Minor Dissertation

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Access to antiretroviral drugs in South Africa: The HIV/AIDS crisis in the light of the TRIPS Agreement, South African Intellectual Property and Competition Law

Research dissertation presented for the approval of Senate in fulfilment of part of the requirements for the LL.M. by coursework in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of LL.M. dissertations, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

Signed by candidate

Janina Voogd

05 September 2011

Abbreviations and Journals

(all other abbreviations used will be explained in the document)

EIPR	European Intellectual Property Review
GRUR	Gewerblicher Rechtsschutz und Urheberrecht (Intellectual Property and Copyright Law)
GRUR Int.	GRUR Internationaler Teil (GRUR international part)
GRUR Ausl.	GRUR Ausland (GRUR foreign countries)
IIC	International Review of Intellectual Property and Competition Law
IP	Intellectual Property
ITPJ	International Transfer Pricing Journal
UNAIDS	Joint United Nations Programme on HIV/AIDS
ZRP	Zeitschrift für Rechtspolitik (Journal of Legal Policy)

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A. Foreword

Throughout this Minor Dissertation, quotes will be taken from and references will be made to sources written in the English as well as in the German language. I have translated the German texts cited or referred to to the best of my knowledge.

Due to the nature of the subject, many sources have been taken from the internet. Whenever an internet-based source is cited, the date given in square brackets shows the date on which I last accessed the source on the internet.

B. Cause and Objective of this Minor Dissertation

The HIV/AIDS crisis has reached a high degree of prominence and awareness in both developed and developing countries. However, at the same time rural areas with no, little or very inaccurate knowledge of the HIV/AIDS problem can still be found all over the world. Furthermore, it seems that the awareness for the problem has had its peak a few years ago and that, since then, it has decreased at least on the international level. It somehow appears that the immense crisis is not seen as such nowadays and that people all over the world – but particularly in many third-world countries – have accommodated to its cruel results. The dimensions of HIV/AIDS seem to be taken as some kind of bizarre normality in many countries. Furthermore, the developed world appears to have acknowledged the fact that developing countries and HIV/AIDS present an inseparable phenomenon.

This is not the case. HIV/AIDS needs to be fought with all possible means. The awareness of people as well as governments needs to be (re-)increased and everybody – people, companies, governments, international organisations – has to understand the responsibility and act accordingly. As for governments who represent the people, many of them in need concerning their health, it has to be clear that politics are able to define a countries' fate regarding the HIV/AIDS crisis. This is also true for international organisations which create rules that apply in many countries of the world - and which at the same time are supposed to be suitable and fair for all member states.

Activists and international organisations are working to draw public attention to the problem. Famous cases such as the lawsuit filed by several pharmaceutical companies against the Republic of South Africa have helped in this respect. The World Trade Organization (WTO) as one of the important international institutions has been forced over and over again to pay attention to the crisis and adapt its rules to realities in developing countries worldwide. Likewise, the World Health Organization (WHO) and the United Nations (UN), which launched its "UNAIDS" programme back in 1996, fight the epidemic amongst others with some success. Recent developments include the establishment of the Medicines Patent Pool as well as the South African government's and SANAC's (South African National AIDS Council) establishment of a major HIV counselling and testing (HCT) campaign in 2010.[1] But even though the number of HIV

[1] When the programme was launched, the South African Minister of Health, Dr. Aaron

infections in sub-Saharan Africa has declined since 2001, this region continuously bears a disproportionate share of the global HIV burden. In particular, with an estimated 5.6 million HIV-positive people, South Africa continues to have the world's largest HIV/AIDS epidemic.[2]

The need to fight HIV/AIDS for, amongst others, humanitarian reasons, however, only shows one side of the coin. Antiretroviral drugs to treat HIV/AIDS are mainly manufactured by U.S. and European pharmaceutical companies. Many of these drugs are protected by exclusive patents. Even though the drugs are often not patent protected in developing countries, patent law nevertheless plays a role when it comes to the access to such medicines in developing countries.

There is a long tradition of criticism when it comes to patent protection,[3] particularly with respect to the accessibility of pharmaceuticals. Several epidemics such as HIV/AIDS, tuberculosis, malaria etc. have contributed to the questioning of patent protection altogether or at least its scope. Regularly, the miseries following from these epidemics were (and are) attributed to the high prices of drugs which, in turn, were considered to result from patent protection. Indeed, in 2005, most of the HIV/AIDS-infected persons in third world countries - which were about 95 per cent of all infected persons worldwide[4] - could not afford therapy. It was estimated that every eighth inhabitant of South Africa was infected, most of whom could not afford the costs of regular retroviral therapy of about 12.000 U.S. $[5] at the time.[6] Likewise, it was assumed that only every twentieth infected person of about a million infected Thais could afford proper treatment.[7] In 2001, the United Nations reported that 150 milligram of the antiretroviral "Flucanozole" only cost 55 U.S.$ in India where it was not patent protected while the costs for the same amount of the same product in Indonesia - where

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Motsoaledi, on 25 March 2010 issued the statement "Outline of the national HIV Counselling and Testing (HCT) campaign", available at http://www.info.gov.za/speeches/2010/10032611051001.htm [10 August 2011].

2 UNAIDS fact sheet Sub-Saharan Africa, Global Report 2010.

3 Already in 1860, in a speech before the House of Commons, *John Stewart Mill* illustrated the criticism of patent protection voiced by some and made clear what the result of the abolishment of patent protection would be:
"I have seen with real alarm, several recent attempts in quarters carrying some authority to impugn the principle of patents altogether - attempts which, if practically successful, would enthrone free stealing under the prostituted name of fair trade",
cited from *Beier*, GRUR Int. 1979, 227.

4 *Von Kraack*, p. 21.

5 *Sykes*, John M. Olin Law & Economics Working Paper No. 140 (2nd Series), p. 1.

6 For current estimates and data see below.

7 *Sykes*, John M. Olin Law & Economics Working Paper No. 140 (2nd Series), p. 1.

patent protection existed - were 703 U.S. $.[8]

The target of (sometimes harsh) criticism has long been the TRIPS agreement, the Agreement on Trade-Related Aspects of Intellectual Property Rights[9] of the World Trade Organization (WTO) as of 15 April 1994.[10] The TRIPS agreement, for the first time in history, established an international minimum standard of IP protection,[11] affecting patents, trademarks, design rights etc. This agreement has been subject to revisions and waivers which will be explained in detail below.

Public policy considerations, however, are not restricted to the limitation of intellectual property (IP) rights. Rather, competition law foresees measures that can equally be used in this respect. Competition law is closely linked to patent law in some areas: Where IP rights owned by dominant undertakings are indispensable and impossible for other market players to replicate or acquire, the refusal to grant a license to use such IP may cause serious harm to vital public interests, such as the supply of life-saving drugs.[12] Therefore, competition law ought to be discussed in this context.

Even though the necessity of patent protection in general and the protection of pharmaceuticals in particular has been acknowledged by many, at the same time, under the past and ongoing discussions, public health considerations have been put at the centre. This is still the case - and still necessary - although the HIV/AIDS crisis has had its peak a few years ago. The questions of access to antiretroviral medicines have thus not lost any of their topicality, in particular not in developing countries. Despite the notable impact of the South African government's HCT programme, South Africa still has to be counted as a country where the questions of access to antiretroviral drugs are crucial: South Africa has the largest antiretroviral therapy programme in the world, but given it also has the world's largest epidemic, access to treatment is still low. At the end of 2009, an estimated 37 per cent of infected people were receiving treatment for HIV,

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8 United Nations Commission on Human Rights, Report of the High Commissioner, The Impact of the agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, 44, E/CN.4/Sub.2/2001/13 (June 2001), available at http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset [09 August 2011].

9 The TRIPS agreement (agreement on Trade-Related Aspects of Intellectual Property Rights), Annex 1C to the Uruguay Round agreements of the WTO as of 15 April 1994, is available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPS [02 March 2011].

10 Cf. *Kur*, GRUR Int. 2004, 837, 839.

11 *Baker*, p. 528.

12 *Liu*, IIC 2008, 757.

according to the latest World Health Organization (WHO) guidelines.[13] In mid-2011, following the launch of the HCT campaign in early 2010, it was announced that the number of people on antiretroviral treatment had increased significantly from 923,000 in February 2010 to 1.4 million in May 2011.[14] This state of HIV treatment in South Africa can, however, only be seen in the context of years of doubting the effectiveness of treatment at the highest levels of government, and the initial delay and slow pace of delivering a public antiretroviral therapy programme. Thabo Mbeki, president of South Africa from 1999 to 2008, often sought the opinions of AIDS denialists, including many of them on his Presidential AIDS Advisory Panel. Both Mbeki and his Health Minister at the time, Manto Tshabalala-Msimang, questioned the effectiveness of antiretrovirals, with the latter infamously promoting beetroot and garlic consumption as a way of fighting HIV infection.

From the outset, this factual situation leads to inevitable - and crucial - questions. First of all, one has to ask, in what way does patent protection (in the shape of the TRIPS agreement) in fact influence the accessibility of antiretroviral medicines? How does it affect the pricing of drugs? What other factors influence the pricing of drugs, in particular, what role does or can competition law play? Furthermore, one has to ask, does an international minimum standard of patent protection make sense for all countries, be they "first", "second" or "third" world countries? Can the same set of rules be applied to differing interests prevailing in first and third world countries? In what way is patent protection indispensable or - and if so in what way - does it have to be limited in order to safeguard public health? Is such limitation possible within a set of rules which is meant to be valid for both developed and developing countries? And last but not least, how can the accessibility of antiretroviral medicines be promoted from a legal point of view, taking into account other areas of law such as competition law?

The aim of this work is to provide a realistic assessment of the development and the current dimension of the HIV/AIDS crisis in South Africa as well as the existing and conceivable or prospective legal means to continuously fight it and improve access to treatment of infected individuals. South Africa has been chosen since it is so heavily

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13 World Health Organization: "Towards universal access: Scaling up priority HIV/AIDS interventions in the health sector", Progress report 2010, available at http://www.who.int/hiv/pub/2010progressreport/en/index.html [10 August 2011].

14 Statement by South African Minister of Health, Dr. Aaron Motsoaledi, "How we're re-engineering the health system" of 31 May 2011, available at http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71656?oid=238984&sn=Detail&pid=71616 [10 August 2011].

affected by the crisis and because its legal framework is particularly interesting as it is comparatively developed and can serve as an example for less developed countries. At the same time, this work aims to show that cutting down on IP rights to a significant extent, particularly on patent protection, is neither necessary in order to improve access to medicines nor is it advisable since the protection of patents in third world countries is just as necessary as it is in the developed world. In order to prove this proposition, first, particular emphasis will be put on the TRIPS agreement and its influences on South African and international (patent) law. After showing and evaluating the existing flexibilities of the patent system, this work aims to show that competition law provides for measures which can and should be used by governments in order to support the accessibility of vitally important medicines.

C. Introduction

I. HIV/AIDS – Definitions and basic knowledge

Acquired immunodeficiency syndrome (AIDS) is a disease of the human immune system caused by the human immunodeficiency virus (HIV).[15] The condition progressively reduces the effectiveness of the immune system and leaves individuals susceptible to opportunistic infections and tumors. HIV is transmitted through direct contact of a mucous membrane or the bloodstream with a bodily fluid containing HIV, such as blood, semen, vaginal fluid, pre-seminal fluid, and breast milk. This transmission can involve anal, vaginal or oral sex, blood transfusion, contaminated hypodermic needles, exchange between mother and baby during pregnancy, childbirth, breastfeeding or other exposure to one of the bodily fluids mentioned above.[16]

There is currently no vaccine for HIV or cure for HIV or AIDS. The only known methods of prevention are based on avoiding exposure to the virus or an antiretroviral treatment directly after a highly significant exposure, called post-exposure prophylaxis (PEP). This treatment, however, can only be used immediately after exposure and has severe side-effects.

