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Patent Rights and Access to Medicines:

**Are patents really the only barrier for a good
health care in Developing Countries**

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Patent Rights and Access to Medicines:

Are patents really the only barrier for a good health care in developing countries

I. Introduction

As the 20th century dawned, disease cast a long shadow. A child born in 1900 could expect to live an average of 47 years, and infectious diseases took many children before they reached their teens.¹

As Roy Porter wrote in *The Greatest Benefits to Mankind, A Medical History of Humanity*:

"Throughout the 19th century, and well into the twentieth, patients were besieged by infections, commonly lethal to old and young alike - diphtheria, chickenpox, scarlet fever, rubella and a multitude of gastro- intestinal and dysenteric troubles claimed millions of infants. Being a family doctor in 1830 and even a century later meant being called out late at night to febrile patients, sweating copiously and hectic in their breathing, suffering from some infant fever or from pneumonia (called the "old man's friend" because it was often speedily fatal). Measles and the other epidemic diseases of childhood were still killers; tuberculosis, syphilis, diphtheria, meningitis, and post-partum sepsis were widely encountered."

Physicians had few weapons in their black leather bags to fight disease. The pharmacopoeia of the time included drugs such as mercury for syphilis and ringworm, digitalis and amyl nitrate for the heart, quinine for malaria, colchicum for gout, and plant-based purgatives.²

But since then much has changed.

¹ History of Pharmaceuticals

² History of Pharmaceuticals

On Christmas day 1891, Emil von Behring successfully treated a sick child with diphtheria antitoxin, signalling the eventual end of this disease.³

In 1894, a young chemist called Felix Hoffman joined the pharmaceutical division of the German medical company Bayer and began searching for compounds to ease the pain of his arthritic father. He came upon salicylic acid, originally derived from willow bark, and made a chemical derivative to reduce the gastric distress it caused, tested it, and developed a commercial method of producing it. The result was aspirin.

In 1928 Penicillin, the great break through against infection of the 20th century, had been discovered. This was the beginning of modern medical history. In the 1950s, known as the decade of antibiotics, new breakthroughs - to treat tuberculosis and other infections - followed swiftly.⁴

Due to new medicines average life expectancy in the U.S. has increased from 47 years in 1900 to more than 76.5 years today.⁵

In the Last 30 years Life Expectancy has risen from 74 to 79 years in Norway, from 71 to 78 in Germany and even from 73 to 81 years in Japan.⁶

In 2000 all the Human genes were identified by the Genom project.⁷

This paves the way for a new dimension for new personal medicines.

A personal medicine is a medicine that has been adjusted to the genetic characteristics of people. It is like custom made clothes that are suitable to the one they are made for, so the user of the medicine has fewer reasons to worry about the negative side effects of the medicine.⁸

Therefore it seems that the whole Human Race can look into a bright future of rising life expectancy and new medicines.

But really the whole Human Race? Have the diseases Roy Porter mentioned in his book really been beaten all over the world?

³ History of Pharmaceuticals

⁴ History of Pharmaceuticals

⁵ History of Pharmaceuticals

⁶ UNDP Global Development Report 2003

⁷ German Human Genom Project

⁸ Personal Medicines: Estonian Genome Project

Whereas life expectancy has been increasing in developed countries in the last 30 years, even from a higher base, life expectancy in developing countries is falling dramatically.

In the last 30 years, life expectancy has fallen in South Africa from 53 to 47 years, in Botswana from 56 to 39 years and in Zimbabwe from 56 to a humble 33 years,⁹ which is therefore even under the 47 years mentioned as life expectancy in 1900 in the US.

Today a newborn child in developing countries has a probability of 20 % of reaching 65 years, whereas the chance for a child in developed countries is 90 %.¹⁰

Simultaneously to the start of the age of biotechnology in developed countries, still 8 million people yearly are infected with Tuberculosis and annual mortality worldwide is estimated at 3 million,¹¹ 95% of whom live in developing countries.¹²

Tuberculosis is still accounting for 7% of total worldwide mortality,¹³ although with proper treatment almost everyone can be cured.¹⁴

From the 1920's to the 1980's as a result of immunization the number of cases of diphtheria in the United States dropped from 150.000 to 24.

At the same time mortality dropped from 13.000 death to 2.¹⁵

Although this immunization is available, still 1,7 million people worldwide died of Diarrhoeal in 2002,¹⁶ because of lack of this treatment.

The same applies to Malaria.

This disease was still widespread in Europe and the US until the 1950s.

In 1947 15,000 malaria cases were reported in the US. By 1951, malaria was considered eradicated from the United States¹⁷ due to the use of DDT against the mosquito fly and new medicines.

With the success of DDT, the advent of less toxic more effective synthetic antimalarials, the World Health Assembly in 1955 made an ambitious proposal for the eradication of malaria

⁹ UNDP global Development report 2003

¹⁰ UNDP global Development report 2003

¹¹ Tuberculosis by James Li

¹² History of Tuberculosis

¹³ Tuberculosis by James Li

¹⁴ Frequently asked questions about Tuberculosis

¹⁵ Diphtheria by Kenneth Todar University of Wisconsin-Madison Department of Bacteriology 2002

¹⁶ WHO World Health report 2002

¹⁷ The History of Malaria, an Ancient Disease by Centers for Disease Control and Prevention

worldwide. But difficulties in obtaining sustained funding from donor countries and lack of community participation made the long-term maintenance of the effort untenable.¹⁸

Thus today for example in Botswana there are still 48.000 malaria cases per 100.000 people every year,¹⁹ and 1.2 million people mainly in developing countries, die per year because of malaria.²⁰ This curable disease still accounts for 9 % of total mortality in Africa.

But not only are the old diseases not defeated in developing countries. Also new diseases are hitting the developing countries much harder as the developed countries

An example for this is the AIDS epidemic.

In the beginning AIDS seemed to be incurable and deadly in a short and inescapable way for all people.

But since 1996, in rich countries, HIV/AIDS is no more a fatal disease. The advent of effective Antiretroviral Treatment (ART) transformed it into a chronic disease manageable although with some difficulties.²¹

But in 2003 there were still 3 million people dying of AIDS per year,²² with Sub Saharan Africa bearing the brunt of the epidemic.

In Botswana 35 % of the population are infected, in Zimbabwe 25 % and in South Africa 20 % of the population are living with this, for them still fast deadly disease.²³

For comparison, in North America and Western Europe the number infected is under one percent.²⁴

But whereas in North America and Europe the coverage of Antiretroviral Therapy available for people in need is between 75% and 100 %²⁵, in Africa just 0.1 % of the 28.5 million people living with AIDS have access to HIV Drugs.²⁶

In these countries 50 percent of the population lacks access to even the essential drugs.²⁷

¹⁸ The History of Malaria, an Ancient Disease by The Centers for Disease Control and Prevention

¹⁹ UNDP global Development report 2003

²⁰ WHO World Health report 2002

²¹ AIDS, Primary Health Care and Poverty p.7 by Maurizio Murru

²² Aids Epidemic update December 2003 p.4 by UNAIDS

²³ HIV/ AIDS Implications for poverty reduction p.3 by UNDP 2001

²⁴ UNDP Statistical Fact sheet

²⁵ Treating 3 million by 2005: Making It Happen, The WHO strategy p.4

²⁶ UNDP Statistical Fact Sheet

²⁷ The Rationale of Essential Medicine: Access, Quality and Rationale Use of Medicines and Essential Drugs by WHO

The question arises why the people in developing countries do not have access to the medicines.

Needless to say the people in these countries require the drugs, but the problem is that they cannot afford them.

For example, the cocktail of antiretrovirals costs between \$ 10.000 and \$ 12.000 per patient per year.

This is a sum unbearable for people in Sub-Saharan Africa where the average income is \$1,600 a year.²⁸

In developed countries a health insurance would pay for the medicine, but in these countries no insurance system exists.

But there is hope, because an Indian manufacturer offers the same drug for just \$ 350.

However, this product cannot be sold in many countries because the inventor has a patent there and the generic drug therefore would infringe the rights granted to the inventor under the international patent system.

Therefore, the inventor has not to fear competition and can sell the drug at any price he likes.

Of course it is only fair to grant the original manufacturer a patent for his product, because he invented it and should therefore be rewarded with a patent for his efforts.

The question is, however, is it really fair that the rights owner sells the product at any price he wants and therefore determines who has access to this life-saving medicine and who has not.

Many people think that this is not fair.

In their view patent rights are an instrument of western pharmaceutical companies to charge, protected by these patents, exorbitant prices.

Until 1994 the problem was rather small, because until then it was the decision of the national states to decide what can be patented or if there should be a patent system at all in their country.

²⁸ Immigration Laws: September, 2000 - Number #22: Africa: Development

Accordingly many developing states decided not to set up a patent system, at least for medicines.

But in 1994 this situation changed due to the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

The TRIPS agreement requires from the member states of WTO to establish a patent system in their country and it is not anymore allowed to exclude certain fields of technology from patentability.

Before TRIPS there were of course other international agreements which addressed the aspects of Intellectual Property Rights.

But the TRIPS Agreement is different from all other earlier treaties.

As you can see from the meaning of the treaty, TRIPS is a part of another treaty which regulates trade. So the TRIPS Agreement is an annex treaty to the GATT Agreement which regulates international trade conditions.

So this agreement managed to link international trade with aspects of intellectual property rights.

A lot of countries want to be part of the GATT Agreement and today 147 countries are party to the World Trade Organisation, which is the host institution to the Gatt Agreements.

This is because under the GATT agreement you can export goods under especially favourable conditions, which are of course favourable for your economy.

These international trade conditions and especially the special rights granted under the GATT Agreement are a must for all countries that don't want to be left behind in the era of globalisation.

In 1994 the problem arose that developing countries which intended to benefit from the advantages of this trade system had also to accept the "disadvantage" of establishing a patent system.

If the states did not follow these new rules they could be penalised by the WTO, with trade sanctions or higher import tariffs and in the last resort could even be expelled from the WTO.

Thus from 1994 all developing countries that were party to the WTO were not free anymore to decide on their own, whether they wanted medicines to be available for all people at the

cheapest possible price, or if they wanted to encourage the development of new drugs and accept that drugs might be more expensive and therefore not affordable to their people anymore.

In 2002 South Africa seemed to be the first country where the negative consequences of the new patent system were clearly visible.

South Africa then declared its intention to allow the local production or the purchase of generic versions of antiretroviral for AIDS on the international market, to make the drug more affordable for its people.

In response to this action, a number of powerful pharmaceutical companies took the South African government to court because the proposed law, if adopted was likely to infringe their IP property rights, .

It seemed that the TRIPS Agreement was a legal instrument which blocked the access to lifesaving medicines in order to get more profits for international pharmaceutical giants, an instrument which found no balance between the needs of the people and the interests of the inventor.

For many critics it seemed to be clear that patents, especially the TRIPS Agreement and the pharmaceutical industries are the main and only cause hindering people in developing countries accessing the new medicines of the world and therefore achieving a life expectancy as high as in developed countries.

The patent system under TRIPS just seemed for them to have the purpose of reallocating even more profits for western pharmaceutical companies at the expense of lives of humans living in developing countries.

But on April 18th 2002 the pharmaceutical companies abandoned the case, as a result of massive public pressure.

And in 2003 the WTO adopted a paper resulting in a new and possibly more flexible patent system.

Nevertheless, the question remains if patents are still the main obstacle in achieving access to medicines in developing countries, or if there are also other maybe even far more severe hurdles on the track to a better health care for people in developing countries.

The question arises whether there is really a clash between the patent rights of western pharmaceutical companies on the one side and the health needs of people in developing countries on the other.

Maybe a balance can, or even has already been found by the TRIPS Agreement.

The scope of this paper is therefore threefold:

- 1. I want to analyse what problems are arising with the adoption of TRIPS Agreement between the access to medicine on the one side and the patent owner rights on the other side.
Therefore I will examine the legal framework of TRIPS and it's possible flexibility concerning public use for medicines**
- 2. I want to illustrate what alternatives for an international patent system are available and whether these solutions are more adequate for the needs of developing countries**
- 3. I want to take a look at the other restraints that make the health care in developing countries difficult**

II. TRIPS AGREEMENT

1. Patent Protection before TRIPS

Prior to the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property concluded in 1883 and revised several times since then, governed international patent relations. The Paris Convention, however, has not been revised since 1979 and lays down few rules regarding patents. It does not, for example, require that patents be available for any particular areas of technology, nor does it require any minimum term of protection or set of exclusive rights to be conferred on patent holders.²⁹

It should be noted that many of today's developed countries used this flexibility of the Paris Convention and excluded pharmaceutical products from patent protection until quite recently:

Germany until 1968; Switzerland until 1977; Italy until 1978; Spain until 1992; Portugal until 1992; Norway until 1992; Finland until 1995, and Iceland until 1997.³⁰ Under the old Paris Convention this was still possible.

Prior to TRIPS a lot of developing countries, like for example, Jordan and Mongolia, still had no product patents for pharmaceuticals.³¹

A study undertaken by WIPO in 1988, for the negotiating group that was dealing with TRIPS in the Uruguay Round, revealed that of the 98 Members of the Paris Convention, 49 excluded pharmaceutical products from protection.³²

Some others like Brazil, Argentina, Mexico and the Andean pact countries introduced laws in the 1970s, but with weaker patent protection in the pharmaceutical sector.³³

Another example for an existing but weak patent system for medicines is India. Its patent law followed the old German system of allowing process patents but not product patents.

In such a process patent system, you can get a patent on your way of fabrication, that means the method you are using can be patented, but not the resulting product.

In a system of product patents, however, you can get a patent on the resulting product.

²⁹ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.24 by Lee Gillespie-White, Venus Griffith, Albena Petrova, Stetson Sanders, Paul Salmon

³⁰ Post Trips Options for Access to Patented Medicines in developing countries p.3 by F.M. Scherer, J. Watal

³¹ Post Trips Options for Access to Patented Medicines in developing countries p.3 by F.M. Scherer, J. Watal

³² developing countries and International Intellectual Property Standard Setting p. 9, by Peter Drahos study prepared for the United Kingdom Commission on Intellectual Property Rights, February 2002

³³ Access to Medicines and Public Policy Safeguards under TRIPS p. 25 by Dr.K.Balasubramaniam

Therefore you can bar a competitor from producing the same product, even if he finds a different way of fabrication.

This difference is extremely relevant for medicines, because these are based on active ingredients. If you develop a new agent, you can bar everyone from producing a similar drug based on this ingredient, even if he finds another method to manufacture it.

Thus a system of product patents is much stronger than a process patent system and gives the rights owner a much better chance to exploit his invention without any competition.

If these types of patents are combined, as it is allowed in some countries, competitors face even bigger hurdles, because they cannot produce the patented product with a new manufacturing solution and they cannot use the patented process to produce any new product.

Another way of encouraging competition, is to shorten the protection period granted to the rights owner. So India³⁴, as well as some other countries, in addition to only allowing process patents, also granted protection for only 7 to 10 years,³⁵ whereas the normal period is 20 years.

Another exception that could be made was to include a so called local working requirement in a patent act.

This means that the patent holder will lose his patent protection in a country if he does not manufacture the product locally. Imports of finished products do not qualify as such a working of the patent.³⁶

Such a rule was often used by developing countries to promote the transfer of technology into these countries. However, it was often not economically sensible to build up a factory in a small developing country just to avoid the loss of patent protection there.

Therefore, the patent owners often lost their patents in developing states, or even did not apply for any right of protection there.

So all things considered, patent protection in developing countries for medical products was rather weak.

³⁴ Access to Medicines and Public Policy Safeguards under TRIPS p.24 by Dr.K.Balasubramaniam

³⁵ UNCTAD, "Review of Recent Trends in Patents in developing countries" TD/B/C.6/AC.5/3, 1981 cited in Access to Medicines and Public Policy Safeguards under TRIPS p.24 by Dr.K.Balasubramaniam

The reason for this can be seen in two aspects.

1. The economic side

The economic rationale behind patents is to reward the developer for his former conducted research efforts.

The developer has to publish his research results and in exchange he gets the right to exclusively exploit the economic value of his invention.

For the public, such a decision; to reward the inventor with such a right; makes sense because firstly, the new revealed knowledge is now open to everyone and can form the base for future developments and secondly, other inventors will be attracted because they know they will be rewarded for their efforts.

The problem of patents however, is that these products have to be paid at higher price by the consumer due to lack of competition.

So a balance has to be found between the reward for the inventor and the financial loss of the rights of holders.

However, this system of balance between consumer losses and company profits, applies only for a pure national system where inventor and consumers live in the same country.

If the paying consumer and the earning developer are living in different countries however this view changes.

In such a situation the profit earned abroad is more than a necessary evil, and the consumers surplus conferred on foreign consumers does not count at all.³⁷

On the other hand, a country has less incentive to grant patents for products which are not developed in its own country, because there is only a financial loss for its economy if the royalty is paid to a company abroad.

In most countries and under most international agreements, however, it is not allowed to make a difference between national and foreign inventions.

Therefore, a country had to decide whether to support the inventors or its consumers.

And if you look at the numbers it becomes clear why developing countries chose to support their consumers.

Simply for the reason that they do not have many national developers and therefore intellectual property rights owners.

³⁶ Access to Medicines and Public Policy Safeguards under TRIPS p. 24 by Dr.K.Balasubramaniam

³⁷The Political Economy of Intellectual Property Treaties p.1 by Suzanne Scotchmer

97 % of all patents worldwide are owned by companies or people in developed countries.³⁸

According to calculations by UNIDO³⁹, 46 of the 133 non-OECD countries, that is about one-third, imported 100 percent of their requirement of medicines in 1989. This increases up to about two-thirds when we include all nations importing more than 50 percent of consumed medicines by value. Only 31 developing countries (or less than one-quarter) supplied three-quarters or more of their consumption domestically.⁴⁰

India and China were the only developing countries amongst the 20 largest exporters of pharmaceutical preparations in the world during 1990.⁴¹

Therefore it is clear why developing countries do not have an interest in installing a strong patent system.

Such a system would be beneficial for the patent owners and these are mainly foreign countries.

2. The Human Rights Side

Of course the economic view was not the only reason for this rather retentive patent legislation.

Developing countries were especially reluctant to grant patents for medicines. The reason for this reluctance is easier to understand if you look at the different interests in drugs and other patented goods.

So for example, a company invents a new computer and gets a patent in a developing country. Afterwards, it will exploit this patent by charging high prices. The result will be that less people can afford the new computer.

However, the people can buy older computers or maybe even do the work by hand.

³⁸ Patents Trade and development: How legal protection affects developing and developed countries by Jonathan Hepburn & Geoff Tansey

³⁹ United Nations Industrial Development Organization (UNIDO) (1992): *International Yearbook of Industrial Statistics, 1992*, Vienna.

⁴⁰ These were Angola, Argentina, Bangladesh, Brazil, Colombia, Chile, China, Ghana, India, Indonesia, Iran, Malawi, Mexico, Morocco, Pakistan, Papua New Guinea, Paraguay, Peru, the Philippines, Republic of Korea, Sierra Leone, Solomon Islands, South Africa, Syria, Taiwan, Thailand, Turkey, Uruguay, Venezuela, and Yugoslavia.

⁴¹ United Nations Industrial Development Organization (UNIDO) (1992): *International Yearbook of Industrial Statistics, 1992*, Vienna.

Even though this result it is not satisfying, the developing country can accept it because it is an inconvenience, but it might result in more patents and maybe even more foreign direct investments.

The question is what happens if the patented good is a new life-saving medicine?

If the state grants a patent, the rights owner probably will charge higher prices and this will probably result in less people being able to afford the medicine.

It is debatable whether you can accept such a result, because in this case if people can not afford the medicine due to higher prices resulting from patents, they will become ill or even die.

Therefore you can not simply compare patent legislation for medicines to patents for other high tech products.

Under a patent agreement therefore, a different solution has to be found for medical patents, so that a state can make an exception in such an emergency.

The question of if and how this is possible under TRIPS will be examined in the following paragraphs.

