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Intellectual Property Rights and Competition Policy: Patent rights, access to life-saving drugs in developing and least-developed countries under the TRIPS Agreement and the future of TRIPS after the Article 31*bis* Amendment.

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

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ABSTRACT

This paper examines the interface between intellectual property rights, the issuing of patent protection under the TRIPS Agreement and access to essential medicines at affordable prices in developing and least-developed countries. It considers the link between patent protection under TRIPS and competition policies by highlighting the clash between intellectual property rights and competition law.

The negative impact of intellectual property rights and patent protection on access to available and affordable drugs plays a major role in the discussion related to the international pharmaceutical market.

In 1995 the World Trade Organization introduced the Agreement on Trade-related Aspects of Intellectual Property Rights. Since the Doha Declaration was adopted in 2001, only a few countries have made use of the flexibilities under TRIPS. This study examines the use of TRIPS flexibilities for the access on essential drugs in developing and least-developed countries and sets out the impact of the Doha Declaration of 2001 and the Amendment to TRIPS of 2005 on the TRIPS Agreement. Governments worldwide are considering whether to ratify the Article 31*bis* Amendment. This study argues that a failure to accept and use Article 31*bis* will undermine the Doha Decision and the General Council Decision of 2003; it will result in an immense negative impact on health treatment for people in poor small countries.

Furthermore the paper discusses the interface between competition law and the intellectual property system under the TRIPS Agreement after the European Microsoft case and explores the relationship between patent protection under TRIPS, monopolies and anti-competitive behaviour in the market by abusing the dominant position granted by the exclusive patent right.

Finally it highlights factors influencing the future of TRIPS, suggests some action for an effective use of the flexibilities of TRIPS for a broader access on affordable and available medicines in developing and least-developed countries and seeks to examine the reconciliation of the clash between intellectual property rights and competition policies.

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TABLE OF CONTENTS

ABBREVIATIONS AND ACKRONYMS

CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
GDP	Gross domestic product
EC	European Comision
EU	European Union
GATT	General Agreement on Tariffs and Trade
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
IPRs	Intellectual property rights
MFN	Most-favoured nation
PC	Personal computer
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
WHO	World Health Organisation
WIPO	World Intellectual Property Organization
WTO	World Trade Organisation

INTRODUCTION

In times of globalization and free markets we live in a world of indifference. In 2008 the world population was estimated to be 6.7 billion people.[1] In 2007 the world's richest countries accounted for one billion people, and were responsible for 76 % of the world gross domestic product (GDP). The world's poorest countries, with about 2.4 billion people, only contributed 3.3 % of the world's GDP.[2] Almost 50 % of the world's population lives on less than US$ 2.50 and at least 80 % live on less than US$ 10 a day.[3] The huge imbalance becomes clear when one considers that the poorest 40% of world's population earn 5 % of the global income, while the richest 20 % earn 75 % of the world income.[4]

Across the globe diseases such as HIV/AIDS, Malaria and Tuberculosis are the greatest threat to the lives of the poor. There are between 350 – 500 million cases of Malaria every year, and 1 million deaths are attributed to this disease annually.[5] Worldwide about 33 million people are living with HIV/AIDS. Almost 2 million people died of HIV/AIDS in 2007; 2.7 million people were newly infected in 2007.[6] AIDS is the most common cause of death in sub-Saharan Africa, where 74 % of HIV/AIDS infected people live.[7]

These deaths are avoidable as scientific and technological innovation has resulted in an obvious advancement in health conditions and treatment options but developing countries are not able to benefit from these modern medical developments. This has lead to inequalities in the health status of those who live in developed, ant those who live in developing countries.[8] The cocktail of anti-retroviral drugs used to treat HIV/AIDS cost about US$ 10.000 per patient per year when this treatment was first made available to the public. Obviously these life-saving drugs

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[1] http://www.census.gov/ipc/www/popclockworld.html [accessed 24 February 2009].
[2] Anup Shah, 'Poverty facts and stats' September 2008, accessed from http://www.globalissues.org/article/26/poverty-facts-and-stats [accessed 24 February 2009].
[3] Ibid.
[4] Ibid.
[5] Ibid.
[6] World Health Organisation, 'Global summary of the AIDS epidemic, December 2007', accessed from http://www.who.int/hiv/data/2008_global_summary_AIDS_ep.png [accessed 24 February 2009].
[7] Until there is a cure Foundation, 'Vital statistics', accessed from http://www.until.org/statistics.shtml?gclid=CLXw2aa3wpcCFYwH3god8nE5Sg [accessed 24 February 2009].
[8] Carlos M. Correa/Abdulqawi A. Yusuf, *Intellectual property and international trade-The TRIPS agreement*, (Kluwer Law International, 2nd Edition, 2008) at 423.

were out of reach of people living in sub-Saharan Africa.[9] In 2001 there was a significant reduction in the price of these drugs when pharmaceutical companies in India began to produce generics of these same drugs. Today the most common antiretroviral cocktail costs about US$ 90 a year.[10] Generic drugs now play an important role in the discussion about access to life-saving drugs for people in poor developing countries. Unfortunately generic drugs cannot be sold in many countries because under the international patent system the 'original' drug is protected by a patent, and the sale of the generic drug would infringe the patent holder's rights.[11]

In balancing the high cost of anti-retroviral products, poorer countries have been forced to reduce expenditure on other necessities, e.g. on training of medical staff and maintaining the health infrastructure.

The access to pharmaceutical products also depends on the 'rational selection and use of drugs, adequate and sustainable financing, [...] and reliable supply systems'.[12] However, the high price is the most significant factor for patients in developing and least-developed countries because the price of medicines directly affects access to pharmaceutical products in these countries.

The development of new drugs is a time-consuming process which requires heavy financial investment.[13] Whether the economy in developing countries will grow successfully, depends on a country's ability to 'generate, acquire and use existing technology'.[14]

The exclusive right to receive the benefit from a new invention which goes with granting of a patent to the inventor is seen as a means to safeguard new innovations. Patents and the access to pharmaceuticals are linked in many different ways. There is a need to find the right balance between making life-saving drugs accessible to everybody and the need of patent protection to bring innovation forward. For many years the relationship between patents, innovation, and access to

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[9] World Bank, 'Cost of providing anti-retroviral therapy', accessed from http://www.worldbank.org/aidsecon/arv/floyd/whoarv-webp3.htm [accessed 24 February 2009].

[10] Medecins Sans Frontier, 'Affordability, Availability and Adaptability of AIDS Drugs in Developing Countries: An On-going Challenge', 2008, accessed from http://www.doctorswithoutborders.org/news/article.cfm?id=2877 [accessed 24 February 2009].

[11] Bjoern Ley, 'Patent rights and access to medicines' in Mpazi Sinjela (editor) *Human Rights and Intellectual Property Rights-Tension and Convergences* (Martinus Nijhoff Publishers, 2007) 101 at 102.

[12] World Health Organisation, 'HIV/AIDS Antiretroviral Newsletter', December 2002, Issue No.8 accessed from http://www.who.int/3by5/en/Dec2002.pdf [accessed 24 February 2009].

[13] World Intellectual Property Organisation, 'Public Health and Patents', accessed from http://www.wipo.int/patent-law/en/developments/publichealth.html [accessed 24 February 2009].

[14] Correa/Yussuf, *supra* footnote 8 at 423.

life saving drugs, is one of the biggest issues in the discussion on intellectual property rights.[15] The debate surrounding patents and public health focuses on two major issues. On the one side there is the acknowledgment that health is one of the most important issues in society and that every individual has the right to access the highest available level of 'mental and physical health'.[16] On the other side, pharmaceutical companies and health services are part of a highly innovative sector, and monopoly pricing will be a result of patenting pharmaceutical products. The enforcement of patents through high pricing effects a limitation of access to 'a sustainable supply of affordable essential medicines' for the poor.[17]

A major arising question arising from this situation: "Are intellectual property rights overprotected?"

The adoption and implementation of the Agreement on Trade-related Aspects of Intellectual Property Rights[18] (TRIPS) on international level and its adoption on national level has provided stronger protection of intellectual property rights.[19] Human rights treaties do not usually contain any provisions on intellectual property rights.[20] The human rights treaties which are relevant to the discussion about the relationship between intellectual property rights and human rights, are the Universal Declaration of Human Rights of 1948[21] and the International Covenant on Social, Economic and Cultural Rights of 1966.[22] Article 27 (2) of the Universal Declaration of Human Rights recognises that 'Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. The International Covenant, Article 15.1, states that any author has the right 'to benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production'. However both treaties also acknowledge the right of everyone to food and health. The International Covenant, Article 12.1, recognises 'The right of everyone to the enjoyment of the

[15] Ibid at 421.
[16] Ibid at 422.
[17] Edwin Cameron, 'Patents and public health: principle, politics and paradox', 19 October 2004, at 4, accessed from http://www.law.ed.ac.uk/ahrc/files/59_cameronpatentsandpublichealth04.pdf [accessed 24 February 2009]
[18] World Trade Organization Agreement on Trade-related Aspects of Intellectual Property Rights of 1995 (TRIPS).
[19] Mpazi Sinjela 'Introduction' in Mpazi Sinjela (editor) *Human Rights and Intellectual Property Rights-Tensions and Convergences,* (Martinus Nijhoff Publishers, 2007) at vii.
[20] Ibid.
[21] Universal Declaration of Human Rights of 1948 (Universal Declaration of Human Rights).
[22] International Covenant on Social, Economic and Cultural Rights of 1966 (International Covenant).

highest attainable standard of mental and physical health'.[23] The Universal Declaration of Human Rights, Article 25 (1), states that 'everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services...'[24]

The implementation of TRIPS in developing countries by the World Trade Organization in 1995 has strengthened the position of intellectual property rights globally. Article 7 and Article 8 of TRIPS consider healthcare,, as well as innovation and research and development as important related to the implementation of intellectual property provisions.

But we have to ask: has the attempt to ensure innovation in the pharmaceutical industry, by protecting research and development, failed to take into account public health issues? Is access to life-saving drugs in developing countries being ignored by the emphasis on patent protection?

The subject of the World Trade Organization and its agreements such as TRIPS are sometimes seen as being contrary to the protection of human rights. Particularly the clash between intellectual property rights and competition policy is subject to discussion in the field. The negotiation of TRIPS addressed concerns of developing and least-developed countries that anti-competitive practices in the field of patent protection could have an adverse impact on these countries.[25] Competition policy describes the measures used by governments to contribute to a successful market and to remedy anti-competitive behaviour. Mostly anti-competitive practices originate from default behaviour of pharmaceutical companies such as excessive pricing, cartels and abuse of a dominant position. Competition policy tries to address such deficiencies by using competition or anti-trust law which includes prohibitions and remedies related to default practices. The government's obligation to secure 'economic, social and cultural rights' justifies competition policies as they help to fulfil these requirements.[26] The TRIPS Agreement acknowledges that competition policies and the abuse of intellectual property rights are linked and that the role of

[23] See Article 12.1 of the International Covenant on Social, Economic and Cultural Rights.
[24] See Article 25 (1) of the Universal Declaration of Human Rights.
[25] Hans Henrik Lidgard/Tu T. Nguyen, 'The CFI Microsoft Judgment and TRIPS Competition Flexibilities' (2008), at 6, accessed from http://works.bepress.com/hans_henrik_lidgard/2 [accessed 24 February 2009].
[26] Robert D Anderson/Hannu Wagner, 'Human Rights, Development, and the WTO: The cases of Intellectual Property and Competition Policy' (2006), *Journal of International Economic Law,* 9 J. Int'l Econ. L. 707-747, at 720, accessed from http://jiel.oxfordjournals.org/cgi/content/full/9/3/707 [accessed 24 February 2009].

competition policy is important in the discussion whether a patent right automatically creates a dominant position in the market for the patent holder.

The structure of this paper is as follows: Chapter one reviews the principle of intellectual property rights, its application to pharmaceutical products and the justification of patent protection. Chapter two discusses the relationship between intellectual property rights and competition policies. Chapter three provides an overview on generic drugs and their effect on competition in the pharmaceutical market. Chapter four examines the Agreement on Trade-related Aspects of Intellectual Property Rights of 1994[27] and its patent rights provisions in the light of public health issues. The penultimate chapter, chapter five discusses the safeguard measures under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and their use for the accessibility of essential drugs. Chapter six focuses on the future of the TRIPS Agreement.

The scope of this paper therefore is:

- Analysis of patent holder's rights, and the right of people in developing and least-developed countries to have access to life-saving drugs, as provided for in the TRIPS Agreement; and the clash between the need to save lives and the need to promote innovation by means of patent protection.
- Examination of the interface between competition policies and intellectual property rights; and the incorporation of competition policies into the TRIPS Agreement.
- The discussion of the safeguard mechanisms incorporated into TRIPS, and of their use in matters of public health, in particular, the issue of access to life-saving pharmaceuticals, in developing and least-developed countries.
- Conclusions about the future of TRIPS and its safeguard mechanisms regarding public health following the Doha Declaration in 2001 and the Amendment on TRIPS in 2005.

[27] World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights of 1994.

CHAPTER ONE
UNDERLYING PRINCIPLE OF INTELLECTUAL PROPERTY RIGHTS

1.1 Introduction

The term 'intellectual property' has its origin in the 19th century.[28] Intellectual property rights grant a person an exclusive right over the creation of his or her mind for a specified time period.[29] Intellectual property rights are private rights. This means that their enforcement is a matter between private parties and for civil courts. The exclusive right goes hand in hand with the means to protect that right. A patent is one form of intellectual property which provides the patent holder the right to exclude third parties from 'making, using, exercising, disposing or offering to dispose of, or importing'[30] the protected good. A patent is a contract between the inventor and a state. It obligates the patent holder to publish information about the invention while the state is obliged to grant an exclusive right as protection of innovation to the inventor so as to protect his or her use etc. of the innovation. This is been seen as incentive to innovation and invention.[31] Paragraph 4 of the Preamble to the Agreement on Trade-related Aspects of Intellectual Property Rights[32] contains the principle underlying the protection of intellectual property: public policy objectives. Public benefit is the reason for governments to provide intellectual property rights and provide 'market exclusivity'[33] through patents. Intellectual property rights can be divided into two categories: copyrights and industrial properties.

- Copyrights cover the rights of creators of artistic work such as paintings, writing, music and computer software. The copyright holder has the right to control use, e.g. the reproduction and adaptation of such creations for a specific time

[28] Michael Spence, *Intellectual Property*, 2007, Claredon Law Series, at 1.
[29] World Trade Organization, 'What are intellectual property rights?', accessed from http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm [accessed 24 February 2009].
[30] Section 45 (1) South African Patents Act, 57 of 1978.
[31] W R Cornish, *Intellectual Property: Patents, Copyright, Trademarks and allied rights* , 4th Edition, 1999, Sweet & Maxwell, at 130.
[32] See Preamble to the Agreement on Trade Related Aspects of Intellectual Property Rights of 1994, paragraph 4.
[33] Edwin Cameron, *supra* footnote 17 at 4.

period.[34] The protection lasts for a minimum period of 50 years after the death of the creator.[35]

- Industrial property again can be sub classified into trademarks, which protect unmistakable signs, and into patents, which protect inventions, industrial designs and trade secrets.[36] Patents usually provide protection for a period of 20 years.

As a result of globalisation and greater accessibility of information, creative work and ideas can be disseminated easily. In particular the internet provides the public with quick and easy access to information from all over the world. Online platforms such as www.youtube.com and www.wikipedia.org provide a good example how information is made available online to a large interlinked global network.

The Business Software Alliance in its annual Global Software Piracy Study reports that because of a 'fast growing PC market in some of the world's highest piracy nations '[37] the global loss from piracy was nearly US$ 48 billion in 2007.

