Patent Protection for Pharmaceuticals: Ensuring Access to Enabling Innovation

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I. Introduction

Though people in developing countries make up around 80 percent of the world’s population, they only account for 20 percent of worldwide pharmaceutical sales. Global health research dedicates less than 10 percent of its spending to those diseases that primarily affect the poorest 90 percent of the world’s population, also known as the “10/90 gap.” Unfortunately, ensuring access to medicine in developing countries proves difficult.

In 1995, the World Trade Organization (“WTO”) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) created obligatory standards of intellectual property protection by which WTO member countries must abide. In 2001, amid mounting concern from developing countries regarding access to medicine, the WTO adopted the Doha Declaration on TRIPS and Public Health. The Declaration recognized the problem many developing countries were having with accessing necessary medicine and, as a result, held that the TRIPS Agreement should not prevent WTO member countries from protecting public health.

Although the Doha Declaration admitted the importance of intellectual property protection, it affirmed WTO members’ right to use the flexibilities of the TRIPS Agreement, which could suspend patent protection.

The right to exploit the flexibilities in the TRIPS Agreement was further emphasized in 2003 when the council announced its decision to allow developing countries that lacked the ability to manufacture pharmaceuticals domestically to issue compulsory licenses to obtain medicine from other countries. Prior to this announcement, because of the wording of Article 31 of the TRIPS Agreement, developing countries without domestic manufacturing capabilities could not utilize the benefits of compulsory licenses. The 2003 council decision made it easier for all countries to take advantage of compulsory licensing and, in doing so, authorized lesser patent protection.

However, the flexibilities provided by the TRIPS Agreement and reaffirmed in the Doha Declaration and the council decision of 2003 may not be in the best interest of developing countries. This paper considers the role of intellectual property rights in the development of pharmaceuticals by exploring the patent protection offered in the TRIPS Agreement and contrasting it with the flexibilities enhanced in the Doha Declaration and 2003 council decision. Part II provides background on the TRIPS Agreement, Doha Declaration, and council decision of 2003. This section also clarifies the importance of the patent system for pharmaceutical research, development, and innovation. Part III considers the Doha Declaration, specifically its promotion of compulsory licenses and parallel imports, and illustrates the detrimental effects it has on public health.

Part IV recommends alternative approaches that would provide medication while still protecting pharmaceutical innovation. The first approach advocates the use of data exclusivity, which protects the patent registrant’s data from generic knockoffs. The second approach supports mechanisms like cost-sharing and prize funds, which enable generic medications but provide adequate remuneration to the pharmaceutical patent holder so that they may effectively recoup the cost of their investment. And the third approach promotes price differentiation, charging different prices in different markets, to enable innovation.

This section also emphasizes the role that countries themselves play in providing access to medicines and recommends strong domestic legislation for providing access to medicine.

Finally, Part V concludes with the assertion that strong patent protection is vital for access to new pharmaceuticals in developing countries.
II. Background

A. The TRIPS Agreement

On April 15, 1994, members of the World Trade Organization (WTO) signed what has become an incredibly controversial agreement: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement requires WTO Members to adhere to defined standards of intellectual property protection while attempting to strike a compromise between the long-term objective of providing incentives for innovation and the short-term objective of utilizing existing ideas, products, and other inventions. The TRIPS Agreement covers a broad spectrum of products, but its effect on access to pharmaceuticals has raised the most concern.

The TRIPS Agreement provides flexibilities that relax its patent protection requirements. Article 31 allows for the use of a patented product without the patent holder’s authorization and thus provides the most important exceptions to the TRIPS Agreement. Member countries have interpreted Article 31 to allow for compulsory licenses and parallel imports. This interpretation has created a conflict with those in favor of strong patent protection.

B. The Doha Declaration

After the implementation of the TRIPS Agreement, WTO member nations expressed concern regarding the provisions in the TRIPS Agreement, which many believed increased the cost of medicine. The Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, addressed these concerns with the adoption of the Declaration on the TRIPS Agreement and Public Health (also known as the Doha Declaration).

The Doha Declaration emphasized the WTO’s commitment to promoting public health and affirmed the right of WTO countries to use the flexibilities of the TRIPS Agreement to meet this goal. Specifically, the Doha Declaration confirmed the use of compulsory licensing as an acceptable measure to promote public health. The Doha Declaration also pronounced the freedom of member countries to establish their own policies on the exhaustion of intellectual property rights. In doing so, the Doha Declaration gave each country the right to determine whether to authorize parallel imports.

Known as the TRIPS “flexibilities,” compulsory licensing and parallel imports serve as the central source of contention within the Doha Declaration. Though the Doha Declaration did not change any provisions within the TRIPS Agreement, it was nonetheless significant because it reinterpreted the TRIPS Agreement in a way that emphasized the right of WTO members to use these flexibilities to protect public health.