2. Patent Protection under TRIPS

2.1. The Negotiating Process

The different interest clashing in the negotiations for the TRIPS agreement can at best be shown by citing some numbers. In 1995 the United States spent around \$167 billion on R&D, whereas the whole developing countries accounted for only a third, namely \$ 57 billion.⁴²

Another fact is the number of patents registered. In 1997 under the Patent Cooperation treaty there were 54.000 Patents filed. The USA alone filed 22.000 Patents or 41,8 % of the total. Western Europe filed another 22.000 or 41.9 %. Japan, Australia, New Zealand and Canada together filed 7.000 patents. So in total these developed countries stand for 96,5 % of all patents filed under the Patent Cooperation Treaty.⁴³ The rest of the world is therefore only a marginal factor in

⁴² "Intellectual Property Rights and Economic Development" page 12 by C.A. Primo Braga, C. Fink, C. Paz Sepulveda

⁴³ Numbers "Intellectual property rights and globalization: implications for developing countries" page 3 by Calestous Juma

the development of new patents. Patenting only becomes of interest to a country when it has developed the capacity to innovate.

Therefore when in 1986 the agenda of the new Trade agreement was determined, though the introduction of Intellectual Property rights was approved as one of the “new issues” at the Ministerial Meeting in Punta del Este, it was limited in principle to the issue of trade in counterfeit goods. Until 1989 developing countries refused to enter into detailed negotiations on standards,⁴⁴ probably to retain the freedom to set the standard of protection suitable to their individual economic situation.

But especially the threat of trade sanctions by the US under the “special 301 “ Section of the US Trade Act lead to a constrained change in the policy of many WTO member states.

When finally agreeing to enter into negotiations about Intellectual Property Protection, the developing countries faced a lot of obstacles in reaching a fair agreement.

The first obstacle was the participation of many developing countries. Of 65 developing country GATT/WTO members when the Uruguay Round began, 20 did not even have delegations in Geneva.⁴⁵ Furthermore, developing country delegations were notably smaller than those of the industrial countries. In 1987, when the Uruguay Round began, the EU had in Geneva a delegation of 10 and EU member states’ delegations included an additional 57 persons. The US delegation numbered 10, the Japanese, 15. Only 12 developing countries had delegations of more than three persons.⁴⁶

Another point is that key parts of the negotiation were conducted in a small drafting group composed of five developed (EU, USA, Japan and Canada regular members) and five developing countries (Brazil, Argentina and India regular members), with occasional reference to a broader reference group of ten countries per side.⁴⁷ With India and Brazil there were two of the major R&D spenders

⁴⁴ The Trips agreement a guide for the south p. 8

⁴⁵ Implementation Of Uruguay Round Commitments: The Development Challenge p. 4 Footnote 4 by J. Michael Finger and Philip Schuler

⁴⁶ Implementation Of Uruguay Round Commitments: The Development Challenge p. 4 Footnote 4 by J. Michael Finger and Philip Schuler

⁴⁷ TRIPS Consequences for developing countries Implications for Swedish development cooperation page 16 by Marie Byström & Peter Einarsson

among developing countries⁴⁸ involved in the negotiating process, who therefore as well had a serious interest in stronger rights.

So even 2 of the 5 developing countries which could participate in the negotiations, had at least divided interests, whilst the core of the developing countries were not represented at all.

Even if the negotiation round was at least in theory evenly divided between developed and developing countries, the power was obviously on the side of the developed countries. The negotiating capacity of developing countries was not only weak due to their vulnerable economic position, but also because of the considerable difference in the specialist knowledge available to them in the conduct of extremely complex discussions.⁴⁹ Many delegations from developing countries were small and lacked persons with the technical backgrounds needed to participate effectively. A competent diplomat without the backing of a technical staff was not an effective delegation.⁵⁰ An indicator of the lack of involvement by developing countries is that, for example of all the written proposals, comments, etc. circulated at the WTO during the Uruguay Round negotiations, less than 3 percent were submitted by sub-Saharan countries.⁵¹

Finally, the composition of each working group was decided at the discretion of the presiding officer, rather than as the result of a consensus or of a search for a balanced representation of countries at different levels of development.⁵²

This uneven negotiating process is even more alarming if you know that other than in prior WTO rounds the member states had no choice to accept just part of the new agreements. The alternative available at the end of the prior Tokyo Round – to sign some agreements but not others – was taken away.⁵³ Therefore developing countries can only accept the package as a whole or stay behind.

Countries that chose to remain GATT members but opted not to accept the Uruguay Round package, that was incumbent on WTO members would have been

⁴⁸ “Intellectual Property Rights and Economic Development” page 12 by C.A. Primo Braga, C. Fink, C. Paz Sepulveda

⁴⁹ “The Trips agreement a guide for the south” page 10

⁵⁰ “Implementation Of Uruguay Round Commitments: The Development Challenge” page 4 by J. Michael Finger and Philip Schuler

⁵¹ ⁵¹ “Implementation Of Uruguay Round Commitments: The Development Challenge” page 4 by J. Michael Finger and Philip Schuler

⁵² “The Trips agreement a guide for the south” page 10

⁵³ “Implementation Of Uruguay Round Commitments: The Development Challenge p. 5 by J. Michael Finger and Philip Schuler

discriminated against, they would not be owed the new obligations that WTO members accepted at the Uruguay Round.⁵⁴ So the content of the new treaty is obligatory to all member states.

If the content, despite these uneven premises, is fair and whether it has a negative impact on the access to medicines will be examined in the following chapter.

2.2. The Content of the Treaty

2.2.1. General Provisions

In the first chapter, the TRIPS agreement opens with regulations that are applicable to all intellectual property rights and not only to patents.

Articles 3, 4 and 5 include the basic principles of all newer international intellectual property rights and lays down the principle of national and most-favoured-nation treatment of foreign nationals. While the national treatment clause forbids discrimination between a Member's own nationals and the nationals of other Members, the most-favoured-nation treatment clause forbids discrimination between the nationals of other Members.⁵⁵

As a result a state is not allowed to distinguish anymore between national and foreign rights owners.

Article 6 TRIPS allows member countries to provide for the international exhaustion of rights and, therefore, to admit parallel imports.

The consequences of parallel imports and the difference between the system of national and international exhaustion will be scrutinized in Section 2.3.2.

The Objectives of the TRIPS Agreement are laid down in the Preamble of the TRIPS Agreement and in Art 7 and 8.

The Preamble states that the agreement should:

reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade

⁵⁴ Implementation Of Uruguay Round Commitments: The Development Challenge p. 5
by J. Michael Finger and Philip Schuler

⁵⁵ Trips : A more detailed overview of the TRIPS Agreement

These objectives are further clarified in Article 7 which states 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 a balance of rights and obligations.

This argument that the absent of patent rights is a main barrier for the transfer and dissemination of technology from developed into developing countries is often seen as one of the main vindications for western diplomats for the installation of patent rights.⁵⁶

Therefore I will briefly examine whether this argument is true.

2.2.1.1. Influence of Patent Rights on Economic Growth

The most important studies of patents and innovation generally have been inconclusive regarding a correlation between patents and invention.⁵⁷

So you can read that “Despite the complexity in the many relationships involved, empirical evidence supports an optimistic view about the potential impacts of stronger global IPR on international economic activity, innovation and growth and development. It is tempting to supplement these observations by pointing out that industrialized countries, which have strong systems of intellectual property protection, remain the overwhelming source of new invention and artistic creation. Developing economies with weak IPRs generate few patentable inventions. These facts support the view that IPRs and innovation go hand in hand and that IPRs are an important factor in technological and cultural development.”⁵⁸

Although these facts are not deniable, even the author questions this result.

He himself admits that ” the difficulty with strong conclusions is that counter examples are abound.”⁵⁹

⁵⁶ The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p.5 by F. M. Abbot

⁵⁷ The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p.5 by F. M. Abbot

⁵⁸ Intellectual Property Rights in the Global Economy p.169 by K.Maskus

⁵⁹ Intellectual Property Rights in the Global Economy p.170 by K.Maskus

So Japan is commonly thought to have engineered its phenomenal technological “catchup” by acquiring foreign technologies at concessionary terms, a process buttressed by a system of industrial property rights favouring the dissemination over its creation. Korea was able to absorb and develop considerable amounts of adaptive technological information in the absence of meaningful IPRs in the 1970s and early 1980s.⁶⁰

Therefore some authors relativize this optimistic view by stating that at least “nowhere do we find evidence that stronger IPR protection reduces growth.”⁶¹

Still there shall even be existing evidence that suggests “that IPR protection has a positive impact on growth, which is often significant.”⁶²

But in the same article it is also stated that this positive and significant relationship between IPR protection and growth in low-income countries clearly does not result from the encouragement of domestic R&D and innovation.⁶³

Two other authors, Thompson and Rushing⁶⁴ (1996), in their paper, state that the impact of increased IPR protection is more beneficial once a country has reached a particular level of development, as measured by initial gross domestic product (GDP) per capita. Their results indicate a break point at an initial level of GDP of \$3,400 (1980 dollars). For countries below this level, no relationship between IPR protection and growth is found, but above it a positive and significant relationship is found.

I think the most honest conclusion is that, while there are indications that strengthening intellectual property rights can be an effective means of inducing additional inward Foreign Direct Investment, it is only a component of a far broader set of important influences.⁶⁵

⁶⁰ Intellectual Property Rights in the Global Economy p.170 by K.Maskus

⁶¹ Intellectual Property Rights and Economic Growth p.17 by Rod Falvey, Neil Foster and David Greenaway

⁶² Intellectual Property Rights and Economic Growth p.4 by Rod Falvey, Neil Foster and David Greenaway

⁶³ Intellectual Property Rights and Economic Growth p.17 by Rod Falvey, Neil Foster and David Greenaway

⁶⁴ “An Empirical Analysis of the Impact of Patent Protection on Economic Growth,” *Journal of Economic Development* by Thompson, M. A. and F. W. Rushing (1996)

⁶⁵ The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer p.29 by Keith E. Maskus

Emerging economies, therefore, should recognize the strong complementarities among IPRs, market liberalization and deregulation, technology development policies, and competition regimes.⁶⁶

The positive impact of IPR protection on growth that works indirectly through trade and inward FDI can be offset by a negative impact slowing the diffusion of knowledge and discouraging imitation.⁶⁷

So in order to get the best possibilities for future economic growth, officials of developing countries should use the maximum flexibility the TRIPS Treaty offers.

Article 8 seems to be such an article which offers flexibility and therefore might be a very important rule for the access to medicines.

Article 8 paragraph 1 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.*

And in paragraph 2 :

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

Even though these two paragraphs sound promising, other than in prior agreements,¹ these measures always have to be in consistence with the

⁶⁶ The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer p.29 by Keith E. Maskus

⁶⁷ Intellectual Property Rights and Economic Growth p.17 by Rod Falvey, Neil Foster and David Greenaway

agreement. Therefore they grant the states only a limited leeway. This provision is more a letter of intent than a hard legal term that can be enforced in a court.

But nevertheless these statements could be important for the interpretation of the treaty.

To what extent such a clause can be important for the interpretation of TRIPS will be shown beneath.

First of all, for all disputes arising under TRIPS between member states the WTO has installed a dispute settlement system.

Under this dispute settlement system it is accepted that it serves “to clarify the existing provisions of the Agreements in accordance with the customary rules of interpretation of public international law.”⁶⁸

Therefore, the TRIPS Agreement has to be interpreted within the concepts laid down in the Vienna Convention on the Law of the Treaties.

And Article 31 of this Treaty states that:

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

2. the context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annex:

The TRIPS Agreement has to be interpreted in a way that is consistent with the statements made in these Articles.

Therefore, the preamble, Articles 7 and 8 provide a guideline for the interpretation and application of the Agreement and constitute the legal basis for the members to reserve domestic control over the rights granted under TRIPS. This is especially important because Article 8 explicitly mentions public health needs as a reason for the limitation of rights.

The purpose of the TRIPS agreement as an instrument that should not avert the access to public health was further clarified in the DOHA Agenda.

⁶⁸ Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the WTO Agreement, adopted on 15 April 1994, LT/UR/A-2/DS/U/1, Article 3.2.

It is important to know that this Agenda was adopted by the Ministerial Conference and Article IX:2 of the WTO Agreement provides that the Ministerial Conference and the General Council of the WTO have the “exclusive authority to adopt interpretations” of the WTO Agreement.

Therefore such a statement is very important for the future understanding of the TRIPS Agreement.

The DOHA Declaration states the following:

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.⁶⁹

Nevertheless, as I set out before, these limitations have to be consistent with the other provisions of the agreement. An interpretation guideline can of course only be used where there is a lack of clarity and room for interpretation in the treaty.

Article 8 gives no exculpation from the other rules laid down in the treaty but it can be helpful to “broaden” the exceptions of the treaty if it comes to public health needs.

2.2.2. General Provisions about Patents

The provisions only relevant to patents can be found under chapter 5 of the TRIPS Agreement.

The first Article in this chapter is Article 27 paragraph 1 which requires member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination,

⁶⁹ Declaration on the TRIPS agreement and public health

subject to the normal tests of novelty, inventiveness and industrial applicability.

2.2.2.1. Inventiveness of a product

The main criterion for a patent is that it is new, involves an inventive step and is capable of industrial application.

Already this examination of the novelty of a product can be a huge barrier for a developing country.

In fact, even in the US, thousands of patents are granted each year for minor, purely trivial developments, or for substances (including genes) that already exist in nature and which have merely been *discovered* but not *invented* by their would-be “owner”.⁷⁰

That happens despite the fact that the US Patent and Trademark Office has an annual budget of \$1 billion and a staff of more than 3,000 scientists, engineers and legal experts.⁷¹

The equivalent office in Pakistan, with half the population of the US, has an annual budget of \$80,000 and seven technical staff. So there might be the risk that patents are especially easily accessible in developing countries. To prevent this and get at least a basic patent infrastructure in developing countries, a study comes to the result that on average each country would need \$1.5 to \$2 million to build a basic infrastructure to implement TRIPS⁷² – money that is often unavailable.

Even if the system would be as good as in the US, the system would be far from perfect.

In the US, 46 per cent of patents when challenged, were found to be invalid.⁷³ In countries with overburdened patent offices and few specialised lawyers, it is likely that a considerable number of patents are invalid but not challenged in the courts.

⁷⁰ Patent Law Trips and R&D Incentives: A Southern Perspective p.8 by C. Correa

⁷¹ Patently absurd ! *The Economist*, 21 June 2001

⁷² Patently absurd ! *The Economist*, 21 June 2001

⁷³ Patents, Pills and Public health: Can TRIPS deliver? p. 18 by Martin Foreman

The median cost for an US patent litigation is \$1.2 million, per side, and the costs of litigation in complex cases is much higher.⁷⁴ A sum unbearable for developing countries.

This problem is especially important if it comes to the aspect of Traditional medicines.

Today, a lot of new medicines are based on traditional knowledge about herbs still available in isolated spots in developing countries.

Although the direct herbs cannot be patented, industrial produced substitutes can be patented, especially if there seems to be a new entity and a new use for this entity. Such exploitation of traditional medicines can only be stopped if there would be databases available in developing countries which could rebut the allegation of novelty.

With such databases, the old knowledge could be made accessible for patent officers all over the world and false claims of inventiveness could be unmasked.

However, for such databases again more money for bigger patent offices is necessary, which is not available.

Therefore there is the risk that in the end traditional medicines are adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent.⁷⁵

From this follows that even in one of the only domains in which the developing countries are leading and would be profiting from new intellectual property rights, they can be often deprived of these fruits.

2.2.2.2. Exclusion of field of sciences

Under the TRIPS agreement in Article 27 paragraph 1 it is no longer possible for the member states to exclude medicines from patentability.

It is not possible anymore for developing countries to exclude this area and therefore to satisfy their needs with generic products.

The potential of generic products can be clearly seen at the example of AIDS treatments.

⁷⁴ December 27th 1998, the New York Times

⁷⁵ Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine Bangkok, Thailand, 6–8 December 2000 p. 6

For example for AIDS, the patented triple-cocktail of antiretrovirals costs between US \$10,000 and \$12,000 per patient per year, while Cipla, the Indian generic drug manufacturer has offered a triple-cocktail for US\$ 350 per patient per year.

In general there is extensive evidence from nations with product patent protection that average pharmaceutical product prices fall sharply when generic entry occurs.⁷⁶

Caves et al. (1991) estimated that in the United States, the average generic substitute's wholesale price was 60 percent of the branded drug's price with just one generic entrant, 29 percent with 10 entrants, and 17 percent with 20 entrants.⁷⁷

Without generic competition, the prices in developing countries will almost certainly rise. Since most of the patent owners are based in developed countries and since most of the developing countries are net importers of pharmaceuticals, not only the accessibility will fall but also the net effects on the economic welfare will be negative.⁷⁸

2.2.2.3. Introduction of product and process patents

Furthermore, it is no longer possible to restrict the patents only to process patents. As already described, the mere protection as a process patent is fostering competition especially for successful patents, because other firms will try to develop other processes to manufacture the same product without violating the process patent of the original rights owner.

One of the main countries exceptionally successful in developing generic medicines is India and this can be attributed to the fact that there are only process patents available and the protection period is short.

The end of these lax circumstances with the introduction of process and product patents required under TRIPS, is not only important for India's economy itself, but also for the rest of the developing countries.

India until now was one of the biggest producers of cheap generics in the world and 65 % of its exports of its products went into developing

⁷⁶ Post-Trips Options for Access to Patented Medicines in developing countries p.5 by F.M.Scherer, J. Watal

⁷⁷ Patent Expiration, Entry and Competition in the U.S.

Pharmaceutical Industry by Caves, Richard E. *et al.* (1991): *Brookings Papers on Economic Activity*, 0(0), Special Issue, pp. 1-62.

⁷⁸ Intellectual Property Rights in the Global Economy p.160 by K. Maskus

countries.⁷⁹ India was the primary source for many developing countries for cheap medicines.

Even in the countries where the import of these generics was not allowed, the cheap Indian generics had a good influence on medical prices.

The lower Indian price was able to serve as a big argument for negotiators to sway the patent holders to lower their prices in developing countries.

But with the end of this recess in the big Indian pharmaceutical market, there might not be enough incentive anymore to develop a generic for a medicine.

Of course in future there will still be some countries where there exist no patents. The problem is whether the market value of these countries will be big enough to attract enough investors to finance the development of generics.

Even though the Indian pharmaceutical market is small, compared to the western markets, it is still much bigger than the market in most developing countries.

For this reason, there was an economic appeal to develop a generic for the big Indian market. Whether this will be the case for small developing country markets is rather doubtful. Accordingly, in future there will be less generic products.

The result of the lack of generics will not only be a smaller direct access to cheap drugs, but also price comparison will be much harder and it will be much easier for pharmaceutical companies to argue that they are already selling their products at manufacturing costs.

2.2.2.4. Local Production Requirements

Under paragraph 1 of article 27, it is also required that patents be available, and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.

⁷⁹ Patents, pills and public health: Can TRIPS deliver? p.13 by Martin Foreman

The proposal of some developing countries to require companies to exploit their intellectual property rights locally, was actively eliminated by industrialized countries.⁸⁰

Nevertheless in October 1999, as a part of the national drugs policy, the Brazilian government regulated some aspects of the patent law, allowing the authorities to issue compulsory licenses if, after three years, the owner of the patent did not begin to manufacture the drug locally.

The new law reads as follows:

Article 68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

Paragraph 1. The following also occasion a compulsory license:
I - non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or...

The aim of the legislation was clear: the government was seeking to increase its bargaining power in negotiations with the suppliers of patented drugs.

The Brazilian strategy has led to Antiretroviral drugs becoming more and more affordable, falling from a peak of \$4,860 per patient per year in 1997 to an estimated \$2,530 in 2001.⁸¹

But this clause triggered a strong response from the US government. After several months of unfruitful negotiations, in January 2001 the US decided

⁸⁰ Foreign Direct Investment and International Agreements; A South Perspective p. 12 by Ajit Singh

⁸¹ Patents, pills and public health: Can TRIPS deliver? p.18 by Martin Foreman

to challenge the Brazilian legislation on patents at the WTO for violating the TRIPS agreement.