Current treatment for HIV infection consists of highly active antiretroviral therapy, also known as HAART. Under this concept, several antiretroviral drugs – typically three or four – are taken in combination.[17] This has been highly beneficial to many HIV-infected individuals since its introduction in 1996. However, HAART can only do so much as to improve the patient's quality of life, reduce complications, and reduce HIV viremia, but it cannot cure the patient of HIV nor does it prevent the return of symptoms once treatment is stopped.

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15 *Sepkowitz*, p. 1769.

16 *Sepkowitz*, p. 1771.

17 United States Department of Health and Human Services (2004). "A Guide to Primary Care for People With HIV/AIDS, 2004 Edition", John G. Bartlett, available at ftp://ftp.hrsa.gov/hab/PCGchap5.pdf [21 August 2011].

Furthermore, there is the problem of development of viral resistance to the drugs taken. [18] If an HIV infection becomes resistant to standard HAART, there are limited options. One option is to take larger combinations of antiretroviral drugs, an approach known as mega-HAART or salvage therapy. Salvage therapy often increases the drugs' side-effects – while the list of severe side-effects of antiretroviral drugs is long anyway. If an HIV infection becomes sufficiently resistant to antiretroviral drugs, treatment becomes more complicated and prognosis may deteriorate. Treatment options in this case and in general continue to improve as additional new drugs enter clinical trials. Thus, research and development in this area are vitally important. However, even if new drugs are sufficiently developed, the limited distribution of many such drugs denies their benefits to patients, particularly in the developing world.

II. Proportions of the HIV/AIDS crisis in South Africa and worldwide

The HIV/AIDS epidemic has changed our world. In those countries most heavily affected, HIV/AIDS has reduced life expectancy by more than 20 years, slowed economic growth, deepened household poverty, and fostered discrimination. In sub-Saharan Africa alone, the epidemic has orphaned almost 15 million children aged under 18 years.[19] The natural age distribution in many national populations in sub-Saharan Africa has been dramatically skewed by HIV/AIDS, with potentially perilous consequences for the transfer of knowledge and values from one generation to the next. In Asia, where infection rates are much lower than in Africa, HIV/AIDS causes a greater loss of productivity than any other disease, and is expected to push an additional 6 million households into poverty by 2015 unless national responses are strengthened. According to the United Nations Development Programme UNAIDS, HIV/AIDS has inflicted the "single greatest reversal in human development" in modern history[20] with an estimated 33 300 000 people living with HIV in 2009.[21]

Although the number of people newly infected with HIV in sub-Saharan Africa fell

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18 United States Department of Health and Human Services (2004). "A Guide to Primary Care for People With HIV/AIDS, 2004 Edition", *ibid.*

19 UNAIDS 2010 Report, Annex 1, p. 186.

20 UNAIDS 2008 Report on the global AIDS epidemic, Chapter 1 (The global HIV challenge), p. 13.

21 UNAIDS 2010 Report on the global AIDS epidemic, Annex 1, p. 180.

from 2.2 million people in 2001 to 1.8 million in 2009 and the HIV incidence rate declined by more than 25 per cent between 2001 and 2009 in 22 countries of sub-Saharan Africa,[22] the HIV/AIDS crisis still has epidemic proportions in South Africa:

HIV and AIDS estimates for South Africa:[23]

Number of people (adults and children) living with HIV in 2009 (in 2007) (in 2001)	5 600 000 [5 400 000 – 5 900 000] (5 700 000) (4 700 000)
Adults aged 15 to 49 HIV prevalence rate in 2009 (in 2007)	17.8 per cent [17.2 per cent – 18.3 per cent] (18.1 per cent)
Adults aged 15 and up living with HIV in 2009 (in 2007)	5 300 000 [5 100 000 – 5 500 000] (5 400 000)
Women aged 15 and up living with HIV in 2009 (in 2007)	3 300 000 [3 000 000 – 3 500 000] (3 200 000)
Young women aged 15 to 24 rate 2009 (in 2007)	13.6 per cent [12.3 per cent – 15.0 per cent] (12.7 per cent)
Young men aged 15 to 24 rate 2009	4.5 per cent [4.1 per cent – 5.0 per

22 UNAIDS fact sheet.

23 Statistics taken from:
- AVERT, available at http://www.avert.org/worldstats.htm [11 March 2011];
- UNAIDS 2010 Report on the Global AIDS Epidemic, Annex 1 (HIV and AIDS estimates and data, 2009 and 2001), p. 180 et seq.; UNAIDS 2008 Report on the Global AIDS Epidemic, Annex 1 (HIV and AIDS Estimates and Data, 2007 and 2001), p. 214 et seq.;
- UNAIDS Progress Report on Declaration of Commitment on HIV and AIDS by the Republic of South Africa; UNAIDS 2006 Report on the Global AIDS Epidemic, Annex 2: HIV Estimates and Data, 2005 and 2003, p. 505 et seq.;
- Report National HIV and Syphilis Antenatal Sero-Prevalence Survey in South Africa 2005.

Low and high estimates are put in squared brackets.

(in 2007)	cent] (4.0 per cent)
Children aged 0 to 14 living with HIV in 2009 (in 2007) (in 2001)	330 000 [190 000 – 440 000] (280 000 [230 000 – 320 000]) (150 000)
Adults and children newly infected in 2009	390 000 [340 000 – 440 000]
Orphans (currently living) aged 0 to 17 due to AIDS in 2009 (in 2007) (in 2001)	1 900 000 [1 600 000 – 2 400 000] (1 400 000) (580.000)
Deaths (adults and children) due to AIDS in 2009 (in 2007) (in 2001)	310 000 [260 000 – 390 000] (350.000) (220.000)

III. Remaining problem of access to antiretroviral medicines

The developments that will be explained below have been somewhat successful and more and more people infected with HIV and/or suffering from AIDS all over the world have gained better access to necessary treatment. However, the wish of international organizations to provide worldwide universal access to antiretroviral medication is far from having come true. The WHO currently estimates that **only 36 per cent** of HIV-infected people worldwide have access to medication.[24]

Even though South Africa has the largest antiretroviral therapy programme in the world and although the AIDS mortality rate has slowed down,[25] access to treatment is still not sufficient. In mid-2011, following the launch of the HCT campaign in early 2010, it was announced that the number of people on antiretroviral treatment had increased

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[24] WHO report "World Health Statistics 2011", available at http://www.doh.gov.za/docs/stats/2011/who.pdf [21 August 2011]

[25] New model estimates AIDS deaths have declined from 257,000 in 2005 to 194,000 in 2010, *Peter Doyle, Rob Dorrington*, 11 March 2011, "ARV roll-out slows mortality rate – ASSA", available at http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71654?oid=225766&sn=Detail [21 August 2011].

significantly from 923,000 in February 2010 to 1.4 million in May 2011.[26] However, according to the latest WHO guidelines and reports, an estimated **37 per cent** of infected people only are receiving treatment for HIV in South Africa.[27] Already in 2009, South African Health Minister Motsoaledi announced that South Africa will not meet a target of providing life-prolonging drugs to 80 per cent of people living with HIV/Aids by 2011 due to logistical problems and a lack of personnel. On 15 September 2009, Motsoaledi said: "We are now covering 700 000 people. Unfortunately it is only 50 per cent of the number that has been targeted. By 2011, we are supposed to cover 80 per cent of the people who need to be on ARVs [antiretroviral drugs]."[28] Likewise, South Africa does not meet its targets with respect to HIV-testing.[29]

Still, for every one person accessing treatment, two people are becoming infected.[30] Clearly, treatment needs are still outpacing prevention efforts showing an urgent need for a new line of treatment, microbicides, vaccines and diagnostics.[31] Likewise, more and more people move or are forced to move towards more expensive and patent-protected second- and third-line antiretroviral medicines. This is due to the fact that these medicines are more efficacious but also because many patients develop drug resistance against the traditional first-line drugs (confirm above). Hence, the problem of access to HIV/AIDS medication remains just as crucial as in the 1990s.

Despite the existence of medications and despite broad efforts to supply affected people with such medications, still too few people living with HIV and AIDS are receiving treatment for their condition. This situation continually contributes to substantial,

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26 Statement by South African Minister of Health, Dr. Aaron Motsoaledi, "How we're re-engineering the health system" of 31 May 2011, available at http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71656?oid=238984&sn=Detail&pid=71616 [10 August 2011].

27 World Health Organization: "Towards universal access: Scaling up priority HIV/AIDS interventions in the health sector", Progress report 2010, available at http://www.who.int/hiv/pub/2010progressreport/en/index.html [10 August 2011]; the same data can be found in the more recent WHO report "World Health Statistics 2011", available at http://www.doh.gov.za/docs/stats/2011/who.pdf [21 August 2011], p. 35.

28 Motsoaledi's statement to Reuters, newspaper article of 15 September 2011, available at http://www.atlanticphilanthropies.org/news/sa-wont-meet-arv-roll-out-target-says-motsoaledi [21 August 2011].

29 Article by *Harriet McLea*,The Times, 16 May 2011, "HIV-testing targets not being reached", available at http://www.bhfglobal.com/hivtesting-targets-not-being-reached-160511 [21 August 2011].

30 UNAIDS Press Statement as of 09 December 2010, available at http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2010/december/20101209pstrips/ [11 August 2011].

31 UNAIDS Press Statement as of 09 December 2010, ibid.

avoidable morbidity and mortality[32] as well as discrimination and numerous other social problems.

[32] UNAIDS 2008 Report on the Global AIDS Epidemic, Chapter 5 (Treatment and Care), p. 130.

D. The TRIPS agreement

I. Introduction

The TRIPS agreement has become the focus of public attention in the debate of IP rights vs. public health, as developing countries that have been hit hard by the HIV/AIDS epidemic try to serve the health needs of their people, while still complying with its provisions.[33]

The agreement was part of the 1994 Uruguay Round of trade liberalization measures adopted by countries that later formed the WTO. Since the WTO was created in 1995, the member governments are required to implement IP rights protection in their respective legal system within certain established transitional periods. The TRIPS agreement thus codifies minimum standards for protection of IP rights.[34] It covers copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, the protection of undisclosed information as well as the control of anti-competitive practices in contractual licences, and establishes general provisions and basic principles, standards concerning the availability, scope and use of these rights, their enforcement, their acquisition and maintenance as well as rules regarding dispute prevention and settlement. In its Art. 68, the TRIPS agreement also establishes the "Council for TRIPS", a body that is supposed to monitor the operation of the agreement and, in particular, members' compliance with their obligations under the agreement, and that shall give members the opportunity of consulting on matters relating to the trade-related aspects of IP rights.

II. General rules regarding (pharmaceutical) patents

For patents, the rules of the TRIPS agreement cover a wide range of products, including pharmaceutical goods. In particular, WTO members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a

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33 *Mutume*, p. 14; *Nérisson/Fischer*, GRUR Int. 2008, p. 1018 et seq; *Otten*, IIC 2007, p. 645 et seq.

