing of a patent application, or 2 years after a request for examination of the application, whichever is later. <a href="#">Subsection B.2.e, Article 9</a>	Extensions given when a delay in the granting of a patent exceeds 4 years from the filing of a patent application, or 2 years after a request for examination of the application, whichever is later. <a href="#">Article 16.7(7)</a> Extensions also given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable" not defined) <a href="#">Article 18.8(4)(a).</a>	Extensions given when a delay in the granting of a patent exceeds 5 years from the filing of a patent application, or 3 years after a request for examination of the application, whichever is later. <a href="#">Article 17.9(6)</a> Also, extensions given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable not specified) <a href="#">Article 17.10(2)(a)</a>	Extensions given when a delay in the granting of a patent exceeds 5 years from the filing of a patent application, or 3 years after a request for examination of the application, whichever is later. <a href="#">Article 15.9(6)</a> Also, extensions given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable not specified) <a href="#">Article 15.10(2)</a>	Extensions given when a delay in the granting of a patent exceeds 4 years from the filing of a patent application, or 2 years after a request for examination of the application, whichever is later. <a href="#">Article 17.9(8)</a> Also, extensions given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable not specified). <a href="#">Article 17.10(4)</a>	Extensions given when a delay in the granting of a patent exceeds 4 years from the filing of a patent application, or 2 years after a request for examination of the application, whichever is later. <a href="#">Article 15.9(7)</a> Also, extensions given to compensate for "unreasonable" delay in granting of regulatory marketing approval. ("Unreasonable not specified) <a href="#">Article 15.10(3)</a>
Parallel Imports	Issue of the exhaustion of rights falls outside of the agreement. <a href="#">Article 6</a>	No mention of parallel imports or exhaustion of patent rights, but TRIPS rules must be followed.	Within five years of signing, countries must review their laws to begin regional exhaustion (for all the FTAA countries.) <a href="#">Subsection B.2.e, Article 7</a>	A allows patent holders to block parallel imports by mandating cross-border enforcement of contracts. <a href="#">Article 16.7(2)</a>	No mention of parallel imports or exhaustion of patent rights, but TRIPS rules must be followed.	No mention of parallel imports or exhaustion of patent rights, but TRIPS rules must be followed.	If a patent holder has placed restrictions on parallel imports through a contract or "other means," than parallel imports will not be permitted. <a href="#">Article 17(9)(4)</a>	Patent holder can prevent the importation of an invention, regardless of whether it has already been sold abroad. Parties can limit this to cases where the patent owner has forbidden parallel imports by contract. <a href="#">Article 15.9(4)</a>