The Brazilian government argued that the local working requirement is TRIPS-compliant, since it is not a blanket, mandatory measure, and may be imposed only when a specific patent -holding company has abused its rights or economic power.

Although the TRIPS agreement includes the issue of a compulsory license in case of abuse, it is very unlikely that the use of a right granted explicitly in the treaty will be seen as such an abuse.

Since Article 27 of TRIPS explicitly states in paragraph 1 that

...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

It is rather doubtful whether the Brazilian Government would have got away with their argumentation.

Nevertheless in June 2001, following a firm response from the Brazilian government and the mobilization of public opinion, the US withdrew its complaint.

However, this was only done after Brazil promised to provide notice to the US government before it demands that patent owners produce locally.⁸²

Even though the US withdrew its complaint, it increased as a response to this law its *ad valorem* import tariffs by 100% for a substantial number of goods exported by Brazil.⁸³ Therefore it would be interesting to study the effect of this and other retaliatory acts taken during the period of study to

⁸² Government of Brazil Press Communiqué 25th June 2001 found in Pharmaceutical Industry – Brazil 2002 by interfarma p.3

⁸³ Access to Drugs, the WTO TRIPS Agreement, and Patent Protection in Brazil: Trends, Perspectives, and Recommendations to Help Find Our Way p. 216 by Jorge Bermudez, Ruth Epsztejn, Maria Auxiliadora Oliveira, Lia Hasenclever

analyze the costs of patent monopoly, as compared to the costs of retaliatory measures.⁸⁴

Despite the possibility under the new law, Brazil has not yet issued a compulsory license for any drugs.⁸⁵

This might be the reason that the law has not been further challenged by other states, even though it is seen by some as a clear breach⁸⁶ of Article 27 of the TRIPS Agreement.

2.2.2.5. Subject of Patents

Article 27 paragraph 2 and 3 describe the limits for a patent concerning the subject of the patent.

Therefore a patent can be denied if it is contrary to *ordre public* or morality. As explicit grounds for exceptions, Article 27.2 mentions inventions dangerous to human, animal or plant life, or health or seriously prejudicial to the environment.

The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality (Article 27.2).

Another exception that the Article contains in paragraph 3 is the principle that diagnostic, therapeutic and surgical methods for the treatment of humans or animals, may be excluded from patentability.

The reason behind this seems to be that such, life-saving treatment, should not be subject to an exclusive right for a single person. In contrast, life-saving medicines can be subject to such a right.

The different treatment maybe explained in the different level of Research and Development (R&D) necessary for such a development.

Whereas medicines often need years of R&D from thousands of people and millions of dollars, this is not the case for surgical treatments.

⁸⁴ Access to Drugs, the WTO TRIPS Agreement, and Patent Protection in Brazil: Trends, Perspectives, and Recommendations to Help Find Our Way p. 216 by Jorge Bermudez, Ruth Epsztejn, Maria Auxiliadora Oliveira, Lia Hasenclever

⁸⁵ Pharmaceutical Industry – Brazil 2002 p.2 by Interfarma

⁸⁶ Pharmaceutical Industry – Brazil 2002 p.2 by Interfarma

It is mostly the “devices” that are new and difficult to develop for a new treatment, so for example devices for heart operations.

These “devices” are subject to patents because they need a lot of R&D.

Of course a doctor can also work for years to develop a new surgical treatment, but another reason for the exclusion might be that historically such treatments were never subject to patents. Most countries do not grant patents on such methods due to ethical reasons, or due to difficulties with actually enforcing those patents.⁸⁷

In addition, a method that is applied to the human body is not considered industrially applicable and, hence, does not comply with one of the key patentability requirements of most patent laws.⁸⁸

Nevertheless, in the United States patent practice increasingly favours the patenting of medical methods if they satisfy the definition of process and the other conditions of eligibility. However, the use of patented surgical procedures is protected from infringement suits under a bill enacted in 1996 (amending US patent law, 35 USC 287.c).⁸⁹

At least under TRIPS States do not have to grant patents for such treatments.

Another exception is that plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes can be excluded from patent protection. However, if any country excludes plant varieties from patent protection, it must provide another effective *sui generis* system of protection.

According to Article 28 the owner of a product patent has the exclusive right of making, using, offering for sale, selling, and importing of these purposes.

A process patent must give rights not only over use of the process but also over products obtained directly by the process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

⁸⁷ Health Concerns into patent legislation in developing countries p.26 by Carlos Correa

⁸⁸ Health Concerns into patent legislation in developing countries by Carlos Correa p.26

⁸⁹ Patents for chemicals, pharmaceuticals and biotechnology p.220 by Grubb, Philip; Health Concerns into patent legislation in developing countries p.27 by Carlos Correa p.27

In exchange for these rights member states shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1).

Member states may provide limited exceptions to the exclusive rights conferred by Article 28, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30).

2.2.2.6. Term of Protection

The term of protection available shall not end before the expiration of a period of 20 years, counted from the filing date (Article 33).

This means that for example the protection period in India has now been almost tripled from 7 to 20 years.

However, especially the pharmaceutical industry argues that such long periods are necessary.

A product's patent term begins when the patent application is filed, typically early in the development process. The time taken in patent prosecution and the time required to conduct preclinical and clinical studies to obtain regulatory approval eliminate a substantial portion of the 20- year term. Manufacturers argue that safety regulation procedures can take even eight or nine years,⁹⁰ thus reducing effective patent life to no more than eleven years, leaving a relatively short period of effective patent life in which the sponsor can enjoy monopoly status for its product and recoup his investments.⁹¹

⁹⁰ OECD "Pharmaceutical Policies in OECD countries: Reconciling Social and Industrial Goals", April 2000 from Patents, pills and public health: Can TRIPS deliver? By Martin Foreman

⁹¹ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p. 9 by Milne, C., K. Kaitin, and E. Ronchi

2.2.2.7. Transitional Arrangements

Art. 65 paragraph 1 states that all member states have a transition period of one year following the date of entry into force, which was 1st January 1995.

Under paragraph 2, all developing countries were granted an additional transitional period of another 4 years. Therefore in sum developing countries had 5 years to introduce the rights laid down in the TRIPS agreement.

This period could be prolonged for another 5 years under Art. 65 paragraph 4 for those areas of technology where patent protection was not available prior to the TRIPS agreement.

However under Art 65 paragraph 5

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

This means that a state that has already fulfilled some of the obligations laid down in the TRIPS agreement cannot lower its status of protection during the transition period, even if it is normally not obliged to fulfill the obligation until the end of the period.

Therefore a reduction of the level of protection is not possible, except for least developing states, which are under Art 66 paragraph 1 released from this obligation.

For least developed countries under Art. 66, the transition period is 10 years, therefore they do not have to install a patent system in general until 2006.

For pharmaceutical patents under the DOHA Agreement this period, was even prolonged until 2016.⁹²

However, due to political pressure, especially by the US, a lot of least developed countries already have implemented patent protection for pharmaceuticals. For example, only two out of thirty African least developed countries do not currently grant patents for pharmaceuticals.⁹³

Least developed countries that already grant pharmaceutical patents could, however, amend their legislation and not grant product patents until 2016, since they are not constrained by the "freezing clause" of Article 65.5 of the TRIPS Agreement.⁹⁴

However under Art. 70 paragraph 8, the so called "mailbox system", members who do not make patent protection available for pharmaceuticals and agriculture chemical products at the day of entry into force, have to make accessible a system where patents can be filed from the beginning of the transitional period.

Though the patent need not to be granted until the end of this period, under Art. 70 paragraph 8 subparagraph (b) and (c) it has to be granted the day the transition period ends, if the patent protection period has not run out beginning from the day the patent has been filed in the transition period. This means that from the day after the transition period ends, a state has to grant all patents, not only for new medicines developed after this day, but also for all the medicines previously developed for which the protection period would not have run out.

Art. 70 paragraph 9 regulates that if the government allows the relevant pharmaceutical or agricultural chemical to be marketed during the transition period, it must provide an exclusive marketing right for the product for five years, or until a product patent is granted, whichever is shorter. These exclusive marketing rights do not prevent the marketing of generic copies under a different name.

⁹² WTO Press release "Council approves LDC decision with additional waiver"

⁹³ Angola and Eritrea. See Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.39 by C.Correa

Only least developed countries are exempt until 2016, by the TRIPS Council waiver of June 27, 2002, from the obligation to provide exclusive marketing rights while patent applications are pending as required by Article 70 paragraph 9 of TRIPS.⁹⁵

2.2.2.8. Conclusion

There seems to be at least for least developed countries, no reason to worry about medicine prices and patents until 2016, because until then they are allowed to use generics and do not have to install a patent system.

But although the framework looks promising, the problem of access to cheap medicines is far from settled, even if it might seem different at the first glance.

Even though least developing countries have the right to use generics, the problem is where do get such generics.

A lot of countries do not have any pharmaceutical industry at all.⁹⁶

And even where a pharmaceutical industry does exist, it is often an industry which is only capable of manufacturing medicines out of finished ingredients which are imported.⁹⁷

Even if these are available, you have to find out what ingredients you need to produce a generic.

In the majority of cases, such a redevelopment of medicines requires firstly sophisticated scientists and secondly, an investor who pays the R&D.

Such an investor will of course be only attracted if there is any chance of return on investment.

The return on investment will be hard to achieve if the market where you are allowed to offer the generic is small. The problem is the market for medicines is small in most developing countries due to the fact that the average income is low.

In addition, an investor might face the problem of not only paying the R&D, but also having to build up the industrial and technological

⁹⁴ Implications of the Doha Declaration on the TRIPS Agreement and Public Health p. 41 by C. Correa

⁹⁵ Compulsory Licensing - TRIPs and Public Health p.3 by The EU committee of the American Chamber of Commerce in Belgium

⁹⁶ Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.52 by C. Correa

⁹⁷ Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.52 by C. Correa

manufacturing resources in such a country and maybe even having to train the scientists, because under the original TRIPS agreement it is not allowed to produce the generic in a country where the patent system already is in place and then export the products to a least developing country, where generics are allowed.

The production without the consent of the inventor in a country where the product is patented, would be an infringement of the rights granted under TRIPS.

Therefore the practical hurdles for cheap medicines are high although the theoretical framework looks promising.

However, these problems have also to be seen by the politicians.

Whether they have found a solution for these problems and if these solutions are workable will be scrutinized in the following Chapter.

2.3. Solutions available under TRIPS

The TRIPS system has some safeguards installed to tackle public health problems. There are three main solutions that are consistent with TRIPS and which are most frequently proposed as a way to facilitate access to cheap medicines in developing countries.

Whether these safeguards and solutions are sufficient will be seen in the following

2.3.1. Compulsory Licensing

The first solution that I will analyse is compulsory licensing.

But what is compulsory licensing?

Compulsory licensing is defined as ‘authorization permitting a third party to make, use or sell a patented invention without the patent owner’s consent’.⁹⁸

Therefore compulsory licensing allows a government or a competitor authorized by the government to temporarily override a single patent.

If a compulsory license is issued, the licensee can manufacture the patented good without the consent of the rights owner and without being exposed to claims for damages by the rights owner.

⁹⁸ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.38 by Cheri Grace

However, in return for this unauthorized use, the licensee has to pay a compensation to the rights owner. Therefore, the original inventor is not totally dispossessed but gets at least a small compensation.

Compulsory licenses are part of most patent acts in the world, even in developed countries.

For example therefore, after September 11th the US threatened the German Bayer AG to issue such a license for the manufacturing of an anti anthrax pill.

Of course these national acts have all now to fulfill the criterias laid down in the TRIPS Agreement which sets new guidelines in respect to compulsory licensing and government use without authorization.

While these measures are still allowed, TRIPS tightens the respective provisions in the Paris Convention.⁹⁹

The question, whether the new rules are still acceptable, will be subject of the following chapters.

2.3.1.1. Requirements for Compulsory License under TRIPS

The rules for compulsory licenses are laid down in Article 31 of the TRIPS agreement.

First of all, if you read the Article, it is astonishing that there is no general rule as to which cases a compulsory license can be issued. Article 31 more or less only lays out the procedure that has to be followed on issuing a compulsory license.

There is no list of reasons for the issuance of a compulsory license.

This relative openness was affirmed in the DOHA Declaration, which states:

5)b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member is free to determine on their own what reasons are sufficient to issue a compulsory license.

However, a compulsory license still has to fulfill the following preconditions.

⁹⁹ Trade-Related Aspects of Intellectual Property Rights p.88 by J. Revesz

2.3.1.1.1. Examination under Individual Merits

First of all, paragraph (a) states that each case shall be considered on its individual merits.

This means that there can be no self-executable law which always allows you to issue a compulsory license if the premises are fulfilled.

Every case has to be handled separately and reviewed on its individual circumstances.

Although this rule seems to be only fair, it of course delays the issuance of a license.

Nevertheless, it is necessary to grant the expropriated rights owner an optimal legal protection.

2.3.1.1.2. Prior Negotiations with Patent Owner

Secondly, under paragraph (b) the government first has to contact the real patent owner and try to reach an agreement with the rights owner on reasonable commercial terms.

However, the prior contact with the patent holder is not necessary if there is a case of national emergency, or other extreme urgency, or in case of public non-commercial use.

Although no examples are given, non-commercial public use might occur when national health authorities distribute drugs at a zero price, or at cost through public health care networks.¹⁰⁰

Regarding the other exemption, there have been many disputes about what constitutes a national emergency.

Many states gave the opinion that such emergency could only be a new, just occurred incident, not a previously known event.

This dispute has now been settled by the DOHA Declaration which explicitly states:

5.c) 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.

It is now accepted that a national emergency can also be a health crisis which is a permanent threat to these countries and not only a sudden uprising epidemic. Therefore with the DOHA Declaration the leeway for the interpretation of this article of the TRIPS Agreement has been expanded and it is accepted that a permanent health crisis can represent a national emergency.

Important is the fact that if a member complains about the qualification of a specific situation by another Member as a “national emergency or other circumstances of extreme urgency”, the language of paragraph 5 (c) places the burden on the complaining member to prove that such emergency or urgency does not exist. This represents an important difference with respect to earlier GATT/WTO jurisprudence outside of the TRIPS context that, under the “necessity test”, put the burden of proof on the Member invoking an exception to its obligations.¹⁰¹

Therefore the risk for being sued before the WTO Dispute settlement panel is minimized and therefore the will to use this exemption might be strengthened in developing countries, due to lower risk of litigation.

The problem is, if this special rule is not relevant, it will remain rather unclear what to reach an agreement “on reasonable commercial terms” means. As long as there is no case law settling this uncertainty, developing states will be rather hesitant to issue a compulsory license. The reason for this is the fact that developing states will often fear the risk of a patent litigation, because these can be very costly.

Therefore, as long as this uncertainty remains, the normal case of compulsory licensing might not often be used by developing countries.

2.3.1.1.3. Non-exclusive use

Another precondition for the grant of a compulsory license is that under paragraph (d) the use shall be non-exclusive.

That means that a license cannot be given just to one company exclusively but if there are several applicants it has to be granted to all.

¹⁰⁰ Post Trips Options for Access to Patented Medicines in developing countries p.14 by F.M. Scherer, J. Watal

¹⁰¹ Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.17 by Carlos M. Correa

This also means that the patent owner himself can continue with the exploitation of the invention and can compete, as aggressively as he wishes, with the compulsory licensee, with the advantages conferred in many cases by the prestige of brand names and abundant resources for marketing.¹⁰²

In fact, the market share that compulsory licensees may obtain may be small and even insignificant on account of the reputation and dominant presence of the patent owner in the market.¹⁰³

If several companies try to develop or sell generics simultaneously, the already small margin might vanish completely.

This will be another obstacle making the assessment of a future investment more difficult and will therefore scare away many potential investors.

2.3.1.1.4. Predominant Supply of Domestic Market

Under paragraph (f) there is the limitation that the use of the license shall be predominantly for the supply of the domestic market.

This limitation seems to be logical, due to the fact that a compulsory license is usually issued to combat a threat in the state granting the license. The logical exception to the predominantly supply of the domestic market is consequently the case when a compulsory license is issued for anti-competitive behaviour under paragraph (f). In these cases the licensee can export the predominant part, or even all of its products manufactured under the license.

Even though this limitation seems logical, it is one of the gravest problems with regard to the provision of developing countries with essential medicines.

The problem arises if a small developing country issues a compulsory license. Some developing countries will have the capacity to manufacture a generic under compulsory license, but there will certainly be developing and least developed countries without that capacity.¹⁰⁴

Even in the countries with such a capacity, it is still often not profitable enough to set up a factory and R&D for a small fraction of the world market. Although a lot of people live in the developing countries, for investors, not the potential

¹⁰² Patent Law Trips and R&D Incentives: A Southern Perspective p.24 by C. Correa

¹⁰³ Pharmaceutical patents, prices and welfare losses: a simulation study of policy options for India under the WTO TRIPS Agreement, by J. Watal, cited in Patent Law Trips and R&D Incentives: A Southern Perspective p.24 by C. Correa

¹⁰⁴ The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p. 14 by F. M. Abbott

numbers of potential people to treat are interesting, but the potential numbers that can be earned and therefore the potential number that can really afford the drugs.

How small this number is can be pointed out by some figures.

For example, all pharmaceutical sales in Africa amount to just 1.3 % of the global market, whereas Africa accounts for roughly 15 % of the global population.¹⁰⁵

Imagine how small the market will be in a small country like Malawi which spends only \$39 per capita in total per year for health expenditures.¹⁰⁶

Even if all of this money would go into the purchase of pharmaceuticals, which of course is not the case because the staff and infrastructure also have to be paid by this \$39, then the Malawi pharmaceutical market would be rather small compared to a developed market like Germany, where \$2.820 is spent per person per year.

Even in such a developed market, not all medicines are produced locally, but also partially imported from other countries.

In fact, according to the WHO, public spending on drugs in over three dozen countries, many in sub-Saharan Africa, is less than \$2 per capita per year.¹⁰⁷

Moreover, developing countries will require a variety of medicines, and it may be important that production of different medicines be allocated among countries.¹⁰⁸

This maybe the only chance to attract any investors. However such an allocation will not be possible if the predominant part of the production has to be for the local market.

To understand how difficult it can be to find producers for generics, the example of Canada is very illustrative.

During the 1970s Canada had one of the most extended compulsory license programs in the world.

¹⁰⁵ UNDP statistical fact sheet 2002

¹⁰⁶ UNDP Development report 2004

¹⁰⁷ WHO Medicines Strategy: 2000–2003 Framework for Action in Essential Drugs and Medicines Policy p. 40

¹⁰⁸ The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p. 14 by F. M. Abbott

Even this country, with high income per capita, excellent universities, and a population during the 1970s of roughly 22 million, found it necessary to import the bulk of pharmaceuticals ultimately supplied under compulsory licenses. Thus, smaller less developed nations will have to issue their compulsory licenses mainly for importation rather than domestic production. Although nothing in the TRIPS Agreement prevents a member from establishing that a compulsory license be worked through importation, and not local production, once the obligation to protect pharmaceutical products becomes fully operative (after 2005), it will not be possible to find independent foreign sources for the importation of a protected product other than the patent owner or his licensees; therefore, the compulsory license would be *de facto* impracticable.¹⁰⁹

Even where one such generic producer exists, to get a really cheap generic, it would be good if a competitive world market for supply sources exists.¹¹⁰

The problem might be that after 2005 when TRIPS has to be installed in most of the developing countries, there might be no such supply source.

Even if another state was willing to help the state in need of the medicine by issuing a compulsory license just for the export into the developing country, this would mean a breach of the TRIPS Agreement, because as laid down before Art 31 paragraph (f) states:

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

Moreover if it is not laid down explicitly what the “predominant part” means. Whether it is 51 % or more and how this should be measured, by sheer numbers or sales volume? But it is clear however that a compulsory license solely for export is not feasible under the TRIPS Agreement in its original form.

So in the end it might be that the countries most needing the use of compulsory licenses, cannot enjoy the advantages of this safeguard because they simply do not have the industrial capacity to produce the generics and will not find another state that is allowed to export the medicines to their state.

