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This paper deals with the problems developing countries face under the current TRIPS Agreement in accessing cheap and affordable drugs in order to fight infectious diseases, especially HIV/AIDS. The paper also focuses on how the Doha Ministerial Conference has impacted on this issue.

Firstly, the reader will be made familiar with some background information on patent protection in general, including arguments in favour and in opposition of patent protection, with a focus on the pharmaceutical industry.

This is followed by information on the economic performance of the pharmaceutical industry and drug prices, arguing that prices currently charged are in general not due to high costs for research and development, but to a large extent caused by extremely high profits.

After providing an overview of the history of international patent protection, and an overview of the relevant regulation in the TRIPS Agreement, the paper examines the outcome of the Doha Ministerial Declaration and the impact of this declaration on compulsory licensing and parallel importing.

The paper supports the suggestion of a group of developing countries to enable Members to give effect to compulsory licenses issued by foreign governments and recommends that this suggestion be adopted in order to improve the access to cheap medicine for the economically weakest developing countries.

Besides that, the Declaration does no more than confirming what has been clear before the Ministerial Conference with regard to compulsory licensing.

The paper supports the Ministerial Declaration in so far as it confirms the right of WTO Member States to decide for themselves the question of the legality of parallel importing and finds that developing countries should make use of parallel importing by applying the exhaustion of rights principle in their national legislation.

It concludes that although the Declaration points towards the right direction, the opportunities for developing countries in accessing cheap medicine depend to a large extent on the approach that will be taken by the Council on TRIPS with regard to compulsory licensing. It is also important that Members not put diplomatic pressure on countries that decide to make use of their legitimate rights under the TRIPS Agreement.

This research paper contains approximately 13,299 words including footnotes.
I INTRODUCTION

The discussions on the TRIPS Agreement and its relationship to public health issues was one of the topics that attracted a lot of interest from observers of the Doha Ministerial Conference in November 2001. The discussions on TRIPS and public health issues were put on the agenda of the conference because developing and least-developed countries had concerns about limitations to the access to affordable medicine imposed on them by the TRIPS Agreement.

The importance of these discussions can also be seen in the fact that the ministers agreed on a special Ministerial Declaration, dealing with this topic.\(^1\)

It is obvious that immediate action is necessary in order to address the problems currently facing developing countries due to the spread of infections such as HIV/AIDS, tuberculosis, and malaria. And the problems are predicted to get worse in the future. 95% of the estimated 36 million people living with AIDS world-wide are living in developing countries.\(^2\) The majority of these people live in sub-Saharan Africa, South or South East Asia and Latin America.

Sub-Saharan Africa is the hardest hit region in the world, accounting for 3.8 of the 5.3 million new infections and for about 2.4 out of 3.0 million deaths annually. South African life expectancy is expected to decline by as much as fourteen years between 2005 and 2010,\(^3\) due to a very high mortality rate as a result of HIV/AIDS with as much as 6000 people dying every day.\(^4\)

Some of the hardest hit countries in sub-Saharan Africa, and later possibly in South and South-East Asia, face a demographic upheaval. HIV/AIDS and associated diseases that will reduce human life expectancy by up to 30 years and kill as many as a quarter of their populations over a decade or less.\(^5\)

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1 WTO “Declaration on the TRIPS Agreement and Public Health” (20 November 2001) WT/MIN(01)/DEC/2 (in the following referred to as “Ministerial Declaration”).
3 Rosalyn S Park, above, 127.
4 Rosalyn S Park, above, 127.
Furthermore, the spread of HIV/AIDS in developing and least developed countries does more than kill infected individuals. The grief suffered by survivors, and the possible lasting psychological damage, especially to young children who lose a parent, are potentially the most damaging consequences of the epidemic.

It is obvious that the effects of the infection go beyond the personal sufferer. The high number of HIV/AIDS infected people living in these countries will lead to consequences like economic downturn, due to the fact that more public funding needs to be spent on healthcare and that the workforce of the countries effected will be weakened.

One of the main problems with regard to the fight against HIV/AIDS in developing countries is that of prohibitive prices for medicine. The cost for a triple AZT cocktail can easily run up to as much as US$ 750 per month, which places the medicine clearly out of reach for the majority of, for example, South African HIV/AIDS victims, due to the fact that the annual per capita income is only US$6000.6

This paper will deal with the possibilities for developing and least developed countries in accessing cheap medicine, with a focus on the production of generics under compulsory licensing schemes and parallel importing strategies. The impact of the Ministerial Declaration on the options developing countries have, will be examined and discussed.

II WHY PROTECT PATENTS AT ALL?

A Different Approaches With Regard to Patent Protection

Granting a patent to a private or publicly owned company means effectively granting a monopoly over the production, use, and distribution of a certain innovation. The negative effects which monopolies have for the consumer, namely no competition on the market for the product which the patent is granted for and consequently higher prices for the product than the would be price in case of working competition, are well understood consequences of monopolies. Indeed, this is the very reason why patents are sought after.

Whether or not the protection of intellectual property makes sense from an economic point of view is subject of considerable controversy. There are essentially two different positions.

On the one hand the creation of intellectual property would be undermined if protection in the form of control over the production, use, and distribution would not exist. Fewer innovations would be made, due to a lack of motivation to develop new innovations. The idea behind this approach is to give patent holders the chance to recover the money they invested on research and development of new drugs and to improve social welfare. If looking at the immense costs that need to be spent on research and development before a drug gets approved for public sale, this argument seems to make good sense. In 1990, the United States government estimated that a single new drug took ten to twelve years to come to market at a cost of US$359 million.

On the other side are those who support the idea that intellectual property should be freely accessible. They argue that any kind of access to information stimulates new developments and makes new innovation more likely.

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"owners" of intellectual property do not have a natural, human right to the knowledge they create, but rather have co-opted the language of natural rights as a proxy to justify their desire for greater economic gain from increased intellectual property protection. People arguing in favour of this approach would support weak intellectual property protection, if any at all. A potential way to justify this approach is to argue that communitarian values and interests in free access to information would outweigh the inventor’s interest in the protection of his/her ideas, as well as that human rights aspects need to be considered when discussing the access to information.

Opponents of strong patent protection argue further, that research companies, especially in the field of pharmaceuticals, often receive public funding. Therefore, the argument runs, it is not justifiable to grant patents in those cases, since this gives companies the chance to “capture” public research expenditure.

Keith A Maskus has undertaken an analysis on the effects intellectual property protection has on countries and whether or not there are benefits in high intellectual property standards. He concludes that the complexity of intellectual property protection supports both optimistic as well as pessimistic claims about how countries will be affected. According to Maskus, none of the arguments in favour or against strong intellectual property regimes may be decisively rejected by theoretical or empirical analysis. He indicates, however, that the work reviewed by him suggests that the short-run impacts of the patent protection standards in the TRIPS Agreement will be essentially redistributive between countries, with the bulk of gains accruing to the United States and other technology developers. Over the longer term, however, he suggests that there are mechanisms that could enhance technical change and growth in the technology importing countries.