Furthermore the internet makes products available to people around the world. Within a few minutes a person can order goods from the other end of the world and get them delivered to his or her home.

This has lead to increased attention being paid to intellectual property rights and their enforcement.

1.2 Intellectual property rights and pharmaceutical products

A new drug will be protected by a patent if the pharmaceutical company which develops it can convince the patent granting authority that the developed drug is "new". The criteria of newness are: 'novelty [or newness in an] inventive step and industrial application.' [38] Newness also means that the pharmaceutical product has

[34] Arai Hisamitsu, 'Intellectual Property Policies for the Twenty-First Century: The Japanese Experience in Wealth Creation', World Intellectual Property Organization Publication Number 834 (E). 2000, accessed from http://www.wipo.int/freepublications/en/intproperty/834/index.html [accessed 24 February 2009].
[35] World Trade Organization, *supra* footnote 29.
[36] World Trade Organization, *supra* footnote 29.
[37] Business Software Alliance, 'Global Software Piracy Study' accessed from http://global.bsa.org/idcglobalstudy2007/ [accessed 24 February 2009].
[38] Bjoern Ley, *supra* footnote 11 at 105.

not been in public domain before.[39] Most 'new' pharmaceutical products are in fact modified versions of existing drugs which command a good price.

In the pharmaceutical sector patent protection is sought in order that the financial investment in research and clinical testing can be recouped by the developer.[40] Patent protection is extremely important in this area as new pharmaceuticals are often very easy to replicate.[41]

The basic principle underlying patent protection is public policy and public benefit. Though patent protection requires that newly developed pharmaceuticals are disclosed by the developer. This disclosure requirement makes sure that the innovative product enters into public domain. 'Market exclusivity'[42] allows a pharmaceutical company to charge a high price for its innovation in order that it can benefit from its investment in research and development.

This raises a number of questions: Does the need to support and reward innovation which is the justification behind patent protection actually work in the public interest or does it subvert the principle of public policy which also underlies the intellectual property rights? Does the patent system restrict access to drugs by making them unaffordable? Does public interest in pharmaceutical products that are affordable and thereby accessible not overweigh the private interest in patent protection?

This thesis focuses on the discussion about the patent system and its relationship to public health and access to life-saving drugs concentrates on essential medicines. According to the World Health Organization 'essential medicines are those that satisfy the priority health needs of the population'.[43] The World Health Organization publishes an 'Essential Medicines List'[44] which was first published in

[39] University of Oxford, 'Intellectual property rights and generic drugs' accessed from http://weblearn.ox.ac.uk/site/conted/biosci/ethicsbiosci/eb_content/BioethicsAndTheDevelopingWorld/IntellectualPropertyRightsAndGenericDrugs.html [accessed 24 February 2009].
[40] Bruce Lehman, 'The pharmaceutical industry and the patent system' at 2, accessed from http://www.earthinstitute.columbia.edu/cgsd/documents/lehman.pdf [accessed 24 February 2009].
[41] Ibid.
[42] Edwin Cameron, *supra* footnote 17 at 4.
[43] World Health Organization, 'Essential medicines', accessed from http://www.who.int/medicines/services/essmedicines_def/en/ [accessed 24 February 2009].
[44] World Health Organization, 'World health Organization Model list of essential medicines', accessed from http://www.who.int/medicines/publications/essentialmedicines/en/index.html [accessed 24 February 2009].

1977.[45] Amongst others there are pharmaceuticals on the list which are necessary for treating serious diseases like HIV/AIDS, Malaria, Tuberculosis and Cholera.

Most drugs on the 'Essential Medicines List' owe their existence to intensive research and development enabled by patent rights. Without patent protection most of the drugs would have not been produced and marketed, but the original research and the development of drugs, for example in the case of antiretroviral medicines, was funded by public money. This built the basis for the later development of newer anti-retroviral drugs by private pharmaceutical industries.[46]

The great demand for these essential medicines allows the developers to charge causes high prices, and because these drugs continue to be essential for the treatment of life-threatening diseases the high prices have not caused a drop in demand.[47]

Patents play an important role in the research and development of drugs but also in commercialization of the new invention. The patent system encourages the pharmaceutical industry to distribute their new inventions in developed countries, which are a highly profitable market. Developing countries are not very attractive for the pharmaceutical companies to market their products where there is little or no profit.[48]

The balance has to be found between patent protection and to support innovation, and research and development on the one hand, and making medicines affordable and thereby accessible to people in developing countries, on the other. The answer to the question if patents are overprotected and if life-saving medicines should be protected by patents at all must be found in the justification of patent rights.

1.3 Principle of justification for patent rights

The protection of intellectual property rights by legal instruments has been justified on economic and moral grounds.[49] There is no single theory accepted by everyone,

[45] Servaas van Thiel, 'Public health versus intellectual property', at 4, accessed from http://www.cid.harvard.edu/cidtrade/Papers/vanthiel.pdf [accessed 24 February 2009].
[46] Edwin Cameron, *supra* footnote 17 at 5.
[47] Idem.
[48] Idem.
[49] Australian National University Canberra, Research School of Social Science, 'Traditional economic justification for intellectual property laws', accessed from http://rsss.anu.edu.au/~janeth/Economics.html [accessed 24 February 2009].

the economic theories are probably the most commonly accepted ones.[50] There are four economic theories dealing with the justification of intellectual property rights: 'the "invention-inducement theory", the "disclosure theory", the "development and commercialization theory" and the "prospect development theory"'.[51] These economic theories are based on the principle that the inventor of intellectual property in exchange for the effort required to create a new invention deserves to be recognised for his or her work and also to be compensated.[52] All four theories pay attention to the so called "free-rider" problem.[53] A "free-rider" refers to someone who benefits from an others invention without investing any effort in research and development. Usually a "free-rider" just copies an invention. All four economic theories argue that only the patentee shall have the right to exploit his or her invention for commercial use. This exclusivity shall ensure that the investment in research and development is rewarded and thereby encourages innovation.

John Locke[54] argued that a person's body and the benefits of his labour belong only to this person. He sets out: 'Though the earth, and all inferior creatures be common to all men, yet every man has a property in his own person. This nobody has any right to but himself. The labour of his body, and the work of his hands, we may say, are properly his.'[55]

The economic theories, however, open to criticism. Each new creation does not necessarily require the same but all are granted the same protection by a patent right.[56] The granting of patent protection should take into account not only the investment but also the social value of an invention.[57] Keeping this in mind it can be argued that every person who creates an intellectual property right does add something to the public welfare as long as the invention enters the public domain. The granting of a patent right ensures that an invention will enter the public domain. Without such protection the creator would most likely keep his invention secret in

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[50] Belinda Isaac, *Brand Protection Matters'*, (Sweet & Maxwell, 2000) at 218.
[51] Australian National University Canberra, *supra* note 49.
[52] Belinda Isaac, *supra* note 50 at 223.
[53] Australian National University Canberra, *supra* note 49.
[54] British philosopher (born 1632, died 1704), Oxford academic and economic writer collected information about trade and colonies. Locke wrote a number of important political and educational work including *Two Treatises of Government*. Information accessed under http://plato.stanford.edu/entries/locke/ [accessed 24 February 2009].
[55] John Locke, *Two Treatises of Government*, (2004) at 12 accessed from http://books.google.com/books?id=z_lMTTx561MC&printsec=frontcover [accessed 24 February 2009] and Belinda Isaac, *supra* footnote 50 at 224.
[56] Belinda Isaac, *supra* footnote 50 at 224.
[57] Ibid at 223.

order to avoid the "free-rider" problem. Patent protection therefore offers an inventor protection from the unfair exploitation of the "free-rider".

The system of patent protection finds it justification in the linkage between innovation and competition. The main argument for the patent system is an instrumental one.[58] It argues that innovation and research and development of new pharmaceutical products will only take place if the inventor will earn the reward of the new invention and third parties will be excluded from the benefits. This argument acts on the assumption that newly invented pharmaceuticals would not be commercialised and not be made available to the public as long as 'market exclusivity'[59] is not granted.

The patent system limits the access to a new innovation in order to support further innovation, and research and development. The new invention will, in turn, be commercialised but again access will be restricted by patent protection.[60]

Patent protection creates a monopoly-like situation for the patent holder. Because of patent protection competition is limited or even absent so the patentee has the opportunity to charge higher prices than he could in a competitive market.[61] This monopoly-like position also affects public interests because demand allows pharmaceutical companies to charge higher prices. Patent protection should be only granted for new innovations, and not to modified versions of already existing products. The justification of patent protection states that such protection is both necessary and effective, and that there is no other way of curbing competition.

The "disclosure theory" is based on the argument that a patent does not encourage the publication of an invention as patent protection usually is important to inventions that cannot be kept secret for a long time any way.

The argument that patent rights lead to more innovation has shown to be flawed in the case of developing countries. Yet they have a massive need of patented medicines these countries cannot afford the high prices. Even taking into account countries like South Africa and Namibia, which are stronger economically than many other African countries, the whole pharmaceutical market in Africa only amounts to about 1 % of global pharmaceutical sales.[62] The markets in developing and least-

[58] Edwin Cameron, *supra* footnote 17 at 6.
[59] Ibid at 4.
[60] Ibid.
[61] Australian National University Canberra, *supra* note 49.
[62] Edwin Cameron, *supra* footnote 17 at 7.

developed countries are most likely of little interest uninteresting to pharmaceutical companies when it comes to investment and research and development. This results in the fact that these markets will only have little impact on new innovations.[63] On markets with limited financial resources, patent protection does not play a major role in strengthening innovation and research and development. The pharmaceutical industry focuses on high-profit markets in developed countries; pharmaceutical research and development and innovation is tailored to meet the needs of people in these countries.[64] The question we have to ask is: "Should the patent system include a tool to encourage research and development without any commercial benefit to secure innovation and to justify itself?

The instrumental argument for the justification of the patent system works perfectly well in high-profit markets, but needs to be re-evaluated when applied to countries with low-profit or non-profit markets.[65] In these countries the moral dimension of human rights has to be considered too. The World Health Organization states on its website that human rights 'are universal legal guarantees protecting individuals and groups against actions which interfere with fundamental freedoms and human dignity'.[66] The main features of human rights are that these rights are 'guaranteed by international standards, legally protected, focus on the dignity of the human being, oblige state and state actors, cannot be waived or taken away interdependent and interrelated and universal.'[67] The World Health Organization's Constitution sets out '...the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...' The right to health is mentioned in many different international and national treaties, such as the Universal Declaration of Human Rights and the International Covenant on Social, Economic and Cultural Rights, as mentioned above.

All these considerations raise the question: Does the right on access to life-saving drugs, in other words public and societal interests, override the inventor's interest in protecting his or her intellectual property? Is there a way to balance and safeguard both interests?

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[63] Idem.
[64] Edwin Cameron, *supra* footnote 17 at 8.
[65] Idem.
[66] World Health Organization, 'Human rights', accessed from http://www.who.int/topics/human_rights/en/ [accessed 24 February 2009].
[67] Ibid.

In summary, it is fair to say that patent rights are justified by the idea that patent protection is necessary to ensure investment in research and development and to encourage innovation. Without intellectual property rights protection many new inventions would probably never enter the market as the creator would not want other people to be able to take advantage of his or her creation. Without patent protection it would not be attractive to the industry to make heavy financial investment for research and development when in the end companies would not have the exclusive right to commercialise their innovations.

It is in the public interest and to the benefit of consumers to encourage innovation. Only research and development can produce new technical and scientific innovations which create new products available to the public. The consumers benefit from competition as it gives them a choice among variety of products and lowers the prices. Competition in the market also encourages innovation as continuing research and development of their products and processes enables firms to meet the competition.

It becomes evident that there is a close connection between the intellectual property system and patent rights on the one hand, and competition policies on the other. Therefore the researcher will take a closer look on the clash between competition policies, the competition law system and intellectual property rights in the next chapter.

CHAPTER TWO

PATENT PROTECTION AND COMPETITION POLICIES

2.1 Introduction

The competition law system and intellectual property rights, the protection of patent rights in particular, are very closely connected. Patent rights seek to protect inventors and aim to prevent others from copying and commercializing foreign innovation. The patent system provides an instrument to provoke a fair behavior of competitors on the market. But competition policies and laws also influence the system in that they regulate the use of patent rights to minimise abuses, for instance monopolistic behavior. For the benefit of consumers it is important to pay attention to both the protection of patent rights and competition issues.[68]

Competition law is aimed at reducing the scope for unfair behaviour and the abuse of a 'market position'.[69] Competition policies apply to patent protection if the use of an exclusive patent right removes the element of competition in the market because others are unfairly prevented from entering the market. Competition law also seeks to prevent the abuse of a dominant market position by means of price fixing, and to ensure that all commercial action pays attention to public policy issues.[70]

The system of patent protection provides different tools to safeguard the patent system as the latter is seen as encouraging innovation; and as promoting behaviour on the market. Therefore only inventions can be protected by a patent, but not discoveries.[71] Patents can only be granted to inventions that are new and in public interest, and patent protection can only be granted for a limited time-period. This should stop the patenting of inventions that in terms of public interest are frivolous, harmful or useless.

The both anti-trust cases against Microsoft, in the United States and in Europe, are probably the most public cases in the competition law field. In both cases the anti-trust authorities investigated Microsoft's abuse of a dominant position. In this paper I

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[68] World Intellectual Property Organization, 'Competition and Patents', accessed from http://www.wipo.int/patent-law/en/developments/competition.html [accessed 24 February 2009].
[69] Idem.
[70] Idem.
[71] Idem.

shall focus on the European case *Microsoft v. European Commission of the European Union.*[72]

2.2 Background of the European Union Microsoft antitrust case

The European Union Microsoft case was initiated by the European Commission of the European Union against Microsoft. In 1993 Novell complained about Microsoft's licensing practices which it saw as an abuse of Microsoft's dominant position in the market. These initial complaints were settled in 1994 when Microsoft stopped certain licensing practices.

In 1998 Sun Microsystems filed complaint with the European Commission that Microsoft had refused to provide information about its operating system, which was necessary to ensure the interoperability of the Sun Microsystems product with the Microsoft PC operating system. At the beginning of 2000 Microsoft's practices with regard to the Windows Media player were also included in the investigation of the European Commission.

By the middle of 2000 the European Commission had filed a report which was then sent to Microsoft. The European Commission concluded that Microsoft had refused to disclose information which would enable competing 'work group server operating system vendors'[73] to make their systems compatible with the Microsoft Windows PC operating system.

A second Statement of Objections was released one month after the first, in this Statement the Commission confirmed the argumentation presented in the first statement with regard to Microsoft's new PC operating system, Windows 2000, and added that Microsoft had tied the Windows Media Player to its Windows PC operating system in an anti-competitive way.

Three years later, in 2003, the Commission sent a third Statement of Objections to Microsoft which again confirmed its finding about the anti-competitive tying and the interoperability.

Microsoft responded to every Statement, and subsequent to the third Statement of Objections demanded an oral hearing.

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[72] *Microsoft v. European Commission of the European Union*, 17 September 2007, Court of First Instance, Case T-201/04, [2007/C 269/80] (European Union Microsoft case).

[73] EU Business, 'EU case against Microsoft-Background', 27 February 2008, accessed from http://www.eubusiness.com/Competition/microsoft-eu-guide/ [accessed 24 February 2009].

In March 2004 the European Commission decided that Microsoft had abused its dominant position in the relevant market in violation of Article 82 of the EC Treaty by:

- 'refusing to supply competitors in the work group server operating system market interface information necessary for their products to interoperate with Windows, and hence to compete viably on the market;
- Harming competition through the tying of its separate Windows Media Player product with its Windows PC operating system.'[74]

The European Commission ordered Microsoft to make the required complete and accurate information available to its competitors within 120 days so that their products could be made compatible with the Microsoft PC operating system.

