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WORLDWIDE ACCOUNTABILITY: THE WTO'S FAILURE TO CREATE AN INFRASTRUCTURE THAT DELIVERS PHARMACEUTICAL DRUGS TO DEVELOPING COUNTRIES

*Arun J. Mohan**

ABSTRACT

In response to the public outcry over the death of millions of people in developing countries because of a lack of access to life-saving drugs, the World Trade Organization (WTO) recognized the need for developing countries to obtain pharmaceutical drugs at a reduced rate. However, the WTO received significant pushback from patent holders and pharmaceutical companies who insisted that their patents be upheld in every country. The dilemma resulted in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The WTO attempted to enforce intellectual property while, at the same time, “protect[ing] public health and nutrition.” This agreement became the subject of intense debate and led to a declaration by the WTO in 2001 (the Doha Declaration) that clarified the need for developing countries to obtain pharmaceutical drugs. A further declaration in 2003 set forth a system to let developing countries obtain drugs from developed countries by importation from these developed countries. Despite these efforts, millions of people are still dying because of a lack of access to pharmaceutical drugs. Furthermore, patent holders’ rights are being violated and the progress of research is being stunted by this violation. The only cure for the failure of the TRIPS Agreement and subsequent WTO actions is for the international community to set up a body that oversees the distribution of drugs to developing countries only when national health emergencies occur.

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INTRODUCTION	2003
I. THE WTO'S ATTEMPT TO ADDRESS A WORLDWIDE HEALTH CRISIS	2004
A. <i>The TRIPS Agreement</i>	2005
B. <i>The Doha Declaration</i>	2007
C. <i>The WTO'S 2003 Declaration on Paragraph 6 of the Doha Declaration</i>	2008
II. AVENUES FOR DEVELOPING COUNTRIES TO RECEIVE LIFE-SAVING DRUGS	2009
A. <i>Compulsory Licenses</i>	2009
B. <i>Parallel Importation</i>	2011
C. <i>The Paragraph 6 System</i>	2012
III. THE REALITY OF THE WTO'S EFFORTS UNDER TRIPS AND THE DOHA DECLARATION	2013
A. <i>Health Statistics from Developing Countries</i>	2013
B. <i>1997 South Africa Patent Dispute</i>	2014
C. <i>Consequences of India's Halt of Generic Drug Production in 2005</i>	2015
D. <i>The Use of Parallel Importation by Developing Countries in the Paragraph 6 System</i>	2016
IV. REPAIRING THE FAILED SYSTEM SET UP BY THE WTO	2017
A. <i>Developing Country Barriers to Drugs & Patent Holder's Violated Rights</i>	2018
B. <i>Unsatisfactory Language in the TRIPS Agreement and Doha Declaration</i>	2020
C. <i>Proposed Regulations to Correct the WTO's Actions</i>	2021
CONCLUSION	2022

INTRODUCTION

Millions of people are dying. They are dying from an epidemic that the civilized world is not discussing. These people are dying in developing countries from diseases that are normally easily treatable by pharmaceutical drugs. These countries cannot afford to pay the high price that pharmaceutical companies and patent holders charge for the drugs that most people in developed countries take for granted. You would think that a humanitarian outcry would force these companies and developed countries to allow the drugs to be provided to the poor at a cheaper cost.

You would be only half-correct, though. In 1994, the World Trade Organization (WTO) recognized the need for third world countries to obtain pharmaceutical drugs at a reduced rate.¹ However, the WTO received significant pushback from patent holders and pharmaceutical companies who insisted that their patent rights be upheld in every country.² The dilemma resulted in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.³ The WTO attempted to enforce intellectual property rights while, at the same time, “protect[ing] public health and nutrition.”⁴ This agreement became the subject of intense debate and litigation, and led to a declaration by the WTO in 2001 that reinforced the need for developing countries to obtain pharmaceutical drugs.⁵ A further declaration in 2003 set forth a system to allow developing countries to obtain drugs from developed countries by importation from these developed countries.⁶

Despite the attempts by the WTO, millions of people in developing countries are still needlessly dying from a lack of access to pharmaceutical drugs.⁷ This article will describe the continuing failure of the WTO to address this issue and propose regulations that would both uphold patent rights as well as give developing countries greater access to lifesaving drugs. Part I of this

¹ See Clark A.D. Wilson, *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, 244–46 (2005).

² See *id.* at 245.

³ *Id.* at 244–45.

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, arts. 7, 8, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

⁵ Wilson, *supra* note 1, at 248.

⁶ Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 BRANDEIS L.J. 623, 636–37 (2007).

⁷ Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 251 (2005).

article will explain the actions of the WTO in its attempt to address a worldwide health crisis as well as uphold patent holder's rights. Part II will explain the options that currently exist for developing countries to obtain drugs from patent holders and pharmaceutical companies. Part III will explain how these options fail to significantly increase access of drugs to developing countries. Part IV will propose changes in regulations that could lower the barriers that prevent people from receiving life-saving drugs while, at the same time, protect the rights of patent holders. I conclude that an international body must be established to oversee the distribution of life-saving drugs to developing countries and to guard the rights of the patent holders.

