WHEN PATENT RIGHTS AND PUBLIC
HEALTH COLLIDE: GOING BEYOND
COMPULSORY LICENSING TO SOLVE THE
DOHA PARAGRAPH 6 PROBLEM

Marcela I Shirsat, American University Washington College of Law
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Marcela I. Shirsat*

It has been almost ten years since the Doha Ministerial Conference’s Declaration on Public Health, however, since that time the developing nation’s access to medicines has not changed. Towards the end of 2001, the Doha Declaration on Public Health ("Doha Declaration") was meant to alleviate the dissatisfaction with aspects of the TRIPS regime by reaffirming the flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines. However, it raised a concern under paragraph 6 that certain members had either insufficient or no manufacturing capacities in the pharmaceutical sector and therefore could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Therefore, the Council for TRIPS set out to find an expeditious solution to this issue. After creating an interim waiver in 2003, the Council decided to turn the waiver into a permanent amendment of TRIPS in 2005, known as Article 31bis. Nevertheless, as of December 2010 only 32 of the 151 members have ratified the change, far less than the two-thirds needed, and an extension for 2011 was issued. With all the negotiations and talks held over a viable solution the fact of the matter is nothing has really changed. In ten years the problems facing developing nation’s is more than just access. In the recent years these countries have had to deal with the transitioning period of other developing nations, like India, thereby affecting their present availability of medicines, the fear of retaliation from the developed world for threatening to use a compulsory license, as was the case for Thailand, not to mention the complicated procedures involved in just trying to navigate through the WTO’s compulsory license regime. Lastly, there is the further constricting of their rights, as reaffirmed in the Doha Declaration, by bilateral and regional trade agreement issues known as TRIPS plus. Therefore, this article will look at the current issues facing developing nation’s access to medicines and reevaluate the current solution. In addition, the innovative interpretation of TRIPS under Article 30 and several policy recommendations will be

* J.D. Candidate American University, Washington College of Law, May 2011; M.S. Mechanical Engineering, University of Texas at El Paso. The author wishes to thank her husband for his boundless support, and Professor Flynn for his insights during the writing process. Finally, the author would also like to thank her parents for always being supportive and encouraging. Any errors remain the responsibility of the author. E-mail: mc1566a@student.american.edu
discussed as possible alternatives for solving the paragraph 6 dilemma.

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INTRODUCTION

Towards the end of 2001, the World Trade Organization (WTO) held a Ministerial Conference in Doha, Qatar to discuss long awaited and heated issues relating to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health. However, this was only one of the many issues discussed during the trade negotiations that had started as early in 2001. The public health issues raised were requested primarily by the African Group \(^{1}\) with support from other developing member states, demonstrating the growing contentions regarding the implication of TRIPS

\(^{1}\) See, Raghavan, C. Africa Group, LDCs outline stands on Doha, SUNS, 2001, issue 4948.
and access to medicines. Even though one of the stated goals of TRIPS was to reduce tensions caused by the protection of intellectual property rights, Progress was made into bringing intellectual property rights into harmonization with fundamental human rights when at the conclusion of the Doha round a Declaration, entitled the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”), was adopted to alleviate the developing countries dissatisfaction with certain aspects of the TRIPS regime.

The most notable portions of the Doha Declaration dealing with access to medicines and rights of WTO member states to act in the welfare of public health are paragraphs 4 to 6. Paragraph 4 of the Doha Declaration, interprets the TRIPS agreement as not causing any conflicts with public health while reaffirming a members right to use the flexibility provided for in the agreement to mutually balance intellectual property rights with public health. Paragraph 5 in light of paragraph 4, can be interpreted as reaffirming the flexibilities found in TRIPS so that member states can, in circumventing patent rights, have better access to essential medicines. These flexibilities include: interpretation of the agreement in light of its purpose, the right to use compulsory licensing, right to determine what constitutes emergency or extreme urgency, and the right to determine what constitutes exhaustion of rights. In addition, the Doha Declaration under

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2 See, Preamble to the Agreement on Trade-Related Aspects of Intellectual Property Rights, para. 7 stating: “Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures. . . .”.


4 Doha Declaration, para. 4 stating: “the TRIPS Agreement does not . . . prevent . . . taking measures to protect public health.”

5 Doha Declaration, para. 5(a) stating: “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.”

6 Doha Declaration, para. 5(b) stating: “right to grant compulsory licences [sic]” a term not used within the four corners of the TRIPS Agreement.

7 Doha Declaration, para. 5(c) stating: “right to determine what constitutes a national emergency or other circumstances of extreme urgency” which is significant concerning it shifts the burden of proof from prior jurisprudence in the case of a complaint.

8 Doha Declaration, para. 5(d) stating: that it “leave[s] each member free to establish its own regime for such exhaustion without challenge . . . “. 
paragraph 6 raised the concern that certain members had either insufficient or no manufacturing capacities in the pharmaceutical sector and therefore could face difficulties in making effective use of the compulsory licensing under the TRIPS Agreement. Therefore, the Council for TRIPS was given the task to find an expeditious solution to this issue. There are three main ways in which members can address concerns regarding the application of TRIPS provisions, mainly: Ministerial Declaration, interpretation, and amendment. The use of a Declaration, being already in use for this issue, provides an inadequate solution to the problem and hence this paper will focus on methods of interpreting TRIPS and the possible amendment of the agreement.

On the road to reaching a possible amendment of the TRIPS agreement that would satisfy the Paragraph 6 dilemma, several steps were taken. First, in August of 2003, an interim waiver under the TRIPS Agreement was created allowing a member country to export pharmaceutical products made under compulsory licenses to least developed and certain other members. This interim waiver was to last until the amendment of the TRIPS Agreement. However, in December of 2005, it was decided to transform the August 2003 “waiver” into a permanent amendment of TRIPS. All that is needed to pass this amendment, the first ever in TRIPS history, is the ratification of the change by two thirds of the WTO’s 153 members. Yet as of December 2010 only 32 members have ratified the change and an extension for 2011 was issued. The problem with trying to amend an

\[\text{9 Doha Declaration, para. 6 stating: that they “recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”} \]


\[\text{12 Complete list of all 153 members along with dates of membership, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited January 11, 2011).} \]

international agreement is that many constitutional systems require legislative consent in order to amend a treaty resulting in an overwhelmingly time consuming process. In addition, amending TRIPS for this, albeit morally justifiable reason could open the door to other proposed amendments being brought to the table thus leading to the eventual chipping away at the purpose and goals of the agreement.

For those reasons I believe the most effective solution to the Paragraph 6 dilemma is a combination of innovative interpretation of the agreement and institution of policy solutions. After all, an interpretation set out by the Ministerial Conference or General Council can resolve any textual uncertainty as demonstrated by the Doha Declaration itself. One possible interpretation to be applied to the TRIPS agreement is that while Article 31(f) states compulsory licensing is only for domestic market Article 30 makes some concessions for international licensure under certain qualifying criteria. This article can be interpreted to allow one WTO member to give effect to a compulsory license on behalf of another member, who lacks the production capacity, for export to that other member. Since under Article 30 a country is allowed to provide limited exceptions to patent rights given that certain other criteria are met, discussed in further detail below, and by taking into account that a member can adopt measures necessary to protect public health and nutrition needs under Article 8.1. While there may still be challenges over how far an interpretation may be stretched to accommodate a given purpose, and the need to adjust the nuances in the language to suit that purpose. The interpretative approach is still a better option for members to support since unlike an amendment that requires a majority vote, the Ministerial Conference or General Council merely pass an interpretation allowing for a more rapid solution to be reached, mitigating the social cost of a time consuming process.

