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Global pharmaceutical patents after the Doha Declaration – What lies in the future

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Abstract

The purpose of this article is to analyse how developments after the Doha Declaration went wrong; how developing countries can best be helped by IPR legislation; and whether such help can be achieved without taking away the incentives for industry to develop medicines. It is submitted that a legal framework maintaining the global protection of IPRs is needed, especially in developed countries, but that such a framework must allow for compulsory licensing in separate, regional “generic markets”, and must further create effective barriers for (re-)import into other countries than those targeted by the compulsory licence. This proposal would create a large market currently unused, in which pharmaceuticals could be produced and sold more cheaply, while protecting developed countries from importation of generic drugs. This way, compulsory licensing should work as a tool to promote innovation whilst also protecting public health globally.

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1. Introduction

“The law, in its majestic equality, forbids the rich as well as the poor to sleep under bridges, to beg in the streets, and to steal bread.”

Anatole France (1844-1924), *The Red Lily*, 1894, chapter 7

Over the past decade harmonisation of intellectual property rights (IPRs) on a global scale has proceeded rapidly, the agenda having been largely driven by developed countries. When the Uruguay Round concluded and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was put into force in 1994 many believed that, although it may have been a step towards reaching a global solution, the TRIPS Agreement was created by a few for the benefit of a few. When considering the differences between developed and developing countries in terms of IPRs, one of the most important areas has been pharmaceutical patents. On one side are the pharmaceutical companies, claiming their right to own their patents and to benefit from them with high prices, considering the high risks and costs of their research and development (R&D). On the other side are developing countries, claiming their rights to buy or manufacture existing medicines at low prices to prevent diseases and to help their people. These interests not only conflict, but it is also unclear how either one is best protected. Not everyone believes that strong IPR protection benefits the pharmaceutical industry, and weak protection is not necessarily good for the users of the drugs. Nevertheless, the general view is that the TRIPS Agreement helps the pharmaceutical industry but, with regard to medicines, makes the situation worse for many developing countries.

The Doha Declaration,¹ approved in November 2001, was in theory a breakthrough for developing countries and for nongovernmental organisations (NGOs) working for low cost drugs in the developing world. The statement affirms the right of all countries to protect public health and it was seen as being fairer for poor countries. However, in the time after Doha, the implementation of the statement has failed as the US and the EC have taken a harder line in order to protect their pharmaceutical exporters. The purpose of this article is to analyse how developments after the Doha Declaration went wrong; how developing countries can best be helped by IPR legislation; and whether such help can be achieved without taking away the incentives for industry to develop medicines. The main focus will be on Article 6 of the Doha Declaration, concerning compulsory licensing, and the analysis will include the Decision on implementing Article 6, taken on 30 August 2003. A question to be raised in connection with this is whether developed countries have breached their obligations under the Doha Declaration, in light of subsequent global pharmaceutical patenting practices and, if so, what lies in the future?

The scope of the article is to find the answers to the questions above on an international policy level, and not from a detailed legislative analysis. Only pharmaceutical patents will be studied, although there are, admittedly, many other closely related areas in which similar questions arise. Regarding method and

¹ Doha WTO Ministerial Declaration on TRIPS and Public Health, adopted in November 2001.

materials, the author has used sources from as wide a spectrum of publications as possible, but has been cautious about the sources relied upon. This is due to the fact that the debate on this topic is, at times, inflamed and many commentators have agendas that do not necessarily correlate well with an academic and neutral study of the problem. In addition, while there are a number of interesting books on the legal aspects of TRIPS, the WTO and the problems surrounding pharmaceutical patents, little has yet been written in books on recent developments in the WTO negotiations and the Doha Declaration, which is why periodical materials have mainly been used.

2. Intellectual Property Rights, TRIPS and Doha – Background and Facts

2.1 Intellectual Property Rights

Before introducing the facts on pharmaceutical patents in relation to the TRIPS Agreement and the Doha Declaration, a very brief overview of why IPRs exist at all may be useful. Patents and IPRs in general are used to give a certain exclusionary right that cannot otherwise be given to the owner of intangible property on a competitive market.² The inventor or owner is given this right since the nature of the property otherwise allows it to be used by several manufacturers at the same time, as the property is not individually appropriable. One of the defences for this argument is the moral right an inventor has to use his own invention.³ Today, however, the argument for protecting IPRs derives mainly from a financial perspective, since the R&D cost is often very high, while the cost of distributing the knowledge from an owner to a manufacturer outside the owner's control is insignificant. Those using this financial argument for the protection of IPRs believe, not undisputedly, that the protection of innovation is required for economic growth.⁴ History shows, however, that many of the countries with the most innovative pharmaceutical industries did not have patents until their industries had already grown to a significant size.⁵ Since the pharmaceutical R&D costs are extremely high and the market for pharmaceutical products is highly competitive and international, the arguments given above lie at the very heart of the debate on pharmaceutical patents.

The modern protection for intellectual property rights developed first as national legislation in developed countries, followed by international agreements such as the

² P Torremans, *Holyoak and Torremans Intellectual Property Law*, 3rd edn (2001) at 13 (P Torremans, *Intellectual Property Law*).

³ S Picciotto, in Drahos and Mayne (eds), *Global Intellectual Property Rights – Knowledge, Access and Development* (2002), 225 (Drahos and Mayne (eds), *Global Intellectual Property Rights*).

⁴ P Torremans, *Intellectual Property Law*, at 14-15.

⁵ For example France, Germany, Italy, Sweden and Switzerland resisted providing pharmaceutical product patents for a long time. During the time when the US industry was still young and developing, the US also refused to respect international IPRs, on the grounds that copying was entitled in furtherance of its social and economic development. See W Pretorius, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, 184.

Paris Convention,⁶ the Berne Convention⁷ and other co-operations, eventually leading to the TRIPS Agreement.⁸

2.2 The TRIPS Agreement

The World Trade Organization (WTO) and the TRIPS Agreement were created in the framework of the General Agreement on Tariffs and Trade (GATT) and agreed upon in 1994. The TRIPS Agreement is undoubtedly the most significant development in intellectual property in recent years, perhaps even in the 20th century, together with the creation of the World Intellectual Property Organization (WIPO) at the 1968 Stockholm Conference.⁹ TRIPS, which sets the minimum standard for IPR protection among the WTO members, became final after many negotiations between 1986 and 1994. The first proposal that had similarities with the final TRIPS Agreement was tabled by the EC in March 1990, and was entitled “Draft Agreement on Trade-Related Aspects of Intellectual Property”.¹⁰ The US closely followed with a very similar draft,¹¹ which also carried the same title. Consultations between the two had probably preceded the tabling of both documents.¹² Many countries disagreed with the proposals in full or in part, filing additional proposals. What the developing countries were especially concerned about was the inclusion of pharmaceutical products in the agreement.¹³

In June 1990 the Chairman of the negotiations put forward a draft called “Chairman’s draft” or “Composite draft text”, which included and combined all of the suggested proposals. Developing countries opposed an all-encompassing agreement on intellectual property, especially as they felt that the proposal by the Chairman adopted an overall structure that was very similar to that of the EC and the US proposals.¹⁴ During further discussions it was clear that the question of protection of pharmaceutical products through patents was one of the major issues to be resolved. However, with a new draft of TRIPS presented by the Chairman, the reactions were mainly positive and although pressure still existed for changes, few amendments were made before the final TRIPS Agreement was adopted at Marrakech in 1994. Regarding pharmaceutical patents, the two parties mainly opposing the agreement were India and the American pharmaceutical industry. Although it was not a party to the Agreement, the American pharmaceutical industry was a powerful lobbyist. The industry felt that it was not receiving the immediate protection it wanted because of

⁶ Paris Convention for the Protection of Industrial Property 1883.

⁷ Berne Convention for the Protection of Industrial Property 1886.

⁸ More about the history of patents can be found in H C Wegner, *Patent Harmonization* (1993) at 1-21.

⁹ D Gervais, *The TRIPS Agreement: Drafting History and Analysis* (1998) at 3 (D Gervais, *The TRIPS Agreement*). Along with the creation of WIPO, the 1968 Conference also adopted revised Berne and Paris Conventions.

¹⁰ Document MTN.GNG/NG11/W/68, cited in D Gervais, *The TRIPS Agreement* at 15.

