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TRIPPING over Patents:

Barriers to Access to Pharmaceutical Medicines In the Developing World and Proposed Solutions to Enhance Access within the WTO Framework

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

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I. INTRODUCTION

Four years after which members of the World Trade Organisation ("WTO") agreed upon a system by which developing countries could import generic versions of patented medicines produced without authorisation of patent holders to address public health needs, no country had yet spoken.[1] On July 19, 2007, Rwanda took a dramatic leap of faith to break the spell of silence and become the first and only country to inform the WTO of its intent to utilise those very procedures. Before Rwanda, no developing country had ever made use of compulsory licensing as a tool to address public health issues.

In its formal submission to the WTO, notification IP/N/R/RWA/1, Rwanda declared that upon evaluation of its public health needs, it plans over the next two years to import 260,000 packs of the HIV/AIDS drug TriAvir, manufactured in Canada by generic producer Apotex, Inc.[2] TriAvir, a fixed dose combination product of the patented antiretroviral drugs Zidovudine, Lamivudine, and Nevirapine, is a generic product that sells for a price cheaper than other HIV/AIDS medicines protected by patents. The generic medications will be manufactured by generic producer Apotex, Inc. under compulsory license in Canada for purpose of export to underdeveloped countries facing public health crises.[3]

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[1] See World Trade Organisation, Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr. 1 (1 September 2003) ("Implementation Agreement").

[2] World Trade Organisation. Council for Trade-Related Aspects of Intellectual Property Rights. Rwanda – Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/7/Rev.2/Add.7 (19 July 2007).

[3] On October 4, 2007, Canada also informed the WTO of its intent to supply Rwanda with the generic medicines for under the terms of the Implementation Agreement. Its notification is pursuant to paragraph 2(c) of the Implementation Agreement. See World Trade Organization. "Canada is First to

Rwanda's notification symbolises a dramatic step in the global campaign for access to affordable medicines. While compulsory licenses to produce generic drugs, as outlined within TRIPS and accompanying WTO agreements, provide for a partial solution to the price of prohibitive costs of pharmaceuticals in developing countries facing public health problems, political, economic and legal circumstances more often than not prohibit countries from utilising those flexibilities. Before Rwanda, no developing country had ever given notice of its intention to utilise the WTO procedures allowing for countries without manufacturing capabilities to import generic medicines made under compulsory license in another country.

The never-before-used August 2003 waiver to the WTO's intellectual property rules, meant to allow poor countries with public health problems to import generics when they cannot manufacture the drugs themselves, is no longer a hypothetical scenario. Rwanda's experience utilising these procedures may very well set the path for determining the effectiveness of the WTO waiver, which was designed to improve access to medicines for the millions of people in developing countries so desperately needing more affordable medicines.

a. The Effect of Patents on Affordable Access to Medicines

The effect of patent protections on the price of pharmaceuticals in developing countries has been one of the most contentious topics of public debate over the last few decades. Of greatest concern is determining how an appropriate balance between intellectual property interests and public health interests can be reached.

In the context of pharmaceutical patents, there is an ongoing struggle to

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Notify Compulsory License to Export Generic Drug." 4 October 2007 [Online]. Available at: http://www.wto.org/english/news_e/news07_e/trips_health_notification_oc/htm

protect legitimate interests of pharmaceutical patent owners with imminent public health needs to access affordably the medications and technologies protected by those patents. On one hand, further technological innovation depends on financial incentives for the costly research and development (R&D) of new medicines.[4] On the other hand, an overly stringent system of patent rights on pharmaceuticals leads to increased price and limited supply of pharmaceuticals in poor and developing countries.[5]

Because patents create a monopoly over the supply and price of the product or process protected, both proponents and critics of patent rights agree that pharmaceutical patents indisputably impact affordability of access to medicines. This statement is particularly the case in developing countries where financial resources are scarce and purchasing power is limited.[6]

There is little contention over the fact that significant gaps exist in the TRIPS Agreement with respect to patent protection and access to life-saving medicines in developing and least developing countries (LDC's).[7] A most primary concern of both developed and developing countries is determining what are the most appropriate and effective means within the WTO framework to strike an appropriate balance between the protection of patent rights with internationally recognised public health interests. The focus of the debate surrounds TRIPS requirements of extensive,

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[4] Wilson, Clark. "The TRIPS Agreement: Is it Beneficial to the Developing World or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?" 10 J. Tech. L. & Pol'y 243, 244 (2005).
[5] UK Commission on Intellectual Property Rights. "Integrating Intellectual Property Rights and Development Policy." November 2002. [Official Report and Online Publication]. Available at http://www.iprcommission.org (last visited 12 July 2007) (hereinafter "CIPR Report"), p. 34.
[6] See Howse, R & Tribilcock, M. The Regulation of International Trade at 309. (2nd ed. 1999).
[7] Mercurio, B. "TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World." 8 Marq. Intell. Prop. L. Rev. 211 (2004).

globally uniform patent protections for pharmaceutical products and processes.[8]

There is an imperative need to identify what measures and improvements can be made to the WTO patent system in order to increase affordability of access to medicines, particularly in the developing countries where pandemics of HIV/AIDS, malaria, tuberculosis, and other diseases have taken a devastating toll.

The issue of access is significant because of the staggering number of people that lack access to affordable medical supplies and treatment. As estimated by the World Health Organisation, one-third of the world's population lacks access to medical supplies, while ninety-five percent of those suffering from AIDS do not receive any form of HIV/AIDS treatment at all.[9] Even though price is not the only reason so many infected persons in Sub-Saharan Africa are left untreated, it is certainly a primary contributing factor. Annual costs of patented antiretroviral cocktails in the range of $12,000 to $34,000 are more than prohibitive to a majority of the world's population, nearly 3 billion of which live on less than $2.00 a day.[10] The effect of patents largely impact affordability of pharmaceuticals because they create legal monopolies over the supply and pricing of essential medicines needed to combat large scale pandemics such as HIV/AIDS, malaria, tuberculosis, among the many.

b. Thesis Outline

This thesis articulates the difficulties in affordability of access to medicines

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[8] Gupta, A. "Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?" 2 Buff. Intell. Prop. L. J. 127 (2004).
[9] World Health Organisation, Drug Management and Supply Strategies. [Online]. Available at http://ww.ho.int/medicines/teams/par/drug_management_and_supply_strat.html (last visited 11 July 2007).
[10] Murthy, D. "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health." 17 Am. U. Int'l. L. Rev. 1299, 1309 (2002).

in developing and least developed countries. It discusses the WTO international patent framework in relation to the pharmaceutical industry and developing countries, specifically referencing global pandemics such as HIV/AIDS. It argues that compulsory licensing of pharmaceuticals is an essential and necessary means toward increasing access to affordable medicines.

Part II provides a general overview of patent protections as intellectual property rights, specifically in relation to their effect on pharmaceutical products in the developing world.

Part III discusses the WTO, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and subsequent WTO agreements concerning the obligations of member states in protecting and enforcing patent protections at their respective domestic levels.

Part IV sets forth the exceptions and flexibility provisions of TRIPS allowing members to override patent protections under defined circumstances. Those options are: (a) limited exceptions to rights conferred under TRIPS Article 30, (b) compulsory licensing under TRIPS Article 31, and (c) parallel imports by way of exhaustion of rights under TRIPS Article 6. Part IV further evaluates the effectiveness of each as policy options within the WTO framework toward enhancing affordable access to medicines and pharmaceutical products in the developing world.

Part V outlines the political events surrounding compulsory licensing in South Africa, Brazil, and the United States, leading to the Doha Declaration. Specific reference to problems surrounding the "paragraph 6 problem" are analysed,

followed by discussion of the benefits and limitations of the Implementation Agreement as the purported solution to those difficulties.

Part VI advocates for implementation of compulsory licensing flexibilities as an essential means of enhancing affordable access to medicines in the developing world. It demonstrates that in order to make productive use of compulsory licensing provisions, developing nations must make full use of compulsory licensing provisions within the WTO framework by implementing legislation at the domestic level. Implementing domestic legislation effectively utilising compulsory licensing flexibilities as a means of lowering the price of patented products are assessed. Demonstrative examples of effective legislation in South Africa and Brazil are used in support thereof. Finally, it encourages implementation of safeguards against trade diversion as a congruent means of enhancing access to affordable medicines. Part VII concludes with final remarks.

c. ***Authorities Consulted***

In support of this thesis, a wide range of authoritative sources were consulted for the purpose of: (1) considering the effect of the intellectual patent framework of the WTO and TRIPS Agreement on public health and access to medicines, (2) analysing policy options within that framework to enhance access to affordability of medicines, (3) examining how countries have utilised compulsory licensing flexibilities as a means of enhancing access, and (4) developing policy guidelines to complement intellectual property regimes.[11]

Primary sources used include the following principal WTO legal documents:

[11] See CIPR Report (stating tasks and purposes of commissioned report on intellectual property rights in developing countries).

The General Agreement on Tariffs and Trade (GATT), The Marrakesh Agreement Establishing the World Trade Organisation (Marrakesh Agreement), The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Final Act of the Uruguay Round), The Declaration on the TRIPS Agreement and Public Health (Doha Declaration), the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Implementation Agreement), and 2005 Amendment of the TRIPS Agreement Decision, and the Chairperson's Statement of December 6, 2005 (Chairperson's Statement). Implementing legislation of specific countries such as South Africa, Brazil, Rwanda, Canada, and the U.S. were also analysed and compared and, where appropriate, cited.

A wide range of secondary sources were also consulted and used in support thereof. They include qualified academics and experts from both developed and developing countries and from diverse backgrounds and disciplines including law, economics, the pharmaceutical industry, government and academia. Among these are recommendations, reports, studies, and writings conducted by Allan Sykes, Bryan Mercurio, Carlos Correa, Brooks Baker, Peter Drahos, Amir Attaran, Lee Gillespie-White, and the UK Commission on Intellectual Property.

II. BACKGROUND

a. Patents as Intellectual Property Rights [Patents, Generally]

Intellectual property rights (IPRs) are legally created rights over creative works such as inventions, literary inventions, literary and artistic works, symbols,

names, images and designs used in commerce.[12] The benefit conveyed to the intellectual property holder is the entitlement to prevent others from making unauthorised use of the intellectual property for a limited period of time.[13]

Patents are a significant form of IPR which grant exclusive rights to an inventor over an invention allowing for the exclusion of others from making, selling, distributing, importing or using the invention without license or authorisation for a fixed period of time.[14] The granting of a patent is described as conferring the right of exclusivity, which is the right to prevent others from copying and selling the invention for a specified number of years.[15] In other words, "the granting of a patent is akin to a grant of a monopoly because it allows the patent holder to manipulate the market price of the product."[16] As long as the legally sanctioned monopoly exists, a patent holder has the right to exclude competitors, set prices, and control the supply of the patented product.[17]

The rationale for the grant of exclusivity to patented inventions is to encourage innovation by providing incentives to inventors. Among those incentives include the following objectives: (1) to recoup costs of research and development of a product or process, (2) to generate profits, and (3) to fund research and development of future inventions.[18] Because of extraordinary costs associated with

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[12] McManis, Charles. "Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies." 2 Wash. U. J. L. & Pol'y. 1 (2000).
[13] CIPR Report at 14 (the intellectual property holder can be a person, group, organisation, or even a state).
[14] CIPR Report at 14.
[15] See Jackson, J. Legal Problems of International Economic Relations: Cases, Materials and Text 884 (3d ed. 1995) (providing a general introduction to the intellectual property rights and policies).
[16] Gupta, A. at 129.
[17] Whobrey, B. "International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries." 45 Brandeis L. J. 623, 630 (2007).
[18] CIPR Report at 34; Murthy, D. at 1309.

the research and development of patented products and processes, the prospect of recouping costs and earning profits are necessary to promote further development in innovative technologies. In the case of pharmaceuticals, for example, the average cost of research, testing, clinical trials, and obtaining government regulatory approval falls in the range of $500 million US dollars.[19]

Proponents of strict intellectual property laws argue that protection is necessary to encourage inventors, manufacturers, and others to invest time and resources into developing new products, processes and creative works.[20] Society, in turn, benefits by new technologies that contribute to social, economic and cultural development. Critics counter the arguments favouring strong IP protections by stating that exclusive rights impose higher costs on consumers and other users of protected technologies, particularly in developing countries. Where consumers or users are unable to pay the prices charged by IP owners, they are deprived of access to the innovations the IP system is intended to make available.[21]

The critical point remains in striking an appropriate balance between private and public interests. As declared by the Commission on Intellectual Property, the critical issue surrounding standards for intellectual property protections is to "reconcile the public interest in accessing new knowledge and the products of new knowledge, with the protection of intellectual property for the promotion of innovation and creativity."[22] TRIPS attempts to strike that balance in the

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[19] Moken, M. "Fake pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices." 29 Am. J. L. & Med. 525, 533 (2003).
[20] Harrelson, J. "TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion." 7 Widener L. Symp. 175, 187-188 (2001) (examining arguments in favour of strong patent protections).
[21] CIPR Report at 6.
[22] CIPR Report at 6.

establishment of global minimum standards for intellectual property protection. In the context of the pharmaceutical industry, the goal, at least in theory, is to strike the balance between short-term objectives of providing access to life-saving medicines and long-term objectives of encouraging and providing incentives to the pharmaceutical industry for the development of new medicines.[23]

b. Relationship Between Pharmaceutical Patents and Access to Medicines

Patent protection in the context of pharmaceuticals remains one of the most controversial discussions surrounding TRIPS, as the essence of a patent is to allow the patent holder to exclude competitors and charge high prices. Critics condemn TRIPS for contravening public health interests by restricting access to affordable essential medicines while millions are faced with the plight and suffering of HIV/AIDS, malaria, tuberculosis, and other epidemics.