In addition, by also addressing policy solutions that deal with re-

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15 While the main focuses of today’s solutions for paragraph 6 revolve around the 2005 proposed amendment the focus prior to Doha was the use of interpreting Article 30 in light of Article 8 to achieve access to medicines for all countries. Supra, Abbott at 15-18, 23-24, and 25-26.

16 Id.

17 Discussing the nuances and textual uncertainties that can be resolved by means of the adoption of an interpretation by the Ministerial Conference and advantage of this method over the amendment method. Id. at 35
importation of goods, infrastructure, and instituting healthcare systems we can guarantee that the people who truly need the medicine will have access to it. Also we can assure ourselves that they will also have access to a stable and steady supply, and access to professionals that can administer the medications and counsel patients on their use. Therefore, the first section of this article will discuss the problems that remain with access to medicines since the Doha Declaration was issued. The second section will discuss the differing solutions proposed to the paragraph 6 dilemma, and the last section will set out the conclusion of which is best suited to fulfill the needs of both the LDCs and the developed countries.

I. TEN YEARS AFTER THE DOHA DECLARATION AND THE PROBLEM WITH ACCESS REMAINS

All countries can agree that every person has a fundamental right to health and well being, however, what we can’t agree on is at what price. This is what brought forth the discussions at the Ministerial Conference, the Least Developed Countries (LDC) did not agree with the inaccessibility of medicines to their people because of their outrageous costs. The original pharmaceutical companies who have patents in those medicines on the other hand would say that the cost of the medicine is reflective of the research and development that went in to developing them. Therefore, without being able to charge what they need to recoup those efforts no one would bother with any research and development for any diseases.18 The Doha Declaration was supposed to help solve these issues and bring the costs down so that all countries regardless of manufacturing capacity could afford to look after the health of their citizens.

Nevertheless since the discussions at the Doha Ministerial Conference in 2001 and the various agreements designed to provide a solution to the Paragraph 6 dilemma over the past decade nothing has really changed in regards to a greater access to medicines. The waiver agreed upon in 2003 remains in place, however, it has not been widely used, until recently, for fear of the repercussions that might ensue against the user by the developed countries. In addition to the waiver the proposed amendment has yet to be ratified by the majority of member states therefore it is still not in force. The longer the amendment takes to be ratified by the majority of members the more people will come to ponder whether it was a good idea to head down that path and whether the majority of states agree with it at all.

In order to make clear whether the amendment was the proper choice as a solution to the paragraph 6 dilemma we need to evaluate what the current

problem is with access to medicines and problems with the current solution as it stands. In what follows, I will outline a few of the current issues still facing LDCs when trying to obtain medicines.

A. Current Issues Facing Importing Countries

1. Present availability of medicines after the transition period

The most obvious issue facing LDCs is that the major generics producers like India have finally transitioned, after 2005, into adopting and enforcing all TRIPS patent standards.\(^\text{19}\) With the end of the transition period there will be more and more medicines being afforded patent protection in an expanding amount of countries; therefore, leaving many LDCs to wonder were they will be able to acquire those generics from. For instance, starting in 2005 India began to go through the patent applications that had been collected from January 1, 1995 to December 31, 2004, and begin their evaluation of them for patent protection for the proscribed 20 year term, including pharmaceutical products, which previously were not patentable.\(^\text{20}\) However, since prior to this transition India took full advantage of its own 10 year transitional period, it was able to develop and maintain one of the leading global generic pharmaceutical manufacturing regimes.\(^\text{21}\) However, it is this access to generics that the LDCs fear they are losing due to the end of the transitional phase. The determining factors in whether people will still have access comes down to the pricing structures put in place by the patent holders and the legal framework placed upon them by the countries under which the patent was granted.\(^\text{22}\)

Not all people are pleased with the transition into full compliance with TRIPS, and therefore, several Indian generic drug manufacturers have considered moving their manufacturing operations to Bangladesh since there they can take advantage of its LDC status and longer transitional period, which lasts until 2016.\(^\text{23}\) This in turn will provide some relief to

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\(^\text{20}\) Discussing India’s supposed patent “mailbox” which is no being reviewed. \textit{Id.} at 934.

\(^\text{21}\) \textit{Id.}

\(^\text{22}\) Discussing the end of the transitional phase for the mid-developed countries and the changing scope of generic medicine availability around the world. \textit{Id.} at 928.

other LDCs since they will still have access to certain medicines at a more cost effective price.

2. The fear and complication in the use of compulsory licenses

Both the August 2003 waiver and the 2005 Amendment, reaffirm a member’s right to issue a compulsory license when the state determines that there is a national emergency or case of extreme urgency. However, it has only been until recently that these measures have been utilized by countries because of fears of repercussions (i.e., sanctions) imposed on them by the developed countries thus furthering the feeling of the North-South divide. As will be seen by the situations below the threat of retaliation by the developed world is very much real even though sometimes the developed countries want to make use of compulsory licensing themselves when they feel that their population is being threatened.

The first three situations being discussed all ended with threats of sanctions and placements on special watch lists for countries that do not provide "adequate and effective" protection of intellectual property rights or "fair and equitable market access". However, the last case did not end up in that manner, but did take over three years for the LDC to receive the medicines it needed.

a. The Brazil, Taiwan, and Thailand Situations

As stated previously the Doha Declaration was meant to alleviate some of the issues dealing with access to medicines by stating that when a country does not have manufacturing capability it has a right to issue a

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24 See Paragraph 6 Decision, supra note 10; and supra TRIPS Amendment at n. 11.

25 Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 J.L. MED. & ETHICS 247 (2009) (tracing the relevant legislative history pertaining to compulsory licensing of patented pharmaceuticals and the effect of the waiver to, and amendment of, Article 31 of the TRIPS Agreement and the impacts these agreements have had on the LDCs).

