Rethinking the TRIPS Agreement to meet the needs of developing countries

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1. Introduction

Towards the end of the 20th Century, it was estimated that over eighty-nine percent of people living with HIV/AIDS resided in countries ranked in the lowest ten percent in terms of Gross National Product.[1] This factor has rendered the cost of and access to HIV/AIDS drugs an issue of great concern to developing countries. When the HIV virus was discovered in the 80s one diagnosed to have it had a short time to live owing to the unavailability of drugs to combat it. However, progress in medical research has led to considerable improvements in HIV/AIDS treatment. Even so these drugs are very expensive and remain largely out of reach for those living with the virus in developing countries. The problem of unavailability and hefty costs of essential pharmaceuticals led to a dispute between South Africa and the United States regarding *South Africa's Medicines and Related Substances Control Amendment Act of 1997 (Medicines Act).*[2] The disagreement centred around interpreting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) so as to achieve a proper balance between the objective of strengthening protection of intellectual property rights worldwide and supplying developing countries with the pharmaceuticals they desperately need.

The pharmaceutical industry in the developed world pursued legal action against the South African government claiming violations of the TRIPs Agreement. This dispute led to the Doha Declaration[3] which gave developing countries more time to meet the standards of the TRIPs Agreement. In this paper I will explore the tension between developed and developing countries relating to TRIPs, compulsory licensing and access to expensive life-sustaining

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1 Margaret Duckett, Compulsory Licensing and Parallel Importing: What Do They Mean? Will They Improve Access to Essential Drugs for People Living with HIV/AIDS?, at http:// www.icaso.org/docs/compulsoryenglish.htm (July 1999)

2 Ford S "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents" *15 American University International Law Review 941, 942 (2000)* Nash D "South Africa's Medicines and Related Substances Control Amendment Act of 1997" *15 Berkeley Technology Law Journal 485, 491-93 (2000).*

3 Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference,4th session World Trade Organisation Ministerial 01 decision 2 November 20 2001 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.html.

pharmaceuticals. Thereafter I will provide a summary of the relevant provisions of the TRIPs Agreement of the World Trade Organization (WTO). I discuss the discourse that led up to the Doha Declaration and the coming into effect of the compulsory licensing system under the TRIPS Agreement. I analyse the TRIPS Agreement and in what way it is till inadequate to meet the needs of developing countries. I thereafter recommend ways in which it can meet this objective.

2. An outline of the WTO

The WTO is an international body constituted to facilitate trade between its member nations and is composed of almost 150 member countries and includes nearly all nations that engage in international trade. [4] It was formed after negotiations held under the General Agreement on Tariffs and Trade (GATT), an international trade agreement that was first signed in 1947.[5] GATT was focused on reducing tariffs to facilitate trade in goods between member countries. With the growth of trade member nations felt the need for GATT to grow as well. This need led to the creation of the WTO following a series of negotiations known as the Uruguay Round that lasted from 1986 to 1994. The WTO comprises the agreements made under GATT although it has a wider range of objectives aimed at promoting international trade. Like its predecessor GATT, the WTO employs a multilateral trade system in regulating trade between members. By crafting agreements between member nations, the WTO aims to promote reliable international markets where producers have more opportunities to sell their goods and services, and consumers have greater access to make a variety of purchases.[6]

The WTO has as one if its objectives to improve the quality of life for citizens of member countries by facilitating economic activity and creating

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4 World Trade Organisation; Understanding the WTO available at http://www.wto.org.innopac.up.ac.za:80/english/thewto_e/whatis_e/tif_e/understanding_text_e.pdf

5 Same as above at 10, explaining the history of the WTO.

6 Same as note 4 above at 9-10, explaining the purposes and benefits of the multilateral trading system employed by the WTO; World Trade Organization, The World Trade Organization, available at http://www.wto.org.innopac.up.ac.za:80/english/res_e/doload_e/inbr_e.pdf

opportunities for mutually beneficial business transactions to take place. Apart from opening new markets, the WTO aims to promote peaceful intercourse between member nations.