In the context of pharmaceuticals, developing countries and non-governmental organisations argue that strong protection and strict enforcement of patent protections result in prohibitively high prices of pharmaceutical products. Prohibitively high prices, in effect, render critical supplies and essential medicines unaffordable to the vast majority of people in poor and developing countries. Because of the relationship between patent protection and the price of pharmaceuticals, the issue of affordable access necessarily involves addressing the issue of appropriate measures within the current patent framework to enhance access on a global scale.

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[23] Mercurio, B. "TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World." 8 Marq. Intell. Prop. L. Rev. 211, 217 (2004).

The main arguments offered by industrialised and developed nations for the maintenance of strong patent regimes are as follows: (1) strong patent protection stimulates future innovations of medical products; (2) patents encourage capital investment in pharmaceutical companies; (3) strong patent regimes attract direct foreign investment, thereby benefiting developing nations in the long term.[24] Developing countries and nongovernmental organisations counter these points by pointing to the fact that the long term benefits of patent protections should not take priority over current public health crises. This point is bolstered by the fact that public health emergencies such as HIV/AIDS continue to ravage populations in developing countries that simply cannot afford the essential medicines needed to treat it.

The immediate impact of intellectual property protection, as stated by the Commission on Intellectual Property, "is to benefit financially those who have knowledge and inventive power, and to increase the costs of access to those without it."[25] Proponents of pharmaceutical patents maintain that other factors inevitably affect access. While patents allow producers to set the price of medicines, barriers to access to medicines result from inadequate infrastructure, ineffective health care and drug distribution systems, and poverty.[26] A major study conducted in 2001 by Amir Attaran and Lee Gillespie-White challenged patent criticisms with empirical evidence of outside factors impeding affordable access to medicines in the developing world.

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[24] Wilson, C. at 261.
[25] CIPR Report at 8.
[26] Attaran, A. and Gillespie-White, L. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" 286 J. Am. Med. Ass'n. 1886 (2001).

> It appears that patents and patent law[s] are not a major barrier to treatment access in and of themselves. We conclude that a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and above all, a lack of sufficient international financial aid to fund antiretroviral treatment.[27]

While these de facto barriers must be recognised, the fact that overly stringent patent regimes impede affordability of access cannot be denied. As Correa, a prominent expert in patent legislation in developing countries, describes, "where denial of affordable access to treatment [with] pharmaceuticals can have life or death consequences, the conditions of price that determine access to medicines are critical, especially for the low-income segments of the population."[28] Further, strong empirical evidence demonstrating the disproportionate negative impact of drug patents on developing countries exists. By way of example, a study conducted in South Africa on the economic effect of pharmaceutical patents estimated a $3.5 billion to $10.8 billion welfare loss by developing nations against a $2.1 to $14.4 billion dollar gain to foreign pharmaceutical companies.[29]

That being said, without international respect for pharmaceutical patents, medical innovation would inevitably suffer. The reason is such that pharmaceutical companies spend on average of $500 million to develop a single medicine.[30] On average, only one of 4,000 compounds that are discovered become marketable

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[27] Attaran, A. and Gillespie-White, L. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" 286 J. Am. Med. Ass'n. 1886 (2001).
[28] Correa, C. "Public Health and Patent Legislation in Developing Countries." 3 Tul. J. Tech. & Intell. Prop. 1, 3 (2001).
[29] See Park, R. "The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients." 11 Minn. J. Global Trade 125, 131 (2002).
[30] Murthy, D. at 1306 (citing Mossinghoff, G. "Progress in the Pharmaceutical Industry, Intro to Intell. Prop. Rights." [Online]. Available at: http://usinfo.state/gov/products/pubs/intelprp/progress.htm (last visited 17 June 2001)).

products.[31] A study of 12 industries conducted by the University of Pennsylvania concluded that "65% of pharmaceutical products would not have been introduced without the [prospect] of adequate patent protection."[32]

Without the patent system, which provides for financial incentive to recoup costs and generate profit and fund future research and development of new products, it is unlikely that private industries would have invested so much in the discovery or development of medicines in the first place.[33] However, as argued by much of the developing world and the NGO community, patent protection offers little incentive for research and development into developing country diseases (neglected diseases) in the absence of a significant market.

Consider, for example, the largest causes of mortality and morbidity in developing countries other than HIV/AIDS. They are tuberculosis, malaria, measles, sleeping sickness, leishmaniasis, and Chagas disease, and predominantly afflict the developing world.[34] Less than 5% of R&D is spent on those diseases because they represent such a small portion of the global market.[35] Thus, as developing countries rightfully condemn, any benefits derived by the patent system do not necessarily flow to the developing world. A majority of illnesses afflicting the developing world remain untouched by ongoing research and development conducted by the pharmaceutical sector. Even strains of HIV/AIDS are different and more devastating

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[31] Murthy, D. at 1306 (citing Fisch, A. "Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem." 34 Jurimetrics J. 295, 303 (1994)).
[32] Murthy, D. at 1306 (citing Mossinghoff, G. "Progress in the Pharmaceutical Industry, Intro to Intell. Prop. Rights." [Online]. Available at: http://usinfo.state/gov/products/pubs/intelprp/progress.htm (last visited 17 June 2001)).
[33] CIPR Report at 34.
[34] CIPR Report at 35.
[35] CIPR Report at 37.

in Africa, requiring distinct treatment than what is required in developed countries.[36]

In the context of HIV/AIDS drug therapies, certainly patent protections have been critical to the development of life-saving medications for what used to be a death warrant disease. The key, of course, is that those that are affected, despite the disparities of their social and economic living conditions, are able to access those life-saving medications. This thesis takes the position that access and affordability are virtually synonymous in that they are mutually dependent upon one another. Access depends on affordability, and affordability is essential to access.[37]

To demonstrate this point, is the cost of anti-retrovirals, the drug treatment used for HIV infections. Recent figures estimate that average per capita health care expenditures in low income developing countries range at $23 per year, while the most inexpensive ARV triple therapies are at $200 per year.[38] The World Health Organisation estimates that less than 5% of those needing ARV treatment actually receive it.[39] As affordability is limited, so is access.

Accordingly and in light of this fact, policy alternatives within the WTO patent framework must be implemented in order to strike the appropriate balance between patent interests and enhancing access to affordable health for all. The options are discussed below, advocating for implementation of compulsory licensing flexibilities under defined circumstances as provided for by TRIPS.

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[36] Most HIV vaccines are being developed for genetic profiles for subtype B, prevalent in developed countries, but most AIDS sufferers in developing countries are types A and C. See CIPR Report at 32.

[37] Even while bearing in mind that other factors, such as those described by the Attaran/Gillespie-White Report, also impact negatively on access.

[38] CIPR Report at 61.

[39] World Health Organisation. "Intellectual Property Rights, Innovation and Public Health: Report by the Secretariat (Geneva: WHO, 56th World Health Assembly Provisional Agenda Item 14.9, A56/17, 12 May 2005).

III. THE WTO FRAMEWORK FOR THE PROTECTION AND ENFORCEMENT OF PATENT RIGHTS

a. The World Trade Organisation

The World Trade Organisation was established in 1995 by the Final Act of the Uruguay Round of negotiations as the international organisation governing global trade between member nations (members).[40] The General Agreement on Tariffs and Trade (GATT), the predecessor agreement on international trade, served primarily on the reduction of tariffs to facilitate trade between member countries.[41] The WTO replaced the GATT by incorporating existing agreements under GATT and adopting a series of additional agreements with a broad range of objectives aimed at promoting international trade.

The purposes and functions of the WTO are to enforce trade agreements, settle trade disputes, provide a forum for global trade negotiations, monitor national trade policies, and provide technical assistance and training for developing countries.[42] To date, the WTO is comprised of 151 members at all stages of economic development and engaged in varying levels of international trade.[43]

The Marrakesh Agreement establishing the WTO requires all ratifying members to accept agreements settled during the Uruguay Round of Trade

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[40] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, April 15, 1994, Legal Instruments – Results of the Uruguay Round vol. 1, 33 I.L.M. 1125 (1994) (establishing the WTO in the last round of GATT).
[41] General Agreement on Tariffs and Trade: Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations. 25 I.L.M. 1623 (Sept. 20, 1986).
[42] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations. April 15, 1994, Legal Instruments – Results of the Uruguay Round vol. 1, 33 I.L.M. 1125 (1994).
[43] World Trade Organisation. "WTO Fact File." [Online]. Available at http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited 23 August 2007) (WTO membership base as of 27 July 2007) (As of 2004 the WTO accounted for over 90% of global trade) (a number of non-member countries are at the time still negotiating membership).

negotiations in order to remain or become members of the WTO.[44] That mandate is referred to as the "single undertaking" (i.e. committing to become bound to each and every agreement annexed to the Agreement Establishing the WTO). Among the annexed agreements is TRIPS.[45] Accordingly, each and every WTO member is bound by TRIPS, articles 27 – 34 of which outline the essential minimum components of patent laws required by all members.

b. TRIPS

TRIPS is known as the most comprehensive international instrument on intellectual property rights (IPRs).[46] As described by Peter Drahos, TRIPS "marked the beginning of the global property epoch."[47] Adopted as part of the Uruguay Round, TRIPS has been ratified by all WTO members.[48] TRIPS requires minimum standards for the protection and enforcement of intellectual property rights by all members countries.[49] In addition to minimum level protections, TRIPS also sets forth procedural requirements, including remedies available and dispute resolution mechanisms, for the enforcement of intellectual property rights.[50] Implementation of

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[44] Marrakesh Agreement Establishing the World Trade Organisation, article XI, XII, April 15, 1994, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 1125, 1126 (1994).
[45] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) (establishing a multilateral agreement creating minimum protection standards for various forms of intellectual property among Member States).
[46] Correa, C. "The TRIPS Review: Some Proposals for Developing Countries." *Third World Network.* [Online]. Available at http://www.twnside.org/sg/title/some.htm (last visited 28 June 2007).
[47] Drahos, P. "Intellectual Property and Human Rights." Intell. Prop. Q. No. 3, 349, 356 (1999).
[48] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) ("TRIPS") (establishing a multilateral agreement creating minimum protection standards for various forms of intellectual property among Member States).
[49] TRIPS, Article 1.
[50] See World Health Organisation. "WTO and The TRIPS Agreement." [Online]. Available at http://www.wto.int/medicines/areas/policy/wto_trips/en/print.html [03 February 2007].

TRIPS has required significant development and change in national legislation by most developing and least developed countries both in terms of substantive as well as procedural laws.[51]

The agreement provides a framework for legislation to be implemented by members at a domestic level. All members are obliged to adapt their intellectual property laws so that they provide for such minimum levels of protection in compliance with TRIPS.[52] In other words, TRIPS does not provide actual operative provisions that members can directly adopt as part of their national legislation. Rather, Members are obliged to formulate and/or adapt their intellectual property laws in compliance with minimum standards required by TRIPS.[53]

While minimum standards must be complied with, TRIPS allows members to determine appropriate methods of implementation within their own legal system and practice.[54] Further, members may enact policies and laws to provide for stronger protection then what is specified in TRIPS.[55]

TRIPS coverage extends to a wide range of intellectual property, including copyrights, trademarks, patents, geographical indicators, industrial design, integrated circuits layout designs, undisclosed information and trade secrets.[56] Among the most controversial of intellectual property protections under TRIPS is

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[51] See Correa, C. "The TRIPS Review: Some Proposals for Developing Countries." *Third World Network.* [Online]. Available at http://www.twinside.org.sg/title/some.htm (last visited 28 June 2007) (any deviation from TRIPS standards may lead to dispute settlement procedures before the Dispute Settlement Board of the WTO, subjecting any non-compliant country with trade retaliation measures).

[52] TRIPS, Article 1.

[53] World Health Organisation. "WTO and The TRIPS Agreement." [Online]. Available at http://www.wto.int/medicines/areas/policy/wto_trips/en/print.html (last visited 28 June 2007).

[54] TRIPS, Article 1.

[55] TRIPS, Article 33.

that of the patent protection for pharmaceuticals medicines. The focus of this thesis surrounds the WTO framework for patent protections and their effect on access to affordable medicines.

i. Substantive Provisions and Their Effects on Access

Patent protections under TRIPS require all members to grant exclusive rights to the patent holder for no less than 20 years from the date of filing.[57] Patents must be made available for any invention, whether products or processes, in all fields of technology.[58] Exclusive rights over a pharmaceutical drug for the duration of the patent term mean that the patent holders retain control over not only the production, supply, and distribution of the product, but also - by virtue of exclusivity - the price of the particular drug.[59] The effect of exclusivity is that patent protections provided under TRIPS inevitably lead to inflated prices of pharmaceutical drugs, making essential drugs highly inaccessible to the developing world.

TRIPS is often criticised for its effect on access to medicines because of its broader coverage and increased protections than agreements prior to its enactment. Before TRIPS came into force, many developing countries did not extend patent protection to pharmaceutical products (only pharmaceutical processes could be patented), while others excluded medicines from the ambit of patent laws. This

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[56] TRIPS, Part II (Standards Concerning the Availability, Scope and Use of Intellectual Property Rights).
[57] TRIPS, Articles 27, 33.
[58] TRIPS, Article 27. (Prior to TRIPS, most Members protected only process patents. Where product patents were not granted, pharmaceutical manufacturers were able to produce generic versions of the patented product by way of reverse engineering – producing the same or substantially similar product by way of different process.(i.e. the same product produced by way of a different process). Under the current TRIPS regime, which extends patent protections beyond the process to the final product itself, reverse engineering is no longer permissible).