I. THE WTO'S ATTEMPT TO ADDRESS A WORLDWIDE HEALTH CRISIS

Prior to 1994, the struggle for developing countries to gain access to pharmaceutical drugs and basic patented technologies existed primarily for four reasons:

First, varying levels of IP protection affect these countries' access to biotechnology. Strong IP protection renders products too expensive for developing countries and prevents researchers from gaining access to basic knowledge. Conversely, weak IP protection discourages technology transfer, foreign investment, and local creation. Second, developing countries lack the infrastructure, capital, and pool of trained scientists necessary to develop their own biotechnology products. Third, the private industry, which conducts the most biotechnology R&D, is motivated by profit and sees no market in developing countries. Finally, anti-biotechnology groups object to increasing developing countries' access to biotechnology.⁸

Because of these barriers, many countries allowed local production of generic versions of these patented medications in violation of international law.⁹ Despite this attempt by developing countries to provide life saving drugs to its people at a lower cost, people continued to be unable to receive the drugs needed to treat life-threatening diseases.¹⁰ As a result, people in developing countries continued to die from both terminal diseases and—even more

⁸ Tara Kowalski, *International Patent Rights and Biotechnology: Should the United States Promote Technology Transfer to Developing Countries?*, 25 LOY. L.A. INT'L & COMP. L. REV. 41, 48 (2002).

⁹ Amit Gupta, *Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?*, 2 BUFF. INTELL. PROP. L.J. 127, 127–28 (2004).

¹⁰ See Outterson, *supra* note 7, at 251 (stating that, of the estimated 5.5 million people living with HIV/AIDS in developing countries, only five percent currently receive the drugs necessary to treat the disease).

astonishing—curable diseases at a greater rate than those people in developed countries.¹¹

Conversely, pharmaceutical companies received no benefits from their patented drugs because the cost of these generic drugs in these countries was considerably lower than the patented drugs sold by the pharmaceutical companies in developed countries.¹² Consequently, both developing countries and pharmaceutical companies had an interest in developing an international trade agreement that would both provide lifesaving medications to the people who need them as well as protect the patent holder's rights to these drugs.¹³

A. *The TRIPS Agreement*

In 1994, the World Trade Organization (WTO) sought to create a framework that would balance patent protection for the pharmaceutical companies and improve access to lifesaving drugs for developing countries.¹⁴ Negotiations between all interested countries in the WTO resulted in the formation of a patent protection system described in “The Agreement on Trade Related Aspects of Intellectual Property Rights” (TRIPS).¹⁵ The agreement was signed by 125 countries and created “a minimum standard for state intellectual property regulations.”¹⁶

The preamble of TRIPS provides that the goal of the agreement is “to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”¹⁷ Furthermore, a provision of Article 8 addresses the impact of

¹¹ Wilson, *supra* note 1, at 251 (stating that “nearly ten million people die in the developing world each year from infectious diseases” and “[m]ost of these people die from just six conditions: HIV/AIDS, malaria, measles, pneumonia, tuberculosis, and various forms of dysentery”).

¹² Alan O. Sykes, *Trips, Pharmaceuticals, Developing Countries, and the Doha “Solution”*, 3 CHI. J. INT’L L. 47, 47 (2002) (noting that “150 mg of the HIV drug flucanazole costs \$55 in India, where the drug does not enjoy patent protection, compared to \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines, where the drug is patented”).

¹³ Whobrey, *supra* note 6, at 624–25.

¹⁴ *Id.* at 625, 630.

¹⁵ Gupta, *supra* note 9, at 127.

¹⁶ Ryann Beck, *Farmers’ Rights and Open Source Licensing*, 1 ARIZ. J. ENVTL. L. & POL’Y 167, 188 (2011).

¹⁷ TRIPS Agreement, *supra* note 4, art. 30.

intellectual property rights on the public health.¹⁸ Specifically, Article 8 states that members are able to “adopt measures 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 th[e] agreement.”¹⁹

In attempting to balance the social welfare of developing countries against the need for patent protection, TRIPS both enforces the patent holders right to “prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing” their products²⁰ while, at the same time, states that the patent protection should be “conducive to social and economic welfare.”²¹ The agreement attempts to provide guidance for when the rights of the patent holders could be put aside for the greater good of welfare.²² Article 30 of TRIPS specifically states:

Members may provide limited exceptions to the exclusive rights conferred by a patent, 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.²³

As will be discussed in greater length in Part III.A. of this paper, Article 31 describes the mechanism of compulsory licensing, which allows the developing countries to utilize the subject matter of the patent without the patent holder’s permission.²⁴ However, the TRIPS Agreement is clear that compulsory licenses should only be used to produce drugs for domestic purposes.²⁵ Thus, the developing country would need to have the manufacturing capacity and infrastructure to produce these drugs.²⁶ Most important, unlike previous attempts to provide patent protection, the TRIPS Agreement sets up a dispute settlement process where developed countries can

¹⁸ Marla L. Mellino, *The TRIPS Agreement: Helping or Hurting Least Developed Countries’ Access to Essential Pharmaceuticals?*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1349, 1355 (2010).

¹⁹ TRIPS Agreement, *supra* note 4, art. 8.

²⁰ *Id.* art. 28.

²¹ *Id.* art. 7.

²² *See id.*; Neel Maitra, *Access to Environmentally Sound Technology in the Developing World: A Proposed Alternative to Compulsory Licensing*, 35 COLUM. J. ENVTL. L. 407, 415 (2010).

²³ TRIPS Agreement, *supra* note 4, art. 30.

²⁴ Maitra, *supra* note 22, at 416.

²⁵ TRIPS Agreement, *supra* note 4, art. 31(f) (stating that “any such use [of drugs via a compulsory license] shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”).

²⁶ Whobrey, *supra* note 6, at 636.

bring claims against other countries for failing to uphold the patent protection provisions in the agreement and, if the claims are not resolved, sanctions will be instituted.²⁷

Furthermore, the TRIPS Agreement leaves open another avenue, known as “parallel importation,” for developing countries to obtain pharmaceutical drugs at a cheaper price.²⁸ Under this practice, which is neither explicitly prohibited nor condoned in the TRIPS Agreement, “goods are sold into a parallel market at a much cheaper price than they could have been sold through the patent owner.”²⁹ This practice will be explained in Part III.B. of this Article.