¹⁰⁹ Patent Law Trips and R&D Incentives: A Southern Perspective p.23 by C. Correa

¹¹⁰ Post Trips Options for Access to Patented Medicines in developing countries p. 29 by F.M. Scherer, J. Watal

If developing and least developed WTO Members are effectively excluded from addressing public interests because of lack of local manufacturing capacity, the purposes of Article 31 are frustrated.

As noted above, the WTO would face the paradox that its most well off members would be able to take advantage of its public interest exceptions, but its least well off would not.¹¹¹

But this problem, known as the paragraph 6 problem, was seen by many activist groups and developing countries, which therefore put pressure onto the WTO Council.

Therefore in November 2001, the Fourth Ministerial Conference in Doha, Qatar gave the Council for TRIPS the assignment to find an expeditious solution to the problem of how member states with insufficient manufacturing capacity can make effective use of compulsory licensing and to report to the General Council before the end of 2002.

Doha Declaration on TRIPS and Public Health: Paragraph 6

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

However, it took until the 30th August 2003 until the General Council adopted a solution to the problem.

The reason for this long period was that there were various proposals to solve this problem. So it was proposed¹¹²:

- (a) To amend Article 31 (f), in order to allow for the granting of a compulsory licence which is not “predominantly” for the domestic market.

¹¹¹ The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p. 17 by F. M. Abbott

¹¹² Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.52 by C. M. Correa

- (b) To provide for a specific exception for exports under Article 30 of the TRIPS Agreement¹¹³, possibly by means of an authoritative interpretation;
- (c) To agree on a moratorium with regard to complaints against countries that export some medicines to countries in need, under certain conditions¹¹⁴.
- (d) To declare exports to a country eligible under paragraph 6 as non-judicable under the WTO rules;
- (e) To allow a Member to issue a compulsory licence to a manufacturer in another country provided the government of that other country recognized the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence¹¹⁵.

It is apparent that some of these solutions are more far reaching than others. For example the US proposal suggesting a moratorium would be only a temporal solution, whereas the first proposal to completely amend the treaty, would be the furthest reaching solution, because it has no temporal limitation and is also not limited in its scope of countries permitted to use the solution.

2.3.1.1.4.1 Implementation of paragraph 6 of the Doha Declaration and its influence on the TRIPS Agreement and access to public health

The solution finally found is a compromise between the different interests.

In general, it is now possible for a second state to issue a compulsory license solely for export to another country.

However, this is only possible under certain conditions, for the importing and exporting countries, which are laid down below:

- (a) The importing country
 - (i) Eligible Importing country
 - First of all, the solution is only usable by the states that made a notification to the TRIPS Council that they will use the solution.

¹¹³ NGO Letter on Compulsory Licensing and Exports sent to the Members of the Council for TRIPS by Consumer Project on Technology, Médecins Sans Frontières, Third World Network, Oxfam, Health Gap Coalition and Essential Action

¹¹⁴ Proposed by the USA delegation at the March 2002 session of the Council for TRIPS.

This notification can be made at any time and a member state can also notify the Council that it will use the system only in special cases. Some members have stated that, if they use the system, it will only be in situations of national emergency or other circumstances of extreme urgency.¹¹⁶

It is also possible to announce that a state won't use the solution at all.¹¹⁷

The only states that can use the system without any notification are least developed countries.

(ii) No manufacturing capacities

Most important is the prerequisite laid down in Article 2 a) ii) of the Declaration. Therefore the importing country has to establish

“that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision”

In the annex of the decision you can find the following concerning least developed countries:

least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

Therefore for least developed countries there is already a disputable presumption that they do not have enough manufacturing capabilities.

For all other states, the insufficient manufacturing capabilities may be established in two ways.

¹¹⁵ Council for Trade-related Aspects of Intellectual Property Rights - Communication from the European Communities and their Member States June 2001

¹¹⁶ Members that announced that if they use the system it would only be for emergencies or extremely urgent situations. They are: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates (see http://www.wto.org/english/news_e/pres03_e/pr350_e.htm)

¹¹⁷ Members that did so : Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America

Therefore, it can be established if the state

*...has established that it has no manufacturing capacity
in the pharmaceutical sector;*

Since this will seldom be the case, even under developing states, there is a second way to prove the insufficient manufacturing capabilities.

A member state will be able to establish its insufficient capabilities if:

it has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

It is positive that the state can examine its capacities on its own and decide whether its capacities are sufficient. However, it seems that at least concerning the second sentence, states are not completely free to decide whether its manufacturing capacities are insufficient. It seems that another state can attack the assessment of the state. However, the burden of proof is on the attacking state.

The leeway for the declaring state is even broader, since the state can also decide individually what “needs” it has that the capacities are insufficient for.

All in all, it will be rather difficult for another state to overthrow the assessment of the declaring state, if it is based on a reasonable base. At least the states really in need of this solution will be able to meet this criterion laid down.

(iii) Specification of Expected Quantities

Another requirement is laid down in Article 2 a) I) which states that the importing country has to:

specify the names and expected quantities of the product(s) needed

and notify the Council of TRIPS of these facts.

This requirement will be rather easy to fulfil, although the estimation of the quantities needed might be difficult. However this estimation will be necessary for the manufacturer too, so there is no special burden in this requirement.

(iv) Notification of intended grant

The importing state also has to notify the Council of TRIPS that if:

*a pharmaceutical product is patented in its territory,
it has granted or intends to grant a compulsory licence in
accordance with Article 31 of the TRIPS Agreement and the
provisions of this Decision*

This prerequisite has only to be met if a patent exists in the importing country. This is important because, especially in least developed countries, for some medicines there simply are no patents, due to the fact that the market there is too small.

In these cases, the importing state does not have to issue a compulsory license.

However, it has to meet the previous requirements.

(b) The Exporting country

First of all, the exporting country will have to issue a compulsory license under the prerequisite of Article 31 if it wants to export a pharmaceutical product to another country and if the product is patented there.

The only matter the new solution excludes the exporting member from, is that its produced generics do not have to be produced predominantly for the domestic market anymore.

However, to be able to use this waiver of the requirement of Article 31

(f) the state has to fulfil the following conditions.

(i) Compulsory license only for needed numbers

Under Article 2 (b) (i) the manufactured products have all to be sent to the importing state and the produced amount cannot be higher than in the notification made by the importing country to the TRIPS Council.

Therefore, in fact the solution is not really a complete waiver of Article 31 (f) but more a new pure export license.

(ii) Special packaging

The manufactured products have to be

clearly identified as being produced under the system set out in this Decision through specific labelling or marking.

It might be feared that such special labelling and marking might be costly and therefore dispatch some of the price advantage the generic product has compared to the original.

Therefore, to ensure this condition does not get too difficult to overcome, the decision also states that such distinction is only necessary if it is

provided that such distinction is feasible and does not have a significant impact on price

Therefore, it seems that this condition will not be too hard to fulfil, but this condition was especially important for the acceptance of western states and its pharmaceutical industries.

One of the main reasons for western pharmaceutical companies to object to generics, is the fear that these generics could be sold not only in developing, but also in developed countries and therefore erode their main profit base. This huge problem will be scrutinized in the following chapter concerning parallel imports.

With the requirement of special packaging this spillover into developed countries market is minimized.

(iii) Post on Website and Notification of Trips Council

Another condition that has to be fulfilled is laid down in Article 2 (b) (iii)

before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and*
- the distinguishing features of the product(s) referred to in indent (ii) above;*

That insures that the information about the special produced medicines is available for all and again the threat of a spillover into developed countries is further minimized.

The exporting countries also have to notify the TRIPS Council of this information, including the address of the website where the information is published.

(c) Payment of Remuneration

The question arises whether in cases where the product is patented in both the importing and exporting country and therefore two compulsory licenses have to be issued, two remunerations need to be paid.

This would be the case if you use the normal solution under paragraph (h) of Article 31 (see 2.3.1.1.5.).

This constitutes a big impediment for the supply of developing countries with cheap drugs, because the double remuneration would logically be added to the price of the generic and therefore lower the affordability. Besides, it would be unfair if the rights owner were to get a double remuneration, even though the harm is the same as if under a normal compulsory license not deemed for export.

Therefore, the decision takes the right arbitration and grants the remuneration only one time (see Article 3 off the decision).

However, the solution found by the General Council is doubtful, because it decides that the remuneration has to be paid in the exporting country.

This, however, neglects that in cases where the produced medicine is not patented in the importing country, no harm is done to the patent owner. In this case if the product would have been produced in the importing country, he wouldn't be qualified for a remuneration. Still, he will be entitled for remuneration, although the product is sold in a country where he has no patent. Therefore no real infringement of his patent has occurred, even though this remuneration

shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member

It is doubtful, whether this means that no remuneration at all has to be paid.

I think, a clear waiver for the payment of remuneration in cases where the product is not patented in the importing country would have been more favourable.

(d) Other Rules

The decision also lays down further details which member states should do to avoid a dissemination of the products in other countries.

It is laid down in Article 8 of the decision that:

Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

Article 10 tries to ensure that the founded solution is workable by stating that

Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

It shall be ensured that no complaints will be raised by other member states.

The nature of this decision as an interim solution is clarified in Article 1, which states that

This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months

Still the new solution then adopted shall be based on this decision.

(e) Assessment of this solution

It is questionable whether this solution is a real solution or whether it will be only a solution on the paper but not workable in practice.

So far no use has been made of this new decision, maybe due to the fact that the transition period of TRIPS will expire at the end of 2005 or 2006 in most developing countries. Therefore, until now, it was not necessary to use the solution, due to the fact that no patents existed in the main producer countries of generics, like India.

The system is rather questionable because the country in need of medicines is dependent on the goodwill of another state that has enough manufacturing capacities.

Most of the countries which have such capacities are developed countries which are in general reluctant to issue compulsory licenses and weaken their own pharmaceutical companies.

The other countries will be developing countries, which are in the majority of cases, very sensitive to political pressure by developed countries, especially the US with its trade sanctions enacted under Section 301 of its trade law.

Although such pressure officially is not allowed for the use of this granted right it is clear that in some cases such pressure will be exerted.

The political willingness of developing countries leaders to resist this pressure for the welfare of another country might be limited.

A solution which is not based on the goodwill of other states and their solidarity might be preferable, although such a solution might be difficult to find, because this would have meant that a foreign country or an international institution, like the WHO, would be granted the right to issue a compulsory license in a foreign country. Such interference with domestic affairs would probably not be accepted by the majority of states.

It is also regrettable that the solution, so far, is not permanent, but only temporary, which therefore does not make the decision process for the huge investments that have to be made to install a generic manufacturing unit, any easier.

A stable and permanent solution would make these decisions much more likely to turn out in favour of these investments.

The biggest obstacle will be if the countries are courageous and solidary enough to issue compulsory licenses for foreign needs.

Still this solution is only applicable if the above mentioned criterias are met, so lets see what other prerequisites are laid down for the normal case.

2.3.1.1.5. Payment of remuneration

Under paragraph (h) the principle of remuneration is laid down. There it is stated that

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

The question arises, what is an "adequate remuneration".

It is evident that an "adequate remuneration" cannot be construed on a "profits lost" basis. Then, compulsory licensing would impose such high royalty payments on the licensed producer that there could be no price reduction and hence no expansion of drug availability at all. Since the purpose of virtually all known compulsory licensing schemes is to increase competitive supply and

reduce prices, the "profits lost" test cannot logically be the standard to be met in determining compensation for compulsory licensing.¹¹⁸

In general it can be said that the question of what is adequate is always dependent on the particular case. For example, in an anti-competitive case it is logical that the remuneration to be paid is much lower than in a normal case. The amount of remuneration is of course also dependent on the policy of the country. So for example, the United Kingdom has provided the most generous compensation in its drug patent licensing decisions; the United States the least generous compensation in key antitrust case orders.¹¹⁹ Canada had one of the worlds most far-reaching compulsory drug-licensing programs, at least in part because of the royalty determination approach adopted:

The enabling statute¹²⁰ declared that:

... in ... fixing the amount of royalty or other consideration available, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention.

Due to this approach, the Canadian courts came to a royalty rate of 4.0 percent, whereas other countries like the UK gave royalties up to 22 %.¹²¹

The problem is that such high royalty rates, as in the British drug licensing example, could undermine the objective of making drugs widely available to low-income consumers on competitive terms; low royalty rates, as in the Canadian example, could provide the basis, assuming that other conditions are satisfied, for competitive drug supplies while compensating patent holders, to at least some extent, for their research and development contributions.¹²²

¹¹⁸ Post Trips Options for Access to Patented Medicines in developing countries p.23 by F.M. Scherer, J. Watal

¹¹⁹ Post Trips Options for Access to Patented Medicines in developing countries p.23 by F.M. Scherer, J. Watal

¹²⁰ Section 41(4) of the Canadian Patent Act, as amended in 1969 from Post Trips Options for Access to Patented Medicines in developing countries p.27 by F.M. Scherer, J. Watal

¹²¹ Post Trips Options for Access to Patented Medicines in developing countries p.26-27 by F.M. Scherer, J. Watal

2.3.1.1.6. Legal Review

Another obstacle is laid down in paragraph (i), which requires that:

the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

Especially, the least developing countries lack financial resources to compete in court with international pharma giants.

Such a review can also take a long time and therefore delay the start of the production of the generics.

Apart from the problem that people often need urgent medicines at cheap prices, there is also the problem that there will be just no company found which agrees to invest in the manufacturing of the product, as long as the legal basis is not solid.

The longer the issuance of compulsory licenses is delayed after patented drugs entered the marketplace, the less time licensees have to recover their start-up costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers.

Thus, if compulsory licensing is to be successful, expeditious licensing procedures are a necessity.¹²³

Here the experience in Canada is relevant. The licensing authority there was required to reach its decisions within 18 months of a license application.¹²⁴

Developing countries should also install such a special fast court procedure, so the rights owner cannot frustrate the intended access to medicines with time-consuming lawsuits.

2.3.1.1.7. Termination of License if situation changes

Another obstacle is that under paragraph (g) of Article 31 the compulsory license has to be terminated if and when the circumstances, which led to the issue of the license cease to exist and are unlikely to recur.

¹²² Post Trips Options for Access to Patented Medicines in developing countries p. 28 by F.M. Scherer, J. Watal

¹²³ Post Trips Options for Access to Patented Medicines in developing countries p. 28 by F.M. Scherer, J. Watal

This precarious nature of a compulsory license is seen by some as a strong risk that discourages the request of any such license by third parties, since they may not have sufficient time to recover their investments.¹²⁵

However, the decision to revoke the license is subject to the “adequate protection of the legitimate interests of the persons so authorized”.

Therefore paragraph (g) will not be a problem in most cases if a good balance is found between the rights of the patent owners and the interests of the licensee.

2.3.1.2. Conclusion

Although one of the main problems concerning the issuance of compulsory licenses is now settled with the decision of the Council of TRIPS, compulsory licenses should not, however, be seen as a “magic wand” for obtaining affordable access to patented medicines in developing countries, as there are some basic limitations¹²⁶:

2.3.1.2.1. Legal obstacles

In general it can be said that the issuance of compulsory licenses especially with the new decision of the TRIPS Council is theoretically a good legal solution.

One of the issues that remains is the problem of remuneration. Here it would have been better if the TRIPS Agreement had installed a framework for the level of royalties to be paid. Since this is not the case, costly and time consuming lawsuit will be the consequence.

The difficulty is that many developing countries do not have the administrative capacities to compete with specialized international law firms.

Moreover, the very high costs of disputes with the world’s leading nations, are frightening and discourage these countries from asserting their rights.¹²⁷

Furthermore the problem remains, that the solution found for the states with no own manufacturing capacities, makes these countries dependent on the generosity of the exporting country.

¹²⁴ Post Trips Options for Access to Patented Medicines in developing countries p. 28 by F.M. Scherer, J. Watal

¹²⁵ Patent Law Trips and R&D Incentives: A Southern Perspective p.23 by C. Correa

¹²⁶ Post Trips Options for Access to Patented Medicines in developing countries p. 29 by F.M. Scherer, J. Watal

¹²⁷ Access to Medicines and Public Policy Safeguards under TRIPS p.18 by Dr.K.Balasubramaniam

Nevertheless, in general the TRIPS Agreement provides theoretically a good flexible framework.

However many states, especially developing, have not adapted this flexibility to its full extent in domestic legislation.

As the UNDP Human Development Report 2001 states:

“Strong government use provisions: The TRIPS agreement gives governments broad powers to authorize the use of patents for public non-commercial use, and this authorization can be fast-tracked, without the usual negotiations. No developing country should have public use provisions weaker than German, Irish, U.K. or U.S. law on such practice.”¹²⁸

In developing countries, however, the laws are sometimes badly drafted due to lack of capacities, therefore the developing states can not often use even the limited flexibility granted by the TRIPS Agreement.

On the contrary, many countries even implemented so called “TRIPS-plus” measures which are much stronger than the rights necessary to be implemented by the TRIPS agreement.

These so-called TRIPS-Plus measures are often the result of pressure by western states, especially the US.¹²⁹

As a result many least developed countries are not using the leeway granted to them through the TRIPS Agreement at all.

As stated before, out of thirty African LDCs only two do not currently grant patents for pharmaceuticals,¹³⁰ although they are not obliged to grant such rights until 2016. This is in part also a result of political pressure.¹³¹

Furthermore, until now, not a single developing country has included compulsory licensing in its national law since the adoption of TRIPS Agreement. In contrast, several industrialized countries have included compulsory licensing and parallel importing in their national laws.¹³²

¹²⁸ United Nations Development Program Human Development Report 2001 page 107.

¹²⁹ Post Trips Options for Access to Patented Medicines in developing countries p. 41 by F.M. Scherer, J. Watal

¹³⁰ Angola and Eritrea. See Implications of the Doha Declaration on the TRIPS Agreement and Public Health p.51 by Correa

¹³¹ Patents, Pills and Public health: Can TRIPS deliver? p. 19 by Martin Foreman

The economic profiles and the scientific and technology capacities clearly indicate that a large number of developing countries do not have the resources to implement and enforce an efficient and effective intellectual property regime.¹³³

Even if these states have the capacities, two additional problems arise. Firstly, there is the problem that these countries are pressurized by western governments not to use the legal leeway subscribed by the TRIPS Agreement. Secondly, they do not install the safeguards due to the fear that they might lose foreign direct investment and therefore will fall even further behind in terms of economic growth.

However, it is rather doubtful whether they would really lose foreign direct investments due to weaker patent rights.

Least developed countries cannot really compete with western countries for R&D facilities.

The main reason, apart from lacking high-qualified scientist or infrastructure, is the fact that pharmaceutical companies benefit substantially from research supported by federal government funding and that many important new drugs are developed with material subsidies from the government.¹³⁴

These subsidies are not only research results of government laboratories, but also big tax reductions for R&D expenses.¹³⁵

In addition, states with big own pharmaceutical companies are often more willing to pay higher prices for medicines in return for the decision of pharmaceutical companies to make future investments in that country. All these advantages are much too important for pharma companies to jeopardize by investing too much into developing countries instead of their domestic markets in developed countries.

¹³² Access to Medicines and Public Policy Safeguards under TRIPS p. 4 by Dr.K.Balasubramaniam

¹³³ Access to Medicines and Public Policy Safeguards under TRIPS p. 4 by Dr.K.Balasubramaniam

¹³⁴ See U.S. National Institutes of Health, *NIH Contributions to Pharmaceutical Development* (February 2000), detailing the substantial dependence of the U.S. pharmaceutical sector on publicly funded research, and noting that “Advances in cellular and molecular biology have created the new biotechnology industry, which is based on an entirely new concept of drugs and medicines. Biotech drug and medicine development is, if anything, **even more based in and interrelated with public sector research than drug development in the big pharmaceutical firms**” out of The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference p. 8 by F. M. Abbott

¹³⁵ Patent Law Trips and R&D Incentives: A Southern Perspective p.17 by C. Correa

It is true that by providing patent protection, developing and least developed members may provide some additional incentive to their local research communities.