"allowed local production of generic versions of patented medicines and kept the prices of formulation at a much lower level then that in the developed world."[60] For example, according to United Nations figures published in 2000, AZT (a drug treatment for treatment of HIV) therapy was produced at a supply cost of $48 per month in India as compared with $239 in the United States, and Larium (a drug prophylactic treatment for malaria) at a cost of $4 as compared with $37 in the US.[61]

In addition to inflating the price of pharmaceutical drugs, the 20-year period of exclusivity under TRIPS unduly delays access of generic pharmaceuticals into the global market. The effect is most noticeable in the developing world where a majority of health consumers lack the resources with which to purchase basic health care, let alone purchase highly expensive pharmaceuticals. Prior to TRIPS, patent protections were significantly shorter – in developed countries between 15-17 years, developing countries between 5-7 years, and in approximately 40 counties pharmaceutical products received no patent protection at all.[62] These combined factors form the basis for which TRIPS is often criticised for its effect on access to affordable medicines.

Furthermore, TRIPS also requires countries to extend patent protection to both product *and* processes in technological inventions.[63] Prior to TRIPS, most

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[59] World Health Organisation, "Access to Medicines, Intellectual Property Protection: Impact on Public Health." [Online]. Available at http://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf [03 February 2007]
[60] Gupta, A. at 129.
[61] See Chapman, A. "Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c)." Discussion Paper Submitted to the Committee on Economic, Social and Cultural Rights, 24th Sess. at 22, U.N. Doc. E/C/12/2000/12 (2000).
[62] E.g. Brazil, Thailand, Korea. See World Trade Organisation. "WTO and The TRIPS Agreement." [Online]. Available at http://www.wto.int/medicines/areas/policy/wto_trips/en/print.html [03 February 2007].
[63] Article 28, TRIPS.

members protected only process patents.[64] Where product patents were not granted, pharmaceutical manufacturers were able to produce generic versions of the patented product by way of reverse engineering (i.e. the same product produced by way of a different process).[65]

Under the TRIPS regime, which protects both product and process patents, reverse engineering is prohibited. Because TRIPS extends patent protections beyond the process to the final product itself, the entry affordable generic medications by way of reverse engineering is precluded, even where technological know-how and demand exists. Accordingly, to the extent that drug patents heavily restrict the development and distribution of cheaper generic medications, TRIPS seriously undermines affordability of access.[66]

TRIPS, Article 27 requires that patents must be made available for any invention, whether products or processes, in all fields of technology.[67] The minimum right that must be conferred with the grant of a patent must be that of exclusivity, i.e. the right of the patent holder to prevent unauthorised third parties from "making, using, offering for sale, selling or importing" the patented

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[64] See Gupta, A. at 127 (describing the difference between a product patent and a process patent. "Patenting a process implies that only the process through which a product is made can be patented. The final product is not included under the right. A patent holder can restrict the other party from using the process, but he can make no claims on the product. Thus, another manufacturer can market the same product as long as she uses a different process.")

[65] E.g. Argentina and India. Lewis, T. "Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries." 30 Int'l. L.R. 835 (1996).

[66] The WTO describes generic medicines as copies of patented drugs made by other manufactures either sold under the name of the chemical ingredient (i.e. paracetamol) or under another brand name (panado, panadol), which means they are still generics from the point of view of patents.

[67] TRIPS, Article 27. (Prior to TRIPS, most Members protected only process patents. Where product patents were not granted, pharmaceutical manufacturers were able to produce generic versions of the patented product by way of reverse engineering – producing the same or substantially similar product by way of different process.(i.e. the same product produced by way of a different process). Under the current TRIPS regime, which extends patent protections beyond the process to the final product itself, reverse engineering is no longer permissible).

pharmaceutical.[68]

ii. Transitional Periods

Members are given discretion to determine the appropriate method of implementing TRIPS provisions within their own legal system and practice.[69] With respect to the transition period during which those provisions were to be implemented, members were given transition periods based on their level of economic development. The following transition periods were agreed upon: (1) developed countries were obliged to have enacted TRIPS within one year of TRIPS having taken effect (by 1 January 1996); (2) developing and transition countries were given give five years (until 1 January 2000), with a further five years to extend patent protection to new areas such as pharmaceuticals); and (3) least developed countries were given until 2006, with an additional allowance of ten years (until 2016) with regard to pharmaceutical products.[70]

With regard to access to medicines, these transitional periods were of paramount importance to developing countries. Delayed implementation of TRIPS allowed countries with generic manufacturing capabilities (i.e. India) to produce cheap generics and sell them for much lower prices than the patented product. After the respective deadlines for implementation, however, when countries become subject to TRIPS, those possibilities are no longer be available.

Developing countries that formerly did not extend patent protections will be required to extend product patent protection to areas of technology not previously

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[68] TRIPS, Article 28.
[69] TRIPS, Article 1.

protected. As this occurs, the global price of medicines has continually increased in all but a few countries worldwide. As prices increase, access decreases. Those claims are affirmed by the Commission for Intellectual Property Rights Report, which revealed considerable evidence that consumption of medicines is most affected by price.[71] As the generic industry phases out, the possibility of compulsory licensing should increasingly become a feasible option for price reductions in developing countries.

iii. Objectives and Balancing Principles

TRIPS contains a number of governing objectives and principles allowing member countries flexibilities in balancing their obligations to protect and enforce patent rights with public health interests. The Preamble begins by declaring that "developmental and technological objectives" should underlie public policy objectives of national systems for the protection of intellectual property."[72]

Article 7 (Objectives) states that the purpose of intellectual property rights is to "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 the balance of rights and obligations."[73] This indicates that members should retain flexibility in developing domestic patent laws in order to address public health. Article 8 (Principles) further elaborates the balancing principle allowing members to

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[70] TRIPS Articles 65-66; Doha Declaration ¶ 5.
[71] Matthews, D. "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?" 7 J. Int'l. Econ. L. 73, 74 (2004) (citing CIPR Report at. 37).
[72] TRIPS, Preamble.
[73] TRIPS, Article 7.

adopt measures necessary to protect public health and promote public interest in sectors vital to their development, as well as to prevent the abuse of patent rights and practices that unreasonably restrain trade and the international transfer of technology.[74]

The balancing principles between patent holders and public health are to be the primary guiding principle in the international patenting framework under the WTO. However, while TRIPS identifies the need to balance rights with obligations, it gives no guidance on how states can achieve that balance. In this regard, it can be said that despite these balancing principles, "the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives."[75]

Nonetheless, under the principles of treaty interpretation set forth by Article 31 of the Vienna Convention on the Law of the Treaties, TRIPS should be interpreted first according to its text, articles, and preambles.[76] It should then be interpreted "according to prior decisions interpreting the treaties, customary international law, other relevant rules of international law, writings of highly qualified publicists related to TRIPS, and the preparatory work and circumstances of the agreement."[77]

Additionally, pursuant to the Doha Declaration, discussed more fully below,

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[74] TRIPS, Article 8. (Provided that such measures are consistent with other TRIPS provisions).
[75] Gupta, A. at 131 (citing Report of the High Comm'r of the Human Rights Comm'n. "The Impact of the Agreement on Trade-Related Aspects of Intellectual Prop. Rights on Human Rights." U.N. Doc. E/CN.4/Sub.2/2001/13 (2001)).
[76] Vienna Convention on the Law of Treaties. 8 I.L.M. 679 (17 January 1980) (the WTO accepts that the Vienna Convention is a codification of customary international law and is therefore binding on all states).
[77] Palmeter, D. & Mavroidis, P. "The WTO Legal System: Sources of Law." 92 Am. J. Int'l. L. 398, 399-413 (1998).

"in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[78] Accordingly, despite any weaknesses contained therein, the objectives, principles, and directing guidelines of TRIPS unambiguously necessitate a balance of rights and interests between intellectual property holders and public welfare.

IV. EXCEPTIONS TO PATENT RIGHTS – POLICY OPTIONS WITHIN THE WTO FRAMEWORK FOR THE ENHANCEMENT OF AFFORDABLE ACCESS TO MEDICINES

Despite the numerous provisions in favour of the exclusive rights granted by a patent, TRIPS recognises that patent rights are not absolute and are subject to certain limitations and exceptions. The most notable exceptions are distinguished into the following three categories: (1) The Limited Exceptions provision of Article 30, (2) the Compulsory Licensing provision of Article 31, and (3) the Parallel Importing provision of Article 6, referred to as Exhaustion of Rights. These provisions are the three policy options within the WTO patent framework for enhancing access to affordable medicines. This section discusses each in substance and form below.

a. Article 30 Limited Exceptions (Exceptions to Rights Conferred)

Article 30 authorises members to provide limited exceptions to the exclusive rights conferred by patents. It states, in pertinent part, that members may legislate for limited exceptions to the exclusive rights conferred by a patent, provided that they do not unreasonably conflict with the normal exploitation of the patent and do

[78] Doha Declaration, ¶ 5.

not unreasonably prejudice the legitimate interests of the patent owner.[79]

In the context of pharmaceuticals, an example of an allowable exception under Article 30 is called the Bolar exception, otherwise known as the "early working exception." The Bolar exception allows generic manufacturers to import, manufacture and test a patented product prior to the expiry of the patent term in order to fulfill regulatory requirements to ensure that the generic drug is ready to market as soon as the patent expires.[80] An exception such as this can enhance access to medicines to the limited extent that it assists timely entry of lower priced generics into the market as soon as a patent expires. However, the benefits are limited, in that the normal life of a patent still runs its course. In this regard, the Bolar exception only prevents the artificial extension of patent rights beyond the normal life of the patent.

The benefits of this exception are that it does not require the issuance and approval of a compulsory license as under the Article 31 option (discussed below), nor does it require an amendment to TRIPS as a solution to enhance affordable access. Some favour this option because it removes the requirement to compensate the patent holder for the rights protected by the patent.

The WTO has made clear that Article 30 must be interpreted as a narrow exception to be used under severely limited circumstances. The WTO, in the Panel Report decision in the Canada-Patent Protection case, interpreted the application of Article 30 limited exceptions. It indicating that an exception permitted under Article 30 must meet three cumulative conditions, each of which must be satisfied in order

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[79] TRIPS, Article 30.
[80] Gupta, A. at 140.

for the exception to fall within the scope of Article 30.[81] The three conditions are as follows: (1) the exception must be of a limited nature; (2) it must not unreasonably conflict with the normal exploitation of a patent; and (3) it may not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties.[82]

The Stockpiling Exception in Sec. 55.2 (2) of the Canadian law permitted generic manufacturers to produce and stockpile generic products for which marketing approval had been obtained during the six-month period before expiry of the patent and then market the generic products as soon as the patent had expired.[83] Stockpiling is the purchase of more medications than the amount actually needed. The WTO rejected Canada's claim that stockpiling is authorised by Article 30 as a limited exception to patent rights.[84]

In light of the WTO's interpretation that stockpiling of a patented product does not qualify as an Article 30 limited exception, it is unlikely that the WTO would allow the manufacture of patented drugs for export as an exception to patent rights. This is because the WTO considers any override of a patent holder's normal rights (encompassing the authority to prevent others from making, using, offering for sale, selling or importing the patented product) to be "diametrically opposed to the

[81] Report of the WTO Panel. Canada-Patent Protection of Pharmaceutical Products. WT/DS114/R (17 November 2000).
[82] Report of the WTO Panel. Canada-Patent Protection of Pharmaceutical Products. WT/DS114/R (17 November 2000).
[83] Report of the WTO Panel. Canada-Patent Protection of Pharmaceutical Products. WT/DS114/R (17 November 2000).
[84] Report of the WTO Panel. Canada-Patent Protection of Pharmaceutical Products. WT/DS114/R (17 November 2000).

subject matter of the patent."[85] Therefore, it remains doubtful that Article 30 will provide any real benefit for the majority of developing countries in terms of enhancing greater affordable access to medicines.[86]

b. Article 6 Parallel Importation (Exhaustion of Rights)

Article 6 contains another exception to patent rights, parallel importation under the doctrine of exhaustion of rights, which can enhance affordable access to medications. The benefit of parallel importation is limited, however, in that it is associated with the risk of actually increasing the global price of patented pharmaceuticals. Accordingly, it is not the most ideal option for enhancing access to affordable medicines. In this regard, as discussed below, parallel importation of patented pharmaceuticals should be discouraged.

Parallel importation occurs when a patent holder sells a product to a buyer who then exports the product to a second buyer in another country.[87] For example, when a manufacturer sells a drug to Country A for $100 and markets the same drug to Country B for $50, Country B could then resell the drug to Country A for any amount above its cost.[88] This practice enhances affordability of access to the extent that it allows consumers to take advantage of differential pricing.

Parallel importation is premised on the doctrine of exhaustion of rights. This doctrine states that the patent holder's right to determine the conditions under which the patented product is resold exhausts (i.e. terminates or expires) after it has been

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[85] TRIPS, Article 28; see also Report of the WTO Panel. Canada-Patent Protection of Pharmaceutical Products. WT/DS114/R (17 November 2000).
[86] Gupta, A. at 143.
[87] Gupta, A. at 139.
[88] Whobrey, B. at 633.

sold for the first time.[89] This ensures that the patent holder receives remuneration at the time the product is sold, while allowing consumers to take advantage of differential pricing in different markets.[90]

While TRIPS does not explicitly authorise parallel importation, it does not prohibit it either. Article 6 states that "Nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights."[91] Critics often describe Article 6 as an indication of a failed agreement between developed country and developing country interests on the issue of exhaustion.[92] Nonetheless, Article 6 (taken in conjunction with accompanying principles discussed throughout) allows for developing countries to determine the extent to which the principle of exhaustion is applied in their own jurisdictions without breaching any obligation under TRIPS.