13 Keith A Maskus, above, 2239.
Theodore Bailey has undertaken another analysis, focusing on the effects of compulsory licensing. He comes to the conclusion that although compulsory licensing might weaken the incentives that firms have in investing in research, this does not necessarily mean that such a reduction will reduce the level of research, or even that such a reduction would be socially undesirable.\(^\text{14}\) He argues that increasing the level of investment for research and development does not, after a certain point, produce benefits commensurate with the costs of such investment, and that the pharmaceutical industry might well have passed this crucial point, so that a decrease in investment would not necessarily lead to a social net loss.\(^\text{15}\)

All in all, one can say that the protection of patents is certainly an important means in order to encourage firms to invest money into research and development, but the grant of monopolies via patents might have a negative influence on the general availability of medicine.

B  The Pharmaceutical Industry

Pharmaceutical companies strongly argue that they need effective patent protection in order to create an incentive for them to undertake the costly research and development necessary to create a drug and bring it to market. Although there can be no doubt about the fact that the development of new medicine is indeed a costly undertaking, it is interesting to take a look at some data regarding the performance of the pharmaceutical industry. This reveals not only that the industry spends considerable amounts of money on research, but also that the industry’s profits are sky high compared to other industries.

1  Differences in drug prices

The price difference between the original product on the one hand and the generic equivalent has in some cases been reportedly so high, that it is hard to believe that the higher prices for the original product result from the costs spent on research and development as often argued by company officials. According to a


\(^{15}\) Theodore Bailey, above, 215.
paper by Harvey E Bale Jr, the Senior Vice President International Pharmaceutical Research and Manufacturers of America, 15-20 percent of the price of an originator’s product are constituted by the research and development costs. Assuming that this is true, it is hard for pharmaceutical companies to avoid the suspicion that they use the monopolies they are granted to charge prices far above prices that would be expected in a competitive market.

A comparison of prices for HIV/AIDS medicines illustrates the fact that the original drugs are usually significantly higher than the prices charged for generic drugs. 3TC, also known as Lamivudine, a drug produced by Glaxo Welcome and patented in a number of countries until between 2009 and 2011, is used by HIV/AIDS patients for antiviral therapy. The drug has reportedly been found to be priced at US$3,271 in the United States whereas Indian producers offer the generic equivalent for US$190 (Cipla Ltd) and US$98 (Hetero Drugs Limited) respectively.

This is not the only case in which producers of generic drugs offer their products at substantially lower prices than the originators. The price of a combination of three anti-HIV/AIDS drugs (3TC, Zerit, and Viramune) for the treatment of one patient amounts up to between US$10,000 and 15,000, while the same therapy can be undertaken with generic medicines supplied by Cipla Ltd at a price US$350 - 600.

When looking at these numbers, it is hard to believe that the high differences in prices are due only to higher costs of production and to research and development costs. If looking at the example of 3TC and the price for the drug in the US, 20% of the drug’s price (the part of the price attributed to research and development costs as stated by Harvey E Bale Jr) would be US$654. After deducting this amount from the original price the medicine would still cost US$2617.

The economic performance of the pharmaceutical industry

According to Fortune’s list of the 500 largest American companies for the year 2000, the average return on revenues was 18.6% whereas the median for returns on assets was 17.7%. Both percentages outweigh by far the overall median for the other Fortune 500 industries. The median for the other industries in the Fortune 500 list is 4.9% return on revenues and 3.9% return on assets. The last category that was evaluated by Fortune was the return on equity. Although the pharmaceutical industry does not occupy the top rank, the 11 pharmaceutical companies in the list, still managed to reach a median return on equity of 29.4%, nearly twice as much as the overall median of 15.4%.

The most successful pharmaceutical company among the 500 largest American companies was Merck. Merck made some US$40.4 billion in sales with profits running up to US$6.8 billion. The profit Merck made in the year 2000 was higher than the profit of all the Fortune 500 companies in the airline, entertainment, food production, metals and hotel/casino/resorts industries combined. Although these numbers are already outstanding, Merck’s drug operation was even more profitable than it seems at first glance, due to the fact that approximately half of the company’s revenues come from its massive pharmaceutical benefit management company, Merck-Medco, which has much lower profit margins than the parent company’s drug business. If only looking at the drug-producing part of Merck, the profits were 44.2% of the revenues in 2000.

Although it can often be heard that pharmaceutical companies need to make higher profits than other industries in order to assure sufficient funds to finance the expensive research and development of new drugs, the Fortune 500 drug companies have spent more money on marketing and administration than on research. While an average of 12% has been spent on research and development, 30% were spent on marketing and administration.

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19 Noshua Watson “Inside the 500” (8 April 2001) Fortune 126.
21 Public Citizen’s Congress Watch, above.
Looking at these numbers it is hard to believe that high drug prices are mainly due to research and development costs, and feeds the suspicion that drugs could be priced considerably lower if the pharmaceutical industry would accept smaller profits, without substantially endangering the pharmaceutical companies.

III THE DEVELOPMENT OF PATENT PROTECTION ON THE INTERNATIONAL SCALE PRIOR TO TRIPS

A The Paris and the Berne Convention

The law of intellectual property is not a creature of the information age, despite its popular association with modern, high-tech industries. The Paris Convention of 1883 and the Berne Convention of 1885 emerged at a time when international agreements were being formed regarding diverse concerns ranging from posts and telegraphs to weights and measures to trade and customs. Prior to this international union, only limited bilateral treaties existed to protect foreign intellectual property.

The Paris Convention was the first international instrument that comprehensively dealt with the protection of patents and trademarks. That the protection of intellectual property rights raised concerns in a lot of countries can be seen by the wide range of countries which signed the treaty in 1883. The treaty was originally signed by Belgium, Brazil, France, Ecuador, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain, Switzerland, Tunisia and the United Kingdom, whereas the United States joined the Agreement three years after it came into effect. Although the Paris Convention does not have as many signatories as the TRIPS Agreement, its 98 signatories were responsible for more than 88% of the world trade in goods in 1985.

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23 Robert J Gutowski, above, 717.
24 Robert J Gutowski, above, 717.
26 Robert J Gutowski, above, 718.
The Paris Convention applies to "industrial property", a term covering patents, trademarks, industrial designs and trade names, and also provides protection against unfair competition. The National Treatment Principle is the core principle of the Paris Convention. According to this principle Members are not allowed to discriminate between foreign and domestic intellectual property. The Convention also obliges its signatories to introduce minimum standards with regard to patent and trademark protection, but does not provide a dispute settlement mechanism for disputes among its Members and does not set standards for the protection of enforcement of the rights conferred to patent holders.

A number of factors now make the Paris Convention look outdated. The lack of a dispute settlement regulation, the lack of rules regarding enforcement of intellectual property rights and in addition the evolution of the world trading system, technological changes, in particular generalised computerisation and digital technology, were all factors that precipitated the development of new regulation regarding intellectual property rights.

The Berne Convention of 1885 does not protect patents and trademarks, but rather sets minimum standards with regard to the protection of author's rights. Therefore, the Berne Convention is not of any further importance for this discussion.

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27 Article 1 (2) of the Paris Convention states:
"The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition."


29 Article 2 (1) of the Paris Convention states:
"Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with."

B World Intellectual Property Organisation

Located in Geneva, Switzerland, the World Intellectual Property Organisation (WIPO) is an international organisation dedicated to the protection of intellectual property rights operating under the United Nations (UN). Established as an organisation being responsible for administering four international treaties in 1889 under the name BIRPI, WIPO nowadays administers 23 different international treaties.