Despite these noble objectives, the WTO has been criticised as creating policies that favour large industries in wealthy countries at the expense of poorer nations, the environment, and overall public health.[7]

2.1 The organisational structure of the WTO

The WTO is governed at the highest level by the Ministerial Conference, a body which includes each member nation and meets biannually. The Ministerial Conference has the powers to make a decision on any matter concerning the WTO. The General Council is second in Hierarchy to the Ministerial Conference and it meets several times a year in Geneva Switzerland. The General Council is comprised of representatives from each member country and manages the day-to-day work of the WTO.[8] When the Ministerial Conference is not in session, the General Council acts as the chief governing body and also functions as the Dispute Settlement and the Trade Policy Review Body. The General Council's responsibilities include inter alia deciding trade disputes between member nations and examining members' trade policies to determine whether they meet compliance standards of applicable WTO agreements. Aside from these two entities, various other committees and councils operate below these two groups to perform the functional and administrative tasks necessary for operation of the WTO.

2.2 Enforcement Mechanism and Dispute Resolution

When WTO members make specific trade agreements, they are bound by those agreements and must uphold promised rights to other countries. When one member challenges another's actions as violating a specific WTO

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7 Sell S "Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property" *14 Florida Journal of International Law 193 (2002)*.

8 See note 6 above.

agreement or principle, the issue is brought before the Dispute Resolution Body (DRB).[9] The DRB holds proceedings and issues decisions based on the specific procedures outlined in the agreement known as the Dispute Settlement Understanding (DSU).[10] If a country loses a dispute and does not cooperate and abide by the DRB's decision, the WTO has the power to authorise trade sanctions against the losing party. The DRB has decided a large number of disputes between member nations, including ten that were initiated in 2005, nineteen in 2004, and twenty-five in 2003.[11]

3. The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement)

3.1 Intellectual Property Policies of the WTO

The most important area regulated by the WTO is that dealing with intellectual property rights. Those in favour of strong intellectual property rights argue that protection is necessary to encourage inventors, manufacturers, and others to invest time and resources into developing new products, processes, and creative works.[12] The potency of this argument is anchored on the proposition that without well-defined and enforceable intellectual property laws, ideas and inventions can be copied and reproduced, thereby preventing the original inventor or producer from realising the benefits and profits from the creation. This in effect reduces the incentive to invest in research and create useful innovations.

Whereas most developed countries have had specific laws concerning intellectual property in place for decades, many developing countries

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9 See World Trade Organization, Understanding the WTO, as note 4 above at 59-63.

10 Same as above, explaining the dispute resolution process.

11 World Trade Organization, Dispute Settlement: The Disputes - Chronological List of Disputes Cases available at http://0-www.wto.org.innopac.up.ac.za:80/english/tratop_ e/dispu_e/dispu_status_e.html

12 Harrelson J "TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion" *7 Widener Law Symposium 175 2001.*

historically have not.[13] The reason for this has been that with very few resources and technology and no viable industries, most developing nations have not found it necessary to devise systems of intellectual property law. However, upon joining the WTO, many developing countries have been compelled to create and enforce new intellectual property laws in order to satisfy the membership requirements of the organisation.

3.2 The substance of the TRIPs Agreement

The TRIPS Agreement governs intellectual property rights on an international scale and has been ratified by all WTO members. It was first adopted by the WTO in 1994 as part of the Uruguay Round negotiations and is the primary set of guidelines for developing and implementing intellectual property laws in member states. In this regard, it seeks to promote innovation and technology benefiting the economic and social interests of all members.[14] The TRIPS Agreement covers many facets of intellectual property, including copyrights, trademarks, industrial designs, trade secrets, and patents. This paper is exclusively concerned with patents, specifically international patent law.

A patent is a monopoly on expertise or knowledge as it essentially allows the holder to exclude competitors, set its own prices and control the available supply of products.[15] The TRIPS Agreement provides guidelines patent law systems that must be implemented and enforced in each member country. On international patent protection, the TRIPS Agreement states that patents should be issued "for any inventions, whether products or processes, in all fields of technology provided that they are new, involve an inventive step and

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13 Berger J M "The Global Aids Crisis: Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity" *17 Connell Journal of International Law 157 2002*.

14 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, April 15 1994, Marrakesh Agreement Establishing the World Trade Organisation (hereinafter WTO Agreement) Annex 1 C, Legal Instruments - Results of the Uruguay Round 33 International Legal Materials 81 1994 (hereinafter TRIPS Agreement).