26 The US faced an anthrax scare shortly after 9/11 and fearing that it would occur again both the US and Canada decided they needed to stockpile on the antibiotic used for treatment. Canada immediately overrode Bayer’s patent, German Company, while the US made the threat of doing so. The US garnered criticism for these actions in such that it is against LDCs doing the same for HIV/AIDS drugs, but the US government feels that it has the right to. See, Sharifah Rahma Sekalala, Beyond Doha: Seeking Access to Essential Medicines for HIV/AIDS Through the World Trade Organization, available at: http://siteresources.worldbank.org/INTRAD/Resources/SSekalala.pdf
compulsory license and find an exporting country that will produce the medication for them.\textsuperscript{27}

The first case of resistance against compulsory licensing is that of Brazil in February 2001, which was prior to the Ministerial Conference in Doha.\textsuperscript{28} The US was against Brazil’s position that if a patent was not worked within 3 year’s of its issuance then it could therefore grant a compulsory license stating that it was against the TRIPS provisions.\textsuperscript{29} During this time Brazil had begun to initiate a successful HIV/AIDS treatment program using generic antiretrovirals (ARVs) free of charge, and the threat of compulsory licensing worked to gain them major price concessions.\textsuperscript{30} However, once the threat of licensure was gone the US withdrew its case from the WTO.\textsuperscript{31} This would not be the last time that Brazil found itself in a compulsory license dispute. Once Brazil came into compliance with the TRIPS agreement in 2005, the previous tactic was no longer available. Therefore, the cost of such medications became a serious issue for the country who decided to threaten to introduce compulsory licensing again, but this time under the permissive rules of the Doha Declaration.\textsuperscript{32} Again with the threat of licensure at hand the pharmaceutical companies conceded, and the flexibilities of the agreement were not contested.\textsuperscript{33}

The second case dealing with compulsory licensing under Doha, involved Taiwan, who in actuality was the first country to issue a license on the grounds of public health.\textsuperscript{34} The Taiwanese government feared the potential for an influenza pandemic and exerted pressure on the patent holder Roche to permit the licensure of the drug for manufacture.\textsuperscript{35} When

\textsuperscript{27} The process of using the compulsory license regime set up by the WTO will be discussed in greater detail in section III.A.


\textsuperscript{29} Discussing that the grant of a license under such conditions was in actually a protective industrial measure inconsistent with the TRIPS Agreement. See, \textit{Id.}

\textsuperscript{30} \textit{Id.}

\textsuperscript{31} \textit{Id.}

\textsuperscript{32} Bradford Kerry V, Lee K. \textit{TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?} 3 Globalization and Health 3, 3 2007.

\textsuperscript{33} \textit{Id.}

\textsuperscript{34} Discussing the Taiwanese compulsory license dispute over Tamiflu. See, \textit{Id.} at 4.

\textsuperscript{35} \textit{Id.}
the government decided to issue the compulsory license it came with safeguards to minimize damage to it’s trading economy including: domestic use only till 2007, utilization of all Roche supplied drugs prior to using local supplies, and the compulsory license would be revoked once an agreement between the government and Roche had been reached.\textsuperscript{36} Despite having the public health rationale for invoking the compulsory license the Taiwanese government still feared repercussions against it, and therefore went the extra length to ensure that its trade would not suffer.

The last case occurred in Thailand and is one of the most notable cases due in part to the US Trade Representative (USTR) placing Thailand under the 2007 Special 301 “Priority Watch List Surveillance”, which will be explained in greater detail below. In November of 2006 the Thai government authorized the manufacture of a generic version of efavirenz (used to treat HIV/AIDS), and for the importation of the same from India until their local manufacture was stabilized.\textsuperscript{37} The US government questioned the validity of these actions along with the patent holder Merck, who conceded they were in their rights to issue a license, claimed the negotiations for a license were not substantial enough, and pressed the Thai government to rescind the authorization.\textsuperscript{38} In response to this in 2007 the Thai government issued two more licenses, another for the treatment of HIV/AIDS and one for the prevention of strokes and heart attacks (Plavix), which was seen as a serious attempt to override patent rights.\textsuperscript{39} 

\subsection*{i. Special 301 Watch List}

In response to these further licensures the US government retaliated against the Thai government, even though they were within their rights under the Doha Declaration, by being placed under the Special 301 Watch List and threatening to terminate Thai’s Generalized System of Preferences privileges to export certain products to the US at either low or no tariffs.\textsuperscript{40}

\begin{footnotesize}
\begin{enumerate}
\item Id. 
\item Discussing the several public licenses issued by the Thai government from 2006 to 2007 under the premise of the public’s health as provided for in the Doha Declaration. Id. at 4.
\item Id.
\item This hostile response by the US government when even the patent holder confirms the Thai government is within it’s rights under TRIPS is a serious demonstration of what countries face when trying to ensure for their citizens public health under the Doha Declaration. See, Id.; see also, Reichman, supra note 25, at 258.
\item The threat of and actual retaliation against LDCs for the use of the compulsory licensing is no more evident than in the case of the US versus the Thai government.
\end{enumerate}
\end{footnotesize}
However, what exactly is the Special 301 Watch List and why is it such a threat? The Special 301 is produced each year by the United States Trade Representative (USTR) who must identify countries which do not provide "adequate and effective" protection of intellectual property rights or "fair and equitable market access to United States persons that rely upon intellectual property rights".\(^4\)

Taiwan was only until recently on this special watch list however, since the USTR believed it was improving Intellectual Property Rights (IPR) protection and enforcement, it was removed from the list in 2008.\(^4\) In order to be removed from the list the US had mandated that three issues be addressed. These issues were: 1) establishment of a Special IPR Court, 2) continuing efforts to improve implementation of the Action Plan for Protecting Intellectual Property Rights on School Campuses, and 3) progress toward passage of amendments to the Copyright Law that provide incentives for Internet service providers (ISPs) to cooperate in addressing infringing activities by users on their networks. The USTR website maintains that these procedures are merely to encourage and maintain effective IPR protection and enforcement worldwide; however, they are often used to retaliate against other countries with who the US believes their policies are against American enterprises.\(^4\)

In both these cases the US could have brought the member country that it believed to be abusively issuing a compulsory license before the WTO dispute settlement panel. However, that is what did not occur, in case of Thailand, instead the US chose to impose its own sanctions which can be seen as an illegal action by the USTR.\(^4\) Therefore, while the Doha

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\(^4\) There has already been a panel decision criticizng the USTR for it’s use in the past of the Special 301 lists in regards to TRIPS-related matters and even discussion of possible sanctions being authorized if such acts continue. See Reichman, supra note 25, at 258-259.
Declaration has maintained that there is nothing in the TRIPS Agreement that goes against a country's right to protect the public health and well being of its citizens, there are still the issues of the possible reactions and retaliations of the developed nations which serve to discourage the LDCs use of the compulsory license provision. This in turn endangers the very existence of both the Doha Declaration and the proposed TRIPS Amendment because the LDCs do no wish to provoke any other their trading partners for any reason even if it is to exercise their rights. As demonstrated from the text above these fears are justified and very real. However, it is not just the fear of retaliation that hinders compulsory licenses it is also the daunting task of not only navigating the procedure instituted by the WTO, but also any added procedures instituted by the exporting nations.

b. Rwanda the First User of the WTO Provision

In 2004, Canada passed its Canada’s Access to Medicines Regime (CAMR), which is meant to allow for the production and exportation of generic drugs to those countries that lack their own manufacturing capabilities. Rwanda in 2007 became the first country to notify the WTO of its intent to use the CAMR in order to import ARVs thus triggering the first set of back-to-back compulsory licenses under the 2003 waiver provision. The main steps involved in the WTO procedure for compulsory licensing involves several steps including: (1) notifying the WTO of intent to import; (2) proof of inability to manufacture domestically; (3) indication of type of product and quantity needed; and (4) request voluntary license. After these steps are completed then both the importing and exporting countries have their own duties such as, issue the compulsory license and determine royalties (importing country), and prepare the drugs for shipment after production (exporting country).