While not wishing to discount the value of this incentive, the quantum of innovation that is likely to be stimulated is very unlikely, in terms of economic return, to offset the level of rent transfer from the developing to the developed countries.¹³⁶

In addition less access to medicine and therefore worse health conditions, will also have a bad influence on the economy of a state. For example there is the estimation that HIV alone will reduce the economic growth of the worst affected countries by 1 to 2 percent per year,¹³⁷ and this again degrades the future chances for access to medicines.

This downward spiral can only be stopped if drugs are made more affordable. So if the affordability is jeopardised with excessively strong patent rights, not just pure lives are at stake, but also the economic health of these countries. Therefore least developed countries should refrain from adopting excessively strong rights, especially TRIPS plus measures, and assure that the flexibility of TRIPS is properly implemented into their domestic legal framework.

The conclusion is that although there are constraints under TRIPS, developing countries still have considerable room to design their own national laws to address public health concerns. It is very important to develop patent rules that promote competition in the pharmaceutical industry and do not hinder access to medicines, especially by the poor. But developing countries, and particularly the poorest ones, will need technical and financial support to establish intellectual property systems that really address their health and, more generally, development objectives.¹³⁸

2.3.1.2.2. Technical problems

The legal constraints are not the only problem that developing countries face when they want to use the flexibility of the TRIPS system.

There are also technical problems.

¹³⁶ Intellectual Property Rights in the Global Economy p.165 by K.Maskus

¹³⁷ UNDP statistical fact sheet 2001

Firstly, compulsory licensees must have the capability to “reverse-engineer” or import the product without the co-operation of the patent owner.

However, this becomes more and more difficult.

First of all, the increased use of biotechnology-based R&D and the complexity involved in the development of pharmacogenomic products means that meeting regulatory bio-equivalence requirements will likely be problematic.

Such tailored products would require increased diagnostics ability and extensive monitoring, requiring a strong customer service component.¹³⁹

These sorts of investments would be problematic for generic companies, as they often do not have the necessary financial resources to invest into a bigger research program or the necessary technical equipment.

This may result in decreased generic competition over time.¹⁴⁰

One solution would be to enforce the technology transfer mentioned in Article 66.2 of the TRIPS¹⁴¹ Agreement.

However, this Article is more a declaration of intent than a binding obligation.

Although this would theoretically create manufacturing capacity in the country in need, the practical benefit, especially in a short run will be very limited.

Another difficulty existing is that the companies that have the required research and development facilities, are often larger companies which are increasingly collaborating with multinational companies to achieve advanced capabilities and reach more markets.

Such cooperation may be accompanied by tacit agreement to restrict competition in some markets.¹⁴²

In addition, the companies that have the necessary R&D facilities will become more and more reluctant to produce generics because they might themselves become the “target” of other generic producers in future.

They might not be interested in encouraging the generic market due to the fact that they might be encouraging their own future competitors.

¹³⁸ Post Trips Options for Access to Patented Medicines in developing countries p. 37 by F.M. Scherer, J. Watal

¹³⁹ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.40 by Cheri Grace

¹⁴⁰ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.40 by Cheri Grace

¹⁴¹ Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights obliges developed countries to provide incentives that promote and encourage technology transfer to enterprises in least-developed countries.

¹⁴² Post Trips Options for Access to Patented Medicines in developing countries p. 30 by F.M. Scherer, J. Watal

The general willingness to invest into the development of generics might decline because of the general tendency of stronger property rights and therefore the decrease of the generic market as a whole.

In addition to these problems there is the problem of the supply with active ingredients.

It is a fact that most manufacturers of generic drugs in developing nations are not capable of producing the ingredients which form the basis of drug protection. They are totally dependent on a relatively small number of companies that have the ability to produce special chemicals. Prior to 1990, the largest producers of such chemicals were located in Europe. As a result of changes in European patent law, from a system which only granted process patents to a system which granted full patent protection for pharmaceutical products, the major markets for production of active pharmaceutical ingredients are now located in the developing countries, such as India, that have not yet implemented patent protection for pharmaceutical products. However, after 2005, this source might be depleted as well.¹⁴³

The generic producer might face the double challenge of not only reverse engineering the medicine, but also engineer the formula of the needed ingredients.

2.3.1.2.3. Economic problems

Even if all these problems are smoothed out, the problem of the economic feasibility of the issuance of compulsory licenses remains.

It is very likely that no private entity will be found, which agrees to invest into the development and manufacturing of the generics needed.

The first and major threat for the profit and therefore interest of private entities in producing generics, is the level of royalties. If these are too high, there might be no profit at all for the private investor.

All in all, the situation for the economic success of generics in developing countries is rather bad.

First of all it is likely that the compulsory license is issued only in a small country with a small population.

¹⁴³ Implementing the DOHA Declaration- A Potential Strategy for Dealing with Legal & Economic Barriers to Affordable Medicines p.2 by Alfred B. Engelberg

Even if all of the population is in need of the medicine, to reach all these people you have to offer the medicine at a price which everyone can afford.

To reach all, or at least most of the population, the price has to be really low. In a region like sub-Saharan Africa, the median health budget is \$10 a year per person¹⁴⁴ and that \$10 has to deal with prenatal care, post-natal care, childhood vaccination, the treatment of childhood diseases, malaria, tuberculosis and AIDS, just to name a few.¹⁴⁵

The market prospects gets even worse if you know that in developing countries most medicines are paid for out of the pocket. So about 50 to 90 % of all pharmaceuticals are paid by the private sector in these countries.¹⁴⁶ That means that due to the fact that the income disparities are really high in these countries¹⁴⁷ and remembering the fact that the median health budget is only \$10 a year, the target market will be even smaller than this median number.

Remembering the fact that the development of generics becomes more and more costly, the chance for the future development of generics declines even more.

Therefore, the only chance for developing countries to access medicines through the production of generics, will often be that they found generic companies themselves and accept that these companies will make losses. But here again the problem arises that these countries where the people cannot afford the medicines, are also the states that cannot afford to found a company, which produces steady losses.

However, the losses for the foundation of such a company will be small compared to the restraints these countries will suffer without adequate health care. For example, it is estimated that in Botswana due to AIDS the government will lose 20 % of public revenue by 2010.¹⁴⁸

Compared to these numbers, an investment of some millions into the foundation of a generic company might be well invested.

¹⁴⁴ Patents and Access to Essential medicines p.3 by Amir Attaran

¹⁴⁵ Patents and Access to Essential medicines by Amir Attaran

¹⁴⁶ Access to Medicines and Public Policy Safeguards under TRIPS p. 12 by Dr.K.Balasubramaniam

¹⁴⁷ Access to Medicines and Public Policy Safeguards under TRIPS p. 10 by Dr.K.Balasubramaniam

¹⁴⁸ UNDP statistical Fact Sheet 2001

However, the problem is that Botswana or other countries, might not have the choice between these two alternatives, due to the fact that they simply cannot afford it.

In general, it can be said that there will certainly be only private investors for generic markets like India or China,¹⁴⁹ not for small countries like Botswana. And even in big pharmaceutical markets like India, generic producer will concentrate on some blockbuster medicines, but not the medicines that are only necessary for only a small part of the population.

A compulsory license strategy can only work in cases where the disease patterns are common to different markets¹⁵⁰ and therefore an original medicine for the disease that can be copied exists.

The problem is even bigger if there simply is not a potent original medicine, which could be copied.

That's for the reason that, whereas the copying or reverse engineering of a medicine already costs some million, the price for the new development of a drug can go up to 500 million \$.

In general the incentive to develop a drug only for markets in developing countries is very small due to the small sales market and high investments costs.

Some people argue that with the issuance of compulsory licenses, the incentive to develop drugs only for developing markets, will further decline.

The investors might fear that their already small profit base will be further reduced if the government overrides their patent.

Whether there is really a negative correlation between the issuance of compulsory licenses and the development of new drugs will be the subject of the next chapter.

2.3.1.2.4. Impact on Research and Development

First of all let's see how important patents are for the pharmaceutical industry in general. Afterwards it will be easier to assess what impact compulsory licence has on the policy of the pharmaceutical industry.

The pharmaceutical industry is among the most R&D intensive industries, measured by the percentage of sales devoted to such activities.¹⁵¹

¹⁴⁹ see also Post Trips Options for Access to Patented Medicines in developing countries p. 30 by F.M. Scherer, J. Watal

Thus in 1996 the R&D expenditure of the pharmaceutical industry alone in the US was 9.8 billion dollars.¹⁵²

However, it is also a fact that the pharmaceutical industry spends up to three times more on marketing than on R&D, therefore marketing seems to be an even bigger factor for the pharmaceutical companies than patents.¹⁵³

Nevertheless, it is not astonishing that the patent system is of particular importance for the pharmaceutical industry, as indicated by many studies and by the high profile that the issue of patent protection has had in industry's national and international public actions.¹⁵⁴

However it is to be noted that the high R&D expenditures are often largely fostered by tax subsidies and public research institutions.¹⁵⁵

Thus 70 % of all drugs with therapeutic gain were produced with government involvement.¹⁵⁶

It is also a fact that between 1981 and 1991 less than 5% of drugs introduced by the top 25 companies in the United States were therapeutic advances.¹⁵⁷

Today, an important part of R&D is spent to develop drugs that are substitutes for successful medicines, but do not fall under their patent range. For example, there are efforts to develop substitutes to viagra or some cardiological blockbusters, although the therapeutical gain is small or non-existent.

Nevertheless the existing patent system is still very important for the pharmaceutical industry and therefore for global health policies.

It is also undeniable that the pharmaceutical industry has developed some very important drugs and medicines which are now available for us and help to tackle our diseases.

But it is also a fact that the patent system totally failed to combat the diseases that only exist in developing countries.

Of the annual health-related research and development worldwide, only 0.2% is dealing with pneumonia, diarrhoeal diseases and tuberculosis—

¹⁵⁰ Post Trips Options for Access to Patented Medicines in developing countries p. 30 by F.M. Scherer, J. Watal

¹⁵¹ Patent Law Trips and R&D Incentives: A Southern Perspective p.6 by C. Correa

¹⁵² US National Science foundation, Division of Science Resources Studies, National Patterns of R&D Resources: 1998 p.51

¹⁵³ Patent Law Trips and R&D Incentives: A Southern Perspective p.16 by C. Correa

¹⁵⁴ Patent Law Trips and R&D Incentives: A Southern Perspective p.5 by C. Correa

¹⁵⁵ Patent Law Trips and R&D Incentives: A Southern Perspective p.17 by C. Correa

¹⁵⁶ United Nations Development Orogram Human Development Report 1999 p.69

¹⁵⁷ United Nations Development Orogram Human Development Report 1999 p.69

yet these account for 18% of the global disease burden.¹⁵⁸ In general these neglected diseases cause 90 % of the global burden of disease, yet they account for only 10 % of the global research.¹⁵⁹

Therefore the UNDP report 1999¹⁶⁰ criticizes that

in defining research agendas, money talks louder than need—cosmetic drugs and slowripening tomatoes come higher on the list than a vaccine against malaria or drought-resistant crops for marginal lands.

The situation has not changed since 1999. There is no visible increase in R&D for diseases such as malaria, schistosomiasis, trachoma, malaria, chagas, leprosy and leishmaniasis, despite the fact that most developing countries already grant product patents for pharmaceuticals and almost all countries will be bound to do so in 2005. Even those countries that have delayed the introduction of product patents, have been obliged to grant “exclusive marketing rights” which are *de facto* – though not *de jure* - equivalent to patent protection.¹⁶¹

It seems to be that there is not much R&D spent at all for diseases, which only exists in developing countries. Therefore not much money can be deterred by the issuance of compulsory licenses for these “developing countries drugs”.

For diseases which also exist in developed countries, the market in developing countries is only small compared to the home markets.

The contribution to R&D that could be made by some developing countries or regions is negligible in global terms.¹⁶²

However, an extensive compulsory license policy in all developing countries could entirely destroy the already small incentive to produce and develop drugs for developing countries.

A case study of C.Chien¹⁶³ comes to the result that also compulsory licensing does not categorically harm invention. Threatening or implementing licenses

¹⁵⁸ United Nations Development Orogram Human Development Report 1999 p.69

¹⁵⁹ Performance Innovation Unit, Cabinet Office, London. Tackling the diseases of poverty: meeting the Okinawa/Millennium targets for HIV/AIDS, tuberculosis , and malaria. 2001 May 8

¹⁶⁰ United Nations Development Orogram Human Development Report 1999 p.68

¹⁶¹ Patent Law Trips and R&D Incentives: A Southern Perspective p.20 by C. Correa

on a regular, predictable fashion, may deter pharmaceuticals from initiating and carrying out R&D investments.¹⁶⁴

Therefore developing countries should follow a twofold policy in issuing compulsory licenses.

On the one hand for medicines which are of global interest and also have a significant market in developed countries, the impact of compulsory licenses will be relatively small.

On the other hand regarding special diseases, the governments of developing countries should be extremely careful with the issuance of compulsory licenses in order not to discourage investment.

Against any compulsory licensing, it is sometimes argued that the pharmaceutical companies would reinvest all their raised income. Therefore every policy that spoils their income will in the end also slow down development for drugs specially for developing countries.

However, in order to leave developing countries citizens as well off as before the introduction of patents, a three-fold increase in the number of new drugs would be required.¹⁶⁵ Such an increase is very unlikely to happen even with higher profits.

Therefore all in all, to get the best results possible for developing countries, they should only issue compulsory licenses on global drugs and not on drugs for special southern diseases.

2.3.1.2.5. Conclusion about Compulsory Licenses

TRIPS offers a good legal framework for compulsory licenses if the legal framework the agreement offers is fully utilized.

However, this is often not the case, because developing countries lack the resources to fully implement the safeguards of this agreement.

Even where it is properly installed the economic hurdles remain. Due to the lack of financial or technological resources, in the most cases the issuance of

¹⁶² Patent Law Trips and R&D Incentives: A Southern Perspective p.21 by C. Correa

¹⁶³ Cheap Drugs at What Price to Innovation: Does the Compulsory Licencing of Pharmaceuticals Hurt Innovation?p. 41 by Colleen Chien

¹⁶⁴ Cheap Drugs at What Price to Innovation: Does the Compulsory Licencing of Pharmaceuticals Hurt Innovation? p.43 by Colleen Chien

¹⁶⁵ Patent Law Trips and R&D Incentives: A Southern Perspective p.20 by C. Correa

compulsory licenses can only be used as a lever to bargain with the original manufacturer for lower prices. Still, for this lever to function, the legal pre-requisites for a compulsory license have to exist.

For the long term view, keeping in mind Article 7, it should also be possible to get the technological pre-requisites in place.

All in all, the impact on the global R&D of the pharmaceutical industry will be small, compared to the gains the developing countries can get with healthier people and as a result healthier economic growth.

However, to even lower the negative impact on the future development of southern drugs, compulsory licenses should not be issued on a regular basis and not be issued for southern medicines.

The only remaining problem is therefore the political pressure from developed countries, especially the US.

It is not astonishing that due to these hurdles, since the adoption of TRIPS, compulsory licensing for pharmaceuticals has occurred in Canada, Japan, the UK and US, but in contrast not one compulsory license has been issued south of the equator.¹⁶⁶

Developing countries should endure this pressure for the welfare of their people and as a result for their economies.

This abstinence from the instruments given by the TRIPS agreement gives a small, but regrettably negative forecast on the future political willingness of developing countries to use the flexibility of TRIPS for their own or even foreign healthcare needs.

2.3.2.Parallel Trade

Compulsory licensing is not the only solution available under TRIPS to get access to cheaper medicines.

Another solution available is parallel trade.

First of all I want to explain what parallel trade means.

Parallel trade occurs when a product covered by intellectual property rights sold by, or with the right holder's consent in Nation A, is re-sold in another nation B without the rights holder's authorization.¹⁶⁷

¹⁶⁶ United Nations Development Program Human Development Report 2001

¹⁶⁷ Post Trips Options for Access to Patented Medicines in developing countries p. 30 by F.M. Scherer, J. Watal

The incentive for its occurrence is a sufficient difference in prices between the price paid in nation A and prices charged in nation B.

If the price difference is big enough to cover shipping and other transaction costs and still offer gains to both the shipper and the Nation B buyer,¹⁶⁸ parallel trade will take place.

Parallel trade ensures that the prices paid in one country are the lowest possible worldwide, less of course taxes, transport costs and a small yield for the importer.

Parallel trade is in general permissible under the TRIPS agreement.

However to set up parallel trade the country has to follow a policy of international exhaustion in contrast to a policy of national exhaustion.

To understand the differences I will explain both policies.

Under both policies there is a normal patent system in place.

In both cases the patent owner can decide whether to place his product on the market or not.

However, the patent owner can no longer exercise control over the product once it is placed on the domestic market.

After the product has been placed in the market with the consent of the patent owner, his rights on the product are extinguished. That means he can no longer control the retail market and cannot forbid the sales of his product anymore. He only has the right to control the first sale of a product.

However, in a system of national exhaustion he may exercise his rights with regard to products placed on the market outside of the domestic market.¹⁶⁹ Countries following this regime choose to isolate their markets from foreign competition. Thus, original manufacturers retain complete authority to distribute goods and services themselves or through dealers, including the right to exclude parallel imports through border controls.¹⁷⁰

¹⁶⁸ Post Trips Options for Access to Patented Medicines in developing countries p. 30 by F.M. Scherer, J. Watal

¹⁶⁹ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.30 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

¹⁷⁰ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 3 by Keith E. Maskus

Under a strategy of national exhaustion it is possible to set up individual prices and conditions for each country.

One country that follows such a policy of national exhaustion is the US.

In a system of international exhaustion a patent owner may not exercise rights over products once they have been put on the market with his consent anywhere in the world. This limitation on the patent owner's exclusive importation right effectively permits others to import the patented product if it has already been put on the market by the patent owner anywhere in the world.¹⁷¹ Therefore in a system of international exhaustion in theory price differences would vanish and one equal price for all countries would be established.

A system in between these two solutions is followed by the European Union, which applies a "regional exhaustion" principle, whereby patent rights are exhausted only with regard to products placed on the market in EU countries.¹⁷²

If and how these policies are allowed under the TRIPS agreement and how this can influence the price for medicines will be scrutinized in the following chapters.

2.3.2.1. Legal Feasibility

The Article which addresses the subject of parallel trade in the TRIPS Agreement is Article 6, which states:

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

Therefore the TRIPS Agreement leaves the decision to the member states whether to follow a policy of national or international exhaustion and therefore allow or ban parallel imports.

¹⁷¹ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.30 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

¹⁷² Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.30 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

In principle a country could even treat parallel imports and parallel exports separately. It is possible that a country might permit parallel imports and ban parallel exports in order to encourage low prices on its market.

It is also possible that a country could ban parallel imports and permit parallel exports in order to sustain export opportunities for its distributors.¹⁷³

Despite this potential segmentation in legal regimes, there is so far no country which makes such distinctions¹⁷⁴, therefore this system will not be examined here.

2.3.2.2. Economic Potential

The reason for parallel imports is to benefit from lower prices abroad and to even price differences between different countries.

However, even between countries where parallel imports are allowed substantial differences remain. Even within the EU, where parallel imports are permitted internally, there remain substantial differences across countries.¹⁷⁵

These differences exist even though transaction costs due to good infrastructure are relatively low.

Nevertheless, despite the potential for parallel imports, there was considerable price variability within the EU, with the British price sometimes being 45% higher than the price in Spain.¹⁷⁶

Thus, there appear to be significant informal impediments to full price integration. Such impediments include consumer concerns that parallel imported drugs may be of lower quality, problems with marketing parallel imported medicines under unfamiliar brand names, differences in packaging, and the like.¹⁷⁷

The question arises whether equal prices are really good for all countries.

In fact, in a worldwide system of equal prices, this would probably amplify the health problems of developing countries rather than alleviate them.

¹⁷³ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 3 by Keith E. Maskus

¹⁷⁴ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 3 by Keith E. Maskus

¹⁷⁵ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 29 by Keith E. Maskus

¹⁷⁶ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 29 by Keith E. Maskus

In such a system the price would most probably be such that people can pay in developed countries, but not in developing countries.

