Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries

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Tvångslicensering av patenterade läkemedel och tillgång till livsnödvändig mediciner i utvecklingsländer
Abstract

For many years pharmaceutical patents and their impact on prices have been at the centre of the international debate over insufficient access to lifesaving HIV/AIDS medicines in developing countries. The conflict has largely revolved around the implementation of an intellectual property system in the developing world, subsequent the adaptation of the TRIPS Agreement, which has made a 20 year pharmaceutical patent protection mandatory for these countries and consequently contributed to high drug prices for patented medicines as well as limited the use of generic drugs.

Developing countries, where patents are already in place, have sought to reduce high drug prices by making use of compulsory licensing, a safeguarding practice allowing the production or importation of a generic medicine without the consent of the patent holder. Compulsory licences are allowed under the TRIPS Agreement, but disagreements about the conditions, under which compulsory licences are available for ‘essential medicines’, have restricted their use. A definition of the extent to which compulsory licensees can export generic drugs to developing countries unable to manufacture their own has been missing, but on 30 August 2003 the WTO announced that it had resolved this problem by lifting the TRIPS Agreement’s restrictions on exports and permitting exports of drugs produced under a compulsory license as an exception to a patent right. The main question is whether the compulsory licensing system as prescribed in the recent Decision is an ample means of improving access to patented AIDS medicines in the developing world.

By means of legal and economic reasoning this master thesis argues that the 30 August Decision on lifting TRIPS’ restrictions on exports of patented pharmaceuticals produced under compulsory licences provides complex and uncertain rules, rendering an unreliable employment of compulsory licensing. It is desirable that further recommendations are given on which generic producing companies should be awarded compulsory licences and also on which premises. In reality, the debate about compulsory licensing is part of a much wider structural problem in development policy. The solution to the inaccessibility problem requires a mix of courses of action with a functioning compulsory licensing system included. However, disagreements such as how necessary funding should be divided equitably between developed countries could protract the reaching of a pragmatic solution.
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PART I

1 Introduction

1.1 Context and Challenge

The Acquired Immune Deficiency Syndrome (AIDS) is the most compelling public health crisis of modern times and the long term evolution of the epidemic is uncertain.¹ The disease has killed more than 20 million people already and is now the leading cause of death and lost years of productive life for adults aged 15-59 years worldwide.² Today, an estimated 40 million people are living with the Human Immunodeficiency Virus (HIV)/AIDS³, of which 95% are to be found in developing countries.⁴ Only in 2004, three million people died and five million became infected.⁵

Antiretroviral treatment is the difference between life and death for the millions of people who are HIV positive as antiretroviral drugs prevent the HIV virus from reproducing and developing into full-blown AIDS, by making it difficult for the virus to multiply inside the body.⁶ However, great inequalities persist globally in access to HIV medicines. Coverage of antiretroviral drugs in developing countries is currently extremely low and therefore, HIV/AIDS infected people in this part of the world are denied access to antiretroviral medicines.⁷

¹ WHO, Fifty-seventh world health assembly, Round tables: HIV/AIDS, 17-22 May 2004
² WHO, Unprecedented opportunity to fight HIV/AIDS and change the course of history, 11 May 2004
⁴ WHO, Round tables: HIV/AIDS, A57/DIV/9, 15 April 2004, item 8
⁷ Borrell and Watal, Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries, p 2
The HIV/AIDS epidemic is a threat to human society and globally, the retrovirus is already having a disastrous domino effect of killing adults in their prime. School systems are deteriorating as teachers fall ill and social and economic activity is set back as communities are deprived of their workers. Moreover, the health sector is under enormous strain as hospitals are overwhelmed with AIDS patients and as doctors are taken ill themselves. An intense debate is now taking place over access to antiretroviral medicines to treat HIV/AIDS. Unless access to antiretroviral therapy is expanded, AIDS will cause even more human damage and inflict long-term economic and social costs. The truth is, people are dying for drugs.

For many years pharmaceutical patents and their impact on prices have been at the centre of the international debate over insufficient access to lifesaving medicines in developing countries. The conflict has largely revolved around the implementation of an intellectual property system in the developing world, subsequently the adaptation of the “Agreement on Trade-Related Aspects of Intellectual Property Rights” (the TRIPS Agreement), which was adopted at Marrakech in 1994. The introduction of TRIPS has brought significant changes for most developing countries, since it has made a 20 year pharmaceutical patent protection mandatory for these countries and consequently contributed to high drug prices for patented medicines as well as limited the use of generic drugs.

With the dramatically spiralling AIDS crisis in the developing world, the extension of patent rights in developing countries has caused deep concern over how it impacts pharmaceutical prices. The patent system is built on the premise that patents provide an incentive for innovation by offering the patent holder a

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8 WHO, Round tables: HIV/AIDS, A57/DIV/9, 15 April 2004, item 3
10 Danzon and Towse, Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, p 1
11 Hereinafter, the terms the TRIPS Agreement, TRIPS or the Agreement will be used interchangeably.
12 Preamble to the TRIPS Agreement
13 Bartelt, Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health, p 283
14 Lanjow, A Patent Policy Proposal for Global Diseases, p 1
limited right to exclude others from using the patented product, which often is referred to as a limited monopoly.\textsuperscript{15} Free from competition, the patentee will be able to set higher drug prices during the period of protection.\textsuperscript{16} This fact has polarised the opinions on the patent systems’ convenience in the developing world. Developing countries claim that patents restrict access to essential medicines by keeping prices at artificially inflated levels, while developed countries argue that the research and development (R&D) of new products require strong patent protection.\textsuperscript{17} What constitutes an appropriate trade off between these two views is very much a matter of debate.

Developing countries where patents are already in place have sought to reduce monopolistic prices by making use of compulsory licensing, a safeguarding practice allowing the production or importation of a generic medicine without the consent of the patent holder.\textsuperscript{18} Compulsory licences are allowed under the TRIPS Agreement, but disagreements about the conditions, under which compulsory licences are available for ‘essential medicines’, have restricted their use.\textsuperscript{19} In the “Declaration on the TRIPS Agreement and Public Health” (the Doha Declaration)\textsuperscript{20}, agreed upon in Doha in November 2001, World Trade Organisation (WTO) Ministers recognised the authorisation of compulsory licensing as an instrument to protect public health and “promote access to medicines for all.”\textsuperscript{21} However, they failed to define the extent to which compulsory licensees can export generic drugs to developing countries unable to manufacture their own, without the risk of facing trade sanctions.\textsuperscript{22} On the 30 August 2003 the WTO announced that it had resolved this problem, by lifting the TRIPS Agreement’s restrictions on exports and permitting exports of drugs produced under a compulsory license as an exception to a patent right.\textsuperscript{23}

\begin{footnotes}
\footnote{Chien, \textit{Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?}, p 1}
\footnote{Oh, \textit{TRIPS and Pharmaceuticals: A Case of Corporate Profits over Public Health}, p 2}
\footnote{Henry and Lexchin, \textit{The Pharmaceutical Industry as a Medicines Provider}, p 1590}
\footnote{MSF, \textit{Trading Away Health}, p 11}
\footnote{Opderbeck, \textit{Patents, Essential Medicines, and the Innovation Game}, p 1}
\footnote{Hereinafter, the terms Doha Declaration or the Declaration will be used interchangeably.}
\footnote{Doha Declaration ¶ 4 and MSF, \textit{Doha Derailed: A Progress Report on TRIPS and Access to Medicines}, p 1}
\footnote{WTO, \textit{TRIPS and Public Health: the Situation Before Cancún},\newline\url{http://www.wto.org/english/tratop_e/trips_e/health_background_e.htm}}
\footnote{WTO, \textit{Decision Removes Final Patent Obstacle to Cheap Drug Imports}, 30 August 2003}
\end{footnotes}
After years of efforts to reach a sensible resolution of the patent controversy, the “Decision of 30 August 2003” (the 30 August Decision)\textsuperscript{24} might be seen as a key to improve access to essential medicines in developing countries. Nonetheless, in light of these recent developments of the compulsory licensing system with special focus on the 30 August Decision following questions may be posed:

How shall the 30 August Decision be perceived in terms of improving access to essential medicines in the developing world? Are there any obstacles to an effective use of its provisions and if so, are they possible to overcome?

Moreover, which are the plausible effects of compulsory licenses in general?