However, besides the already cumbersome requirements from the WTO the CAMR is itself fraught with deficiencies and more procedural hoops for


47 See Reichman, supra note 25, at 250.

48 This step in the WTO procedure is not required in cases of extreme urgency or national emergency or in cases of public non-commercial use. See TRIPS Amendment, supra note 11.

49 Id.
the LDCs to jump through. The CAMR is a complicated application process for countries to undertake, only includes a limited list of eligible medicines, restrictions on NGOs as eligible importers, requirements to declare a national emergency, and restrictions that prevent re-exportation to facilitate bulk procurement.\(^{50}\)

After Rwanda managed to navigate its way through these layers of bureaucracy and procedures it still took three years from their initial notification date to get a modest shipment that was only enough to treat 21,000 people for a single year, and managed to convince\(^{51}\) them not to try and repeat the experience in the future.

The sheer complexity of having to navigate the system set up by the WTO not to mention any legislative procedures set up by the exporting countries can prove to be too much for the LDCs. These systems are setup to help the LDCs achieve their and the WTO’s goals of access to medicines with the false impression that the LDCs will be able to figure these systems out on their own accord. For these reasons these system can prove to be too overwhelming, forcing many to shy away from utilizing the WTO notification system and the fear of retaliation stops many others from using the threat of licensure thereby leaving the LDCs back where they began prior to the Doha Declaration.\(^{52}\)

3. Bilateral and regional trade agreement issues

The confusion and difficulty with having to navigate through bureaucratic systems are not the only issues facing LDCs access to medicines there are also the barriers setup through bilateral and regional trade agreements. These agreements, also known as TRIPS plus, have been focused on compulsory licensing, ensuring that parallel imports of these medicines do not occur, and include provisions for data exclusivity.\(^{53}\) These negotiations are pursued by the industrialized nations, in order to regain what was lost in the Doha Declaration, and are agreed to by the LDCs for the opportunity to expand into a more lucrative market.\(^{54}\) For example, the Free Trade Agreements (FTAs) negotiated between the US and several other countries all have provisions restricting when and under what conditions a compulsory license may be issued like, only after the

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\(^{50}\) See Cohen-Kohler, supra note 47.

\(^{51}\) See Reichman, supra note 25, at 255.

\(^{52}\) For a more complete discussion on the LDCs and others thoughts on systems like the CAMR and manners in which these situations can be avoided see Cohen-Kohler, supra note 47.

\(^{53}\) See Bradford Kerry, supra note 32, at 5.

\(^{54}\) Id.
patent on the product has expired and detailing what constitutes a national emergency. In addition to these restrictions the agreements have also focused on the data exclusivity. This data exclusivity guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity. This gives the original pharmaceutical companies another 6 or 10 years of market exclusivity, plus the time it takes to register and market the generic medicine, which could be another 1 to 3 years. The inclusion of these restrictions within FTAs thereby disallows any LDC from sustaining its own generic capabilities since they are precluded from having access to the original test data which prevents the regulatory authorities from assessing, by comparison and use of the protected data, the safety and efficacy profile of a generic medicine.

Requirements such as the ones mentioned above are slowly chipping away at the rights granted and reestablished within the Doha Ministerial Conference. LDCs agree to have these rights hijacked from them because they wish to ensure a more lucrative trade market. However, the public needs to take a step back and reevaluate how all these policies are affecting public health and reassess what needs to be done in order to maintain the collective goal of access to medicines.

B. Issues Facing LDCs Beyond Mere Manufacturing Capabilities

The solutions presented in response to the paragraph 6 issue of the Doha Declaration all focus on the lack of capacity in manufacturing with the need for importation, however, this singular focus is a crucial problem with the solution proposed and accepted by the WTO. The Waiver/Amendment solution is faulty since it does not address the full gamut of what the problems are in the LDCs namely, the lack of infrastructure, health care systems, and personnel. A proposed solution incorporating these policy alternatives however, will be further discussed in the section that follows.

55 Detailing the FTAs setup between the US and places like Mexico, Canada, Australia, Morocco, Southern African Customs Union, Jordan, and Singapore to name a few. See Bradford Kerry, supra note 32, at 5.


57 Id.

58 See Matthews, supra note 23, at 98. Discussing the various policy alternatives to solving the access to medicines issues.
II. SOLUTIONS TO THE PARAGRAPH 6 DILEMMA

As can be seen from the preceding text even though a solution was posed through an amendment pending by which the WTO wishes to help solve the crucial dilemma involving access to medicines, the solution has not be enough. There are still too many issues left open with the current framework thereby demonstrating that another look at the solutions proposed during the original Doha discussion is needed in order to determine what else can be done. Therefore, to ensure that the proposed solution, the Amendment, is the proper one this section will reevaluate several of the paragraph 6 solutions proposed. Specifically this section will explore the Amendment to TRIPS, the innovative interpretation of TRIPS, and some policy alternatives to solving paragraph 6.

A. Amendment to the TRIPS Agreement

The issue that was the main concern during the Doha Ministerial Conference was in regards to TRIPS Art. 31(f) which states:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: . . . . (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.\(^{59}\)

Article 31(f) is seen as confining the compulsory licensing solely for the use of the domestic market of the country that issues the license. Thereby, this article prevents the use of compulsory licensing for rendering aid to a country in need of generic medicines and who does not have the production capabilities or whose own capabilities are insufficient.\(^{60}\) This idea that LDCs or any other country would not be able to have access to medicines in times of national emergency or extreme urgency is what drove the talks leading to the special adoption of the Doha Declaration. The Doha Declaration reaffirmed the flexibilities found within the TRIPS agreement for countries to institute regulations that favor public health while at the same time pointing to the issue of those countries who have no means to solve.


manufacture medicines of their own.\textsuperscript{61}

Therefore, in August of 2003, an interim waiver under the TRIPS Agreement was created that allowed one member country to export pharmaceutical products made under compulsory license to least developed and certain other members.\textsuperscript{62} The waiver procedure could be applied to all forms of pharmaceutical products needed to address public health, and was only meant to be a temporary solution until the amendment of the TRIPS Agreement.\textsuperscript{63} The waiver procedure consisted of the needy country issuing a compulsory license then seeking help from another country with capacity that would in turn would also issue a compulsory license for the requested medication.\textsuperscript{64} Once this had been done and if the supplying country had complied with the specified registration and packaging requirements then, it could produce the medicine solely for export to the needy country.\textsuperscript{65} In addition to these requirements, the patentee still had to be paid adequate remuneration, only once, in the exporting country based on the conditions of the importing country.\textsuperscript{66} Therefore, the waiver worked off of back-to-back licensing for an LDC to seek generic medications without the interference of the patent holder and with full support from the WTO.\textsuperscript{67}

After several more years of negotiations the WTO reached the decision in December of 2005, to transform the August 2003 “waiver” into a permanent amendment of TRIPS.\textsuperscript{68} As previously stated, the main steps involved in the WTO procedure for compulsory licensing involves several steps including: (1) notifying the WTO of intent to import; (2) proof of inability to manufacture domestically; (3) indication of type of product and quantity needed; and (4) request voluntary license.\textsuperscript{69} After these steps are completed then both the importing and exporting countries have their own duties such as, issue the compulsory license and determine royalties.