After the passage of the TRIPS Agreement, many critics argued that the agreement would do nothing to ensure that drugs would be made more readily available to developing countries and that the agreement simply reinforced the standard that the developed countries’ goals were paramount to those of developing countries.³⁰ For example, critics pointed to Article 1(1) of the TRIPS Agreement, which provides that members “shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”³¹ Critics argued that, by giving both developing and developed countries the ability to decide for themselves how to implement the agreement, the WTO was neither providing any direction as to when developing countries are considered to be in a public health emergency nor describing when developed countries would be able to enforce their patent rights.³²

B. *The Doha Declaration*

Due to the concerns about the inequity between patent holder’s rights and the public health need for pharmaceuticals, the WTO issued a clarification of the TRIPS Agreement in 2001 during a conference in Doha, Qatar.³³ This

²⁷ Sara DeForge, *A Tough Pill to Swallow: The United States’ Passive Efforts in Curtailing Intellectual Property Rights in Favor of Humanity*, 4 LOY. L. & TECH. ANN. 75, 77–78 (2004).

²⁸ Mellino, *supra* note 18, at 1357.

²⁹ *Id.*

³⁰ DeForge, *supra* note 27, at 78 (stating that “[c]ritics claim [TRIPS] ‘was a result of the efforts of industrialized and developed nations to ensure that their goals were met over those of developing countries’”).

³¹ TRIPS Agreement, *supra* note 4, art. 1.

³² Gupta, *supra* note 9, at 135–36, 138 (noting that “provisions of the TRIPS can be interpreted to allow member countries flexibility in balancing their obligations to accord exclusive patent rights in fulfillment of their obligations to protect the right to health”).

³³ Whobrey, *supra* note 6, at 635.

clarification, known as the “Doha Declaration,”³⁴ stressed that the TRIPS Agreement should be “part of the wider national and international action to address” the public health crisis in third world countries,³⁵ and maintained that the flexibilities given to these developing countries include the use of compulsory licenses.³⁶ The declaration was clear in its stance that the TRIPS Agreement should specifically be used to help those developing countries that have epidemics of “HIV/AIDS, tuberculosis, [and] malaria.”³⁷

Perhaps the most important provision of the Doha Declaration was the WTO’s recognition that some developing countries have “insufficient or no manufacturing capacities in the pharmaceutical sector” to make “effective use of compulsory licensing under the TRIPS Agreement.”³⁸ The WTO instructed the Council for TRIPS to find a way for these countries to acquire drugs through an avenue that did not include compulsory licenses.³⁹ The solution to the problem outlined in Paragraph 6 of the agreement was finally provided by the TRIPS council on August 30, 2003.⁴⁰

C. *The WTO’S 2003 Declaration on Paragraph 6 of the Doha Declaration*

The “2003 Declaration” provided by the WTO altered Article 31(f)’s specification that “compulsory licensing must be predominately for the supply of the domestic market” in regards to countries that did not have the manufacturing capabilities to supply their people with drugs domestically.⁴¹ Prior to 2003, countries with sufficient manufacturing capabilities could not export pharmaceutical drugs to developing countries that did not have sufficient manufacturing capabilities because these exported drugs would not be supplied to that exporting country’s “domestic market.”⁴² Accordingly, the 2003 Declaration granted these exporting countries a waiver “with respect to the grant by it of a compulsory license to the extent necessary for the purposes

³⁴ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2 I.L.M. 746 (2002) [hereinafter Doha Declaration].

³⁵ *Id.* para. 2.

³⁶ *Id.* para. 5.

³⁷ *Id.* para. 1.

³⁸ *Id.* para. 6.

³⁹ See Stephanie A. Barbosa, *Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals*, 36 RUTGERS L.J. 205, 206, 213–14 (2004).

⁴⁰ Kojo Yelpaala, *Quo Vadis WTO? The Threat of Trips and the Biodiversity Convention to Human Health and Food Security*, 30 B.U. INT’L L.J. 55, 70–71 (2012).

⁴¹ Whobrey, *supra* note 6, at 636.

⁴² *Id.*

of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).⁴³

Perhaps most important in regards to patent rights, the 2003 Declaration expressly permitted the use of parallel exportation. This practice utilizes the doctrine of patent exhaustion,⁴⁴ which states that “the unconditioned sale of a patented article ends the patentee’s monopoly right to control its use.”⁴⁵ Under this doctrine, the holder of the underlying patent would only receive payment for their product one time, either by the exporting country or the importing country.⁴⁶ Furthermore, to limit the abuse of this waiver by importing countries, the 2003 Declaration required that the exporting country only provide the amount of pharmaceutical drugs necessary to meet the needs of the importing country and that both countries provide the amount of the specific drug exported.⁴⁷ The requirements given by the WTO—provided to clarify Paragraph 6 of the Doha Declaration—gave importing and exporting countries a basic framework for a system, now known as a “Paragraph 6 System,” for the proper use of parallel importation.⁴⁸

II. AVENUES FOR DEVELOPING COUNTRIES TO RECEIVE LIFE-SAVING DRUGS

Because of the WTO’s efforts to address the conflict between pharmaceutical companies’ desire to protect their patent rights and the public health crises in developing countries, three options are currently available to allow developing countries the ability to acquire medicines at a potentially lower price and within the WTO guidelines: compulsory licenses,⁴⁹ parallel importation,⁵⁰ and Paragraph 6 Systems.⁵¹

A. *Compulsory Licenses*

As previously described, Article 31 of the TRIPS Agreement described the mechanism of compulsory licensing, which allowed the developing countries

⁴³ World Trade Organization para. 2, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (2003) [hereinafter 2003 Declaration].

⁴⁴ See Maitra, *supra* note 22, at 418; BLACK’S LAW DICTIONARY 1240 (9th ed. 2009).

⁴⁵ BLACK’S LAW DICTIONARY 1240 (9th ed. 2009).