Finally, does compulsory licensing provide an ample means of facilitating access to essential medicines or should alternative courses of action be considered?

\textbf{1.2 The Purpose of the Thesis}

The purpose of this master thesis is to become engrossed in the compulsory licensing system to examine whether the safeguard is an ample means of improving access to patented AIDS medicines in the developing world. Moreover, the recent 30 August Decision will be reviewed to see whether it is possible to make full use of its provisions. Additionally, the plausible effects of compulsory licensing in general will be investigated. In case of negative answers to the just mentioned purposes, a brief discussion on alternative courses of action will be conducted.

\textsuperscript{24} Hereinafter, the terms 30 August Decision or the Decision will be used interchangeably.
1.3 The Scope of the Thesis

In order to do full justice to the information and arguments that will be given, as well as to be able to focus fully on the chosen topic, the thesis is written on the following conditions:

- The reasons for the lack of access to essential medicines are manifold. Logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, taxes, unreliable health care systems, prohibitive prices and lack of financing for health care all play a role. In many cases, however, the price of medicines remains the most formidable barrier to needed treatments and prohibitive drug prices are often the result of strong intellectual property protection.\(^{25}\) It will therefore be assumed that the influence of patents on prices is the fundamental cause of limited access to essential medicines.

- The TRIPS Agreement contains more safeguards than compulsory licensing, namely parallel importation and measures to accelerate the introduction of generics.\(^{26}\) As the scope of this thesis is limited to only encompass the practice known as compulsory licensing, the other safeguard provisions held by the TRIPS Agreement will not be touched upon in the thesis.

- It will be assumed that the interests of the players at the international arena of intellectual property rights are polarised to encompass developed and developing countries only. It might seem abstract, simplistic and unrealistic to disregard differences in interests between countries on a multilateral level; however, such a division will only benefit the clarity of the thesis.

- It will be assumed that people in developing countries are financially restrained.


\(^{26}\) TRIPS Articles 7 and 8
• As this thesis is intended for scholars in both law and economics, it will be assumed that the reader has fundamental knowledge in these fields. Therefore, the linguistic wording of the thesis, that is to say the use of legal and economic terminology, will be adjusted thereafter.

• Although the author has chosen to exclusively focus on the access to essential AIDS medicines in developing countries it should be observed that the complex of problems which is elucidated in this thesis also may apply to other medicines and diseases such as vaccine against malaria and tuberculosis. However, the author has deliberately chosen to leave these diseases open, as the legal and economic line of argument adherent to them is different and deserves to be illuminated in a separate paper.

1.4 Applied Method

In order to facilitate the understanding of the international patent rules relating to compulsory licensing, the flaws they suffer from as well as the challenges they are confronted with, relevant passages of the TRIPS Agreement, the Doha Declaration and the 30 August Decision will be mapped out. Furthermore, by means of legal and economic reasoning, the possible economic and social effects of patent rights and compulsory licences will be explained, as will be the rationale of patents and compulsory licensing.

As the fundamental idea of patent protection as well as the general idea of compulsory licensing is mirrored in the TRIPS Agreement, there is a risk of being repetitive when giving an account of the rationales and rules in question. However, for the sake of clarifying the general content of TRIPS’ patent regulation and directing the reader onto both legal and economic reasoning, which is a necessity for the chosen topic, a pinch of repetitiveness should be tolerated.

Solely assessing the 30 August Decision and its accompanying Chairman’s Statement more closely in the analysis of the thesis and not the described provisions of TRIPS or the Doha Declaration, is motivated by the mere fact that
the Decision is the most recent development of the international compulsory licensing system. However, if the reader shall be able to follow the connecting thought through the thesis an omission of the course of events leading to the 30 August Decision cannot be motivated.

In order to carry out a rational analysis of compulsory licensing as a means to increase access to essential medicines, it is vital to view the safeguard in a wider perspective. This is the reason for including the discussion on complementary courses of action to find a solution to the inaccessibility problem. However, as the aim of the thesis does not include an extensive analysis of possible solutions, motivates the inexhaustible line of reasoning provided at the very end of the thesis.

Regarding the materials employed, use has been made of relevant sources from as wide a spectrum of resources as possible, and the sources have been relied upon cautiously. The carefulness involved is motivated by the changes the international compulsory licensing rules have undergone recently by for instance the 30 August Decision, which in turn has outdated some available information. Since the subject is a current affair and new information is published everyday, little has yet been written in books on recent developments in the WTO negotiations and the 30 August Decision. Therefore, use has mainly been made of official papers and publications, as well as journals and online materials in addition to the TRIPS Agreement, the Doha Declaration and the 30 August Decision.

1.5 Thesis Disposition

The author has decided to divide the thesis into two parts, of which part I will constitute the frame of reference and part II the analysis. Part I begins with an introductory description of the current public health and development crisis in the developing world, followed by an explanation of the differing views of patent implications between developed and developing countries. Thereafter, an account will be given of the rationale of patent protection. In the ensuing section, the
international patent regime will be surveyed. An explanation will be given of the TRIPS Agreement and its general provisions of the compulsory licensing safeguard, as well as the interpretive issues revolving around the use of the safeguard. At the end of part I, a background is given on past and recent changes in the compulsory licensing system, entailing the adoption of the Doha Declaration and the 30 August Decision and its accompanying Chairman’s Statement.

Part II commences with an assessment of the 30 August Decision and its complementary Chairman’s Statement, followed by a reflection upon additional interpretive issues. Thereafter, the possibility of amending the TRIPS Agreement for an unambiguous compulsory licensing is discussed. The ensuing section sheds light on possible twists of expectations followed by a discussion of complementary courses of action. The thesis ends with a final sentence and a conclusion of compulsory licences and the problem of inaccessible access to essential medicines in the developing world.
2 Intellectual Property Rights

2.1 Patents

Intellectual property rights are the exclusive rights awarded by society to individuals or organisations over creative works, which give the originator the right to prevent others from making unauthorised use of the property for a limited period of time.\textsuperscript{27} Patents are one type of intellectual property rights that establish ownership rights to inventions and other technical improvements.\textsuperscript{28} They are designed to encourage innovation and public disclosure, by awarding exclusive rights to practice an invention for a fixed period of time.\textsuperscript{29} By obtaining a patent, the patent holder is granted with a temporary monopoly, generally of 20 years, over the invention.\textsuperscript{30} In return, however, society requires the patent applicant to disclose the invention and make publicly available, though not for commercial use, the knowledge on which the invention is based.\textsuperscript{31} By this means, the patents seek to achieve an appropriate balance between inciting R&D and allowing the employment of existing inventions.\textsuperscript{32}

2.2 The Economic Rationale of Patent Protection

The economic argument for protecting patents is that it generally costs far more to discover and develop a new product than to copy it.\textsuperscript{33} If protection was unavailable, imitators could easily enter the market and erode the profit available to the actual inventor, hence discouraging potential inventors from taking an

\textsuperscript{27} CIPR, \textit{Integrating Intellectual Property Rights and Development Policy}, p 12
\textsuperscript{28} CIPR, \textit{ibid}, p 12
\textsuperscript{29} Opderbeck, \textit{Patents, Essential Medicines, and the Innovation Game}, p 5
\textsuperscript{30} WIPO, \textit{The Impact of the International Patent System on Developing Countries: Study Drawn Up by Aziz Bouazzaoui}, p 6
\textsuperscript{31} CIPR, \textit{Integrating Intellectual Property Rights and Development Policy}, p 14
\textsuperscript{32} WIPO, \textit{The Impact of the International Patent System on Developing Countries: A Study by NG Siew Kuan, Elizabeth}, pp 9-10
\textsuperscript{33} Lanjouw, \textit{Intellectual Property and the Availability of Pharmaceuticals in Poor Countries}, p 6
active interest in R&D. The granting of temporary market exclusivities, which economists often term monopolies, allows patent holders to set prices above the marginal cost of production (Pm). When prices of patented products exceed the cost of producing them, monopoly rents are created (Pc → Pm) and output is reduced (Qc → Qm). In economic parlance, this outcome is called the deadweight loss (A), meaning that those consumers who are willing to pay the production cost but less than the monopoly price will not be served.