Further, the permissibility of parallel importation was confirmed by the Doha Declaration in the affirmation of every member's right to establish its own regime of exhaustion of intellectual property rights.[93] Accordingly, parallel importation is not in and of itself a violation of any WTO agreement. Rather, individual members are free to decide at what stage exclusive rights are exhausted, and thus whether and when parallel importation is permissible in a respective country.

Parallel importation can be a significant way of increasing access to essential medicines where the prices charged by patent holders are unaffordable. Parallel imports, in the context of patented pharmaceuticals, enhance affordability where

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[89] Correa, C. "The TRIPS Review: Some Proposals for Developing Countries." *Third World Network.* [Online]. Available at http://www.twnside.org/sg/title/some.htm (last visited 28 June 2007
[90] Gupta, A. at 139.
[91] TRIPS, Article 6.
[92] See Mwalimu, U.A. "Implications of WTO/TRIPS in East Africa – with Special Emphasis on Pharmaceutical Patents." Working Paper for the Economic and Social Research Foundation (ESRF). Workshop on Globalisation and East Africa. (16 April 2002).

prices are set differently in different markets based on varying market factors and levels of economic development. However, this thesis discourages overuse of parallel importation of patented pharmaceuticals because, more often than not, it results in an overall increase of price rather than enhancing affordability. In this regard, parallel importation represents somewhat of a double-edged sword.[94] While on one hand they allow for importation into third markets at a cheaper rate than what is charged in the importing country, they also have the effect of raising global prices because patent holders generally impose higher prices in the wealthier markets to make up for potential losses incurred as a result of parallel imports.

As emphasized by Correa, overuse of the exhaustion doctrine for parallel imports increases the likelihood that patent holders will raise the global price of pharmaceuticals.[95] An increase in the supposedly lower price that may otherwise be charged in low-income countries would certainly negate the intended purpose of allowing for parallel imports in the first place.

Therefore, while parallel importation is an option for developing countries to enhance affordable access to medicines in a TRIPS-compliant manner, it is advisable for all member countries to maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products, particularly those originating from developing countries. The purpose of doing so is to avoid product diversion of lower priced pharmaceuticals, for example those that are part of donations by pharmaceutical companies or a part of a differential pricing system, from the

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[93] Doha Declaration, ¶5 (d).
[94] Mercurio, B. at 223.

populations for whom the discounted medicines are intended.[96] In this regard, where patent protections are enhanced at appropriate levels, affordability of medicines will actually be enhanced. Measures to reduce product diversion for the end result of enhancing access are further discussed below in Section V.

c. Article 31 – Other Use Without Authorisation of the Right Holder (Compulsory Licensing)

Compulsory licensing is a mechanism built within TRIPS that is critical toward the enhancement of access to affordable medicines through the production of generic substitutes. Compulsory licensing should be granted under limited circumstances as appropriate within the WTO framework. This can be accomplished through member implementation of the existing flexibilities by way of domestic implementation.

TRIPS Article 31 (Other Use Without Authorisation of the Right Holder) provides the framework under which WTO members can grant compulsory licenses.[97] Article 31 does not specifically refer to the term "compulsory license", but its reference to "other use" is understood to allow compulsory licensing and government use under defined circumstances. The difference between compulsory licensing and government use is simply a matter of whether it is a third party or a government exploiting a patented product or process. When a third party is authorised by a government to exploit a patent, it is referred to as a compulsory

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[95] Gupta, A. at 139-140 (citing Correa, C. "Integrating Public Health Concerns into Patent Legislation in Developing Countries." [Online]. Available at: http://ww.southcentre.org/publications/publichealth/publichealth.org (last visited 1 March 2007).
[96] CIPR Report at 49.
[97] See TRIPS, Article 31 (delineating the requirements and restrictions on "authorized other use" or compulsory license) (Proposed user must negotiate with the patent holder. Art 31 (b). The scope and

license.[98] When the government itself exploits a patent, it is known as government use. For purposes of this thesis, both will be referred to as compulsory licensing.

Article 31 (b) outlines the prerequisites before a member can issue a compulsory license. First, any intended licensee (whether a country of a third party entity) must have made prior effort to negotiate the terms of an ordinary commercial license of the patented pharmaceutical.[99] Second, the party seeking the license must allow a reasonable period of time to achieve a mutual agreement.[100]

The requirement of prior negotiation efforts is waived, however, under circumstances of national emergency, extreme urgency, or non-commercial use.[101] It is important to note that the national emergency or urgency clause of Article 31(b) is merely a basis for waiving licensing negotiations with the patent holder, not an automatic permissive grant of compulsory license.

Under either scenario, adequate remuneration is due to the patent holder, taking into account the economic value of the authorisation. [102] Members are given discretion to determine grounds upon which constitute a national emergency or other circumstance of extreme urgency.[103]

Even if a compulsory license is granted, the patent holder retains its underlying patent rights. For example, the license granted is non-exclusive (meaning competition between the patent holder and other licensees still exists) and non-assignable (meaning only the party specified in the license is authorised to such other

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duration of the license must be limited to the original purpose. Art. 31 (c). The license shall be non-exclusive. Art. 31 (d). The license shall be non-assignable. Art. 31 (e)).

[98] TRIPS, Article 31.

[99] TRIPS, Article 31(b).

[100] TRIPS, Article 31 (b).

[101] TRIPS, Article 31 (b).

[102] Article 31(b), (h), TRIPS.

use).[104] In addition, the term of a compulsory license is not infinite. Once the circumstances that justified the original issuance of the license cease to exist, the license must terminate.[105]

i. *Domestic Market Limitation*

The most serious limitation, indeed the paradox of Article 31, is that it limits production of generic medicines under a compulsory license to the predominant supply of the domestic market of the country issuing the compulsory license.[106] In effect, even if a country produces affordable generics pursuant to the issuance of a compulsory license in compliance with TRIPS, it cannot then export them to an impoverished country whose population desperately needs access to affordable medications. For countries that have the capacity to produce, the domestic market requirement prevents the export of pharmaceuticals produced under the rightful issuance of a compulsory license. Even worse, smaller less developed countries lacking manufacturing capabilities of their own are left unable to take advantage of Article 31 compulsory licensing flexibilities because of the domestic market restriction.

The domestic market requirement of Article 31(f) drastically limits the ability of least developed countries to use the compulsory licensing exception because the vast majority of LDC's lack manufacturing facilities or other resources to produce pharmaceuticals domestically. Because Article 31(f) is predicated on the capacity of a nation to produce, the purported safeguard provision of Article 31 is deemed

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[103] Doha Declaration, ¶ 5.
[104] TRIPS, Article 31 (d), (e).
[105] TRIPS, Article 31 (g).

entirely useless to least developed country members needing them the most.

ii. Undefined Standards

A further limitation is that Article 31 neglects to define crucial terms upon which the use of the compulsory licensing exception depends. The text fails to define or create standards, guidelines, or interpretations of significant terms such as "reasonable period of time",[107] "reasonable commercial terms",[108] "national emergency",[109] "predominantly for the supply of the domestic market",[110] or "adequate remuneration".[111] As a result, members were largely unsure of the conditions under which they could utilise the compulsory license exception for public health considerations.

For example, how much time and effort to negotiate a voluntary license of a patent is required to be considered reasonable? What are reasonable commercial terms and by what standards are they to be determined – developed country standards or developing country standards? What might be considered a national emergency in one country (i.e. the threat of further anthrax attacks in the United States and Canada in 2001) might pale in comparison compared to the actual figures of HIV/AIDS infections in Sub-Saharan Africa, Southeast Asia, and South America.

Similarly, while remuneration to the patent holder is required, there is no standard by which to determine what amount is adequate, by whom that determination is to be made, or by what standards those determinations should be

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[106] See TRIPS, Article 31(f) (requiring that authorisation of a compulsory license be given only when predominantly for the supply of the domestic market of the member authorising such use).
[107] TRIPS, Article 31. See also Sykes, A. "TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution." 3 Chi. J. Int'l. L. 47, 52 (2002).
[108] See TRIPS, Article 31.
[109] See TRIPS, Article 31.
[110] See TRIPS, Article 31.

made. Adequate payment in a severely impoverished least developed country like Rwanda would unlikely be considered adequate in an economic superpower such as the United States, the United Kingdom, Germany, or Japan.

These ambiguities largely contributed to the reluctance of members to utilise the flexibilities built within TRIPS and led to further negotiations at the Doha Conference in 2001. Because the text of Article 31 neglects to fully develop the factors required for the issuance of compulsory licenses under legitimate circumstances, member use of compulsory licensing was virtually non-existent prior to the Doha Declaration, discussed more fully below.

V. *POLITICAL EVENTS LEADING TO DOHA – SOUTH AFRICA, BRAZIL, AND THE NOTORIOUS US POSITION ON COMPULSORY LICENSING*

While it is accepted that TRIPS authorises the issuance of compulsory licensing, many developed nations, most notably the US, have condemned developing countries for violating TRIPS by enacting laws that allow for the issuance of compulsory licenses.[112]

a. South Africa

In the late 1990's, the US strongly criticised the South African Medicine and Related Substances Control Amendment Act 90 of 1997 (the Medicines Act) for being "clearly inconsistent" with South Africa's TRIPS obligations for allowing the

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[111] See TRIPS, Article 31.

[112] See Bass, N. "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century." 34 Geo. Wash. Int'l. Rev. 191 (2002); Sykes, Alan. "TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution." 3 U. Chi. J. Int'l. L. 47 (2002).

issuance of compulsory licenses of patented medicines.[113]

The Medicines Act, among other things, authorised South Africa's Minister of Health to prescribe conditions for the supply of affordable medicines where necessary to protect public health. The legislation was enacted to address the fact that South Africa had more people infected with HIV/AIDS than any other country in the world. At the same time, despite its status as a developing country, South Africa still faced among the highest prices of pharmaceuticals in the developing world.

By allowing the issuance of compulsory licenses, South Africa could produce generic drugs and distribute them to the millions in need at discounts of up to ninety percent of private pharmaceutical costs.[114] Also, the allowance of parallel importation allowed South Africa to purchase patented drugs from outside markets at a portion of the cost then what it would cost to purchase directly from the patent holder. For example, for the patented drug Fluconazole, used to treat fungal infections, could be purchased from Thailand for $0.60 instead of $4.10 from the patent holder.[115]

In 2001, backed by the political position of the US and the EU, forty pharmaceutical companies filed legal action in a domestic South African court

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[113] Boseley, S. "At the Mercy of Drug Giants: Millions Struggle With Disease as Pharmaceutical Firms Go to Court to Protect Profits." *The Guardian Archives.* [Online]. Available at http://www.guardian.co.uk/Archive/Article0,4273,4134799,00.html (12 February 2001) (last visited 11 November 2006). See also Murthy at 1236 (citing U.S. Dept. of State Report: U.S. Govt. Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15 (c) of the South African Medicines and Related Substances Act of 1965).

[114] Wilson, Clark. "The TRIPS Agreement: Is it Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?" 10 J. Tech. L. & Pol'y. 243, 255 (2005).

[115] Wilson, C. at 255.

against the South African government for alleged violations of TRIPS obligations.[116] The suit contended that section 15 (c) of the Medicines Act, which allowed for the compulsory licensing of pharmaceuticals and allowed for parallel importation measures, violated TRIPS provisions pertaining to the protection and enforcement of patent rights. In particular, the suit alleged, section 15 (c) failed to comply with TRIPS 27, 28, 6, and 31.[117] The US added fuel to the fire by withholding trade benefits and threatening further trade sanctions if South Africa failed to repeal its Medicines Act.[118]

With regard to TRIPS requirements, the Medicines Act was non-compliant because it lacked a number of necessary provisions required by Article 31. Among the most serious omissions were provisions specifying that compulsory licensing be granted only on non-exclusive and non-assignable bases, that judicial review of the license would be made available, and that adequate remuneration would be given to the patent holder.[119]

The ensuing media coverage and sustained campaigns by NGOs and activists created public outrage that pharmaceutical companies prioritised their own financial interests at the expense of millions of lives. The case derived great attention because South Africa, at the time, had an estimated 4.5 million citizens affected with HIV while access to antiretroviral treatment was seriously constrained by the

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[116] Pharm. Mfrs. Ass'n of S. Africa v. President of the Republic of S. Africa. Case No. 4193/98 (18 Feb. 1998).
[117] See Gupta, A. at FN8 (drawing attention to the peculiar fact that the suit's primary objection was not that section 15 (c) violated TRIPS, but that it violated the South African Constitution by granting overly broad powers to the Health Minister to abrogate all rights of pharmaceutical patent holders.)
[118] Wilson, C. at 255.
[119] Matthews, D. at 79.

prohibitively high prices of medications such as AZT (Zidovudine).[120]

Of course, the high price of medicines was not the only culpable barrier to access. The South African government's unconventional treatment policy refusing to implement an anti-retroviral drug distribution program was highly criticised, and rightfully so. In 2003, South Africa's official position, as reiterated by South African Health Minister Manto Tshabalala-Msimang, was that purported HIV/AIDS problems did not warrant an anti-retroviral drug program. Instead, HIV/AIDS sufferers were to eat garlic, onion, olive oil, and African potatoes to boost their immune systems.[121]

The South African Court never had opportunity to reach a decision on the legality of the Medicines Act. The devastating impact of the media coverage - described as "the public relations nightmare" - resulted in the pharmaceutical companies' strategic decision to drop their suit in early 2001.[122] However, as a result of maintained pressure on South Africa by the pharmaceutical industry, implementation of the Medicines Act was suspended and delayed for years to follow.[123]

b. Brazil

That same year, the US similarly attacked enabling compulsory licensing

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[120] See Baker, B. "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health." 14 Ind. Int'l. & Comp. L. Rev. 613 (2004).