⁴⁶ Maitra, *supra* note 22, at 418.

⁴⁷ See Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 236 (2004).

⁴⁸ Mellino, *supra* note 18, at 1361–62, 1364.

⁴⁹ See *infra* Part II.A.

⁵⁰ See *infra* Part II.B.

⁵¹ See *infra* Part II.C.

to utilize the subject matter of the patent without the patent holder's permission.⁵² However, the use of a patent without the patent holder's permission required compliance with many provisions of TRIPS.⁵³ These provisions provide, among other things, that the "proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."⁵⁴ However, the TRIPS Agreement fails to define "reasonable commercial terms."⁵⁵ Furthermore, even if the negotiations between the proposed user (i.e., the developing country) and the patent holder fail, the patent holder must still be paid "adequate remuneration . . . taking into account the economic value of the authorization."⁵⁶ One frequent criticism of this TRIPS provision is that it does not describe the process in which "adequate remuneration" is determined.⁵⁷

In addition, the TRIPS Agreement specifies that negotiations with a patent holder can be waived in "the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."⁵⁸ Like the term "adequate remuneration," the term "national emergency" is not defined by the TRIPS Agreement and many opponents of compulsory licensing argue that the term could be used broadly and that developing countries will use the exception in all circumstances where it could possibly fit.⁵⁹ These opponents fear that the use of compulsory licenses will lead to sharp price reductions in drugs that are not normally seen until generic drugs are introduced.⁶⁰ Thus, because of this fear of broad use of the compulsory licensing mechanism, developed countries have been successful in thwarting attempts by developing countries to use the broad language in the TRIPS Agreement.⁶¹

⁵² Barbosa, *supra* note 39, at 212.

⁵³ *Id.*

⁵⁴ TRIPS Agreement, *supra* note 4, art. 31(b).

⁵⁵ Mellino, *supra* note 18, at 1356.

⁵⁶ TRIPS Agreement, *supra* note 4, art. 31(h).

⁵⁷ Maitra, *supra* note 22, at 416.

⁵⁸ TRIPS Agreement, *supra* note 4, art. 31(b).

⁵⁹ Wilson, *supra* note 1, at 247.

⁶⁰ *Id.*

⁶¹ Naomi A. Bass, *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 L. REV. 191, 199-200 (2002) (citing Karl Vick, *African AIDS Victims Losers of a Drug War*, WASH. POST, Dec. 4, 1999, at A18).

B. *Parallel Importation*

As previously stated, parallel importation under the TRIPS Agreement relies on the principle of patent exhaustion.⁶² Under this practice, the pharmaceutical drugs that are “marketed by the patent owner . . . with the patent owner’s permission in one country [are] imported into another country without the approval of the patent owner.”⁶³ The principle of patent exhaustion ensures that the patent holder is only compensated for one sale of his patented product, while the product is re-sold to the developing country that needs it.⁶⁴

The practice of parallel importing is very controversial, with proponents arguing that patent holders should lose control of their product after they are sold⁶⁵ and opponents arguing that patent exhaustion is inherently detrimental to the public health of these developing countries because it gives pharmaceutical countries less incentive to sell their patent products directly to developing countries.⁶⁶ Opponents also argue that the practice of parallel importing is useless to people in developing countries that actually need the drugs as the governments in these developing countries only sell the drugs received to the richest people in the country.⁶⁷ Thus, the opponents of parallel importing argue that this practice of favoring profits over people is particularly prominent in developing countries that are “prone to corruption.”⁶⁸

Perhaps the biggest detracting feature of parallel importation is that developed countries in the WTO can ban this practice on all drugs manufactured in their country.⁶⁹ For example, the United States has two legal restraints that prevent parallel importation of prescriptions:

⁶² See *supra* Part I.C.

⁶³ *Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Dec. 13, 2012).

⁶⁴ Whobrey, *supra* note 6, at 633–34 (stating that “[t]he [pharmaceutical] company has exhausted its interests in the goods, and they can be resold to other nations for a profit by the original importing country).

⁶⁵ *Id.* at 634.

⁶⁶ *Id.* at 633 (stating that “[m]any pharmaceutical firms argue that parallel importing decreases profitability and removes incentive to sell drugs to poor countries at lower prices”).

⁶⁷ *Id.* (arguing that “the incentives created by parallel importing encourage governments to favor profits over people” and “the general public in [developing countries] sees neither the critical medications nor realizes any benefits or improvements from the sale of drugs”).

⁶⁸ *Id.*

⁶⁹ See, e.g., Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries*, WORLD INTELLECTUAL PROPERTY ORG. 5 (Apr., 2001), http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

First, American patent owners are protected from parallel imports by an explicit right of importation. Second, PI [parallel importation] of trademarked, prescription drugs are explicitly excluded under terms of a 1988 law covering pharmaceuticals. An attempt to relax this restriction through new legislation was passed in 2000 but not implemented by the Clinton Administration,⁷⁰ which cited that it could not guarantee the purity of imported drugs.

Opponents of parallel importation suggest that, if parallel importation is banned, there will be an incentive for pharmaceutical companies to sell to developing countries as they will lower their prices based on the free-market demand in that country.⁷¹ Thus, as long as parallel importation is possible, these companies have no incentive to help developing countries if their patent rights are exhausted by the practice of parallel importation and sold at a comparably lower price than the free market would dictate.⁷²

C. *The Paragraph 6 System*

As opposed to parallel importation, which is generally banned in developed countries, the use of the Paragraph 6 System has become the only avenue for many developing countries—which do not have sufficient manufacturing abilities—to receive drugs.⁷³ The 2003 Declaration sets forth different requirements that the importation and exportation of drugs must satisfy to set up a Paragraph 6 System.⁷⁴ For example, the importing country's requirements include “specification of ‘the names and expected quantities of the product needed.’”⁷⁵ Likewise, the exporting country must publish the amount of the drug that is being supplied and the destination of the shipment.⁷⁶ While the use of a Paragraph 6 System allows developing countries to utilize parallel importation with developed countries, at the same time, the rights of patent holders are still abrogated because of the principle of patent exhaustion.