¹¹ Document MTN.GNG/NG11/W/70, cited in D Gervais, *ibid*.

¹² D Gervais, *The TRIPS Agreement*, at 15.

¹³ F M Abbott, “The Doha Declaration On The TRIPS Agreement and Public Health: Lighting A Dark Corner At The WTO” (2002) 5 *JIEL* 469 (F M Abbott, “The Doha Declaration”).

¹⁴ D Gervais, *The TRIPS Agreement*, at 18-19.

the transition rules (subsequently amended), which stretched the transition periods for least developed countries (LCDs) even further.¹⁵ India was, and still is, concerned about restrictions on compulsory licensing of patents, found in TRIPS, Article 31.¹⁶ It seems evident that the two could not have found a draft with which they were both satisfied.

2.3 The Doha Declaration

In light of this, it is not surprising that certain parties continued their own agendas, unconvinced that the TRIPS Agreement was the best way forward. Together with threats of economic sanctions from the EC and the US, large pharmaceutical companies also filed a lawsuit in 1998 to force South Africa to drop an amendment to its patent laws.¹⁷ This developed into a public-relations nightmare created by NGOs, where broadcasts from the courtrooms and protests outside made people in wealthy countries ashamed, as it was perceived as if the greed of “the North” and its industry was killing people in the south in their millions.¹⁸ The lawsuit was dropped in 2001.¹⁹ Subsequently, the WTO was asked by the US to overturn a Brazilian law on overriding patents, but again the public criticism became too much and the case was dropped.²⁰

When the WTO met in November 2001, pharmaceutical patents were again on the agenda and the wealthy countries were more defensive due to the developments described, although the US and its allies were still reluctant to agree on anything substantial. Eventually, the WTO approved a statement, the Doha WTO Ministerial Declaration on TRIPS and Public Health (The Doha Declaration), adopted on 14 November 2001, which affirmed the right of all countries to protect public health. In the general Ministerial Declaration of the Doha Conference,²¹ Article 17 states that the WTO countries realize the importance of the implementation and interpretation of TRIPS in a manner supportive of public health. It further points to the separate declaration, the Doha Declaration on TRIPS and Public Health. The Doha Declaration does not amend the rights and obligations laid down in TRIPS, but provides guidance for the interpretation of the relevant parts of the Agreement.

¹⁵ The least developed countries have until 2016 to implement the TRIPS Agreement. See the Doha Declaration on TRIPS and Public Health, para 7.

¹⁶ D Gervais, *The TRIPS Agreement*, at 21-25.

¹⁷ See EC paper *Developing Countries and Access to Medicines: How did we get here?* (EC paper *Developing Countries*); F M Abbott, “The Doha Declaration”; and J Love, “WTO Reneges on Drug Patents – Prescription for pain” *Le Monde Diplomatique*, March 2003. Incidentally, the EC paper does not mention the threat of sanctions from the EC and the US.

¹⁸ The US backed away from its threats as the issue threatened to disrupt the political campaign of Vice President Al Gore. See F M Abbott, “The Doha Declaration”.

¹⁹ EC paper *Developing Countries*; and D Murthy, “The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health” *17 Am. U. Int’l L. Rev.* 1299 at 1313 (D Murthy, “The Future of Compulsory Licensing”).

²⁰ The US instead chose to pursue private bilateral negotiations. See D Murthy, *ibid* at 1314.

²¹ Doha WTO Ministerial Declaration of the Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, adopted on 14 November 2001.

According to paragraph 1 of the Doha Declaration the member states recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/Aids, TB, malaria and other epidemics.²² The Declaration further points out the need for the TRIPS Agreement to be part of actions to address these problems, and that IP protection is important for the development of medicines, but that the effects on prices is concerning.²³ Therefore, the parties to the Declaration agreed that the TRIPS Agreement should not prevent measures to protect public health.²⁴ This is developed in paragraph 4, which provides that the TRIPS 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**”.²⁵ In order for countries to have flexibility in using the TRIPS agreement, paragraph 5 goes on to state, *inter alia*, that TRIPS shall be read in light of the object and purpose of the Agreement, found in Articles 7 and 8 of TRIPS, and that each member has the right to grant compulsory licences and the freedom to determine the grounds for such a licence.²⁶ When using compulsory licensing in accordance with TRIPS Art 31, the Doha Declaration further gives the member states the right to determine what constitutes a national emergency or other circumstances of extreme urgency, which are conditions to issue compulsory licences.²⁷ Article 5 also leaves each member free to establish its own regime for the exhaustion of intellectual property rights without challenge.²⁸ Recently, on 30 August 2003, a decision was reached in the WTO regarding new rules for the export of pharmaceutical products under compulsory licences. This decision, and the debate leading up to it, and the debate which will surely follow it, derives from Article 6 of the Doha Declaration.²⁹ The article, cited in full, reads:

*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 **before the end of 2002**.*³⁰

²² Ibid para 1.

²³ Ibid paras 2-3.

²⁴ Ibid para 4.

²⁵ Doha Declaration, Art 4, emphasis added.

²⁶ Doha Declaration, Art 5a) and b). The objectives of the TRIPS Agreement, found in Art 7, are, *inter alia*, to promote intellectual property in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The principles, found in Art 8, state that members may 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.

²⁷ Doha Declaration, Art 5c). It is understood that public health crises, including HIV/Aids, TB, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

²⁸ Doha Declaration, Art 5d).

²⁹ The Decision on implementation of Article 6 of the Doha Declaration on TRIPS and public health. The decision is analysed in section 4.

³⁰ Doha Declaration, Art 6, emphasis added.

Paragraph 7 of the Declaration provides, *inter alia*, an extension to the transition periods for LDCs as regards the pharmaceutical products, until 2016. As was indicated above, one main area of debate since the Doha Conference has been paragraph 6 of the Declaration, which addresses the effective use of compulsory licensing. As the Council for TRIPS was given until the end of 2002 to find a solution, it did put forward a proposal. Most countries found the proposal acceptable, with the US being the only country to object to it. On 20 December 2002, as the US made clear that they would not accept the proposal, it was obvious that the Council for TRIPS had failed in the task given to it in November 2001. With a new decision in place from August 2003, some of the problems may have been solved, but as will be developed below, there is still no solid solution and this will remain one of the main issues of debate. In further discussions, it will become evident that the wording of the other Doha Declaration paragraphs are also important and their meaning not yet entirely agreed upon.

At present, as companies are reluctant to invest in pharmaceutical research unless the potential outcome is a product with annual sales around \$1 billion, and the R&D in the pharmaceutical sector in 2000 was an estimated \$44 billion, one can understand why medicines do not come cheap.³¹ Public spending on drugs in over three dozen countries, many in sub-Saharan Africa, is less than \$2 per capita per year.³² The retail prices of proprietary drugs in some of the poorer countries are higher than the prices in wealthy countries, and in many developing countries these proprietary brands of drugs are the only products available.³³ Izaak Walton once wrote: “Look to your health, and if you have it, praise God [...], for health is [...] a blessing that money cannot buy.”³⁴ He may have been right in his day, but times have certainly changed.

3. Analysis – Problems and Proposals

“The pure and simple truth is rarely pure and never simple”

Oscar Wilde

As outlined above, the international framework on intellectual property rights is now in place, but the parties on the international scene do not agree on what direction the future development of IP protection should take. Not only are there issues of future changes to the legislation, but there is also a debate on the legitimacy and interpretation of the existing wording of the TRIPS Agreement and the Doha Declaration. The analysis in this section will present the opinions of the involved parties, and analyse the underlying political agendas and the proposals put forward. The proposed solutions will then be analysed and compared below in order to find the best path for future development and also the most likely one, which are not necessarily the same.

³¹ CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at 32 (CIPR, *Integrating Intellectual Property Rights*).

³² IPI, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, 53.

³³ K Balasubramaniam, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, at 100.

³⁴ I Walton, *The Complete Angler* (1653), pt 1, ch 21.