15 See Berger as note 13 above at 168.

are capable of industrial application."[16] It also provides that members must provide protection for at least twenty years as a minimum standard that all member states must comply with on an individual basis.[17] Article 1 of the TRIPS Agreement provides that WTO members "shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[18] Nonetheless, countries are permitted to enact policies and laws to provide for stronger protection than what is specified in TRIPS if they so choose. This practice has been characteristic of major industrial players based in wealthy nations who have historically lobbied for increased protection above and beyond the minimum standards outlined in TRIPS.[19] Harrelson notes that the pharmaceutical industry, much of which is based in the United States, has consistently funded large campaigns in support of enacting and enforcing more stringent patent laws.[20] Greater patent protection safeguards the interests of pharmaceutical manufacturers by making it harder for countries to create or import generic drugs or otherwise purchase the patented products at lower prices.

4. Exceptions to patent enforcement obligations under TRIPS

As affirmed earlier, TRIPS generally mandates that inventors and manufacturers receive twenty years of patent protection for their products or processes. However, the WTO has recognised that special circumstances may exist that should excuse countries from performing their obligations and in this vein specific exceptions have been written into TRIPS. Article 8.1 of TRIPS provides that member nations may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".[21] In other relevant provisions, TRIPS is more specific about what protective measures countries may take and when a government

16 TRIPS Agreement article 27.1.
17 TRIPS Agreement article 33.
18 TRIPS Agreement article 1.
19 Harrelson J as note 12 above at 176.
20 Harrelson J as above.
21 TRIPS Agreement article 8.1

may choose not to provide patent protection to inventors. For example, a government can refuse to issue a patent for an invention that is harmful to the public. This includes any invention that would negatively impact human, plant, or animal life, or the environment.[22] Further, governments may also advance public health objectives by refusing to provide patent protection for surgical or treatment methods used in caring for humans or animals.[23] There is another exception for biological processes creating plants or animals "other than micro-organisms".[24]

5. TRIPS provisions with regard to the Pharmaceutical Industry

The TRIPS Agreement contains some provisions that are relevant to the pharmaceutical industry and public health initiatives in developing countries. Article 30 of the Agreement provides that WTO member nations may provide exceptions to an inventor's patent rights "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner taking account of the legitimate interests of third parties." Thereafter Article 31 details the circumstances under which a country may rightly engage in compulsory licensing. Compulsory licensing is a specific process whereby a government disregards a patent holder's rights and allows another manufacturer to produce a patented medication without the patent owner's consent. It is an important exception to member countries' patent obligations that may be utilised in limited circumstances. The general rule is and has required countries to purchase medications from the patent holder or get the permission of the patent holder to license another firm to manufacture the drug. However, Article 31(b) creates exceptions for situations that qualify as "national emergencies" and whenever certain medications are urgently needed due to public health crises. In these cases, governments can engage in compulsory licensing to allow other firms to produce the drug without first attempting to get voluntary licenses from the patent holder.

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22 TRIPS Agreement article 27.2
23 TRIPS Agreement article 27.3A
24 TRIPS Agreement article 27.3B

In addition to compulsory licensing, the TRIPS Agreement also permits developing countries to engage in parallel importing.[25] Parallel importing occurs when a drug manufacturer sells products to different countries at different prices and then distributors resell the products for profits in other countries. For example, if a manufacturer sells a drug to Country A for $100 and markets the same drug to Country B for $50, Country B could resell the drug to Country A for some amount above its cost ($50) but below the price which Country A would have to pay the manufacturer ($100). This places distributors in Country B in direct competition with the manufacturer, destroying the monopoly on the drug achieved through the patent and making the manufacturer less profitable in return.[26] The practice of parallel importing has been controversial and is generally opposed by pharmaceutical companies and large manufacturers in other industries. The central debate is based on the principle of exhaustion. Many pharmaceutical firms argue that parallel importing decreases profitability and removes the incentive to sell drugs to poor countries at lower prices.

Alternatively, others argue that allowing governments in Least Developed Countries (LDCs) to resell medications instead of dispersing them to needy citizens is detrimental to health in LDCs and primarily benefits the parallel importers and the wealthy nations that are able to buy the drugs at a discount.[27] The incentives created by parallel importing encourage governments to favour profits over people, and since many governments in developing countries are unstable and may be prone to corruption, the general public in LDCs sees neither the critical medications nor realises any benefits

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25 World Trade Organization TRIPS and Public Health: The Situation in Late 2005 available at http://www.wto.org.innopac.up.ac.za:80/english/tratop_e/trips_e/health_background_ e.html

26 World Trade Organization, Fact Sheet: TRIPS and Pharmaceutical Patents - Obligations and Exceptions, available at http://www.wto.org.innopac.up.ac.za:80/english/tratop_ e/trips_e/factsheet_pharm02_e.html

27 Sherman P and Ellwood "Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs" *41 American Business Law Journal 353, 353-55 (2004)*

or improvements from the sale of the drugs.[28] In contrast, proponents of parallel importing argue that a manufacturer loses control of its products after the products are sold.