34 *Abbott*, The Enduring Enigma of TRIPS: A Challenge for the World Economic System, p. 499; *von Kraack*, p. 29.

method of producing the chemical ingredients for a medicine)[35], while allowing certain exceptions (see below). Patent protection has to last at least 20 years from the date the patent application was filed.[36] During this period, no one may use, make or sell a product without the owner's authorization.[37] After the patent expires, other firms can sell "generic" versions of the product. Furthermore, the TRIPS agreement sets out that members cannot discriminate between different fields of technology in their patent regimes nor can they discriminate between the place of invention and whether products are imported or locally produced.[38]

The TRIPS agreements establishes three criteria in order for an invention to qualify for a patent: an invention has to be new ("novelty"), it must be an "inventive step" (i.e. it must not be obvious) and it must have "industrial applicability", which means that it must be useful.[39]

Furthermore, the TRIPS agreement sets out rules regarding the disclosure of the invention, which is a key part of the social contract that the grant of a patent constitutes. [40] Details of the invention have to be described in the application and therefore have to be made public. Member governments have to require the patent applicant to disclose details of the invention and they may also require the applicant to reveal the best method for carrying it out.[41]

III. No compulsory extension for pharmaceutical products

It should be noted that TRIPS does not contain an obligation to introduce a system to extend the patent term in order to compensate for regulatory delays in the marketing of new pharmaceutical products, although this issue has been raised in the Uruguay Round negotiations. The period of patent protection for inventions of new chemical entities is in effect much less than the full 20 years, because a large part of that period will have expired before marketing approval is obtained from the public health regulatory bodies. For this reason, most of the major developed countries have introduced systems

35 Art. 27.1 of the TRIPS agreement.
36 Art. 33 of the TRIPS agreement.
37 Art. 28.1 of the TRIPS agreement.
38 Art. 27.1 of the TRIPS agreement.
39 Art. 27.1 of the TRIPS agreement.
40 *Benkard*, § 1 ref. no. 3.
41 Art. 29.1 of the TRIPS agreement.

whereby a prolonged period of protection can be obtained to compensate, at least in part, for this loss of the effective period of protection.[42] The European Union, for example, has issued a regulation for the creation of a supplementary protection certificate for medicinal products.[43] This supplementary protection certificate grants an additional period of protection of five years to the owner of a medicinal patent (Art. 13 of Regulation (EEC) No 1768/92). The Council hereby recognized the fact that pharmaceutical research plays a decisive role in the continuing improvement in public health while medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research. Without such legislation, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market would make the period of effective protection under the patent insufficient to cover the investment put into the research, which would lead to a lack of protection penalizing pharmaceutical research.[44]

IV. Impact of rules on antiretroviral medicines

Before looking at the TRIPS rules in more depth, it has to be made clear that patent laws - and thus the TRIPS agreement's rules on (pharmaceutical) patents - are inseparably linked to antiretroviral medicines.[45] Even if the first-line drugs should no longer be patent-protected, most newer drugs are. As shown above, the treatment of HIV/AIDS requires not only one drug but several. Furthermore, the move from known products to newly invented drugs is crucial as resistances develop quickly.

Likewise, even if patent protection does not (yet) exist in some (developing) countries, the patent systems of the other (developed) countries affect these countries: Most new-line drugs are patent-protected in developed countries which means that the products the developing country without patent protection wants to import from the developed

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42 WTO, Pharmaceutical patents and the TRIPS agreement.

43 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, available at http://eur-lex.europa.eu/Notice.do?mode=dbl&lang=de&lng1=de,en&lng2=bg,cs,da,de,el,en,es,et,fi,fr,hu,it,lt,lv,mt,nl,pl,pt,ro,sk,sl,sv,&val=186915:cs&page=1&hwords=1768%2F92~ [11 March 2011].

44 Confirm the introduction to the Council Regulation (EEC) No 1768/9.

45 *Hestermeyer*, GRUR Int. 2004, p. 197.

country are usually expensive.[46] The incentive for compulsory licensing within the developed countries is usually rather low (confirm below). Parallel importing, i.e. international comparison-shopping for the best price of a drug, which is obviously allowed without limitations if a country does not have patent protection, is only possible from countries which have low-price medicines eligible for export – and those are only the few countries that a) do not have patent protection while at the same time being able to manufacture antiretroviral medication themselves or b) do have patent protection but have lowered prices for whatever reason, the possible reasons which will be dealt with in the following.

This impact has to be kept in mind when considering the TRIPS agreement's as well as national rules on patents.

V. Justification of TRIPS rules on patents

The minimum standards of IP protection codified by the TRIPS agreement unquestionably have an impact on any jurisdiction which, prior to TRIPS, has not had IP protection at all or a lower level of protection.[47] This impact, which may also affect social circumstances, requires justification. Thus, the rules of the TRIPS agreement are usually justified in three different ways:

Firstly, invention and creativity in themselves are considered to provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity.[48] This encourages new inventions, such as new drugs, the development costs of which can sometimes be extremely high. As a result, the private rights conferred also bring social benefits.[49] This idea, however, is not "TRIPS-specific".[50] Rather, it is generally used to justify IP protection.

Secondly, the way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the

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46 Aden, ZRP 2008, p. 154.
47 *Von Kraack*, p. 41 et seq.
48 *Benkard*, Introduction, marginal note 2 and § 1 no. 1a)-b).
49 *Was*, GRUR Ausl 1965, p. 609.
50 *Von Kraack*, p. 40.

invention even while its patent is being protected.[51] This helps technological progress and technology dissemination and transfer. After a certain period the protection expires, which means that the invention becomes available for others to use. All of this avoids "re-inventing the wheel".[52] Like the first justification, this thought is not a characteristic of the TRIPS agreement. Rather, it is also generally used as a justification put forward for IP protection.[53]

Thirdly, and most importantly when it comes to access to drugs, the TRIPS agreement was meant to provide flexibility for governments to fine tune the protection granted in order to meet social goals.[54] For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled (confirm below). Even though this thought was present from the outset, these flexibilities had to be clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health, which will be discussed later on.

VI. The "original" TRIPS agreements' attempt of balanced outcomes

Already the TRIPS agreement in its "original" form (i.e. before the introduction of waivers and enhancements) attempted to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. This balance is obviously not easy to achieve, particularly not in the field of pharmaceutical patents where the tension between the need to provide incentives for research for and development of new drugs and the need to make existing drugs as available as possible can be acute.[55]

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51 *Was*, GRUR Ausl 1965, p. 610.
52 *Benkard*, § 1 no. 1a)-b).
53 *Von Kraack*, p. 40.
54 *Böttger*, GRUR Int. 2008, p 881 et seq.
55 *Abbott*, The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference, p. 28.

The TRIPS agreement with its rules regarding patents as well as its general rules tried to find an appropriate balance: Its Art. 7 ("Objectives") recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. Furthermore, the TRIPS agreement contains "public health safeguard provisions". The agreement provides for special practices that countries can use in order to override the normal TRIPS requirements which can be categorized in two groups: on one hand, countries may refuse to grant patents in certain cases. On the other hand, they can override the protection conferred by a patent without touching the validity of the patent. This can be done by engaging in compulsory licensing and parallel importing, or by invoking the so-called "Bolar" exemption. These measures have the following peculiarities and prerequisites:

1. Permitted refusal to grant patent protection

Governments can refuse to grant patents for three reasons that may relate to public health. Firstly, inventions can be excluded from patentability in case their commercial exploitation needs to be prevented to protect ordre public or morality, including human, animal or plant life or health[56], diagnostic, therapeutic and surgical methods for treating humans or animals[57] and certain plant and animal inventions[58].

2. Means to override patent protection

Art. 30 and Art. 31 of the TRIPS agreement allow member states to create limited exceptions to the exclusive rights conferred by a patent. Exceptions pursuant to Art. 30 are permitted provided that they "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". Although the term "third parties" is not defined in the agreement, it can well be understood to relate not only to the interests of the potential patent infringer but also to the interests of

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56 Art. 27.2 of the TRIPS agreement.
57 Art. 27.3a of the TRIPS agreement.
58 Art. 27.3b of the TRIPS agreement.

a country's population in sufficient medical and nutritional supply.[59] Exceptional use other than that allowed under Art. 30 of the TRIPS agreement can be authorized pursuant to Art. 31.

3. Compulsory licensing

The term "compulsory licensing" itself is not used in the TRIPS agreement. However, the concept is covered by the term used in Art. 31 of the TRIPS agreement, "other use without authorization of the right holder".[60] Compulsory licensing is only a part of this, since "other use" also includes use by governments for their own purposes. Compulsory licensing allows governments to permit a person other than the patent holder to use the patented invention without the owner's consent.

The TRIPS agreement does not define the substantial grounds where "use without authorization of the right holder" may be granted.[61] At the same time, nothing in the TRIPS agreement limits the grounds on which governments can authorize the compulsory licensing of a patented product. However, although member states are given fairly free hand to determine the grounds for granting compulsory licensing,[62] this does not mean that their governments may grant compulsory licenses on frivolous grounds or no grounds at all: only social and collective interests justify the granting of compulsory licenses.[63]

Art. 31 of the TRIPS agreement establishes a number of requirements for the grant of a compulsory license. Firstly, pursuant to Art. 31 lit. a) of the TRIPS agreement, the grant of a compulsory license has to be considered on its individual merits. This rule is supposed to prevent automatic compulsory licenses.[64] However, it does not deny member states the right to establish universal legal frameworks concerning the requirements and the procedure of the grant of compulsory licenses, as long as the respective set of rules accommodates the principle of consideration on individual merits.[65]

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59 *Fromm-Russenschuck/Duggal*, p. 84.
60 *Von Kraack*, p. 84; *García-Castrillón*, p. 215; *Dreyfuss/Lowenfeld*, p. 311; *Vaughan*, p. 88.
61 *Liu*, p. 758.
62 *Fromm-Russenschuck/Duggal*, p. 84.
63 *Liu*, p. 758.
64 *Busche/Stoll*, p. 521.
65 *Busche/Stoll*, p. 522.

Before the licence can be awarded, the applicant must – at least in most cases – try to obtain a voluntary licence on reasonable commercial terms. This is established in Art. 31 lit. b) of the TRIPS agreement, which states that compulsory licenses can only be permitted if 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. There are, however, exceptions to this requirement. Firstly, it does not apply where the use of the patent is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive (Art. 31 lit. k)). Secondly, Art. 31 lit. b) of the TRIPS agreement sets out that the requirement may be waived by a member government 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 only has to be notified as soon as reasonably practicable.

Art. 31 lit. b) of the TRIPS agreement has been clarified by para. 5 lit. c) of the Doha Declaration on TRIPS and Public Health (for details confirm below). According to the declaration, every member government has the right to determine whether circumstances amount to a national emergency or a state of extreme urgency.

Furthermore, Art. 31 lit. c)-f) of the TRIPS agreement establish that the scope and duration of the grant of compulsory licenses are to be limited to the purpose for which the grant was authorized, and that the license has to be non-exclusive (that is, the patent-holder can continue to produce the patented invention) and generally non-assignable. Likewise, and strikingly, authorization shall predominantly be awarded for the supply of the domestic market of the member authorizing the grant of the compulsory license. This requirement, however, does not apply where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive (Art. 31 lit. k)).

Pursuant to Art. 31 lit. g) of the TRIPS agreement, the authorized use of the patent has to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. This means that the compulsory license must be rescinded once conditions change. Furthermore, the right holder has to be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. In other words, the licensee has to pay a market-rate fee.[66] Any decisions relating to the remuneration provided in respect of the grant of a compulsory license are subject to judicial review (confirm Art. 31 lit. h) and j) of the TRIPS agreement).

Likewise, the legal validity of any decision relating to the authorization of use under Art. 31 of the TRIPS agreement is subject to judicial review (Art. 31 lit. i)).