Furthermore the Commission ordered Microsoft to produce and make available a version of the Windows PC operating system without the Windows Media Player, within 90 days.

2.3 Court proceedings

Microsoft filed an action for the annulment of the European Commission decision with the Court of First Instance of the European Union in June 2004.
On applying to the Court of First Instance Microsoft requested the orders given by the European Commission be suspended until the end of its appeal. Microsoft applied for the interim measure as it feared it would sustain irreparable damage if the orders of the European Commission were implemented.

Microsoft argued that the enforcement of the European Commission's decision would:

- infringe its intellectual property rights;
- infringe its freedom to decide how to commercialise its products;
- change market conditions irreversibly.

[74] Idem.

Regarding the anti-competitive tying, Microsoft argued that the enforcement of the Commission's decision would:

- infringe 'commercial freedom',[75] as it would have to change the 'basic design concept'[76] of the Windows PC operating system;
- Furthermore the implementation would cause severe damage to Microsoft's prestige as developer of high quality software in the PC operating systems market.

The Court of First Instance rejected Microsoft's application in December 2004. The court argued that Microsoft could not prove that the implementation of the European Commissions decision would cause any severe and irreparable damage.

In September 2007 the Court of First Instance pronounced its judgment which affirmed the European Commission's decision that there was an abuse of Microsoft's dominant position under Article 82 of the EC Treaty.

The Court of First Instance ruled that the tying of the Windows Media Player with the Windows operating system was abusive, and that the interoperability of work group server operating systems of other software developers and Microsoft's Windows operating system was necessary if competitors were to be able to compete.[77]

Microsoft was ordered by the Court of First Instance to pay the original fine of EUR 497 million.

2.4 Conclusion

The European Union Microsoft case raised the question-Does a monopolist firm have anti-competitive intentions when it seeks to benefit from this monopoly? Does a patent holder have a monopoly and is he abusing a dominant position by working the patent protection and excluding third parties from using his product?

In economics a monopoly occurs when a person or a firm has control over a product or service and can determine the terms on which third parties have access to

[75] Idem.
[76] Idem
[77] Idem.

it.[78] A monopoly position is characterised by its anti-competitive impact on the market for this product or service, and the absence of any substitute products. The patent protection creates a monopoly position for the patent holder as it excludes third parties from using the invention without first being licensed by the patent holder. In effect this gives the patent holder a much better market position than would be gained under perfect competition. Perfect competition refers to a market situation where there are low entry and exit barriers; where many buyers and sellers produce homogenous products and there is a perfect information flow between producers and consumers.[79] Monopolies often result in excessive pricing, and the abuse of the dominant position in the market. Competition law provides measures to restrict monopolies. Under most national competition law systems monopolies are not prohibited; to abuse the exclusive position is.

The European Competition Law, Article 82 of the Treaty establishing the European Community,[80] addresses the abuse of a dominant position in the market. Article 82 (1) of the Treaty establishing the European Community states:

'Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market insofar as it may affect trade between Member States'.[81]

First of all, this means, it has to be determined if a dominant position in the relevant market has been established. Under European competition law a firm is dominant if its market share is very large, but this presumption is disprovable.[82] In the European Community a market share of over 39.7 %[83] is the lowest market share that can be presumed to be a dominant position.

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[78] World net, accessed from http://wordnetweb.princeton.edu/perl/webwn?s=monopoly [accessed 24 February 2009].
[79] Tutor2u, 'Perfect competition-The economics of competitive markets' accessed from http://tutor2u.net/economics/content/topics/competition/competition.htm [accessed 24 February 2009].
[80] See Article 82 of the Treaty establishing the European Community of 1958.
[81] Ibid.
[82] *Hoffmann-La Roche & Co AG v. European Commission* C-85/76 [1979] ECR 461 accessed from http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&numdoc=61976J0085&lg=en [accessed 24 February 2009].
[83] Commission Decision, Case IV-D-2/34.780 - *Virgin Atlantic vs. British Airways PLC*, [2000] O.J. L 30/I, at paragraph 88; in the decision British Airways was found to have a dominant position in the relevant travel agency market by having a market share of 39.7 % because the competitor Virgin Atlantic had only a much smaller market share in the relevant market.

Turning the European Microsoft case discussed above, it is also an abuse to refuse to give information and other facilities to competitors if this is necessary to enable potential competitors to compete in the relevant market.

In the field of pharmaceutical products the case of *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v. Commission of the European Communities*[84] dealt with the abuse of a dominant position by a pharmaceutical manufacturer. It deal with the provisions under Article 82 of the Treaty establishing the European Community.[85] In this case, a producer of raw materials, who manufactured his own derivates, was found to have abused his dominant position in the raw materials market by failing to supply raw materials to a competitor. This behaviour prevented the competitor from producing its own derivates. The intention behind this practice is to eliminate all competition on the relevant market.[86]

The case of '*Commercial Solvents v. European Commission'* is linked to the 'essential facilities doctrine'. The Doctrine has its roots in American case law, but has also been adopted by the European Union, Australia and South Africa. In European competition law the 'essential facilities doctrine' is covered by Article 82 of the Treaty establishing the European Community. The antitrust rules are applicable to the national intellectual property system under the European competition law.[87] Basically it deals with the anti-competitive behaviour of firms which use their dominant position to deny competitors entry into the market. It is closely linked to a claim of 'refuse to deal'. There are four requirements a plaintiff has to meet when drafting a claim under the 'essential facilities doctrine' under American antitrust law. To establish liability a plaintiff has to prove:

- control of the essential facilities by a monopoly firm,

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[84] *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v. Commission of the European Communities*, joined cases C-6/73 and C-7/73 [1974] accessed from http://eur-lex.europa.eu/Notice.do?val=40165:cs&lang=en&list=418716:cs,287453:cs,203802:cs,189902:cs,176615:cs,40165:cs,40136:cs,14600:cs,&pos=6&page=1&nbl=8&pgs=10&hwords= [accessed 24 February 2009], (*'Commercial Solvents v. European Commission'*).

[85] At the time the case took place it was a matter of Article 85 and Article 86 of the Treaty establishing the European Community. Today Article 82 of the EEC contains these provisions.

[86] *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v. Commission of the European Communities, supra* footnote 84.

[87] Ingo Brinker/Thomas Loest, 'Essential facilities doctrine and intellectual property law: Where does Europe stand in the aftermath of the IMS Health case?' at 1, accessed from http://www.gleisslutz.com/media.php/Ver%C3%B6ffentlichungen/Downloads/GleissLutz_BrinkerundLoest.pdf [accessed 24 February 2009].

- the competitor is not able to reproduce the essential facility in a practicable and reasonable way,
- the monopolist denies the use of the essential facility to a competitor,
- the ability of the monopolist to provide the essential facility to its competitors.[88]

Additionally, the plaintiff has to prove that the facility concerned is 'essential' for his ability to compete in the relevant market. The 'essential facilities doctrine' has been applied to natural monopolies. A natural monopoly can be a firm which can produce its product at a lower cost than two or more other firms;[89] or if in a particular industry only one firm can survive in the long term, even if there are no legal instruments or anti-competitive practices by the monopolist.[90] Though the 'essential facilities doctrine' usually applies on monopolies, it can also be used in situations involving intellectual property rights,[91] for example it would apply if a competitor refused to sell products protected by a patent or copyright.

The European Microsoft case has drawn attention to the 'essential facilities doctrine' and its relationship to intellectual property rights because it raises the question - If competition law is needed to address intellectual property rights?
It is difficult to reconcile the two competing interests of competition policies and intellectual property right policies. Both try to protect and prevent different types of conduct which results in a clash between competition law and the protection of intellectual property rights. Intellectual property rights give the holder a monopoly-like position. Measures are needed to prevent him or her from abusing this exclusive right. The 'essential facilities doctrine' should not be used as an instrument to abolish the protection of intellectual property rights only because the holder of such a right might have an advantage on the competitive market. Any regulation in the field of intellectual property rights can only aim to prevent businesses from abusing their dominant position and to undercut competition; it cannot be require firms to maximise

[88] Robert Pitofsky, 'The essential facilities doctrine under United States antitrust law', at 2-4, accessed from http://www.ftc.gov/os/comments/intelpropertycomments/pitofskyrobert.pdf [accessed 24 February 2009].
[89] Michael Martin, 'Natural Monopolies in Antitrust, Patent, and Copyright Law: The Essential Facilities, Reverse Doctrine of Equivalents, and Originality Doctrines as Triggers for Compulsory Licensing Remedy', January 2006, at 32 accessed from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1123575 [accessed 24 February].
[90] Ibid.
[91] Ibid.

competition against their products.[92] It is important that the owner of an intellectual property right can exercise this right and exhaust the full potential of the market, but if an abuse of a dominant position takes place the competition law system should come into action. If the application of the 'essential facilities doctrine' is taken too far and is applied in such a way as to undermine intellectual property rights, the meaning and importance of intellectual property rights and the protection they grant will be eroded. It is necessary that intellectual property rights are provided for, but in certain circumstances, for example, in the field of patents for pharmaceutical products, ethical responsibilities should be considered too. I think there is no easy way of resolving the clash between intellectual property right issues and competition law. One solution to balance the different interests could be to look at every case in detail. This might be the more effective and much fairer approach. The risk of this approach is that it might be difficult for the parties involved to determine the facts of the case and criteria for granting the intellectual property right. By establishing criteria for granting intellectual property rights which included considering the social benefit of the innovation could ensure that the 'essential facilities doctrine' is not being abused through the granting of unrestricted access to intellectual property rights and to undermine their protection.

Another way of reconciliation of the clash between intellectual property law and competition policy is through the issuing of compulsory licenses. The justification of compulsory licenses is based on the idea that competition can only be sustained if different firms in the same field have access to the market. Compulsory licenses provide a useful tool in preventing the abuse of a dominant position in the case of a firm which refuses to deal with its competitors; and it also provides an opportunity to consider ethical issues.

The laws on compulsory licenses find their justification in a number of international agreements such as the Paris Convention on the Protection of Industrial Property of 1883.[93] All relevant provisions of the Paris Convention are also covered by the Agreement on trade-related Aspects of Intellectual Property Rights (TRIPS).[94]

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[92] James Turney, 'Defining the Limits of the EU essential facilities doctrine on Intellectual property Rights: The Primacy of securing optimal Innovation', *Northwestern Journal of Technology & Intellectual Property*, Vol.3, 179, at paragraph 19, available from http://www.law.northwestern.edu/journals/njtip/v3/n2/5/ [accessed 24 February 2009].

[93] World Intellectual Property Organization Paris Convention on the Protection of Industrial Property of 1883 (Paris Convention).

[94] World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights of 1994.

TRIPS provides for compulsory licenses as an exception to the minimum requirements for protection of intellectual property which usually grants exclusivity the intellectual property right holder during the term of protection.

Because of the importance of TRIPS for the reconciliation of the conflict between competition policy and intellectual property rights I will examine the case of generic drugs and how they promote competition in the market for pharmaceutical products and then have a more detailed look on the TRIPS Agreement in my following Chapter four. In Chapter five I will examine compulsory licenses and the safeguard measures under the TRIPS Agreement more detailed as they play an important role in the discussion on access to drugs.

CHAPTER THREE

GENERIC DRUGS AS A TOOL FOR ENCOURAGING COMPETITION IN THE MARKET FOR PHARMACEUTICAL PRODUCTS

3.1 Introduction

A generic drug is a drug which is produced by pharmaceutical industries without any patent protection and without a license from the company inventing the brand drug. The production of generic drugs plays a major role in the fight to lower the prices of life-saving drugs and the attempt to make those drugs available to poor countries.

Competition increases if a drug is no longer protected by a patent and several producers can compete against each other depending on the prices and availability of generic drugs.

The production and sale of generic drugs provide for the possibility of making patented pharmaceutical products available to the public at a lower price.

Generic drugs have to be distinguished from counterfeit drugs; both generic and branded medicines can be found to be counterfeited. Counterfeit pharmaceutical products are mislabeled in an attempt to conceal their identity and source.[95] They may contain the original ingredient, another wrong ingredients, or wrong ingredients or they may lack one or more of the original ingredients or may not have the right quantity of the ingredients.[96] This compromises their effectiveness, and safe use. The safety of counterfeit drugs cannot be relied on upon as is the case with banded drugs because counterfeit drugs conceal their true nature and source.

A generic drug contains the same active ingredients as the original patented drug and is used in the same way as the original drug; and is as safe.[97] The only difference between generic drugs and the original brand named drug is the price. 'Generic drugs are identical or bioequivalent to their brand name counterpart with respect to their pharmacokinetic and pharmacodynamic properties'.[98] Pharmaceutical

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[95]Unites States Food and Drug Administration, 'Counterfeit drugs questions and answers', accessed from http://www.fda.gov/oc/initiatives/counterfeit/qa.html [accessed 24 February 2009].
[96] Ibid.
[97] Avert, 'Aids, drug prices and generic drugs' accessible from http://www.avert.org/generic.htm [accessed 24 February 2009].
[98] Unites States Food and Drug Administration, 'What are generic dugs?', accessed from http://www.fda.gov/cder/ogd/#Introduction [accessed 24 February 2009].

companies producing generic drugs can charge lower prices as they do not have to invest money in research and development or testing. The prices charged for generic drugs may be low enough so that developing and least-developed countries can afford them.

3.2 Generic drugs and patent rights

Generic drugs can be produced without infringing patent rights if:

- the patent protection has expired;
- the original drug never was protected by a patent
- the pharmaceutical company producing the generic drug can prove that the production will not infringe a patent or the patent is invalid or can not be enforced;
- in countries where the original brand drug is not protected by the patent system.

Pharmaceutical companies argue that the production of generic drugs reduces their profits. Smaller profits result in less money being available for research and development, which in turn prevents further innovation in the pharmaceutical field. Only the protection of innovation by patents will encourage investment and the development of new pharmaceutical products.

According to the World Health Organization the competition between drug companies and generic drug producers had more influence on the price of life-saving drugs than any previous negotiation with the pharmaceutical industry which attempted to lower the costs of patented drugs.[99]

The pharmaceutical industry and generic manufacturers began to fight about drug prices when different Indian generic drug companies started to produce HIV/AIDS drugs for about US$ 350 per year, per patient, while branded drugs in the United States cost about US$ 10,000 per year per patient. When Indian companies

[99] World Health Organisation, 'Generic drugs', accessed from http://www.who.int/trade/glossary/story034/en/index.html [accessed 24 February 2009].

started to produce generic drugs they could do so because the Indian Patent Act[100] only applied to process patents, but not product patents.[101]

In 1995 member states to the World Trade Organization introduced a new legislative instrument in favour of the pharmaceutical industry. The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) ensures the right of the pharmaceutical industry to patent protection. TRIPS has had a big impact on the production of generic drugs as it applies to all WTO members equally. Developing countries were given a 10 year time period to meet the requirements of TRIPS. In terms of generic drugs it is worth to mention that TRIPS does not free governments from requiring labelling generic substitution by their national laws.[102] Under the TRIPS Agreement generic drugs can be accessed through compulsory licenses under Articles 30 and 31 of the TRIPS Agreement.[103]

3.3 Conclusion

The increasing number of generic drug manufacturers, the production of generic drugs and their commercialization in the pharmaceutical market, has lead to stronger competition in the pharmaceutical market. This caused a drop in the prices of medical products. The usefulness of generic drugs in lowering drug prices and, thereby improveing availability and access to life-saving drugs for people in developing and least-developed countries is closely connected to the provisions of the TRIPS Agreement. The TRIPS Agreement improves the legislation regarding intellectual property rights protection, but also provides for the production of generic drugs within its legal framework. In my next chapter I will examine the TRIPS Agreement and its applicability to pharmaceutical products, including generic drugs.