The legitimacy and the efficiency of TRIPS and the Doha Declaration cannot be fully analysed here, as it is not necessary for the scope of this essay. However, to describe the issue of legitimacy in short, what has been argued is that the TRIPS Agreement was not reached through democratic bargaining, as there was an imbalance of power between the net exporters and the net importers of IPRs. There was, for example, not full disclosure of information between parties and coercion was used by the wealthy countries during the negotiations.³⁵ Regarding the Doha Declaration, its legitimacy has not been questioned from its negotiating process, since it seems to capture the middle ground between the positions adopted by developing and developed countries.³⁶ Perhaps the power balance was found through the affect public opinion had on governments and industry after action was taken due to the TRIPS Agreement. It was also, however, due to the fact that developing countries established and maintained a coalition through the negotiations.³⁷ The Doha Declaration can, nonetheless, be questioned on its merits as a declaration.³⁸ It is debateable whether it is a subsequent agreement on interpretation of TRIPS, evidence of practice, or a non-binding commitment, which would not constitute an enforceable legal obligation.³⁹ Whether legitimate or not, the texts of the TRIPS Agreement and the Doha Declaration still contain many problems that remain unsolved. Those concerning the topic of this paper will be addressed and analysed below.

3.1 General Problems

The general complaint made from developing countries regarding IP is that it has shifted too far in favour of producers. In the case of drugs this means that IPRs have shifted too far towards the protection of the pharmaceutical patents owners. According to the critics, IPRs are not inherent, natural rights and should not be treated as such.⁴⁰ This debate revolves around the general issue of the monopoly and private rights granted through patents, as opposed to the public interest and social benefits deriving from science and technology.⁴¹ Due to this conflict, patent laws that are

³⁵ For more reading about the legitimacy and efficiency of TRIPS, see P Drahos, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, ch 10.

³⁶ Middle ground of positions meaning that it embodies commitments on both patent protection and availability of drugs. See paras 3 and 4 of the Doha Declaration.

³⁷ F M Abbott, "The Doha Declaration".

³⁸ J T Gathii, "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties" 15 *Harv. J. Law & Tec* 291 at 301 (J T Gathii, "The Legal Status of the Doha Declaration"). It should be added, though, that Gathii in his article also considers the process the "lawful process of negotiation and agreement that characterizes the GATT/WTO". The comment cannot be considered as a conclusion generally agreed upon regarding GATT/WTO processes, see, *inter alia*, P Drahos, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, ch 10.

³⁹ An analysis of the matter would include, *inter alia*, interpretation through the Vienna Convention on the Law of Treaties. For further reading, see D Murthy, "The Future of Compulsory Licensing" at 1328; F M Abbott, "The Doha Declaration"; and I Brownlie, *Principles of Public International Law*, 4th edn (1990), quoted in J T Gathii, "The Legal Status of the Doha Declaration" at 314.

⁴⁰ W Pretorius, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, 183.

⁴¹ *Ibid.* Pretorius claims that some interest groups are promoting IPRs as natural rights – "rights that have a moral force that somehow elevates them above political challenge".

strong for protecting private interest are thus weak for protecting the public interest, at least initially.⁴²

When looking at the actual problems of the existing agreements, the most important parts of the TRIPS Agreement regarding pharmaceutical patents are articles 28 (rights conferred), 30 (exceptions to rights conferred) and 31 (other use without authorisation of the right holder). One of the problems addressed by the Doha Declaration is the compulsory licensing rules under TRIPS, found in Art 31(f).⁴³ Article 6 of the Doha Declaration gives the member countries until the end of 2002 to address the specific problem. At the end of 2002, all members of the WTO, except the US, had accepted a draft presented by the Chairman of the Council for TRIPS. However, since an agreement could not be reached, a solution is still on the agenda for the WTO. If the international policy changed in favour of developing countries, or if the wording of the Doha Declaration was taken seriously, and a change in the TRIPS Agreement or the interpretation thereof took place, there are a number of possibilities to create such a legal framework. As will be developed further below, it is considered by many economically insufficient to require domestic production for every medicine a country may need.⁴⁴ When a developing country that has a significant drug manufacturing capability, like Brazil and India, implement pharmaceutical patent enforcement, the ability to develop and export generic versions of patented drugs⁴⁵ in those Member states may disappear, or at least the costs of the drugs will increase significantly.⁴⁶

A WTO member with insufficient or no manufacturing capabilities faces difficulties in making effective use of compulsory licensing under the TRIPS Agreement to manufacture domestically. The lack of fundamental manufacturing capacities in the sector is one obvious problem, but others exist as well. Regulatory barriers, scarce know-how and trade secrets are all barriers to local production.⁴⁷ In many developing countries most drugs are not patented today, but this does not help the countries.⁴⁸ At first glance, this may seem strange, but those countries are the ones with no possibility of manufacturing the products within their borders, since the costs are too high and the markets too small. They rely on imports and, at the moment, they can issue a compulsory licence to an importer, who can then source the supply from a generic manufacturer in a country where there is no patent for the product. This will not be

⁴² V Shiva, *Protect or Plunder? Understanding Intellectual Property Rights* (2001) at 6 (V Shiva, *Protect or Plunder?*).

⁴³ Doha Declaration, paragraph 6. TRIPS, Art 31(f): “any such use [of compulsory licensing] shall be authorised predominantly for the supply of the domestic market of the Member authorising such use”.

⁴⁴ See, *inter alia*, N Ansari, “International Patent Rights in a Post-Doha World” 11 *Currents Int’l Trade L.J.* 57 at 59 (N Ansari “International Patent Rights”); and S Haochen, “A Wider Access to Patented Drugs Under the TRIPS Agreement” 21 *B.U. Int’l L.J.* 101 at 109 (S Haochen, “A Wider Access to Patented Drugs”).

⁴⁵ The word “generic” is given a wide definition here, not only covering drugs with no patent protection but also patented drugs produced by producers using licensing or piracy. The medical definition is “Medication sold without an indicated brand name and not protected by trademark”, a definition which supports a wider use of the word.

⁴⁶ C Correa, *Intellectual Property Rights, the WTO and Developing Countries – The TRIPS Agreement and Policy Options* (2000), 163.

⁴⁷ S Haochen, “A Wider Access to Patented Drugs”, at 109.

⁴⁸ CIPR, *Integrating Intellectual Property Rights*, at 35.

possible when all developing countries have implemented patent legislation, which, in accordance with TRIPS, does not allow for extensive exports of patented drugs.⁴⁹ The patent holder also often has control of the distribution channels in those countries.⁵⁰ Hence, the problem is not the same for all developing countries. The situation is quite different when comparing, for example, South Africa and its poorer neighbours, such as Mozambique and Zimbabwe, but they are all experiencing the same problem, albeit from different directions.

While South Africa wants legislation to allow them to produce and export generic drugs to create a larger market allowing for lower prices, neighbouring countries desperately want the same legislation in order to import the drugs.⁵¹ None of this is possible through TRIPS, but may change through the WTO decision of 30 August 2003, which will be analysed below.

There are, however, those who feel that the international framework of the TRIPS Agreement does in fact increase, instead of decrease, the possibility for developing countries to go into R&D and to produce drugs. The argument is that the generic drug companies that have been engaged in producing pirate drugs from developed countries will, when encouraged with higher IP protection, start inventing and developing drugs themselves. The incentives for R&D into diseases that mainly occur in developing countries should then increase, which would help to combat those diseases.⁵² What is also argued is that the strengthening of the technological infrastructure in developing countries can increase their competitiveness in the international scheme.⁵³ What is lacking from the argument, according to this author, is a sense of the reality of the situation that most developing countries are in at this time. In the future, it is hoped that the goal to “strengthen infrastructures” can be achieved, and that through investment in R&D pharmaceutical products will be invented in some of those countries. As the situation stands today, however, it is clear that there is still a long way to go before this can be achieved. Twenty countries have an annual GDP of less than US\$500 million each (half of the annual sale of many medicines!); some countries have a higher per capita external debt than the per capita GNP; and some poor countries have little or no manufacturing industry today, with primary commodities representing more than 90% of their export, if they have exporting trade.⁵⁴ Before an R&D industry can be created in such countries, there are many

⁴⁹ Transitional rules of the TRIPS Agreement, see TRIPS, Articles 65-66 and the Doha Declaration, paragraph 7. See also CIPR, *Integrating Intellectual Property Rights*, at 45. However, this may change as the new decision on implementation of Art 6 of the Doha Declaration allows for exports under compulsory licences.