⁷⁰ *Id.*

⁷¹ Sykes, *supra* note 12, at 64.

⁷² *Id.* (stating that “[w]hen parallel imports are possible . . . [pharmaceutical companies] will likely be unwilling to sell at low prices in markets where demand is weak”).

⁷³ Mellino, *supra* note 18, at 1371–72.

⁷⁴ *Id.* at 1362.

⁷⁵ *Id.*

⁷⁶ *Id.* at 1363.

III. THE REALITY OF THE WTO'S EFFORTS UNDER TRIPS AND THE DOHA DECLARATION

Despite the WTO's best efforts to balance the rights of patent holders and increase the access of drugs to developing countries, the health statistics in developing countries overwhelmingly show that the rights of patent holders are succeeding, much to the detriment of the people in the developing countries.⁷⁷ One attempt by a developing country to curtail the AIDS problem resulted in a lawsuit by developed countries and pharmaceutical countries.⁷⁸ Furthermore, increasing pressure after the passage of the Doha Declaration and 2003 WTO resolution resulted in a significant decrease in generic drugs provided by India.⁷⁹ Finally, the WTO's description of a "Paragraph 6 System," which has been touted as a breakthrough from the 2003 Declaration, has thus far resulted in only one successful implementation.⁸⁰

A. Health Statistics from Developing Countries

Despite the best intentions by the WTO to reduce the disparity in deaths from treatable diseases between developing and developed countries, people are still dying from treatable diseases in developing countries. For example, in 2012, the WTO indicated that "[t]he highest malaria mortality rates are being seen in countries that have the highest rates of extreme poverty."⁸¹ Furthermore, forty-seven percent of the 103 million malaria cases in 2012 exist in six African nations: Nigeria, Democratic Republic of the Congo, United Republic of Tanzania, Uganda, Mozambique and Cote d'Ivoire.⁸² Furthermore, in 2012, the WTO reported that more than ninety-five of tuberculosis cases and deaths were in developing countries.⁸³ In regards to the spread of HIV and AIDS, the numbers are even more staggering. The Foundation for AIDS Research estimated that "[m]ore than two-thirds (70%) of all people living with HIV . . . live in sub-Saharan Africa—including 91% of the world's HIV-

⁷⁷ See *infra* Part III.A.

⁷⁸ See *infra* Part III.B.

⁷⁹ See *infra* Part III.C.

⁸⁰ See *infra* Part III.D.

⁸¹ *World Malaria Report 2012 Fact Sheet*, WHO 1 (Dec. 17, 2012), http://www.who.int/malaria/publications/world_malaria_report_2012/wmr2012_factsheet.pdf.

⁸² *Id.*

⁸³ *Tuberculosis Fact sheet No. 104*, WHO (Oct. 4, 2012), <http://www.who.int/mediacentre/factsheets/fs104/en/>.

positive children.”⁸⁴ Furthermore, an estimated 1.5 million people became newly infected with HIV.⁸⁵ Despite the steps taken by the WTO in 1994, 2001, and 2003, there still appears to be people in developing countries who cannot gain access to drugs that treat HIV as well as drugs that can cure diseases like malaria and tuberculosis.

B. 1997 South Africa Patent Dispute

A large reason for the ever-present disease problem in developing countries can be traced back to resistance by developed countries in allowing developing countries to utilize the provisions in the TRIPS Agreement. For example, shortly after the TRIPS Agreement was passed in 1994, South Africa attempted to utilize compulsory licensing and parallel importation to address its growing HIV/AIDS problem.⁸⁶ The backlash from pharmaceutical companies and developed countries was massive.

In the early 1990s, South Africa became the country with “the highest absolute number of people living with HIV/AIDS.”⁸⁷ Despite the growing HIV population, the majority of South Africans suffering with the disease could not afford even three months of drugs to treat their disease on one year’s salary.⁸⁸ Thus, the parliament in South Africa passed the South African Medical and Related Substances Control Act (MRSCA) in 1997.⁸⁹ In this legislation, the South African Health Minister was given the power to override drug patents and authorize compulsory licensing and parallel importation in an effort to reduce the prices of HIV/AIDS antiretroviral drugs.⁹⁰

The backlash to this piece of legislation from pharmaceutical companies and developed countries resulted in a lawsuit, filed in South African courts by more than 40 multinational manufacturers and the United States, challenging

⁸⁴ *Statistics: Worldwide*, FOUND. AIDS RES. (Nov. 2012), http://www.amfar.org/about_hiv_and_aids/facts_and_stats/statistics_worldwide/.

⁸⁵ *Id.*

⁸⁶ Wilson, *supra* note 1, at 254–55.

⁸⁷ William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, HARV. L. SCH. 3 (Feb. 10, 2005), <http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf>.

⁸⁸ *Id.* (stating that “with an average annual income of \$2,600, most South Africans suffering with HIV/AIDS could not afford to pay for treatment with antiretroviral drugs, which at that time cost about \$1,000 a month”).

⁸⁹ Mercurio, *supra* note 47, at 223.