The small, least-developed countries would certainly not be served by pharmaceutical companies in such a case of a globally uniform price.¹⁷⁸

All together, developing countries market would be set aside, even though developing countries account for 80% of the world population, but they account for only 20% of the global pharmaceutical market¹⁷⁹.

So the main beneficiaries of uniform pricing would be consumers in high-income countries.¹⁸⁰

In a perfect world there should be different prices in different markets.

The best way to determine the best price for the individual state and for the global economy is the so-called Ramsey Pricing (Ramsey, 1927).

It was developed to address the problem of paying for joint costs that simultaneously serve many consumers.

R&D in pharmaceuticals is such a fixed, globally joint cost; that means the cost for a new drug is largely invariant to the number of patients or countries that ultimately use the drug and cannot be causally attributed to specific countries.

Once R&D has developed a compound to serve affluent countries, no incremental R&D expense is needed to serve low-income countries.¹⁸¹

The development costs are sunk, unattached to how many people use it.

The recovery of these sunk cost (e.g., past R&D in a pharmaceutical product) is accomplished by charging a markup of price over marginal distribution costs to consumers in different markets based on elasticity of demand.¹⁸²

¹⁷⁷ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 25 by Keith E. Maskus

¹⁷⁸ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 14 by Keith E. Maskus

¹⁷⁹ Patent Law Trips and R&D Incentives: A Southern Perspective p.20 by C. Correa

¹⁸⁰ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 14 by Keith E. Maskus

¹⁸¹ Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents p.5 by P. Danzon

¹⁸² Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 27 by Keith E. Maskus

Ramsey pricing comes to the conclusion that for an optimal consumer and investor welfare, all markets should be supplied with the new drug as long as they can pay a price that is above the marginal production costs.

Ramsey pricing implies prices that vary across markets inversely with each market's price sensitivity or demand elasticity.¹⁸³

That means that for each country there should be a balance found between the maximum number of people served and the maximum amount of money earned with each pill.

The pharmaceutical company will accept such a strategy of individual price settings because in such an optimal system of totally separated markets, the lower prices in one country will have no negative impact to the high prices in another country.

A company, in theory, will therefore always be willing to sell the goods as long as it can sell the product above manufacturing costs and therefore can earn profits.

As a result, the global economic surplus is maximized, because the optimal balance is found between the number of people accessing the product and the profit of the company.

However, this seemingly simple solution requires optimal preconditions.

Firstly, strictly speaking the Ramsey formula is efficient only if a regulator aims to set prices that would generate only a normal return (that is, zero monopoly profits) for a utility with given sunk costs.

However, pharmaceutical companies naturally are interested in earning more-than-normal profits and would resist efforts at global rate-of-return regulation.

Still, with a good anti-monopoly policy and a good regulator, this system seems to be a good solution, at least in theory.

Therefore, theoretically parallel imports seem to be a tool that undermines the health care in developing countries. It forces pharmaceutical industries to set one higher uniform price and therefore demand higher prices in developing countries because they cannot risk their profits in developed countries.

¹⁸³ Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents p.2 by P. Danzon

Therefore, it seems to be that parallel imports should not be allowed. However, if the pharmaceutical industry would really rely on the system of Ramsey pricing there would be indeed no need for parallel imports in developing countries. In such a perfect system, per capita income would be an important determinant and could serve as a good approximation, possibly adjusted by burden of specific diseases such as HIV-Aids.¹⁸⁴ Therefore, prices in developing countries should be lowest and there should be no need to import “prices” from other countries.

However, Scherer and Watal made a price comparison for a number of AIDS antiretroviral drugs sold under brand names by multinational pharmaceutical companies in 18 low-income and middle-income countries over the period 1994-1998.¹⁸⁵

Across all country drug pairs they found that the average price relative to the U.S. price was only 0.85, suggesting that prices in developing countries averaged just 15 percent below those in the United States.

Indeed, in 98 cases the prices in developing countries were even higher than in the US, and that despite the income differences.¹⁸⁶

In another study Maskus¹⁸⁷ found out that in 10 of the 18 cases for which prices existed in both Italy and/or Spain, on the one hand, and in South Africa, on the other hand, the price was higher in South Africa.

That despite the fact that Italy has a GDP of \$26.000 whereas South Africa has only a GDP of \$10.000.¹⁸⁸

Again, in some cases the prices in developing countries even exceeded those in the United States, which typically has the highest prices of any country.¹⁸⁹

Therefore it is a fact that pharmaceutical companies sometimes afford excessive prices in developing countries.

The reason for that is often that it might be more profitable to serve only the rich people in a country and neglect the poor, which cannot afford a fraction of the price.

¹⁸⁴ Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents p. 3 by P. Danzon

¹⁸⁵ Post Trips Options for Access to Patented Medicines in developing countries p. 37 by F.M. Scherer, J. Watal

¹⁸⁶ Post Trips Options for Access to Patented Medicines in developing countries p. 39 by F.M. Scherer, J. Watal

¹⁸⁷ Parallel Imports in Pharmaceuticlas: Implications for competition and prices in developing countries p. 29 by Keith E. Maskus

¹⁸⁸ United Nations Development Program Human Development Report 2004

Another reason is that developed countries often have price regulations in place. The market for pharmaceuticals in developed countries is often dominated by state-run or controlled insurance companies, which often negotiate the prices. The bargaining power of these agencies is of course much higher than that of private people in developing countries. Even where in developing countries there is a state agency in place, this agency has of course a much weaker position than an agency in a developed country.

Another reason for the high prices in developing countries is the so-called “External Reference” system of many countries. This means that the agencies that negotiate the prices with the pharmaceutical companies do so by referring to prices the company demands in other countries.

Given these linkages across markets, basic economics predict that manufacturers will rationally seek to maintain much higher prices in LDCs than they would require if markets were separate and price leakages did not occur.¹⁹⁰

A major conclusion of this analysis is that assuring low prices in LDCs requires that higher-income countries abstain from trying to “import” low LDC prices and that policies be established which enforce such market separation.¹⁹¹

Another conclusion is that low-income countries do not have to abstain from a policy of parallel imports. In fact they already should have very low prices so parallel import will not occur simply for the fact that it would not be profitable. However, where prices in other especially developed countries are lower, developing countries should try to import these lower prices by allowing parallel imports.

However, in many developing countries, such imports are not permitted or are under different, in some cases, quite restrictive, conditions.¹⁹²

¹⁸⁹ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 29 by Keith E. Maskus

¹⁹⁰ Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents p. 3 by P. Danzon

¹⁹¹ Differential Pricing for Pharmaceuticals: Reconciling Access, R&D, and Patents p. 3 by P. Danzon

¹⁹² Patent Law Trips and R&D Incentives: A Southern Perspective p.26 by C. Correa

Even in those developing countries where parallel imports are permissible, they are often restricted by high tax tariffs.

While almost all industrialized countries have zero tariffs on pharmaceuticals, many developing countries still have import duties and tariffs on these products.¹⁹³

Tariffs at the high end of the spectrum are on average upwards of 30 percent in some countries, including Burkina Faso, Pakistan, India, Tanzania and others.¹⁹⁴

2.3.2.3. Impact on R&D

Again, the question has to be answered what impact parallel import has on R&D.

Generally it can be said that of course every parallel import reduces the profit of the pharmaceutical industry and therefore reduces the future amount to invest in R&D.

However, it has to be kept in mind that a balance should be kept between the access to the patented products and the profits of the pharmaceutical industry. When developed countries refrain from using parallel imports, especially from developing countries, the negative impact of parallel trade will not be very big. On the other hand parallel import laws in developing countries are a very easy method to protect these countries from over exaggerating prices.

Developing markets are not very important for the R&D refunding of most drugs, therefore the impact of parallel imports in developing countries on R&D will be very small.

2.3.2.4. Conclusion

Parallel Imports are more a safeguard to protect developing countries from excessive price differences than to lower drug prices under the already existing scope.

However, to accomplish this it is an easy and effective tool. If developed countries abstain from parallel imports from developing countries, it is also a tool, which will do little harm to R&D.

¹⁹³ Consumption and Trade in Off-Patented Medicines p. 8 by Harvey E. Bale

¹⁹⁴ Consumption and Trade in Off-Patented Medicines p.8 by Harvey E. Bale

However, to get an optimal result, a system of several regional exhaustion zones should be followed. In this system, the different zones would be authorized to import from higher income countries but not lower income countries.

The result would be an almost Ramsey Pricing system with a safeguard against monopoly pricing.

Of course this result is difficult to achieve. Therefore in the meantime developing countries should follow a system of international exhaustion.

At least the developing countries should have a system where they can allow parallel import on a case by case basis, so as to use the accessing parallel imported drugs as a negotiating leverage with original manufacturers to accept lower prices.¹⁹⁵ Thus, parallel imports can be a complement to compulsory licensing programs.

2.3.3. Tiered Pricing

Another option available under TRIPS for the access to cheaper medicines is the use of price controls.

The TRIPS agreement does not forbid the use of price controls and price controls are already a feature of the pharmaceutical industry in rich and poor countries.¹⁹⁶

Although price controls affect the profits of the manufacturer similar to compulsory licenses, the willingness of the rights owner to accept these might be bigger because the innovator company which chooses to serve the price-controlled market would retain control over distribution, and therefore control the colour, shape and size of products manufactured and distributed in poor countries.¹⁹⁷

This lessens the opportunities for the production of counterfeit goods, or the possibility that these products can easily be exported to developed countries and therefore undermine the profits there.

¹⁹⁵ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 41 by Keith E. Maskus

¹⁹⁶ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.48 by Cheri Grace 2003

¹⁹⁷ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.48 by Cheri Grace

The problem however, is that the companies might not accept the set prices in developing countries as easily as in developed countries.

In developed countries with the power to include or exclude new drugs in indexes for authorized or reimbursed drugs, national authorities can negotiate lower initial prices, or extract assurances that prices will not be raised above the introductory levels.¹⁹⁸

However this is not the case in developing countries. Again the financial background that might be used as a threat is missing.

In developing countries, there are often no big insurance companies which can negotiate lower prices by using their purchasing power as a lever.

Whereas in OECD countries as a group, almost 75 percent of pharmaceutical expenditures are reimbursed in some way,¹⁹⁹ in contrast few developing countries have universal public health insurance schemes or public drug reimbursement systems.²⁰⁰

A price control system also needs a big administrative body.

This is difficult for countries with limited regulatory capacity, because these

governments have weak infrastructure to monitor costs of production or prices.²⁰¹

For example the experience of Colombia and India in monitoring costs and enforcing prices has been poor.²⁰²

Another difficulty appears if the prices are set too low. In such a case patent holders could simply keep patented products off the market altogether.²⁰³ This already happens. Recently the head of Pfizer announced that the company would threaten to withhold new treatments for France unless the government allowed higher prices. Similarly such threats were put into practice in Pakistan during 2000, when government price controls (levied at retail pharmacy level) had not kept up with inflation and new import taxes, and therefore were seen as too restrictive by multi national companies, and many products were consequently withdrawn from the market. Under current rules, a refusal to

¹⁹⁸ Post Trips Options for Access to Patented Medicines in developing countries p.50 by F.M. Scherer, J. Watal

¹⁹⁹ Pharmaceutical Policies in OECD countries: Reconciling Social and Industrial Goals p.4 by S. Jacobzone

²⁰⁰ Post Trips Options for Access to Patented Medicines in developing countries p.51 by F.M. Scherer, J. Watal

²⁰¹ Post Trips Options for Access to Patented Medicines in developing countries p.51 by F.M. Scherer, J. Watal

²⁰² Post Trips Options for Access to Patented Medicines in developing countries p.49ff by F.M. Scherer, J. Watal

supply might be sufficient to trigger the national emergency provision allowing compulsory licensing.²⁰⁴

However, as discussed, compulsory licensing may not be economically feasible for some countries, unless certain conditions exist.

On the other hand, if the price controls are typically lax, the administrative costs of establishing and maintaining an effective price control regime over all patented pharmaceuticals may outweigh the benefits.²⁰⁵

As a conclusion it can be said that price controls are more a tool for states with a good administrative body and at least partial insurance system in place.

Again, it might be better to only use the potential system as a threat.

The risk of a too harsh price control system might be that the producers will stop supplying the market completely. Although in such a case the way is free for the issuance of a compulsory license, a compulsory licensing program for more than a few products will not be workable, even in a developed market.

Therefore the price control system has to be used very cautiously.

3. Conclusion on the Conflict between TRIPS and Access to Medicines in developing countries

With the new Doha Declaration it can be said that a balance has been found between the interests of developing countries and the interests of patents rights owners.

Therefore the TRIPS Agreement as a legal framework grants sufficient leeway for developing countries to address their public health problems.

However, the solution found is a good one in theoretical terms, but not so much in practical life.

Although, for example, least developing countries are not obliged to introduce patents until 2016 for medicines, the problem is that they will not profit from this exception, if they do not have the technical resources to produce the non-patented medicines on their own, or find a state that is willing to issue a compulsory license for them.

Least developing countries will become even more dependent on foreign aid, be it technical aid, financial aid or willingness to issue a compulsory license for them.

²⁰³ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms p.49 by Cheri Grace

²⁰⁴ Equitable pricing of newer essential medicines for developing countries: Evidence for the Potential of Different Mechanisms footnote 82 p. 49 by Cheri Grace

²⁰⁵ Post Trips Options for Access to Patented Medicines in developing countries p.53 by F.M. Scherer, J. Watal

The impact on least developing countries and their public health problems will not be direct but indirect through closure of supply sources.

For developing countries the impact is more direct. Most have to pay royalties from 2006 to developed countries for the use of their patents.

At least in the short term the financial effect will be negative, resulting in a negative flow of resources to the developed countries.

However, the developing countries will be paid off for these patent rights with better trade tariffs.

If these advantages can, at least partly, counteract the disadvantages of the patent introduction, remains to be seen and is not the aim of this paper.

In the long-term view it might be likely that the introduction of intellectual property rights will have a positive impact on foreign direct investment and maybe even development and transfer of technology to developing countries.

If these goals are achieved, it will also have a positive impact on the public health concerns of these countries.

In the end, poverty remains the major public health threat.

Meanwhile, developing countries are advised to use the full flexibility of TRIPS.

The impact of too strong and unaffordable patent rights for medicines, will not only result in a direct drain of financial resources, much more important is the indirect loss. Sick people can not work and people who die early cannot use their acquired skills and can not hand them on to the next generation.

It has to be asked whether it was really necessary to introduce patent rights for medicines in developing countries or whether it would not have been better to exclude this topic for some time from protection in all developing countries.

In the end, developed countries will pay the price for new medicines.

With patent systems in developing countries in place, they have to, or at least should give, higher development aid to cure the harm the property rights have done.

Without patents they would have to accept a higher burden of recompensation through higher medicine prices in their countries.

Higher foreign aid gives the state a morally higher standing. However, to give to the poor with one hand and to take it back with the other is a doubtful help.

One major advantage of the new rights in developing countries should be that now there will be specific medicines developed for the needs of developing countries.

This is one of the biggest problems for developing countries. As was stated before, of the annual health-related research and development worldwide, only 0.2% goes for pneumonia, diarrhoeal diseases and tuberculosis – yet these account for 18% of the global disease burden.²⁰⁶

Virtually all of the latter research was performed by public agencies and military authorities.²⁰⁷

If this situation has or will change with the introduction of patent rights in developing countries, will be subject of the following chapter.

4. TRIPS and the incentive to develop drugs for developing countries

To illustrate the problem of how difficult it is to develop a drug only for a “developing country illness”, I want to show one example of an already developed drug.

The drug is called Eflornithine and is useful at either stage of the African sleeping sickness, but its availability has been illustrative of the problems with R&D of medicines for tropical diseases in the current environment.²⁰⁸

The death toll from human African sleeping sickness in 1996 was 150,000, and there were 200,000 new infections. (Pécoul 1999) It is believed that 450,000 people may be currently infected and 60 million are at risk.²⁰⁹

Eflornithine was developed during the 80’s and approved by the FDA in 1990.²¹⁰

Marion Merrell Dow (later Hoechst Marion Roussel, now Aventis) announced that it would manufacture eflornithine under the tradename Ornidyl as the first new medicine in 40 years for African sleeping sickness.

It was later discontinued due to poor sales. (Silverstein 1999).²¹¹

The license for eflornithine was then offered to the WHO, but the WHO was not able to find a manufacturer for the drug at a low enough cost. Eflornithine was licensed to Ilex Oncology, which wanted to pursue the compound as a cancer drug and was willing to produce it for the WHO, but at a prohibitive cost.

²⁰⁶ United Nations Development Orogram Human Development Report 1999 p.69

²⁰⁷ Developing and Distributing Essential Medicines to Poor countries the Defend Proposal p.9 by M.Ganslandt, Keith E. Maskus, Eina V. Wong

²⁰⁸ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.45 by Milne, C., K. Kaitin, and E. Ronchi

²⁰⁹ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.44 by Milne, C., K. Kaitin, and E. Ronchi

²¹⁰ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.45 by Milne, C., K. Kaitin, and E. Ronchi

²¹¹ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.45 by Milne, C., K. Kaitin, and E. Ronchi

In late 1999, MSF stated that it would be willing to guarantee purchase of the drug for 2-3 years, and assist with distribution, registration, and pharmacovigilance. At that time, Aventis planned to produce a batch of 10,000 vials as an interim measure. (Pécoul 1999)

However, in February 2001, only 1,000 doses of eflornithine remained, because early hopes that it would be a new cancer drug were dashed.

Aventis then decided to no longer produce the drug. (McNeil 2001)²¹²

Even though the drug was already developed, the market in Africa was not big enough to encourage the manufacturing of this drug and this despite the fact that with MSF a potent partner engaged in a long-term contract.

From this example you can see how unlikely it is that a pharmaceutical company invests its money to develop a drug only for the developing market.

Another example is malaria. Malaria kills 1-3 million people annually and accounts for 300-500 million new infections every year.²¹³

Malaria is a major public health problem in more than 100 countries, inhabited by some 2.4 billion people. (Persidis 2000)²¹⁴

The good news is that the malaria product pipeline is currently active. There are developers in Australia, UK, USA and India.

The bad news is that their interest is primarily in the lucrative traveller market.²¹⁵

While the prospect for a short-term vaccine for temporary residents and tourists in tropical countries is expected in the near future (Newman 2001), prospects for a long-term vaccine providing protection to inhabitants of an endemic area are still 7-15 years away. (Persidis 2000)²¹⁶

²¹² Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.44 by Milne, C., K. Kaitin, and E. Ronchi

²¹³ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.39 by Milne, C., K. Kaitin, and E. Ronchi

²¹⁴ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.39 by Milne, C., K. Kaitin, and E. Ronchi

²¹⁵ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.42 by Milne, C., K. Kaitin, and E. Ronchi

²¹⁶ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.42 by Milne, C., K. Kaitin, and E. Ronchi

The whole anti-malaria market is currently about \$200 million, for the most part limited to the traveller market. (Ridley 2001)²¹⁷

Thus, even though there is a lucrative market for travellers and the military, a transferable exclusivity would be needed as an incentive for vaccines designed for patients in the developing world and to stay ahead of the wave of resistance to currently available drugs.

These examples make it clear that even with TRIPS in place the incentive for private pharmaceutical companies to develop new drugs for specific “southern” diseases is too small.

The problem is that the patent system that worked well for developed countries, does not have the same affect for developing countries.

Even though the patent rights grant the right to demand higher prices and therefore recoup the investment in theory, in practice this does not work in developing countries. The reason for that is that higher prices are not affordable for most people in developing countries, even if they are willing to pay.

The companies can often only sell their goods, at least in large quantities for little more than their production costs. With these prices, the companies are unable to cover their development costs.

At the first glance, this result seems to be contradictory to the results in the first case, where I stated that the medicines are often overpriced in developing countries and it can be more lucrative to supply only the rich people.

However, in these cases, the money earned in developing countries is only a surplus to the money already earned in developed countries. For such global drugs it can be more lucrative to sell only small shares to rich people, than to supply the mass market with cheap products and to risk the problem of spillovers in developed Markets.

But in the cases where the medicine will be sold only in developing countries, like a malaria serum, the money earned in these markets is not a surplus but the only profit the producers can earn.