⁵⁰ CIPR, *Integrating Intellectual Property Rights*, at 35.

⁵¹ When comparing prices, Flucanazole, patented in South Africa but not in Thailand, costs US\$21.4 in South Africa, but only US\$0.3 in Thailand. Two anti-retroviral drugs cost US\$92 per month in Thailand but US\$342 in Uganda. See V Shiva, *Protect or Plunder?*, at 87.

⁵² If this development were to take place, one of the potential outcomes would be further R&D into drugs helping HIV/Aids victims in developing countries. The majority of the HIV vaccines today are being developed for genetic profiles of subtype B, prevalent in developed countries, but most Aids sufferers in developing countries are types A and C. More information on this can be found in CIPR, *Integrating Intellectual Property Rights*, at 33.

⁵³ N Ansari, “International Patent Rights”, at 58.

⁵⁴ K Balasubramaniam, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, at 91, quoting reports from UNDP and the World Bank.

issues to be addressed. The money is not there to invest in industry and infrastructure. If such funding was found through international sources, it would need to be on a grant basis and not as loans, as any prospect of repayment only undermines the economic development that is needed for a substantial change.⁵⁵ A large injection of additional public funds is needed to address the health needs, services and infrastructure of developing countries.⁵⁶

So what are the options for the LDCs and developing countries that cannot manufacture pharmaceutical products? Since intellectual property laws are territorial, the right to import does not amount to the right to export unless the law in the country where manufacture for export takes place authorizes such production. Some commentators have observed that the only way to dismantle the barrier is through importation of low-price drugs under compulsory licences.⁵⁷ Nevertheless, Art 31(f) of TRIPS provides that “any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use”. If the TRIPS Agreement was amended in such a way as the EC Medicinal Directive, giving the right to manufacture for use in a third country, that would create a solution for the problem mentioned.⁵⁸ The importance of compulsory licensing in a country other than the user country, or other sources of generic drugs, such as parallel imports, cannot be underestimated. There is substantial evidence that availability of generic drugs, especially from multiple sources, substantially reduces prices.⁵⁹

As mentioned above, there is a new decision from the WTO regarding exports of pharmaceutical products under compulsory licensing. This decision is a temporary waiver while negotiations take place for changes to TRIPS. If an amendment to TRIPS Art 31(f) regarding compulsory licensing is too difficult to agree upon, an alternative is to address the issue of importation of low priced drugs through the “limited exceptions” in Art 30. However, this would need to be formally recognized.⁶⁰ The benefit of such a solution is that it solves the problem of double remuneration under Art 31. No amendment would be required to TRIPS, nor a compulsory licence in the exporting country. It is not clear, however, if under this solution, the “Doha exception” would be compatible with the exceptions under Art 30.⁶¹ Furthermore, changes to Art 31 or new interpretations of Art 30 will require national legislations to be amended to incorporate the exceptions or changes. A third option, which has been seen recently, is a moratorium or waiver for exports in the “Doha circumstances”. This solution is expeditious as it needs no amendment or authoritative interpretation of the TRIPS Agreement, which is why it can be and is currently used as a temporary instrument. For a waiver to be of use, the conditions would obviously need to be set

⁵⁵ F M Abbott, “The Doha Declaration”.

⁵⁶ CIPR, *Integrating Intellectual Property Rights*, at 31.

⁵⁷ S Haochen, “A Wider Access to Patented Drugs”, at 110.

⁵⁸ Council Directive 2001/83/EC. See also section 3.2.

⁵⁹ F M Abbott, “The Doha Declaration”, and V Shiva, *Protect or Plunder?*, at 87. According to Shiva, the average price difference between patented Aids medicines in the US and generic products in developing countries is 82%. One product, Flucanazole, is not patented in Thailand. As a result, the Thai manufacturer is able to sell their product 207 times cheaper than the price of the original product, sold by Pfizer.

⁶⁰ F M Abbott, *ibid.*

⁶¹ CIPR, *Integrating Intellectual Property Rights*, at 47.

out very clear, and there is a risk that the goal may be compromised in negotiations on the criteria. Whether this is true or not with regard to the current waiver is analysed below. That risk is, of course, present in other options as well, such as reopening the TRIPS Agreement for amendments. Two other options are mentioned by the CIPR in their report, but the outcome of them is uncertain. One is a non-justiciability option, regarding the exhaustion of rights.⁶² It would make sure that settlement disputes under TRIPS would not be used in relation to exports undertaken as envisaged in the Declaration.⁶³ The other possibility is for a country with a large market and a generic pharmaceutical industry to export under the current rules of Art 31(f). This option depends on whether there is a legitimate ground to issue a compulsory in the manufacturing country to start with, and is not an ideal solution for sustainable development in the area.

To conclude this section on the problems of pharmaceutical patents regarding developing countries and international policy, the global protection of IPRs in pharmaceutical products is perceived by many as going too far. TRIPS Art 31(f) is part of the problem, as the article does not allow for export under compulsory licensing with reasonable conditions, which is too restrictive for developing countries. Net importers of IPRs, which have manufacturing capacities, are weakened by the TRIPS Agreement as they cannot reverse-engineer and cannot use a large international market to export their generic products. A further problem is that many nations do not even have the fundamental know-how or manufacturing capacities. The new decision of 30 August 2003 presents an attempted solution. Whether it goes far enough is analysed below.

3.2 Politics and Proposals

The text of the Doha Declaration seems to be a clear policy statement, which leaves little room for doubt. However, since November 2001, the text has been interpreted very differently by various members of the WTO. This issue is not only interesting from the member states' and the peoples' point of view, but also from the pharmaceutical industry's side. Some of those protesting against the way developing countries are treated are blaming the industry for what is happening, claiming that they have a moral obligation to lower the prices or somehow make the pharmaceutical products available to the people in poor countries. One response to this has been that the debate revolves around the price of medicines and not the delivery of health care, and that this is a big mistake. As Richard Ley remarked, "This is a complicated issue and is about wider poverty. No industry could possibly try to tackle this but what they can do is work with other organisations and governments to overcome the problem. We are playing our part. The question is whether governments are playing their part".⁶⁴ When presented with the idea of tiered pricing schemes, as recommended by the CIPR in 2002,⁶⁵ one official from the pharmaceutical company Pfizer said that "[t]he notion that some body out of Europe or the US should come up and start

⁶² TRIPS, para 6.

⁶³ CIPR, *Integrating Intellectual Property Rights*, at 48.

⁶⁴ Richard Ley, spokesman of ABPI, quoted by S K Templeton, *The Drugs Trade*, *The Sunday Herald*, 11 May 2003.

⁶⁵ CIPR, *Integrating Intellectual Property Rights*, "Differential Pricing".

dictating what prices ought to be somewhere else strikes us as a rather radical notion. We do pricing by markets".⁶⁶ He also said that they (Pfizer) are comfortable with the position that the US government has taken as a whole. As the US blocked the proposal regarding compulsory licensing from the Council for TRIPS in December 2002, one relieved commentator from the industry said the agreement would have been a "licence to steal".⁶⁷ The position of the pharmaceutical industry needs no further explanation. The lobbyists working for them are targeting governments, the US government in particular, to ensure that no changes are made. From this it seems natural to analyse the position of the net exporters of IPRs.

The EC and the US have, before and after the failed negotiations on compulsory licensing in 2002, both presented proposals for alternative agreements. The new decision of 30 August 2003 in the WTO, which will be analysed further below, bears some resemblance to the proposals by the EC and the US.⁶⁸ The proposals contained suggestions such as a list of diseases for which compulsory licences would be given, and listings of the countries which would receive help. One example is the EC communication of 20 June 2002.⁶⁹ The suggested changes to the TRIPS Agreement are honest attempts to solve the problem. One of the major problems, which has already been mentioned, is Art 31(f) of the TRIPS Agreement regarding compulsory licences. The article limits the possibility to export products manufactured under a compulsory licence, as it states that use under a compulsory licence should be authorised predominantly for the supply of the domestic market. What the EC suggested was an amendment to TRIPS Art 31, clearly giving the circumstances for exceptions to the restrictions imposed by Art 31(f).⁷⁰ As the EC points out, such a solution would be clear, legally secure, effective and permanent.⁷¹ Many other solutions, such as waivers, dispute settlement moratoriums or authoritative interpretations of Art 30, may not, according to the EC, provide those advantages mentioned. What the EC suggested so far was generous and did not seem to particularly protect the interests of the EC Members and their pharmaceutical industry. However, the additional paragraphs of the proposal can more easily be recognized as the work of net exporters of IPRs.