⁹⁰ Andrea M. Curti, *The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS*, 27 AM. J.L. & MED. 469, 476–77 (2001).

the MRSCA.⁹¹ These multinational companies stated that the use of compulsory licenses and parallel importing was in violation of the TRIPS Agreement, despite the language in the TRIPS Agreement allowing for compulsory licensing and implicitly authorizing parallel importing.⁹² In addition, the United States withheld trade benefits from South Africa and threatened to further impose trade sanctions if the country did not repeal the Act.⁹³ Despite the lawsuits and threat of trade sanction, South African President Nelson Mandela signed the law into effect in 1997.⁹⁴ It was not until worldwide public outcry over the lawsuit⁹⁵—and the offer from India to provide South Africa with generic HIV/AIDS drugs at a price that pharmaceutical companies could match—that the lawsuit was dropped.⁹⁶ After the lawsuit was dropped and the crisis had settled, the WTO passed the Doha Declaration and clarified its stance on TRIPS and the ability of developing countries to utilize compulsory licensing and parallel importation.⁹⁷

C. Consequences of India's Halt of Generic Drug Production in 2005

Just as India was able to provide generic drugs to South Africa in 1997, India enjoyed the benefits of relaxed patent law compliance standards that were granted to many developing countries until 2005.⁹⁸ After 2005, however, India became fully compliant with the TRIPS Agreement and, thus, the production of generic drugs under the relaxed standards ceased.⁹⁹ In addition, exports of all generic drugs stopped.¹⁰⁰ As a result, developing countries were forced to follow the mechanisms described in the TRIPS Agreement and the Doha Declaration: compulsory licenses, parallel importation, or a Paragraph 6 System.¹⁰¹

⁹¹ Wilson, *supra* note 1, at 255.

⁹² Fisher & Rigamonti, *supra* note 87, at 5.

⁹³ *Id.* at 7.

⁹⁴ *Id.*

⁹⁵ Wilson, *supra* note 1, at 255–56 (stating that “[t]he pharmaceutical companies eventually dropped the case in 2001, but only in response to the worldwide public outcry against the action”).

⁹⁶ Curti, *supra* note 90, at 477 (noting that Cipla (an Indian producer of generic drugs) offered to sell AIDS medications to South Africa and this prompted Bristol-Myers Squibb and Merck to match the Indian drug producer’s price).

⁹⁷ Wilson, *supra* note 1, at 256; Fisher & Rigamonti, *supra* note 87, at 15.

⁹⁸ Curti, *supra* note 90, at 477–78.

⁹⁹ Yelapaala, *supra* note 40, at 91–92.

¹⁰⁰ *Id.*

¹⁰¹ Mellino, *supra* note 18, at 1370–72.

The use of compulsory licenses slowly began to be implemented by developing countries, although none of the countries that utilized these licenses were considered least developed countries (LDCs).¹⁰² The reason for the limited use of compulsory licenses is likely the lack of manufacturing capabilities in the developing countries that desperately need the drugs.¹⁰³ Thus, the only avenue for these developing countries to receive drugs at a lower cost is the use of parallel importation from the set-up of a Paragraph 6 System.¹⁰⁴

D. The Use of Parallel Importation by Developing Countries in the Paragraph 6 System

As stated earlier, the use of compulsory licenses under TRIPS was not feasible for most developing countries because the agreement specified that the drugs manufactured were for domestic consumption only.¹⁰⁵ This limitation, coupled with the fact that most countries have banned parallel importation, meant that the only real avenue for developing countries to receive pharmaceutical drugs was the formation of a Paragraph 6 System with a developed country.¹⁰⁶ Shortly after the 2003 Declaration, however, many countries—including the United States, Australia, and New Zealand—stated that they would not set up a Paragraph 6 System with developing countries, even if the system met the specific requirements and guidelines established in the 2003 Declaration.¹⁰⁷ Furthermore, other countries—including China, Israel, Turkey, and Mexico—stated that they would only use the system in cases of national emergencies.¹⁰⁸

In fact, Canada is the only developed country to set up a Paragraph 6 System—known as Canada’s Access to Medicines Regime (CAMR)—with developing countries, and Rwanda is the only country to take advantage of the CAMR.¹⁰⁹ Canada set up the CAMR in 2004 in order to “facilitate timely

¹⁰² *Id.* at 1371 (noting that, while Thailand, Brazil, and the Philippines began to utilize compulsory licenses, “these countries are not [as] financially destitute” as LDCs, or least developed countries).

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 1371–72.

¹⁰⁵ *See supra* Part I.C.

¹⁰⁶ *See Mellino, supra* note 18, at 1361–62 (stating that “[t]he 2003 Decision specifically took into account the instruction of the Doha Declaration to find a solution to the problem of the difficulties that ‘WTO members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face in making effective use of compulsory licenses’”).

¹⁰⁷ *Id.* at 1365.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 1372.

access to generic versions of patented drugs and medical devices, especially those needed by least-developed or developing countries to fight HIV/AIDS, malaria, tuberculosis and other diseases.”¹¹⁰ The CAMR “requires the good will of pharmaceutical companies to participate in the Regime” by granting compulsory licenses to Canada for the manufacture and export of generic versions of patented drugs to developing countries without the capacity to manufacture these drugs.¹¹¹ The effects of the system were utilized by Rwanda in 2008:

In 2008, upon the authorization of GlaxoSmithKline and the Canadian subsidiaries of Shire and Boehringer Ingelheim, general drug maker Apotex manufactured a “fixed dose triple combination antiretroviral medicine” for export to Rwanda. Apotex has since sent out two total shipments of the AIDS drug to Rwanda.¹¹²

Notwithstanding these successful shipments to Rwanda, no other country has utilized the CAMR.¹¹³

IV. REPAIRING THE FAILED SYSTEM SET UP BY THE WTO

Despite the WTO’s desire to adopt legislation in the hopes of getting life-saving drugs to the world’s poorest people, the realities described above show that the TRIPS Agreement, the Doha Declaration, and the 2003 Declaration are failing.¹¹⁴ Critics of the WTO’s actions state that the TRIPS Agreement and the Doha Declaration “fail[] to address” the various “political and educational barriers” in developing countries and, instead, focus on “penalizing” the pharmaceutical companies by depriving them of their patent rights.¹¹⁵ Furthermore, critics state that the language used in the TRIPS Agreement is too broad to have any real force in international trade.¹¹⁶ The WTO will need to address these failures by drafting another declaration that adds some teeth to

¹¹⁰ *Canada’s Access to Medicine Regime: Background*, CANADA’S ACCESS TO MEDICINE REGIME (March 13, 2008), <http://www.camr-ream.gc.ca/intro/context-eng.php>.