The company in this case has exhausted its interest in the goods, and they can be resold to other nations for a profit by the original importing country. Further, that the importing country is free to make decisions concerning the ultimate use of the medications based on its own priorities, resources, and opportunities to resell for a profit.[29]

The text of the TRIPS Agreement does not directly authorise parallel importing neither does it prohibit it. Article 6 states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". When TRIPS was clarified in 2001, the WTO members agreed that each member nation is “free to establish its own regime for such exhaustion without challenge, subject to the MFN (Most Favoured Nation) and national treatment provisions of Articles 3 and 4.”[30] This suggests that despite the objections of manufacturers and other critics, parallel importing is permissible as long as importing countries abide by the basic trade principles contained in other WTO agreements.[31]

6. Monitoring Compliance with TRIPS and Interpreting Its Provisions

The TRIPS Council is a body constituted under Article 68 of the TRIPS Agreement and is responsible for monitoring, enforcing and reviewing the Agreement. Member nations are compelled to notify the TRIPS Council of any

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28 Wei S The Brookings Institution, Corruption in Developing Countries: A Summary of Remarks (2003) available at http:// www.brookings.edu/views/speeches/wei/20030312.pdf

29 Maskus K Final Report to the World Intellectual Property Organization: Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries 2 (2001)available at http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

30 World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746, 746-747 (2002) (hereinafter Doha Declaration).

31 Maksus K as note 30 above.

national intellectual property laws passed so the Council can determine whether the laws are consistent with the relevant provisions of TRIPS.

This system allows members to question and critique the others' national laws and assists the WTO in keeping policies open and transparent among the nations. The TRIPS Council also offers consultations to member nations on various issues and proposed actions.[32] When a country is considering passing a law or engaging in some endeavour that involves intellectual property procedures on an international scale, it may seek advice from the TRIPS Council in advance to be sure the proposed action does not run afoul of the Agreement.[33] This advising function of the Council is particularly helpful for developing countries that are faced with building or restructuring complex new systems of intellectual property law.

7. The TRIPS Agreement and Pharmaceutical Patents: The debate

7.1 The Doha Declaration

Subsequent to the adoption of the TRIPS Agreement, many developing countries were concerned about how strictly the agreement would be enforced and whether compliance with it would harm public health at the expense of patent holders.[34] In particular, many poor nations were uneasy about the feasibility of meeting intellectual property enforcement deadlines and how much flexibility they would have in using the TRIPS Agreement's exceptions provisions to deal with public health issues.[35] In 2001 at the Doha Conference, the WTO issued a statement, the Doha Declaration, clarifying the Agreement and its purposes. The Doha Declaration states that the Agreement "can and should be interpreted and implemented in a manner supportive of WTO

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32 World Trade Organization, TRIPS Frequently-Asked Questions, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#TripsCouncil

33 Same as above.

34 World Trade Organization, TRIPS and Public Health: The Situation in Late 2005 available at http://www.wto.org.innopac.up.ac.za:80/english/tratop_e/trips_e/health_background_ e.htm

35 Doha Declaration 4.

members' right to protect public health and, in particular, to promote access to medicines for all."[36] Members also agreed to extend the deadline for LDCs to enact and enforce TRIPS in relation to pharmaceuticals until 2016 to give poor nations more time to make internal adjustments to meet WTO standards, develop new intellectual property regulations and design systems of enforcing the new laws.[37]

7.2 The 2003 General Council Decision on TRIPS

The TRIPS Agreement further clarified by the WTO General Council in a more specific decision in 2003.[38] The 2003 Decision addressed and modified Article 31(f) of the Agreement. Article 31(f) provides that "compulsory licensing must be predominantly for the supply of the domestic market."[39] On its own, this provision drastically limited the ability of LDCs to use the compulsory licensing exception because the vast majority of LDCs have no manufacturing facilities or other resources to produce the drugs domestically. Prior to the 2003 Decision, it was difficult to find WTO member countries who could export generic medications under compulsory licenses without violating Article 31(f) because any exports would not be for the domestic market of the exporting countries. The 2003 Decision resolved this problem, stating that obligations under Article 31(f) "shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)."[40] In essence, the 2003 Decision waives duties under Article 31(f) by allowing any WTO member to export generic drugs made under compulsory licenses to any other countries that need the medications. In order to import drugs via compulsory licensing under the 2003 Decision, the importing country must simply inform the TRIPS Council of the names and quantities of the drugs needed. The exporting country may then export the

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36 Doha Declaration as above.