\[ P_m = \text{Monopoly price} \quad \text{Qm} = \text{Quantity in a monopoly} \]
\[ P_c = \text{Price in a competitive market} \quad \text{Qc} = \text{Quantity in a competitive market} \]
\[ = \text{production cost} \quad \text{MC} = \text{Marginal Cost} \]
\[ MR = \text{Marginal revenue} \]

The justification of tolerating this loss of consumer surplus (A) is that the temporary monopoly provides a desirable return to inventors. Invention is costly,
the argument runs, and if inventions can be copied and sold by competitors of the inventor firm immediately, its prices will be driven down to the marginal cost of producing them exclusive of the cost of innovation. As a result, inventors will be unable to recoup R&D development costs. Knowing that fact ex ante, potential inventors will be unwilling to incur such costs as explained above and technical progress will be hampered. Patent rights overcome this problem by affording the patent holder a fixed period of monopoly rents that allow the holder to recoup the costs of investing in R&D.38

Expressed in economic terms, patent protection is a bargain struck by society on the premise that, in absence, there would be insufficient innovation and invention. The assumption is that in the longer run, consumers will be better off in spite of the higher costs conferred by monopoly pricing, because the short term losses to consumers are more than offset by their valuations of new inventions created through additional R&D.39

In the case of pharmaceutical innovation, the importance of patents follows from the characteristics of the pharmaceutical R&D process. The investment costs of pharmaceuticals are extremely high, and the fact that only 1% of all R&D efforts to produce a new medicine results in a marketable and patentable product makes the investment in any one pharmaceutical product exceedingly risky.40 In essence, it takes US$ 500-600 million to discover and develop a new medicine, while drug innovations are relatively straightforward to imitate and imitation costs in pharmaceuticals are extremely low.41 To reiterate, absent patent protection, new and better drugs run the risk of not being developed at all. There is an inherent logic behind the general formula for patent protection that it is a necessary precursor for innovation.42 Why would a pharmaceutical company invest large amounts of resources in a product if imitators could free ride on the innovator’s financial input, ingenuity and research, and duplicate the compound for a small fraction of costs?43

38 Sykes, TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution”, pp 12-13
39 CIPR, Integrating Intellectual Property Rights and Development Policy, p 14
40 Grabowski, Patents, Innovation and Access to New Pharmaceuticals, p 851
41 Henry and Lexchin, The Pharmaceutical Industry as a Medicines Provider, p 1592
43 Grabowski, Patents, Innovation and Access to New Pharmaceuticals, p 851
3 The TRIPS Agreement

The TRIPS Agreement is an integral part of the WTO Agreements, which create binding international obligations among WTO Member States. TRIPS is a multilateral agreement establishing a common set of minimum standards for protection of intellectual property. All Member States have to conform to these standards by modifying their national regulations to accord with the rules of the Agreement.

3.1 Patent Protection under the TRIPS Agreement

The TRIPS Agreement requires Member States to make patent protection available for “any interventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application”, which includes pharmaceuticals. The term of patent protection “shall not end before the expiration of a period of 20 years counted from the filing date.” In addition, the Agreement stipulates that “[a] patent shall confer on its owner the/…/exclusive rights/…/to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.” Differently expressed, this provision means that unauthorised copies of patented drugs only can be produced and commercialised with the authorisation of the patent holder.

However, the patent rights awarded by the TRIPS Agreement are not absolute, but may be subject to exceptions. Member States are allowed to adopt certain measures that mitigate the impact of exclusive rights and facilitate access to

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46 TRIPS Article 27(1) and WIPO, Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa, p 26
47 TRIPS Article 33
48 TRIPS Article 28(1)(a)
medicines. As already mentioned in the introductory chapter, one of the safeguards of the protection of public health is compulsory licensing\textsuperscript{50}, which will be dealt with more fully in the subsequent sections.

\textbf{3.2 Compulsory Licensing}

Compulsory licences are neither defined nor expressly mentioned in the TRIPS Agreement.\textsuperscript{51} They fall under a provision entitled “Other Use Without Authorisation of the Right Holder,” which establishes a system for the granting of licences where Member States are allowed to make “use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government.”\textsuperscript{52} In practical terms, this means that a third party may be permitted to use, manufacture or commercialise an invention, which de facto is still under patent and in this respect, the public interest goal of achieving broader access to the patented invention is considered more important than the private interest of the right holder in fully exploiting his exclusive rights. What this means in the context of public health imperatives is that compulsory licensing is intended to permit countries to produce generic drugs that are more affordable than patented medicines.\textsuperscript{53} Since this amounts to an exception to the exclusive rights of the patent holder, the TRIPS Agreement imposes specific conditions on Member States to admit compulsory licenses.\textsuperscript{54}

Before a compulsory licence is granted the proposed user must have first attempted unsuccessfully for a reasonable amount of time to obtain a voluntary

\textsuperscript{51} Bartelt, \textit{Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health}, p 288
\textsuperscript{52} Preamble to TRIPS Article 31
\textsuperscript{53} Matthews, \textit{WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?}, p 77
licence on “reasonable commercial terms.” However, the requirement of trying for a voluntary licence can be waived if there is “national emergency” or “other circumstances of extreme urgency.” Basically, compulsory licences could be granted by developing countries without prior negotiation with the holder of rights to key pharmaceutical patents in the case of a public health crisis of epidemic proportions. However, the use of compulsory licensing shall be authorised “predominately for the supply of the domestic market of the Member authorising such use.” This has the practical effect of preventing exports of generic drugs to countries that do not have significant pharmaceutical industries themselves.

Furthermore, the scope and duration of the use of compulsory licensing is “limited to the purpose for which it was authorised” and the authorisation of use can be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur.” Finally, if a compulsory licence is issued, right holders shall be paid “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.”

### 3.2.1 The Rationale of Compulsory Licensing

In contrast to compulsory licensing, voluntary licensing logically means that patent holders license production or distribution rights of free will. In a perfectly competitive market, there would be no need for compulsory licensing, as the market incentives should motivate patentees to utilise their patents in the most

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55 TRIPS Article 31 (b)  
56 TRIPS Article 31 (b)  
57 Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, p 77  
58 TRIPS Article 31 (f)  
59 Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, p 78  
60 TRIPS Article 31 (g)  
61 TRIPS Article 31 (h)
economically efficient way.\textsuperscript{62} In such a market licences would be contracted voluntarily and yield an efficient use of resources: patent holders would obtain their preferred remuneration in exchange for a complete transfer of technological information and know-how.\textsuperscript{63}

The reality is different though, as the granting of patent rights motivates monopolistic pricing.\textsuperscript{64} A patent holder who dominates the market is expected to cut output and raise prices, a profit increasing move, which reduces both consumer and social welfare.\textsuperscript{65} Furthermore, the desire to retain monopoly profits and corporate goals of research may induce the patent holder to refrain from reaching an agreement on authorising licences voluntarily.\textsuperscript{66} For this reason, it is necessary to have access to compulsory licences to promote production and distribution of cheaper generic medicines in poor countries.\textsuperscript{67}

On one hand, the main benefit of compulsory licences is that they introduce the dynamic effects of competition. Hence, by exerting competitive pressure on the originator firm’s prices, compulsory licenses may increase the affordability and accessibility of essential medicines.\textsuperscript{68} Another closely related benefit of compulsory licensing is that it can advance technological capabilities by letting licensees reengineer the innovations of originator firms at low cost. A good example is India, which developed its technological capabilities and established an efficient medical industry exactly by concentrating on process innovations to produce patented drugs.\textsuperscript{69} On the other, in order to make use of the safeguard, compulsory licensees must foresee a sufficiently profitable market to justify the costs of production. Therefore, a cost of compulsory licensing may be advantageous solely for commercially workable medicines.\textsuperscript{70}

\textsuperscript{63} Maskus, \textit{Ensuring Access to Essential medicines: Some Economic Considerations}, p 12
\textsuperscript{65} Rose, \textit{ibid}, pp 8-9
\textsuperscript{66} Rose, \textit{ibid}, pp 3-4
\textsuperscript{67} MSF, \textit{Trading Away Health: Intellectual Property and Access to Medicines in the Free Trade Area of the Americas (FTAA) Agreement}, pp 4-6
\textsuperscript{68} Chien, \textit{Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?}, p 19
\textsuperscript{69} Maskus, \textit{Ensuring Access to Essential Medicines: Some Economic Considerations}, p 15
\textsuperscript{70} Maskus, \textit{ibid}, p 15
3.2.2 The Effect and Prevalence of Compulsory Licensing