It is pointed out that it is important to "strike the right balance" between restrictions to exports of pharmaceuticals and the underlying rationale of Art 31(f). The EC states that the "modalities under which the mechanism will operate, such as for instance the

⁶⁶ Robert Mallett, vice-president for corporate affairs, Pfizer, quoted by Boseley and Pratley, *The Guardian*, London, 24 April 2003.

⁶⁷ H Bale, Director-General of the International Federation of Pharmaceutical Manufacturers Association, quoted by F Williams, "US Move on Drug Patents Under Attack", *Financial Times* 23 May 2003.

⁶⁸ Council for TRIPS Decisions of 30 August 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, document WT/L/540. Called Decision on implementation from here on.

⁶⁹ Communication from the European Communities and Their Member States to the TRIPS Council Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Brussels 20 June 2002.

⁷⁰ *Ibid* para 4.

⁷¹ *Ibid* para 5.

product scope, will have to be clearly spelled out”.⁷² As the EC interprets the Doha Declaration, the product scope is already set out. Taking the words from the Doha Declaration, paragraphs 1 and 6, the scope would be pharmaceutical products⁷³ needed to deal with public health problems afflicting many developing countries and LDCs, especially those relating to HIV/Aids, tuberculosis, malaria and other epidemics⁷⁴. The suggestion, in other words, makes sure that only products that are not too profitable in the developed countries are included. The EC also points out the need for necessary measures to be taken to avoid abuse and trade diversion. This is a neutral and natural point which needs to be dealt with. What makes the suggestion harder to accept for developing countries is that the EC wants the importing state to be responsible for enforcement measures, such as border controls, supervision of distribution and necessary constraints on distributors.⁷⁵ Even though the EC acknowledges the burdens this puts on the importing country, and suggests that the measures are to be reasonable and proportional, the future of such a system could easily become yet another hurdle impossible to overcome for developing countries. This is especially so if developed countries or pharmaceutical companies in the future take legal actions to question the enforcement of the measures. The risk of this happening, or threats of revenge through bilateral arrangements, may be enough to stop developing countries from using such imports at all.⁷⁶

In defence of the EC, though, there is also a proposal for a council regulation to avoid trade diversion into the EU of certain key medicines.⁷⁷ This would be an attempt to put some burden on to the possible re-importer, in this case the EU Member States. Furthermore, in October 2002, the European Parliament adopted an amendment to the European Medicines Directive which states that: “manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country”.⁷⁸ This creates a good policy framework to balance the objectives of

⁷² Ibid para 10.

⁷³ Doha Declaration, para 6.

⁷⁴ Ibid para 1.

⁷⁵ Communication from the European Communities, 20 June 2002, para 14(iv).

⁷⁶ Bilateral agreements overriding multilateral agreements such as TRIPS can, unfortunately, be common as the poor nation is often more dependent on a trade agreement than the wealthy party. The outcome of bilateral agreements is also easier to keep out of the public’s critical view than that of multilateral agreements.

⁷⁷ Proposal for a Council Regulation to avoid trade diversion into the European Union of certain key medicines, 30 October 2002. It seems as if this will have to be implemented as legislation since the new Decision on implementation by the Council for TRIPS states that members shall ensure availability of effective legal means to prevent importation into their territories of products produced under the new system of compulsory licensing. See Decision on implementation, para 5 and analysis in section 4 below.

⁷⁸ Council Directive 2001/83/EC. Amendment 196 to the European Medicines Directive, adopted 23 October 2002. See also S Haochen, “A Wider Access to Patented Drugs”.

paragraph 4 of the Doha Declaration,⁷⁹ while protecting the interests of patent owners.⁸⁰

Some proposals by the north also encourage the WHO to take part in the process to decide on where help should be provided.⁸¹ This has been criticised from many directions, as will be developed below. The proposals are seen as attempts to safeguard the IPRs of the pharmaceutical industry and are claimed by some to make, at best, no difference at all, and at

worst, to make the situation even more dire for the people in developing countries and LDCs. One of the main reasons for the massive criticism is that the lists of diseases consist only of diseases of little commercial interest, and that the WHO would be given very restrictive powers, mainly working as a cosmetic framework. Diseases such as cancer and asthma, from which many patients suffer in the developed world, are not on the lists, despite the fact that most of those suffering and dying from these diseases live in developing countries and have little or no chance of treatment. The EC and the US, along with other allies mainly in the north, have not only their international trade and reputation on the line, but also internal concerns such as powerful lobbyists. The national legislations protect the pharmaceutical industry, but the powerful industry also needs the international legislation to provide safe exporting conditions. Private laws governing these issues in developed countries today are highly protective of IPRs and this trend cannot be broken by one nation alone. There are many national as well as international elements to please for the governments trying to reach solutions in this matter.

Patent protection is important and it is not a question of reducing it to zero. What is controversial is the high level of protection. The argument repeated is that a lower level of protection would reduce the expected income stream, meaning less money would be invested into research. That is not a desirable effect for long-term R&D.⁸² The problem with this argument is that long-term R&D is a different issue from, for example, the HIV/Aids crisis in developing countries, or research into and licensing of medicines for diseases on the US and EC lists of acceptable diseases. The question of who is really in control of the agenda, governments or the pharmaceutical industry, depends largely on who needs what from whom. As long as the pharmaceutical industry is stronger than the NGOs, developing countries and the public, they are likely to control the direction of government policy. This is particularly evident in the US. The outcome of this is that if licensing is allowed on a wider basis than that of the TRIPS Agreement, it will be on a list of drugs or diseases affecting developing countries, and not on specifically financially rewarding drugs. At least this might lead to an acceptable solution regarding diseases such as HIV/Aids, malaria and TB.

The WTO chairman, Dr Supachai Panitchpakdi, has expressed his understanding and concern of the two-edged problem. Regarding support for the Doha Declaration, he

⁷⁹ Paragraph 4 of the Doha Declaration states that the TRIPS Agreement can and should be interpreted in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

⁸⁰ S Haochen, "A Wider Access to Patented Drugs".

⁸¹ See also Communication by the EC to the TRIPS Council, "The implementation of the Doha Declaration on the TRIPS Agreement and Public Health".

⁸² F M Abbott, "The Doha Declaration".

said, “these pledges of support must be translated into action soon if the Cancun Ministerial Conference and our subsequent efforts are to provide benefit for the world’s citizens, particularly for the two billion who live in dire poverty”.⁸³ He went on to say that he understood “the difficulties involved in developing a system for enhancing access to medicines for people in poor countries while preserving the incentives that entrepreneurs require if they are to continue to make the investments that are necessary to continue the R&D of new drugs”.⁸⁴ These comments from the WTO chairman do define the problem rather clearly, but do not offer any hints as to a solution. His comments were made after he was presented with a letter from the African, Caribbean and Pacific Group of States (ACP), calling for a solution to the problem during the Cancun Ministerial Conference, which took place in September 2003.⁸⁵ In the letter, the ACP claims that a solution must be found as a matter of urgency. They also reject the proposals made by the European Commission, which calls for a list of diseases for which drugs would be guaranteed, and using the WHO as a trusted third party.⁸⁶ As developing countries accepted the TRIPS Agreement this may have been in order to join the WTO and enjoy other benefits of the trade organisation. There is no doubt that if they were to agree on a proposal as restrictive as the European or American ones, it would not be due to their satisfaction, but rather that they have been overrun by threats or other reprisals again. Most of the developing countries and the LDCs in particular, have no political agenda other than to receive as much help as possible for their people. However, it is of course also important to remember that some of the developing countries, such as Brazil and India, do have economic interests in the developments in the same way that the EC and the US do. The difference is that their interest lies in the generic industry and not in the research industry owning the IPRs.