²¹⁷ Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty p.42 by Milne, C., K. Kaitin, and E. Ronchi

As long as the developing countries are not big enough to support their own medicine developments, the TRIPS Agreement might have only a negative impact.

The reason is that “Global” medicines are only sold to the rich people protected by the patent system, whereas “Southern” drugs are not developed because the market size in developing countries is not big enough.

However, with the risk of spillovers into developed markets banned, the pharma companies might be willing to supply developing markets on a “Ramsey” Pricing system, partly due to economic interests and especially due to moral pressure in developed countries.

The negative impact with a one way barrier between developing and developed countries for their pricing policies in developed countries and therefore their future investments in new “developed countries drugs” will be limited.

There also will be no negative impact for future investments in “developing country drugs”, because there are at the moment simply virtually no new drug developments for “Southern” diseases apart from public paid studies.

As a conclusion we can state that the TRIPS Agreement will probably not harm the access to medicines in developing countries, as long as the flexibility is used and the political willingness to support the other countries will not decline.

With bigger developing markets and maybe cheaper new drugs developed in the biotechnology sector, there might even be a new incentive for private companies. If pharmaceutical companies really adhere to “Ramsey” pricing there is no harm done by the new system, rather a little bit more incentive and therefore probability for new medicines is developed.

But even if there is a little progress made and the chances for new “southern” medicines has grown a bit the normal patent system might give too little incentive to develop such drugs.

Therefore there are suggestions to revise the system as a whole, or at least modify it with additional stimuli for neglected diseases.

In the next chapter I want to analyse some of these proposals to see whether they are promising or not.

III. Modifications for Patent Protection

As I stated before, the situation for new drugs for southern diseases is far from satisfying.

The normal patent system develops too little incentive to invest in drugs for “southern” diseases.

To generate more drugs for “southern” diseases several proposals are made.

I will review some of these proposals on their positive effects for new drug developments and on their workability.

1. The Two Markets Modification

The first modification I want to analyse has been brought forward by J. Lanjouw²¹⁸ With his proposal, he tries to minimize the payments of developing countries for “Global” disease treatments and then to reinvest the saved money into the “Southern” disease.

The system works as follows.

Under his proposal there are still patent rights.

However, there are two separate regimes, one for developing countries and one for developed countries.

The rationale behind the proposal is that a patent applicant can only choose to protect his invention in one of these regimes.

He can either choose to protect his invention in developing or developed countries, but not in both regions.

That means he has the choice to choose one region where protection is granted but not both together.

Therefore, for all drugs the inventor will make an estimation where he can earn more profits, in developed or developing countries.

As a result, the inventor will always choose to protect his invention in developed countries if the drug medicates a northern or global disease, because he gets more financial gains there.

Therefore this proposal practically limits the negative impact of “northern” medicine payments.

For “Southern” drugs, however the inventor will choose to protect his invention in developing markets.

²¹⁸ A Proposal to Use Patent Law to Lower Drug Prices in developing countries

The result of this proposal is that developing countries can effectively free ride on northern or global diseases, whereas the developed countries can free ride on southern diseases.

The result looks promising because southern states have to bear most of the costs for “Southern diseases” anyway.

However, they will not get any remuneration for all the other drugs that can be used in both developed and developing countries.

On a first glance the system seems very simple, but there are still a lot of problems.

Most important is of course, the practical chance of such a proposal. It remains unclear why northern politicians should accept this system, since they just introduced a world wide system of patent protection to gain these extra returns from developing countries and in return gave them better trade access.

It seems very unlikely to me that the Northern politician would suddenly in an attack of pure gratitude and total ignorance of national lobbyists accept such a proposal.

Apart from that, the next problem is that Northern Companies might be totally unwilling to supply the Southern market with “global” or “northern” medicines, because they can not gain much there.

Even though the developing countries as a result to such a non-supply strategy would be free to produce and sell generics, to develop a generic industry and therefore extra supply source for all such medicines is very unlikely to happen on a midterm perspective.

In the end, the developing countries might end up by having to import all these drugs from developed Markets and therefore pay higher prices nevertheless.

Another problem is that all states have to be categorized in developing and developed Markets. This might become a problem for transitional countries, like India or Brazil and these countries will probably be the most benefiting countries.

Furthermore, it is problematic whether for the pure “Southern” diseases the incentive to produce drugs will grow.

First of all, due to the above stated difficulties it is questionable whether so much money is saved with the purchase of “global” and “northern” drugs which can be reallocated for the purchase of higher priced “southern drugs”.

Even if some money is saved and can be reallocated on the negative side, there will be also income losses from developed markets.

Although most of the earnings for “southern” drugs are made in developing countries, there is for nearly all drugs, a small market in developed countries, too. Even though this market in pure sold quantities might be small, this is often not the case for profit.

Special medicines are often sold in developed countries for extremely high prices.

In a worst case scenario an inventor has to resign 49 % of his profits.

In these cases he would still have to choose to protect the medicine in only one region, which might be the developing country markets.

This in mind, the incentive to develop products for developing markets might get even smaller than it already is.

In addition, developed states might be very unwilling to pay high prices for products where pre-eminent numbers are sold in developing countries.

The willingness to pay such subsidy prices will be low, because the consequence might be that in response to the higher profits earned there, the rights owner might choose to protect his medicine in the developed country regime.

Therefore the goodwill to subsidize “southern drugs” will be penalized with the introduction of patents in the “northern” zone, because the market will be more lucrative than the “southern” zone.

But if developed countries try to pay low prices for medicine, in the end they will be rewarded with a “southern” patent and can get the products almost totally free. This proposal would therefore undermine the efforts to develop more medicines for the south with northern subsidy programs.

Maybe the most important problem might be that the markets of developing and developed countries under this proposal will be completely segmented.

On a first glance this seems to be good because market segmentation is very important for “Ramsey” pricing, but it is of course not good for trade numbers.

It will be very difficult to establish the system in such a way that, for example a product is produced in India and then sold to Europe, with the patent owner getting his rightful share of this transaction.

Under the usual system, the Indian manufacturer would need a license but under the proposal he would not need one because there is no patent in India.

This will be a difficult problem and would undermine the prospect to expand international trade.

Still, if patents rights owner would really refrain from using “Ramsey” pricing and demand excessive prices in developing Markets, this system would have a big advantage.

There would be a lot of money saved that would otherwise have to be paid to rights owners for “global” and “northern” drugs and this money could be used to pay higher prices for “Southern” drugs and therefore, in an optimal system, lead to a higher incentive for drug development, despite the losses from developed markets.

Another advantage is that the decision where to protect a drug, would not be made by a bureaucrat, but be the rights owner himself.

Therefore there would be no risk of financial losses due to an uneconomic decision process.

It would also take away the burden of developing country governments to resist the lobbyist’s pressure and to issue compulsory licenses despite this pressure.

However, this system would only be good in such a worst-case scenario, where companies demand excessive prices and developed countries governments bend to the lobbyist pressure.

In a good, or normal scenario, the rights owners have to demand prices closer to manufacturing cost and therefore the financial gain of the new system will not be very high.

On the contrary there might be the problem that developed countries would think that these efforts are enough and would stop other financial aids and the pharmaceutical industry might stop their drug donation programs for developing countries.

One big problem, however, cannot be solved by this system, or by any other. Even without patents, most of the population in developing countries can not even afford medicines priced on manufacturing cost.

Therefore the problem of unattractive “southern” diseases remains and might get even worse.

Therefore the ” two markets system” does not seem to be a very good, or especially easily installable system.

2. Push and Pull Programs

Another proposal made to specifically approach this problem of neglected diseases is the so called “push” or “pull” programs.

To understand the rationale behind these programs let me first explain what the terms mean.

The term push programs means that the development of a new drug is subsidized by public funds. This happens, for example, through grants to academics, public equity investments in product development, research and development tax credits, or work in government laboratories.²¹⁹

Pull programs, on the other hand reward the full development of a new drug. That means if a company invents a new defined product, it gets a bonus payment from the state.

Therefore roughly, the distinction is between paying for research inputs and paying for research outputs.²²⁰

The good thing about both proposals is that they are consistent with the already existing patent rights system.

They are only an add-on, but not a complete break with the system.

Therefore, the political willingness to introduce such a system might be much bigger.

²¹⁹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.29
By M. Kremer

²²⁰ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.29
By M. Kremer

Which of these two programs is better and how they can be incorporated into the existing system will be scrutinized in the following.

2.1. Push Programs

The big advantage of the push programs is that it does not bring only results in one specialized predefined area, but can be successful in all areas.

For example, a tax credit program fosters development as a whole and not only in one special area or for one special disease.

For the development of new drugs, it is also necessary to perform some basic research and not only product-aimed studies.

For example, it can be wise to firstly perform some basic studies about a disease and then after you have understood the whole circle of a disease, decide how best to cure it.

However, if you support basic research, the result can be that even though there are millions of dollars spent, in the end there is not even one suitable product developed.

If you want to minimize the risk of financing fruitless studies, you should give narrow aims and that means you should focus your support on a finished and applicable drug.

Therefore, although push programs are advantageous for basic research, they are unsuitable for the development of a finished and applicable product.

Even if you are lucky with your push programs and a new drug is developed, such a development does not improve the accessibility of the product once it is developed.²²¹

The reason is that for your financial support you do not get anything as a trade-off.

Of course with your financial support you can direct the R&D in the right direction and therefore foster the development of a new drug.

However, with your financial support you have not secured any rights on the finally developed drugs.

²²¹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.35
By M. Kremer

This means the rights owner can, after getting maybe millions of dollars of tax subsidies, still decide where to sell the product and even more important at what price.

Therefore, in the end you might have a product developed, subsidized by tax money, which is still unaffordable to most of the people in developing countries.

In fact, this is already the case today because every R&D performed by a company in most of the developed states, can be brought in to reduce the tax payment in one way or another.

The second problem is that these programs have to be administered very thoroughly so that the research is directed in the right direction.

This monitoring might be quite difficult and you could end up subsidizing the development of a “lifestyle” drug and therefore only increasing profits instead of finding a drug for a neglected disease.

The problem of tax credits is also that firms tend to use creative accounting to claim credits for inappropriate expenses.²²²

In addition, tax credits are an incentive only for those firms that have tax liabilities. Most biotechnology firms have no current profits or tax liability and thus would not benefit from an enhanced R&D tax credit, unless they were able to pass their tax credits through to their investors, which would be problematic.²²³

The solution for this problem would be actively funded public research.

These public founded researches, however, are even more difficult to handle.

The problem starts with deciding which projects should be actively funded by public research.

This is especially difficult in cases where projects are purely funded by public research, because in these cases no one else will look at the success chances of

²²² Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.36
By M. Kremer

²²³ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.37
By M. Kremer

the project. Where a project is also funded by private investors, these investors will scrutinize whether the project has the chance of success or not.

However, in a pure government research, the government itself has to monitor these chances of success. How badly this works can be seen in one very illustrative example.

The example is taken from Desowitz and deals with the USAID Case²²⁴
USAID was founded to develop a malaria vaccine by using a push program.

It started in 1980 to fund efforts focused on three research teams.

Tests of a candidate vaccine developed by the first team found that only two of nine volunteers were protected from malaria, and suggested that the vaccine created side effects. These results, mixed at best, led USAID to claim that there had been a “major breakthrough in the development of a vaccine against the most deadly form of malaria in human beings. The vaccine should be ready for use around the world, especially in developing countries, within five years.” That was in 1984. The world is still waiting for a malaria vaccine.

Early work by the second team yielded disappointing results, but not surprisingly, the principal investigator argued that his approach was still worth pursuing and requested an additional \$2.38 million from USAID. The expert consultants assigned to review the project recommended that the research not be funded. However, USAID’s malaria vaccine project director told the USAID Office of Procurement that the expert panel “had endorsed the scientific methodology and the exceptional qualifications and experience of the researchers.” Once the grant came through, the principal investigator transferred grant funds to his personal account. He was later indicted for theft.

The external evaluations of the third proposal called it mediocre and unrealistic. The USAID project director ignored the report and arranged for the project to be fully funded. The principal investigator and his administrative assistant were later indicted for theft and criminal conspiracy in diverting money from the grant to their personal accounts. Two months before his

²²⁴ See *The Malaria Capers: Tales of Parasites and People* by Desowitz, Robert S. 1991 cited in *Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases* p.30 by M. Kremer

arrest, the Rockefeller Foundation had provided him with a \$750,000 research grant, and on the very day that he was arrested, USAID announced it was giving him an additional \$1.65 million for research.

By 1986, USAID had spent over \$60 million on its malaria vaccine efforts, with little progress. Since USAID believed that there would soon be many candidate malaria vaccines suitable for testing, it tried to obtain monkeys as test subjects for these vaccines. USAID's malaria vaccine project director, James Erickson, arranged for a contract to acquire monkeys to go to an associate who paid him a kickback. Erickson eventually pleaded guilty to accepting an illegal gratuity, filing false tax returns, and making false statements.

USAID had arranged for independent oversight to be provided by the American Institute of Biological Science (AIBS). This proved ineffective – unsurprisingly – as Erickson and the AIBS-assigned project manager were having an affair.

The USAID case is extreme, and many push programs are quite successful. But more generally, researchers funded for promises rather than for delivering a product, have incentives to report overoptimistic assessments to their superiors and even to divert resources away from the search for the desired product (although this does not usually take such a dramatic, criminal, form). These incentive problems occur whether research is publicly funded, governments make equity investments in private research, or government's award targeted R&D tax credits.²²⁵

Push programs in general have the high risk of financial losses without strict monitoring process.

However, this monitoring process also can be very costly and in the end bureaucrats might even tend to overestimate the chances simply for the risk of otherwise making themselves obsolete.

As Kremer writes in his paper "A public entity on the other hand may acquire its own bureaucratic momentum, which can lead governments to throw good

²²⁵ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.31 by M. Kremer

money after bad. Public sector institutions are notoriously difficult to shut down.”²²⁶

And “there is a strong incentive for firms considering research investments to realistically assess the prospects for success.”²²⁷

However, public institution often lack this realistic view.

As a conclusion it can be stated that although push programs are critical for stimulating basic research, their record in stimulating actual product development is decidedly mixed.²²⁸

Because of all these flaws it is not astonishing that the proposal of push programs is not very popular, but whether the results of pull programs are more favourable will be seen in the following chapter.

2.2. Pull Programs

Different from “push programs“ “pull programs” only reward successful past R&D with a certain extra bonus.

Therefore the risk of financing useless studies is minimized.

There are, however, several ways to organize pull programs and of course such programs are also not unproblematic.

2.2.1. Research Tournaments

One way is to organize pull programs in so called “research tournaments”.

In a research tournament, a sponsor promises a reward to whoever has progressed the farthest in research by a certain date.²²⁹

One advantage of a research tournament is that you can stimulate several research teams, while only paying the best out of public treasury.

²²⁶ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.32 by M. Kremer

²²⁷ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.33 by M. Kremer

²²⁸ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.29
By M. Kremer

However, such tournaments have several limitations and are therefore not well suited to encourage vaccine and drug research.

Firstly, a payment must be disbursed no matter what is developed. While tournaments provide incentives for researchers to devote effort to develop a product, they do not focus effort on the diseases with scientific prospects for success. Advocates for a particular disease and scientists working on the disease, will always want to encourage the establishment of tournaments for research on their disease, even if the prospects for ultimate success are low.

Another problem with tournaments is that once research has been completed, the award committee might be tempted to allocate the reward on grounds other than progress in research. The committee might award the reward to a more politically correct firm, to a university team, or to whoever had done the most scientifically interesting work, rather than to the team that had made the most progress toward the desired technology. Anticipating this, firms might invest in political correctness or scientific faddishness rather than in producing an effective product.

Therefore research tournaments are not really the best way to get results for the cure of neglected diseases.

2.2.2. Milestone payments

Another way of encourage research are so called Milestone payments. Milestone payments means that you offer a certain reward for the first to reach a certain predefined goal.

Of course such milestone payments are not useful if you want to foster basic research because, in basic research areas you cannot give clear aims or milestones.

However, for the development of a vaccine, for example for malaria, they are a good alternative.

²²⁹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.471 by M. Kremer

Milestone payments again have the advantage that they attract more research teams and that they are cheaper to finance than push programs.

However, milestone payments do not target the ultimate objective of the development of the desired technology, and hence might stimulate wasteful investments in research lines that were unlikely to lead to a viable product. For example, researchers might try to demonstrate efficacy in animal models for a product that was unlikely to be safe in humans.

This problem is greater the larger the milestone payment; if a milestone payment is greater than the cost of performing the research, firms might find it profitable to reach the milestone even if they know they can go no further. Milestone payments will be less likely to stimulate wasteful research on candidates unlikely to yield a viable product, if they are given in the form of subsidies for future research on the candidate product.²³⁰ However, such rewards might not be so attractive, because not only the scientist want future research funds, but also, probably as important, the investors want profits.

Another more promising way might be that you reward only the full development of the product.

2.2.3.Full Development Pull Programs

A full development program could work in different ways.

You could reward certain development aims or even only the full development of a new drug.

The major flaw of all these programs is that they might be slower than “milestone payments” or a “research tournament”

In a research tournament or with milestone payments you could oblige the teams to publish their results after the milestone is reached or the tournament is over.

²³⁰ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.41 by M. Kremer

And these published results can stimulate other research teams also to start the development and therefore, in most cases with more research teams, the period of time until a final result is found is shortened.

In contrast, such programs which tie incentives to the development of a product, would encourage researchers to keep their research results private as long as possible in order to have an advantage in the next stage of research.²³¹

However, if you look just at the promptness, grant funded academics and scientists in government laboratories should be even faster, because they have career incentives to publish their results quickly.

However, as was laid down before these results are not always helpful on the way to a final solution.

Full development programs still might be the better choice if you observe certain points.

2.2.3.1. Clear Criteria

One very important point is that you have to establish very clear criteria as to what the developed drug should accomplish.

On a first glance, it seems to be adequate to lay down the objective that a workable and successful drug against for example malaria has to be developed.

However, the problem is to determine what is meant by a workable or successful drug.

First of all, you have to decide what sort of drug you want.

You have to give clear criteria if you want to have a drug that stops a disease from spreading, that can cure its effects, or can immunize the person.

Even if you have found out and decided what is best, there are still a lot of things to observe.

²³¹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.41 by M. Kremer

It could happen that one company offers you a drug that cures the disease but has disastrous side effects.

The problem is that all medicines have side effects and you have to lay down clear criteria as to what is acceptable and what is not.

Additionally most medicines do not have a 100 % treating rate, so you have to determine what is adequate.

The next problem is that there might be a medicine that fulfils all these criteria but costs \$200 to manufacture it.

Therefore it is unlikely to be suitable to cure millions of people in Africa because they cannot afford it.

If you want the drug to be usable in developing countries it should better be a drug that is not very susceptible for false stocking and can also be applied by unskilled doctors. If it is a vaccine it would be better applied in one single dosage and not to be refreshed in less than 5 years.

As you see there is a whole catalogue of criteria to be laid down and the problem is that all these criteria have to be preassigned.

Even if the developed product fulfils all these criteria you still have to find a way to reward the winner.

There are different proposals of how to reward the winner.

As you will see this decision is also very important because the practice of gratification has to be acceptable to both sides, the developer and the organization that posted the reward.

2.2.3.2. Methods of gratification

2.2.3.2.1. Patent extension

The first proposal to reward the inventor of a new drug for a neglected disease, is to grant him a patent extension for one of the existing drugs he owns.

Such a patent extension can be very valuable especially if it is used on one of the blockbuster drugs.

And on a first glance, nobody has to pay a direct compensation for the work so it might be politically very acceptable.

However, such a reward would only stimulate the big pharmaceutical companies and shift the burden of remuneration to one small group of people which is dependent on that other drug, instead of sharing the burden together.

It could even happen that the research team would be sold to the biggest pharmaceutical company just to get the maximum reward with the patent extension for the biggest blockbuster drug.

From this it follows that patent extensions do not seem to be very recommendable.

2.2.3.2.2. Fixed Reward

Another idea is to just give the first inventor a certain reward, like a trophy in a normal race. This way he can recoup his investments.

However, if you use this alternative, you will get the problem that the inventor is still the owner of his patent.