1. Parallel Imports

Parallel importation occurs when the patent holder sells a drug to a country and the buyer exports the drug to another country—without the authorization of the patent holder—where the price for the patented drug is higher. The existence of parallel imports depends on the domestic legislation of the exporting country. If the country’s domestic legislation extinguishes the rights of the patent holder once the product sells, then parallel importation will likely occur. For instance, if domestic legislation forces a patent holder to relinquish her rights to the product once it sells, then the patent holder cannot further regulate the product and has no legal right to prevent the sale of the product to a more expensive market (parallel importation). However, if the domestic legislation prohibits the exhaustion of the patent holder’s rights, then the patent holder can prevent parallel importation because she still has rights to the product.

The following example further clarifies parallel importation and illuminates the importance of the exhaustion of intellectual property rights. Suppose a pharmaceutical patent holder sells a drug into the market of Country X for $1/unit. In Country Y, the patent holder charges $2/unit. If, after selling the product, the patent holder exhausts his rights, he has no right to prevent Country X from exporting the drug to Country Y, charging a lesser amount (i.e., parallel importation), and thereby undercutting the patent holder’s desired price in Country Y. To enhance access to medication, pharmaceutical companies will often sell drugs in developing markets for discounted prices. However, the parallel importation of medicine into more expensive markets hurts these companies financially and, therefore, deters such philanthropy.

The TRIPS Agreement does not address the principle of exhaustion and parallel imports, but the Doha Declaration actually enforces them both. The TRIPS Agreement specifically reads, “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” By not addressing the topic, the TRIPS Agreement avoids encouraging WTO member countries to take a particular stance on the exhaustion of intellectual property rights. Conversely, by leaving the decision of whether to authorize the exhaustion of intellectual property rights up to the individual countries, the Doha Declaration validates the use of parallel imports.

2. Compulsory Licenses

A compulsory license is the governmental authorization to itself or a third party to use a patent without the permission of the actual patent holder. The TRIPS Agreement establishes a country’s ability to issue a compulsory license, and the Doha Declaration reinforces that right. Specifically, the Doha Declaration states, “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” The benefit of compulsory licenses, however, is a pivotal point of dispute between those who favor stronger patent protection and those who do not.

The TRIPS Agreement specifically states that WTO member countries may authorize compulsory licenses for “the supply of the domestic market of the Member authorizing such use.” This means that a WTO member country may, without the authorization
of the patent holder, authorize a compulsory license, either to the government or to someone within that country, to reproduce a patented product within its own borders and for its domestic market. A country cannot export a product produced under a compulsory license. This is problematic for those countries lacking domestic manufacturing capabilities that are thereby prevented from importing products manufactured in another country under a compulsory license. This language affected countries like Brazil and India, which heavily exported drugs to countries without domestic manufacturing capabilities, as well as the countries that relied on these imported drugs.

In paragraph 6 of the Doha Declaration, the WTO ministers recognized that countries lacking domestic manufacturing capabilities in the pharmaceutical sector could face difficulties in effectively using compulsory licensing under the TRIPS Agreement. The WTO ministers instructed the Council for TRIPS to find “an expeditious solution” so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory license. The WTO General Council adopted Paragraph 6 of the Doha Declaration on August 30, 2003.

C. The Council Decision
In 2003, the Council for TRIPS agreed to waive temporarily the domestic supply requirements of Article 31 of the TRIPS Agreement, thereby allowing countries to import products made under compulsory license in another country. The council held that the inability of least developed countries to access medicine constituted an “exceptional circumstance” warranting a waiver of the obligations in the TRIPS Agreement.

D. The Importance of Patent Protection for Pharmaceutical Development
Intellectual property rights and patent protection serve as a critical stimulus for pharmaceutical innovation. In contrast to many other research-intensive industries (such as the computer industry), the pharmaceutical industry heavily relies on patent protection. Pharmaceutical companies view patents as a necessity because of the extremely lengthy, expensive, laborious, and risky research and development process for pharmaceuticals. From the discovery of the drug to Food and Drug Administration (FDA) approval takes ten to fifteen years, and only one out of every five thousand medicines tested receives FDA approval. Prior to the introduction of a new drug, research and development results in a negative cash flow for pharmaceutical companies. Because the majority of drugs are not successful, pharmaceutical companies must recoup the costs of their investments in their highly profitable drugs. Thus, these few successful drugs serve as the money making source and thereby sustain the company.