The opinion of the World Health Organisation (WHO) cannot be dismissed in the matter of pharmaceutical patents, regardless of whether the organisation becomes part of the procedure on TRIPS classifications, as suggested by the US and the EC, or not. The standpoint of the WHO is that

*In the context of the Doha Declaration on the TRIPS Agreement and Public Health, we have supported the public health principle that the people of a country which does not have the capacity for domestic production of a needed product shall be no less protected by compulsory licensing provisions (or other TRIPS provisions) than people living in countries capable of producing the product. We are taking the line that the need of poor countries for lower prices should have a broad basis.*⁸⁷

Regarding the EC and US attempt to enlist WHO support for patent protection for medicines, health campaigners have claimed that this will push drug prices higher in poor countries. They have claimed that “the US has broken every promise made

⁸³ Dr Supachai Panitchpakdi, quoted in Market Pharmaletter, 9 June 2003.

⁸⁴ Ibid.

⁸⁵ Cancun Ministerial Conference, Cancun Mexico, 10-15 September 2003.

⁸⁶ Communication from the ACP to the Chairman of the Council for TRIPS, 23 May 2003. Letter also referred to in Pharma Marketletter, 9 June 2003.

⁸⁷ Dr Gro Harlem-Brundtland, former Director-General of the WHO, quoted in Consumer Project on Technology, 5 March 2003. @ www.cptech.org/ip/wto/p6/cptech03052003.html.

concerning developing countries' right to access low-cost generic medicines... and is using the world health assembly to champion monopoly protections on life-saving drugs".⁸⁸ The US resolution put forward to the WHO annual assembly in May 2003 urged members to promote pharmaceutical research and development by boosting incentives for industry, including better patent protection. Campaign groups such as Medecins Sans Frontiers (MSF) and Oxfam say patents have little or no impact on research into diseases of the poor.⁸⁹ This argument is backed by the UK Commission on Intellectual Property Rights (CIPR) in their report from 2002.⁹⁰ Surprisingly, it has also been backed by the US. Before the Doha Declaration, the US claimed that very few patents exist in sub-Saharan Africa for medicines for HIV/Aids. The opening position of the United States Trade Representative (USTR) was that patents were therefore not an issue.⁹¹ This was meant to be interpreted as "we should introduce patent regimes in developing countries, since it does not matter for HIV/Aids victims whether they are in place or not". Of course, the more logical way of interpreting what was stated is that there is no need to introduce patent regimes, since the patents do not matter. The argument made by the USTR would, therefore, justify the result opposite to the one the USTR was pursuing. James Love, writing in *Le Monde Diplomatique*, March 2003, claims that the wealthy countries "have conspired against the poor, undermining and breaking the promises made in 2001". This opinion is backed in the article by the fact that the US did not accept the proposals in the WTO talks in Geneva, December 2002. Furthermore, the list of suitable diseases accepted when overriding patents in accordance with the Doha Declaration consists only of diseases that are, as stated above, mainly of little commercial interest. In the article, Love also claims that the wealthy countries raised technical questions in order to further restrict the scope of the agreement, such as limiting the number of countries authorised to override patents; restricting qualifying technologies; and creating complicated, costly and restrictive legal requirements that threaten supplies of generic equivalents of patented drugs. Whether or not wealthy countries have conspired against developing countries and broken promises, having analysed the proposals put forward, the criticism against the EC and the US is justified due to the heavy restrictions used as conditions for their approval of a future change.

Many feel that the TRIPS Agreement as a whole is a failure, especially as regards pharmaceutical patents. One rather strong verdict, given in 2000, is that "TRIPS does not involve mutual gain; rather, it positions the WTO primarily as a collector of intellectual property-related rents on behalf of multinational corporations (MNCs). This creates a negative image for the WTO and in the view of many, especially the non-governmental organisations, reflects the "capture" of the WTO by the MNCs."⁹² Whether this is true or not will be analysed below.

Two arguments recur when analysing the politics of the US. One is the need for strong IPR protection for the investment into long-term R&D. The other is the acceptable list of diseases, for which compulsory licences could be granted – diseases

⁸⁸ B Baker, of Health GAP, US, quoted by F Williams, in *Financial Times*, 23 May 2003.

⁸⁹ F Williams, *Financial Times*, 23 May 2003.

⁹⁰ CIPR, *Integrating Intellectual Property Rights*, at 33.

⁹¹ F M Abbott, "The Doha Declaration", at ch. II A3.

⁹² B Jaghdish (2000), cited in CIPR, *Integrating Intellectual Property Rights*, at 160.

mainly existing in poor countries and with little commercial interest. The two arguments work well together, as the long-term R&D of the drugs needed for the diseases mentioned is, at least in the US, very small. If these arguments were to prevail, the US pharmaceutical industry would be fortunate enough not to lose anything, as they do not try to sell drugs of little commercial interest in developing markets anyway. The same politics could earlier be detected in European proposals, but it must be said that there is a substantial difference in the current approach by the EC. The WHO standpoint is clearly a good policy goal for the future, and must be kept as an ultimate end. The standpoint is that the people of a country, which does not have the capacity for domestic production of a needed product, shall be no less protected by compulsory licensing provisions than people living in countries capable of producing the product. Proposals of the north, up until recently, have worked efficiently against this, and it is especially upsetting to commentators to see the US, a country which has, to say the least, a capacity for production, threatening to override patents immediately at the occurrence of a potential outbreak of disease, while refusing to acknowledge the need from others for the same legal options.

4. Analysis – Responsibilities and Solutions

“We make a living by what we get; we make a life by what we give.”

Winston Churchill (1874-1965)

The TRIPS agreement is fairly permissive regarding government decisions to authorise, for example, compulsory licensing.⁹³ However, not all countries use these instruments. In the US, the legislation for public use of patents, under 28 United States Code s. 1498, allows the government to use patents or authorize third parties to use patents for virtually any public use, without negotiation. Similar rules exist in the UK, Germany, Philippines and Malaysia.⁹⁴ The TRIPS Agreement allows these rules to be used. However, no African country has issued a compulsory licence for any medicine, despite the public health crisis. One of the reasons is that developing countries, due to financial restraints, lack the capacity to thoroughly examine a patent application before its approval. By comparison, the US spends \$1 billion annually on its patent and trademark office, and still it is found that many of the patents issued are not valid.⁹⁵ The patent examiners in developing countries, when and where they exist, have much less money and less training than their colleagues in developed countries such as the US. This leads to “bad” patents, meaning that they are overreaching. In the large markets the incentive and possibility for generic drug companies to evaluate and litigate “bad” patents is very high. The same incentive does not exist in the small, national markets in developing countries, meaning that the patents will remain unchallenged. The countries themselves are often reluctant to sue or be sued as they

⁹³ See TRIPS, Art 31.

⁹⁴ J Love, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, at 75.

⁹⁵ *Ibid* at 76-77.

do not have any significant capacity to litigate.⁹⁶ Due to this lack of knowledge and finances the governments of developing countries are not able to involve themselves in the patent industry to the same extent that governments of developed countries can. Furthermore, this only covers the problem of compulsory licensing as such. In order for the authority to be able to grant a compulsory licence there must be an existing generic drug company that has the ability and the will to take up the production of the drug within the country. If the market is small and unprofitable the only possible way is for the government itself to start the production, and if a pharmaceutical industry and infrastructure does not exist, the costs of building one will be overwhelming, especially at an initial stage. A change in the international legal framework of TRIPS is the best way, and perhaps the only way, to create a substantial possibility for the LDCs to use licensing arrangements or parallel importing.

In cases in which the TRIPS Agreement allows for compulsory licences and other measures, in countries that do have the generic pharmaceutical industry, for example Brazil and India, there is a chance that compulsory licensing will be used. However, the pharmaceutical industries in those countries have previously only produced patent-protected medicines through reverse engineering, something that the TRIPS agreement prohibits. Without the capacity to reverse-engineer it is, according to some, open to question whether these national pharmaceutical industries will survive.⁹⁷ In these cases, there is a risk that the developing countries that stand a chance of issuing compulsory licences may soon lose their ability to do so. What is needed, again, is a change in the international framework of TRIPS. It may be undesirable to have a large amount of piracy of IPRs, but the solution to this is not simply to impose strong IPR legislation. In order to create a long-term solution, where countries such as India and Brazil can maintain their pharmaceutical industry, a better solution is to introduce IPRs with clear, legal possibilities to licence and export the patented drugs.