Accordingly, he can decide what prices to charge and what profits to be made and where to sell the goods.

Again, you can end up again with a nice medicine that is unaffordable, on which you have spent millions of dollars to develop.

However, there are two ways to solve this problem.

2.2.3.2.3. Buyout or Purchase Commitments

You could use so called “buyout” or “purchase commitments”

The advantage of both is that no public funds are spent unless the desired product is developed.²³²

The first option that I will analyse are the so-called “buyout” commitment.

²³² Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.48 by M. Kremer

“Buyout commitment” means that a certain sum will be paid to the inventor if, in return, he assigns you his patent rights.

The good thing about this solution is that you have full control over the invention and you could start a competition between several licensees, to produce the product the cheapest.

Besides, if you declare the patent afterwards as free for public use, other research teams can start using the invention to find a better solution, which is based on the former patent.

With your waiver such following inventions may be developed faster and might be sold for a lower price to the consumers.

However, there are also a lot of disadvantages if you use patent buyouts.

While patent buyouts and commitments to purchase desired products are economically quite similar, purchase commitments more closely link payment to delivery of appropriate products and avoid the risk of buying out a patent only to discover that the original developer maintains effective monopoly rights because it possesses a trade secret.²³³

Compared to patent buyouts, product purchases also provide a closer link between payments and product quality.

For example, suppose that a vaccine received regulatory approval, but was later found to have side effects.²³⁴

If a patent buyout had been made at the date of regulatory approval, a long, uncertain, and wasteful legal fight might be needed to recover the money.

Vaccine purchase commitments, on the other hand, could be suspended as soon as evidence appeared of unacceptable side effects.²³⁵

²³³ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.43 by M. Kremer

²³⁴ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.45 by M. Kremer

²³⁵ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.45 by M. Kremer

Moreover, purchase commitments are likely to be politically more attractive than patent buyouts, and thus more credible to potential product developers.²³⁶

Purchasing malaria vaccine for 50 million children each year at a few dollars a dose for ten years, is likely to be more politically appealing than awarding a multi-billion dollar windfall to a pharmaceutical manufacturer.²³⁷

Therefore it might be the better choice to offer the first inventor to buy, for example, one million dosages per year for a period of ten years.

Of course there has to be a fair balance price, but with such a purchasing power, it should be possible to negotiate an appropriate price.

If you propose a purchase of several millions dosages, enough developers should be attracted, if this proposal is reliable.

2.2.3.3. Reliability

Reliability is one of the key aspects of every pull program

In a “pull program” the investors always have to do their work in advance.

For example, in case of a purchase commitment for a malaria vaccine the potential investor probably has to invest millions of dollars in R&D before a suitable product is developed.

The problem is that he cannot recoup his investments by selling the medicine on the normal market, because the demand elasticity is not high enough to be able to refinance his investments through higher prices .

Therefore the investor is dependent on the purchase commitment if he wants to get his money back.

²³⁶ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.45 by M. Kremer

²³⁷ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.46 by M. Kremer

Hence, to attract enough venture capital, the monitoring team has to be highly authoritative and the financial basis has to be highly reliable. Such a financial reliable basis can not be guaranteed by most developing states for two reasons.

Firstly, the political stability in such countries is often not so good. A research project will probably take up to 10 or 15 years. Such a long political stability can not be guaranteed in many states.

The second reason is that the rewarded price will have to be quite high and there will probably not be many states that want to pay such a high financial burden.

Kremer²³⁸ comes, in his paper, to the result that the annual revenue that has to be earned by a successful vaccine should be around \$336 million.

This high number is a logical result of the high risk potential investors are facing.

In evaluating their chances they have to take into account that their research team might not be the first that reaches the aim, or might even fail totally to find a solution.

In order to have incentives to conduct their investments, they will expect to more than cover their research expenses if they succeed. For example, if potential biotechnology investors expect that a candidate product has a 1 in 10 chance of succeeding, they would require at least a tenfold return on their investment in the case of success, to make the investment worthwhile.²³⁹

However, to limit the costs you could limit the product purchase phase to ten years and lay down the condition to participation to be an agreement to license the products to producers in developing countries, after ten years of purchases at an appropriate level.²⁴⁰

A ten-year purchase commitment would likely be sufficient to motivate research, given that potential developers are likely to heavily discount sales after this period, and that competing products

²³⁸ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.81 by M. Kremer

²³⁹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.78 by M. Kremer

are likely to emerge after ten years in any case, and drive down prices to the point at which they could be more broadly affordable without subsidies.²⁴¹

To further limit the costs, it might be helpful also to reward the second inventor. Although this seems to be curious, it might be helpful. Because if you also reward the second inventor the probability of success will grow and therefore the stimulating reward for the first inventor can be smaller.

Still, the money to be rewarded is very high and therefore it is probably very unlikely that one state alone will be willing to pay it. Most probably it has to be a team of several developed countries or an international institution, like for example the World Bank or the International Monetary Fund, which guarantees for the financial background.

Of course the committee that determines the winner also has to be highly reliable and as independent as possible.

Only if these criterias are fulfilled will a purchase commitment or any pull program have any chance of success.

3. Conclusion

Especially the Pull programs in form of purchase commitment can be a solution to develop the necessary new medicines for such diseases as Malaria or Tuberculosis. With the spreading resistance of the viruses against the existing medicines such new vaccines are really important.

Other than in case of foreign aid, developed countries might be more willing to spend money for such a fund because most certainly the developer of the new vaccine will be one of their pharmaceutical giants.

In the end it is just another form of subsidizing their own industry with the side effect of helping the developing countries.

²⁴⁰ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.82 by M. Kremer

²⁴¹ Public Policies to Stimulate the Development of Vaccines and Drugs for the Neglected Diseases p.82 by M. Kremer

If around ten states join in, the necessary sum for each state will be just around \$30 million. A small price compared to the damage these diseases do in developing countries.

In addition, such a purchase commitment compared to foreign aid will be more appealing for the developed states because they themselves can control the spending of the money and therefore the risk of corruption will be minimized.

Another advantage of these pull programs is that they are consistent with the already existing property rights system and therefore easy to introduce. However, with such pull programs only a few major diseases can be cured. There simply cannot be such a purchase fund for every “southern” disease. However, even two or three funds for the major diseases are a major breakthrough. The money that is invested in such a program will very likely have a good return rate even for developed countries.

Compared with the anticipated loss of \$22 billion alone of South African Gross domestic product in the year 2010, even the high sum of \$12.1 billion calculated by Wong, Maskus and Ganslandt for a comprehensive purchase program does not seem to be so high.²⁴²

And the treatment with such a push program would also be a very cost effective one.

A standard way to assess the cost-effectiveness of a health intervention is the cost per Disability Adjusted Life Year (DALY) saved. For example, in the 1993 *World Development Report*, the World Bank treats health interventions as cost-effective for poor countries if they cost less than \$100 per DALY saved (In contrast, health interventions are considered cost-effective in the U.S. at up to 500 to 1000 times this amount – \$50,000-\$100,000 per year of life saved).²⁴³

In his paper²⁴⁴ Maskus comes to the conclusion that the net present value of expenditures per discounted DALY saved over a ten-year horizon would be \$10 for malaria, \$12 for tuberculosis, and \$44 for AIDS.

²⁴² Developing and Distributing Essential Medicines to Poor countries the Defend Proposal p.21 by M.Ganslandt, Keith E. Maskus, Eina V. Wong

²⁴³ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 26 by Keith E. Maskus

²⁴⁴ Parallel Imports in Pharmaceuticals: Implications for competition and prices in developing countries p. 84 by Keith E. Maskus

Therefore for the economic observer such a push program would not only be remunerative in terms of economic return but also very cost effective.

Still, such a program would only be a step in the right direction but not the solution for all health problems in developing countries.

What else will be necessary will be shortly discussed in the following chapter.

IV. Other problems arising with access to Medicines in Developing Countries

Even if the new medicines are invented with the help of pull programs and developing states introduce a flexible, but with TRIPS consistent legal framework, developing states will still need a lot of help with their medical systems.

A very important point is the education of the people. According to a WHO report an average of only 50% of patients take their medicines correctly.²⁴⁵

Therefore, even if the people have access to drugs they still have to be taught how to use them in a right way.

One disease for which education is very important is AIDS. If the people know how to protect themselves, tremendous results will be achieved.

A study found out that a woman with primary education is 2.5 times more likely than women without schooling to correctly identify the main ways to prevent HIV.²⁴⁶

Due to this education, during the 1990s the HIV infection rate fell by almost half among educated women, but there was little decline for women without any formal education.²⁴⁷

Education has not only these direct effects it also helps these countries to more economic growth and again this economic growth saves people from diseases, because the main factor for health worldwide is the economic status of the person

For example, if you compare the under 5 mortality rate of the richest fifths and the poorest fifths in less developed countries you will find out that the mortality rate for the poorest fifths is 2.2 times higher than for the richest.²⁴⁸

And the same applies to all other important health numbers.²⁴⁹

²⁴⁵ World Health Report 1997 WHO

²⁴⁶ Global campaign for Education: Learning to survive:How education for all would save millions of young people from HIV/AIDS p.9

²⁴⁷ World Bank, Window of Hope;Vandemoortele and Delamonica. Cited in Global campaign for Education: Learning to survive:How education for all would save millions of young people from HIV/AIDS p.10

²⁴⁸ Improving the Health of the Worlds poorest p. 8 by Dara Carr

The economic status is very important and the main factor to determine the economic status is the education level. Accordingly, to raise the level of education has a double positive impact on health care.

The bad thing is that AIDS has a double negative impact on education.

Zambia lost 1,300 teachers due to AIDS in the first ten months of 1998, the equivalent of two-thirds of all new teachers trained annually and in Central African Republic, 85% of the 300 teacher deaths in 2000 were due to AIDS. The epidemic is responsible for the closure of more than 100 education establishments.²⁵⁰ Less education establishments again mean less educated people and therefore higher infection rates. From this follows that public health has not only a direct but also a much bigger indirect impact on the economy of these states.

Another aspect is the whole infrastructure in these countries. They often lack the necessary medical personal to treat people right and especially to detect diseases at an early stage.

50 % of patients taking their medicines wrongly can be attributed to badly educated medical personnel , if there is any personnel at all.

One major problem is that, in many countries, the bulk of public spending on health is directed toward hospitals in urban areas and specialist care at the expense of rural primary care facilities. As a result, primary care facilities are often short-staffed and lacking medicines.²⁵¹

By increasing and strengthening these rural primary care facilities, programs could address important accessibility issues for the poor: travel time to the nearest facility or to a facility with needed or desired services and residence in a rural or neglected area, where services are scarce or unavailable. In Ghana, researchers estimated that reducing the average distance to the nearest public clinic could increase use by more than 90 percent.²⁵²

Again, the money spent for health care is not only a gift to these countries but an aid to help themselves. A recent World Bank study with 127 case studies examining why families fall into poverty, provides further evidence of medical impoverishment.

²⁴⁹ see Improving the Health of the Worlds poorest p. 7 by Dara Carr

²⁵⁰ UNDP statistical fact sheet

²⁵¹ Improving the Health of the Worlds poorest p. 21 by Dara Carr

²⁵² Improving the Health of the Worlds poorest p. 21 by Dara Carr

In reviewing these cases, analysts identified health problems as the single most common trigger for the descent into poverty.²⁵³

The reason for this is the fact that in these countries health insurance is not available and most of the medical care or medicines has to be paid out of pocket.

When people have to pay for services at the time they need them, access to care is limited to those who can afford the fees. This type of system exposes the poor to potentially large, unexpected costs. Often, the poor lack the cash reserves to cover these types of expenses. Since the poor are also less likely to participate in job-based health prepayment or insurance schemes, they are more vulnerable to impoverishment as a result of fees.²⁵⁴

The solution to this problem is risk pooling or prepayment schemes, but these require far greater institutional and organizational capacity than out-of-pocket financing. Many low-income countries lack the managerial capacity required²⁵⁵ and the financial resources to uphold such a system.

v. Conclusions

In the end, it all comes down to the question of adequate financing.

You could say patent rights are no problem if you have the money to pay monopoly prices.

In most cases the pharmaceutical companies do not charge these monopoly prices anymore in developing countries. And if there is enough political will and persistence in developing countries, they can use the flexibility laid down in the TRIPS system to stop them in doing so in the remaining cases.

Developed countries, especially the US., also have to refrain from political pressure to preclude the countries from using this flexibility.

Certainly a patent system always includes the risk that some companies might use their monopoly powers in a wrong way, but with efficient antitrust policies you can prevent them from doing so. The problem is just that most developing countries do not have such efficient antitrust agencies. The reason for that is that they lack the financial resources to install such an authority which can match with the lawyers of international pharmaceutical companies.

²⁵³ The World Bank, *Dying for Change* (Washington, DC: The World Bank, 2002): 23 cited in *Improving the Health of the Worlds poorest* p. 21 by Dara Carr

²⁵⁴ *Improving the Health of the Worlds poorest* p. 25

²⁵⁵ *Improving the Health of the Worlds poorest* p. 27 by Dara Carr

The framework given by TRIPS is not bad but it has to be accompanied by rising financial and technical aid to prevent the outgrowths already known in developed countries.

But even if there would be an adequate antitrust policy, the flexibility of the TRIPS system would have been used to its full extent and the pharmaceutical companies would not charge excessive prices, the problem would remain that the people still cannot afford the drugs, even at normal rates.

This can be documented by the lack of patents in many developing countries. For example, a study in 2001 in 53 African countries concluded that patents on antiretroviral drugs for HIV had only been applied for in 172 of 795 possible cases.²⁵⁶ This means that the importation of generics is allowed in 623 cases. Still the majority of the African people are still not taking part in an antiretroviral program.

Therefore the reason for the lack of access to medicine are not only patents. Laying blame for the problem on the WTO and the TRIPS Agreement is overly simplistic and wrong, and does nothing to alleviate the crisis.²⁵⁷

While it may be easy to use the drug industry as a scapegoat, patents are not alone blocking the access to HIV/AIDS medications in sub-Saharan Africa. Even if antiretroviral HIV/AIDS drugs were made available for free tomorrow, there is a lack of health care infrastructure to conduct testing, store and distribute medications, and monitor patient compliance with what are often very complicated regimens.²⁵⁸ Nils Daulaire, President of the Global Health Council, is among a growing chorus acknowledging that the challenge is much deeper than cheaper medications. “Even if AIDS drugs were free, no more than 10 to 20 percent of Africans would benefit as the health infrastructures do not exist to manage infections in each individual”²⁵⁹

Another fact is that according to WHO, 95% of products on the Essential Drug List, which is the main internationally recognized list of medicines considered to be

²⁵⁶ Patents, Pills and Public health: Can TRIPS deliver? p. 13 by Martin Foreman

²⁵⁷ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.52 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

²⁵⁸ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.52 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

²⁵⁹ Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub Saharan Africa 2000 p.53 by Lee Gillespie-White, Venus Griffith, Alben Petrova, Stetson Sanders, Paul Salmon

essential for the majority of the populations of countries, especially developing countries, are off-patent.²⁶⁰

Even these off-patented drugs are often not affordable. One reason for that is that developing countries often still have import duties and tariffs on these products while almost all industrialized countries have zero tariffs.²⁶¹

Tariffs at the high end of the spectrum are on average upwards of 30 percent in some countries, including Burkina Faso, Pakistan, India, Tanzania and others.²⁶²

The reason for that is partly that they need the money and import tariffs are often a big income source for a state where a normal tax system only works in parts. Still, this of course is a bad option because in the end if the people can not afford the drugs it will cost the state much more than it will earn with such tariffs.

Again it is wrong to blame the pharmaceutical companies alone but it is also wrong to completely let the industry off the hook.

The pharmaceutical industry is to blame for the high prices in the past and only massive public pressure have “convinced” them to behave better.

Besides the pharmaceutical industry has not tackled the problems of “southern diseases”.

Of course you could say that they just worked consequential economical, but maybe the drug industry despite its shareholders has to do better.

To see how badly they did, here are some numbers. Of the 1223 new drugs approved between 1975 and 1997, 13 (less than 1 %) were specifically to treat tropical diseases.²⁶³

Of course it might not be as lucrative to develop a drug for Malaria as for diet pills, but the pharmaceutical companies always claimed that they are a special industry and they need their high profits to develop new drugs that are not so lucrative.

But they did much less.

For years, the pharmaceutical industry has been making huge profits, while spending relatively little on R&D. For more than two decades it was the most profitable industry in the US. In 2002, for example, the 10 drug companies in the Fortune 500 made

²⁶⁰ Consumption and Trade in off- Patentee Medicines, Harvey E. Bale p.5

²⁶¹ Consumption and Trade in off- Patentee Medicines, Harvey E. Bale p.8

²⁶² Consumption and Trade in off- Patentee Medicines, Harvey E. Bale p.8

²⁶³ 4 Trouiller P, Olliaro P. (1999) Drug development output from 1975 to 1996: What proportion for tropical diseases? *Int Journ Infect Diseases*. Vol: 3: 61-63.cited Access to medicines should not be a luxury for the rich but a right for all p.2 by Ellen F. M. 't Hoen

profits of 17 per cent of sales, compared with a median of 3.3 per cent for all the Fortune 500 companies, and spent only 14 per cent of sales on R&D.²⁶⁴

It seems that again the public and that means the developed countries have to step in by financing pull programs.

To keep costs low they could finance such a program by lowering drug prices in their countries by using tiered pricing. The pharmaceutical companies could surely endure such a small decrease of their incomes because the pharmaceutical companies are one of the winners of the new worldwide patent System. According to a World Bank economist the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) would amount to a minimum of US\$ 3.5 billion and a maximum of US\$ 10.8 billion, while the gains to foreign patent owners would be between US \$2.1 billion and US 14.4 billion.²⁶⁵

There will probably be higher drug prices in some countries, otherwise there could be no such financial gains.

Most certainly these higher prices will occur in such “richer” developing countries like India, where the people can afford higher prices.

This view is consistent with the above-mentioned study about patents in Africa.

Of all the patents in Sub Saharan, most were applied in South Africa where the income is higher and therefore the economic interests are bigger.

Fortunately these “richer” developing countries will probably also be those countries that profit most from the new trade tariffs.

Still, it would be a fair deal if some of the new profits made by the pharmaceutical industry were taken away from them in form of higher taxes or lower medical prices in developed countries and sent back to developing countries in form of foreign aid, or even to the pharmaceutical industry itself, in form of a pull programs.

Such an aid for the health care of people in developing countries is not only a human rights aid, but also an economical reasonable aid.

A Zambian study shows that two thirds of urban households that have lost their main breadwinner to AIDS have experienced a loss of income of 80 %.²⁶⁶ The same study found out that 39 % lost access to piped water and 21 % of the girls and 17 % of boys dropped out of school.

²⁶⁴ Financial Times, “Big Pharma is a two-faced friend” by Marcia Angell 19th July 2004

²⁶⁵ Nogue J (1990) “Patents and pharmaceutical drugs; Understanding the pressure on developing countries”, *Journal of World Trade Law*, Vol. 24, Number 6 cited in Access to Medicines and Public Policy Safeguards under TRIPS p.13 by Dr.K.Balasubramaniam

²⁶⁶ UNDP Statistical Fact sheet p. 2

Again bad education is one of the main obstacles for economic growth

As I laid down before, even if the costs for such a program of help are higher in the short term, on a long term perspective it is the only way to get the developing countries independent from foreign aid.

In summary, it is fair to say that the new patent system is not as bad for developing countries as many people say. They just need foreign aid to establish a national legal framework that enables them to use the full flexibility of TRIPS.

If the extra profits are partly skimmed and used for the development of new drugs and for foreign aid, the developing countries will probably be better off than before.

Although one should not forget that developing countries did not accept these new property rights without a trade-off.

In return they got better market entrances and trade chances. The main winners are also the main losers of the new patent rights like India or China.

Whether the trade-off can really compensate for these losses is hard to say and not the aim of my paper.

My aim, however, was to show that TRIPS grants a flexible system, reveal how to use this flexibility and what else, especially developed states, could do to foster the human and therefore economical health of developing countries.

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