VI THE TRIPS AGREEMENT

After providing the reader with an overview of the history of negotiations that finally led to the current TRIPS Agreement, the reader will be introduced to the principles and articles that are of special interest with regard to the protection of patents and therefore pharmaceuticals.

A The Way to TRIPS

When the Uruguay Round of negotiations started in 1986, the subject of intellectual property rights was completely unfamiliar to international trade economists.\textsuperscript{31} It must be assumed that this was the case due to the fact that global trade policy concerns had not moved into questions of domestic business regulation. As at the end of the 1980’s some 40 countries across the world did not grant patents for pharmaceutical product innovations.\textsuperscript{32}

Those who felt that there was a need for new standards for intellectual property protection used the Ministerial Conference at Punta del Este (Uruguay) in September 1986 to inscribe the matter of intellectual property protection on the


\textsuperscript{32} According to Wolfgang E Siebeck, Robert E Evanson, William Lesser, Carlos A Primo Braga “Strengthening the Protection of Intellectual Property in Developing Countries: A Survey of the Literature” (World Bank Discussion Paper No 112, World Bank, Washington DC 1990) 95, the following countries did not provide patents for pharmaceutical product innovations: Chad, China, Ghana, India, Pakistan, Vietnam, Bolivia, Ecuador, Egypt, Lebanon, Morocco, Peru, Poland, Syria, Thailand, Tunisia, Argentina, Greece, Hungary, Iran, Iraq, Libya, Portugal, Romania, Uruguay, Venezuela, Yugoslavia, Canada, Finland, Iceland, Norway, Spain, Bulgaria, Cuba, Czechoslovakia, German Democratic Republic, Mongolia, and the USSR.
agenda of the Uruguay Round. Although the protection of intellectual property rights did not have a very long, if any, tradition, in most developing countries, at the end of the Uruguay Round, the TRIPS Agreement was signed by 117 nations on 15 April 1994. Since then the number of signatories has increased to 144 as of 1 January 2002.

Seeing markets lost to successful imitators, US industry, with the aid of the US government, in the early 1980’s began to make energetic efforts to strengthen patent regimes in the developing world. With the support of other industries, American representatives from pharmaceutical firms and trade associations argued that intellectual property should be included in the Uruguay Round of the GATT negotiations. In alliance with their counterparts in Europe and Japan, they were finally successful in getting the intellectual property issues on the agenda.

The US finally managed to achieve an agreement that satisfied most of the interests of the US industry, including the requirement that signatory countries grant patent protection for pharmaceutical innovations. However, some compromises to developing country concerns were included in the final draft. These included the exclusion of patents on life forms, the ten-year transition period for developing countries, and the allowance of compulsory licensing, albeit with stringent restrictions.

Developing countries usually do not have access to large numbers of well educated researchers and scientists, and cannot compete in the production of research intensive products, but often have a comparative advantage in actually making products rather than developing them. A high standard of patent protection which limits the possibilities to legitimately imitate certain products can actually be to the

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35 see: www.wto.org/english/thewto_e/thewto_e.htm.
37 Jean O Lanjouw, Iain Cockburn, above, 5.
38 Jean O Lanjouw, Iain Cockburn, above, 5.
39 Jean O Lanjouw, Iain Cockburn, above, 6.
detriment of developing countries. This is due to the fact that prices in monopolistic markets are, generally speaking, of a higher average than in markets with working competition and secondly because of the decline in revenues and employment in industries specialised in imitating products.

The main basis for the developing countries’ opposition to an agreement within the GATT was the idea that WIPO was a more appropriate forum for questions dealing with patent protection. Developing countries were also concerned that the objectives of those in favour of a strong patent protection system under the roof of the WTO were contrary to the economic interests of developing countries. 41

Finally, the developing countries overcame their doubts and decided to join the TRIPS Agreement. One reason which was given by the developing countries for doing so was not the conviction that an agreement on intellectual property rights would contribute to the liberalisation of world trade, but rather to use their approval as a “bargaining chip” in return for access to the markets of developed countries. 42 Thus, rather than putting their main focus during the Uruguay Round on intellectual property issues, developing countries focused their attention on potential gains in other areas, such as agriculture or textiles. 43

B Important Principles in the TRIPS Agreement Regarding Pharmaceuticals

1 National Treatment principle and Most Favoured Nation principle

The two core principles which are included in the TRIPS Agreement are the National Treatment principle (see Article 3) and the Most Favoured Nation principle (see Article 4). They are not only core principles of TRIPS but are the principles upon the WTO is founded and it can be assumed that these principles are well understood and do therefore not require further explanation. Both principles are subject to exceptions under certain conditions.

43 May L Harris, above, 457
2 Articles 7 and 8 of the TRIPS Agreement

Two further basic principles that need to be taken into account when interpreting the TRIPS Agreement can be found in Articles 7 and 8 of the Agreement.

Article 7 requires that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations.

Article 8 (1) is of special importance with regard to this topic, due to the fact that it states:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 8 (2) states further that

Appropriate measures, provided that they are consistent with the provisions of the Agreement, may be needed to prevent the abuse of intellectual property rights by right holders through the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

3 Article 27 – Patentable Subject Matter

Article 27.1 of the TRIPS Agreement, the drafting of which was inspired in part by Article 10 of the draft WIPO Patent Law Treaty,44 establishes a general principle of eligibility of patents.45

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44 Daniel Gervais The TRIPS Agreement: Drafting History and Analysis (Sweet & Maxwell, London 1998) 147.
45 Daniel Gervais, above, 147.
The general principle of eligibility of patents does not only require patent protection to be granted for any kind of invented products, but explicitly requires patent protection for the process of the product manufacture as well as for the finished product.

Member States are obliged to ensure patent protection is granted under their national laws where the applicant for a patent can prove that the invention is new, involves an inventive step, and is capable of industrial application. Due to the fact that the TRIPS Agreement contains only minimum standards with regard to the protection of patents, Members States are free to set out lower standards before a patent is granted. This is, of course, rather of academic interest, especially with regard to the case of developing countries and their access to affordable medicine, since these countries have an interest in a lower standard of protection rather than a higher standard of patent protection.

Article 27.1 requires further that patents must be granted on a non-discriminatory basis, which means that patents need to be granted regardless of the field of technology, the place of invention and whether the product is an imported or locally made product. The latter is an application of the fundamental National Treatment doctrine.

Subsections 2 and 3 contain exceptions with regard to the patentability of inventions which fulfil the conditions as set out in subsection 1 and for which Member States would normally have to grant patent protection.

Article 27.2 provides that

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

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46 See Article 1.1.
This provision therefore allows Members States to refuse to grant patent protection where the commercial exploitation of a patent could endanger the ordre public or morality within the territory of the Member State.

This means that patentability may not be denied in cases in which the invention itself leads to a risk to ordre public or morality, but rather only where the commercial exploitation threatens to harm ordre public or morality.

Article 27.3 allows a Member State to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. It also allows the exclusion from patentability of plants and animals, other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

When talking about the patentability of medicine, it should be noted that those countries that did not provide patent protection for pharmaceuticals but were forced to do so as a result of the TRIPS Agreement, do not need to protect pharmaceuticals for which a patent application was filed before 1 January 1995. This means that other products, including those already applied for or patented in other countries, or commercialised before that date, will remain in the public domain, unless the national law allows (as in the case of Brazil) the retroactive protection of the so-called "pipeline" products.