[121] See Matthews, D. at 79-80 (referencing South African Health Minister Manto Tshabalala-Msimang's reiteration in 2003 of the government's refusal to implement an anti-retroviral drug profram, proposing instead that HIV/AIDS sufferers eat garlic, onions, olive oil and African potatoes to boost their immune systems).

[122] See Newsweek International. "Paying for AIDS." 19 March 2001 [Westlaw Online]. Available at 2001 WL 8109129 (discussing South Africa's 1997 Medicines Act as an example of enabling legislation to legalize compulsory licensing and parallel trade authorized by TRIPS).

[123] Gupta, A. at FN8.

legislation enacted in Brazil, this time before the WTO. The US initiated action against Brazil at the WTO Dispute Settlement Body by requesting WTO consultations and the establishment of a panel against Brazil. The US complaint claimed that Article 68 of Brazil's Industrial Property Code violated TRIPS standards with which members were required to comply when issuing compulsory licenses (which are exceptions to the general rule of exclusivity under the WTO patent regime).[124] The US further alleged that Article 68 violated most-favoured nation and non-discrimination principles of TRIPS Articles 27.1 and 28.1.[125]

Article 68 of Brazil's Industrial Property Code provided, in pertinent part, that Brazilian patent holders were required to manufacture the patented product in Brazil, and that the failure to do so during any three-year period would result in an automatic grant of a compulsory license by the Brazilian government.[126] The only exception provided to this rule was if the patent holder could demonstrate that it was financially impossible to comply with the regulation.[127] Brazil insisted that its compulsory licensing provision was TRIPS compliant because TRIPS authorises members to take legislative measures as deemed appropriate in providing for the grant of compulsory licenses.[128]

In response to widespread criticism, the US withdrew its complaint in June 2001. The withdrawal, however, was only after the US persuaded Brazil to enter into its negotiated settlement agreement, which was heavily weighted in favour of

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[124] Brazil—Measures Affecting Patent Protection—Request for the Establishment of a Panel by the United States. WT/DS1993/3 (9 January 2001).
[125] Id.
[126] Brazilian Industrial Property Law. Article 68. (Law 9.279/96).
[127] Id.
[128] Doha Declaration, ¶5.

the US and its interests. Pursuant to the terms of the settlement agreement, Brazil agreed to limit its authority to grant compulsory license provisions expressly authorised under TRIPS unless it gave prior notice to the US.[129] In particular, Brazil was required to consult and negotiate with the US and interested pharmaceutical manufacturers before granting any future compulsory licenses under Article 68 of the Industrial Property Code.[130]

c. The US and Cipro

The U.S. position against compulsory licensing became untenable in the aftermath of the terrorist attacks of September 11, 2001. In the midst of the anthrax scare in the fall of 2001, the US reacted in panic to the possibility of future threats of anthrax poisoning. The only antibiotic used to treat anthrax poisoning was Ciprofloxacin Hydrochloride (Cipro), patented by the German pharmaceutical company Bayer AG. Feeling the need to stockpile large amounts of Cipro in case of further anthrax attacks, the US threatened to issue a compulsory license to produce Cipro generically unless Bayer reduced its selling price of Cipro to the US. [131]

The irony of the US position, of course, was that it followed the very practice for which the US had previously held other countries accountable. In addition to the obvious inconsistent position taken by the US, the gravity of the anthrax scare paled in comparison to the public health crises suffered by poor and underdeveloped nations.

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[129] Id.

[130] Notification of Mutually-Agreed Upon Solution. Brazil – Measures Affecting Patent Protection. WT/DS/1999/4. 19 July 2001.

[131] See Murthy, D. at 1315 (illustrating how the US change of position on compulsory licensing as a means of lowering price destroyed any credibility left in the US argument that compulsory licensing for pharmaceuticals was an undesirable option to address public health crises).

Without downplaying the unfortunate events of the 2001 anthrax events, the fact that it resulted in only five fatalities cannot be ignored.[132] The shocking facts and figures for rates of disease infection and mortality in the developing world, particularly as a result of HIV/AIDS, should most certainly take priority for purposes of determining standards by which countries can enact implementing legislation for compulsory licensing.

The end of fallout between the US and Bayer occurred when the parties eventually reached a mutual agreement whereby the US purchased one hundred million pills of Cipro from Bayer AG at a discounted price.[133] The international community was again outraged at the inconsistent stance on compulsory licensing as a means of lowering drug prices. Observations were made that the US threat of compulsory licensing of Cipro for an outbreak that had not even occurred "gave developing countries the impression that a double standard was in place."[134]

After the US threat of compulsory licensing over Cipro, the US was in a difficult position to object to broader conditions under which members could grant compulsory licensing of pharmaceuticals. Perhaps in recognition of this fact, the US publicly stated that it would not object to member attempts to avail themselves of the flexibilities contained within TRIPS to address major health crises.[135]

Despite the change of position by the US with regard to threatening compulsory licensing as a means of reducing price, developing countries remain

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[132] Gathii, J. "Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-Terrorism: An Analysis of In Re Ciprofloxacin Hydrochloride Antitrust Litigation." 13 Alb. L. J. Sci. & Tech. 651 (2003).
[133] Matthews, D. at 81.
[134] Mercurio, B. at 224.
[135] Murthy, D. at 1309.

hesitant to enact compulsory licensing provisions to avoid WTO litigation and sanctions such as those described against South Africa and Brazil.

As more fully discussed below, the significance of the US/Cipro events demonstrates the effectiveness of compulsory licensing in lowering price. More often than not, the mere threat of compulsory licensing operates as a effectine means of reducing the price of expensive drugs.

d. The Doha Declaration

A direct consequence of the political events described in South Africa, Brazil, and the US was that developing and least-developed country members became understandably concerned about compliance with their respective TRIPS obligations. Concerns were particularly strong with respect to the legality of domestic implementation of compulsory licensing flexibilities of TRIPS. Members convened in 2001 in Doha, Qatar to clarify textual ambiguities relating to member use of flexibilities codified by TRIPS.[136] In particular, the goal was to define the circumstances under which members could authorise compulsory license exceptions when confronted with widespread epidemics such as HIV/AIDS, tuberculosis, malaria, and other diseases.

In 2001 at the fourth WTO Ministerial Conference members adopted a formal declaration, the Doha Declaration on TRIPS and Public Health, in effort to address the gravity of public health problems affecting many developing and least developed countries.[137] Notably, the Doha Declaration sought to clarify the interpretation of

[136] Mercurio, B. at 212.
[137] Doha Declaration.

TRIPS and to emphasise the flexibilities already written into the agreement, so that members could make full use of invoking those provisions when needed. In doing so, it attempts to reflect the balancing principles reiterated throughout TRIPS by recognising the importance of rights protected under TRIPS while at the same time affirming the need for developing nations to protect public health.

Acknowledging that TRIPS obstructs access to affordable medicines, members agreed on what they considered to be a pivotal endorsement of public health in the developing world. Members declared that TRIPS should be interpreted and implemented in a manner consistent with the right to health and to promote access to medicines for all.[138] While encouraging governments to utilise available flexibilities under TRIPS, the Doha Declaration acknowledged the futility of compulsory licensing provisions to least developed countries without manufacturing capabilities.[139]

i. Substantive Provisions

The Doha Declaration affirms the primacy of public health over intellectual property rights and the rights of governments to make full use of the public health safeguards in TRIPS. The opening paragraphs begin by recognising the gravity of public health problems in developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics[140] It continues by recognising that patent protections impact the price of pharmaceuticals.[141] The recognitions contained in paragraphs 1-3, however, take a rather passive stance as to

[138] Doha Declaration, ¶4.
[139] Doha Declaration.
[140] Doha Declaration, ¶1.
[141] Doha Declaration, ¶2.

the effect on public health or whether a balance between private property interests and public welfare interests has been achieved.

Paragraph 4 sets forth the principle that the protection of public health and promotion of access to medicines is a legitimate basis for members to enact exceptions to patent protection in domestic legislation. It declares, in pertinent part, as follows:

> "TRIPS does not and should not prevent Members from taking measures to protect health. Accordingly ... we affirm that [TRIPS] can and should be interpreted and implemented in a manner supportive of WTO members' right to protect pubic health and, in particular to promote access to medicines for all. In this connection, we affirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[142]

Paragraph 5 notably declares that all members have the right to grant compulsory licenses and freedom to determine grounds upon which licenses are granted. It grants members with the discretion to determine what constitutes a national emergency or other circumstances of extreme urgency. A significant recognition was made that public health crises, particularly those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, represent national emergency or other circumstance of extreme urgency for purposes of making that determination.[143] Other factors as to defining parameters to be taken into account before declaring a national emergency, however, are not provided.

Paragraph 6, discussed more fully below, recognises that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector face difficulties in making effective use of compulsory licensing under TRIPS. In recognition of this fact, the Council for TRIPS was instructed to find an "expeditious

[142] Doha Declaration, ¶ 4.

solution" to what is referred to as "the paragraph 6 problem" and report back to the General Council before the end of 2002.[144]

Paragraph 7 extends the deadline for least developed countries to implement domestic legislation enforcing patent protections until January 2016.[145] This extension, however, provides for limited benefit, because a majority of least-developed countries already provide for patent protections.[146] In order to take advantage of this extension, those countries would have to amend their legislation to actually remove protection of pharmaceuticals. It is highly unlikely that this would happen. In other words, this extension will only enhance access to the extent that those countries that have not already implemented TRIPS take advantage of this provision.

ii. ***Limitations***

1. Non-Binding Legal Status

The Doha Declaration represents a significant political recognition that TRIPS 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 medicine.[147] However, declarations are non-binding from an international law perspective.[148] They merely represent the formal position of the majority of WTO members.

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[143] Doha Declaration, ¶5.
[144] Doha Declaration, ¶6.
[145] Doha Declaration, ¶7.
[146] See CIPR Report at 60 (stating that at least 70% of the population in LDCs are in countries that provide pharmaceutical patent protection, and that 27 of the 30 LDCs in Africa also provide it.)
[147] See Charnovitz, S. "The Legal Status of the Doha Declaration." 5 J. Int'l. Econ. L. 207 (2002) (offering a discussion of the varying interpretations of the legal status of the Doha Declaration).

Therefore, the Doha Declaration's nonbinding legal status serves as a serious limitation on any potential to increase access to affordable medicines. This is because members are not bound by any real legal obligation stated anywhere within the text of the declaration. Without legal obligation, there is no enforcement mechanism for non-compliance at the WTO level or elsewhere between member countries. It is for this reason that some critics argue that the principles stated within the Doha Declaration, however important the political recognition of public health interests, are worth little more than the paper on which they are put forth.

A fairer account would be that the declaration constitutes an interpretative supplement to TRIPS.[149] Despite its non-binding legal status, the Doha Declaration constitutes a momentous step forward in the WTO's acknowledgment that the international patent regime has a major role to play in the accessibility of medicines.

2. *Domestic Production Requirement*

While the Doha Declaration clarified some of the contentious issues surrounding patent protection of pharmaceuticals in the developing world, it left one of the most important and highly contentious issues unresolved: the unavailability of compulsory licensing exceptions to patent protection for countries with public health crises with insufficient or no manufacturing capabilities of their own. Paragraph 6 merely recognised that countries lacking manufacturing capabilities of their own (for whom TRIPS flexibilities were designed to benefit in the first place) were unable to take advantage of compulsory licensing flexibilities. In doing so, it stated only the

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[148] See Gathii, J. "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties." 15 Harv. J. L. & Tech. 291 (2002) (citing Article 32, Vienna Convention on the Law of Treaties).
[149] Id.

obvious: "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."[150]

As Mercurio observes, the importance of Doha's failure to resolve this critical issue cannot be understated:

> TRIPS Article 31(f) conditions the issuance of compulsory licenses on them being predominantly for the supply of the domestic market of the Member authorising such use, meaning a nation could override valid patent laws only so long as that nation ordered the generic drugs from domestic producers. This requirement precludes a nation with insufficient or no manufacturing capabilities from using the system, and as most countries needing to make use of the patent exceptions are economically troubled nations with insufficient or no manufacturing capabilities, the **exceptions in TRIPS failed to satisfy the needs of those countries that the exceptions were designed to benefit.** (emphasis added).[151]

Accordingly, WTO Ministers instructed the TRIPS Council to find a solution to this problem and report back by the end of 2002.[152] Not surprisingly, the deadline was not reached even after heavy negotiation efforts between members to reach a solution acceptable to both developed and developing/LCD countries. Developing countries, in particular the group of Africa, Caribbean and Pacific countries called for the paragraph 6 solution to make specific reference to all of the public health diseases afflicting developing and least developed countries.[153] Developed countries insisted that the scope of diseases be limited to only HIV/AIDS, tuberculosis, and malaria.[154]

Finally, just days short of the start of the 2003 Cancun Ministerial

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[150] Doha Declaration, ¶ 6.
[151] Mercurio, B. at 213.
[152] Doha Declaration, ¶ 6.
[153] Statement on the Considerations for Paragraph 6 Modalities Delivered by Kenya on Behalf of the African Group, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand at the TRIPS Council Meeting on March 5, 2002. IP/C/M/35 (22 March 2002).