\textsuperscript{61} See Doha Declaration, supra note 3, at para. 4-6.
\textsuperscript{62} See Paragraph 6 Decision, supra note 10.
\textsuperscript{63} See Paragraph 6 Decision, supra note 10; see also, Reichman, supra note 25, at 249.
\textsuperscript{64} Id.
\textsuperscript{65} Id.
\textsuperscript{66} See Reichman, supra note 25, at 249.
\textsuperscript{67} Id.
\textsuperscript{68} See TRIPS Amendment, supra note 11.
\textsuperscript{69} This step in the WTO procedure is not required in cases of extreme urgency or national emergency or in cases of public non-commercial use. See TRIPS Amendment, supra note 11.
(importing country), and prepare the drugs for shipment after production (exporting country).\(^{70}\) There are two forms of notification under the WTO procedure: first, the general intent notification to make and use of the system as an importing country\(^{71}\), and second, pertaining to use of the system in certain specific transactions.\(^{72}\) For example, the certain specific transaction that the second use pertains to could be notification of use of the system solely as an exporting country. In order, to be eligible to import under this licensure provision a country needs to attest to having insufficient or no capacity for manufacturing. When this is done the importing country can exclude the production facilities either owned or controlled by the patent holder, and the evaluation is only done for the specific medicine in question, therefore, it does not look to the country’s pharmaceutical industry as a whole.\(^{73}\)

As for procedures that only affect importing or exporting members they are as follows. If an importing member is an LDC or there is no patent in the country of import there is no requirement to issue a compulsory license.\(^{74}\) However, if the member country does not fall in one of the above categories then it must notify the WTO of its intent to issue the compulsory license prior to its issuance. In addition to issuance and notification requirements, there is also the requirement of negotiation with the patent holder. However, if the importing nation is looking to import medicines for noncommercial public use to deal with a case of national emergency or extreme urgency then this prior negotiation does not apply.\(^{75}\) There are also requirements imposed on the WTO that state that an importing member must specify the name of the product(s), the expected quantities, and notify the council of such.\(^{76}\) However, if the amount originally specified changes then the importing member must merely notify the WTO of the change in circumstances. This can prove to be difficult for the importing country

\(^{70}\) *Id.*

\(^{71}\) The LDCs do not have to notify the WTO in this manner since they are already entitled to use the system to gain access to medicines.

\(^{72}\) *See* Abbott and Reichman, *supra* note 19, at 937-938.

\(^{73}\) *See* Abbott and Reichman, *supra* note 19, at 939. Describing the manner in which a country other than an LDC must determine it’s manufacturing capabilities.

\(^{74}\) *See* Abbott and Reichman, *supra* note 19, at 940. Describing the regulations imposed upon importing members.

\(^{75}\) *See* TRIPS Amendment, *supra* note 11; *see also*, *Id.*

\(^{76}\) *See* TRIPS Amendment, *supra* note 11; *see also*, Abbott and Reichman, *supra* note 19, at 941.
since it is almost impossible to know exactly how much of any one medication will be needed, and more time will invariably be expended in modifying any request to the WTO to represent the changing circumstances. In addition, in the case of a sudden emergency or extreme urgency in the time it takes for the importing country to navigate its way through the bureaucratic red tape to get the license approved by the WTO several thousands of lives may have been lost in the process.

Under the WTO amendment procedure, the exporting member is also required to issue a compulsory license under certain specified conditions. Those conditions are laid out in Paragraph 2(b) of the Annex to the TRIPS Amendment as follows: only the amount necessary to meet the needs of the importing member; products under this license must be clearly identified as such through special labeling, marking, and special product packaging; and prior to product shipment the licensee must post on a website the quantities being supplied to the destination and the distinguishing features of the products. These conditions can also prove to be a burden to the exporting country. For example, if the exporting country will only be able to produce the amount necessary to satisfy the importer’s needs with the added distinguishing features to the product and its packaging then invariably the price of the production will be more costly than if the licensee was able to produce thousands of orders simultaneously. Therefore, one solution to this would be for LDCs to pool together their respective licenses therefore, bringing the costs down on the production thus making it more worthwhile for an exporting country to take up the endeavor.

77 (b) the compulsory licence [sic] issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence [sic] and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence [sic] shall be clearly identified as being produced under the system through specific labelling [sic] or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website7 the following information:

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above.
Aside from these notifications the WTO also provides that the patent holder must be reasonably compensated as was previously decided for the 2003 waiver.\textsuperscript{78} Also the importing countries must take preventative measures to ensure that there will be no diversion or parallel importation of the products manufactured under this licensure agreement.\textsuperscript{79} The WTO also added a provision in the amendment that expressly prohibits any cause of action against any member who issues a license in conformity with the amendment.\textsuperscript{80}

However, for this proposed amendment to become a permanent fixture of the agreement as Article 31\textit{bis}, it needs the ratification of two thirds of the WTO’s 153 members.\textsuperscript{81} The two thirds majority is an alternative in the absence of a consensus, however, by using this method to pass the amendment it will only become binding on Members that accepted it.\textsuperscript{82} In addition, if the amendment is adopted by three-fourths majority as binding on all Members, those who did not accept it may simply withdraw or if they do not wish to withdraw ask the consent of the Ministerial Conference to remain as Members without accepting the amendment.\textsuperscript{83} Yet as of December 2010 only 32 members have ratified the change and an extension for 2011 was issued.\textsuperscript{84} The problem with trying to amend an international agreement is that it is an overwhelmingly time consuming process because many constitutional systems require legislative consent in order to amend a treaty, and this can take a long time to pass through each nation’s legislative procedures.\textsuperscript{85} The longer the amendment takes to be ratified by the majority of members the more people will come to ponder whether it was a good idea to head down that path and whether the majority of states agree with it.

\textsuperscript{78} See TRIPS Amendment, supra note 11, at Art. 31\textit{bis} Para. 2.

\textsuperscript{79} See Id. at Para. 3; see also, Abbott and Reichman, supra note 19, at 944. Describing the regulations imposed upon importing members to ensure that the re-exportation and diversion of the products does not occur.

\textsuperscript{80} This provision in Para. 4 was meant to help alleviate some of the fears held by the LDCs which had stopped them from making use of the waiver provision in the past. The provision is found in TRIPS Amendment, supra note 11, at Art. 31\textit{bis} Para. 4.

\textsuperscript{81} Complete list of all 153 members along with dates of membership, supra note 12.

\textsuperscript{82} WTO, Marrakesh Agreement Establishing the World Trade Organization, Art. X.1 and X.2, available at: \url{http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm} [hereinafter Marrakesh Agreement].

\textsuperscript{83} See Marrakesh Agreement, supra.

\textsuperscript{84} For a list of which WTO Members have accepted and ratified the TRIPS amendment, see supra note 13.