48 Carlos M Correa, above, 3.

4 Article 28 – Rights Conferred

Article 28 deals with the rights a patentee shall at least be granted under the national law of the TRIPS Member States. It has been said that article 27 was inspired by the draft Patent Law Treaty. The same is true for article 28.1 which sets minimum standards for the exclusive rights Members States are obliged to confer to patentees.

The standards included in the article can be considered common for industrialised nations, due to the fact that each of the terms included appeared in one or
even more national laws before the TRIPS Agreement. Article 28.1(a) obliges national governments to ensure that third parties do not make, use, offer for sale, sell or import any goods under patent protection without the patentee’s consent in cases where the patent is granted for a product.

Article 28.1(b) obliges Member States to ensure that where a patent is granted for a process rather than a product, the process may not be used without the holders’ consent. Products which are directly obtained from a patented product may not be made, used, offered for sale, sold or imported for the mentioned purposes.

Article 28.2 provides that Member States shall make available the opportunity of assigning and licensing of a patent to a third party.

5 Article 29 – Test on patent applications

Article 29.1 introduces a substantial rule to the Agreement, which was lacking in the Paris Convention, but which is quite common in patent laws, namely the precise test imposed on patent applications in respect of the description of the invention. Article 29.2 allows Members to require information on the grant of patents regarding the same inventions under foreign jurisdictions, as long as the requested data is relevant to the application concerned.

6 Articles 30 and 31

Articles 30 and 31 both deal with exceptions to the exclusive rights that Members need to grant to patent holders in compliance with the TRIPS Agreement. The difference between both articles is that article 30 must be seen as a general clause, whereas the exceptions under article 31 are limited to the cases explicitly dealt with in that section.

Looking at the structure of articles 27 to 31 it becomes obvious that the articles start with the general rule of article 27.1 under which Member States are obliged to ensure the protection of patents, regardless of the field of technology. In subsequent articles, the Agreement allows certain exceptions with regard to the standard of patent protection that must be granted.

Whereas article 27.2 and 27.3 allow Member States to exclude a certain product completely from patentability, articles 30 and 31 do not go that far, since they do not allow a Member State to deny patentability to certain products per se, but only allow the use of patents as long as the conditions set out in the articles are met. In both cases, article 27 on the one hand and articles 30 and 31 on the other, a general clause is followed by a more detailed rule with regard to the exceptions that are allowed.

It can probably be taken as being a general principal, that a general clause can only apply to cases which are not covered by a specific regulation. This means, for the relationship of articles 30 and 31, that the general clause of article 30 cannot apply to cases which are explicitly dealt with under article 31.

Since, as indicated above, the exceptions provided within article 27 allow the denial of patentability per se, they go further than those in articles 30 and 31, and these articles must seen to be in a hierarchy.

This means that the exception with the weakest impact on the interests of the patentee needs to be looked at first. If the aim which Member States wish to legitimately achieve cannot be achieved under that particular exception, then, but only then, it is legitimate to make use of the next step.

Member States must therefore try to achieve their legitimate aims by making use of the exceptions under article 31 first, due to the fact that this has the weakest impact on the patentee’s interest.

If the Member States can prove that the exceptions provided for in article 31 are not sufficient, then it must be legitimate to make use of the exceptions under article 27.

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50 Daniel Gervais, above, 156.
The TRIPS Agreement, unlike the Paris or Berne Convention, requires Member States to implement enforcement procedures, therefore setting out minimum standards with regard to lawsuits involving patent infringement. The requirements that member States need to comply with are set out in Articles 41 to 45.

The procedural standards required by the TRIPS Agreement include a wide range of legal sanctions, such as the requirement to provide legislation under which patent holders must be given the chance to apply for injunctive relief (Article 44). Member States are also obliged to ensure that national authorities are given the power to order the payment of damages, including legal fees, payable by the infringer to the patent holder (Article 45).

V PROBLEMS WITH REGARD TO ACCESSING AFFORDABLE MEDICINE UNDER THE CURRENT TRIPS AGREEMENT

This section will discuss different ways in which developing countries can access medicine at affordable prices without violating their obligations under the current TRIPS Agreement and take into account the effects that the Ministerial Declaration on the TRIPS Agreement and public health might have in the future.

A Compulsory Licensing

1 Compulsory licensing in general

The term “compulsory licensing” refers to practices under which national governments license the use of a patent without the patent holders consent. Provisions which allow the granting of compulsory licensing can be found in a

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51 Article 1.1 states: Members shall give effect to the provisions in this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement."

number of national patent laws. In international intellectual property law the three most common situations in which a compulsory license is granted are where a dependant patent is being blocked, where a patent is not being worked on, or where an invention relates to food or medicine.\footnote{Gianna Julian-Arnod “Compulsory Licensing and Patents” in Anthony D’Amato and Doris Estelle Long (ed) \textit{International Intellectual Property Law} (Kluwer Law International, London, The Hague, Boston, 1997) 357.} Additionally, provisions that allow governments to issue compulsory licenses can often be found in patent or antitrust laws where they are included in order to give governments the opportunity to remedy behaviour that is illegal under the national antitrust law, or where the invention is important to national defence or where the entity acquiring a compulsory license is the sovereign.\footnote{Gianna Julian-Arnod, \textit{above}, 357.}

\subsection*{(a) Use of compulsory licenses}

Compulsory licenses have been granted extensively in developed countries, such as Japan, European countries or by Canada and the United States. These licenses were not only granted for specific industries of high importance for a country’s social benefit, for example the food or the pharmaceutical industry, but have occurred in a number of different industries, such as the computer, software or other modern technologies. Compulsory licenses have for example been granted in the United States for tow truck technologies in the year 2000.\footnote{James Love “Compulsory Licensing: Models For State Practice In Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord” (Paper Prepared for the United Nations Development Programme, 21 January 2001) Paragraph 5 <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html> (last accessed 21 January 2002).}

Canada has a long history of granting compulsory licenses on pharmaceuticals, and compulsory licenses were granted nearly automatically. However, Canada was pressured by the United States to review its practice as a condition to join the NAFTA.\footnote{Gianna Julian-Arnod, \textit{above}, 357.}

\subsection*{(b) Effects of compulsory licenses}

There can be no doubt that the granting of compulsory licenses will usually have negative effects on the benefits derived from the exploitation of the protected
intellectual property right.\textsuperscript{57} Nations granting compulsory licenses argue that these “takings” represent the negotiated exchange for recognising foreign intellectual property rights.\textsuperscript{58}

The threat of granting compulsory licenses encourages the involved parties to grant licenses voluntarily\textsuperscript{59} so that granting of a compulsory license might lead to competition on the specific market, which leads usually to lower prices for the branded product.

The main aim of compulsory licenses, however, will usually not be to lower prices for the original product, although this might be the case where compulsory licenses are granted to remedy contraventions of antitrust laws. Instead, the objective is generally to obtain benefits which go beyond reduced prices, such as improvements in a country’s social welfare.

\section*{2 Compulsory licensing under the TRIPS Agreement}

Article 31 of the TRIPS Agreement deals with the use of patented products without the authorisation of the holder. It provides regulation under which Member States may implement legislation in their national laws which allow their governments to authorise patented products under certain circumstances.