[100] Indian Patents Act of 1970.
[101] Kavaljit Singh, 'Patents vs. patients: AIDS, TNCs and drug price wars' accessed from http://www.twnside.org.sg/title/twr131c.htm [accessed 24 February 2009].
[102] Ibid.
[103] See Article 30 and Article 31 of the TRIPS Agreement.

CHAPTER FOUR

THE WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS OF 1994

4.1 Introduction

Intellectual Property Rights grants creators the right to keep other persons from freely making use of their creations, and also gives them the right to demand payment if someone wants to use them.[104] Apparently increasing international trade and the linking-up of people all over the world through the expanding of the internet make the enforcement and the protection of intellectual property rights an international issue. New agreements at an international level were seen as instruments which would achieve more structure in the international intellectual property system, making for more practicability and predictability.[105]

To achieve these aims in 1994, the World Trade Organization (WTO) at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiated the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

TRIPS' purpose is to protect intellectual property rights all over the world, and to set a minimum standard that a nation's domestic law must meet. Although TRIPS only provides minimum standards, it strengthened the protection of intellectual property rights by implementing stricter standards than those previously provided for in the national laws of developing countries.[106] TRIPS makes sure that WTO member countries provide national rules for patent protection in all technological areas, for both process and product innovations. It is important to make a distinction between process and product patents. If a product is protected by a patent, only the holder of the patent is allowed to produce or sell the protected product, everyone else needs to get permission from the patent holder. If a process is

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[104] World Trade Organisation, 'Intellectual property: protection and enforcement', accessed from http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm [accessed 24 February 2009].

[105] Ibid.

[106] Cecilia Oh, 'Compulsory licenses: recent experiences in developing countries' (2006) 1 1-2 *International Journal of Intellectual Property Management* 22 at 22 accessed from http://inderscience.metapress.com/app/home/contribution.asp?referrer=parent&backto=searcharticlesresults,1,1 [accessed 24 February 2009].

patented, no one other than the patent holder use the protected process to make the product.[107]

This means countries like India cannot any longer exclude the provision covering product patents and exclude pharmaceutical products from patent protection as they had before the TRIPS Agreement came into force. Even if the TRIPS Agreement sets out mandatory rules for the protection of intellectual property rights the WTO member states can still draft their own system of intellectual property rights but they have to meet their obligations under TRIPS.

Critics see the TRIPS Agreement in a different light, because they think it provides a 'one size fits all model'[108] of intellectual property rights which does not consider the different interests and priorities of developed and developing countries. The member countries of TRIPS have very different social and economical backgrounds. A single model may cause difficulties for developing countries that have to grapple with the intellectual property system while attempting to address public health issues and to achieve balance between the incentives for the need of access to life-saving inventions and the need to promote for innovation.[109] The discussion about the balance between innovation and public health issues, in particular, access to life-saving drugs against the HIV/AIDS crisis in poor countries, was addressed by the WTO and resulted in the Doha Declaration on the TRIPS Agreement and Public Health.

In this chapter I will present an overview of the TRIPS Agreement and then outline its applicability to patent rights in the pharmaceutical sector. Furthermore I will examine the implications of the Doha Declaration on the TRIPS Agreement.

4.2 Overview of TRIPS

Article 1 of TRIPS is related to the WTO members' obligation to protect pharmaceutical products and processes under the TRIPS Agreement.[110]
The TRIPS covers five broad problems:

[107] World Health Organization, *supra* footnote 12.
[108] Centre for the Study of the Public Domain, 'International', accessed from http://www.law.duke.edu/cspd/international.html accessed [24 February 2009].
[109] Cecilia Oh, *supra* footnote 106 at 23.
[110] Carlos M. Correa/Abdulqawi A. Yusuf, *supra* footnote 8 at 426.

- 'How basic principles of the trading system and other national property agreements should be applied;
- How to give adequate protection to intellectual property rights:
- How countries should enforce those rights adequately in their own territories;
- How to settle disputes over intellectual property between members of the WTO and
- Special transitional arrangements during the period when the new system is being introduced.'[111]

A patent grants exclusive rights to someone who has invented a new process, a new article of manufacturing, or a new machine; or who improves one of these in a new and useful way. Different types of intellectual property rights fall under the term of patent in some jurisdictions. Industrial designs are sometimes called design patents while plant breeders' rights are also known as plant patents and utility models. Industrial designs in Germany they are called 'Gebrauchsmuster', are known as petty patents or innovation patents.

In 1911 the Circuit Court of Appeals in the United States dealt with patent issues in the case of *Herman v. Youngstown Car Mfg. Co.* [112] when the court stated that as generally applied a patent gives the owner the right to exclude third parties from importing, using, producing or selling a patented good.

Article 27.1 of TRIPS contains the obligation that signatories provide patents for inventions, including products and processes, in every technological field. The process or product has to be 'new, involves an inventive step and must be capable of industrial application'.

This Article also includes a non-discrimination clause.[113] The non-discrimination requirement in Article 27.1 of TRIPS applies to 'availability' and 'enjoyment' of patents. This means that both, the purchase and the enforcement of

[111] World Trade Organization, *supra* footnote 104.

[112] *Herman v. Youngstown Car Mfg. Co.*, Court of Appeals, 6th Circuit, April 4 1911, 191 F. 579, 584-85, 112 CCA 185 accessed from http://bulk.resource.org/courts.gov/c/F1/0191/001/00000594.txt accessed [24 February 2009].

[113] Carlos M. Correa, *'Trade-related aspects of intellectual property rights, A comment on the TRIPS agreement'* (Oxford, 2007) at 281.

patent rights, have to be made available without any discrimination.[114] This provision applies to discrimination that takes place:

- 'in the place of invention;
- in the field of technology; and
- whether the products are imported or produced locally.'[115]

Article 27 of TRIPS contains three exceptions on patentability. According to Article 27.2 of TRIPS inventions that are against the public policy or against morality do not have access to patents rights. The provision explicitly states that 'inventions that are dangerous to human, animal or plant life or health or seriously prejudice to the environment' cannot be protected by patent rights. The application for a patent can only be rejected in terms of this provision if the commercial use of this invention must be prevented, and if prevention is necessary to protect public policy or morality.[116]

Another exception is contained in Article 27.3 (a) of TRIPS. Members can deny access to patents for 'therapeutic, diagnostic and surgical methods for the treatment of humans and animals.'

The last exception can be found in Article 27.3 (b) of TRIPS. Members can exclude 'plants and animals that are not micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes' from patentability. Member countries shall provide measures for the protection of 'plant varieties' through patents or through a 'sui generis system'.

This provision does recognise differences between developed and developing countries regarding the patenting of animal and plant life under the TRIPS agreement.[117]

A product patent covers the 'making, using, offering for sale, selling, and importing for these purposes, of the protected product'.[118] The provision includes both products and processes. Article 28 of TRIPS also enables the owner of a patent right to transfer the patent to third parties in order to conclude contracts for the

[114] Ibid at 282.
[115] Idem.
[116] World Trade Organization, *supra* footnote 104.
[117] Carlos Correa, *supra* footnote 113 at 293.
[118] Article 28 (1) (a) of the Agreement on Trade-related Aspects of Intellectual Property Rights.

commercial use of patents. It gives the owner the right to 'assign, transfer by succession and conclude licensing contracts'.[119]

Article 29 of TRIPS contains one of the basic principles of the patent right system which deals with the disclosure of an invention. If an invention is not completely disclosed this is a ground refusing to grant a patent application under most jurisdictions. The disclosure requires that it should be sufficient for a person 'skilled in the art' to decide about the invention.

WTO member countries can provide certain exceptions to patent rights, in terms of Article 30 of TRIPS. There are three requirements: the exception must be (1) 'limited', (2) not 'unreasonably conflict with a normal exploitation of the right' and (3) not 'unreasonably prejudice the legitimate interests of a patent owner'.[120] There are certain categories of exceptions recognised as legitimate under Article 30 of TRIPS:

- 'the import of goods that were on the market somewhere else with the explicit consent of the owner of the patent right;
- private acts without any commercial purpose;
- scientific use of the invention in terms of research and experimentation and for educational purposes;
- the use of medicines in single cases if a prescription was permitted'.[121]

Article 31 of TRIPS lays down conditions for compulsory licensing and government use of patents. This article deals with the use by third parties without authorisation of the patent right owner. A license will only be granted if an earlier application for a voluntary license was unsuccessful.[122] The conditions set out in Article 31 of TRIPS should be read together with Article 27.1 of TRIPS that deals with the non-discrimination requirement.

Article 31*bis* of the 2005 Amendment to TRIPS provides for situations where there is a lack of capacity for manufacturing pharmaceuticals. This provision

[119] Article 28 of TRIPS.
[120] Carlos Correa, *supra* footnote 113 at 303.
[121] Idem.
[122] World Trade Organisation, *supra* footnote 104.

implements the WTO Decision of 30 August 2003 and is applicable to patents for pharmaceuticals.[123]

The period of protection shall be at least 20 years, starting from the date of the filing, Article 33 of TRIPS.

Article 34 of TRIPS deals with the burden of proof in legal proceedings. The judge has the right to require the defendant to prove that the 'process to obtain an identical product is different from the patented process'. This provision should have been included in Part III of the TRIPS agreement rather than in Part II, because it deals with procedural matters and is closely connected to the enforcement of intellectual property rights.

TRIPS was the first agreement that established intellectual property law within the international trading system and it is still the broadest international agreement on intellectual property.

4.3 The implementation of the TRIPS Agreement

The TRIPS Agreement lays down provisions for the time periods within which WTO member countries must incorporate the implementation the TRIPS requirements into their national legal system. TRIPS lays down two time periods for developing and least-developed countries.

Developing countries had until 1 January 2000 to meet their obligations under TRIPS to implement the protection of inventions. They were required to provide patent protection for process and product inventions. In the field of pharmaceutical products member countries which previously had no such patent protection before TRIPS, were given an additional five years until 1 January 2005 to implement the new legislation.

Least-developing countries[124] were given until 1 January 2006 to incorporate the TRIPS requirements into their national law. In 2001 the Doha Declaration on the TRIPS Agreement and Public Health extended this transition period until 1 January 2016.

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[123] Carlos Correa, *supra* footnote 113 at 325.

[124] Countries on the United Nations list of least developed countries, http://www.wto.org/english/tratop_e/trips_e/intel2c_e.htm#transitional [accessed 24 February 2009].

When these periods had elapsed the TRIPS provisions had to apply to both new patents, and extant patented processes and products.

4.4 Patents and the right of access to life-saving drugs under TRIPS

The TRIPS agreement and the patent system, together with the pharmaceutical industries are seen as the main obstacle preventing people in developing countries from having access to new drugs and the same medical treatment as people in first world countries.[125] The main question is: In reality is there a clash between the interests of the pharmaceutical industry and the right of people in developing countries to access life saving drugs? If the answer is "yes", a balance can be found in the TRIPS agreement.

TRIPS tries to balance the long-term interests of innovation, and research and development, and the short-term goals of effective protection and of access to essential medicines.[126] It is difficult to reach an equitable balance as the need to encourage and strengthen innovation is opposed by an increasingly urgent need for access to drugs by poor countries which cannot afford to pay the same price as rich countries.

The basic principle underlying the implementation of intellectual property rights is to be found in Article 7 of the TRIPS agreement:

> 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology [...] in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[127]

The underlying principle in the TRIPS Agreement is that patents shall be made available for inventions, whether they are product or process inventions and irrespective of the field of technology. As has been mentioned an invention is patentable if it meets the criteria of novelty, inventive step and industrial applicability. But TRIPS also requires that the member states shall require the

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[125] Bjoern Ley, supra footnote 11 at 103.
[126] World Trade Organization, 'Pharmaceutical patents and the TRIPS Agreement' accessed from http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm [accessed 24 February 2009].
[127] Article 7 of the Agreement on Trade-related Aspects of Intellectual Property Rights.

disclosure of the invention in order for a patent to be granted. Disclosure is key issue in the granting of patent protection as it makes the invention accessible to the public, useable by third parties and takes account of matters of public interest. Without the disclosure requirement patent protection would be pointless as the granting of patents only makes sense if after the patent term has expired the invention will fall into public domain. The public can only benefit from the invention if it is not been kept private.

4.4.1 Exceptions to patent rights under TRIPS

The exclusive rights granted in terms of patent protection are not absolute rights. Under the TRIPS Agreement exceptions make sure that the basic principles set our in Article 7 of TRIPS, are being followed. These basic principles are:

- the 'protection of intellectual property rights contributes to the promotion of technological innovation by allowing, for example, experimental use of patents, and for the transfer and dissemination of knowledge,
- and there is a balance between the advantages that accrue to the patent owners, [...], and those that accrue to consumers,...'[128]

There are three circumstances which permit the making of an exception to the general rule of patentability:

- where 'the prevention of [this inventions'] commercial exploitation is necessary to protect *'ordré public'* or morality, including to protect animal or plant life or health;
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.'[129]

A patent granted under the provisions of TRIPS gives an inventor the right to stop third parties from using the patented process, or to use, make, offer or import the protected product without the permission of the patentee.

[128] Correa/Yusuf, *supra* footnote 8 at 434.
[129] World Trade Organization, *supra* footnote 126.

As mentioned above the protection of patents lasts for 20 years. This has meant that in certain countries the term of protection was extended considerably. In India, for example, a patent granted protection for only seven years before the TRIPS Agreement was implemented.

The TRIPS Agreement contains a number of exceptions and limitations to these patent rights.

Article 8 of the TRIPS Agreement pays attention to public interest and provides action to ensure public health and nutrition. Its purpose is to prevent abuse of intellectual property rights in general, and aims at practices that would hinder free trade and have a negative impact on the transfer of technology.

Article 30 of TRIPS sets out the general rules for exceptions to patent rights as outlined in Article 28 of TRIPS.

Before the TRIPS Agreement had come into force several exceptions to patent rights already existed in national law, in particular, the research and experimentation exception, the early working exception and preparation of medicines for personal use, prior use and parallel imports.[130]

The research and experimentation exception aims to promote dissemination of knowledge and encouragement of innovation. The purpose of this exception is to ensure invention and improvement of generic drugs in the pharmaceutical industry.

This exception is also known as the 'Bolar' provision. It derives its name from the case *Roche Products Inc. v. Bolar Pharmaceutical Co.* which took place in the United States.[131] Bolar Pharmaceutical Co. used the patented drug Valium to research if their generic product was bioequivalent to the original drug before the drug's patent had expired. TRIPS allows member countries to make such an exception if this exception does not infringe the normal exploitation of the patent and does not harm the interest of the patentee. A common example of this exception allows third parties to do scientific and technological research with a patented invention in order to encourage innovation.

The early working exception gives competitors the opportunity to use an invention without the permission of the patentee in order to prepare for the

[130] Correa/Yusuf, *supra* footnote 8 at 435.

[131] *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 04/23/1984), paragraph 18, accessed from http://biotech.law.lsu.edu/cases/ip/patent/roche_v_bolar.htm [accessed 24 February 2009].

registration of a generic drug before the actual patent expires.[132] This encourages generic drug production, and in the long-term will enable the public to benefit from lower drug prices. The early working exception also promotes compulsory licensing which is important for generic drug manufacture industries.