In the context of improving access to essential medicines in developing countries, compulsory licensing has been defined as being a crucial element in pharmaceutical patent policy.\(^71\) Scholars have acknowledged the merits of generic drugs, in particular their effect on prices.\(^72\) For example, the lowest discounted price of Boehringer Ingelheim’s Nevirapine, a drug used in many first-line antiretroviral therapies, is US$ 438 per patient per year, while a generic version costs only US$ 166 per patient per year, which is 38% of the originator price.\(^73\) More important has been the 97% reduction in price of combination antiretroviral drugs after marketing by Indian generic drug manufacturing companies.\(^74\)

Although the availability of generic drugs has proved to reduce prices, some developing countries have been reluctant to use compulsory licensing for fear of trade sanctions\(^75\) by the developed countries.\(^76\) The South African AIDS case is a good illustration. When the South African government sought to enact the Medicines and Related Substances Control Amendment Act 90 of 1997, somewhere around 40 pharmaceutical companies accused it of violating the South African Constitution and the TRIPS Agreement. The objections were directed at ambiguous provisions in the South African patent law that would allow for compulsory licences and parallel imports of pharmaceutical products in order to increase availability and lower the cost of medicines. The companies filed suit to block the implementation of the 1997 Amendment Act and in particular, the US began pressuring the WTO to issue sanctions against the country, including denying it tariff relief on certain exports. It was only after immense public

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\(^{71}\) Mwalimu, Implications of WTO/TRIPS in East Africa – With Special Emphasis on Pharmaceutical Patents, pp 21-22
\(^{72}\) Henry and Lexchin, The Pharmaceutical Industry as a Medicines Provider, p 1592
\(^{73}\) MSF Comments on the Draft Chairman’s Statement of 21 August ’03, 26 August 2003
\(^{74}\) Henry and Lexchin, The Pharmaceutical Industry as a Medicines Provider, p 1592
\(^{75}\) However hard research has been done, no formal definition or other explicable stipulation has been found regarding the implication of trade sanctions. Nevertheless, gathering from the extensive material read and relied upon, trade sanction can be composed of penalties as well as of the withdrawal of trade benefits such as tariff reductions originating from bilateral agreements. See for instance Sen Gupta, Pharmaceutical Industry, Profits of US Cos. vs.Millions of Lives, http://www.delhiscienceforum.org/pharm9.html and Mutume, Health and ‘Intellectual Property’, Poor Nations and Drug Firms Tussle over WTO Patent Provisions, p 14. Hereinafter, it will be alluded to the just mentioned measures of trade sanctions when using the term in question.
\(^{76}\) Oh, TRIPS and Pharmaceuticals: A Case of Corporate Profits over Public Health, p 3
pressure that the US retreated from its position and the pharmaceutical firms dropped the lawsuit in April 2001.  

At this point, it is also worth calling attention to the irony in the situation. While being reluctant to the use of compulsory licensing in developing countries, empirical evidence shows that it is the developed countries that have been the most active users of compulsory licensing for a number of purposes, largely in the pharmaceutical field. Very recently the US were at the verge of issuing compulsory licences prior to negotiations with the patentee, the German pharmaceutical company Bayer, to produce generic equivalents of the drug Ciprofloxacin to deal with the bio-terrorism fright of anthrax attacks, which followed the September 11 terrorist attacks in New York 2001.

3.3 Timetable for Implementing TRIPS

3.3.1 Transitional Agreements for Implementation

When the TRIPS Agreement came into effect on 1 January 1995, it set out transitional periods for implementation for developed, developing and least developed countries, allowing member countries time to introduce the various TRIPS obligations into their national legislation and regulations in order to become fully TRIPS compliant. The Agreement makes some concessions to the particular needs of developing and least developed countries that lack the economic and administrative infrastructure to implement a pharmaceutical patent system, by extending their transition periods. The TRIPS implementation deadline for developed countries was 1996, and 2000 for developing countries.

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77 Bartelt, Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health, pp 290-294
78 Mwalimu, Implications of WTO/TRIPS in East Africa – With Special Emphasis on Pharmaceutical Patents, p 21
79 CIPR, Integrating Intellectual Property Rights and Development Policy, p 42
80 MSF, The Effects of the 2005 TRIPS Implementation Deadline On Access to Medicines, p 1
Those developing countries that did not grant pharmaceutical product patents prior to the TRIPS Agreement had until 2005 to harmonise their national legislation on intellectual property rights with the international TRIPS obligations.\(^{82}\) Least developed countries are given until 2016, to bring domestic law into compliance with the patent protection requirements in TRIPS.\(^{83}\) Moreover, countries that fail to adopt national legislation in time or in keeping with TRIPS can incur penalties.\(^{84}\)

 Nonetheless, not all developing countries made full use of the 2005 transition period. Many of the thirteen WTO members, such as Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay, who had the opportunity to take advantage of the extra transition period, introduced pharmaceutical patent protection before the 2005 deadline.\(^{85}\) In practice, many of these countries were pressured by developing countries and the US in particular, to prematurely implement patent protection in their national laws. Among other countries, they were also pressured to agree to provisions in regional and bilateral trade agreements which go beyond the TRIPS Agreement, so called TRIPS plus provisions. The principal reasons for including intellectual property rights commitments in separate agreements have been defined as the increased interest of developed countries in enhanced protection for their technologies and creations from “free riders”, as well as the need to consolidate and expand market access for products and services with a high technological value in developing countries.\(^{86}\)

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\(^{82}\) TRIPS Article 65 (1) and 65 (4) and WTO, *Pharmaceuticals in the Trade Related Aspects of the Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation: A Briefing on TRIPS*, pp 12-13

\(^{83}\) TRIPS Article 66 (1) and CIPR, *Integrating Intellectual Property Rights and Development Policy*, pp 161-162. The TRIPS implementation deadline for least developed countries was extended from 2006 to 2016 at the WTO Ministerial Conference in Doha, which is mentioned in section 5


\(^{86}\) Vivas-Eugui, David, *Regional and Bilateral Agreements and a TRIPS-plus World: the Free Trade Area of the Americas (FTAA)*, p 7
TRIPS-plus stipulations can feasibly limit the access to low cost medicines, for instance by extending the life span of patents and thereby further delay generic competition, or by raising the requirements of compulsory licensing and thus restricting the use of the safeguard.\textsuperscript{87} By way of example the European Commission, the US and Japan have raised issues concerning drug pricing in various bilateral trade discussions. In 1999, the European Commission and the US asked Korea to accept hefty prices for patented medicines. In addition, the European Commission brought a similar case against Turkey in 2003.\textsuperscript{88}

### 3.3.2 When Transition Periods Come to an End

There is one prominent hypothesis that access to medicines will worsen when the TRIPS Agreement’s transition periods come to an end and developing countries have to fully adopt pharmaceutical patent laws.\textsuperscript{89} Scholars expect the introduction of patent coercion to make life saving drugs unaffordable by posing challenges on the public health policies.\textsuperscript{90} Above all, pharmaceutical patent holders are anticipated to exploit their monopoly positions to keep drug prices at inflated levels and not until patents expire can generic drugs be manufactured and sold at more affordable prices.\textsuperscript{91}

Many developing countries cannot afford expensive patented medicines and most neither have sufficient manufacturing capacities to produce cheaper generic versions.\textsuperscript{92} Actually, only about a dozen developing countries, among them India, China, Brazil, Argentina and South Africa, have the level of manufacturing capacity capable of producing significant quantities of generic drugs. For


\textsuperscript{88} Hubbard and Love, Comment - Make Drugs Affordable: Replace TRIPS-plus by R&D-plus, p 3

\textsuperscript{89} Attaran, How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?, p 161


\textsuperscript{91} WTO, Pharmaceuticals in the Trade Related Aspects of the Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation: A Briefing on TRIPS, pp 5-6

\textsuperscript{92} WHO, TRIPS, Intellectual Property Rights and Access to Medicines, p 5
countries with insufficient manufacturing capacity, the only realistic sourcing mechanism is importation.93 Prior to 1 January 2005, they could import generics from a few other developing countries that made full use of the 2005 transition period such as India, which have the knowledge and capacity to produce such medicines by a process of reverse engineering.94 In fact, since 1970, India’s Patent Act has allowed Indian manufacturers to legally produce generic versions of medicines patented in other countries.95 India’s expertise in reverse drug engineering fast established its pharmaceutical manufacturing industry as the prime source of cheap generic medicines in the world. For instance, an estimated 70% of the 25,000 AIDS patients treated by Médecins Sans Frontières (MSF) in 27 countries are taking Indian generics.96