\textbf{(a) Members are free to determine grounds for granting compulsory licenses}

Although negotiators considered setting out specific grounds for the granting of compulsory licenses, they finally decided not to do so, preferring instead to leave the decision whether or not to grant compulsory licenses (and in which cases to grant compulsory licenses) to the national governments.\textsuperscript{60} Due to the fact that the TRIPS Agreement does not set out the grounds on which a compulsory license may be

\textsuperscript{56}James Love, above, Paragraph 5.
\textsuperscript{58}Anthony D’Amato and Doris Estelle Long, above, 360.
granted, Member States may grant licenses on any grounds. In short, the grounds for granting compulsory licenses are subject to the Members’ discretion.

In so far as the Ministerial Declaration states “each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”, the Ministerial Declaration does not contain anything new, but rather simply confirms the existing position.

By allowing Member States to grant compulsory licenses, Article 31 does not allow removal of patent protection for certain patented products, but gives the opportunity to allow certain companies to legally produce copies of the patented original. Granting a compulsory licence does not affect a patent holder’s right to take judicial action against companies who do not hold the necessary license but nevertheless produce the drug for which a compulsory licence is issued.

(b) Safeguards to be respected before compulsory licenses are granted

Rather than setting out specific cases in which compulsory licenses may be granted, Article 31 provides a number of conditions which need to be complied with before a compulsory licenses is granted. These conditions can be described as safeguards for the protection of the patent holders interests.

Generally speaking, it can be said that the granting of compulsory licenses underlies strict safeguards, considerably restricting the opportunity to grant a compulsory license.

Member States shall only grant such licenses where the proposed user has previously tried to obtain a license from the right holder on reasonable commercial terms and conditions. A compulsory license may be granted only if such efforts have been without any success within a reasonable period of time. This condition is subject to

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60 Daniel Gervais The TRIPS Agreement: Drafting History and Analysis (Sweet & Maxwell, London 1998) 166.
61 see paragraph 5(d) of the Doha Ministerial Declaration.
62 Carlos M Correa, above, 43.
63 Daniel Gervais The TRIPS Agreement: Drafting History and Analyses (Sweet & Maxwell, London 1998) 166.
64 See article 31(b) of the TRIPS Agreement.
one exception and may be waived in cases of “a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use”.

Article 31 contains further conditions, such as a limitation with regard to the time for which the licence shall be granted,\textsuperscript{65} that the use shall be non-exclusive,\textsuperscript{66} the use shall be non-assignable,\textsuperscript{67} and that “any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use” (as discussed below, a particularly contentious condition). It is further required that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation”.\textsuperscript{68} Member States are further obliged to ensure that the legal decision to grant a compulsory license is subject to judicial review or “other independent review by a distinct higher authority in that Member”.\textsuperscript{69}

3 Compulsory licenses, developing countries and medicines

Because of the special situation facing many developing countries, developing countries that did not provide patent protection for pharmaceuticals prior to the TRIPS Agreement are allowed until 1 January 2005 to implement such protection, and in the case of least developed countries, until 1 January 2006.

This extended period for compliance with the TRIPS standards has been further extended by the Ministerial Declaration on the TRIPS Agreement and Public Health, which states under paragraph 7:

We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without

\textsuperscript{65} See article 31(c) of the TRIPS Agreement.
\textsuperscript{66} See article 31(d) of the TRIPS Agreement.
\textsuperscript{67} See article 31(e) of the TRIPS Agreement.
\textsuperscript{68} See article 31(h) of the TRIPS Agreement.
\textsuperscript{69} See article 31(j) of the TRIPS Agreement.
prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Because of this exception, developing country Members are not obliged to provide patent protection for pharmaceutical products, which means that there is no need to make use of the opportunity of compulsory licenses for developing countries until they actually provide patent protection for pharmaceuticals. The granting of compulsory licenses is nevertheless important in those developing countries which have already provided patent protection regulation which is consistent with the TRIPS standards.

The production of generics under compulsory licenses is limited by article 31(f) of the TRIPS Agreement. Article 31(f) provides that "any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use".

This provision creates a trap for those developing countries that need access to cheap medicine but cannot afford to produce medicine themselves. This is because article 31(f) does not allow other countries, for example developing countries which can afford to produce generics, to export these drugs to the poorest countries which cannot afford to produce their own generics, since production under a compulsory licence may only be authorised to predominantly supply the domestic market. The wording of article 31(f) is unambiguous, so that it is difficult to find an interpretation of the TRIPS Agreement which would allow the export of generics to countries that cannot afford to produce their own medicine.

It has been argued, however, that the TRIPS Agreement would allow a Member State to issue a compulsory licence to a manufacturer in another country, provided that the government of the other country recognised the licence, and provided that all the goods provided under the licence were exported to the country...
granting the original licence.\footnote{WTO “Communication from the European Communities and Their Member States” (12 June 2001) IP/C/W/280, Paragraph 13.} Given the rigidity of article 31, it seems that such an exception could only be justified under article 30 of the TRIPS Agreement.

Paragraph 5 (b) and (c) of the Ministerial Declaration deal with compulsory licensing.

It has been pointed out earlier that the relationship between articles 30 and 31 of the TRIPS Agreement must be seen as that of a general clause on the one hand and a special provision on the other hand. It must be considered a basic rule of statutory interpretation that a general clause cannot apply to cases which are explicitly dealt with. In this case, article 31(f) says explicitly that the authorised use should be predominantly for the domestic market. This implies that it should not be possible for a government to authorise the production generics for export to a foreign market.

It may well be that the negotiators of the TRIPS Agreement were not aware of the consequences of the provision or that they did not intend to prevent least-developed countries from importing generics. This, however, does not change the fact that article 31(f) provides an obstacle to the export of generics.

In order to solve this problem, it is necessary to change the text of the Agreement, rather than trying to argue around the clear wording of the TRIPS Agreement. Indeed, it is impossible to predict whether WTO Dispute Settlement Organs would adopt a permissive interpretation of the TRIPS Agreement\footnote{WTO “Communication from the European Communities and Their Member States” (12 June 2001) IP/C/W/280, Paragraph 13.} that would be contrary to the explicit text of the Agreement.

4 Compulsory Licensing and the Ministerial Declaration

Compulsory licensing and the problems caused by the TRIPS Agreement were the subject of discussions during the Ministerial Conference, and the Ministerial Declaration deals explicitly with the subject of compulsory licensing.
Paragraph 5 (b) and (c) of the Ministerial Declaration deal with compulsory licensing. It has been indicated earlier that paragraph 5(b) does not contain anything new, but that it is of rather confirming character in that it acknowledges that Member States are free in determining the grounds on which Members may grant compulsory licenses.

Paragraph 5(c) states:

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that the 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.

It is unlikely that anyone would challenge a determination by a developing country heavily hit by HIV/AIDS that they are faced with a national emergency or a circumstance of extreme urgency within the meaning of article 31(b). Indeed, the EU, in a paper prior to the Doha Conference, expressed the view that

"as for the level of HIV/AIDS infection reported in some developing countries, there would appear to be very good reasons for describing it as a 'national emergency' or as a 'circumstance of extreme urgency'."\(^2\)

The inclusion of paragraph 5(c) in the Ministerial Declaration is a step forward insofar as it gives legal certainty to developing countries hit by HIV/AIDS or other infectious diseases. It confirms that a health crisis of this nature can indeed constitute a "national emergency" or other "circumstance of extreme urgency" in terms of article 31(b).