The early working exception was the subject of the case *Canada v. Patent Protection of Pharmaceutical Products*[133]. At that time in the United States, the early working provision was allowed, but at the same time extension of the patent period for the patentee as compensation for the loss of his exclusive right. Similarly Canada also allowed the early working exception, but did not give any extension on the patent terms to the patent holder. The European Community argued in the case that the patentee has a 'legitimate interest in extension as a compensation for time lost in regulatory processes'.[134] In the European Community patent holders, who have to accept a limitation of their exclusive right in the market, should be given the extension to cause a delay in the possibility of competing products to enter the market.[135] In Canada the patentee would be given a private economic advantage by the granting of an extended patent period, and the patentee who has no legitimate interest in using the exclusivity of the patent right within the period of patent protection would get an extension of that patent term. This would undermine the principle underlying patent protection, a social contract between patent holder and public. The WTO Panel decided that the interest claimed by the patent holder could did not fall under the 'legitimate interest' of Article 30 of TRIPS.[136]

The TRIPS Agreement also provides measures for compulsory licensing and government use. Compulsory licenses allow member countries to grant permits to third parties, while government use allows use without the permission of the patentee for public purposes without commercial intention. TRIPS imposes several conditions for the granting of a compulsory license. The purpose of these conditions is to protect the patent owners' interest. I will discuss the safeguards under TRIPS and their use to assure access to life-saving drugs in developing countries more in more detail in the next chapter. TRIPS also addresses the relationship between competition law and intellectual property rights. It contains provisions against anti-competitive behaviour.

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[132] Ibid at paragraph 16.
[133] *Canada – Patent Protection of Pharmaceutical Products*, Panel Report (2000) WT/DS/114/R at paragraph 7.82.
[134] Correa/Yusuf, *supra* footnote 8 at 436.
[135] Ibid.
[136] *Canada – Patent Protection of Pharmaceutical Products supra* footnote 131.

Under TRIPS the issuing of compulsory licenses is easier and there is more flexibility if a patent was used in an anti-competitive way. Furthermore the TRIPS Agreement allows its member states to act co-operatively against anti-competitive behaviour on the markets.

4.4.2 Exhaustion of rights under TRIPS

Under TRIPS the WTO dispute settlement system does not apply to the exhaustion of intellectual property rights in member countries.

Exhaustion of rights in context of intellectual property deals, basically, with the loss of legal control over a protected product. Usually this loss takes place by the sale of the product or by putting it into the public domain in any other way for commercial use.

The principle of exhaustion regulates the situation where a patentee can prevent others from importing a patented product like pharmaceuticals from another country where the patent holder has sold the product.[137] The exhaustion of rights principle focuses on so called parallel import, which describes a situation when a third party imports a product without the permission of the patent holder after the product was manufactured in a foreign country and put on the market there. This means the parallel imported product will compete with the locally produced product of the patent holder.[138]

In terms of Article 6 of the TRIPS Agreement sets WTO member states are free to choose their own rules for the exhaustion of rights.[139]

Exhaustion of rights plays a big role in the discussion about access to drugs. Since the pharmaceutical industries charge different prices in different countries, parallel importation provides an option which can prevent discrimination through pricing practices. Parallel importation gives patients a means to access drugs at the lowest price by ordering them in foreign countries. The principle of parallel importation means developing and least-developed countries have a chance to acquire drugs at an affordable price level.

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[137] Correa/Yusuf, *supra* footnote 8 at 428.
[138] Ibid.
[139] Ibid.

4.4.3 Revocation of patent rights

Several reasons for the revocation of patent rights can be found in the national law systems of the WTO member countries. The TRIPS Agreement itself does not address the grounds for revocation or forfeiture of patent rights. It only gives standards for the procedural requirements. Article 32 of TRIPS states that 'an opportunity for judicial revision of any decision to revoke or forfeit a patent shall be available'.[140]

Patent rights have a direct influence on prices and access to pharmaceutical products, as well as on innovation and competition in the relevant market. Revocation and forfeiture are instruments which will in turn also have a direct impact on public health issues. Therefore it is important if a patent is defective, to have a way to revoke or forfeit the granted patent.

4.4.4 The Doha Declaration on the TRIPS Agreement and Public Health

On 14 November 2001 the WTO member governments met at the WTO's Fourth Ministerial Conference in Doha and adopted the Doha Declaration on the TRIPS Agreement and Public Health.[141]

Member states had concerns that the TRIPS Agreement did not promote easy access to drugs for patients in developing or least-developed countries. Among the members the flexibility of the TRIPS Agreement was questioned, in particular, its ability to encourage research and development while supporting public health issues, especially providing access to pharmaceutical products.[142] Member countries were uncertain about the scope of the flexible provisions under TRIPS, the provisions providing for compulsory licenses and how to interpret these provisions were particular concerns. Some member governments were worried that the governments would be free to use this flexibility to its full potential without paying attention to the interest of industry.

The Doha Declaration tries to address these points by stating that the TRIPS Agreement does not and should not keep member countries from making provisions

[140] See Article 32 of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[141] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(0)/DEC/W/2.
[142] World Trade Organization, 'The separate Doha Declaration explained' accessible from http://www.wto.org/english/tratop_e/healthdeclexpln_e .htm [accessed 24 February 2009].

to protect public health.[143] The Doha Declaration is not only an interpretation of the TRIPS Agreement and its provisions, it is also a political message which tries to clarify the provisions. The Declaration is a statement of the WTO's policy on access to essential pharmaceuticals for developing and least-developed countries. Member governments are free to apply the provisions of TRIPS to fulfil this purpose. The WTO member countries are obliged to not prevent each other from making fully use of these rules.[144] When implementing the TRIPS Agreement into national law, governments have to make sure to meet their obligation to protect public health and to make affordable pharmaceutical products available for everyone.

Regarding compulsory licensing the Doha Declaration sets out that every member state has the right to draft and implement its own set of rules. These rules have to outline reasons when compulsory licenses will be granted. This responds to the opinion that an emergency situation is one of the conditions for the granting of a compulsory license. Indeed the TRIPS Agreement mentions national emergencies or any other situation of extreme urgency in its provisions about compulsory licensing but the purpose of this provision is that the requirement to obtain a voluntary license from the patent holder before applying for a compulsory license is waived.[145] The definition of national emergency or any other situation of extreme urgency lies with the member countries. The WTO member governments are free to find their own parameters to define these terms. Therefore actually all public health crises, for example pandemics like tuberculosis, malaria, cholera and HIV/AIDS, can be summarised under one of the terms. Together with the TRIPS Agreement and the WTO Decision on Paragraph 6,[146] the Doha Declaration provides the legal framework for compulsory licensing regarding public health issues.[147]

The Doha Declaration responds to the problem of developing and least-developed countries not being able to produce their own pharmaceuticals. If smaller countries with no domestic pharmaceutical industry do not have the capacity to produce drugs this actually means that these countries can not make use of the compulsory licensing mechanism under TRIPS. The declaration tries to consider different models to solve this problem and addresses one of the main disputes arising

[143] Ibid.
[144] Ibid.
[145] Article 31 (b) of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[146] World Health Organization, General Council Decision on Paragraph 6 of the Doha Declaration, 30 August 2003, WT/L/540.
[147] Cecilia Oh, *supra* footnote 106 at 24.

during the negotiation of the Doha Declaration. In fact many developing countries and least-developed countries lack manufacturing capacities and therefore can not make use of the compulsory licensing tool under the TRIPS Agreement. The Doha Declaration responds to this discussion in its Paragraph 6 addressing import possibilities for countries with little or no manufacturing capacity. Paragraph 6 recognizes this problem for developing countries in the field of pharmaceutical products and seeks the Council for TRIPS to consider different approaches to solve the difficulties. In 2003 the 5th WTO Ministerial Conference adopted the Decision to apply paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.[148] The WTO Decision of 30 August 2003 also called the 'Waiver Decision' is incorporated in the TRIPS Agreement through Article 31*bis*. The member states agreed on the adoption of Article 31*bis* on 6 December 2005. This was the first amendment to the TRIPS Agreement,[149] adopting the Protocol amending the TRIPS Agreement submitted by the General Council.[150] At the moment governments worldwide consider provisions of the Article 31*bis* Amendment and have to decide if they want to accept and ratify it. Two-third of the WTO member countries have to ratify Article 31*bis* before it becomes part of the TRIPS Agreement. Currently 20 of the 153 member countries to the WTO and the European Communities have accepted the Amendment.[151] The WTO Decision of 30 August 2003 applies to products, patented in the exporting country or in exporting and importing country.[152] I will have a more detailed look on compulsory licenses and the lack of manufacturing capacity in pharmaceuticals of developing countries in chapter five.

In regards to parallel imports and exhaustion of rights the DOHA Declaration clarifies the member states right to allow parallel imports and sets out that the TRIPS Agreement is clear about the fact that member state's action in terms of parallel import and exhaustion of rights can not be brought before the WTO dispute settlement body. All member governments have the right to implement their own system.[153]

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[148] Carlos Correa, *supra* note 113 at 325.
[149] See Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/l/641.
[150] Protocol amending the TRIPS Agreement, IP/C/41.
[151] WTO, 'Members accepting amendment of the TRIPS Agreement', accessed from http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [accessed 24 February 2009].
[152] Carlos Correa, *supra* note 113 at 325.
[153] World Trade Organization, 'The separate Doha Declaration explained' accessed from http://www.wto.org/english/tratop_e/healthdeclexpln_e .htm [accessed 24 February 2009]

Summarising the Doha Declaration is an important statement which helps WTO member countries to interpret the TRIPS Agreement. The Declaration acknowledges the importance of public health problems in developing and least-developed countries and states that the agreement should be interpreted and applied in a way promoting public health problems, the development of new pharmaceuticals and the access to essential drugs for every person. The Doha Declaration uses the term 'compulsory licenses' in the context of public health issues and is promoting the role of compulsory licenses to limit patent protection and to improve access to affordable pharmaceuticals in all WTO member states.

4.5 Competition law and the TRIPS Agreement

The interface between competition law and the TRIPS Agreement raises the question: What is an anti-competitive practice in the field of patent rights?

Article 6, 8, 31 and 40 of TRIPS are addressing anti-competitive practices related to intellectual property rights. Article 8.2 of TRIPS empowers member countries to implement domestic legislation to prevent three different kinds of anti-competitive practices related to intellectual property: the abuse of intellectual property rights by the patent holder, behaviour that creates a barrier to trade and practices that have a negative impact on technology transfer.[154] Article 40 of TRIPS is '*lex specialis*' to Article 8 of TRIPS[155] and plays a main role in the clash between intellectual property rights and competition law. It provides for measures taken by WTO member countries to remedy anti-competitive behaviour. The purpose of Article 40 of TRIPS is to ensure that rights issued under TRIPS serve the public benefit by applying competition policies.[156] Furthermore Article 40 of TRIPS recognizes that some licensing practices under TRIPS may have a negative impact on trade.[157] Article 40.2 of TRIPS acknowledges certain practices related to contractual licenses as anti-competitive, in particular: 'grant back conditions, conditions preventing challenges to validity and coercive package licensing'.[158] Article 31 of TRIPS considers competition policies in context with compulsory licenses in respect

[154] Article 8.2 of TRIPS.
[155] Hans Henrik Lidgard/Tu T. Nguyen, *supra* footnote 25, at 8.
[156] Anderson/Wagner, *supra* footnote 26, at 723.
[157] Article 40.1 of TRIPS.
[158] Article 40.2 of TRIPS.

of patent rights and sets out certain requirements member countries must meet when issuing a compulsory license. Under Article 31 of TRIPS[159] competition law can be used to increase access to life-saving drugs. For example, the requirement of predominant supply of the domestic market is waived if a compulsory license has been issued to remedy anti-competitive behaviour.

Intellectual property rights lay down certain standards for intellectual property to 'be valued and exchanged'.[160] Competition rules try to add value to intellectual property on the market.[161]

The TRIPS Agreement does not contain any obligations to its member countries how they have to apply competition law policies in the field of intellectual property rights. Article 8, 31 and 40 of TRIPS are enabling governments to remedy and control anti-competitive behaviour in the field of intellectual property rights by providing flexible provisions and ample scope to implement and enforce domestic competition rules.

4.6 Conclusion

Most of the developing and least-developed countries already had provisions for patent protection of pharmaceutical products before TRIPS entered into force. In these countries the implementation of TRIPS did not cause major changes in the national legislation, but lead to some corrections mostly related to terms of protection and safeguard measures like compulsory licensing and government use.

The TRIPS Agreement seeks to find the balance between the private rights of patent holders and public health issues. The basic principle of disclosure and encouraging research and development which seeks to safeguard innovation on the one hand, but providing exceptions to exclusive rights on the other, is a useful system to gain this balance. The question is: Are the safeguard measures under TRIPS powerful and useful enough to meet the public demand on access to life-saving drugs particularly in developing and least-developed countries? Seeking to find an answer I

[159] Article 31 (k) of TRIPS.
[160] Dr. S Chakravarthy, 'Competition Policy and Intellectual Property Rights' at 9, accessed from http://www.competition-commission-india.nic.in/competition_forum/IPRs_by_Dr.Chakravarthy_22July2005.pdf [accessed 24 February 2009].
[161] Idem.

will examine the safeguard mechanisms under the TRIPS Agreement more detailed in the following chapter.

CHAPTER FIVE

REMEDIES UNDER THE TRIPS AGREEMENT

5.1 Introduction

As mentioned above the patent right system under TRIPS is not absolute. The TRIPS Agreement provides exceptions to patent rights and has some safeguards which can be used to address public health problems. Under TRIPS three different solutions can be found: compulsory licensing, tiered pricing and parallel import. These three models are the most commonly used methods for making drugs available to the public and to lower prices of pharmaceutical products.

In South Africa the issue of compulsory licensing and parallel imports gained a large amount of public interest in 1998 when 39 pharmaceutical companies filed a lawsuit against the South African government. The pharmaceutical companies challenged Amendment 15 (c) of the South African Medicines and Related Substances Act[162] which allows for compulsory licenses and parallel imports of pharmaceutical products in South Africa. Under extremely high pressure by the public and international organizations the applicants dropped the case.

In this chapter, I will discuss the three safeguard measures under TRIPS and examine their use for making essential drugs available to the public in developing and least-developed countries.

5.2 Compulsory licenses under the TRIPS Agreement

The first safeguard measure I will discuss is compulsory licensing. Compulsory licensing allows governments to grant licenses to third parties to produce a patented

[162] Medicines and Related Substances Control Act No.90 of 1997 accessed from http://www.info.gov.za/gazette/acts/1997/a90-97.pdf [accessed 24 February 2009].

product or process without the permission of the patent holder.[163] Compulsory licenses, therefore, give states the right to pass over the patent holder and his exclusive intellectual property right. Therefore the patent holder loses his exclusive right for the benefit of the public.[164] Worldwide, most countries have compulsory licensing tools implemented in their national laws and enable their governments to use patented inventions for public reasons with less administrative barriers than for private purposes.[165] The purpose of a compulsory license is to make an invention available to a broader use than the patent holder would probably permit voluntarily.[166] Compulsory licensing in the context of pharmaceutical products means that this tool enables the domestic pharmaceutical industry to produce or import generic medicines for private as well as public use. Therefore, compulsory licenses help to get over patent rights which might cause a barrier to access to life-saving drugs.[167]

Already the Paris Convention on the Protection of Industrial Property of 1883 contains a provision requiring the member states to take measures for the permission of compulsory licenses. The Paris Convention on the Protection of Industrial Property states in Article 5A (2) that:

'each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work'.[168]

Compulsory licenses are allowed under the WTO's TRIPS Agreement, however, certain requirements have to be fulfilled.[169] Article 30 of the TRIPS Agreement provides limited exceptions to the exclusive rights which are conferred by Article 28 of TRIPS.[170] Article 31 of the TRIPS Agreement contains the basic rules for compulsory licenses under the TRIPS Agreement.[171] However, Article 31 of

[163] World Trade Organization, 'Compulsory licensing of pharmaceuticals and TRIPS' accessed from http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm [accessed 24 February 2009].
[164] Daniel Cahoy, 'Confronting myths and myopia on the road from Doha' 2007 at 134 accessed from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=989817 [accessed 24 February 2009].
[165] Cecilia Oh, *supra* footnote 106 at 24.
[166] Ibid.
[167] Ibid.
[168] See Article 5A (2) of the Paris Convention on the Protection of Industrial Property of 1883.
[169] World Trade Organization, 'Compulsory licensing', accessed from http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm [accessed 24 February 2009]
[170] See Article 28 and 30 of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[171] See Article 31 of the Agreement on Trade-related Aspects of Intellectual Property Rights.