Competition from generic drugs provides substantial risk to the investment of pharmaceutical development, thus, without patent protection, the pharmaceutical company’s investments in research and development are jeopardized. The upfront costs associated with pharmaceutical production, such as research and development, account for 70 percent of the drug cost, while manufacturing accounts for only 30 percent. Thus, absent patent protection, a generic drug manufacturer could reproduce the drug for a fraction of the cost and sell it for less than the patent holder. Because the manufacturing costs are significantly less than the research and development costs that the patent holder pays, the generic manufacturer does not have to recover this expense in the form of higher prices. When the same product is sold in the same market for two different prices, consumers will most likely buy the less expensive generic version. Thus, the patent holder takes on all of the cost of creating the drug and gets little in return.

Because it takes many years to recoup the high costs associated with drug research and development, an effective patent life is a particularly important economic incentive for innovation. Absent a period of restricted competition, pharmaceutical creators cannot recoup their research and development costs and will lack any incentive to continue to develop new drugs. Thus, patent provisions serve as the primary incentive for commercial enterprises to undertake research and development on new and innovative pharmaceutical products.

II. Analysis
A. The lack of patent protection established in the Doha Declaration contradicts the intent of the TRIPS Agreement.

The preamble to the TRIPS Agreement presents the desire among WTO members to promote international trade, which the TRIPS Agreement recognizes as requiring adequate and effective protection of intellectual property rights. However, the patent protections encoded in the TRIPS Agreement, which prevents against the unauthorized use of the product by a third party, are essentially eviscerated in the Doha Declaration’s commitment to compulsory licensing. The TRIPS Agreement focuses predominantly on the importance of intellectual property protection and recognizes the dependency of innovation on intellectual property protection, whereas the Doha Declaration takes a substantial step back from this position by relinquishing a large portion of the patent owner’s exclusivity by permitting compulsory licensing and parallel imports.

Though the Doha Declaration recognizes the importance of intellectual property protection in developing new medicines, it declares that a decrease in patent protection through compulsory licenses is essential to promoting public health. The Doha Declaration notes that the development of new medicine relies on intellectual property protection but simultaneously proclaims that the TRIPS Agreement should be read in a manner that promotes public health, particularly, universal access to medicine. In order to enhance public health and access to medicine, the Doha Declaration states that WTO member countries have the right to issue compulsory licenses. Ironically, as is argued in the following paragraphs, by utilizing compulsory licensing as a vehicle to advance public health, the Doha Declaration actually demeans public health because compulsory licensing leads to decreased innovation in pharmaceutical products and grossly subpar medicine.
B. The Doha Declaration’s objective of enhancing public health in developing countries through compulsory licensing and parallel imports is ineffective because the Doha Declaration actually decreases incentives for pharmaceutical companies to enter the market.

The patent protection intended under the TRIPS Agreement increased the incentive for investment by providing a period of restricted competition, which would generate enough revenue to enable patent holders to pay off the cost of their investment in the product. However, the Doha Declaration’s allowance of compulsory licensing and parallel imports weakened the integrity of the patent and thereby decreased the incentive to conduct research and development for much needed medication. By permitting the use of compulsory licenses and parallel imports, the Doha Declaration substantially decreased the amount of money that patent holders can potentially earn and thus destroyed the ability of patent holders to recoup the cost of their investment; thereby impeding incentives to conduct research and development on neglected diseases affecting developing nations.

1. The Doha Declaration grants member countries too much authority to issue compulsory licenses, which deters investment in pharmaceutical research and development.

The Doha Declaration gives each member country the right to grant compulsory licenses and the freedom to determine the grounds upon which compulsory licenses may be granted. This broad discretion facilitates abuse by countries that use the compulsory license to avoid buying patented products or to address non-urgent health problems. For instance, when Thailand issued a compulsory license for Kaletra, an AIDS medication manufactured by Abbot Laboratories, Abbot Laboratories was already selling the drug to Thailand at a substantially discounted rate. In 2007, Thailand also issued a compulsory license for Plavix, a heart disease medication. Thailand’s use of the compulsory license was controversial because Thailand is a middle-income country, as opposed to a developing nation; moreover, the compulsory licensing of Plavix served as the first time a country issued a compulsory license for a medication geared towards a chronic disease as opposed to an infectious disease. This issuance may signal a new era where countries issue compulsory licenses for drugs that treat illnesses beyond infectious diseases and for any drug available on the market, which may exceed the purpose of the Doha Declaration.