Nonetheless, from 2005 onwards, all developing countries but the least developed countries and the occasional non WTO countries have to fully comply with the TRIPS Agreement.97 They are therefore bound to grant patents for pharmaceutical products and are no longer able to produce and export cheap generic versions of patented medicines.98 In other words, access to essential medicines could become dramatically more difficult in the coming years. Estimates suggest prices of new drugs will increase by a mean of 200%.99

What about the compulsory licensing safeguard provided for in the TRIPS Agreement, which allows countries to override patent rights? Recall the condition that a compulsory licence must be “predominantly for the supply of the domestic market of the Member authorising such use.”100 The provision rules out the possibility to issue a compulsory licence just to produce and export generic medicines to countries dependent on imports. This means that with the

93 Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, p 78
95 MSF, The Effects of the 2005 TRIPS Implementation Deadline on Access to Medicines, p 2
96 MSF, Ibid, p 2
98 Oxfam International, TRIPS and Public Health. The Next Battle, pp 5-6
99 Scherer and Watal, Post-TRIPS Options for Access to Patented Medicines in Developing Countries, pp 15-16
100 TRIPS Article 31(f)
implementation of the TRIPS Agreement in India or any other generic producing country, these countries can issue compulsory licences to address their own health problems, but they can not grant licences for the sole purpose of addressing the health problems of other countries.\textsuperscript{101} As a result, developing countries that lack domestic production capacities and rely on imported medicines may face problems finding a source of supply of generic drugs.\textsuperscript{102}

Apart from this problem of how to improve the access to medicines in developing countries with insufficient or no manufacturing capacities, the TRIPS Agreement’s provisions have given rise to other interpretive issues.\textsuperscript{103} In particular, it has been questioned what constitutes a “national emergency” or what “adequate remuneration” amounts to.\textsuperscript{104} The developing countries pushed for and sought clarification on these and related questions, largely settled, at the fourth WTO Ministerial Conference in Doha, which was held in November 2001.\textsuperscript{105}

\textsuperscript{101} Oxfam International, \textit{TRIPS and Public Health. The Next Battle}, p 6
\textsuperscript{103} MSF, \textit{New Deal from the World Trade Organisation May not Provide Essential Medicines for Poor Countries}, 13 September 2003
\textsuperscript{104} Sykes, \textit{TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution}, p 7
\textsuperscript{105} WTO, \textit{TRIPS and Public Health: the Situation Before Cancún},
\url{http://www.wto.org/english/tratop_e/trats_e/health_background_e.htm}
4 The Doha Declaration

At the Doha Ministerial Conference, WTO Members adopted the groundbreaking Doha Declaration, which explicitly acknowledges that public health and access to medicines should have primacy over commercial interest. The core of the Declaration states that “the TRIPS Agreement should not prevent Members from taking measures to protect public health” and encourages Member Countries to interpret TRIPS in a manner that protects public health and promotes access to medicines for all. Furthermore, it emphasises the employment of compulsory licensing and declares that each Member is free to determine the grounds upon which such licences are granted. The Doha Declaration also clarifies that “[e]ach Member has the right to determine what constitutes a national emergency” and provides that AIDS qualifies for representing a national emergency, thereby precluding the need for prior negotiations for voluntary licences with the right holder before issuing compulsory licences.

While the Doha Declaration affirms the right of Member Countries to use compulsory licensing, it does not address the TRIPS condition that medicines produced under this safeguard shall be “predominantly for the supply of the domestic market.” During the WTO meeting in Doha, Trade Ministers recognised 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, and instructed the Council for TRIPS to find an expeditious solution to this problem before the end of 2002. However, not until 30 August 2003, did the TRIPS Council announce that a compromise decision had been reached.

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106 Doha Declaration ¶ 1 and MSF, One Step Forward, Two Steps Back? - Issues for the 5th WTO Ministerial Conference (Cancún 2003), p 1
107 Doha Declaration ¶ 4
108 Doha Declaration ¶ 5(b) and Chien, Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?, p 19
109 Doha Declaration ¶ 5(c) and Sykes, TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution, p 9
110 Bagley, Legal Movements in IP: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS, p 106
111 Doha Declaration ¶ 6
112 Opderbeck, Patents, Essential Medicines, and the Innovation Game, pp 13-14
5 The 30 August Decision

5.1 Lifting TRIPS’ Restrictions on Exports

On 30 August 2003 the WTO broke eight months of bitter deadlock over intellectual property protection and public health when it agreed on legal changes to give poor nations access to cheap lifesaving drugs for conditions such as AIDS. The WTO agreed to allow developing countries, unable to manufacture the medicines they need to address public health problems, to import low cost generic drugs from abroad. Supachai Panitchpakdi, the director general of the WTO, hailed the 30 August Decision as historic: "The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules to deal with the diseases that ravage their people."

The “Decision of 30 August 2003” waives the condition that production under compulsory licensing must be predominantly for the domestic market and states that any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries, provided certain conditions are met. The 30 August Decision states that the importing Member must notify the TRIPS Council of the type and quantity of licensed product and, except in the case of a least developed country, must establish that the importing country has “insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question.” This latter requirement can be met by showing that the importing member “has no manufacturing capacity in the pharmaceutical sector” or that any existing capacity “is currently insufficient for the purpose of meeting its needs.”

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113 MSF, Telegraph SA: Africa to Receive Cheaper Aids Drugs, 1 September 2003
114 MSF, Lancet: WTO Takes a First Step, 6 September 2003
115 MSF, Guardian: Deal Reached on Cheap Drugs for Poor Nations, 1 September 2003
116 30 August Decision ¶ 2, MSF, Lancet: WTO Takes a First Step, 6 September 2003
117 30 August Decision ¶ 2 (a)(ii)
118 30 August Decision Annex (i)-(ii)
In order to prevent the products produced under compulsory licensing from being re-exported to developed markets and undermining patent systems, the Decision declares that they shall be clearly distinguished through specific labelling, packaging or product colouring” and continues stipulating that importing Members shall take “reasonable measures within their means, proportionate to their administrative capacities” to prevent trade diversion.\(^{119}\) “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 assist with technical and financial cooperation to facilitate control measures against trade diversion.\(^{120}\)

The responsibility to provide “adequate remuneration” to the patent holder continues as under Article 31 (h) of TRIPS, but extends only to the exporting member.\(^{121}\) Moreover, All WTO Member countries are eligible to import under the 30 August Decision, although 23 developed country Members are listed in the decision as announcing voluntarily that they will opt out of using the system to import drugs.\(^{122}\)

The current Decision is only a temporary waiver and will terminate when the TRIPS Agreement is amended to adopt the issues covered by the Decision.\(^{123}\) This was scheduled to take place before the end of 2004; however, the already extended deadline to 31 March 2005 has not yet been met.\(^{124}\)

\(^{119}\) 30 August Decision ¶ 2 (b)(ii) and ¶ 4 and MSF, *International Herald Tribune: A WTO Deal on Drugs*

\(^{120}\) 30 August Decision ¶ 4

\(^{121}\) 30 August Decision ¶ 3

\(^{122}\) Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States of America. See 30 August Decision ¶ 3 and Raja, *Report of Trips Council Meeting on 8 March 2004: Differences Remain on Trips/Health Issue, and Developing Countries Present Paper on Checklist ForTrips/Biodiversity Issue*, [http://www.cptech.org/ip/wto/p6/suns03102004.html](http://www.cptech.org/ip/wto/p6/suns03102004.html)

\(^{123}\) 30 August Decision ¶ 11

\(^{124}\) 30 August Decision ¶ 11 and ICTSD, *TRIPS Council Considers Public Health, Biodiversity*
5.2 The Chairman’s Statement

The US, which has had a dominating role in the compulsory licensing negotiations, first refused to adhere to the text of the 30 August Decision, as the American pharmaceutical industry feared that the new compulsory licensing system would be abused for commercial purposes. Its main concern as to lifting TRIPS’ restrictions on exports was that generic drugs imported to developing countries would find their way back into developed markets. As a matter of fact, the US has already declared that it will take action against generic drug producers whose exports will be seen as an attempt to profit from “legal loopholes”. Not until the Decision was accompanied by a separate Statement by the WTO General Council Chairperson, Carlos Pérez del Castillo, clarifying how the Decision should be employed did the US agree to it.