TRIPS does not provide a general rule under which circumstances a compulsory license has to be issued but rather provides the procedural rules that have to be followed when granting a compulsory license. The specification of cases in which a compulsory license will be granted lies with the member states to the TRIPS Agreement and has to be set out in their national law systems. Therefore, the situations when a compulsory license will be issued will vary from state to state, yet Article 31 of TRIPS sets out certain minimum standards for permitting compulsory licenses. The DOHA Declaration states in Paragraph 5 (b)[172] that the member countries have full control of the reasons for granting compulsory licenses.

5.2.1 Requirements for the permission of a compulsory license under the TRIPS Agreement

All important and significant patent systems worldwide meet the requirements of TRIPS, as almost every country is signatory to the agreement. TRIPS contains certain rules that have to be followed when granting a compulsory license, and specific requirements of the licenses.

5.2.1.1 Voluntary license by patent holder?

Firstly, Article 31 (b) of TRIPS requires the government to try to negotiate with the patent holder on getting a voluntary license and to agree on 'reasonable commercial terms'.[173] This means it is necessary that the government tried to get a voluntary license issued by the patent holder but was unsuccessful in its attempt before a compulsory license is issued. This requirement can be waived by national law in case 'of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.[174] However, it is not very practical that the TRIPS Agreement does not specify what 'reasonable commercial terms' means. This makes it difficult for developing countries to grant compulsory licenses as they have to fear high costs of dispute settlement if for example litigation would be needed to define the meaning of this term in a certain case.

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[172] See Paragraph 5 (b) of the Doha Declaration on the TRIPS Agreement and Public Health, *supra* footnote 141.
[173] See Article 31 (b) of the Agreement on Trade-related Aspects of Intellectual Property Rights of 1994
[174] Ibid.

As mentioned above, the Doha Declaration addressed the discussion about the definition of 'national emergency', dealing with the claim of several member countries that the national emergency must be a new situation and cannot be an 'already known incident'. Since the Doha Declaration, it became clear that the provision also applies on public health emergencies. Although this provision of Article 31 (b) of TRIPS has to be seen separately from non-commercial public use as it can also be applied on commercial use. Paragraph 5 (c) of the Doha Declaration states:

'Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'[175]

This implies that the requirement of prior negotiations of the government with the patent holder can be waived to solve public health issues. It is common sense now that 'national emergency' includes every health crisis that threatens states permanently and not only in a sudden outbreak of a disease (e.g. HIV/AIDS v. cholera). Since the Doha Declaration extended the scope and the interpretation of the TRIPS Agreement governments can use the provision of Article 31 (b) of TRIPS to address urgent public health issues. The TRIPS Agreement mentions it as 'public, non-commercial use' and talks about patents 'used by or for the government'.[176] The distinction between compulsory licenses for the use of private or public purposes would be in the nature or the object of the patent in question.[177]

5.2.1.2 Remuneration

Another requirement for granting a compulsory license under TRIPS is the obligation of paying an adequate remuneration to the patent holder. The TRIPS Agreement does not provide any guidelines for compensation only a general rule in Article 31 (h) of TRIPS[178] which says:

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[175] Paragraph 5 (c) of the Doha Declaration on TRIPS and Public Health, supra footnote 141.
[176] Article 31 (b) of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[177] Cecilia Oh, *supra* footnote 106 at 24.
[178] See Article 31 (h) of the Agreement on Trade-related Aspects of Intellectual Property Rights.

'The Right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.'

Together with the basic principle in Article 1 of TRIPS which states that governments 'shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice',[179] this gives the member countries the freedom to set their own compensation guidelines.[180]

Thus, within the limits of Article 31 of TRIPS, a huge variety of different approaches for the remuneration of the patent holder exists. For example in Germany the royalty guidelines vary between 2 to 10 per cent, while Japan has rates between 2 to 4 per cent.[181] In 2006 Thailand issued several compulsory licenses for the manufacturing of HIV medication and set the compensation rate at 0.5 % royalty on generic drugs sales.[182] It is important that the compensation will be reasonable and that a fair process will lead to the decision about the rate of the remuneration being paid to the patent holder. Without guidelines accepted by the member states the requirement of Article 31 (h) of TRIPS seems to be a barrier for countries to issue compulsory licenses as they have a certain risk of alternative dispute settlement and lawsuits. Both procedures can become very expensive as the amounts in question will depend on the value of the patented products. It is difficult to reach a consensus as the perspectives of developing and developed countries differ in many ways. To meet their moral and social responsibility in public health issues governments need to be able to limit strong patent rights. Compulsory licenses are one way to limit patent protection but considering the economic value of patent rights and their impact on investment, compulsory licenses might also have a negative impact on innovation and research and development. Compulsory licenses on patented products are aimed at the '*conditio sine qua non*', the absolute basic principle or essential element, of the intellectual property rights system as they address the patent holder's exclusive right to exclude other people from using the product without permission.

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[179] Article 1 of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[180] James Love ,'Compulsory Licensing: Models for State Practices In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord' (2001) at 7, accessed from http://www.cptech.org/ip/health/cl/recommendedstatepractice.html [accessed 24 February 2009].
[181] Ibid at 8.
[182] Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public use of patent for Pharmaceutical Products at (3) accessed from http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html [accessed 24 February 2009].

One of the problems for setting compensation is the economic value of patent rights. The impact of compulsory licenses on patent rights needs to be measured in a monetary loss by the patent owner as only then the loss of an exclusive right can be remedied with an adequate compensation. Compulsory licensing regarding pharmaceutical products means that drugs will be sold by a person different from the patent holder. Therefore it means a loss of profits to the patentee. The system of remuneration will have a direct impact on the patent holder. If it compensates the whole loss and, thus, the patent holder does not lose any profit, the issuing of a compulsory license will have no negative impact on him and he will most likely not oppose the compulsory license. On the other hand, if the compensation only covers the loss of profit partially than every compulsory license means a direct monetary loss to the patent holder.[183] This will cause discrepancies as the patent holder will defend its exclusive property right against infringement by third parties.

The flexibility of WTO member countries on how they implement the minimum standards under TRIPS in their national legislation is one of TRIPS biggest advantages but this flexibility causes problems when it comes to the definition of the value of compulsory licenses. It is obvious that there can not be one general guideline for compensation equally applicable to developing and developed countries. Particularly in public health issues it might be reasonable to treat different countries differently. Cahoy[184] argues to lower the barriers for developing and least-developed countries the requirements of Article 31 of TRIPS should be abolished and the provision of prior negotiations with the patent holder being eliminated.[185] He promotes the adoption of a provision focusing on compensation of the patentee. Following Cahoy's approach, a three-tiered arrangement will deal with the compensation. The system is based on the economic status of a country and differentiates between developed, developing and least-developed countries. According to his model developed countries always have to pay the full market price of pharmaceutical products even in a situation of emergency. Developing countries would be allowed to use compulsory licenses and pay compensation depending on the countries financial abilities. Least-developing countries would even have the ability to issue compulsory licenses without payment of royalties in cases of health emergencies.

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[183] Cahoy, *supra* note 164 at 148.
[184] Daniel R Cahoy, Associate Professor of Business Law at Smeal College, Pennsylvania State University, United States of America.
[185] Cahoy, *supra* note 164 at 177.

According to Cahoy's approach the full market price has to be paid if compulsory licenses are issued not in a public health crisis or an antitrust situation addressing anti-competitive behaviour.

I think the principle of Cahoy's royalty model could gain the necessary balance between better access to life-saving drugs in poor countries and protection of innovation. Cahoy's proposed licensing regime meets government's responsibilities to solve public health crises but also prevents the abuse of dominant positions through anti-competitive behaviour of patent owning pharmaceutical industries.

However, it is important to adopt reasonable and fair royalty guidelines to reach practicability of the system of compulsory licensing under the TRIPS Agreement for developing and least-developed countries. The absence of royalty guidelines creates limitations for poor countries to make use of the TRIPS safeguards under Article 30 and 31 of the Agreement.

5.2.1.3 Non-exclusive use

Article 31 (d) of TRIPS sets out that a compulsory license can not be granted only to one company and, therefore, the use of a compulsory license can not be exclusive.[186] Practically this means that in a situation where more then one applicant seeks for a compulsory license the government has to grant it to all of them. This encourages competition on the market and brings benefits for the consumers as it will cause lower prices. This also means that the patent holder still can exploit his invention and can compete with the compulsory licensee on the market. Usually the patent owner will be well known and present in the market which might be a barrier for the compulsory licensee to be successful in the market and might make investment in the same market more difficult. Although, this is not a problem caused by Article 31 (d) of TRIPS. The same situation exists in free markets where different producers compete with each other.

[186] See Article 31 (d) of the Agreement on Trade-related Aspects of Intellectual Property Rights.

5.2.1.4 Basic principle of predominant supply of domestic market

In terms of issuing a compulsory license Article 31 (f) of the TRIPS Agreement sets out that 'any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use'[187] but export is also being allowed under this provision. The basic rule of 'predominant supply of domestic market' makes sense, as the purpose of a compulsory license, is usually, granted to solve a problem in the country which grants the license. As mentioned above a compulsory license enables a local manufacturer to produce a patented product for the domestic market and, therefore, to overcome the exclusive patent right of the patent holder.

The provision of Article 31 (f) of TRIPS seems to be consequential but an important question arises from this principle: What happens if developing and least-developed countries want to issue a compulsory license but do not have the capability of producing pharmaceutical products under a compulsory license in a domestic factory? Does Article 31 (f) of TRIPS limit smaller countries to access compulsory licenses and using them?

If a country grants a compulsory license to a domestic manufacturer for the purpose of exporting to a developing country this would be an infringement of Article 31 (f) of TRIPS. This leads to the conclusion that the provision of Article 31 (f) of TRIPS might be a barrier for countries with the highest need of compulsory licenses to make essential drugs available and affordable to the public, to benefit from this safeguard measure under the TRIPS Agreement. It actually would be contrary to the purpose of Article 31 of TRIPS if poor countries can not address their public health issues because of lack of manufacturing capacity on their domestic market. This is known as the paragraph 6 problem. Different developing countries were lobbying for changes. So the problem was discussed by the WTO Conference in Doha in 2001 and a solution adopted by the General Council in 2003 in its WTO Decision of 30 August 2003 on paragraph 6 of the Doha Declaration on TRIPS and Public Health.[188]

As mentioned above, the WTO Decision of 30 August 2003 on paragraph 6 of the Doha Declaration is dealing with the key issue of import mechanisms for countries with no or little manufacturing capacity in the pharmaceutical sector. The WTO

[187] James Love, 'Implementing TRIPS safeguards with particular attention to administrative models for compulsory licensing of patents', WHO Meeting in Harare (2001) at 4 accessed from http://www.cptech.org/ip/health/cl/harare-aug2001.html accessed [24 February 2009].
[188] See WT/L/540 and WT/MIN(0)/DEC/W/2.

Decision of 30 August 2003 waives the requirement of Article 31 (f) of TRIPS that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use' and the provision of Article 31 (h) of TRIPS which says 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'.[189] The WTO Decision of 30 August 2003 contains of twelve different parts: 'the product and disease coverage; eligibility of Members to import or export; the waivers to Article 31 (f) and the conditions attached; the terms of the waiver to Article (h); safeguard measures; special rules for re-export; transfer of technology; annual review; the relationship between the WTO Decision and existing rights, obligations and flexibilities; non-violation and situation complaints; the process for adopting a permanent solution including the relationship between the permanent solution and the WTO Decision, and determination of lack of manufacturing capacity'.[190]

In regards to compulsory licenses, it is possible now for a second country to grant a compulsory license only for the export to and the sale in another state. The requirement is that the importing government informs the WTO about the import and the state must have no own manufacturing capacities. To prevent illegal re-import the goods must be specified and marked by both the importing and the exporting state. This approach to supplement small poor countries with essential medicines is far from perfect as the developing country in need of the goods depends on the will of another country to supply it with the goods. In other words developing and least-developed countries still depend on developed countries which usually have the manufacturing capacities, however, are rather unwilling to issue compulsory licenses fearing the loss of investment by pharmaceutical patent holders.

On 6 December 2005, the General Council, on behalf of the WTO Ministerial Conference, adopted an amendment to the TRIPS Agreement.[191] The amendment implemented the General Council Decision of 30 August 2003 in the TRIPS Agreement. The newly adopted Article 31*bis* states in Paragraph (1):

'The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible

[189] Article 31 (h) of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[190] Correa/Yusuf, *supra* note 8 at 451.
[191] Amendment to the TRIPS Agreement of 6 December 2005, WT/L/41.

importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.'[192]

Article 31*bis* contains a waiver of the provisions in Article 31 (f) and (h) of TRIPS. Therefore, the implementation of Article 31*bis* into the TRIPS Agreement would expand the access to pharmaceutical products. Since the adoption of this provision the export of pharmaceuticals is allowed. Nevertheless, importing countries have to implement safeguards in their national law to prevent re-exportation under Article 31*bis*.

Developing and least-developed countries without manufacturing capacities could greatly benefit with the Amendment to the TRIPS Agreement in 2005 if it would become part of the TRIPS Agreement itself. On the basis of Article 31*bi:s* smaller and poor countries will have the possibility to make use of compulsory licenses as safeguards under the TRIPS Agreement now.

5.2.1.5 Review

Article 31 (i) of TRIPS requires that member states have to provide an institution to review compulsory licenses. There must be a possibility to control default compulsory licenses which do not meet the requirements of the TRIPS Agreement. This provision causes problems for developing and least-developed countries as they usually do not have the financial capacity to meet with pharmaceutical firms on the same level in courts or for litigation. Furthermore, a lot of money is needed to provide an institution, infrastructure and trained staff to review the issued compulsory licenses. The review process also could be abused by patent holders to delay the production of generic drugs as nobody will invest in the production of a pharmaceutical as long it is uncertain if the compulsory license is legally correct. In the interest of competition in the market and for the benefits of the consumer licensing processes should not take too much time as delays mean less time for compulsory license holder to cover their investment and to compete with generic manufacturers in the market.

[192] See Article 31*bis* (1).

5.2.1.6 Remedies for anti-competitive practices

Article 31 (k) of the TRIPS Agreement provides for governments to remedy anti-competitive practices which includes the abuse of a dominant position on the market by high pricing. In cases of anti-competitive practices the government can even allow for the export of products. According to Article 31 (k) of TRIPS the countries can choose between 'judicial or administrative processes'[193] to make the decision whether a compulsory license is needed to remedy anti-competitive practices. The provision of this article is very important as it can allow the export of drugs. If a compulsory license is issued to remedy any anti-competitive behaviour under Article 31 (k) of the TRIPS Agreement the provision of Article 31 (f) of TRIPS is waived.[194]

In the past compulsory licenses have been used to remedy anti-competitive behaviour in many different cases, including cases concerning pharmaceutical giants like Novartis and Sandoz.[195] When the pharmaceutical companies Ciba-Geigy Ltd. and Sandoz Ltd. merged into Novartis AG they were required to issue several compulsory licenses as remedy for anticompetitive behaviour in the market.

5.2.1.7 Government use under the TRIPS Agreement

Related to the idea of compulsory licensing is the principle of government use. Government use is defined as 'public, non-commercial purpose' in terms of Article 31 (b) of the TRIPS Agreement, however, the agreement does not provide a definite term for government use. Government use means that the government 'itself uses or authorizes other persons to use the rights over a patented product or process, for government purposes, without the permission of the patent owner.'[196]

It is widely accepted that the requirements for compulsory licenses under the TRIPS Agreement applies on both government use and compulsory licenses.