4. Pros and cons of compulsory licensing

The compulsory licensing regime under the TRIPS agreement as presented above intends to, inter alia, offset the non-use of the invention by the patentee or his refusal to grant voluntary licenses; in other words, compulsory licensing can enable third parties to exploit the patent or invention in case of non-use or abuse by the right holder.

On one hand, therefore, compulsory licenses are said to reduce the adverse effects of patents on price and availability. They mitigate the restrictive effects of exclusive rights and strike a balance between the title-holder's interests and those of the public in the diffusion of knowledge and access to, and affordability of the outcomes of innovation and creativity. Moreover, granting compulsory licenses for pharmaceuticals is largely considered an important tool to promote competition and to lower prices.[67]

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66 *Von Kraack*, p. 14.

67 *Correa*, Intellectual Property Rights and the use of Compulsory Licenses: Options for Developing Countries, p. 24.

On the other hand, by granting compulsory licenses, the economic intrinsic value of a patent right is substantially reduced as the major value of the patent is the temporary exclusivity conferred to its owner.[68] Compulsory licensing has even been blamed to have expropriational character, or at least has been called a "creeping expropriation":[69] Intellectual property rights are protected investments and thus proprietary rights according to the TRIPS agreement's standard of IP protection.[70] This is at least true for all WTO members after the expiration of the transitional periods of Art. 65 et seq. of the TRIPS agreement. Under international law, a legal or factual limitation of a protected right can amount to an expropriation.[71] It has also largely been emphasized that countries should examine the potential negative impact of compulsory licensing, as with other measures limiting patentee's rights. The consequences include the possibility of discouraging foreign investment, transfer of technology and research, including research into diseases.[72]

Hence, compulsory licensing is not undisputed.

5. Parallel importing

Likewise, governments can permit parallel importing, in which a product manufactured under a patent held in one country but sold at lower prices in another country, can be imported from that second country without permission from the patent holder.[73] Parallel importing thus allows countries to "comparison-shop" for the world's best market price of a drug.[74] The legal principle behind parallel importing is exhaustion, meaning that, in general, the first sale of a patented good exhausts the patent in that the right holder cannot control the distribution or resale of the good. This means that once company A as the right holder has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch. Therefore, if A sells the batch to company B, then B can sell to company C without the approval of A.

Art. 6 of the TRIPS agreement deals with the concept of exhaustion and establishes that,

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68 *Benkard*, § 1 ref. no. 6 et seq.
69 *Von Kraack*, p. 91/92.
70 *Gildeggen*, p. 188 et. seq.
71 *Von Kraack*, p. 92.
72 *Correa*, Integrating Public Health concerns into Patent Legislation, p. 91 et seq.
73 *Rott*, GRUR Int. 2003, p. 106 et seq.
74 *Baker*, p. 530.

for the purposes of dispute settlement under the TRIPS agreement, nothing in the agreement shall be used to address the issue of the exhaustion of intellectual property rights. The TRIPS agreement thus states that governments permitting parallel imports cannot be challenged under the WTO dispute settlement system, provided they do not discriminate on the grounds of the nationality of the patent holder.[75] In other words, even if a country allows parallel imports in a way that another country might think violates the TRIPS agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. Art. 6 of the TRIPS agreement therefore only addresses the question of dispute settlement in cases of exhaustion. Whether or not the TRIPS agreement contained rules regarding the requirements for exhaustion was in dispute. However, this question has been clarified by the Declaration on the TRIPS agreement and Public Health issued on the occasion of the Doha Ministerial Conference in 2001 (for details confirm below). In its declaration, the Ministerial Conference established that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives: "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 (...)".[76]

Therefore, the TRIPS agreement can now be understood to merely contain an "agreement to disagree" as it leaves the determination of the requirements for national and international exhaustion to the respective member state.[77] As a result, parallel importing is possible under the TRIPS agreement if member states have adopted the respective legal framework for it.

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75 *Von Kraack*, p. 46.

76 Declaration on the TRIPS agreement and Public Health, 20 November 2001, Document WT/MIN(01)/DEC/2, para. 5 lit. d).

77 *Busche/Stoll*, p. 163.

6. "Bolar" exemptions

As mentioned before, Art. 30 of the TRIPS agreement allows exceptions to be made provided that they do not "unreasonably" conflict with the "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. Thus, for example, many countries allow third parties to use a patented invention for research purposes where the aim is to understand more fully the invention as a basis for advancing science and technology. These so-called "Bolar" provisions (also referred to as "Roche-Bolar-exception" or "regulatory exception") hence allow generic manufacturers to prepare production and regulatory procedures before patents expire so that products can be ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process only after the patent period is over.

As an example for a "Roche-Bolar-exception",[78] Germany's patent law, the Patentgesetz (PatG), states in its sec. 11 that

> *"The effects of a patent shall not extend to (...)*
> *2.) acts done for experimental purposes relating to the subject-matter of the patented invention; (...)*
> *2. b) studies and trials and the resulting practical requirements which are necessary for obtaining regulatory marketing approval of a medicine in the European Union or regulatory authorization for a medicine in the Member States of the European Union or in third countries; (...)".*

The German patent law in its sec. 11, subsec. 2 therefore clearly allows (clinical) trials that relate to a patented invention. Sec. 11, subsec. 2 lit. b) contains a "Roche-Bolar-exemption" which was introduced on 06 September 2005, implementing Art. 10 (6) of the European Directive 2001/83 and Art. 13 (6) of the European Directive 2001/82. In the German example, the exemption even exceeds the exemption for clinical trials as the subject-matter of the studies and trials under sec. 11, subsec. 2 lit. b) does not have to be the patented invention itself.[79]

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78 Many countries all over the world have included provisions allowing regulatory exceptions in their patent laws. A well-known example is Canada

79 *Schulte*, p. 366.

VII. Evaluation of the "original" TRIPS agreement's attempt of balanced outcomes

From the measures explained above it can be seen that TRIPS was not meant to simply maximize the level of protection for intellectual property, which is emphasized particularly by the WTO.[80] However, it is generally acknowledged that the success of the Uruguay Round of multilateral trade negotiations largely depended on the fact that the developing countries were offered greater access to market for traditional manufactured goods and for their agricultural products in exchange for codified obligations to respect intellectual property rights in the non-traditional products and processes that are the stock in trade of the technology-exporting countries.[81] Prior to the enhancement of the TRIPS agreement and the waivers, the agreement in fact did not strike the balance it attempted. This can be seen from several concrete examples. To name just a few:

The agreement in its Art. 65.4 provided most of the developing countries with a 10-year (1 January 1995 - 1 January 2005) delayed application of patent protection for pharmaceutical products. However, the agreement placed restrictions on this transitional arrangements with the so-called "mailbox rule". This rule required developing countries to establish a mechanism for receiving and preserving priority in respect of pharmaceutical product patent applications and also required them to grant exclusive marketing rights to the applicants.[82] If these "mailbox" and exclusive marketing rights requirements had to be implemented, this would have materially reduced the time during which generic products of low price would have been available.

Moreover, having regard to the granting of compulsory licenses, the agreement provided (and still provides) many complicated restrictive provisions, one of which especially established that compulsory licenses shall be authorized predominantly for the supply of the domestic market of the member state.[83] Obviously, this paragraph operated as a significant restriction on the capacity of developing countries to make and acquire medicines and other public health-related products.

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80 WTO, Pharmaceutical patents and the TRIPS agreement.

81 *Reichman/Lange*, p. 18.

82 See Art. 70.8 and 70.9 of the TRIPS agreement.

83 Cf. Art. 31 (f) of the TRIPS agreement.

Consequently, United Nations Commission on Human Rights pointed out in its Report of 2000 on "Intellectual Property Rights and Human Rights" that there were apparent conflicts between the IP rights regime embodied in the TRIPS agreement on the one hand and international human rights law on the other, since the implementation of the TRIPS agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination.[84] Accordingly, appeals for mainstreaming human rights into the TRIPS agreement became stronger.[85]

VIII. The Doha Declaration, the Para. 6 system and further developments

1. The Doha Declaration and the Declaration on TRIPS and Public Health (2001)

In line with these appeals, subsequent to the TRIPS agreements' introduction, many governments – and particularly those of developing countries – considered the flexibilities of the agreement to be insufficient and were unsure of how they would be interpreted, and how far the governments' right to use these flexibilities would be respected. The African Group (all the African members of the WTO) were among the members pushing for clarification. As shown above, the rules of the "original" TRIPS agreement were indeed insufficient with regard to public health problems in developing countries.

A large part of this request was dealt with at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.[86] They therefore adopted a separate declaration on TRIPS and Public Health. In this declaration, the Ministerial Conference

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84 UN Commission on Human Rights: Intellectual Property and Human Rights, 2000, E/CN/.4/Sub2/2000,/7, para. 2.

85 *Petersmann*, The WTO Constitution and Human Rights, p. 21; *Petersmann*, From "Negative" to "Positive" integration in the WTO: Time for "Mainstreaming Human Rights" into WTO Law?, p. 1370; *Petersmann*, Human Rights and International Economic Law in the 21st century: The need to clarify their interrelationships, p. 4 et seq.; *Lim*, p. 275 et seq.; *Rott*, GRUR Int. 2003, p. 103 et seq.

86 Doha Ministerial Declaration, 20 November 2001, document WT/MIN(01)/DEC/1, para. 17.

recognized 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. They stressed the need for the TRIPS agreement to be part of the wider national and international action to address these problems while at the same time recognizing that intellectual property protection is important for the development of new medicines and recognizing the concerns about its effects on prices. [87] Furthermore, the Ministerial Conference agreed that "the TRIPS agreement does not and should not prevent members from taking measures to protect public health." Accordingly, they affirmed 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, they reaffirmed the right of WTO members "to use, to the full, the provisions in the TRIPS agreement, which provide flexibility for this purpose."[88] The Ministerial Conference recognized that these flexibilities include the following:

1. 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.
2. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
3. 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

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87 Declaration on the TRIPS agreement and Public Health, 20 November 2001, document WT/MIN(01)/DEC/2, para. 1-3.

88 Declaration on the TRIPS agreement and Public Health, 20 November 2001, document WT/MIN(01)/DEC/2, para 4.

other epidemics, can represent a national emergency or other circumstances of extreme urgency.

4. 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.[89]

Furthermore, the Ministerial Conference, in the famous para. 6 of the declaration, recognized "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 therefore instructed the Council for TRIPS "to find an expeditious solution to this problem and to report to the General Council before the end of 2002."[90]

Finally, the Ministerial Conference agreed to extend exemptions on pharmaceutical patent protection for least-developed countries (LDCs) until 1 January 2016.[91]

Although there were some conflicting views regarding the conditions under which the flexibilities of the TRIPS agreement could be used, the Doha Declaration helped to prevent situations where developing countries' governments could not avail themselves fully of these flexibilities because of the pressure from interested groups such as the African Group. The Doha Declaration thus marked a turning point of political and legal relations at the WTO. The declaration is therefore considered to be a significant milestone.[92]

2. The Para. 6 system (2003)

This famous enhancement was put into practice in 2003 with a decision that enabled countries that cannot make medicines themselves to import pharmaceuticals produced under compulsory licence as referred to in para. 6 of the declaration. The decision of 30

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89 Declaration on the TRIPS agreement and Public Health, 20 November 2001, document WT/MIN(01)/DEC/2, para 5.

90 Declaration on the TRIPS agreement and Public Health, 20 November 2001, document WT/MIN(01)/DEC/2, para 6.

91 Declaration on the TRIPS agreement and Public Health, 20 November 2001, document WT/MIN(01)/DEC/2, para. 7.

92 *Abbott*, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a dark corner at the WTO, p. 480 et seq.