The Chairperson’s Statement “represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented.” It underlines that “the [new compulsory licensing] system that will be established by the Decision should be used in good faith to protect public health” and not as “an instrument to pursue industrial or commercial policy objectives.” What is more, in the Statement a number of WTO Members have voluntarily asserted that if they use the system as importers, it will only be in situations of national emergency or other circumstances of extreme urgency.

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125 MSF, The Economist: The right Fix?, 1 September 2003
126 MSF, Ibid, 1 September 2003
128 30 August 2003 Statement of General Council Chairperson. Hereinafter the Chairman’s Statement or the Statement. The § will be used interchangeably.
129 WTO, Decision removes Final Patent Obstacle to Cheap Drug Imports, 30 August 2003
130 Chairman’s Statement, the first paragraph
131 Chairman’s Statement, the second paragraph
132 Hong Kong China, Israel, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and the United Arab Emirates. Until the accession to the EU, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia had all agreed to only use the system as importers in situations of national emergency or other circumstances of extreme urgency and, upon their accession to the EU, opt out of using the system as importers altogether. See the Chairman’s Statement, the eight and ninth paragraphs.
Apart from what is pointed out in the Statement, that it is limited in its implications to paragraph 6 of the Doha Declaration\textsuperscript{133}, treated in section 4 above, the potential legal implications as well as consequences of the Statement are rather unclear. WTO Members have questioned the weight of the Statement as its remarks are set out, not in the formal text of the 30 August Decision itself, but in a kind of “gentleman’s agreement” accompanying the text of 30 August Decision.\textsuperscript{134} Conversely, a specific concern for countries that have voluntarily agreed upon a limited use of compulsory licensing for imports is to avoid turning their voluntary statements into something that might be more binding legally.\textsuperscript{135}

\textsuperscript{133} Chairman’s statement, the first paragraph
\textsuperscript{134} MSF, \textit{The Economist: The right Fix?}, 1 September 2003
\textsuperscript{135} Raja, \textit{Report of Trips Council Meeting on 8 March 2004: Differences Remain on Trips/Health Issue, and Developing Countries Present Paper on Checklist ForTrips/Biodiversity Issue}, 10 March 2004,
Part II

6 Analysis

6.1 WTO Deal on Generic Drug Exports

After years of efforts of trying to reach a clarifying agreement on compulsory licensing as well as elucidating the TRIPS condition that medicines produced under this safeguard shall be predominantly for the supply of the domestic market, it is understandable that tribute has been paid to the 30 August Decision. Owing to it, countries such as India are now allowed to maintain their generic industries and make use of their reengineering skills to address public health problems in developing countries. Furthermore, giving manufacturing licensees access to larger markets could probably add to economies of scale, thereby decreasing drug prices additionally. At least from these points of view, lifting the TRIPS Agreement’s restrictions on exports could be seen a step in the right direction to facilitate the supply of affordable generic drugs. Nonetheless, it is questionable whether the 30 August Decision and the Chairman’s Statement merits full celebration or provides good grounds of scepticism.

6.1.1 Limitations of the 30 August Decision

6.1.1.1 Complex Rules and a Generous Compulsory Licensing Market

Starting from the aim of the 30 August Decision, namely to provide greater access to low cost generic medicines by allowing exports of medicines produced under compulsory licences, a justified concern is that the Decision’s fairly complex procedural conditions on developing countries seeking to export and import cheap
copies of patented drugs adds many constraints on the business practices within these countries and may also render the new compulsory licensing system more difficult to use than it appears. The obligations to first unsuccessfully attempt to obtain a voluntary licence and to establish a lack of manufacturing capacity before notifying the TRIPS Council of the licence, and to clearly identify the generic drugs could be regarded as time consuming and could delay the arrival of generic drugs on the market. Furthermore, the requirement to establish incapacity to manufacture can be questioned. The 30 August Decision leaves unclear the grounds on which a lack of manufacturing capacity in the importing country should be determined, opening the door for trade sanctions.

Strictly speaking though, the requirement of having to establish a lack of manufacturing capacity before notifying the TRIPS Council of the license is rather ambiguous. What is really meant by having no or insufficient manufacturing capacity in the pharmaceutical sector? The issue of having no manufacturing capacity is doubtlessly settled if the developing country in question completely lacks a medical industry. In opposition, should it have even a small industry, on what basis should insufficient manufacturing capacity then be assessed? There is a danger of interpreting this prerequisite extensively. The import of compulsorily licensed pharmaceuticals risk being turned into the primary tool of addressing public health imperatives in developing countries, thereby avoiding a more preferable solution to the patentees in question, for instance, by first trying to reach an agreement about voluntary licences.

Moreover, a liberal interpretation of the compulsory licensing provisions might also undermine the general assumption that greater patent protection increases the levels of R&D. The risk lies in that pharmaceutical companies might consider investing in R&D unviable if a subsequent issuance of compulsory licences can be anticipated to be at hand. Hence, the potential adverse impact of accepting a system that may lead to more frequent recourse to compulsory licences could be the dearth of R&D.
The previously conducted lines of reasoning, that the potential of alternative and more innovative policy instruments may be obscured, also applies to the permission to export under compulsorily licences.

Moreover, there is a conflicting point of view to the argumentation about the potential adverse impact of accepting a system that may lead to more frequent recourse to compulsory licences. Stressing the fact that AIDS not only is to be found in the developing world, but also in the developed world where patients are assumed to have resources to spend on antiretroviral medicines, it is possible to pose that the pharmaceutical companies’ profits derived from having a monopoly over sales in the developing world makes only a marginal contribution to total profits. This reasoning is additionally supported by what is the starting point of this thesis, namely that AIDS patients in the developing world are financially restrained and so, unable to purchase patented pharmaceuticals. For these reasons, an extensive use of compulsory licensing should be no menace to R&D investment.

6.1.1.2 Royalty Rates

Another issue is the determination of royalty rates under compulsory licensing. The 30 August Decision, which calls for “adequate remuneration”, fails to define the term “adequate”, leaving licensees some leeway in this respect. Conversely, in respect to say the US’ ardour of threatening with trade sanctions, as they did in the South African case told about in section 3.2.2, there might be a need for executing caution, because if patent holders regard royalty rates as being inadequate, licensees may face legal proceedings.

A more important reflection is what adequate remuneration should amount to. Due to the obvious reason that most developing countries lack available funds, may of course make them unable to pay even modest royalties without financial assistance and so, leaving the flexibility unreachable. The consequence will be the same if royalty rates are set too high. Conversely, low royalty rates may well lead
to an excessive use of compulsory licenses, which in turn, might be perceived by pharmaceutical companies as excluding monopoly profits and so, putting investments at stake. Hence, the risk in this situation is that compulsory licensing could undermine incentives for R&D investments and slow down the development of new drugs.

6.1.1.3 Trade Diversion

Moreover, even if it is not open to question that the Decision must contain provisions to discourage trade diversion, it is debateable how far reaching these provisions should be. Keeping in mind that developing countries are sensitive to prices, the distinctive marking provision, implying labelling and different packaging or colouring from the patented original, is likely to increase the cost of generic drugs. In this respect, added costs associated with drug alterations might even deter the incentives for generic drug companies to embark upon compulsory licensing if they find it cost prohibitive to produce identifiable pills. In addition and although it is inevitable, it is worth pointing out the fact that compulsorily licensed products that are ready for export to developing countries in need also require resources for transport costs, something that must be calculated upon when developing countries chose trusting to compulsory licences.