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[193] See Article 31 (k) of the Agreement on Trade-related Aspects of Intellectual Property Rights.
[194] James Love, *supra* footnote 180 at 4.
[195] Federal Trade Commission, 3 January 1997, Ciba-Geigy Ldt., et all., 'Proposed consent agreement' accessed from http://www.cptech.org/ip/health/cl/uscl/ftc-970103-ciba-geigy.html [accessed 24 February 2009].
[196] World Trade Organization, *supra* footnote 169.

5.2.2 Conclusion on compulsory licensing and government use under TRIPS

In summary, it can be said that compulsory licensing provides a substantial legal solution. The DOHA Declaration gains a good balance between the interest of patent holders and the interest of developing and least-developed countries in public health issues and TRIPS provides the adequate framework for this purpose. Nonetheless different problems and limitations remain. Governments can use compulsory licenses to obtain affordable and accessible pharmaceutical products in developing and least-developed countries and to approach new inventions. At the same time these safeguards under TRIPS enable governments to meet public health issues. Safeguard tools such as compulsory licensing and government use empower states to limit patent rights and intellectual property rights so that even if the measures are not being used they may prevent the abuse of dominant positions and anti-competitive practices in the market.

Despite the fact that the TRIPS Agreement provides a good framework for compulsory licenses, it is still difficult for developing and least-developed countries to meet the requirements of TRIPS as they do not have the resources to implement and profit from the safeguard measures under TRIPS. The solution under TRIPS might be theoretically a good one, however, it lacks practicability. It is not only necessary for developing and least-developed countries to implement the TRIPS safeguards in national law it is also important to have a system of fast working and transparent decision finding. The legal status of compulsory licenses and government use has been clarified by the DOHA Declaration. The example of Zimbabwe shows how developing countries have used the flexibilities under TRIPS.

The government of Zimbabwe was one of the first countries issuing a compulsory license after the DOHA Decision to meet public health issues regarding the HIV/AIDS crisis in the country. The Zimbabwean Patents Act provides in Section 34 and Section 35[197] for the authorization of the use of patented inventions by the government or other persons for public policy issues. In 2002 the Minister of Justice released an emergency declaration,[198] enabling the Zimbabwean government to:

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[197] See Section 34 and Section 35 of the Zimbabwe Patents Act Cap. 20 of 1994 accessed from http://www.cptech.org/ip/health/c/zimbabwe/patentsact.html [accessed 24 February 2009].

[198] Declaration of Period of Emergency (HIV/AIDS) Notice 2002, General Notice 240 of 2002 accessed from http://www.cptech.org/ip/health/c/zimbabwe/zim05242002.html [accessed 24 February 2009].

'make or use any patented drug, including any anti-retroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions'.[199]

According to Section 2 (a) of the Declaration of Period of Emergency, the time period was initially 6 months but the period of emergency was extended to a time period of 5 years until the end of 2008.[200] Medicines Sans Frontieres expected the price for HIV/AIDS medication to go down from about 1,200 US$ to about 420 US$ due to the issuing of the compulsory license.[201] The Declaration of Period of Emergency enables the Zimbabwean government to use generic drugs as it allows for domestic manufacturing of patented drugs.[202] Furthermore, it enables import of generic anti-retroviral pharmaceuticals for the treatment of HIV/AIDS patients in Zimbabwe.[203] Under the Declaration, the Zimbabwean government issued a compulsory license to a pharmaceutical company registered in Zimbabwe, Varichem Pharmaceuticals (Pvt) Limited. This company supplied the Zimbabwean government with a generic drug combining the two antiretrovirals Zidovudine and Lamivudine. The combination of these two drugs in the United States was about 200 US$ a year. Varichem could make the generic drugs available to the Zimbabwean government for 15 US$ per month.[204]

This example shows that compulsory licenses have a positive effect on prices of essential medicines in developing countries. The emergency declaration of the Zimbabwean government issued a license which was not limited to one pharmaceutical company. Therefore, different companies can make use of the compulsory license which will ensure competition in the market and also lower prices for HIV/AIDS drugs even more. Facing the world economic crisis, inflation and exchange rates the prices for anti-retroviral treatment in Zimbabwe are still unaffordable for most people. The average monthly income is less than 1.5 US$ and most people can not even get a job.[205]

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[199] Ibid.
[200] Cecilia Oh, *supra* footnote 106 at 26.
[201] 'Justice Ministers Declaration of Emergency' for Zimbabwe accessed from http://www.cptech.org/ip/health/c/zimbabwe/ [accessed 24 February 2009].
[202] See Section 2 (a) of the Declaration of Period of Emergency, *supra* note 198.
[203] See Section 2 (b) of the Declaration of Period of Emergency, *supra* note 198.
[204] Cecilia Oh, *supra* footnote 106 at 26.
[205] Wow Gambia, 'Zimbabwe: Cheaper, more accessible drugs might be on the cards' accessed from http://wow.gm/africa/zimbabwe/harare/article/2008/2/6/zimbabwe-cheaper-more-accessible-arvs-might-be-on-the-cards [accessed 24 February 2009].

Despite the positive impact of compulsory licenses on public health issues in developing and least-developed countries most governments fear the loss of investment if they make use of the safeguard measures under the TRIPS Agreement. Countries are concerned that foreign companies would stop investments if the national legislation provides for safeguard measures to limit intellectual property rights.[206] The flexibilities under TRIPS can only find practical application if they are transferred into national law. This means developing and least-developed countries, first of all, have to adopt the safeguards under TRIPS. Most of the countries worldwide actually do have a national system of patent law and safeguard measures,[207] the legislation only needs to be adjusted to meet public health requirements.

Compulsory licenses and government use should not be exercised to undermine or overrun patents. It is important that the safeguards under TRIPS are being used in a sustainable way in order to consider the needs and interest of the patent owner. For a forceful system of TRIPS flexibilities which broadens the access on affordable essential drugs, it is necessary to have a plain administrative procedure which does not provoke high costs. Furthermore, it is important to implement straightforward and transparent royalty guidelines for the compensation of the patent owner. For the process of issuing compulsory licenses it is important that governments have access to updated information about the patent status of the most important drugs. This means all patent offices worldwide should be included in a patent database which incorporates patents granted globally. The pharmaceutical market changes daily as pharmaceutical products and their use for health treatment are part of a highly innovative sector. Without an actual database it is almost impossible to keep track of pharmaceuticals and their global patent status.

Countries need to balance the benefits and costs of patent systems to encourage investment and innovation with the importance of authorizing use of non-voluntary licenses and of exports into countries with no capacity to manufacture drugs to address public health issues. Therefore, they need to find a practical national legislation within the framing of the TRIPS Agreement.

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[206] Cecilia Oh, *supra* footnote 106 at 31.

[207] Sangeeta Shashikant, 'More countries use compulsory license, but new problems emerge' (2005), accessed from http://www.twnside.org.sg/title2/health.info/twninfohealth004.htm [accessed 24 February 2009].

5.3 Tiered pricing of pharmaceutical products

The second safeguard measure under TRIPS is the control of prices. Countries use a wide range of different mechanisms to control prices of pharmaceutical products.[208] Price controls are legal under TRIPS and are used by both developed and developing countries. Tiered pricing refers to differential pricing and equitable pricing. Differential pricing means that pharmaceutical companies charge different prices in different countries for their products according to the countries purchasing ability.[209] Equitable pricing means that the height of the prices being charged depends on the economical background of the country and its ability to pay.[210]

Differential pricing is based on the idea that a balance of profitability will be reached by making pharmaceutical products accessible at lower prices in markets with small purchasing power, whilst giving manufacturers the ability to charge higher prices in richer markets.[211] This approach shall secure investment and research and development in the pharmaceutical sector. Even under full patent protection pharmaceutical companies might charge lower prices for their products in poor countries if they adopt this form of price discrimination.[212] The higher economic power of developed countries leads to differences in demand between developing and developed countries. A patent owner is permitted by his exclusive right to fix his prices, according to demands and costs, in each market differently or in all markets together.[213] If a manufacturer would have to sell its products for the same price this might not be profitable for him. Prices profitable in developed countries might be too high for the market in developing countries so products would not be sold there at all. For making any profit and to sell the products in developing countries at a uniform price the manufacturer would have to reduce its prices in the developed country. This

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[208] Jean Lanjouw, 'Patents, price controls and access to new drugs: How policy effects new market entry' (2005) at 19 accessed from http://www.nber.org/papers/w11321.pdf [accessed 24 February 2009].
[209] Global Health Council, 'Differential Pricing & Financing of Essential Drugs' accessed from http://www.globalhealth.org/view_top.php3?id=712 [accessed 24 February 2009].
[210] Cheri Grace, 'Equitable pricing of newer essential medicines for developing countries: Evidence for the potential of different mechanisms' (2003), at 11 accessed from http://www.dfidhealthrc.org/publications/atm/equitable_pricing_essential_med.pdf [accessed 24 February 2009].
[211] World Health Organization, 'Key concepts: Tiered pricing' accessed from http://www.who.int/immunization_financing/options/en/briefcase_pricingtiers.pdf [accessed 24 February 2009].
[212] F M Scherer/Jayashree Watal, 'Post-TRIPS options for access to patented medicines in developing nations' (2002) *Journal of International Economic Law,* 5 J. Int'l Econ. L. 913 at 919 accessed from http://jiel.oxfordjournals.org/cgi/content/abstract/5/4/913 [accessed 24 February 2009].
[213] Ibid at 9.

might lead to the decision not to sell the product in developing or least-developed countries but rather charge higher prices in rich markets for the product. Also pharmaceutical manufacturers will have difficulties to accept fixed prices in developing countries as there are usually no negotiations between authorities and the pharmaceutical industries about why cheaper prices should occur. In developing countries many times no big insurance companies can been found which negotiate lower drug prices as the health system often is based on public health insurance schemes or public drug reimbursement.[214] If manufacturers can consider price discrimination it might be more profitable for them to put its product on both markets and to sell it at different prices.[215] Therefore, it is not in the interest of developing or least-developed countries for uniform prices to be charged for pharmaceutical products. Pharmaceutical companies often charge excessive prices in low-income countries. The reason for this lies in price regulations of developed countries. In these markets, insurance companies, which are often run by the government or at least controlled by it, negotiate drug prices. Small and poor countries do not have the capacity for price negotiations.[216]

Another barrier for developing and least-developed countries in making use of price controls is the need of an efficient administrative structure to control the costs of production or prices to implement a price control system. If prices are fixed too low it may encourage the patent owner not to put their products on the market which would have an adverse effect on public health issues.

5.4 Parallel trade

Tiered pricing, compulsory licensing and government use are not the only safeguards under the TRIPS Agreement which can be used as a legal instrument to lower high prices of pharmaceuticals and to get a broader access to cheaper medicines. The principle of differential pricing occurs in what is called parallel trade. The arising question is if parallel trade can achieve the right balance between patents and affordable access to drugs?

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[214] Bjoern Ley, *supra* footnote 11 at 122.
[215] Ibid.
[216] Ibid at 120.

Parallel trade, also called grey-market import,[217] is a third option and means that a patented product was exploited by the patent holder or at least with the patent holder's permission in one country and is resold without the patent holder's permission in another country. Parallel trade is also seen as an option to solve public health issues, related to access to pharmaceutical products in developing countries. The idea of parallel trade becomes interesting if the price of a specific drug varies in different countries or if different versions of a product are for sale in different markets and different countries. The consumer will always try to gain access to a product at the lowest price possible. Article 6 of the TRIPS Agreement deals with the issue of parallel trade. It sets out:

'[...]nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.[218]

As seen above, the principle of the exhaustion of rights prevents the import of patented drugs from other countries where the product was put on the market. Article 6 states that governments can choose their own system of exhaustion of rights.

To allow for parallel trade in their national law, governments have to adopt the principle of international exhaustion. International exhaustion allows for the import of patented drugs if it has been in a foreign market with the permission of the patent holder.[219] The policy of international exhaustion might be able to achieve a price balance between different states. The principle of national exhaustion is contrary to the international exhaustion as it allows the patent holder to still exercise his exclusive right after he put his product on some foreign market.[220]

Parallel imports seem to have a huge benefit for consumers as they permit countries to use differences in drug prices in different countries to make them available to the public at lower prices.

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[217] EurActive, 'Parallel trade in medicines' accessed from www.euractiv.com/en/health/parallel-trade-medicines/article-117528 [accessed 24 February 2009].

[218] See Article 6 of the Agreement on Trade-related Aspects of Intellectual Property Rights.

[219] Mattias Ganslandt/Keith E. Maskus, 'Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union', (2004) at 1 accessed from http://www.ifn.se/Wfiles/wp/WP622.pdf [accessed 24 February 2009].

[220] Ibid.

5.4.1 Legitimacy of parallel trade

The criticism about the legitimacy of parallel trade actually includes two main aspects. Supporting the model of parallel importation it can be said that parallel trade does lower prices and competition leads to a broader rage of products on the market. Criticizing parallel importation, the other side argues that it does have a negative impact on investment and innovation. As discussed above in chapter three, patents provide their owners a monopoly-like position on the market. Under patent protection the patent holder can charge much higher prices than he could on a market with other competitors. Parallel trade does prevent the patent holder from abusing his dominant position through his exclusive right. This means due to the possibility of parallel imports the patent holder might not charge different prices on different markets in different countries.

5.4.2 Conclusion

Parallel trade seems to have benefits for the public. Consumers have a wider choice and access with the lowest prices. But these benefits sound better than they actually are. Even if the pharmaceuticals meet the legal requirements of the country they are produced in, they might not comply with the law in the country were they are going to be used. Medical products for example might have been repackaged by the importers which can cause a risk for their safety and quality. Furthermore, instructions for the use of the medicines might not be written in foreign languages so consumers might have difficulties to follow the advices for the use of the product.[221]

Parallel import does not really intend the lowering of high drug prices. It is more a measure to prevent excessive price differences. It is necessary that developed countries do not encourage parallel imports from developing or least-developed countries but developing countries should provide a system of parallel importation in certain cases. If parallel importation is not used in an excessive way to undermine patent protection it will not prevent or discourage research and development or investment by pharmaceutical companies. Parallel trade could be limited by charging uniform prices for pharmaceuticals. Additionally, equal prices would not be to the

[221] EurActive, *supra* footnote 217.

benefit of the poorest countries or of the patients. The pharmaceutical industry is focused on high-income markets in developed countries, therefore, small and least-developed countries would not benefit from equal prices as the price level would most likely be unaffordable for these nations.

The best system would consist of different prices in different markets. This principle is addressed by an approach called Ramsey[222] pricing. The Ramsey pricing deals with the price a monopolist should charge in order to maximize the social and the investors' welfare. According to the Ramsey principle: the best pricing system that combines equity with the protection of research and development issues, like costs, would charge lower prices in countries with smaller purchasing power and higher prices in high-income countries with high ability to pay.[223] This is based on the idea that once a new pharmaceutical product has entered a high-income market no further costs for research and development will occur, thus, there is no reason not to supply markets with smaller purchasing power. In considering the Ramsey pricing model, parallel trade seems to have a negative impact on the access to drugs in developing and least-developed countries. The phenomenon of parallel trade provokes pharmaceutical manufacturers to charge one equal price globally for their products which would have the adverse effect intended by parallel trade, namely to make pharmaceutical products accessible at the lowest obtainable price. If the Ramsey pricing model would be applied, parallel trade would be unnecessary as the charged prices would consider the countries ability to pay pharmaceutical prices. This would result in affordable prices in developing and least-developed countries. In order to encourage Ramsey pricing, parallel trade should be banned and price controls should not determine the prices charged for poor countries.[224]

[222] Frank Plumpton Ramsey (born in 1903) found the result in 1927 in the context of taxation. Biography accessed from http://www-groups.dcs.st-and.ac.uk/~history/Biographies/Ramsey.html [accessed 24 February 2009].
[223] Scherer/Watal, *supra* footnote 212 at 1.
[224] Ibid.