On 30 August 2003, the WTO Council for TRIPS reached a decision, in the form of a temporary waiver until an amendment to TRIPS can be made,⁹⁸ in an attempt to address the problems of compulsory licensing and developing countries.⁹⁹ This decision on implementation of paragraph 6 of the Doha Declaration allows an exporting member to waive the obligations under Art 31(f) of TRIPS with respect to the grant by it of a compulsory licence. The waiver can be used to the extent necessary for the purposes of producing a pharmaceutical product for export in accordance with certain terms.¹⁰⁰ The importing member must be either an LDC, or a developing country having established insufficient capacity in the pharmaceutical sector, and having granted a compulsory licence in accordance with Art 31 of the TRIPS Agreement.¹⁰¹ One of the concerns aired before the decision was that the remuneration to the patent owner may have to be paid in both the exporting and the

⁹⁶ As another comparison, in 1998 the New York Times reported that the median cost of litigation regarding US patents was \$1.2 million, per side The New York Times, 27 December 1998, cited by J Love, *ibid* at 76.

⁹⁷ K Balasubramaniam, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, at 97.

⁹⁸ Decision on implementation, paras 2 and 11.

⁹⁹ Decision on implementation. It should be said that the decision may deserve further attention.

¹⁰⁰ See Decision on implementation, para 2.

¹⁰¹ *Ibid* para 2(ii-iii).

importing countries. This has been solved through a waiver for the importing country.¹⁰² The problem with the above waivers, effective immediately through the decision, is that the technical questions of Art 31 of the TRIPS Agreement remain, including what constitutes “reasonable commercial terms”, “national emergency” and “circumstances of extreme urgency”.¹⁰³

Furthermore, establishing an incapacity to manufacture can still be questioned. The concern raised earlier regarding necessary measures to prevent re-export of the product is still at hand, as the new decision holds that the importing country shall take reasonable measures within their means. Although the importer’s administrative capacities are taken into account, the measure must also be proportionate to the risk of trade diversion, something that must be considered likely regarding certain products and countries. Developed countries are to cooperate when requested in order to facilitate this implementation, but on mutually agreed terms and conditions. It was argued above that exports of products produced under compulsory licences were necessary for economies of scale. This new decision will create a sustainable solution for that part. However, it does not solve other problems, which may hamper the use of the new rights under the decision. The technical issues raised by the EC and the US in earlier proposals, such as measures to be taken and what constitutes a national emergency, still remain and can effectively put a stop to the use of compulsory licensing. The threat of retaliation for states that agree on exporting generic drugs is also very real. The US government in particular is, according to critics of the new decision, likely to take action against exporting countries, whose attempts will be seen as eroding the profits for the pharmaceutical industry.¹⁰⁴ It will, though, be interesting to follow the development and see if the two main countries that have the ability to use the new exporting rules, Brazil and India, will do so.

The opinion that patents today have little impact on the situation in many developing countries is supported by many sources, including the industry itself. Since this is the case, developing countries are not a market for IPR owners as it is. The only way for them to actually get access to those markets, as this author sees it, is to sell cheap licensing agreements to generic companies in the developing world. For a system to work, where the markets are divided with substantial differential pricing, control mechanisms such as customs and secured distribution chains must be in place, as must predictable compensation schemes. Such mechanisms must be easily run and administered or they will be very expensive. They cannot be easily manipulated by litigation, as this would not only take away the purpose but also make developing countries avoid use of it.¹⁰⁵ If an easily run and administered system could not be found, the rather extensive bill for the procedures needed must be picked up by governments in the international community. The logical response would be for IPR

¹⁰² Ibid para 3.

¹⁰³ TRIPS, Art 31(b).

¹⁰⁴ Oxfam and MSF believe that few poor countries are prepared to take the risk of retaliation from big pharmaceutical companies or governments protective of patent owners. See J Hari, *The world is dying for drugs and the west has a moral duty to provide them*, *The Independent*, 3 September 2003, p. 16 and H Stewart, *Deal reached over cheap drugs for poor nations*, *The Guardian*, 1 September 2003, p. 16. Celine Charveriat of Oxfam, quoted in *The Independent*, claims that “the proposed deal is largely cosmetic”.

¹⁰⁵ J Love, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, at 78.

exporters to protect their IPR owners in order to keep the system working. What is needed is a legal framework which:

- A) Maintains the protection of IPRs globally, and especially in developed countries, through legislation such as TRIPS Article 28, but;
- B) Allows for exporting and importing under (compulsory) licensing agreements, and;
- C) Creates effective barriers for (re-)import into other countries of the products produced and distributed for a developing country under compulsory licence. The control of the barriers are to be kept at a basic cost level or, if extensive costs are necessary, paid for by developed countries.

The points above are, at least theoretically, in place through TRIPS and the new decision on the implementation of paragraph 6 of the Doha Declaration. However, what is further needed for a working system are:

- A) Clear definitions of what constitutes circumstances in which compulsory licences can be issued, that is, an amendment or interpretation decision of TRIPS Art 31(b). The definitions should, however, still be wide and should not exclude diseases common in developed countries.
- B) Legally binding agreements, clearly defining rights and obligations, including liabilities for measures to prevent re-importation, making sure those countries with insufficient funding and capacity are not held liable for actions taken to protect public health.

Definitions of circumstances in which compulsory licences are accepted, and a clear articulation of which party will bear liability for control measures, are necessary in order for developing countries to be able to foresee the international reaction to such measures. If the definition is vague, there is a great danger of future retaliation in trade, something that developing countries cannot risk. If the definition is not wide, it needs to, at least, clearly include a situation such as the HIV/Aids crisis in Sub-Saharan Africa.

The proposal above would create a large market which is currently unused. As the producers of the generic drug under licence would then have access to a larger market than one country, it would be possible to exploit economies of scale. The proposal would create a solution that should be acceptable for all parties, and which would not only include HIV/Aids, TB and malaria, as suggested by the exporters of IPRs.¹⁰⁶ Compulsory licensing can promote competition and low prices. Used as in the proposal above, compulsory licensing should work as a tool to promote innovation while also protecting public interests. The new decision of the Council for TRIPS is a step towards a solution, as at least the compulsory licensing for exportation is recognized as a necessary building stone for future developments. It does not, however, create a fully developed solution to the problem.

Future developments after this decision can, according to this author, take two directions. One direction is where developed countries will not allow a new “generic market” to be created, but rather maintain a cosmetic and superficial framework, which does not work so long as the divide between wealthy and poor countries

¹⁰⁶ See section 3.

remains. The other direction is where it is acknowledged that the creation of such a generic products market does not threaten the profit of the pharmaceutical industry, since they have no sales in that market as it is, and rather take on the moral duty to provide drugs at lower prices to developing countries, including those to treat diseases common in wealthy countries as well as poor ones. If the decision and the points made above were allowed to be used internationally, it could work effectively to substantially lower prices and create programmes for helping those who most need it. It would be interesting, for example, to see an international and wider use of a programme such as the Brazilian STD/Aids programme.¹⁰⁷ If all developing countries cooperate in creating the market and also manage to negotiate internationally as a group, there is a real possibility of affordable medicines on that generic market. Still, many “ifs” and “buts” remain, and it is not likely that the US government and pharmaceutical industry will idly stand by and watch such a development take place.

Regarding the argument that the pharmaceutical industry is to blame for high pricing or even the deaths of people in developing countries, it is important to remember the basic responsibilities of the companies. As with any corporation the main reason the pharmaceutical industry exists in today’s society is to create the most profitable result possible for its owners. Considering this, the only time a company will lower prices, apart from when forced by competition, is either from being pressured by the public or by legislation. What has happened in recent times is that the pharmaceutical companies have taken on some responsibility and have suggested that they can offer some assistance through donations. The reason for this is the public pressure that has been put on them from people in developed countries in “the North”.¹⁰⁸ The problem with this, however, is that donations are not enough. First of all, what happens when the public pressure eases off, or when the company finds something more important to spend their donation accounts on? Secondly, the amount of help needed is far too vast to be helped by donations. What is needed is systematic long-term medicines provision for about 90% of the world’s population, something that, according to Medecins sans Frontières (MSF), cannot realistically be done on a donation basis. Instead, the solutions need to be found in the trade area.¹⁰⁹ MSF is not alone in criticising the donations schemes.¹¹⁰ IPRs as incentives for an industry that works primarily for the development and production of products for the western, wealthy market. Patent-based R&D into, for example, malaria is unlikely to be strong unless

¹⁰⁷ The Brazilian programme makes HIV/Aids medicines available free of charge to all citizens through the national health system. It must be added, though, that the system is costly and not affordable to all developing countries. The author’s hope and belief is that it could be made more affordable through creating a larger market by better exporting possibilities for generic pharmaceuticals. For more information about the Brazilian STD/Aids Programme, see CIPR, *Integrating Intellectual Property Rights*, at 43.