\textsuperscript{85} See Abbott, supra note 14, at 33.
One of the major criticisms of both the waiver and amendment solutions is that fact that it imposes to many bureaucratic obstacles in order to make effective use of the compulsory licensing provision. Therefore, while the amendment does serve the purpose of ensuring that all countries have access to the medicines that they need it does not do it in the most practical or simple manner neither does it provide for the importing country to get them in a prompt manner. The reason for this could be that while the LDCs were petitioning for greater access to medicines for the sake of public health the more developed countries were negotiating on behalf of their pharmaceutical industry, which did not want to give any ground in respect to their IPRs. The result then is this amendment, which can be seen by either side as not being exactly what they wanted, but under the given circumstances was the best solution that could be mutually agreed to. In light of that I believe that if these negotiations were held again today the outcome may well come out the same or perhaps all sides would just come to an impasse.

B. Innovative Interpretation of TRIPS Under Article 30

Prior to the discussions involving a waiver or amendment to TRIPS Article 31(f) others had proposed to interpret Article 30 as giving allowance, as a limited exception, for the compulsory licensing to aid an LDC. The reason for this is that Article 30 states that

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.

As can be seen from the text above Article 30 can be used to allow for the compulsory licensing of a medication provided that the following requirements are met: it must be limited, not unreasonably conflicting with the normal exploitation of the patent, and it must not unreasonably prejudice the legitimate interests of the patent owner, while still taking into account the legitimate interests of any third party. In addition, if any

86 See Abbott and Reichman, supra note 19, at 932.
87 See e.g., Abbott and Reichman, supra note 19, at 932-33. Discussing the differing reasoning’s why the amendment as it stands is fraught with problems.
88 TRIPS Agreement, supra note 60, at Art. 30. (emphasis added)
89 Id.; see also, Abbott, supra note 14, at 15.
WTO member would want to make legislation that gives Article 30 this effect they would need to do so in light of Article 8.1, which identifies that members “may adopt regulations or legislation necessary to protect public health and nutrition as long as such measures are consistent with the provisions” of TRIPS. However, there were several member countries that agreed for a stricter reading of Article 30, like the US. On the other hand, members like the EC and Brazil are for this solution and even proposed that the interpretation of Article 30 could be used to supply generic medicines to others. Yet, as of June 2002 the EC began to have changing emotions as to whether there was sufficient scope within the agreement for such an authoritative interpretation however, despite this the European Parliament proposed an Article 30 solution in October of 2002 for compulsory licensing.

Even more doubts were raised after the WTO dispute settlement involving the Canada Patent Act case, wherein the three conditions listed previously were enumerated and stressed the strict limited nature of the exceptions allowed. The panel did state that Article 30 is like Article 9(2) of the Berne Convention (copyright fair use) in that it allows similar exceptions for the grant of compulsory licensing on health grounds however, it would be difficult to meet the requirement dealing with the conflagration of the patent holder’s rights since a compulsory license does not allow a patentee to exploit their rights as they see fit. However, when the provision is looked at through the lens of Articles 7 and 8 which have been indicated to state the object and purpose of the TRIPS Agreement which must be borne in mind when examining any provisions of the Agreement including those measures taken by members to meet their respective health objectives. Therefore, reading Article 30 in light of Article 8 suggests that the measures adopted by members to address public health should be deemed to be in compliance with TRIPS thereby shifting the burden of

90 See TRIPS Agreement, supra note 60, at Art. 8.1.
91 See Matthews, supra note 23, at 88.
92 See Id. at 89-90.
93 Id. at 89.
94 See Canada-Patent Protection of Pharmaceutical Products Case, WT/DS114/R 17 March 2000, [hereinafter Canada Case]; for discussion of the Canada Case see Id. at 89-90.
95 Discussing the negative impacts of the Canada Case on the continuing evaluation of Article 30 as a legitimate solution to paragraph 6. See Id. at 91-92.
96 See Canada Case, supra note 95; see also, Correa, supra note 61, at 24.
proving otherwise to the complaining member. 97

In addition, if members were to decide to use the Article 30 interpretation instead of the proposed amendment they would find that the process is more streamlined and simpler to implement due to the lack of amendment required or parliamentary approval, and the exporting member would not have to grant case-by-case compulsory licenses. 98 The reason for the lack of parliamentary approval is that an interpretation of TRIPS allowing for the use of compulsory licensing to aid LDCs access to medicines could be adopted by the Ministerial Conference or General Council in much the same way that the Doha Declaration was adopted. However, the only issue with this is that an interpretation given by a panel or appellate body is not binding on all members, who may decide not to adopt this interpretation given their right to exclusive authority to adopt interpretations under Article XI.2 of the Marrakesh Agreement. In addition, to the ease of instituting such a solution the current proposed solution, the TRIPS Amendment, also leaves open a member’s right to exercise other rights as allowed for under TRIPS thereby saying it is permissible to use Article 30 for these very purposes. 99 After all, the argument can be made that the patent holder’s rights will not be conflicted within the exporting member’s market since none of the medicines produced will be sold there thereby allowing the compulsory license to be invoked under Article 30. 100 The only question to be settled under this provision would be to determine the patent holder’s expectations in the importing market, which could be offset by the circumstances within that market that led to the licensure. 101 In addition, another benefit of utilizing the Article 30 exception instead of going through the Amendment is that Article 30 permits the exportation of generic medicines to countries that are not part of the WTO since unlike the Amendment, Article 30 does not require notification to the WTO that a “member” wishes to make use of the system. Of course, the patent holder or exporting country may want some assurance to be provided that the nonmember will abide by certain conditions, like safeguards to ensure no re-exportation or diversion of the products.


98 See Correa, supra note 61, at 28. Discussing the untested alternative approach to access to medicines under Article 30.

99 See TRIPS Amendment, supra note 11, at 31bis Para. 5.

100 See also, Abbott and Reichman, supra note 19, at 957.

101 Id.
C. Policy Solutions to Address the Access to Medicines Problem

The last type of solutions that this article will analyze deals with policy solutions which were not at the center of the discussions that occurred at Doha or shortly thereafter. However, the fact that the previous two solutions discussed aren’t looking beyond the issues dealing with compulsory licenses there is a notable pitfall in that just giving someone the medications is not enough. The other issues causing barriers to access in the LDCs are: regulatory issues, high taxes/tariffs on imported drugs, manufacturing practices, licensed pharmacists, legislation for market authorization, integrity of the drug supply, and corruption. Therefore, some of the issues that need to be addressed in order to assure proper access to medicines are drug regulation in the importing country along with professional training and health services improvement. In addition, many LDC representatives have in fact stated that their ultimate goal is to create both sustainability of treatment and supply, therefore, many are looking to the future development of their own manufacturing capabilities, which is not addressed in either the Article 30 or Amendment solutions. Other sentiments that can be found recurring among several LDCs is that since each country is unique there is a need to understand and appreciate the circumstances and systems in the beneficiary countries. Without this understanding on the part of the developing countries any passage of a procedure that is perceived to benefit LDCs may be based on unfounded assumptions that the LDCs’ have the requisite knowledge and human resource capacity to make use of the regime, which may not always be true instead it may be too complicated to use. Therefore, these policy solutions look to ensuring access to medicines by addressing the wide range of issues presented above.