¹¹¹ *Id.*

¹¹² Mellino, *supra* note 18, at 1373.

¹¹³ *Id.*

¹¹⁴ *See supra* Part III.

¹¹⁵ Barbosa, *supra* note 39, at 236 (stating that the Doha Declaration “fails to address developing nations’ political and educational barriers to pharmaceuticals and resorts to penalizing the industry that brings life-saving medicines to the world”).

¹¹⁶ Mercurio, *supra* note 47, at 236–37 (stating that the TRIPS Agreement “fails to satisfactorily resolve [the following] . . . (i) the scope of diseases and product coverage; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other market”).

the language used in the TRIPS Agreement, the Doha Declaration, and the 2003 Declaration.

A. Developing Country Barriers to Drugs & Patent Holder's Violated Rights

The use of compulsory licenses by developing countries is a significant penalty to patent holders. By allowing developing countries to bypass patent rights after failed negotiations with pharmaceutical companies, these companies may be discouraged from developing drugs and continuing research for diseases, such as HIV/AIDS and malaria, that typically only affect developing countries because there is no financial benefit for this research.¹¹⁷ It costs a pharmaceutical company hundreds of millions of dollars to bring a drug to market¹¹⁸ and the number of new drugs seeking approval by the FDA is already declining.¹¹⁹ With little chance of profiting off any new drugs for diseases that primarily affect developing countries, the number of new drugs that are brought to market will continue to decline.

Furthermore, patent rights and high prices may not even be the most significant barriers to providing life-saving drugs to developing countries.¹²⁰ To begin, developing countries spend one-tenth of their budget on pharmaceutical drugs for their people.¹²¹ This lack of spending by governments leads to increased out-of-pocket spending—as much as ninety percent of the average person's total out-of-pocket expenditures—by individuals for drugs they need.¹²² The large out-of-pocket expenditure for drugs leads to less money for food, clothing, and housing, thereby prompting many to equate illness as a

¹¹⁷ Barbosa, *supra* note 39, at 245 (arguing that “[i]f companies do not envision that research into new therapies for HIV/AIDS, malaria or other diseases typically affecting developing countries will be profitable, they will stop spending valuable research dollars for the development of drugs used predominantly in the developing world”).

¹¹⁸ *Id.* at 244.

¹¹⁹ *Id.* at 245 (stating that “the number of new drugs seeking approval by the FDA is already declining” and “[i]t is becoming increasingly difficult for pharmaceutical manufacturers to develop new therapies, resulting in few innovative drugs being launched into the market”).

¹²⁰ *See id.* at 248 (stating that “[p]rice is not the only hurdle in eradicating disease in developing countries” and that “‘poverty, corruption, and lack of health-care infrastructure’ are significant obstacles that poorer countries face”).

¹²¹ Jillian Clare Cohen, *Pharmaceuticals and corruption: a risk assessment*, WORLD BANK.ORG 1 (Aug. 11, 2005), <http://www1.worldbank.org/publicsector/anticorrupt/corecourse2007/Pharmaceuticals.pdf> (stating that developed countries “generally devote US \$239 in annual spending on drugs per head, compared to less than US \$20 in developing countries”).

¹²² *Id.* (stating that, in developing countries, “pharmaceutical expenditures are anywhere from 50-90 percent of total individual out-of-pocket expenditures”).

major cause of household poverty.¹²³ Further exacerbating the problem is the fact that, even when people can afford these drugs, the absence of proper healthcare providers means that the right drugs do not get to the right people.¹²⁴ For complex drugs such as retrovirals to treat HIV and AIDS, developing countries do not have the infrastructure to provide laboratories that can monitor needed blood tests or doctors that can properly administer the retrovirals.¹²⁵

The lack of infrastructure and decreased government spending on pharmaceuticals can largely be traced back to corruption in developing countries.¹²⁶ Government officials in developing countries are susceptible to taking “kickbacks for purchasing medicines”¹²⁷ and, when this occurs, officials tend to hoard these drugs or select the wrong kind of medicines for their people.¹²⁸ The following are just a few of the ways that corruption can affect the access to pharmaceutical drugs:

[P]roducts can be diverted or stolen at various points in the distribution system; officials may demand ‘fees’ for approving products or facilities, for clearing customs procedures, or for setting prices; violations of industry marketing code practices may distort medical professionals’ prescribing practices; demand for favours may be placed on suppliers as a condition for prescribing medicines; and counterfeit or other forms of sub-standard medicines may be allowed to circulate.¹²⁹

Thus, even with the provision in TRIPS that aimed to lower prices or work around patent holders’ rights in cases of emergency, the lack of infrastructure and corruption will continue to be a barrier for the poorest people in developing countries to receive life-saving drugs.

¹²³ *See id.*

¹²⁴ Barbosa, *supra* note 39, at 248 (arguing that “the absence of proper health care providers presents a formidable barrier to drug access”).

¹²⁵ *Id.*

¹²⁶ Cohen, *supra* note 121, at 77.

¹²⁷ *Id.* (stating that “when officials accept kickbacks for purchasing medicines, pharmaceutical expenditure is reduced and fewer of the right drugs get to the right people when they need them”).