August 2003 is often referred to as the "Para. 6 system", i.e. implementing para. 6 of the Doha Declaration. The background for this was the remaining legal issue of importing under compulsory licensing pursuant to para. 6 of the Doha Declaration: Article 31 lit. f) of the TRIPS agreement states that products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies to countries that can manufacture drugs as it limits the amount they can export when the drug is made under compulsory licence. At the same time it has an impact on countries unable to produce medicines and therefore wanting to import generics as these countries would find it difficult to find countries that can supply them with drugs made under compulsory licensing. For example, a developed country such as Germany could manufacture antiretroviral medicines under compulsory licenses. However, if these products had to be predominantly for the supply of the domestic market, Germany could only export a very limited amount of the medicines to a developing country in need of the products. On the other hand, a developing country such as, for example, Lesotho, where the HIV/AIDS epidemic is severe and which does not have the capacity to produce medication itself,[93] could not import the drugs made under a compulsory license in Germany. Due to the requirement of the product being predominantly for the supply of the domestic market, the compulsory licensing rule has no or little positive effect for those countries in need of imported medicines. At the same time, compulsory licensing in developed countries makes a lot less sense if the products cannot or can hardly be exported.

This legal problem was addressed on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.[94]

The decision reached on 30 August 2003 contains three waivers: Firstly, exporting countries' obligations under Article 31 lit. f) of the TRIPS agreement are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries. Secondly, importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.[95] Thirdly,

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93 *Sihanya*, IIC 2007, p. 649.

94 Decision of the General Council of 30 August 2003, WT/L/540 and Corr.1, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [09 March 2011].

95 *Von Kraack*, p. 13.

exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

The conditions that apply to pharmaceutical products were carefully negotiated. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. Furthermore, they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries. In particular, para. 2 of the decision sets out conditions under which the

obligation of an exporting member under Art. 31 lit. 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 and its export to an eligible importing member. Among these conditions are the notification to the TRIPS Council by the eligible importing country of the names and expected quantities of the products; the need for the importing country to prove its incapacity to manufacture the products in question locally; and confirmation that a compulsory licence has been granted in conformity with Art. 31 of the TRIPS agreement. The compulsory licence issued by the exporting country shall contain the only amount necessary to meet the needs of the eligible importing country; products produced under licence shall be clearly identified (through specific labelling or marking), including special packaging and/or the colour or shape of the products. The re-exportation of these products is strictly prohibited.

When members agreed on the decision, the General Council chairperson also read out a statement setting out members' shared understandings on how the decision would be interpreted and implemented.[96] This was designed to assure governments that the decision would not be abused. Thus, the decision of 30 August 2003 yet again aimed to strike a fair balance of interest for both developed and developing countries. Now, pharmaceutical products can be made under compulsory licence in one country, exclusively for exporting to another country which lacks its own production capacity, provided certain conditions are met.

3. Decision to amend the TRIPS agreement (2005)

The 2003 waivers were (and are) interim; the ultimate goal was and remains to amend the TRIPS agreement itself, and a decision to do this was reached on 06 December 2005,[97] accompanied again by a chairperson's statement.[98] The amendment — a direct translation of the waivers — enters into force when two thirds of members accept it, which is, however, not yet the case. In a decision of 18 December 2007, the General Council extended the period for the acceptance of the amendment of the TRIPS agreement until 31 December 2009, noting that the acceptance was taking longer than

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96 Statement available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [09 March 2011].

97 Amendment of the TRIPS agreement, Document WT/L/641, available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [09 March 2011].

98 Chairperson's statement available at http://www.wto.org/english/news_e/news05_e/trips_319_e.htm [09 March 2011].

initially foreseen. In its Annual Report 2009, the Council for TRIPS agreed to forward to the General Council a proposal for a decision to extend the period of acceptance by members until 31 December 2011.[99] The General Council therefore extended the period of acceptance to 31 December 2011 by decision on 17 December 2009.[100] So far, 33 member states have accepted the amendment.[101]

As with the 2003 waiver, the permanent amendment will allow any member country to export pharmaceutical products made under a compulsory licence for this purpose. Therefore, all WTO member countries are eligible to import under this decision. They may need to change their own laws in order to do so. However, several developed countries have announced voluntarily that they will not use the system to import.[102] After they joined the EU in 2004, another ten countries have been added to the list.[103] Eleven countries said they would only use the system to import in national emergencies or other circumstances of extreme urgency.[104]

Subsequently, a few potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under compulsory licence. So far, Norway, Canada and India have informed the WTO that their laws are complete, while the Republic of Korea and the EU have said their new laws are on the verge of coming into force.

IX. Evaluation of the developments

The 2001 WTO Doha Declaration on the TRIPS agreement and Public Health gave a political answer to the criticized one-sidedness of the TRIPS agreement and formally recognized the right of countries under the TRIPS agreement to use to the full this

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99 Annual Report 2009 of the Council for TRIPS, 5 November 2009, Document IP/C/52, available at http://www.wto.org/english/thewto_e/minist_e/min09_e/official_doc_e.htm [25 February 2011].

100 Decision of 17 December 2009, Document WT/L/785, available at http://www.wto.org/english/tratop_e/trips_e/wt-l-785_e.pdf [09 March 2011].

101 List available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [09 March 2011].

102 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 the United States of America.

103 Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

104 Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and the United Arab Emirates.

flexibility in the agreement to protect public health and to promote access to medicines for all.[105] At the same time, the decision to permanently amend the rules of the TRIPS agreement presents a big step: it is the first time that a basic WTO agreement is permanently amended. However, although the waivers agreed upon in 2001 and 2003 are in force in their temporary form, the agreement has not yet been permanently altered as the implementation process has been proven to be difficult, and so far, the para 6 system has only been used once.[106] And although the decisions of the General Council seem politically acceptable to both developed and developing countries, they may, in practice be burdensome for eligible countries.

Some countries have argued that the Para. 6 system is too cumbersome. For instance, at the October 2010 meeting of the WTO Intellectual Property Council, India said that an application for compulsory licences under its Patent Act for three medicines to be exported to Nepal was withdrawn in an early stage.[107] It said that the Indian generics manufacturer concerned withdrew the request because the potential importing country had not granted a compulsory license to import the medicines, nor had it notified the TRIPS Council of its intention to do so. This, India said, showed that the system's notification requirements and built-in safeguards were too costly and burdensome and represented a disincentive for the generic supplier to produce.

However, Canada's use of the Para. 6 system shows that, in principle, the system is effective: In May 2005, the Canadian Access to Medicines Regime (CAMR) came into force. In 2008 and 2009, Canada exported the medicine Apotex's generic Apo-TriAvir to Rwanda.[108] At the October 2010 meeting of the WTO Intellectual Property Council, Canada explained that the export took so long because Apotex did not have a buyer when it first sought approval for its generic in 2006 and the procurement tender in Rwanda after the compulsory licence had been issued in September 2007.[109] Canada

105 Para. 6 of the Declaration on the TRIPS agreement and Public Health, 14 September 2001. See also "Public health, innovation and intellectual property rights", Report of the Commission on Intellectual Property Rights, Innovation and Public Health, available at the WHO website at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf [06 June 2011], p. 117.

106 So far, the Para. 6 system has only been used by Canada, exporting generic drugs to Rwanda. For details confirm below.

107 A summary of the topics discussed at the 26-27 October 2010 meeting is available at http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm [11 March 2011].

108 Article by Universities Allied for Essential Medicines (UAEM), available at http://essentialmedicine.org/issues/patents/case-studies [05 September 2011].

109 Canadian HIV/AIDS Legal Network, press release of 20 July 2007, "Rwanda first to try buying affordable AIDS drug from Canada using Access to Medicines Regime", available at http://www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=755 [05

said that the generic medicine was approved by Health Canada in less than six months through a special review stream established by the Health Ministry in order to speed up the approval process, instead of the usual time of up to a year. The compulsory licence itself was approved in only 15 days in September 2007, Canada said. The requirement to negotiate a voluntary licence with the patent holders first (GlaxoSmithKline, Boehringer Ingelheim and Shire BioChem Inc) was handled swiftly and the three waived the royalty payment that was eventually offered to them, Canada went on. It added that Apotex eventually secured the deal to sell to Rwanda in the face of competition from other generics suppliers in an open tender by selling at below cost (19 cents per pill). At the meeting in October 2010, Canada also rejected some members' arguments that anti-diversion conditions (preventing the medicines going to the wrong markets) were burdensome since it argued that the colouring and labelling requirements and the need to publish information on a website were simple.

This shows that the Para. 6 system presents an opportunity for developing countries to gain better access to antiretroviral medicines. Although developing countries need to adopt a good national policy in order to benefit from the system,[110] the necessarily rules from the WTO's side are in place. The fact that the waivers are currently still in a temporary form does not change this fact. The recent developments have led to a lot more legal certainty with respect to the interpretation of the TRIPS flexibilities.[111]

At the same time, the scarcity of use of the revised TRIPS flexibilities shows that this system – while presenting an opportunity – is de facto limited to one. An international minimum standard of patent protection with sufficient exemptions alone thus does not lead to the "golden aim" of universal access to antiretroviral medicines. It appears that either a good national policy or a strong partner in the developed world (such as Canada in Rwanda's case) is necessary in order to actually make use of the rules.

E. South African movements towards better access to antiretroviral drugs

Although numerous campaigns and cases could be cited here, the focus is put on three

September 2011].

110 This view is also expressed by *Kongolo/Shyllon*, p. 261, 262.

111 *Avafia/Berger/Hartzenberg*, p. 3.

events that have become prominent: the antiretroviral drug cases and the initiatives based on competition law by the Treatment Action Campaign (TAC). This is because both cases illustrate an important interface. The first case concerns the ability of the South African government to maintain parallel importing and compulsory licensing measures, hence pure patent law questions. The second and third cases deal with competition law complaints. Both areas of law, as will be shown below, are closely linked when it comes to the question of access to antiretroviral medicines in particular and public health issues in general.

I. The antiretroviral drug cases in South Africa: Pharmaceutical companies v. the Republic of South Africa

For South Africa, an important part of the debate on access to HIV/ADIS medication and an important step towards easier access to medicines and the development of the respective legal framework was the dispute between the pharmaceutical companies holding the patents of the drugs and the Republic of South Africa regarding intellectual property rights, compulsory licensing and parallel importing of HIV/AIDS medication.

In early 2001 – and thus before the Doha Declaration and the Para. 6 system came into existence – a lawsuit at the Pretoria High Court was brought against the South African government by 39 foreign drug manufacturers, seeking to block the 1997 Medicines Act [112] enabling the health minister to import generic versions of patented drugs or to license their domestic production.[113] The pharmaceutical companies questioned the

[112] Medicines and Related Substances Control Amendment Act, Act 90 of 1997, hereinafter referred to as the Medicines Act, available at http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf [04 September 2011].

[113] Confirm Sec. 15 (c), 22 (c)-(h) of the Medicines Act, citation of the most relevant parts:

15 (c) Measures to ensure supply of more affordable medicines
The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—
(a) (...) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard (...) as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered (...), may be imported;
c) prescribe the registration procedure for, as well as the use of, the medicine referred to in para. (b).

22 (c) Licensing
(1) Subject to the provisions of this section— (...)

constitutionality of these parallel importing and compulsory licensing measures. They also challenged Art. 28, 31, 39.3 and 41 of the TRIPS agreement.