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102 See Cohen-Kohler, supra note 47, at 5. Discussing the other barriers that exist when it comes to access to medicines that go beyond merely manufacturing them.

103 See supra, at 3. Quoting a LDC representative as saying:

"...take for instance in my country, we also think that you don't only give us fish because we want fish, but you teach us how to do the fishing. Because as a country we must begin to think ten or fifteen years to count, what would happen if we just continue to just import from developed countries?"

104 See Id., at 3. Discussing several interviews with people at all levels of governance that must have some interaction with CAMR and gauging their opinion on its effectiveness.

105 Id.
1. Pressure for good practice companies

The first policy solution may come as a simple one, merely that investors and customer’s alike pressure companies to demonstrate good practices. It really does not seem all that difficult, after all, why would you want to put your money into an organization that uses shady practices; however, in reality it is not that simple since pharmaceutical companies expend a lot of resources in developing new medicines, getting them approved, and marketed. In so doing they also try to ensure that they have adequate protection for these products in all markets. However, we can still ask whether they are doing their part in trying to alleviate the public health crises that occurs around the globe due to the lack of medicines.

One method of confirming that they do more to help the LDCs is to follow an example by the United Kingdom (UK). Several investors in the UK in 2003 began to exert pressure on pharmaceutical corporations to exhibit good practices. In addition to pressure, a framework was drawn up by which to assess the companies commitment to this idea by looking at how enforcement of patents or licensure grants are conducted in the developing world in light of their local circumstances. One company in the early 2000s Boehringer Ingelheim, a German company, has responded to pressures by investors with the donation of medicines.

However, what is the reasoning behind this turn around in the investors thinking namely, from profits to public welfare. This can be found in a Pharmaceutical Shareowners Group summary report on the public health crisis in the emerging markets that was to be presented to institutional investors within the industry. The report stated that their reasoning stems from the “marked shifts in societal perceptions of pharmaceutical companies following the lawsuit involving 39 pharmaceutical companies and the South African government in March 2001 and the negative publicity surrounding the WTO TRIPS negotiations in 2003.”

106 The ISIS Asset Management in conjunction with the UK Universities Superannuation Scheme (USS) published an investor statement urging pharmaceutical companies and governments to improve access to medicines in developing countries. See Matthews, supra note 23, at 98.

107 It is important to have a means by which to assess a companies commitment to any goal set by it’s investors, especially when the topic concerns as in here an issue that is sensitive with the public who wishes to aid it’s fellow man. See Matthews, supra, at 98.

108 See Id. at 98.

109 The entire report goes on to lay a framework for the pharmaceutical investors as to why the public health crisis is an issue, the response of companies so far, and a basic
pressures can also be used so that the pharmaceutical corporations work their influences on the governments thereby getting them to contribute to aide organizations like the Global Health Fund or to public-private partnerships, which will be discussed below. These kinds of pressures are useful in ensuring that it is not only the government’s responsibility to deal with health crisis but also that of the patent holders.

2. Addressing differential pricing and prevention of re-exportation

An issue that truly impacts access deals with the exhaustion of rights, which the TRIPS Agreement addresses in Article 6 and Doha Declaration Para. 5(d). These provisions dissuade patent holders from offering products at the lowest prices possible in LDCs because they state that rights are exhausted once the product is on the shelves in that individual market unless that member says otherwise. Therefore to ensure access the issue of exhaustion needs to be addressed by putting procedures into place that prevents these products from being directed back to the more lucrative markets of the developed countries who want to take advantage of the lower priced medicines offered in the LDCs. Pharmaceutical companies are not comfortable with the idea of price differentials because if there is a large gap between the price of a product in the LDC and the developed market then consumers in the latter market feel as if it is an unfair price they are forced to pay. This idea of pricing being unfair then causes the idea of parallel importation to look more lucrative to people in the latter market who wish to gain access to the price that they think their entitled to.

This issue can be addressed by merely ensuring that the diversion of the products meant for the LDCs are prohibited from entering the market elsewhere. The Amendment solution does this by requiring that the products sent to the LDCs be housed in self-identifying packages to ensure that customs agents from other markets can recognize when they are intended for a different market. However, this can at times add to the cost of the medicine’s productions and thereby add to the overall amount the LDC needs to pay in order to import, but with these safeguards in place both the importing and exporting countries can be sure that the products are

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110 See Matthews, supra note 23, at 98.

111 See Id. at 99. Discussing the Pharmaceutical companies issues in regards to differential pricing and the need for prevention of trade diversion.

112 See Id. at 100.
getting to where they are needed.

3. Encouragement of research and development, and health improvements

Many of the concerns that come with the access to medicines issues also stem from the lack of research and development (R&D) and/or health infrastructure available in the least developed countries. The medicines that are being supplied to LDCs through compulsory licenses are not enough if there is no steady supply, and infrastructure or healthcare system to ensure that the people who need the medication are receiving it along with the proper instructions. Therefore, the solution proposed and adopted by the WTO needs to encourage the R&D into the diseases that LDCs are most afflicted by and the methods of ensuring that the structure is there to ensure that the patients who really need the care are getting it. One such policy is the 2003 World Health Assembly’s Resolution on IPRs, Innovations, and Public Health (WAHR), which is designed to encourage the creation of new medicines for diseases affecting LDCs with a progress report that was to be submitted in 2005. Then in May of 2006, this group prepared a global strategy and plan of action to address conditions disproportionately affecting developing countries which culminated adoption of resolution WHA 61.21 in May of 2008, to secure an enhanced and sustainable basis for needs-driven, essential health R&D for the relevant diseases with clear objectives and priorities, and the estimated funding needs in this area. The progress of this group is to be monitored and reported to the World Health Assembly twice a year from 2010.

In addition to the WHA, there have also been steps to create public-

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113 90% of global pharmaceutical sales developed countries, whereas of the 14 million global deaths due to infectious diseases, 90% of deaths occur in the developing countries therefore Member States should urge the pharmaceutical industry to reinvigorate its efforts to develop innovations that add real therapeutic advantage in treating the world’s major killer diseases, especially in developing countries. See 56th World Health Assembly, Intellectual property rights, innovation and public health, 28 May 2003, WHA56.27, available at: http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf (last accessed January 13, 2011).

114 The WHA Commission reviews the interfaces and linkages between intellectual property rights, innovation and public health in the light of current evidence and examines in depth how to stimulate the creation of new medicines and other products for diseases that mainly affect developing countries. The analysis of the Commission will take into account how intellectual property rights can promote innovation relevant to public health, and how funding and other incentive mechanisms, including institutional arrangements, may contribute to this end. http://www.who.int/intellectualproperty/documents/en/
private partnerships (PPP). These partnerships are meant to initiate research into the diseases mentioned by the WHA however, companies will provide the technology and development/distribution experience while the public sector provides the funding to ensure the medicines and vaccines get to who needs them the most. In these PPP relationships the government often times provides the strength of its purchasing power, outlines goals for an optimal health system, and empowers private enterprise to innovate, build, and manage the delivery of agreed-upon services over the term of the contract which could be anywhere from 5 to 10 years. In return, the private sector receives payment for its services and assumes substantial financial, technical, and operational risk while benefiting from the upside potential of shared cost savings. A policy solution that could be combined with the PPP system is the Global Health Fund, which is committed to financing the health improvements around the world. The only issue with this latter system is that it relies on funding from the developed countries whose commitment to financing its efforts can be difficult to receive.