Furthermore, although the anti trade diversion safeguards proposed in the 30 August Decision may seem to be too onerous, it is still imperative to have distinct trade diversion rules, which prevent generic drugs from being re-exported to developed countries. Apart from stating that importing developing countries shall take “reasonable measures within their means, proportionate to their administrative capacities” to prevent the re-exportation of drugs, the Decision fails to identify acceptable measures against trade diversion. Hence, considering the fact that many developing countries lack administrative and legal infrastructures, it is uncertain whether these countries will be capable of forestalling the diversion of compulsorily licensed products, which justifies the American drug industry’s concerns at trade diversion. However, the 30 August
Decision partly deals with this issue by providing that developed countries shall help with technical and financial cooperation to facilitate control measures against trade diversion, which is a practicable method in itself. A problem though, provided that developed countries engage in such assistance, is that the Decision leaves unanswered which party will be held liable if measures taken to prevent re-exportation are unsuccessful. This, in turn, could constitute another fertile ground for duelling lawyers.

6.1.2 Limitations of the Chairman’s Statement

6.1.2.1 Uncertain legal implications

At a first glance, the Chairman’s Statement seems reasonable by clarifying how the new compulsory licensing system should be employed, but on second thoughts, it might appear to do the reverse by establishing some sort of quasi-policy framework. Perhaps the main issue is that the Statement’s legal weight is still unclear, thus disordering its significance in connection with the provisions of the 30 August Decision. The Chairman’s Statement could in fact have far reaching consequences both if it is considered to be legally binding for WTO Members and if its avowals solely are considered to be voluntary guiding principles.

The former option could, for instance, imply that the countries that agreed to use the system only in situations of national emergency or other circumstances of extreme urgency may become legally bound by their consent. This approval may also carry with it the significant implication that WTO Members, other than those explicitly listed in the Statement, may use the system more liberally in circumstances other than in situations of national emergency or other circumstances of extreme urgency. The latter apprehension could have the same consequences as argued above regarding a too generous compulsory licensing system.
The latter option, however, could be a major setback for the US, as the pronouncements maintained in the Statement were a main reason for agreeing to the 30 August Decision, thereby also realising the concerns of the US that some countries will not opt out from the arrangements as promised. Evidently, there is a risk in not knowing a document’s legal meaning, the practical implication being uncertainty as to the extent to which WTO panels will apply and draw guidance from the Chairman’s Statement when deciding upon complaints that may arise in the future.

6.1.2.2 Unbalanced Interests

Judging from the reasoning above, the conclusion of WTO’s director general rendered in section 5.1, that the 30 August Decision ultimately remedies the limitations of the TRIPS Agreement’s compulsory licensing rules, seems to be premature. As pointed out, there are in the present situation many remaining issues that can thwart the effective use of compulsory licences.

The essential problem with the 30 August Decision and its accompanying Chairman’s Statement is that it fails to balance the interests of developed and developing countries respectively. On one hand and albeit the need to provide cheap medicines to developing countries dependent on supplies without creating parallel markets is recognised, there is still uncertainty over how far the right to use compulsory licensing for exports will be respected. Not knowing whether lack of manufacturing capacity has been established aptly or, again, what constitutes “adequate remuneration” makes the risk of sanctions apparent and the generic industry may refrain from entering export markets at all. On the other, there is cause for developed countries to question whether developing countries will be able to maintain a secluded market for generic equivalents under new safeguarding system, meaning a safe prevention of trade diversion.

Furthermore, considering the US’ initial reluctance to adopt the 30 August Decision, it is not unlikely that ambivalent compulsory licensing rules also may
pave the way for TRIPS plus provisions included in bilateral trade agreements outside the remit of the WTO. And as long as it is unclear when and how compulsory licences may be issued, developing countries may well be prepared to sign such agreements in order to avoid losing access to developed country markets.

**6.2 Additional Interpretive Issues**

Relating to the reflections about a generous compulsory licensing system, a justified question is who exactly should be granted compulsory licences. Should many generic producing companies or only one in each developing country with manufacturing capacity be qualified to utilise the safeguard?

Prices could be cut if many companies were free to make use of compulsory licensing, as an organisational form of the kind induces competition and competition, in turn, is known to force prices down. However, assuming that the line of argument about limited monopoly profits in developing country markets is not supported, again; the more extensive use is made of compulsory licensing, the greater the risk of weakening R&D incentives. Conversely, awarding compulsory licensing to only one company could be compared to granting a monopoly right. Free from competition, this sole company could set prices at its own discretion. In that case, patients dependent on generic drugs would run the risk of having to pay comparatively higher prices.

Seen from a slightly different point of view, a drawback to compulsory licensing is that it may be used for the wrong purposes. To repeat, patents allow pharmaceutical firms to benefit from temporary market power, which enables them to charge prices above marginal cost of production. Unless there are multiple competitors, there is a risk that compulsory licensees will be induced to do the same. Correspondingly, a sole compulsory licensee might “shadow” the original prices, meaning set prices just below the price of pharmaceutical firms. In other words, compulsory licensees might take advantage of the flexibility to
achieve profitable mark-ups instead of using it as a means to provide access to affordable medicines.

On one hand, the negative effects of “monopoly pricing” could be overcome by setting a price ceiling, within which the generic producing company still could enjoy some profit adjusted to the conditions on the market in developing countries. On the other, there is a major drawback with such an arrangement. Assuming that the sole manufacturer of generics is granted a constant percentage in profits, an increase in productivity is unlikely to be awarded with higher revenues, thereby taking away any potential spur to render production more cost effective – a highly unattractive course of business development for any company.

Disregarding the possible negative effects on R&D, a multiple manufacturing of generics ought to provide more patients access to essential medicines than if merely one producer were awarded a compulsory licence. Hence, the alternative to grant many generic producing companies compulsory licences stands out to be the most plausible one in the long run. The same reasoning applies to the question whether compulsory licensing should granted to all developing countries with manufacturing capacity or only one, with the small difference that competition would take place between countries and a country would gain a monopoly like generic market position.

An accompanying yet as important question is on which premises compulsory licenses should be awarded to the one or the other company, or to the one or the other country. Assuming that TRIPS’ all conditions to utilize the compulsory licensing system are met, do reasons for selection such as “lowest price of generics” or “effective prevention of trade diversion” constitute adequate bases for granting a compulsory license, or should they be supplemented by other conditions. It involves considerable risk to grant compulsory licensing on an arbitrary basis. For one thing, this could lead to an overly insistent use of the safeguard rendering R&D investments doubtful under the same assumptions as outlined above. For the second, alternative courses of action to ameliorate access to essential medicines could fall into oblivion. For the third, compulsory licensees
could abuse the safeguard as a means to line their pockets at the patentees’ expense.

6.3 Legal Amendment of TRIPS...

By studying the limitations of the 30 August Decision and the Chairman’s Statement, as well as reflecting upon some alternative interpretive issues, compulsory licensing is by no means an obvious remedy to the problem of access to medicines in developing countries. However, putting compulsory licensing in an isolated perspective, a change in the legal framework of TRIPS could overcome the stated obstacles above, thereby paving the way for its effective employment. The challenge is to implement clear definitions of who, why, when and how the issuance of compulsory licences is justified, in order to avoid possible legal disputes, as well as to protect public interests while also promoting innovation. Likewise, secure and reliable measures to prevent trade diversion are imperative for a balanced compulsory licensing system, as certainty about re-exportation rules is crucial to the pharmaceutical industry in developed countries considering long term R&D investments.

Moreover, in order to overcome the reluctance of issuing compulsory licences for fear of ending up in court just like South Africa did, it is necessary that developing countries are able to foresee the reactions of pharmaceutical companies in developed countries. For that reason, it is vital to give an account of the grounds triggering liability, for instance by providing unquestionable remuneration schemes to disentangle the obscurities surrounding the term “adequate” and identifying the grounds for determining a lack of manufacturing capacity.

Viewing compulsory licensing solely in the light of its purpose, namely to ameliorate access to medicines in case of national emergencies or other circumstances of extreme emergency which encompass the AIDS pandemic, a modification of the TRIPS Agreement by including the given recommendations...
could in fact turn compulsory licensing into an effective tool to restrain and reduce drug prices, thereby increasing access to cheaper generic medicines in developing countries. And as there is ample evidence, exemplified in section 3.2.2, that the availability of generic drugs significantly reduces prices the safeguard’s potential to promote competition among generic manufacturers and cut drug prices should not be underestimated. Therefore, letting patent reforms drift off and leave a poorly designed compulsory licensing system in the lurch, would only mute the benefits of compulsory licences.

6.4…Feasible in Reality?