The suit filed against the government was withdrawn by the companies in late April 2001.[114] By dropping their suit, the companies signalled their unwillingness to continue contesting the South African governments' ability to take advantage of access provisions of the – at the time still "original" - TRIPS agreement.[115] Indeed, when evaluating the TRIPS agreements' rules in their form of 2001 in respect of the lawsuit, it becomes clear that the lawsuit would most likely not have been successful as the TRIPS agreement would not have forbidden the South African rules contested by the pharmaceutical companies:

As explained above, already the "original" TRIPS agreement allows for measures limiting patent rights, however, it only does so without further requirements in the instance of public health or other national emergencies. Given the magnitude of the AIDS epidemic in South Africa (confirm the statistics above), this requirement should have been fulfilled at the time of the lawsuit and should still be fulfilled today, making compulsory licensing – from the TRIPS point of view - possible without further requirements. The epidemic in South Africa is usually referred to as an exceptionally

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(b) the council may, on application (...) and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine. (...)

22 (d) Period of validity and renewal of licence
A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the council, as the case may be, may allow and on payment of the prescribed fee.

22 (g) Pricing committee
(1) The Minister shall appoint such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
(2) The Minister may, on the recommendation of the pricing committee, make regulations—
(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;(...).
(3) (a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
(b) No pharmacist or person licensed in terms of section 22C(1)(a) shall sell a medicine at a price greater than the price contemplated in paragraph (a) (...).

114 Cf. the comment of the South African Health Minister at the time, Dr Manto Tshabalala-Msimang, of 19 April 2001, informing the public about and at the same time welcoming the withdrawal, available at http://www.doh.gov.za/show.php?id=164 [04 September 2011].

115 *Mutume*, p. 14.

severe one.[116] Thus, due to the national emergency situation South Africa was faced with, the TRIPS agreement did not place any additional requirements on South Africa with respect to a limitation of patent protection.

However, as shown above, the TRIPS clauses dealing with extreme urgency and the protection of the public were very vague before any clarification was made through the Doha Declaration and the other developments shown above. In 2001, it was not up to the member countries to determine themselves whether or not a state of national emergency was given. Yet, even if one did not define the HIV/AIDS epidemic in South Africa as a national emergency or a circumstance of extreme urgency, Art. 28, 31, 39.3 and 41 of the TRIPS agreement would not have been violated by the respective rules of the Medicines Act challenged by the pharmaceutical companies:

Art. 28 of the TRIPS agreement limits parallel importing and it does indeed prevent third parties from "making, using, offering for sale, selling, or importing" a product without the consent of the owner. However, Art. 6 of the TRIPS agreement allows the national government to decide when such patents are exhausted. In fact, it is exclusively the right of the national government to make that determination.

According to Art. 39.3 of the TRIPS agreement, pharmaceutical data should be protected against disclosure. Generally, this provision allows for data exclusivity and disclosure by a government to third-party manufacturers. However, this rule also has an exceptional clause which allows disclosure "when necessary to protect the public".

Finally, Art. 41 of the TRIPS agreement provides for enforcement: member countries must enforce intellectual property rights. It is, however, the sole discretion of the government of South Africa to set up a dispute resolution procedure for patent violations. This type of case cannot be brought before the WTO Dispute Settlement Panels.

Hence, all TRIPS provisions mentioned allowed the South African government to pursue parallel importing and compulsory licensing.[117] Since the pharmaceutical

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116 AVERT, South Africa HIV and AIDS statistics, Conclusion, available at http://www.avert.org/safricastats.htm [11 March 2011].

117 The "Bolar" exception could not be invoked by the South African government in this case since the patents of the pharmaceutical companies did not cease soon enough.

companies have withdrawn their case, the legal issues have been largely decided. Their withdrawal essentially conceded that it is within South Africa's right to pursue compulsory licensing and parallel importing under the TRIPS agreement. This is particularly true after the subsequent developments beginning with the Doha Declaration and aiming at permanently altering the TRIPS agreement.

II. Initiatives by the Treatment Action Campaign: Anti-competitive behaviour of patent owners

The aim to make HIV/AIDS medication more accessible has been tried to be reached by using competition law measures.

1. The 2002 complaint

On 19 September 2002, a non-governmental organization called the Treatment Action Campaign (TAC) brought, together with other individuals, a first complaint to the South African Competition Commission, alleging that GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) – two manufacturers of HIV/AIDS medication – were charging excessive prices for antiretroviral drugs,[118] thereby contravening sec. 8 of South Africa's Competition Act,[119] and that this fact was directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS. The TAC complaint compared the prices of patented antiretroviral drugs in South Africa with generic prices available elsewhere in the world, and alleged that the prices of patented drugs were far in excess of the generic prices, even with an allowance for research and development, higher profits, licensing fees, and the incentive to develop new drugs. Apart from excessive pricing, the TAC in its complaints also alleged a breach of the essential facilities doctrine (sec. 8 lit. b) of the Competition Act) by alleging that the pharmaceutical companies denied a competitor access to an essential facility by refusing to license their products to generic manufacturers.[120] Likewise, they alleged the

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118 The TAC complaint is available at http://www.tac.org.za/Documents/DrugCompaniesCC/DrugCompaniesCC.htm [05 September 2011].

119 South African Competition Act, Act 89 of 1998,as amended by Competition Amendment Act, No 35 of 1999 (Date of commencement 1 September 1999), Competition Amendment Act, No. 15 of 2000 (Date of commencement 1 September 2000), Competition Second Amendment Act, No. 39 of 2000 (Date of commencement 1 February 2001).

120 Cf. the TAC complaint, available at http://www.tac.org.za/Documents/DrugCompaniesCC/DrugCompaniesCC.htm [05 September

pharmaceutical companies' behaviour to constitute an exclusionary act pursuant to sec. 8 lit. c) of the Competition Act.[121]

On 16 October 2003, the Competition Commission referred the complaint to the Competition Tribunal, indicating that it believed in the establishment of a prohibited practice. According to a media release issued on the same day, the Commission found that the firms had a) denied a competitor access to an essential facility, b) engaged in excessive pricing and c) engaged in an exclusionary act, thereby contravening sec. 8 lit. a), b) and c) of the Competition Act.[122]

Shortly thereafter, it was publicly announced that the pharmaceutical companies, the Competition Commission, and the TAC had entered into settlements pursuant to which the two companies would grant non-exclusive licenses to several other firms for antiretroviral drugs in exchange for the withdrawal of the complaint.[123]

Although these settlements prevented a decision by the Competition Tribunal, the claim of excessive pricing would most likely have been substantial under South African competition law. Excessive pricing by firms in a dominant position is prohibited by sec. 8 lit. a).[124] According to sec. 7 lit. a), a firm is deemed to be dominant if its market share is above 45 per cent.[125] Since hardly any licensing had taken place before the complaint, both companies were dominant within the field of their respective patented medication.

According to sec. 1 (1) (ix) of the Competition Act, an excessive price is defined as a price for a good or service that bears no reasonable relation to the economic value of that good or service, and is higher than the said economic value. This is to say that dominant firms are not allowed to charge prices that are "too high", or "unfair". For the purposes of competition analysis, the economic value of a good or service is its competitive price as the competitive price incorporates all the elements of objective and subjective values.[126] In order to establish excessive pricing, thus, the price charged must

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121 Ibid.

122 Competition Commission Media Release No. 30 of 2003, 16 October 2003, "Competition Commission finds pharmaceutical firms in contravention of the Competition Act".

123 Competition Commission Media Release No. 33 of 2003, 16 December 2003, "Competition Commission concludes an agreement with pharmaceutical firm".

124 Sec. 8 lit. a) states: "It is prohibited for a dominant firm to charge an excessive price to the detriment of consumers."

125 Sec. 7 lit. a) reads: "A firm is dominant in a market if it has at least 45% of that market."

126 Competition Commission: Competition News, September 2001, p. 6-7, "Excessive pricing,

include an unreasonable plus over the competitive price.

As mentioned above, the TAC complaint compared the prices of the patented drugs in South Africa with generic prices available elsewhere in the world. They alleged that the prices of patented drugs were far in excess of the generic prices, even with an allowance for research and development, higher profits, licensing fees, and the incentive to develop new drugs, and proved this allegation by providing the Competition Commission with the different prices charged.[127]

The Commission found that despite the fact that the competitive provision of the drugs was feasible, GSK's and BI's patented products were being sold in South Africa at prices which were unaffordable to almost all South Africans living with HIV and which were between five and fifteen times higher than that of generic equivalents.[128] According to the Commission, this practice fulfilled the requirements of excessive pricing pursuant to sec. 8 lit. a) of the Competition Act. Furthermore, despite it being economically feasible, GSK and BI had refused competitors access to their patents that were non-duplicable resources, which were necessary to enable the competitors to provide the drugs.[129] In this practice, the Commission saw the refusal to give a competitor access to an essential facility pursuant to sec. 8 lit. b) of the Competition Act.[130] Additionally, the Commission found that GSK and BI had impeded generic suppliers from entering the South African markets for anti-retroviral drugs by refusing to grant licences to generic manufacturers at reasonable royalty rates, when there were no legitimate business reasons for such refusals and where the anti-competitive effects of the refusals significantly outweighed any technological, efficiency or other pro-competitive gains from the refusals[131] The Commission saw an exclusionary act pursuant to sec. 8 lit. c) of the Competition Act in this.[132]

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fairness and economic value".

127 *Böttger*, GRUR Int. 2008, p. 885 et seq.

128 Official Newsletter of the Competition Commission of March 2004, Ed. 15, "Towards a free and fair economy for all", "GSK and BI issue anti-retroviral licenses", p. 1, available at http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/March-04-Newsletter.pdf [05 September 2011].

129 Ibid, p. 2.

130 Sec. 8 lit. b) reads: "It is prohibited for a dominant firm to refuse to give a competitor access to an essential facility when it is economically feasible to do so."

131 Ibid, p. 2.

132 Sec. 8 lit. c) reads: "It is prohibited for a dominant firm to engage in an exclusionary act (...) if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain."

Thus, the TAC would have been able to show anti-competitive practices on the side of the pharmaceutical companies. Hence, the TAC complaint most likely would have been successful, even if the parties had not entered into settlements.

2. The 2007 complaint

On 6 November 2007, the TAC together with the AIDS Law Project (ALP) filed a second complaint with the Competition Commission about the alleged anti-competitive conduct of the world's largest pharmaceutical company Merck and its South African subsidiary MSD.[133]

The complaint alleged that MSD and Merck were violating sec. 8 of the Competition Act as their refusal to license the antiretroviral drug "efavirenz" to a sufficient number of generic companies on reasonable terms threatened access to comprehensive treatment for HIV/AIDS. The complaint alleged that the pharmaceutical companies were abusing a dominant position by preventing cheaper generic efavirenz products from being brought to market, by preventing co-formulated and co-packaged antiretroviral products containing efavirenz and at least one other antiretroviral medicine from being brought to market; and by placing the sustainability of supply of efavirenz products in South Africa under threat because of the risk of stockouts.[134]

The background of the complaint was that Merck effectively had a monopoly on the sale of efavirenz in South Africa. At the time of the complaint, the TAC reasoned, nearly 400,000 people with HIV were on HAART in South Africa in the public and private sectors, thus taking at least three antiretroviral medicines daily. Two thirds of people initiating HAART took efavirenz. However, efavirenz cost both the state far more than the combined price of the other two drugs. Even though several companies across the world manufactured cheaper and a wider range of efavirenz than produced by MSD and Merck, these were not available in South Africa. Furthermore, there had been at least three stockouts of efavirenz in Southern Africa.[135] Merck and MSD had refused licenses to at least two generic manufacturers. Licenses had been given to two local

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133 The full complaint is available at http://www.tac.org.za/documents/TACvMSDFinalCompCompapersFinalOf041107.zip [05 September 2011].