This position is not without controversy. Alan O Sykes commented, in regards to paragraph 5(c), that

\(^2\) WTO “Communication from the European Communities and Their Member States” (12 June 2001) IP/C/W/280.
the apparent position of developing nations and their supporters is that they can
now declare a “national emergency” at their sole discretion on grounds of a
public health problem, and thereafter issue compulsory licenses for production
to serve their domestic markets without prior negotiation and with minimal
royalties payable to the patent holder.73

The concern expressed by Alan O Sykes may be overstating the effect of
paragraph 5(c). The paragraph does nothing more than clarify that Members accept
that a national health crisis constitutes a national emergency or other circumstances
of extreme urgency within the meaning of article 31 (b). In any event, Member States
always had the right to determine for themselves what constitutes a national
emergency of other circumstance of extreme urgency. It does in no way broaden the
ambit of article 31 (b) in a way that would be detrimental to patent holders. Indeed,
it does not in fact broaden the ambit of article 31 at all.

(b) Paragraph 6 of the Ministerial Declaration

Paragraph 6 of the Ministerial Declaration states:

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

By identifying the lack of access for the poorest of the developing countries as
one of the main problems of the TRIPS Agreement, the Ministerial Conference has
unquestionably taken a step in the right direction. However, one should not be too
enthusiastic, as it is by no means foreseeable additional solutions the Council will
propose.

Alan O Sykes wrote “the Doha Declaration opens the door wider to
compulsory licensing ... of patented pharmaceuticals by developing countries”.74

73 Alan O Sykes “TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution” John M
74 Alan O Sykes, above, 10.
Again, this may be overstating the effect of the Ministerial Declaration, given that the Ministerial Declaration does not go beyond what was already accepted. The Ministerial Declaration does not offer a concrete solution to the more fundamental problem of access to cheap pharmaceuticals for countries that cannot afford to produce their own generics. It is on this point that clarification is desperately needed.

5 Suggestion of developing countries to solve the problem constituted by article 31(f)

Faced with the problems of article 31(f), a group of developing countries suggested including the following provision in a Ministerial Declaration:

A compulsory licence issued by a Member may be given effect by another Member. Such other Member may authorise a supplier within its territory to make and export the product covered by the licence predominantly for the supply of the domestic market of the Member granting the licence. Production and export under these conditions do not infringe the rights of the patent holder.

This approach potentially offers a solution to the current problem, and is worthy of consideration. Implementing a provision which would allow other countries to give effect to compulsory licenses granted by other Member States would in effect largely repeal the current article 31(f).

This would allow Member States capable of producing generic medicine to export generic medicine without infringing patents granted to inventors. Under the current TRIPS regime, this option is only available when the producing country does not grant patent protection for the original product.

The suggested approach would not only allow developing countries greater and cheaper access to medicine, but might also promote the introduction of patent protection by developing countries before the end of the transition period provided for in the TRIPS Agreement. This is because the opportunity of exporting generics is currently limited by article 31(f). Developing countries capable of producing...
generics that wish to help other developing countries that are not capable of producing their own medicine, are only able to do so if they do not provide any patent protection at all. If they would be given the opportunity, as suggested by the group of developing countries, then countries capable of the production of generics could grant patent protection for medicine and legally supply other developing countries with generic medicine.

The Council on TRIPS was instructed to find an expeditious solution to the problem of exporting generics and should definitely take into account the solution offered by the developing countries, since the approach offers an opportunity which is fair to all parties involved. It is fair for the poorest developing countries because they would be granted an opportunity to legally access cheap medicine under the TRIPS Agreement, but it is also fair to the pharmaceutical industry, which loses no more in benefits than it would lose if the poorest developing countries were capable of producing their own generic versions of patented medicine, and granted a compulsory licence.

A further effect of this proposal suggested in the draft Ministerial Declaration of the group of developing countries would be that developing countries which are not able to produce generics on their own could start producing medicine together in the form of joint ventures. The problem under the current Agreement is that the joint production of pharmaceuticals by a number of developing countries would not be legal, due to the fact that the country in which the medicine is actually produced could not licence the production of medicine on its soil for the exportation to other countries. This new opportunity provides an additional argument for allowing Member States to give effect to foreign compulsory licenses.

Abbott recommended that developing countries that are subject to the transitional period and wish to have access to low-price medicines under patents granted elsewhere, should not provide patent protection for pharmaceuticals until they are required to comply with the TRIPS standards. Now that the least developed countries have an extended period of time until they are required to comply with the standards set out in the TRIPS Agreement, these
countries should follow this advice and not introduce patent protection for pharmaceuticals before the end of that extended period, unless the Members decide to implement provisions that allow Members to export generics to countries which cannot themselves afford the production of medicine.

The approach taken in the draft Ministerial Declaration by some developing countries is certainly an option that would help to improve the situation for least developed countries as well as encourage developing countries to introduce patent protection for pharmaceuticals. Therefore, the Council on TRIPS should adopt the approach taken by the developing countries and suggest a change of the TRIPS Agreement.

6 Compensation

A question which is directly linked to the problem discussed above is the question of compensation payable to the patent holder upon the granting of a compulsory licence. It might be arguable that if a future form of the TRIPS Agreement allows the exportation of generics, the patent holder should receive a consideration from the producing country on the one hand and from the importing country on the other hand. However there is no good reason why both the exporting and importing country should pay a consideration to the patent holder, where this amounts to a duplication in payment of compensation. The patent holder should not receive a consideration exceeding that which they would have received if the importing country had produced its own generics. In that case each country would have paid a consideration dependent on the amount of produced medicine. Since the overall amount of produced generics does not increase if one country produces generics in order to supply a second country, there is no greater impact on the legitimate interests of the patent holder. Therefore there is no reason for paying a consideration higher than that which the patent holder would receive if both countries, ie the producing and the importing country, would produce their own generics.

\[\text{Footnote: Frederick Abbott} \quad \text{"The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference" (Quaker United Nations Office, Geneva, 8 September 2001) 9.}\]
One important obligation Member States have with regard to the enforcement of intellectual property rights is that they must ensure availability of "judicial or other independent review by a distinct higher authority in that Member" of decisions regarding both the granting of a compulsory license and as well as the remuneration patent holders are entitled to as compensation.

Some Member States may suffer from a lack of administrative and judicial capacity necessary to guarantee an adequate standard of review. It is unambiguous that the obligation in the TRIPS Agreement to make available review "distinct higher authority in that Member" requires that the decision must be made by a national authority. However, this provision does not preclude developing countries from working together when examining decisions made with regard to compulsory licenses. Since the TRIPS Agreement only requires that the review must be undertaken by a national authority, it is therefore legal for developing countries to appoint foreign experts, for example from other developing countries, to the reviewing authority. Such an approach might not only help developing countries to reach an improved standard of review, due to the fact that they can "join forces", but it may also help to establish a certain standard of uniformity with regard to the decisions made by developing countries. Greater uniformity in decisions means that it is more likely a Dispute Settlement Body will accept the common praxis among developing Members in their decisions. Therefore, developing countries should take into consideration the appointment of experts from other countries to their reviewing authorities.