In contrast to what has just been said and without denying the potentials of compulsory licensing, a legitimate reflection is whether an amendment to define clear rules is feasible in reality. The complicated nature of the inaccessibility problem, which strictly polarises the opinions of developed and developing countries respectively in relation to patented pharmaceuticals, may obstruct reaching an agreement on how a fully functioning compulsory licensing system should be designed. Actually, as developed and developing countries are in various stages of technological, economic and social development, it is unlikely that any patent rules and compulsory licensing provisions will move in tandem with the subjective needs of every country.

Additionally, the danger of designing compulsory licensing rules that cannot be interpreted in a different way than what is written down to the last letter is that the interests of the conflicting countries may fail to be met. On one hand, patentees are interested in pharmaceutical profits to recoup R&D expenditures, but if for instance anti trade diversion provisions are inefficient, investments in health R&D may never be realised. On the other, developing countries call for a flexible, yet unambiguous compulsory licensing system, but if for example royalty rates are set too high, many otherwise potential manufacturers could desist from generic production. Seemingly, a failure in balancing interests and finding an appropriate
trade off between patent protection for pharmaceutical products and production of generic equivalents may have dear and far reaching consequences.

However, adhering to the tolerably realistic argument that patentees enjoy their main profits in developed markets, by which an extensive use of compulsory licensing should not be detrimental to R&D expenditures, it should make no difference to patentees that compulsory licensing rules are to the advantage of developing countries. In that case and provided that patentees abstain from forcing excessively restrictive requirements for the issuance of compulsory licences, an amendment of TRIPS to define clear rules may well be achieved.

### 6.5 Curious Twists of Expectations

It is unquestionable that developing countries are facing many new challenges on account of the end of the 2005 transition period, when full implementation of patent protection will cause amplified drug prices in this part of the world. As well as risks, the future also holds out opportunities even if they merely are short termed ones. Least developed countries remain the only group of WTO Members that can benefit from the extended transitional arrangements until 2016, provided that they do not grant or enforce patent protection for pharmaceuticals prematurely. In addition, other developing countries which have the capacity to manufacture generics but are obliged to adhere to TRIPS’ patent rules, could practically also take advantage of the 2016 transition period. For instance, could India, which is market leading in the field of generics, exploit the least developed country status by moving its manufacturing operations to countries of that kind.

Indeed, it will be interesting to see how generic producing countries as India will react upon the implementation of TRIPS’ patent rules. Seemingly, by having made full use of extracting technology from the process of reengineering, India has, as explained in section 3.2.1, established a self supporting pharmaceutical industry. By this circumstance India may very well take an active interest in R&D efforts of its own that in case of successful patentable pharmaceutical inventions
would guarantee high profits. The cutthroat effect would be major if India chose to trade in its hailed status of being the market provider of generics for monopolistic revenues of patented drugs, as the whole developing world is counting on India’s generics. However, it must be pointed out that an Indian generic manufacturing industry will not save the world from AIDS, but solely make a profit from selling generic medicines without spurring R&D investments and consequently not contributing to pharmaceutical inventions. It is not unimaginable that such a bewildering event actually could take place and this also applies to other developing countries with generic manufacturing industries.

### 6.6 Complementary Courses of Action

To judge from my lines of argument above, it can indeed seem a distraction to continue arguing only over compulsory licensing, when the problem of insufficient access to medicines appears to be a part of a much wider structural problem in development policy. The danger of solely relying in the potentials of compulsory licensing to restrain and reduce drug prices is, for example, the neglect of other equally practicable or even better courses of action to facilitate access to essential medicines in developing countries. An unambiguous compulsory licensing system may very well be a means to an end, provided that there are drugs to licence, because it is vital to recognise the danger of failed incentives to develop new and better medicines if pharmaceutical companies perceive a weakening of patent protection. Hence, from this angle, it should not be alleged that compulsory licensing provides a complete solution, but may very well be one part of the solution to the problem of limited access to essential medicines in developing countries.

The argument that pharmaceutical companies most likely enjoy their primary returns in the developed world could in fact motivate the introduction of differential pricing, whereby different prices would be available for the same medicine depending on whether it is sold and purchased in developing or developed countries. Provided that reliable anti trade diversion provisions are in
place, patentees would then be allowed to sustain their high prices in some markets, while providing a marginal, more affordable price to the neediest countries in the world.

Progress made in the context of the Doha based negotiations, culminating in the 30 August Decision, bears witness to that political will can be found among WTO Members to ameliorate access to essential medicines in developing countries. In this respect, it is likely that the fairly one tracked focus on compulsory licensing in the long ongoing debate over and protracted negotiations on patented pharmaceutical products will be redirected to encompass other policy areas, pragmatic initiatives as well as incremental steps in search for a solution to the inaccessibility problem.

Nonetheless, in order to find an answer to the controversy of access to medicines it is rather simple to list a number of facilitating actions without actually mediating upon obstacles that may arise along the way. Without penetrating the bottom of the potential number of alternative solutions, the three following are mentionable. First and naturally, the actions of corporate donors of low cost or even free medicines and public private partnerships are parts of a resolution, as are increased foreign direct investments into local manufacturing facilities. A bigger health effort of this kind, meaning more easily deliverable drugs and services over a wider population, could in fact arouse the financial incentives for new health R&D. Second, even moderately basic modes of procedure, such as improving public health awareness via education programmes, which unnecessarily is a matter of course in developing countries, may be crucial. Third, another price decreasing effect could be attainable by combining governmentally set price ceilings for medicines with governmental subsidisation of medicines, as is done in many western countries, but with the difference that the governmental subsidisation would be covered by Third World aid (like many other types of Third World aid). Then, with a fixed maximum price, largely covered by aided subsidisation, the patient in need would preferably have to cover only a fraction of the drug price.
Putting the problem of insufficient access to essential medicines at the top of the political agendas worldwide, could indeed reinforce the important part governments play in ensuring sufficient, sustainable and long term financing of public health. But as in every other case where international, large scale funding is involved, an inevitable question is which party shall bear the main costs. Posing that developing countries are out of the question due to the obvious reason that they lack resources, what constitutes a fair division of expenses among developed countries. And how shall the fact that welfare statuses differ within the group of developing countries be taken into account? For instance, a first thought may be that a country’s yearly earmarking of funds for health expenditure is a good ground for apportioning grants. On second thoughts though, how should the fact be dealt with that heath politics, including various levels of public and private medical services respectively, are different in different developed countries. Questions like these prove that attempts to find an expeditious, if at all possible, solution to the problem of insufficient access to essential medicines are easily obstructed. The greatest obstacle to bring about various courses of action may lie with public sector acceptance of higher expenditures, as well as with the long term commitment of governmental policymakers. It remains to bee seen what lies in the future.
7 Final Sentence

All things considered, the conveying message of this master thesis is that the employment compulsory licensing as a tool to solve the problem of insufficient access to medicines in the developing world depends on each operator’s outlook, that is whether compulsory licensing is considered to be detrimental to R&D incentives or an ample means to reduce drug prices. Nonetheless, if a mix of policy approaches can assist and operate alongside a functioning compulsory licensing system and ensuring that generic drugs remain in the markets for which they were intended, there is still great potential to achieve progress in the battle to address the public health crises that afflict much of the developing world.
8 Conclusion

Although the 30 August Decision on lifting TRIPS’ restrictions on exports of patented pharmaceuticals produced under compulsory licences may very well ameliorate access to essential medicines in developing countries, but both the Decision and its accompanying Chairman’s statement provides complex and uncertain rules, rendering an unreliable employment of compulsory licensing. Nonetheless, this could be remedied by changing the legal framework of the TRIPS Agreement to encompass clear and unambiguous rules.

Furthermore, if seen isolated and provided that TRIPS is modified, compulsory licensing might be an effective tool to restrain and reduce drug prices. However, seeing compulsory licensing from a wider angle in addition to adopting an extended compulsory licensing system, the safeguard suffers from the risk of being detrimental to future R&D initiatives, of obscuring the potential of alternative innovative policy instruments as well as of being abused for commercial purposes. In addition, it is desirable that further recommendations are given on which generic producing companies should be awarded compulsory licences and also on which premises.

In reality, the debate about compulsory licensing is part of a much wider structural problem in development policy. The solution to the inaccessibility problem requires a mix of courses of action with a functioning compulsory licensing system included. However, disagreements such as how necessary funding should be divided equitably between developed countries could protract the reaching of a pragmatic solution.
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