¹⁰⁸ One example is Pfizer’s donation programme for its drug fluconazole (brand name Diflucan) to nations where it is needed to treat, *inter alia*, cryptococcal meningitis, one of the common infections of Aids victims and others with weakened immune systems. See Boseley and Pratley in *The Guardian*, 24 April 2003.

¹⁰⁹ Ellen t’Hoen of MSF, quoted by Boseley and Pratley in *The Guardian*, 24 April 2003.

¹¹⁰ According to the US-based Global Aids Alliance, the pharmaceutical companies have, regarding donations, “been extremely slow to offer them, they implement cumbersome enrolment and eligibility criteria, they protect the patent system and the allow the company tax write-offs and good public relations, but they do not solve the problem”. Paul Zeitz, of Global Aids Alliance, quoted by Boseley and Pratley, *The Guardian*, 24 April 2003.

the disease overtakes obesity and impotence as a problem in developed societies.¹¹¹ The MNCs of the pharmaceutical industry can offer a price discrimination giving better prices to developing countries, but one problem remains: it still would not make the product affordable to people making \$2 per day.¹¹² Even so, the pharmaceutical companies do offer cheaper medicines for Aids, malaria and TB in developing countries, and this may be a good effort, but they want to draw a line between those diseases and the profitable diseases such as cancer. The list of diseases that the pharmaceutical industry can offer discount prices on to developing countries today much resembles the lists proposed by the EC and the US.

The author tends to agree with Richard Ley, quoted above, in that the critique of the pharmaceutical industry is somewhat misdirected. The industry follows the rules laid down by governments, but have no obligation to give away profits outside what is legislated. Instead, it can be argued that the moral obligation of the industry is rather turned in the other direction, towards the owners. This obligation to create profit even includes the powerful lobbying that the industry is using to influence the authorities.

This leads us to the next question: are the governments of the developed countries to blame instead? First, the obvious difference between an industry and a government is their overall aim. While industry has financial gain as its aim, government must have human gain as the first and highest aim. Since this is the case, it seems more accurate to analyse the government's actions rather than those of industry. The problem with the proposals from the EC and the US are that they are not making the basis for aid to people in need wide enough. When putting limits on the number of countries that should be helped and what medicines or diseases to apply the Doha Declaration to, they are not only seemingly breaching the intention of the Doha Declaration, but they are making it impossible for the most poor to get the much needed help. What happens is that the countries they approve of are the ones without capacity for domestic production of pharmaceuticals, meaning that they are not helped by the current compulsory licensing provisions. As a comparison to what is acceptable and not, it is interesting to see the American reaction when, in 2001, the US was facing a threat of biological terrorism. The authorities immediately threatened to override Bayer's patent for the anthrax medicine Cipro.¹¹³ Although this was, of course, a permitted action, the US nevertheless attempted to prevent Brazil and South Africa from taking similar steps in the fight against Aids.¹¹⁴ Narrow distinctions on technical legal grounds might be drawn between the situations,¹¹⁵ but at the macro level the double standard is clear.

There is an imbalance of power between wealthy and poor countries. Developed countries, having the power that comes with being financial leaders, use their power for their own means. Although this can be questioned from an ethical and moral point of view, it is hardly a surprising discovery. What is also obvious is that developing

¹¹¹ P Drahos, in Drahos and Mayne (eds), *Global Intellectual Property Rights*, 6.

¹¹² Ibid. See also CIPR, *Integrating Intellectual Property Rights*, at 31. The average per capita health expenditure in low income developing countries is \$23 per year, while the most inexpensive anti-retroviral triple treatments for HIV is over \$200 per year.

¹¹³ See, *inter alia*, D Murthy, "The Future of Compulsory Licensing".

¹¹⁴ F M Abbott, "The Doha Declaration", and J Love, *Le Monde Diplomatique*, March 2003.

¹¹⁵ F M Abbott, *ibid.*

countries, which are dependent on the more powerful nations, are not going to question the legality of the actions taken by developed countries, due to fear of future reprisals one way or the other. Therefore, the TRIPS Agreement and the actions taken after the Doha Declaration are questioned, but will remain legally upheld. It is, however, positive to note the co-operation between developing countries taking place around the Doha Declaration, as it is only as a larger group that they will achieve any bargaining power in the future. There is a great need for the international legal framework to be clarified in order to maintain a protection for IPRs while also developing a better system for pharmaceutical products to be used to promote public health. Matters such as when and how compulsory licences can be issued need to be addressed in detail, or at least with guarantees that no remedies in trade will occur when compulsory licensing is used in light of the Doha Declaration. Developing countries are, due to the imbalance in power, reluctant to take the risk of issuing licences when they might end up in court with companies or in trade retaliation actions from the US. This means that the framework of TRIPS needs to be amended to create clearer legislation, which can be interpreted in no other way than as giving the developing markets a right to produce, export and import pharmaceutical products in cost-efficient ways. The new decision on the implementation of paragraph 6 of the Doha Declaration is a start, allowing for the exportation of products produced under compulsory licensing. However, it does not create a sustainable solution since the technical and interpretive questions of TRIPS Art 31 remain and make it possible to stop such exports. What is lacking is a clearer definition of when compulsory licensing is allowed. Further, what is needed is also funding from developed countries for maintaining a high level of measures to prevent re-importation from the poor countries into the producer/exporter country.

5. Conclusions

“Salus Populi Suprema Est Lex”

“The welfare of the people is the ultimate law”

Cicero (106 BC-43BC).

As it is acknowledged that the TRIPS Agreement is not, in its current format, clear enough on its support for public health, the Doha Declaration is an important interpretive tool. However, the wording of the Declaration has not been followed and the deadline for an answer on how to address the inefficient compulsory licensing scheme has not been met. The Decision on the implementation of paragraph 6 of the Doha Declaration was not only delayed eight months, but is also insufficient. Both the Doha Declaration and the new Decision are steps towards helping the people suffering in poor countries, but they do not address the issue fully. The international legal framework for exports and imports of pharmaceutical products produced under compulsory licensing is in place, but is not clear enough to be used, as the issue tends to fall flat as a victim of negotiations with unequal parties, the US and its pharmaceutical industry being able to dictate the technical terms and conditions under which to promote global public health. The pharmaceutical industry is too powerful as a lobby group but cannot be blamed for this, as it is up to governments to act and react

to help people in need. The funding schemes created by said industry is not enough but should be replaced by funding out of grants, allowing for certain stability. The view of this author is that the wording of the Doha Declaration has not been taken seriously by the net-exporters of IPRs and that this lack of political courage is, although legal, still immoral and is causing unnecessary harm not only to international relations but also to millions of people suffering from lack of medical care and pharmaceutical products. What needs to be added to the framework are clear definitions of circumstances in which compulsory licences can be issued; legally binding agreements defining rights and obligations for exporters and importers, not making issuers of licences liable to future reprisals; and funding and cooperation regarding the measures to prevent re-exportation of cheap pharmaceutical products sold in poor countries under compulsory licences. As it would be possible to create a separate “generic market” incorporating these measures into TRIPS, the Doha Declaration and the new Decision on implementation, the developed countries’ markets would not suffer from re-importation and the pharmaceutical industry would actually benefit from selling licensing agreements, albeit cheaply, to a market they are currently not in at all. In general terms, the wealthy countries must take on responsibility for the matter, while developing countries need to stay together and cooperate in order to create a balance in negotiations. However, as hard as it may be to reach a sustainable compromise between negotiating parties, the most complex balance to find will always be the one between the protection of private interests in pharmaceutical patents and the protection of public interest and health.

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