These policy goals look beyond the mere delivering of medicines to the issue of what happens once the medicines arrive at those LDCs. If there is no healthcare system or infrastructure in place to ensure that the medicines being imported are going to who needs them, then there is still a lack of access.

CONCLUSION: SOLUTION TO THE PARAGRAPH 6 DILEMMA IS MORE THAN ONE

Since the Doha Ministerial Conference in 2001 there has been a lot of discussion involving a nation’s right to access to medicines. However, since that time the problem has not seemed to improve. There have been countless negotiations amongst the members of the WTO in which they strived to move towards a solution, which would balance the IPRs held by the patent owners and the LDC’s right to public health and access to

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115 These partnership initiatives have already begun as demonstrated by the Lapdap initiative between GSK, the WHO, the University of Liverpool and the London School of Hygiene and Tropical Medicine, who received funding of £2.5 million from the UK Government’s Department for International Development which lead to the approval of this malaria drug in 2003. See Lang, T. and Greenwood, B., The development of Lapdap, an affordable new treatment for malaria 3 The Lancet Infections Diseases 162 (2003).


117 See Matthews, supra note 23, at 103. Giving a brief discussion of the Global Fund and it’s commitments to public health.
medicines. Yet after all those stepping stones the LDCs still have little access to what they need in order to guarantee their people their right to public health and well being.

The solution chosen by the WTO, the amendment, was first premised by the institution of a waiver to Article 31(f) of TRIPS, which was only to last until a more permanent solution was settled upon. However, from the waivers conception in 2003 till the proposal of making it permanent in 2005 not a single country tried to invoke its use. The reasoning being that they feared the repercussions that might ensue had they tried to exercise their rights not to mention the vehement opposition of the waiver by the more developed nations. After 2005 began the long process of trying to get a majority of the WTO members to ratify the proposed amendment to TRIPS in Article 31bis. This solution, while not currently in force, is fraught with bureaucratic obstacles which LDCs find difficult to navigate through not to mention the difficulty in expending resources whose sole purpose would be to aid in this navigational this process. However, besides the procedures instituted by the WTO the other issue with trying to amend the TRIPS Agreement is that it can be an overwhelmingly time consuming process because many constitutional systems require legislative consent in order to amend a treaty. In addition, the longer the amendment takes to be ratified by the majority of members the more people will come to ponder whether it was a good idea to head down that path and whether the majority of states agree with it at all.

For the reasons set forth above I have to disagree with the WTO community in that I do not believe the amendment is the best solution for dealing with the issue of access to medicines under the TRIPS Agreement. Instead I believe that the better solution is one which addresses the licensing issue for LDCs while they have no or insufficient manufacturing capability, and that strives to address the other barriers facing their access until such time as they develop their own capabilities. Therefore, to address the first prong of the solution, the access to medicines part, the innovative interpretation of TRIPS should be chosen. The reasoning for this is that while it may not be as binding on all members as an amendment it would be simpler to pass. The Ministerial Conference or General council, as explained in Section II, would merely pass the interpretation resolving any textual uncertainty by reading Article 30 in light of Article 8.1. This would allow a country to aid an LDC without the need for back-to-back licensing or procedural notifications to the WTO thereby streamlining the procedure so long as a matter of public health was concerned. The reason for this is that a license to manufacture a product solely for the export to an LDC would meet the requirements within the article. These requirements being:
it must be limited (i.e., solely for export and not commercial domestic use), not unreasonably conflicting with the normal exploitation of the patent (i.e., not unreasonable depending on destination market expectations held by patentee), and it must not unreasonably prejudice the legitimate interests of the patent owner, while still taking into account the legitimate interests of any third party (i.e., the legitimate interest being public health as stated in Art. 8.1). In addition, making the process of licensure simpler it would also allow for the rendering of aid to countries that are not members of the WTO since there would be no notification requirement on behalf of the importing country.

In addition to ensuring that the countries can import the necessary medicines they need to be able to make use of such imports, for this reason the best solution must also involve three policy solutions. The first policy that I recommend is premised after the UK’s pressure on pharmaceutical companies to have good practices within their company. By this I am referring to realizing that they have a part to play in access to medicines, and the management of health crisis emerging in the developing nations. These good practices can be achieved by taking into account the local circumstances when it comes to enforcing a patent or determining whether to grant a license. In addition, the companies could institute a program wherein donations of medications are made to the developing nations. This would in fact benefit the companies since the products are donated and not sold the issue of whether their rights in them have been exhausted never come into play given that the products were never on the market in that country. This would facilitate the patent holder’s attempts to ensure that those products do not end up for sale in another market.

The next policy recommendation actually stems from the first in that a primary concern and hindrance to the access issue is the need to prevent the re-exportation of goods while at the same time dealing with the differing prices depending on the market. Pharmaceutical companies already have expressed unease about the use of price differentials because it can be seen as unfair to those forced to pay the higher price thereby making them want to gain access to the price that they think their entitled to from the LDC market. Therefore, to stop the diversion of products from one market to another the rights of the patent holder must not have been exhausted and/or safeguards must be put into place. For these safeguards to work the products going to the LDCs must be readily identifiable such that customs agents know when they are being brought into a prohibited market. For this we look at what has been done to prevent this already such as, the safeguards instituted under the WTO. The industry could adopt an industry wide standard in identifying generic products meant for the developing
country markets, or even by merely changing the packaging used. With these safeguards in place, the pharmaceutical companies should feel reassured that their products will not be diverted from the destination and reenter another market.

The last policy recommendation looks to encourage R&D as well as infrastructure and instituting health improvements to guarantee that the people who truly need the medicine will have access to it. However, as stated previously access to a stable and steady supply is not enough, access to professionals that can administer the medications and help implement methods of distribution to patients is also needed. This policy recommendation can be instituted in a variety of ways. For one, there is the creation of public-private partnerships, which are used to meet both the public sector’s needs and the private sector’s goals. These contractual agreements between a public agency, whether federal, state or local, and a private sector entity allow for the skills and assets of each sector to be shared in delivering a service or facility for the use of the general public. In this case the resource used by the public would be the access to medicines that would otherwise not be available. In conjunction with such partnerships are entities like the Global Health Fund or the World Health Assembly who are funded by the developing countries for the sole purpose of funding health improvements (i.e., community-based programs, healthcare systems), and to encourage the creation of new medicines and other products geared toward diseases that affect developing nations. These programs encourage R&D to be established within the developing countries since they are the intended beneficiaries. This in turn will promote the creation of the infrastructure needed for these countries to develop their own manufacturing capabilities through the transfer of technology, solely moving the world to its goal of access to medicines for all who need them.

Therefore, the best solution that can be implemented to ensure access to medicines under the Doha Declaration is not one, but a combination of solutions drafted to address the countervailing issues that LDCs face when trying to ensure their citizens right to public health.

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