37 The Doha Declaration Explained available at http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.html

38 Decision of General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003).

39 TRIPS Agreement article 31(f).

40 See Decision of General Council as note 39 above.

drugs but is limited to exporting only the amounts necessary to meet the needs of the importing country. Though the 2003 Decision allows all WTO members to waive their obligations under Article 31(f) and import generic drugs, many developed countries have announced that they will not use the waiver to undermine the patent system by importing generics.

Some of these countries include Australia, Canada, Japan, the United States, the United Kingdom, Germany, and several other European countries. Some other countries, including Israel, Turkey, and several provinces in China, have promised to use the waiver only in cases of national emergencies.[41] Countries have made these pledges in order to ease concerns that nations will use the 2003 Decision to import cheaper drugs unfairly in circumstances that do not warrant the use of compulsory licenses.

8. Recent Developments: Making the 2003 Decision Permanent

When the 2003 Decision was issued, it specifically called for a permanent amendment incorporating the articulated principles into the TRIPS Agreement.[42] On December 6, 2005, the WTO members officially approved changes to the Agreement that were permanently included upon ratification by two thirds of the members in the end of 2007. Following the modification of TRIPS to reflect the 2003 Decision, three sections have been added to the original text. The amendment closely parallels the language of the 2003 Decision, stating in relevant part that compulsory licenses may be issued for pharmaceuticals to be imported into countries that do not have the ability to produce them domestically.[43] The amendment also defines the process for using some of the flexibilities permitted by TRIPS.

9. A critical appraisal of TRIPS: The existing inadequacies

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41 World Trade Organization, Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions as note 27 above.

42 See the Decision of General Council as note 39 above

43 World Trade Organization, TRIPS and Public Health: The Situation in Late 2005 as note 35 above.

The TRIPS Agreement is highly detailed and fairly thorough in explaining member countries' rights and obligations in terms of international patent law. On its face, it appears to be flexible in that it specifies minimum standards with which countries must comply but allows each nation to enact its own policies for enforcement.[44] Wealthier nations that are more likely to host a greater number of patent holders benefit from the concrete rights outlined in it, while poor nations are supposed to retain the ability to protect the health and welfare of their citizens through the exceptions provisions and recent clarifications.[45] The Agreement endeavours to strike a balance between protecting the interests of the developed countries and providing for the needs of LDCs. Despite the protections and exceptions written into it making it seem balanced and fair to both poor countries and wealthy patent holders, it is not as effective as it should be when it comes to promoting public health and access to medications in LDCs. It generally does not impose official requirements on patent holders to provide assistance or use their resources to increase access to medications in the countries that have struggled to enact and enforce new patent laws. In many circumstances, people in poor countries who cannot afford lifesaving medications are negatively impacted by the strong patent protection given to pharmaceutical companies that keep drug prices high and do not require price reductions in favour of poor nations.[46]

Though there is currently no cure for HIV/AIDS, there are pharmaceutical and other treatment regimens that dramatically improve the quality of life and the lifespan of people living with the disease. However, because of the high price of the drugs, most people living with HIV/AIDS particularly in developing countries are unable to gain access to treatment. TRIPS has not yet been successful at ensuring that LDCs can improve public health by gaining access to pharmaceuticals to effectively treat and care for their infected citizens.[47]

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44 TRIPS Agreement article 1.