8 Conclusion

Although the Ministerial Declaration has brought some clarity to the area of compulsory licensing, the main issue remains to be solved, that is, whether Member States should be able to give effect to compulsory licenses issued by other Members. As argued above there are good reasons for adopting the approach taken by the developing countries.

77 See article 31(i) and (j) of the TRIPS Agreement.
It is important to ensure, however, that developing countries which intend to make use of their right under the TRIPS Agreement to issue compulsory licenses are not deterred from doing so by threats from other Members.

Until now no Member has ever made use of the opportunity to issue a compulsory license under article 31. When Thailand, having an adult HIV/AIDS infection rate of 5%, intended to make use of compulsory licensing in order to produce the drug Didanosine owned by Bristol-Myers Squibb, they reportedly faced considerable trade pressure from the US.78 Given that a decision in favour of compulsory licensing might have endangered trade relations between Thailand and its most important trading partner, the Thai Public Health Minister ultimately did not authorise the production of the drug.79

In the future Member States must stop putting pressure on developing countries wishing to use the compulsory licensing scheme, other than by using the means that are provided in compliance with the TRIPS Agreement to challenge national authorities’ decisions.

**B Parallel Importing**

1 Parallel importing in general

The increasing globalisation of businesses, trade, brands and products, coupled with the unequal distribution of wealth across the world has made the practice of parallel importing an attractive business. The term parallel importing refers to the practice of importing goods protected by intellectual property rights without the authority of the owner of relevant intellectual property rights, to be sold alongside those placed directly on the market by the owner of the same rights.80 The intellectual property right does not necessarily need to be a patent; it may be that the intellectual property right involved is a trademark or a copyright or even a combination of different intellectual property rights.

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79 Judy Rein, above, 402/403.
80 Stuart Jackson and Richard Kempner “Parallel Imports Into and Within the European Union” in Melvin Simensky, Lanning Bryer, and Neil J Wilkoff (ed) *Intellectual Property in the Global*
It is important to note that the imported products are not illegal products, i.e., counterfeited products, but original products that have been placed by the rights holder on the market in another country.

As mentioned above, parallel imports gain their attractiveness from the fact that not all countries in the world have the same standards of living, wealth, and income. Due to this fact, companies with international operations are making use of so-called “discriminatory pricing” practices.

Companies that operate across borders often charge different prices across different markets, if the elasticity of demand in different markets differs at a common price. The lower the elasticity in market is, the higher the product’s price will generally be. A further factor which has an influence on the prices companies will charge across different markets, is the average income, since consumers in higher income countries will usually be able to pay higher prices than consumers in countries with lower incomes. The practice of price discrimination can therefore lead to considerable differences with regard to the prices charged across different markets.

Although one might think that the benefits for developing countries which they can obtain by applying parallel importing strategies should be limited, this conclusion can not be drawn with regard to pharmaceuticals. Generally speaking, prices for the same medicine in developed countries will be higher than the prices charged in developing countries, so that it would not make sense to import medicine from developed countries. The reason why parallel importing strategies can still make sense for developing countries is that the prices for patented pharmaceuticals differ among the markets of different developing countries.

The theoretical approach behind parallel importing strategies is quite simple. It leads to competition on the market to which the products are imported and might encourage the patent holder to lower prices for products which are imported by either himself or the person which has obtained a license for importing the product to a specific market.


82 Alan O Sykes, above, 19.

83 Alan O Sykes, above, 19.
Criticism and lessons from the EU

Parallel importing occurs quite frequently throughout the world and has been permitted in many developed as well as developing countries. For instance, in the European Communities (EC) the European Court of Justice has applied the doctrine of regional exhaustion of rights to the entire EC and to different types of IPRs, in order to prevent market segmentation. Once a patented product has been sold in an EC country, it can be resold in any other member country without infringing on the IPR holder’s rights. Parallel importing has also held to be legitimate in Japan.

Critics of parallel importing strategies argue, that the legality of parallel trading policies might be detrimental in the long run to countries which need cheap medicine the most, rather than being beneficial to these countries. Critics argue that parallel pricing policies might prevent market segmentation and price discrimination by patent holders, thereby eliminating the key conditions for parallel pricing to be justifiable. While there seems to be a good logic behind this approach, the conclusion is nevertheless questionable.

One of the most important underlying structures of the European Union is the Common Market, the pursuit of which is guaranteed by article 30 of the Treaty of Rome. This article guarantees the free movement of goods within the Member States, regardless of whether or not a certain product has patent protection.

In 1974 the ECJ had to deal with the *Centrafarm v Sterling* case, in which the patent rights for a certain drug in several Member States were owned by Sterling Drug Inc, the parent company, and were licensed to several subsidiaries who then sold the drug in several Member States, including the UK, Germany, and the

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88 *Centrafarm BV v Sterling Drug Inc* [1974] 2 CMLR 480 (ECJ).
Netherlands. Centrafarm imported patented drugs that were legally put on the UK and German market by Sterling and its subsidiaries to the Netherlands, without Sterling’s consent. Sterling challenged this practice arguing that it would infringe their exclusive rights as the patent holder for the imported drug.

The ECJ found that a patentee cannot use his exclusive rights in a Member State to block imports of a product that has been marketed by either himself or with his consent in another Member State, irrespective of the existence of price differences and reasons for the difference of prices.

The ECJ supported its findings by stating that the exclusive rights to use an invention with a view to manufacturing industrial property and putting it into circulation for the first time was the reward given to the patentee in exchange for his creative efforts. Once this reward is reaped by the patentee, the free movement of goods prevails over the patentee’s interest in further controlling the product in circulation.

The Court noted two exceptions. Firstly, this principle does not apply where the patent holder in the importing country is economically and legally independent from the patent holder in the exporting country. Secondly, it does not apply in cases in which the product was not patentable and had been manufactured there by a third party without the patentee’s consent.

Later the ECJ had to decide a case in which goods were imported from a Member State where they had been sold with the patentee’s consent but where patent protection was not available. Merck was the patent holder for the drug “Moduretic” in the Netherlands, which was imported by the defendant into the Netherlands from Italy, where no patent protection for the specific drug was available. Merck itself tried to use its patent in the Netherlands against the importation of the drugs from Italy by the defendant, as the defendant sold the imported drug at lower prices than Merck. Merck argued that the importation of drugs from a Member State in which no patent protection was available, constituted an infringement of Merck’s patent in the Netherlands. Even in this case the ECJ decided that the patent holder (Merck) could

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not take action against the importation of the drug to the Netherlands, although the drugs imported in competition were imported from a jurisdiction under which the patent holder had not had the chance to collect a reward for its creativity due to the lack of patent protection.

The ECJ took the position that it is the patent holder’s decision where and under which circumstances he decides to market his product. In case he decides to market the product in a Member State which does not grant patent protection, then the patent holder must bear the consequences of his choice as regards the free movement of the product in the Common Market. 90

These decisions show that the principle of exhaustion is recognised within the European Union and that parallel imports are therefore perfectly legal.

If the critics of parallel importing policies would be right, one should expect that pharmaceutical companies would charge uniform prices in all of the EU Member States. Indeed, this would seem to be a highly probable result since the export of drugs within the European Union is relatively easy and not very costly, due to a sophisticated transportation infrastructure throughout Europe.

However, UNICEF, UNAIDS, the WHO and MSF have undertaken a survey in which they collected data on the supply of certain drugs used in the treatment of HIV/AIDS. 91 The survey was published in October 2000 and provides, amongst other data, the price for each medicine that was charged in the UK on the one hand and in Spain on the other hand.