134 See article "TAC complains to the Competition Commission about the anti-competitive conduct of the world's largest pharmaceutical company" of 07 November 2007, available at http://www.tac.org.za/community/node/2127 [05 September 2011].

135 Ibid.

companies, but the terms of the licenses were considered unreasonable and neither company had been able to bring generic efavirenz products to market up until the lodge of the complaint. The two companies who had been refused licenses had registered generic efavirenz with the Medicines Control Council and would have been able to bring their medicines to market immediately if licensed.[136]

By June 2008, MSD a) agreed to license four generic drug companies – two local producers and two locally-based importers – to bring stand-alone efavirenz products to market, b) agreed that all four licensees are entitled to bring co-packaged products containing EFV to market, c) agreed that all four licensees will not unreasonably be refused consent to bring co-formulated products containing EFV to market, d) that all licensed products can be sold to both public and private sectors in South Africa and 10 other southern African countries,[137] and d) waived any right to a royalty.[138]

Due to these developments, the Competition Commission saw no reason to refer the complaint to the Competition Tribunal for adjudication. However, is can be assumed that this case, too, would most likely have been successful.

III. Evaluation of the cases in the light of the previous findings: Role and interface of patent and competition law

The cases explained above show a number of things. First, already in 2001, the TRIPS agreement allowed South Africa to maintain a legal system foreseeing parallel importing and compulsory licensing. As shown above, the Medicines Act foreseeing such measures – or rather: allowing the Health Minister to determine and prescribe conditions under which these measures would have been possible – was in line with the

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136 Ibid.

137 Angola, Botswana, DRC, Lesotho, Madagascar, Mauritius, Namibia, Seychelles, Swaziland and Zimbabwe.

138 Cf. article "TAC complaint increases access to efavirenz: MSD finally agrees to grant licenses on reasonable terms" of 01 June 2008, available at http://www.tac.org.za/community/node/2329 [05 September 2011].

TRIPS agreement. The withdrawal of the lawsuit by the pharmaceutical companies essentially conceded this.

Second, already in 2001, South Africa had the necessary legal basis for allowing measures such as parallel importing and compulsory licensing in place, although it took years until the rules were finally implemented and used. In 2001, access to antiretroviral medication in South Africa was extremely low – much lower than today.

Third, the first TAC complaint would – most likely - have been successful under South African competition law, a law that dates back to 1998/1999. The same can be assumed for the second complaint, having regard to the reasoning of the Competition Commission in the first case and the similarity of both situations in 2002 and 2007.

Thus, the establishment of a world-wide system of minimum IP protection in the form of the TRIPS agreement did not prevent access to medicines in the sense that rules allowing for exceptions from its prescribed protection standard were possible. Neither, however, did it facilitate access. This is in line with the previous findings, namely that the revised TRIPS agreement presents an opportunity for developing countries to gain better access to antiretroviral medicines, yet, at the same time, a good national policy or a strong partner in the developed world is necessary in order to actually make use of the rules. The fact that access to antiretroviral medicines was extremely low in 2001 must – among other factors – thus be attributed to the fact that South Africa's national policy was not particularly advanced. Although the Medicines Act in principle allowed for the measures explained above, these rules had not been implemented and used in 2001. At the same time, this shows that access to reasonably priced antiretroviral medication is not linked to patent law alone, even though the influence of patent protection on prices [139] shall not be denied here. The two TAC complaints show that a competition law system with built-in public policy considerations such as, for instance, the essential facilities doctrine, is equally able to promote access to medicines. In fact, the two complaints based on competition law, which came from a "demanding" and not a "defending" position (such as the lawsuit initiated by the pharmaceutical companies), were de facto successful. What becomes clear from this is that a national policy allowing for measures of easier access to medication – be they patent law or competition law measures - is obviously necessary in order to enable people suffering

[139] This impact has long been argued, cf. *Kongolo/Shyllon*, p. 260.

from HIV/AIDS to actually gain better access to medication. Waivers and exceptions from patent protection alone do not help those people.

As this becomes clear, one has to ask which remedy is the better remedy: exceptions from patent protection or competition law measure? In order to find an answer to this question, the respective current legal frameworks as well as their impact need to be considered.

F. Current legal framework in South Africa

I. The South African Patents Act

The South African Patents Act[140] provides for the measures envisaged in the TRIPS agreement to promote public health: It allows the grant of compulsory licenses, comprises a Bolar exemption, and it also allows for parallel importing. South Africa thus has implemented three very important measures that can help in the public health context even though it has not taken full advantage of all available flexibilities available to it through the TRIPS agreement.[141]

1. Rules on compulsory licensing

Sec. 56 of the South African Patents Act provides for the grant of a compulsory licence in case of abuse of patent rights. In its subsec. 1, it stipulates that "any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent." Sec. 56 (2) sets out a number of reasons as to when the rights in a patent shall be deemed to be abused. An abuse is given if "(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent" after the expiry of a certain time period (three to four years), "and there is (...) no satisfactory reason for such non-working" or "(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms" or "(d) by reason of the refusal of the

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140 South African Patents Act No. 57 of 1978 as amended by Patents Amendment Act, No. 14 of 1979, Patents Amendment Act, No. 67 of 1983, Patents Amendment Act, No. 44 of 1986, Patents Amendment Act, No. 76 of 1988, General Law Amendment Act, No. 49 of 1996, Intellectual Property Laws Amendment Act, No. 38 of 1997, Patents Amendment Act, No. 10 of 2001 and Patents Amendment Act No. 58 of 2002.

141 *Avafia/Berger/Harthenberg*, p. 3.

patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic (...) is being prejudiced, and it is in the public interest that a licence or licences should be granted" or "(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee (...) for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee (...)", i.e. if excessive pricing is found.

The patentee is entitled to oppose the application for a compulsory license, sec. 56 (3). The commissioner then considers the application on its merits and orders the grant of a licence on conditions that he or she deems appropriate. In the event that a licence is granted, it has to include a provision that the licence shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the commissioner, are unlikely to recur. Any licence granted under sec. 56 has to be be non-exclusive and, in principle, not transferable. In determining the conditions on which any licence is granted, the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements. The rules are, thus, quite similar to the TRIPS agreement's regulations.[142] The different cases in which an abuse is presumed, however, are more detailed and clearer than in the TRIPS agreement.

[142] *Engelke/Stahlmann*, GRUR Int. 2010, p. 31 et seq.

2. Rules regarding parallel importing

Parallel importing is allowed for by sec. 45 (2) of the South African Patents Act. Read in conjunction with sec. 15C of the Medicines Act (confirm above), it becomes clear that these rules have been set up in order to facilitate affordable drugs through parallel importing.

3. Bolar provision

Sec. 69 lit. a) contains a so-called "bolar provision". According to subsec. (1) this rule, it is not an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product. Yet, pursuant to subsec. (2), it is not permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information described above.

II. South African Competition Law

The rules of South African competition law have mostly been mentioned above in the context of the TAC complaints. In order to avoid repetitions, the relevant rules will only be mentioned briefly here.

Pursuant to sec. 8 lit. a) of the Competition Act, a dominant firm may not charge excessive prices to the detriment of consumers. According to sec. 7, a firm is dominant in a market if (a) it has at least 45% of that market, (b) it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power, or (c) it has less than 35% of that market, but has market power.

Sec. 8 lit. b) of the Competition Act prohibits the refusal of a dominant firm to give a competitor access to an essential facility when it is economically feasible to do so. According to sec. 1 (1) (viii) of the Competition Act, essential facility is defined as an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.

According to sec. 8 lit. c) of the Competition Act, it is prohibited for a firm to engage in

an exclusionary act if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain.

Thus, under South African competition law, dominance itself suffices as a reason to investigate. From sec. 8 of the Competition Act it can be seen that competition law is designed to be a measure to promote economical equality for competitors rather than to keep competitors away from a market in which one firm is dominant – may it be due to its own innovations or to some kind of abuse.

G. Discussion

The question that remains is: what is the relationship of the South African patent law and competition law rules shown above and should the national government rather use

exemptions from patent protection in order to facilitate better access to antiretroviral medicines or should it make use of competition law remedies?

I. Impact of patent law rules

Sec. 56 (2) lit. c of the Patents Act, i.e. the presumption of an abuse if the demand is not being met to an adequate extent and on reasonable terms, could be applied to antiretroviral drugs. Likewise, sec. 56 (2) lit. e), i.e. excessive pricing, is specifically designed for the pharmaceutical industry. However, interestingly, sec. 56 of the Patents Act has never been used for pharmaceuticals. Likewise, under the rules of sec. 45 (2) of the Patents Act and sec. 15C of the Medicines Act, not a single permit has been issued so far. The "failure" of sec. 45 (2)'s intention is illustrated by the case Stauffer Chemical v. Agricura[143] A simple "not for export" label made the pharmaceutical company get around sec. 45 (2). Since then, it is the usual practice that the patentee puts this label on its product.

One could thus ask whether the patent law rules have not achieved their objective. However, while no compulsory licence has ever been issued for an essential medicine, having the correct regulatory framework in place has been indispensable assistance to generic companies in the negotiating and granting of licences to produce generic versions of essential medicines.[144] This becomes clear from the successful negotiations after the two TAC complaints. Yet, this does not alter the fact that the use of patent law remedies has obviously been difficult.

II. Impact of competition law rules

The competition law remedies, on the other hand, have helped to facilitate access to drugs – at least de facto, since the challenged companies committed to licensing in order to prevent a decision by the Competition Tribunal.

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143 Stauffer Chemical v. Agricura 1979 BP 168 (CP).

144 *Avafia/Berger/Hartzenberg*, p. 3.

1. Awareness and will to act of the Competition Authorities

Furthermore, it appears that both the Competition Commission and the Competition Tribunal are aware of the necessity of access to medicines as well as the legal possibilities at its hands.

In the case National Association of Pharmaceutical Wholesales v. Glaxo,[145] the applicant argued that the pharmaceutical industry was characterized by unusually low levels of inter-brand competition. This, the applicant argued, appeared to derive from two features associated with the market for pharmaceutical products. These were, first, the widespread use of intellectual property protection of pharmaceutical products. And, second, the "must-have" nature of the product, the fact that product and brand selection of pharmaceutical products was made by the prescribing doctor thus eliminating the ability of the actual purchaser of the product to exercise any competitive choice.[146] The Competition Tribunal which had to decide the case stated that, clearly, patent protection conferred a degree of monopoly power as this was its manifest intention. It made clear that there could be little denying the power conferred by a patent and the controversies surrounding the alleged willingness of the pharmaceutical manufactures to milk this power for all that it was worth.

Furthermore, when faced with the first TAC complaint, the Competition Commission made clear that critics who believed that the Commission's findings may threaten the existence of patents were misled.[147] Critics had stated that the use of competition law measures may lead to the fact that companies might no longer wish to invest in research and development of products that would benefit South Africa. However, the Commission emphasized that it was important to note that although patent holders were granted a legal monopoly, they were not allowed to abuse their patent rights. Abuse of patent rights could take various forms. One form of abuse found in both the Patents Act and the Competition Act was that of charging an excessive price for the patented products.[148] As in South Africa, in several international jurisdictions, another form of abuse is recognised, namely, that of refusing to grant competitors access to an essential

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145 National Association of Pharmaceutical Wholesales v. Glaxo, CPLR, p. 93.