¹²⁸ Transparency International, *Summary sheet: Corruption in the pharmaceutical sector*, GLOBALAGING.ORG 1, (2006) [http://www.globalaging.org/health/world/2006/World%20HE%20Feb1%20Pharma%20Corruption%20\(phcorrupt\).pdf](http://www.globalaging.org/health/world/2006/World%20HE%20Feb1%20Pharma%20Corruption%20(phcorrupt).pdf).

¹²⁹ *Id.*

B. *Unsatisfactory Language in the TRIPS Agreement and Doha Declaration*

Apart from the ambiguous terms in the TRIPS Agreement that have previously been discussed,¹³⁰ the language in the Doha Declaration has also been accused by many as too broad and unsatisfactory in guiding all WTO countries with regards to the utilization of compulsory licensing and parallel importation.¹³¹ To begin, the largest undefined term in the Doha Declaration is that of a “public health problem.”¹³² Under paragraph 1 of the Doha Declaration, the WTO recognized the gravity of “public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹³³

However, by only listing those specific diseases, the WTO leaves open for interpretation what other diseases a country could consider a “public health problem.”¹³⁴ Thus, critics argue that a patent holder could be forced into a compulsory license for a drug treating a disease that is arbitrarily determined to be a health emergency, such as erectile dysfunction.¹³⁵ While this example may seem to be extreme, it does illustrate the lack of direction that the Doha Declaration gives and also indicates how a country could use the lack of direction in a manner that is not in the spirit of the WTO’s goals.¹³⁶

Another ambiguity in the WTO’s action occurs in Paragraph 6 of the Doha Declaration, which states that countries can utilize parallel importation of drugs under a Paragraph 6 System if the country has “no manufacturing capacities in the pharmaceutical sector” or if the country has “difficulties making effective use of compulsory licensing under the TRIPS agreement.”¹³⁷ There is no language in the Doha Declaration that states a country must face a genuine health problem and must lack the resources to acquire the drugs from the patent holders.¹³⁸ Thus, critics of this language argue that countries that do

¹³⁰ See *supra* Part II.A.

¹³¹ See, e.g., Mercurio, *supra* note 47, at 236–37 (arguing that “several paragraphs of [TRIPS] lend themselves to the possibility of abuse or are otherwise unsatisfactory and potentially destabilizing to the entire system of compulsory licensing”).

¹³² See Doha Declaration, *supra* note 34, para. 1.

¹³³ *Id.*

¹³⁴ Mercurio, *supra* note 47, at 239.

¹³⁵ *Id.* (arguing that “without any hesitation, a country could declare a health emergency and be granted a compulsory license on any drug, including Viagra”).

¹³⁶ *Id.* (arguing that the use of a compulsory license on Viagra is an example of a result that “is contrary to the spirit of the Doha Declaration”).

¹³⁷ Doha Declaration, *supra* note 34, para. 6. See Mercurio, *supra* note 47, at 240.

¹³⁸ Mercurio, *supra* note 47, at 240.

not have a health emergency, but merely choose not to manufacture drugs in their country, can utilize the Paragraph 6 System to receive drugs at a cheaper price.¹³⁹

C. Proposed Regulations to Correct the WTO's Actions

As shown above, the actions of the WTO to balance health emergencies and uphold patent rights have failed in accomplishing either goal. Allowing individual developing countries to decide the terms of what constitutes an “emergency” and utilize compulsory licenses or parallel importation deliberately works around patent holders’ rights and has the potential to stunt research on diseases that are currently incurable. Furthermore, statistics show that developing countries are still not receiving the drugs that they need to solve national health emergencies. Thus, the WTO must find a way to work within its constraints and power in order to give more teeth to the TRIPS Agreement, the Doha Declaration, and the 2003 Declaration. Until the WTO does this, millions of people will continue to die.

I propose that the WTO establish an international body from which all developing countries can get access to pharmaceutical drugs, but only in health emergencies. Having individual developing countries—and potential exporting countries—negotiate with patent holders does not help either the developing country receive the drugs nor does it uphold a patent holder’s rights. Thus, an international body must be established to both determine when a health crisis exists in a specific country and oversee the distribution of the life-saving drugs to that country. This will require an international agreement among all countries to forgo patent holders’ rights in certain, limited circumstances so that people do not continue to die.

An area of regulation that is far beyond the scope of the WTO is the infrastructure and corruption in developing countries. However, setting up an international body to oversee the distribution of life-saving drugs to developing countries will cut down on the back-door government corruption and kick-backs to corrupt officials. This international organization can also oversee that the needed health infrastructure is provided in these developing countries for people to receive life-saving drugs from qualified health professionals.

¹³⁹ See *id.* (stating that a lack of manufacturing capabilities, even when the country does not “lack the resources to purchase needed medicines from the manufacturer,” could allow for rich or healthy countries to utilize a Paragraph 6 System in order to obtain drugs at a cheaper cost).

Furthermore, in order for the WTO to give this new international more guidance and enforce the TRIPS Agreement, the Doha Declaration, and the 2003 Declaration, the WTO must provide greater guidance on the broad and ambiguous terms described in this paper. The WTO must begin by clarifying the meanings of the terms “adequate remuneration,” “public health problem,” “national emergency,” and “reasonable commercial terms.” Until the language in the TRIPS Agreement and Doha Declaration is clarified, no organization or country will be able to properly enforce these agreements in the spirit the WTO intended.

CONCLUSION

In conclusion, while the WTO has taken steps in an attempt to balance the need for life-saving drugs to be provided to developing countries and the right of patent holders to profit off these drugs, the end result of these steps is insufficient. Patent holders are being deprived of their exclusive rights to the drugs they invented and people in developing countries are still not receiving the drugs they need. Thus, an international body must be established to both oversee the distribution of these life-saving drugs to developing countries as well as ensure that a patent holder's rights are upheld absent a national health emergency.