5.5 TRIPS mechanisms versus competition law as resolution in developing and least-developed countries

Firstly, it is important to mention that the protection of intellectual property rights and the goals of competition policy are not contrary and not inconsistent. As discussed above intellectual property rights, patent rights in particular, can help to strengthen competition and research and development. The tension between intellectual property rights and competition law originates in different situations. For example, the acquisition of intellectual property rights, licensing agreements and cooperative agreements such as patent pools create conflicts. Regarding patent protection, the refusal to deal and the abuse of a dominant position are important for the issue of access to life-saving drugs in developing and least-developed countries. The case *IMS Health Inc. v. European Commission*[225] sets out that the refusal to deal can mean the abuse of a dominant position. Furthermore, tie-ins, territorial market limitations and grant-backs are anti-competitive behaviour linked to intellectual property rights.

The purpose of the TRIPS Agreement is to protect and strengthen trade on the international level by providing minimum standards for the protection of intellectual property rights. The provisions under TRIPS dealing with competition policies are exceptions to the protection of intellectual property rights granted by the agreement. To make full use of the flexibilities under TRIPS, the member countries need to adopt legislation addressing anti-competitive behaviour related to intellectual property protection. TRIPS requires that the measures implemented by governments in national legislation are consistent with the agreement and appropriate.[226] Anti-competitive behaviour by patent holders may have a negative impact on the use of intellectual property rights. Rules under TRIPS dealing with the clash between competition policies and intellectual property rights aim to prevent such practices. Furthermore, measures to prevent and remedy anti-competitive behaviour related to intellectual property rights should not be used to undermine the minimum standards of intellectual property protection set out by the TRIPS Agreement.[227] Competition law should be used as a control mechanism to get the balance and the use of intellectual property rights correct. An excessive application of competition policies

[225] *IMS Health Inc. v. European Commission*, Case T-184/01 R [2001] ECR II-3193.
[226] Hans Henrik Lidgard/Tu T. Nguyen, *supra* footnote 25, at 10.
[227] Ibid, at 11.

would infringe intellectual property rights protection under TRIPS. The application of competition law to remedy market distortions should always be the second choice.[228] Firstly, it is important to establish a system of intellectual property protection which works in practice. Competition law should not being used to correct scope and applicability of a default legislative tool regarding intellectual property rights.

Therefore, competition policies should secure that the balance between intellectual property rights and trade and development issues is being kept. Competition law can help to prevent abuse of intellectual property rights like monopolization or excessive pricing and ensure that the use of these rights meets the public interest and economic welfare.[229]

This means the resolution of problems originating from intellectual property rights protection, such as the access to patented essential drugs, should come from within the intellectual property rights system. Legal mechanisms like the TRIPS Agreement, dealing with the protection of intellectual property, must implement safeguards able to resolve problems that are created by its exercise. Competition law cannot reach further than being a control mechanism. Competition law cannot be a substitute for practicable and enforceable intellectual property rights legislation.

CHAPTER SIX

THE FUTURE OF THE TRIPS AGREEMENT REGARDING ACCESS TO LIFE-SAVING PHARMACEUTICALS IN DEVELOPING AND LEAST-DEVELOPED COUNTRIES

Introduction of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights and its provisions on copyrights, patents and other intellectual property rights provides a framework of minimum protection for the transfer of innovations and products on the global market. The Doha Declaration seeks to establish a balance between the interests of patent-owning pharmaceutical companies on one hand, and the interests of developing and least-developed countries, which are seeking to tackle significant public-health issues. However the solution offered by

[228] Robert D Anderson/Hannu Wagner, *supra* footnote 26, at 228.
[229] Idem.

TRIPS is not very practical, as least-developed countries need not implement domestic patent protection legislation until 2016. But the 2005 amendment illustrates that TRIPS remains a work in progress. Innovation and research and development into diseases that mostly threaten citizens of developing countries and also processes outside WTO jurisdiction will have a direct influence on TRIPS in the future.

TRIPS must be reviewed and updated if it is to meet public health needs. The question is one of whether more or less patent protection is needed.

The General Council Decision of 2003 and the 2005 amendment to TRIPS have been cited as creating unnecessary barriers to the use, by developing and least-developed countries, of compulsory licenses in the form of complicated administrative processes. Despite this, the interests and perspectives of different parties appear to be balanced by implementation of a formal procedure aimed at reducing patent protection in cases where there is a public benefit.

The flexibility of TRIPS can be made to work in addressing public-health issues. Compulsory licensing of patented drugs is the agreement's main tool to safeguard available and affordable drugs in developing and least-developed countries. Thus poor countries should implement an administrative process for issuing and controlling patent rights to avoid the threat of expensive litigation. Articles 31 (h), (j), (k) and 44 (2) of TRIPS provide the legal framework for implementing administrative processes. Furthermore, governments need strong rights to use TRIPS to achieve public health goals. Compensation for the patent owner should also be set out in administrative processes and these should be aligned with royalty guidelines based on countries' level of development. Royalty guidelines must differentiate among developed, developing and least-developed countries to find a workable solution for remuneration of patent holders where compulsory licenses have been issued. Finally in urgent public health matters governments must be empowered to waive the requirements for prior negotiation with the patent holder. For small countries with no domestic capacity to produce drugs, compulsory licenses for import and export must be expressly allowed under TRIPS.

The provision under the General Council Decision of 2003 waiving the requirements of Article 31 (f) and (g) of TRIPS is permanent until the 2005 Amendment to TRIPS is accepted and ratified by WTO member states. Therefore governments should ratify and implement as soon as possible the amendment into national legislation to take full advantage of TRIPS.

But TRIPS' future and that also of the public health situation in developing and least-developed countries depends on processes outside the scope of the WTO and its legal instruments.

The WHO established in 2006 the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to improve public health-care for citizens of developing countries. Prevention, diagnosis and treatment of diseases have experienced drastic improvement in the last few years but the benefits of new medical technologies and methods are not being felt in developing and least-developed.[230] IGWG aims to draft a global strategy and a plan of action on public health, innovation and intellectual property to tackle the devastating ill-health and poverty cycle that so heavily affects least-developed countries.[231] The working group is debating how innovation, built capacity and access to better health care are linked and what can be done to achieve better results in terms of public-health issues. In May 2008 the sixty-first World Health Assembly adopted a resolution regarding the 'Global strategy and plan of action on public health, innovation and intellectual property'.[232] The aim of the global strategy can be found in Paragraph 13 of the 'Global strategy and plan on public health, innovation and intellectual property'. It seeks to:

> 'promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.'[233]

The CIPIH report was produced by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2006. CIPIH was established by the WHO in 2004. CIPIH's report examines the links among intellectual property rights, innovation and public health considering the differing perspectives of public and private

[230] World Health Organization, 'Public Health, Innovation and Intellectual Property', accessed from http://www.who.int/phi/en/ [accessed 24 February 2009].
[231] Ibid.
[232] World Health Organization Resolution WHA 61.21 accessed from http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf [accessed 24 February 2009].
[233] Ibid, paragraph 13.

stakeholders.[234] The report promotes innovations that benefit the health needs of citizens of developing and least-developed countries, makes recommendations and addresses the issue of access to pharmaceutical products in developing countries.

The report also asserts that patent protection is an important tool for governments to attract investment and encourage innovation. But intellectual property rights must not be the only mechanism to secure and encourage innovation. Other incentives and financial mechanisms are also needed. CIPIH's report states that it is necessary for the public to benefit from access innovative products. One section of the report addresses the conditions under which products can be accessed.[235] The report also addresses the ongoing debate over intellectual property and ratification of the TRIPS Amendment as a measure to increase access to pharmaceutical products in developing and least-developed countries without domestic manufacturing capacities.

The situation for developing and least-developed countries under TRIPS remains unclear. Threatened by HIV/AIDS and the high cost of essential medicines the DOHA Declaration, the General Council Decision and the 2005 Amendment to TRIPS sought to confirm that TRIPS' flexibility is applicable to public-health issues and thus facilitates poor countries' meeting of their public health obligations. Although this was confirmed by the DOHA Declaration not many developing and least-developed countries have made use of this aspect of TRIPS, from fear of international political pressure and the loss of investment. Nonetheless in terms of access to available and affordable pharmaceutical products it is important that both producing and supplier nations as well as importing states make full use of TRIPS' flexibilities. This means the Amendment to TRIPS must be ratified. Specialised United Nations agencies such as WIPO, WTO and UNCTAD should support developing and least-developed countries in enacting and establishing TRIPS safeguards and Article 31*bis* of the Amendment on TRIPS. These organizations can provide the requisite technical, administrative and infrastructural expertise to poor countries.

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[234] Commission on Intellectual Property Rights, Innovation and Public Health, 'Frequently asked questions' accessed from http://www.who.int/intellectualproperty/documents/thereport/questions/en/index.html [accessed 24 February 2009].

[235] Ibid.

CHAPTER SEVEN
CONCLUSION

At a seminar on 'Humanizing Globalization' in 2006, Ricardo Lagos, President of Chile, stated that 'Human beings must be at the centre of the world we are building, a world that must be able not only to think, create, reason and dream, but also to dialogue.'[236]

The global political, economic and social situation is changing every day but the public health crisis persists. According to WHO, UNAIDS and UNICEF, about three million people in developing and least-developed countries were treated with antiretroviral medicines at the end of 2007.[237] The report states that the increasing number of people receiving antiretroviral therapy is based on different factors: the higher availability of drugs due to lower prices; and the improvement of drug regimes, infrastructure and personnel, which leads to better health care even in the poorest countries. Despite these developments, an estimated 6.7 million people still do not have access to essential medicines.

Before the implementation of TRIPS developing and least-developed countries were relatively free in the way they drafted public-health regulations. There was no interference from any international system of intellectual property rights. As a consequence, developing and least-developed countries developed a range of models to secure access essential medicines depending on procurement methods, domestic manufacturing capacity, economic background and public health policies.[238] This situation changed when middle-income nations such as India began to manufacture generic drugs at much lower prices than the patented versions.[239] The TRIPS Agreement requires all 150 WTO members to implement and enforce its patent standards. As previously mentioned TRIPS rules apply to pharmaceutical products.

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[236] Pascal Lamy, Remarks at the seminar on 'Humanizing Globalization' by accessed from http://www.wto.org/english/news_e/sppl_e/sppl16_e.htm [accessed 24 February 2009].
[237] World Health Organization/UNAIDS/UNICEF, '3 million receiving life-saving drugs now' (2008), accessed from http://www.who.int/mediacentre/news/releases/2008/pr16/en/index.html [accessed 24 February 2009].
[238] F.M. Abbott/J.H. Reichmann 'The DOHA Round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions' *Journal of International Economic Law*, 10 J. Int'l Econ. L. 921, 2007 at 3 accessed from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1025593 [accessed 24 February 2009].
[239] Ibid.

The legal tools and the legal framework of member countries have a direct impact on domestic prices and availability of drugs.

As an answer to the discussion about the applicability of TRIPS flexibilities on public health issues, the WTO Ministerial Conference in 2001 adopted the Doha Declaration on the TRIPS Agreement and Public Health. The Doha Declaration addresses governments' responsibility to tackle public health issues and to make essential life-saving drugs available and affordable to the public. The Doha Declaration sets out that the flexibilities under TRIPS are applicable to public health issues and that member countries have the right to grant compulsory licenses in situations related to public health issues. In 2003 the WTO General Council adopted the Decision on paragraph 6 of the Doha Declaration. The Decision waived requirements under Article 31 (f) and (g) of TRIPS and was transferred in the Amendment to the TRIPS Agreement in 2005. The amendment known as Article 31*bis* needs to be ratified by the WTO member countries to become part of the TRIPS Agreement. Member nations' decision on the legislation implementing the Article 31*bis* and the other flexibilities under TRIPS into their national set of legal provisions will have a direct impact on innovation including research and development and the future of access to life-saving drugs in developing and least-developed countries. Furthermore domestic legislation will determine the extent to which developing and least-developed countries can access essential drugs in the form of compulsory licenses for import and export. Importing and exporting countries must not only ratify the amendment to TRIPS, they must also construct a forceful domestic framework of legislation. The manner in which governments adopt TRIPS' flexibilities and how these are transferred into national law will have a direct impact on the balance between the private interest in innovation and exclusive patent protection for inventions and the public interest in free competition and development. Developing and least-developed countries need time to implement useful and forceful legal tools to access the TRIPS flexibilities and to actually make them work. Compulsory licenses seem to be a good instrument to encourage price negotiations with patent holders in developing and least-developed countries and to allow for domestic manufacture, importation and distribution of drugs under patent protection at low prices to the broader public.

Patents create a problem when their use prevents competition. If competition is restricted the patent holder has the power to decide price, distribution and production

of his product. This creates a monopoly for the patent holder and might end in an abuse of the exclusive right, such as excessive pricing.

TRIPS addresses monopolies in the sphere of intellectual property rights, acknowledging that competition policies need to be considered when dealing with anti-competitive behaviour. Intellectual property rights and competition policies can be linked in different ways. The abuse of an intellectual property right can arise from the intellectual property right itself and the remedy can be found in the patent act. Alternatively, the abuse of the intellectual property right may originate from the intellectual property right and the remedy may lie in the anti-competitive effects. TRIPS enables member states to adopt and implement competition legislation to remedy these practices. The needs of developing and developed countries in terms of social and economic development are extremely different. Therefore developing countries should implement legislation related to intellectual property rights that meet the needs of their internal market. In terms of access to life-saving drugs developing and least-developed countries should focus on anti-competitive behaviour that has a direct impact on their citizens such as excessive pricing, abuse of dominant position and refusal to deal. From the European Union's case against Microsoft[240] we learn that the enforcement of domestic competition legislation is compatible with the TRIPS Agreement.[241] For developing and least-developed countries the ruling in the European Union Microsoft case[242] offers a breakthrough as the ruling body invoked TRIPS competition flexibilities which provides a precedent for these countries to apply their national competition law on intellectual property rights.[243] Developing and least-developed countries should implement the flexibilities under TRIPS in a reasonable and practicable way. The use of national competition law should only be the second resort for resolution of public health issues related to intellectual property rights.

But even if developing and least-developed countries make full use of the flexibilities under TRIPS and under a good antitrust system most people in these countries will still not have access to essential medicines. If pharmaceutical companies began to reduce excessive prices for essential drugs, the problem of infrastructure remains the same. To make essential life-saving medicines available to citizens of poor countries requires not only to question, review and improve patent rights and

[240] See *supra* footnote 72.
[241] Hans Henrik Lidgard/Tu T. Nguyen, *supra* footnote 25, at 14.
[242] See *supra* footnote 72.
[243] Idem, at 15.

intellectual property rights legislation. Patent rights are not the only barrier to access of affordable medicines. Testing and counseling facilities, storage and distribution of drugs, trained medical staff and patient awareness about treatment procedures also must be improved.

In summary, resolution of the issues comes down to achieving the right balance. The focus of the discussion about accessible and affordable medicines in developing and least-developed countries must be human beings. Governments and the pharmaceutical industry must be mindful that the 'human being' is the centre of everything when negotiating the future of the intellectual property system and public health issues. I hope this study proves that TRIPS provides a flexible system to address public health problems in the context of patent rights for pharmaceutical products and to balance the need to promote innovation and protect investment on the one hand and the interest in free competition on the market and governments' responsibility to meet public health obligations on the other. For TRIPS to work in future, and to make essential medicines accessible to the broader public in developing and least-developed countries will depend on WTO member countries' interest and ability to address the public health crisis by incorporating these flexibilities in their domestic legislation.

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