Conference, the Council for TRIPS reached a decision.[155] The Implementation Agreement of Paragraph 6 of the Doha Declaration was reached on August 30, 2003 as the purported solution to how countries with limited manufacturing capabilities could take advantage of compulsory licensing provisions.

e. The Implementation Agreement of Paragraph 6 of the Doha Declaration

i. Temporary Waiver

The Implementation Agreement attempts to address the difficulties surrounding the domestic manufacturing requirement imposed by Article 31(f). It also addresses Article 31(h) obligations to pay remuneration to the patent holder in the event of overriding a patent by the issuance of a compulsory license. It creates an exception to Article 31(f) and 31(h) to allow for nations with insufficient or no manufacturing capabilities to override patent protections and import generic copies of patented drugs to combat public health crises. The Implementation Agreement is referred to as the waiver provision in that the domestic market requirement of Article 31(f) is relinquished to allow for the production of generic pharmaceuticals made under compulsory license for export to countries lacking production capacity of their own.

The waiver attempts to serve as the "paragraph 6 solution" to address the

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[154] Communication from the United States. IP/C/W/340 (14 March 2002); Second Communication from the United States. IP/C/W/358 (9 July 2002).

problems identified in paragraph 6 of the Doha Declaration (i.e. that members with insufficient or no manufacturing capacities in the pharmaceutical sector face in making effective use of compulsory licensing under TRIPS). In light of the gravity of those problems, the General Council recognised that "exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products."[156] [157]

ii. Substantive Provisions

The Implementation Agreement sets forth various administrative and legal requirements that must be met by both importing and exporting countries before the domestic market restriction of Article 31 will be waived. In addition, both importing and exporting members must meet certain eligibility criteria in order to qualify for the waiver. An eligible member is considered one that issues a compulsory license for the purpose of producing pharmaceutical products for export to an eligible importing member.[158] An eligible importing member is considered one that receives and uses those products only for the purpose of addressing public health needs.[159] Outside the scope of the public health exception, the waiver does not apply.

iii. Eligibility and Required Notifications

To qualify as an eligible importing member, the country must be *either* a least developed country *or* any other member that notifies the TRIPS Council of its

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[155] Gupta, A. at 149.
[156] Implementation Agreement, Preamble.
[157] For purposes of the Implementation Agreement, pharmaceutical product means any patented product or product manufactured through a patented process. The definition encompasses diagnostic kits as well as active ingredients necessary for the manufacture of those products or processes. See Implementation Agreement, ¶1 (a).
[158] Implementation Agreement, ¶1(c).
[159] Implementation Agreement, ¶4.

intention to use the waiver.[160] If the country falls in the latter category, then it will qualify for the waiver only in the event of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.[161] With regard to notification to the WTO, prior approval by the WTO is not required.[162] The notice must, however, confirm and specify the following: (1) the names and expected quantities of the product, (2) that the importing member has insufficient or no manufacturing capacities in the pharmaceutical sector for that product; (3) that a compulsory license has been granted for the patented product.[163]

The exporting member must first issue a compulsory license for the production of a patented pharmaceutical. Among the conditions required by the exporting member are as follows: (1) no more than the amount required by the importing country may be manufactured and the entire production must be sent to the importing country; (2) the product exported must be clearly identified through specific labelling or marking either by special packaging, colouring or shaping of the product to differentiate it from the patented product; (3) the information related to the compulsory license and export must be made publicly available on a website; and (4) notice of these factors must be given to the WTO.[164] All members are obliged to implement effective legal means to prevent further importation and sale of products made under the waiver.[165]

iv. Assessment of Manufacturing Capacities in the

[160] Implementation Agreement, ¶1(b).
[161] Implementation Agreement, ¶1(b).
[162] Implementation Agreement, FN 2.
[163] Implementation Agreement, ¶2(a)
[164] Implementation Agreement, ¶2(b).
[165] Implementation Agreement, ¶5.

Pharmaceutical Sector by Importing Member

Least developed countries are automatically deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.[166] Therefore, least developed countries are automatically eligible importers regardless of actual capacity.[167]

Any other eligible importing member must establish insufficient or lack of manufacturing capacities before using the paragraph 6 solution. The Annex to the Implementation Agreement describes that members can establish insufficient or lack of manufacturing capacity in one of two ways. The member must either: (1) have "established that it has no manufacturing capacity in the pharmaceutical sector"; or (2) where the member has some manufacturing capacity, establish that it has examined that capacity and determined that it is insufficient for the purpose of meeting its needs.[168]

The problem with the unspecified form of self-examination is evident. The circular requirement that a member must "establish lack of manufacturing capacity" "by establishing that it has no manufacturing capacity" fails to give any direction whatsoever to an importing member seeking to utilise the compulsory licensing flexibilities provided by TRIPS. As for countries with some manufacturing capacity, the Annex provides equally as little guidance. To what level of detail is required of the examination of existing capacities? And how is insufficiency defined – by standards of impossibility or economic infeasibility?

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[166] Annex to the Implementation Agreement: Assessment of Manufacturing Capacities in the Pharmaceutical Sector.
[167] Baker, B. at 638.

Moreover, members are required to monitor their domestic manufacturing capacity so that as soon as capacity becomes sufficient, "the system shall no longer apply."[169] Again, the Implementation Agreement omits to define standards by which the processes for monitoring procedures are to be conducted. Because importing members are subject to ad hoc review of determinations of insufficient manufacturing capacity, developing countries have been deterred from risking involvement in damaging and costly WTO dispute resolution process.[170] Overall, the uncertainty associated with the standards by which establishment of insufficiency of manufacturing capacity has led to serious non-use of the purported "paragraph 6 solution."[171]

v. Remuneration

With regard to TRIPS Article 31(h) remuneration requirement, the Implementation Agreement waives that obligation from the importing member. However, the waiver only applies if the exporting member has adequately remunerated the patent holder, taking into account the economic value to the importing country.[172] In effect, the burden is merely shifted to the exporting country. The remuneration requirement generally operates as a disincentive to exporting countries who would have to first issue a compulsory license for the sole purpose of export, only then to have to bear the cost of paying due compensation to the patent

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[168] Annex to the Implementation Agreement: Assessment of Manufacturing Capacities in the Pharmaceutical Sector.
[169] Annex to the Implementation Agreement: Assessment of Manufacturing Capacities in the Pharmaceutical Sector.
[170] See Baker, B. at 638.
[171] See World Trade Organisation. General Council's Chairperson's Statement Accompanying Amendment of the TRIPS Agreement. 6 December 2005 (subjecting importing members to ad hoc review of determinations of insufficient manufacturing capacity).
[172] Implementation Agreement, ¶3.

holder. This expectation is unrealistic at best.

vi. Stringent Procedural and Administrative Red Tape

While in theory sounding to rectify the imbalances contained in TRIPS, the waiver provision of the August 2003 agreement is heavily laden with overly stringent requirements. As described above, the requirements can be summarised as the following: (1) eligibility criteria for both importing and exporting countries; (2) prior notice given to the WTO by both importing and exporting country to include specifics of the names and quantities of products needed; (3) variation in size, shape, colour, label, and packaging of the exported drug from that of the actual patented product; and (4) remittance of adequate remuneration by the exporting country to the patent holder.[173]

Because of the complex costs and procedures necessitated by these requirements, developing countries already lacking in disposable income find themselves unable to make use of the waiver provisions allowing for the production and export of affordable essential medicines. In fact, prior to Rwanda's recent notification of July 27, 2007, no single member had ever given notice to the WTO of any intention to use this waiver provision.[174] The significance of this fact is that a majority of people in the developing world - those that are most in need of access to affordable medicines - are left watching from the sidelines without any access at all.

The most controversial limitation of the Implementation Agreement is the product differentiation requirement - that products must be differentiated from the

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[173] Implementation Agreement, ¶1-3.

[174] By virtue of its LDC status, Rwanda is deemed to be insufficient in manufacturing capacity and it did not have to establish national emergency, extreme urgency, or other circumstance of public non-commercial use.

patented product by way of special packaging, colouring or shaping. The purpose of this requirement is to ensure that medicines manufactured under compulsory licensing arrangements and intended for developing countries are not diverted to developed country markets to the detriment of the patent holder. However, genuine concerns have been raised by developing countries that added costs associated with having to alter the packaging, pill size, colour, and more have a detriment effect on the availability of essential medicines.[175] The costs and burdens necessitated by the product differentiation requirement make it less cost-efficient to generic drug companies that would otherwise be producing cheaper medicines for developing countries facing public health crises. Furthermore, developing country governments are reluctant to use the waiver as it opens the door to TRIPS Council scrutiny by way of ad hoc reviews.

vii. Countries Opting Out

Although the Implementation Agreement expressly authorises members to waive the domestic market requirement of TRIPS Article 31(f) to import generic medicines, a significant number of members, mostly developed and developing countries, have committed to *never* issue compulsory licenses for importation.[176] Others agreed to use the waiver only on an emergency basis.[177] The significance of

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[175] Matthews, D. at 96.

[176] Implementation Agreement, at n.3 (those countries include the United States, the United Kingdom, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, and Switzerland) (since joining the EU the list now includes Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia) (It appears that Canada has since retracted from this group in notifying the WTO of its intention to supply Rwanda with generic ARVs).

[177] World Trade Organisation. "Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions." [Online]. Available at: http://www/wto/org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited 12 May 2006) (those countries include Hong Kong, China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar,

this fact is that while the legal framework exists for the production of generics made under compulsory licenses for export to countries that lack production capacity, 45 members to date have already committed to refrain from utilising the waiver provision. The likely impact of those commitments will be that countries that can and should use the waiver provision in the interest of furthering public health will also refrain out of political pressure from taking advantage of those flexibilities.

viii. The Struggle to Integrate the Implementation Agreement as a Permanent Amendment to TRIPS

On December 6, 2005, the General Council issued a decision to integrate provisions of the Implementation Agreement as a permanent amendment to TRIPS.[178] This is a significant step, as it signifies the first amendment to be made to any core WTO agreement. Members have until the end of December 2007 (or until a later date as decided by the Ministerial Conference) to ratify those changes.[179] To date, only 11 of the 151 WTO members have ratified the amendment, representing a mere 7.3% of the total membership base.[180] The process is far from complete, as two-thirds (67%) of WTO members must ratify before the amendment takes force.[181]

Singapore, Chinese Taipei, Turkey, and the United Arab Emirates) (voluntary announcement was recorded in a separate statement not part of the waiver).

[178] World Trade Organisation. Amendment of the TRIPS Agreement, General Council Decision of 6 December 2005. WT/L/641 (8 December 2005).

[179] See *Id.*

[180] See World Trade Organisation. "TRIPS and Public Health: Countries Accepting Amendment of the TRIPS Agreement." [Online]. Available at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 8 October 2007) (countries include the United States, Switzerland, El Salvador, Republic of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore).

[181] *Id.*

Until formal ratification is complete, the Implementation Agreement remains in tact.

If two-thirds member ratification takes place, TRIPS would include significant provisions set forth in the Implementation Agreement, namely that compulsory licenses may be issued for pharmaceuticals to be imported into countries that do not have manufacturing capabilities to produce them domestically. It would further reflect the procedure and process by which members may utilise the flexibilities as permitted by TRIPS.[182] The amendment will add three sections to the text of TRIPS and reflects language that is identical in substance and form to that contained in the Implementation Agreement.[183] However, at the current pace, it is unlikely that the process will take place in the foreseeable future, let alone before the end of December 2007.

VI. THE CASE FOR COMPULSORY LICENSING

This section argues that the issuance of compulsory licenses is an essential but difficult means of enhancing affordable access to medicines in the developing world. More often than not, it is the mere threat of compulsory licensing that is most effective in increasing affordable access. Even where only the threat, not the actual use, of compulsory licensing is employed, developing countries must take full use of compulsory licensing provisions within the WTO framework by enacting effective legislation enabling for license to use patented products. In accordance with TRIPS, enabling legislation must allow for the issuance of compulsory licensing only under limited and fact-specific circumstances. Those circumstances include public health

[182] World Trade Organisation. WTO Press Release. "Members OK Amendment to Make Health Flexibility Permanent." Press/426. 6 December 2005. [Online]. Available at: http://www.wto.org/english/news_e/pres05_3/pr426_e.htm (last visited 28 June 2007).

emergencies (i.e. national emergency, extreme urgency, or non-commercial use) or to remedy anti-competitive activities. Furthermore, the restriction of parallel imports or the prevention of trade diversion is a critical means of maintaining an appropriate balance between patent holder interests and public health interests.

a. Compulsive Licensing is an Essential Means To Enhance Affordable Access to Pharmaceuticals in Developing Countries

Compulsory licensing is an essential means for achieving more affordable access to patented medicines. The utility of compulsory licensing is two-fold. First, a compulsory license can be used by way of the actual grant of authorisation to use and exploiting the patent (i.e. overriding the exclusive patent rights of the patent holder by authorising use with adequate remuneration). Second, the mere threat of the issuance of a compulsory license more often than not influences the patent holder to lower its pricing and supply strategy.[184] More often than not, the possibility that a compulsory license can be issued pursuant to enabling legislation creates greater affordability of access. Accordingly, compulsory licensing of pharmaceuticals, whether by the actual grant of license or by the mere threat of its use, serves as a formidable force for reducing prohibitive costs of essential medicines in the developing world. As a result, greater affordability of access can be achieved with appropriate implementation at the domestic level by member countries.

Justifications for compulsory licensing include the reduction of country dependence on imports, the promotion of industry competition, and the protection of

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[183] See Article 31*bis*, TRIPS. Annex to the Protocol Amending the TRIPS Agreement. Decision of 6 December 2005. WT/L/641 (8 December 2005).
[184] As demonstrated by negotiated price reductions by the US, Canada, South Africa, and Brazil.

local industries.[185] While it is indisputable that market exclusivity of patent protections are necessary to generate profit to fund further research and development, the potential for loss of revenue by the threat of compulsory licensing in developing countries is minimal. This is because the developing country population accounts for 75% of the world's population but only 10% of the global pharmaceutical market.[186] In addition, even if compulsory license were to be granted, TRIPS guarantees adequate remuneration to the patent holder as a required condition to the granting of a compulsory license.[187]

A serious limitation with compulsory licensing is that it is an extreme and unlikely remedy. As described by Attaran, "compulsory licensing is an "extraordinary remedy that has the potential to alienate and offend many developed countries and large multinational companies."[188] Countries with production capabilities are unlikely to take political, economic, and financial risk to assist a poor country in need of cheaper pharmaceuticals. This is especially true in developing countries where governments are often slow to act on their own needs, as was the case of South Africa in the early 2000's. Therefore, the likelihood of those governments taking the necessary effort, logistics, cost, and political and financial risk associated with producing generics to assist another country facing public health crises is remote.