45 Berger J M as note 13 above at 181-83.

46 Ganslandt M, Maskus E and Wong E "Developing and Distributing Essential Medicines to Poor Countries: The Defence Proposal 1; The Research Institute of Industrial Economics Working Paper No. 552, 2001 available at http://www.naringslivsforskning.se/Wfiles/wp/WP552.pdf

47 Same as above.

10. Restructuring the TRIPS Agreement to Improve Public Health in Developing Countries

In order to improve access to critical medications in developing countries, the TRIPS Agreement should be restructured to contain a pharmaceutical pricing scheme that will obligate patent holders to sell medications at lower prices to LDCs.[48] With a tiered pricing approach, it would be viewed as both a right and an obligation in terms of manufacturing pharmaceuticals for the international market. Once a company receives a patent for a pharmaceutical product, the company owns a long-term, valuable resource. The company can sell the drug internationally and has the potential to recoup its research and development costs and be extremely profitable. The Pharmaceutical company essentially receives assurance from every country in the WTO, which includes nearly every country involved in international trade, that its rights will be protected. In exchange for this considerable benefit and the large financial gains that patent rights bestow, companies or inventors enjoying those rights should be obligated to use some of that wealth to support increased access to their products in countries that urgently need them but cannot afford to pay the prices charged elsewhere in the world.

One logical way to impose obligations on pharmaceutical companies that correspond to the protections they receive upon being awarded patents for critical medications is to devise a pricing scheme for the products based specifically on the purchasing country's gross domestic product (GDP).[49] Calculating a country's GDP is a way to measure the size and viability of the country's economy. In basing pharmaceutical pricing scales on a particular country's GDP, the country's domestic resources and financial capabilities are taken into account. Countries that have higher GDPs and are relatively wealthy within the world market are able to devote larger sums to healthcare expenditures, including pharmaceutical products.[50] Countries that have very low GDPs and are incapable of paying higher prices for pharmaceuticals

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48 Outterson K "Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries" *American Journal of Medicine 159, 159-60 2006*.

49 Crook J "Balancing Intellectual Property Protection with the Human Right to Health" *23 Berkeley Journal of International Law 524, 537 2005*.

50 Maskus K as note 30 above at 13-14.

should pay lesser amounts for critical medications. This type of pricing structure would allow pharmaceutical companies to recoup research and development costs and manufacturing expenses, without denying developing countries the opportunity to improve public health. This method of regulating the pharmaceutical industry would advance the purposes and goals of the 2003 Decision on public health and the impending amendment to the TRIPS Agreement.

10.1 Effecting a pricing scheme order

In order to enact a pricing structure based on countries' respective GDPs, the TRIPS Agreement would have to be amended to specify the changes in rights and obligations of the WTO member countries. An amendment should detail some sort of formula or sliding scale to calculate the prices that countries would pay for pharmaceuticals based on their GDPs. Pharmaceutical companies holding patents in member countries would then be obligated to comply with the Agreement in charging LDCs prices for medications based on this formula or pricing scale. Another crucial amendment to the TRIPS Agreement should be a provision stating that parallel importing in the pharmaceutical sector is specifically prohibited upon enacting a GDP-based pricing structure for pharmaceuticals. With the TRIPS Agreement requiring tiered pricing, and parallel importing is still allowed under its terms, there will be substantial incentives for governments in LDCs to resell the drugs to wealthier countries for a profit, as opposed to actually dispersing the medications to their citizens in need. The only way to ensure that the pharmaceutical products physically reach those who need them in LDCs under a mandatory tiered pricing structure is to bar parallel importing so that wealthier countries do not attempt to buy off the stock of medications inexpensively purchased by LDCs.[51] Parallel importing in this scenario is detrimental to LDCs, in that their impoverished citizens in need of medications are deprived of the products, and only wealthier countries benefit by securing drugs at lower prices. By using LDCs as re-distributors of

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51 Ganslandt M, Maskus E and Wong E as note 47 above at 1-6.

lifesaving medications under these circumstances, the spirit of the TRIPS Agreement and its public health goals would be severely undermined.

11. Conclusion

In response to the controversies and differing views concerning how to effectively assist developing countries in terms of improving public health through international trade, the WTO formulated the TRIPS Agreement in an attempt to balance the interests of the many different stakeholders involved. The Agreement claims to further the interests of nations at both ends of the economic spectrum in terms of pharmaceutical patents. It offers adequate protection for firms in developed nations by compelling all WTO members to enact systems for regulating and enforcing patent rights. It also contains provisions that allow developing nations to escape their obligations under some circumstances to stave off crises or deal with public health emergencies. However, to more completely address the needs of developing countries, The Agreement should be amended to reflect the obstacles developing countries face in effectively gaining access to patented pharmaceuticals. By creating a pricing structure that takes each nation's resources and economic strength into account, as well as prohibiting parallel importing in the pharmaceutical industry, the TRIPS Agreement would better serve its purpose by increasing access to critical medications and thereby improving international public health.