One of the medicines compared was Amphotericin B, a drug which is of importance in connection with the treatment of infections that affect people living with HIV/AIDS. Amphotericin B is an relatively old, but difficult to manufacture drug and generic versions of the drug do not exist. The drug is marketed world-wide by Bristol-Myers-Squibb.92 Although the same company markets the drug all over the world, there was a considerable price difference between the price charged in the

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91 UNICEF, UNAIDS, WHO/EDM, MSF “Selected Drugs used in the Care of People Living with HIV: Sources and Prices” (October 2000) <http://www.unaids.org/acc_access/access_drugs/Drug_Database.htm> (last accessed 21 January 2002).
92 UNICEF, UNAIDS, WHO/EDM, MSF, above, Paragraph 1.2.
The price charged in the UK was US$5.20 for a 50mg unit, whereas the price for the same amount of the drug in Spain was only US$2.28. In other words, the price within one Member State of the EU was 56% below the price in the UK.

The survey revealed similar results for the oral version of Itraconazole, a drug which is important in the treatment of fungal infections affecting HIV/AIDS patients. Whereas the drug was sold for US$73.53 in the UK, the price charged for the same 150ml unit was only US$48.07. Again, a substantial price difference.

Further examples in the list show that the price differences within the EU are often substantial, although parallel importing is, as we have seen, legal within the EU. Substantial price differences within the EU cannot only be seen in the area of pharmaceuticals, but occur also with regard to different products.

Only recently, the EU Commission Directorate-General for Competition undertook a survey of the prices of cars within the EU, taking into account the prices before tax of a number of top selling cars in the Member States. The Commission found substantial price differences when comparing the prices of several models in Europe, with price differences ranging up to above 30 per cent.

The examples given from the European market indicate that even in markets where parallel pricing is legal and where the exporting and importing of products is relatively easy to manage, the possibility of parallel importing does not necessarily lead to uniform pricing across markets. On the contrary, these companies are able to maintain their differential pricing policies.

93 Unicef, UNAIDS, WHO/EDM, MSF, above, Paragraph 1.2 Table 2.
94 Unicef, UNAIDS, WHO/EDM, MSF, above, Paragraph 1.2 Table 2.
3 The legality of parallel importing

The legality of parallel importing strategies depends largely on the question of whether or not the lack of authority for the importation of the protected goods necessarily renders these strategies illegal. The question depends on whether or not countries decide to follow the principle of exhaustion. Where countries decide to do so, parallel importing strategies do not constitute an infringement of the patent holder's rights.

Under the principle of exhaustion of rights the exclusive rights guaranteed to patent holders by national legislation on intellectual property ends once the patent holder places the product on the market. The principle of exhaustion acknowledges the patent holder's right to exclusively determine the terms under which the patented product is put on the market, but that once the product has been distributed by the terms of his choice, the patent holder has been sufficiently rewarded for his efforts.\(^{96}\) Therefore, the patent holder shall not be given the right to further influence the use or resale of the product, and the patent holder's right is exhausted once it has been put on the market.

4 Parallel importing, TRIPS, and developing countries

A problem with regard to the current TRIPS Agreement is that the option of parallel importing is neither explicitly declared legal or illegal. Thus both positions have been argued to be right.

The subject of international exhaustion was one of the most difficult subjects during the TRIPS negotiations. Article 6 leaves the question open, and states that the matter of international exhaustion cannot be brought before the WTO's dispute settlement system.\(^{97}\)


\(^{97}\) Daniel Gervais The TRIPS Agreement: Drafting History and Analysis (Sweet and Maxwell, London, 1998) 61.
This solution is best described as an agreement to disagree, rather than a statement in favour of or against the practice of the exhaustion of rights principle. Because of this agreement to disagree, there has been a discussion about the legality of parallel importing strategies under the TRIPS Agreement.

What can be said is that article 6 itself does not make a statement on the legality of parallel importing, but that the decision depends on other articles of the TRIPS Agreement. In case one takes the position that parallel importing is illegal under the Agreement, one would effectively come to the conclusion that although parallel importing is illegal, it could not be challenged before the dispute settlement bodies.

Arguing in favour of the legality of parallel importing under the current TRIPS Agreement is problematic, due to the exclusive rights conferred to the patent holders under article 28(1)(a), which includes the guarantee of marketing and importing the product. Footnote 6 of the TRIPS Agreement makes it clear that all of the rights conferred on the patent holder are subject to article 6 of the TRIPS Agreement. Although article 28.1 and 2 establish the rights that must be granted to the patent holder, it does not say anything about when these rights are exhausted.

Looking at the rights which must be conferred to the patent holder by Member States in order to comply with TRIPS and the link between article 28 and article 6, established by footnote 6 of the TRIPS Agreement, the only conclusion can be that the TRIPS Agreement leaves the question of exhaustion to its Member States. Otherwise one would have a situation in which parallel importation would be illegal under the TRIPS Agreement, but in which the patent holders and Member States would not be able to enforce their rights in cases of parallel importing. This situation would be completely paradox.

The Ministerial Declaration therefore did nothing more than clarify the rights of Member States when saying in paragraph 5(d):

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of articles 3 and 4.
Although this passage has only clarifying character, it might well help to encourage developing countries in adopting parallel importing schemes the fear that this will cause costly litigation.

Nonetheless, the same that has been said about compulsory licensing is equally true with regard to parallel importing. Member States, regardless of whether or not they like the idea of parallel importing, should not try and deter other Members from making use of what is their right under the TRIPS Agreement.

VI CONCLUSION

This paper has looked at the two most important ways in which developing countries can access cheap medicine. Throughout, there has been an emphasis on the question of whether or not the Doha Ministerial Declaration goes further than simply confirming already accepted legal opinions.

Looking at the situation with regard to compulsory licensing and parallel importing, it seems that the Doha Ministerial Declaration does not go beyond this confirming character. Given this, it would seem that the position of developing countries has not been substantially improved.

It must, however, be considered a positive step forward that the community of WTO Member States has confirmed legal interpretations that are in favour of developing countries' interests.

One particularly positive aspect of the Doha Ministerial Declaration is that the Members expressly acknowledged that the TRIPS Agreement does not declare parallel imports as being illegal, so that developing countries do not need to fear costly litigation when making use of parallel imports by applying the exhaustion of rights principle.

With regard to compulsory licensing, there is a need to await the further suggestions of the Council on TRIPS. It has been shown that the approach taken by a number of developing countries, namely to give Members the right of giving effect
to compulsory licences issued by other Members, makes sense. Therefore, one can only hope, that this approach will be followed by the Council on TRIPS.

Although the Ministerial Declaration points towards the right direction, one thing needs to be kept in mind. That is, that developing countries will only have a fair chance to access cheap medicine within the TRIPS framework if they do not need to fear that making use of the TRIPS exceptions will lead to political pressure by other countries’ government or lobbyists. Other Member States have of course the right to challenge decisions by other governments within the WTO dispute settlement process as well as under national legislation. There can be no doubt that these are important rights. It must however be assured that a Member’s legitimate right to allow exceptions for patent protection are challenged only by the use of the WTO settlement mechanism, rather than trying to thwart these “through the backdoor” by underhand means.
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