In sum, the Commission on Intellectual Property summarises the primary reasons for which developing countries have not used available flexibilities, as

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[185] Murthy, D. at 1307-1308.
[186] Wilson, C. at 263.
[187] TRIPS, Article 31 (h); Implementation Agreement.
[188] Attaran, A. at 869.

described above, as follows:

> First, it requires an administrative and legal infrastructure that is absent in many developing countries. Secondly, developing countries have learned that sanctions might be threatened, bilaterally or multilaterally. Thirdly, compulsory licensing has to be predominantly for the domestic market. Fourthly, the word compulsory refers to the legitimate limitation of patent owner rights by a government. The actual producer of the licensed drug manufacturers voluntarily and for profit (at least in the case of a private sector licensee). Thus the licensee must have the know-how to reverse engineer and manufacture the drug without the cooperation of the patent owner, and must also foresee a sufficiently large market to justify the costs of investment and manufacture and adequate remuneration to the patentee. **If these conditions are not fulfilled, the threat of a compulsory license will not be credible.** (emphasis added).[189]

Where the necessary conditions are credible, however, "the real value of compulsory licensing, in large part, can be found not in its actual use, but in the mere threat of its use."[190] The leveraging role of compulsory licensing as a tool for developing countries to negotiate more affordable price of pharmaceuticals is evident by the successes of Brazil in negotiating more affordable prices for antiretrovirals as well as the US in negotiating a lower price for Cipro. The recent experiences of Brazil demonstrate that the mere threat of compulsory licenses, where the necessary conditions exist, serves as a most powerful means of enhancing access to affordable medicines in developing countries facing serious health crises such as HIV/AIDS.

b. Domestic Implementation of Compulsory Licensing

As explained above, even though TRIPS sets forth minimum levels of standard for patent protections, member countries must implement TRIPS at the domestic level by way of national legislation those protections. Further, members are free to decide measures as appropriate to implement minimum levels of protection for patent protections. Correa indicates that due to the broad coverage of TRIPS, implementation of the TRIPS Agreement requires a significant body of

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[189] CIPR Report at Chapter 2.

national legislation both in terms of substantive as well as procedural rules.[191] Accordingly, in many developing and least developed countries, implementation of TRIPS has required significant development of legislation.

A significant challenge to compulsory licensing in developing countries is the implementation of effective and straightforward legislative and administrative procedures. Brazil and South Africa offer demonstrative examples of successful implementation of compulsory licensing at the developing country level. They demonstrate that the mere threat of compulsory licensing is a powerful means of enhancing access to affordable medicines in the developing world.

i. *Brazil*

Brazil's National STD/AIDS Program is a successful, although unique example of a developing country's successful use of reducing the price of patented pharmaceuticals by way of mere threat of compulsory licensing. In the 1990's, Brazil had an estimated population of 536,000 people infected with HIV/AIDS, representing one of the highest rates of HIV/AIDS infections in the world.[192] In response to the grave public health crises, Brazil implemented the National STD/AIDS Program.

The program created universal access to health care and supplied HIV/AIDS medications to all Brazilians free of charge.[193] As part of that program prioritising the HIV/AIDS crises, the Ministry of Health developed its local production

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[190] Matthews, D. at 82.
[191] Correa, C. "The TRIPS Review: Some Proposals for Developing Countries." *Third World Network.* [Online]. Available at http://www.twnside.org/sg/title/some.htm (last visited 28 June 2007).
[192] Wilson, C. at 243.
[193] CIPR Report at. 50-51.

capabilities by establishing national laboratories and manufacturing capabilities. As a result, Brazil placed itself in a strong bargaining position for negotiating price reductions with foreign producers. In 2001, the Health Minister successfully negotiated significant price reductions by up to 70% with Roche and Merck for the drugs Nelfinavir and Efavirenz.[194] Over a seven year period, a remarkable price drop from $10,000 to $130 for ARV combination therapies was achieved by Brazil's AIDS Program.[195] Reduced prices contributed significantly to increased access to affordable life-saving mediations.

Brazil's unique position of being a relatively affluent developing country with sufficient manufacturing capabilities of its own, however, means that this type of program will unlikely succeed in lesser developed countries facing equal, if not graver conditions of public health needs.[196] This is particularly true where countries lack insufficient technological capacity. Where capacities are limited, the threat of compulsory licensing is not credible, making for an ineffective means for lowering the price of medicines.

More importantly, Brazil was, in large part, able to achieve success because the restrictions imposed by Article 31 domestic market requirement, paragraph 6 of the Doha Declaration and its purported solution (the Implementation Agreement), either did not apply at the time (because of the transitional period for implementation) or had not yet been enacted (prior to 2001). In other words, the prevailing legal circumstances which allowed for success in Brazil are virtually

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[194] Id.

[195] Intellectual Property Watch. "Brazil Takes Steps to Import Cheaper AIDS Drug Under Trade Law." 7 May 2007. [Online]. Available at http://www.ip-atch.org/weblog/index.php (last visited 30 July 2007).

obsolete for other developing countries. Nonetheless, Brazil's success in reducing price and increasing access serves as a demonstrative example of how the mere threat of compulsory licensing is a powerful means of effectively reducing the price of patented pharmaceuticals in developing countries.

ii. Anti-Competitive Compulsory Licenses as a TRIPS-Compliant Means of Enhancing Access to Affordable Medicines

The development of national competition laws also has the potential to significantly counteract the imbalances created by TRIPS with regard to promoting access to medicines in developing countries. As referenced above, a compulsory license can also be granted to remedy anti-competitive practices.[197] Anti-competitive abuse of a patent may include excessive pricing or refusals to license under ordinary commercial terms.[198]

Because TRIPS does not define anti-competitive practices and pursuant to TRIPS Article 1, members are free to implement competition laws within their own legal system and practice. Competition laws are TRIPS-compliant where, among other things, they are designed to prevent abuse of intellectual property rights that have the effect of unreasonably restraining trade.[199]

In the context of pharmaceuticals, for example, it would be TRIPS-compliant for a member to legislate that excessive pricing and refusals to license may under certain circumstances be anti-competitive, particularly where the product dominates

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[196] CIPR Report at. 50-51.
[197] TRIPS, Article 31(k).
[198] Baker, B. at 665.
[199] Baker, B. at 665.

a therapeutic class, where product substitution is not feasible, or where excessive pricing prevails.[200] In a scenario where anti-competitive measures are implemented, members are not constrained by the domestic market requirement of Article 31 (k) or by the restrictions set forth in Paragraph 6 of the Doha Declaration.

As indicated by the Commission on Intellectual Property, most developed countries already have in place "sophisticated systems of competition regulation to ensure that abuses of monopoly rights cannot unduly affect public [health] interests."[201] Developing countries have begun to follow this trend by enacting similar pieces of legislation suitable to their particular legal and economic situations.

The utilisation of competition laws to produce generics is an example of how domestic implementation of TRIPS-compliant measures can assist to enhance access to affordable medicines. The South African Competition Act is a prime example.

1. The South African Competition Act 89 of 1998

The South African Competition Act 89 of 1998 ("Competition Act") provides remedies for anti-competitive practices and allows for the issuance of compulsory licenses for anti-competitive pricing practices by the pharmaceutical industry. [202] Section 8 of the Competition Act "prohibits dominant firms from engaging in excessive pricing, refusing access to an essential facility, and engaging in other

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[200] See Baker, B. at 665.

[201] CIPR Report at 54. (Expanded intellectual property remedies have been granted in US anti-trust cases involving pharmaceutical companies); See also Pitofsky, R., et. al. "The Essential Facilities Doctrine Under U.S. Antitrust Law, 70 Antitrust L. J. 443 (2002) (anti-trust/intellectual property regulations and jurisprudence in the United States and European Union have generally evolved to support the interests of intellectual property holder at the expense of consumers and of market competition).

[202] The Republic of South Africa Competition Act 89 of 1998 ("Competition Act"), consolidated with amendments enacted by Act 35 of 1999.

exclusionary acts."[203] Section 8 provides, in pertinent part, as follows:

> Abuse of dominance prohibited: It is prohibited for a dominant firm to -
>
> (a) charge an excessive price[204] to the detriment of consumers;
> (b) refuse to give a competitor access to an essential facility[205] when it is economically feasible to do so;
> (c) engage in an exclusionary act[206] ... if the anti-competitive effect outweighs its technological, efficiency, or other pro-competitive gain.[207]

A dominant firm is one that retains dominance in a particular market. Dominance exists where a firm in a particular market retains one of the following: (1) at least 45% of the market, (2) between 35-45% of the market *unless* shown that it does not have market power, or (3) less than 35% of the market but with market power.[208] Market power equates to "the power of a firm to control prices, or to exclude competition or to be have to an appreciable extent independently of its competitors, customers or suppliers."[209]

In a precedental complaint by Treatment Action Campaign on behalf of HIV/AIDS patients against pharmaceutical companies GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), three theories for the issuance of compulsory licenses of patented medicines were advanced under Section 8 of the Competition Act.[210]

Remarkably, the Competition Commission upheld each of the three theories

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[203] Baker B. at 680-681 (citing Section 8, Competition Act).
[204] See Section 1 (ix), Competition Act (defining "excessive price" as price for a good or service which bears no reasonable relation to the economic value of the good or service and is higher than that value).
[205] See Section 1 (viii), Competition Act (defining essential facility as an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers).
[206] See Section 1 (x), Competition Act (defining exclusionary act as an act that impedes or prevents a firm from entering into or expanding within a market).
[207] Competition Act, Section 8.
[208] Competition Act, Section 7 (a) – (c).
[209] Competition Act, Section 1 (1) (xiii).
[210] See Competition Commission Press Release, "Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act." 16 October 2003. [Online]. Available at: www.cptech.org/ip/health/sa/cc10162003.html

by concluding that both pharmaceutical companies abused their dominance in the South African markets for anti-retroviral drugs (ARV's) by: (1) excessively pricing ARV's in violation of section 8 (a); (2) refusing competitor access to their patents in violation of section 8 (b); and (3) excluding generic suppliers from entering the South African markets where the anti-competitive effects of the refusals significantly outweighed any pro-competitive gains in violation of section 8 (c).[211]

The Commission concluded that the GSK and BI, as dominant firms, had refused to license their patents to generic manufacturers in return for a reasonable royalty, to the detriment of consumers that would otherwise benefit from cheaper generic versions of the patented ARV's. In doing so, the Commission requested an order from the Competition Tribunal for a compulsory license of the patented medicines in return for reasonable payment. It further recommended a penalty of 10% annual turnover of ARV's in South Africa for each additional year in violation of the Act.[212]

Whether the Commission's decision would have withstood the Tribunal's and/or Appeal Court's scrutiny remains unknown. Perhaps as a strategic decision to avoid penalty or to avoid the cost of further litigation, both pharmaceutical companies negotiated confidential settlement agreements authorising voluntary licensing arrangements with the complainants. Pursuant to the terms of those agreements, the pharmaceutical companies agreed to allow generic versions of ARV

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[211] Competition Commission Press Release, "Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act." 16 October 2003. [Online]. Available at: www.cptech.org/ip/health/sa/cc10162003.html; and "GSK and BI Issue Anti-Retroviral Licenses." [Online]. Available at: www.compcom.co.za/resources/Comp%20Comm%20March%20HTML/1%20GSK

[212] Id.

products to be produced by South African based companies at low cost, in addition to allowing South African companies to export the products to other countries in sub-Saharan Africa.[213]

South Africa's Competition Act and the Competition authorities' interpretation of the law "demonstrate aggressive, pro-access competition policy that can be a formidable weapon in countries' efforts to obtain access to generics."[214] As South Africa's interpretation of the Competition Act more fully evolves, the Competition Act will serve as a useful example to other developing countries of effective implementation of TRIPS-compliant measures as a means of enhancing more affordable access to medicines.

iii. Implementation of Adequate Safeguards for the Prevention of Trade Diversion

Adequate safeguards to prevent trade diversion of lower cost medicines should operate alongside compulsory licensing as a means to improving access to low-cost essential medicines and ensuring that drugs remain in the markets for which they were intended.[215] Initiatives and regulations to prevent diversion of trade are necessary to ensure that exports are used for their intended purpose of providing affordable access to the differential needs of developed countries and LDCs, particularly those without manufacturing capabilities.

The European Union (EU) Regulation is an excellent example of the

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[213] Alcorn, K. "South African Drug Deal Bring $140 a Year Treatment Within Reach of African Nations." [Online]. Available at www.aidsmap.com/en/news/BA7BA5B6-429F-4BE5-A615-1A39FOCFF20.ASP?TY (last visited 31 March 2007).
[214] Baker, B. at 678; see also Glaxo Wellcome (Pty) Ltd, et. al. v. Nat'l Assoc. of Pharmaceutical Wholesalers, et. al., case no. 15/CAC/Feb 02, CAC, at 28.
[215] Matthews, D. at 75.

effectiveness of trade diversion as a necessary supplement to compulsory licensing options. The EU Regulation was agreed upon on May 23, 2003 by the Council of the European Union as a means of preventing trade diversion in essential medicines that have been donated or sold at low cost by patent holding pharmaceutical companies.[216]

The EU Regulation prohibits the re-importation of medicines sold under a tiered or differential pricing system at discounted prices to developing countries. Its mechanism for diverting trade diversion was by requiring all pharmaceuticals sold under this system to carry the distinctive logo of a winged staff of the mythical character Aesculapious surrounded by a coiled serpent and a twelve-started circle.[217] The purpose of the distinctive logo is to allow for easy identification by customs authorities examining imported goods at EU borders.