146 Ibid., p. 121.

147 Official Newsletter of the Competition Commission of March 2004, Ed. 15, "Towards a free and fair economy for all", "GSK and BI issue anti-retroviral licenses", p. 1, available at http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/March-04-Newsletter.pdf [05 September 2011].

148 Ibid.

facility.[149] The Commission made clear that patent holders were not exempt from these provisions and that no law gave patent holders the right to abuse their patents. Judging a practice to be anti-competitive, therefore, did not threaten the existence of patents any more than existing patent law always has, the Commission concluded. The Commission agreed that the purpose of conferring patent rights was generally that of granting an exclusive right. However, "when it appears those rights are being abused, it would be detrimental to consumers if authorities allowed such abuse to continue merely because a firm held a patent."[150]

A second concern the Commission dealt with was that the way in which the Commission defined the relevant product market in the HIV/AIDS cases posed a threat to patent holders because it appeared that the mere holding of a patent conferred monopoly status (100 per cent market share) on the patent holder in respect of the product which was the subject of the patent. The Commission opposed this concern as unsubstantiated, arguing that a product market definition depended not on whether a product was the subject of a patent but on the substitutability of the relevant product with other, comparable products.[151] Lastly, the Commission had to face the concern raised in the media that the Commission's finding in the TAC complaint case was largely based on sentiment and not on sound legal and economic principles. The Commission argued that this was not the case as all its findings were rooted in competition law. The Commission emphasized that competition law exists not only for the benefit of large enterprises, as is commonly thought, but is ultimately there for the benefit of the ordinary citizen as well.[152] Hence, the competition authorities are clearly aware of their powers and role in the public health sector.

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149 For example, confirm several decisions of the European Courts, for instance: *Bronner v. Mediaprint*, Case C-7/97 [1998] ECR I-7791; *Magill TV Guide*, OJ L 78/43 (1989), affirmed by the Court of First Instance in *RTE v Commission*, Case T-69/89 [1991] ECR II-485; *ITP v Commission*, Case T-76/89 [1991] ECR II-575; *BBC v Commission*, Case T-70/89 [1991] ECR II-535; affirmed by the Court of Justice in *RTE and ITP v Commission*, Cases C-241 and 242/91 P [1995] ECR I-743; *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, Case C-418/01, 29 April 2004.

150 Official Newsletter of the Competition Commission of March 2004, Ed. 15, "Towards a free and fair economy for all", "GSK and BI issue anti-retroviral licenses", p. 1, available at http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/March-04-Newsletter.pdf [05 September 2011].

151 Ibid.

152 Ibid.

2. *Advantages of competition law measures*

There are different advantages that speak for the use of competition law measures when it comes to better access to medicines. First, unlike the degree of consensus reflected in the Doha Declaration, which clearly sets the boundaries of what is permissible in terms of patent law, there is sufficient disagreement between and within developed countries on the relationship between competition policy and intellectual property to provide with significant space within which to manoeuvre.[153] This is not to imply that developing countries should take their lead from the industrialised world if and when it reaches consensus on the relevant issues. Instead, it is simply to draw attention to the window of opportunity that such a lack of consensus provides.

Secondly, competition law and policy is well suited to implementation by an independent competition authority vested with strong investigative powers. Unlike patent law, the effective use of competition law is ordinarily not reliant on the conduct of certain parties that may be reluctant to act.[154] In particular, it may facilitate action by a range of interested parties other than the state and generic pharmaceutical manufacturers, providing a mechanism for action that does not necessarily require such parties to invest significant resources in risky litigation that may drag on for years. Instead, the regulatory authority may pursue the matter in the public interest simply on the basis of a third party complaint.[155] The willingness of the competition authorities to take a stand in such proceedings became clear in the TAC complaints.

Thirdly, the experience of South Africa in using competition law to increase access to medicines for the treatment of HIV infection and AIDS-related diseases provides helpful insights into the potential benefits of exploiting competition law in a developing country context.[156] While South Africa may differ in many respects from its African neighbours and other developing countries, the lessons learnt in the two TAC complaints (both of which focused on allegations of excessive pricing) can be of broader application, both in South Africa and in other developing countries.

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153 *Avafia/Berger/Harthenberg*, p. 15.
154 *Fikentscher*, IIC 2007, p. 165.
155 *Von Kraack*, p. 57 et seq.
156 *Avafia/Berger/Hartzenberg*, p. 17.

3. *Advantages not offset for other reasons*

These advantages are not outbalanced for other reasons. On the contrary, large-scale limitation of patent protection is not advisable.

First, as previously discussed, the use of patent law exemptions has disadvantages. Compulsory licensing has been called to have expropriational character.[157] Even if one does not agree with this view, compulsory licensing is by no means the universal remedy it has been considered to be by some authors:[158] the establishment of compulsory licensing rules in South Africa have only helped indirectly (confirm above).

Furthermore, severely cutting down on IP protection holds certain dangers, especially for developing countries. Sufficient protection of IP rights is necessary in order for these countries to become or remain trade partners of developed countries and in order for them to gain access to technology.[159] Furthermore, it is not only the Goliaths of this world who need IP protection. When it comes to trademark protection, for example, small entrepreneurs fighting to increase their share of the market against the Goliaths strive energetically to identify their uniqueness and that of their products and services.[160] Furthermore, denying patent protection to pharmaceuticals has profound effects as it eliminates the incentive to conduct research and development (R&D) locally and drives pharmaceutical companies to perform these valuable activities in other jurisdictions.[161] Further effects include fewer pharmaceutical products, reduced future growth of the domestic industry and, most importantly, poorer health for the country's residents.[162] Also, patent protection enables pharmaceutical companies to obtain a degree of exclusivity with respect to a particular market.[163] This exclusivity is needed to provide drug companies with significant profits on "winner" drugs in order to offset the losses associated with the many failures that occur during the long developmental process.[164]

Bearing this in mind, it becomes clear that even though exemptions from patent protection and competition law measures may lead to the same results in many (access

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157 *Von Kraack*, p. 91/92.

158 This view, namely that compulsory licensing is not a "magic bullet", is also expressed by *Von Kraack*, p. 228 et seq.

159 *Fromm-Russenschuck/Duggal*, p. 43.

160 Laugh It Off Promotions CC v. South African Breweries (SAB) International (Finance) B.V. t/a Sabmark International 2006 (1) SA 144 (CC), para 80.

161 *Hejazi*, p. 8.

162 *Rapp/Rozek*, p. 79, 80.

163 *Imam*, IIC 2006, p. 245 et seq.

164 *Hejazi*, p. 8.

to pharmaceuticals-related) cases, it is generally advisable to find solutions via competition law instead of patent law. This result is further supported by the following "technical" thought:

It is generally understood that the simple exercise of exclusive rights in patents cannot in and of itself provide a basis for using competition policy to advance public health. In such circumstances, which patent law ordinarily does not regard as abusive, states are nevertheless permitted by TRIPS to take a range of regulatory measures to increase access to essential medicines and other patented technologies necessary for safeguarding public health (see, in particular, Articles 7, 8, 27.2, 30 and 31 of the TRIPS agreement, as well as the Doha Declaration). Yet, there are various ways in which competition law may appropriately be used to advance the public interest even where the conduct of the exclusive rights holder is not necessarily abusive nor have any direct anti-competitive effect. The various regulatory options available under competition law are remedies, preventative measures and measures that serve the public interest by promoting competition, whether directly or indirectly. Thus, the simple existence of measures to remedy anticompetitive practices, for example, may act as a sufficient disincentive for exclusive rights holders to engage in abusive or otherwise problematic conduct. In such cases, there may be no need to deal proactively with the problematic conduct.[165] Hence, competition law offers more "technical"options to react to health needs of the general public than patent law.[166]

Finally, the use of competition law remedies in cases related to public health are not too detrimental for IP rights owners and are in line with the South African legal system. According to sec. 10 (4) of the Competition Act, a firm may apply to the Competition Commission to exempt an agreement or practice, or category of agreements or practices, that relates to the exercise of intellectual property rights, including a right acquired or protected in terms of the Patents Act, from the application of the rules in Chapter 2 covering prohibited practices. Thus, if a pharmaceutical company can show legitimate reasons why its agreements or practices which de fact constitute prohibited practices should still not be challenged, it can apply for such exemption. This rule is unique for South Africa and is not found in United States of European Union law. It

165 This may be particularly important for countries without significant institutional capacity to regulate proactively. In contrast, those countries with such capacity may rather choose to frame such measures in the language of prevention, such as by subjecting licensing agreements to prior approval processes of the sort ordinarily associated with merger regulation.

166 This is also expressed by *Avafia/Berger/Hartzenberg*, p. 15.

acknowledges how difficult the balancing exercise is and underlines that even if competition law measures are used in order to promote public health, a fair and just balance can be struck vis-à-vis patent protection.

H. Conclusions

What can be concluded is that the TRIPS agreement, particularly after the clarification of its flexibilities through the Doha Declaration, does not render sufficient access to medicines impossible. The necessary rules on patent law exemptions are in place.[167] The problem of making use of these rules is a national problem and it cannot be solved by further macerating the TRIPS agreements' rules on patent protection.

Many factors contribute to a lack of access to existing medicines in developing countries: tattered health systems, insufficient numbers of health workers, weak regulatory regimes, and poor procurement and distribution systems. Other conditions - import duties and taxes, mark-ups throughout the distribution chain, and even corruption and product diversion - coalesce to produce high drug prices. Furthermore, weak research and development capacity and limited investment in research and development combine to restrict research on neglected diseases in developing countries.[168]

In order to facilitate better access to HIV/AIDS drugs, different things are necessary. A strong national policy and the governmental or organizational will to push for access has been proven necessary. On the other hand, a strong international partner is helpful as can be seen in the example of Canada.

When it comes to national policy, it is important to maintain a sufficient level of IP protection in general and patent protection in particular. This protection is a necessity particularly in developing countries. This is not only due to the TRIPS agreements' requirements. Rather, the establishment of a strong IP protection system offers a chance to developing countries to benefit economically from this protection: these countries become more attractive as an investment location. At the same time, the transfer of

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167 *Klopschinski*, GRUR Int. 2007, p. 870 et seq.; see also: *von Kraack*, p. 228 et seq.

168 *Baker*, p. 528 et seq.

innovative ideas and capital is stimulated, which, in turn, promotes the independent research and development process in these countries and thus positive economic effects.[169]

National policy should foresee competition law measures to ensure a just balancing for interests in the public health sector. The main advantages are a greater flexibility than what can be established in patent law as well as authorities that are more likely to intervene. Said flexibilities are enabled by no fixed policy requirements from the TRIPS agreement's side.

This is not to say that patent law rules on compulsory licensing, parallel importing and the research exemption should be deleted. As shown above, these rules have been highly beneficial in the past in licensing negotiations. Furthermore, the South African Competition Commission has repeatedly backed its results by referring to these rules. Also, it is not certain that these rules may not be beneficial in future. They could still be invoked and used at any time.

The positive conclusion of this analysis is that competition law can provide for flexibilities that are necessary to promote public health and lead to better access to HIV/AIDS medicines. However, there has to be a national system containing such rules and governments or organizations pushing for better access. No legal system alone, be it on a national or international level, can help if it is not used. As can be seen in the South African example, even though access to drugs has been improved by competition law means, a "ground-breaking" improvement of access to medicines (which is still far away from universal access!) could only be reached once the government decided to initiate large-scale free antiretroviral medicines programmes.

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169 *Fromm-Russenschuck/Duggal*, p. 43.