While the purpose of the EU Regulation differs slightly than the focus of this thesis (i.e. the prevention of trade diversion of low-cost medicines produced under compulsory license), it demonstrates that trade diverting measures can assist in increasing access in the broad spectrum of the access to medicines debate. Implementation of similar measures will undoubtedly be useful in preventing export of generic medicines produced under compulsory licenses into developed country markets, which would have the effect of undermining the entire purpose of the system intended to benefit those needing increased access to affordable medicines.

Other examples of effective anti-diversion measures to ensure delivery of products to their intended markets are corporate procedures developed by major

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[216] Council Regulation (EC) No. 953/2003of 26 May 2003. OJL 135/5 (3 June 2003).

pharmaceutical companies that have provided lower cost medicines in an effort to enhance affordable access in developing countries. The primary method of trade diversion is by way of special labelling, colouring, shaping, and sizing to differentiate products supplied through donor or discounted price programs. Examples of these measures include the following:[218]

- Bristol Myers Squib used different markings/imprints on capsules supplied to sub-Saharan Africa.
- Novartis used different trademark names and distinctive packaging for anti-malarial drugs provided to developing countries.
- GlaxoSmithKline (GSK) used different outer packaging for the HIV/AIDS medications Combivir, Epivir and Trisivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine Crixivan through special packaging and labelling using different colours and sized bottles.
- Pfizer used different colour and shaping for Diflucan pills supplied to South Africa.

While these measures are demonstrative, alterations of trade name, size, coating, shape, and packaging are costly burdens, especially for developing countries and generic producers that are trying to make access more affordable to the populations most in need.

CONCLUSION AND FINAL REMARKS

Compulsory licensing is an effective means toward accomplishing the end to achieve the lowest possible cost of medicines in developing countries in order to facilitate access. In order to enhance affordable access in accordance with the

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[217] See Matthews, D. at FN 118 (according to Greek mythology, Aesulapius was the legendary God of Medicine).
[218] Baker, B. at 649-650.

provisions of the current WTO framework for international patent protection, it is advisable for developing countries to implement enabling legislation to take advantage of TRIPS flexibilities to the fullest extent.

In order to maximise flexibilities provided by TRIPS, the Doha Declaration, and the Implementation Agreement, developing countries should enact legislation with respect to being both importers and exporters of generic medicines. Compulsory licenses should be authorised on permissible grounds within the current framework. These include the designation of certain public health matters in grave proportions as emergencies and other matters of extreme urgency as well as to remedy anti-competitive practices. Enabling legislation should allow for simplified procedures to promote use by members lacking resource and manufacturing capacity.

Compulsory licensing is a built-in safeguard measure intended to achieve broader access to patented pharmaceuticals for countries facing public health crises. As described by Rozek and Rainey, the real value of compulsory licensing, in large part, can be found not in its actual use, but in the mere threat of its use. The leveraging role of compulsory licensing as a tool for developing countries to negotiate more affordable price of pharmaceuticals is evident by the successes of Brazil in negotiating more affordable prices for antiretrovirals as well as the US in negotiating a lower price for Cipro. Recent developments in the interpretation of South Africa's Competition Act will further demonstrate the futility of anti-competitive measures in implementation of compulsory licensing schemes.

As renowned world economist Jeffrey Sachs once said,

> "There is an opportunity to re-think the intellectual property rights regime of the world trading system vis-à-vis the world's poorest countries. There is little doubt that the new IPR arrangements can make it more difficult for consumers

> in the poorest countries to access key technologies, as we have seen vividly in the case of essential medicines. [WTO members] have committed to re-examining the IPR issue in light of public health priorities, and they are wise to do so. .... This is an area for close observation, policy attention, and continuing research."[219]

Indeed, the time is ripe for evaluating possible solutions toward reaching a compromised solution to the grave crises concerning unaffordable access to medicines within the current patent framework.[220] A fair and balanced system of patent protection which takes into account the interests of public health and the developing world is the missing link in the affordable access debate. Compulsory licensing regimes that ensure adequate remuneration and fair parallel importing schemes are effective means of enhancing access to affordable medicines.

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[219] Sachs, Jeffrey. "The Global Innovation Divide." in Jaffe, A., Lerner, J. and Stern, S. eds. Innovation Policy and the Economy: Vol. 3. Cambridge: MIT Press (1999) (internal citations omitted).

[220] It is of course without doubt that the issue of global access to medicine requires measures and policies beyond simply amending global intellectual property protection. Policies outside of the current WTO framework, however, are outside the scope of this thesis.

BIBLIOGRAPHY OF REFERENCES

Primary Sources and Legal Texts:

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) ("TRIPS").

Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, April 15, 1994, Legal Instruments – Results of the Uruguay Round vol. 1, 33 I.L.M. 1125 (1994) ("Marrakesh Agreement").

General Agreement on Tariffs and Trade: Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations. 25 I.L.M. 1623 (Sept. 20, 1986) ("GATT").

World Trade Organisation. Annex to the Protocol Amending the TRIPS Agreement. TRIPS, Article 31*bis*. Decision of 6 December 2005. WT/L/641 (8 December 2005).

World Trade Organisation, Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr. 1 (1 September 2003) ("Implementation Agreement").

World Trade Organisation. Fourth Ministerial Conference. Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (20 November 2001) ("Doha Declaration").

World Trade Organisation. Council for Trade-Related Aspects of Intellectual Property Rights. Rwanda – Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/7/Rev.2/Add.7 (19 July 2007).

World Trade Organisation. General Council's Chairperson's Statement Accompanying the Annex to the Protocol Amending the TRIPS Agreement. Decision of 6 December 2005. WT/L/641 (8 December 2005).

UK Commission on Intellectual Property Rights. "Integrating Intellectual Property Rights and Development Policy." November 2002. [Official Report and Online Publication]. Available at http://www.iprcommission.org (last visited 12 July 2007) ("CIPR Report").

WTO Decisions and Member Communications:

Brazil—Measures Affecting Patent Protection—Request for the Establishment of a Panel by the United States. WT/DS1993/3 (9 January 2001).

Brazil – Measures Affecting Patent Protection - Notification of Mutually-Agreed Upon Solution. WT/DS/1999/4. (19 July 2001).

Canada-Patent Protection of Pharmaceutical Products – Report of the World Trade Organisation Panel. WT/DS114/R (17 November 2000).

Communication from the United States for Consideration on Paragraph 6 Modalities. IP/C/W/340 (14 March 2002).

Second Communication from the United States for Consideration on Paragraph 6 Modalities. IP/C/W/358 (9 July 2002).

Statement on the Considerations for Paragraph 6 Modalities Delivered by Kenya on Behalf of the African Group, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand at the TRIPS Council Meeting on March 5, 2002. IP/C/M/35 (22 March 2002).

Secondary Sources:

Abbot, F. "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO." 5 J. Int. Econ. L. 469 (2002).

Alcorn, K. "South African Drug Deal Bring $140 a Year Treatment Within Reach of African Nations." [Online]. Available at www.aidsmap.com/en/news/BA7BA5B6-429F-4BE5-A615-1A39FOCFF20.ASP?TY (last visited 31 March 2007).

Attaran, A. "Doha Declaration on TRIPS Agreement & Public Health, Access to Pharmaceuticals." 12 Fordham Intell. Prop. Media & Ent. L. J. 859 (2002).

Baker, B. "Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health." 14 Ind. Int'l. & Comp. L. Rev. 613 (2004).

Bass, N. "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century." 34 Geo. Wash. Int'l. Rev. 191 (2002).

Boseley, S. "At the Mercy of Drug Giants: Millions Struggle With Disease as Pharmaceutical Firms Go to Court to Protect Profits." *The Guardian Archives.* [Online]. Available at http://www.guardian.co.uk/Archive/Article0,4273,4134799,00.html (12 February

2001) (last visited 11 November 2006).

Chapman, A. "Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c)." Discussion Paper Submitted to the Committee on Economic, Social and Cultural Rights, 24th Sess. at 22, U.N. Doc. E/C/12/2000/12 (2000).

Charnovitz, S. "The Legal Status of the Doha Declaration." 5 J. Int'l. Econ. L. 207 (2002).

Competition Commission Press Release. "Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act." 16 October 2003. [Online]. Available at www.cptech.org/ip/health/sa/cc10162003.html; and "GSK and BI Issue Anti-Retroviral Licenses," available at www.compcom.co.za/resources/Comp%20Comm%20March%20HTML/1%20GSK (last visited 28 October 2006).

Correa, C. "Public Health and Patent Legislation in Developing Countries." 3 Tul. J. Tech. & Intell. Prop. 1 (2001).

Correa, C. "The TRIPS Review: Some Proposals for Developing Countries." *Third World Network.* [Online]. Available at http://www.twnside.org/sg/title/some.htm (last visited 28 June 2007).

Drahos, P. "Intellectual Property and Human Rights." Intell. Prop. Q. No. 3, 349, 356 (1999).

Howse, R & Tribilcock, M. The Regulation of International Trade at 309. (2nd ed. 1999).

Gathii, J. "Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-Terrorism: An Analysis of In Re Ciprofloxacin Hydrochloride Antitrust Litigation." 13 Alb. L. J. Sci. & Tech. 651 (2003).

Gathii, J. "The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties." 15 Harv. J. L. & Tech. 291 (2002).

Gupta, A. "Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?" 2 Buffalo Intell. Prop. L. J. 127 (2004).

Harrelson, J. "TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion." 7 Widener L. Symp. 175 (2001).

Intellectual Property Watch. "Brazil Takes Steps to Import Cheaper AIDS Drug

Under Trade Law." 7 May 2007. [Online]. Available at http://www.ip-atch.org/weblog/index.php (last visited 30 July 2007).

Jackson, J. Legal Problems of International Economic Relations: Cases, Materials and Text 884 (3d ed. 1995).

Matthews, D. "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicine Problem." 7 J. Int. Econ. L. 73 (2004).

McManis, Charles. "Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies." 2 Wash. U. J. L. & Pol'y. 1 (2000).

Mercurio, B. "TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World." 8 Marq. Intell. Prop. L. Rev. 211 (2004).

Moken, M. "Fake pharmaceuticals: How They and Relevant Legislation or Lack Thereof Contribute to Consistently High and Increasing Drug Prices." 29 Am. J. L. & Med. 525, 533 (2003).

Murthy, D. "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health." 17 Am. U. Int'l. L. Rev. 1299 (2002).

Mwalimu, U.A. "Implications of WTO/TRIPS in East Africa – with Special Emphasis on Pharmaceutical Patents." Working Paper for the Economic and Social Research Foundation (ESRF). Workshop on Globalisation and East Africa. 1-29 (16 April 2002).

Newsweek International. "Paying for AIDS." 19 March 2001 [Westlaw Online]. Available at 2001 WL 8109129 (last visited 20 October 2006).

Palmeter, D. & Mavroidis, P. "The WTO Legal System: Sources of Law." 92 Am. J. Int'l. L. 398 (1998).

Park, R. "The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients." 11 Minn. J. Global Trade 125 (2002).

Pitofsky, R., et. al. "The Essential Facilities Doctrine Under U.S. Antitrust Law, 70 Antitrust L. J. 443 (2002).

Sachs, Jeffrey. "The Global Innovation Divide" in Jaffe, A., Lerner, J. and Stern, S. eds. Innovation Policy and the Economy: Vol. 3. MIT Press: Cambridge MA (1999).

Sykes, A. "Trips, Pharmaceuticals, Developing Countries, and the Doha 'Solution.'"

3 Chi. J. Int'l L. 47 (2002).

Whobrey, B. "International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries." 45 Brandeis L. J. 623 (2007).

Wilson, C. "The TRIPS Agreement: Is it Beneficial to the Developing World or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?" 10 J. Tech. L. & Pol'y 243 (2005).

World Health Organisation. "Drug Management and Supply Strategies." [Online]. Available at: http://ww.who.int/medicines/teams/par/drug_management_and_supply_strat.html (last visited 11 July 2007)

World Health Organisation. "Intellectual Property Rights, Innovation and Public Health: Report by the Secretariat (Geneva: WHO, 56th World Health Assembly Provisional Agenda Item 14.9, A56/17 (12 May 2005)

World Trade Organisation. "Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions." [Online]. Available at: http://www/wto/org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited 12 May 2007).

World Trade Organisation. "TRIPS and Public Health: Countries Accepting Amendment of the TRIPS Agreement." [Online]. Available at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 8 October 2007).

World Trade Organisation. WTO Press Release. "Members OK Amendment to Make Health Flexibility Permanent." Press/426. 6 December 2005. [Online]. Available at: http://www.wto.org/english/news_e/pres05_3/pr426_e.htm (last visited 28 June 2007).

Legislation:

Brazilian Industrial Property Law. Article 68. (Law 9.279/96).

European Council Regulation (EC) No. 953/2003 of 26 May 2003. OJL 135/5 (3 June 2003).

The Republic of South Africa Competition Act 89 of 1998 ("Competition Act"), consolidated with amendments enacted by Act 35 of 1999.

The Republic of South Africa Medicines and Related Substances Control Amendment Act ("Medicines Act"). No. 90 of 1997 (12 December 1997).