Because of the Doha Declaration, countries may issue compulsory licenses for whatever reason they choose, including broad interpretations of what constitutes the public interest. For instance, the Doha Declaration allows countries to determine that an epidemic constitutes a “national emergency” for which the country may issue a compulsory license. Thus, pharmaceutical companies contemplating research and development on a disease affecting developing nations now have the added disincentive of knowing that in the event they develop a successful new drug, a developing country may arbitrarily declare an epidemic a “national emergency” and award compulsory licenses to copy the drug. Forcing a patent owner to give up their exclusive rights to the product or process strips the patent of its entire purpose and prevents patent holders from fully recouping the costs of their investments. As a result, the incentive for investing in research and development for new medicines declines.

2. The Doha Declaration’s allowance of parallel imports discourages pharmaceutical patent holders from selling their product in developing nations for cheaper prices.

The Doha Declaration interprets the TRIPS Agreement in a manner that allows member countries to establish their own policies on the exhaustion of intellectual property rights and thereby enables each member country the decision of whether to allow parallel importation. Without parallel importation, pharmaceutical patent holders are more willing to sell their products at lower prices in developing nations. This willingness stems from the knowledge that their low-priced products will not be re-exported to undercut their prices elsewhere. However, where the market for needed medications is weak, the availability of parallel imports diminishes this willingness to sell for less. As a result, many developing nations are priced out of the market, without access to medication.

Because pharmaceutical production is such an extensive and costly process, pharmaceutical patent holders rely on patents to protect their investment. Yet, compulsory licenses and parallel imports destroy the patent protection that pharmaceutical patent holders require for innovation. In doing so, compulsory licenses and parallel imports discourage research and development for new medicine and thereby restrict medicine in developing nations.

C. Compulsory licensing and parallel imports jeopardize the public health in developing nations.

Despite their endorsement by the Doha Declaration, compulsory licenses and parallel imports are not a panacea for developing countries’ access to medicine problems. The amount of time it takes to issue a compulsory license can be lengthy while the administrative and regulatory steps for negotiating and issuing a compulsory license can be extensive and burdensome. Moreover, the narrow scope and duration of a compulsory license provide only temporary relief for countries seeking access to medicine. Fear of trade retaliation from developed countries deters countries from issuing compulsory licenses. Additionally, parallel imports prevent medication from reaching the general public in developing nations and run the risk of creating low quality drugs that may harm and even kill people.

1. The Compulsory licensing process takes too long and is too complicated to provide countries with the medicine they need.

The Doha Declaration touted compulsory licenses for pharmaceutical products as a mechanism to improve public health and, consequently, promoted compulsory licenses through broad language of support; but the Doha Declaration failed to provide specific requirements regarding the implementation of compulsory licenses. This lapse failed to clear the various obstacles associated
with issuing a compulsory license such as the length of time it takes to issue a compulsory license and the cumbersome process of issuing a compulsory license. For instance, it took nearly three years of negotiating for Malaysia to procure much needed antiretroviral treatment after issuing a compulsory license.101 For those countries in need of immediate access to medicine, the lengthy compulsory licensing process prevents the public from receiving medicine, thereby putting the public’s health at risk.

Additionally, many countries find the process of issuing a compulsory license too cumbersome, which prevents compulsory licenses from being used.102 For example, after the 2003 council decision, Canada modified its drug patent legislation to export drugs to least developed countries.103 The goal was to facilitate timely access to generic medicine and medical devices for developing countries.104 Though the drug shipments were successfully shipped to Rwanda, the regulatory process was so complex that no other developing country has tried to order drugs from Canada.105

A country that lacks domestic manufacturing capacities must go through a long series of different steps to import a drug issued under compulsory license.106 The process is further complicated by the fact that the steps must be followed each time a country exports the drug, even if the same drug is exported to a different country.107 These complex procedures contradict the Doha Declaration’s goal of providing access to medicine because they make it more difficult for countries to provide medicine for the public.108 Thus, for the least developed countries, the amount of time it takes to issue a compulsory license is too long, and the overall process is too complex.109

2. Developing countries cannot rely on compulsory licensing as a central source for access to medicine.

The compulsory license is an inadequate treatment for medically needy countries.110 By continuously importing medicines, a developing country will never learn how to sustain itself and will remain reliant on other more developed countries.111 Consequently, countries that are trying to establish their public health program and gain access to medicine should not rely on compulsory licenses.112

3. Compulsory licenses often result in trade retaliation.

Although the Doha Declaration proclaimed compulsory licenses as a right, and despite the fact that most WTO member countries have incorporated this right into their domestic legislation, WTO members’ governments rarely award compulsory licenses for pharmaceuticals for fear of trade retaliation.113 When Thailand issued a compulsory license in 2007, the United States retaliated by placing Thailand on the Section 301 Report, which allows the United States to place trade sanctions against those countries that do not provide adequate intellectual property protection.114 South Africa attempted to pass legislation enabling compulsory licenses in 1997,115 but the Clinton administration listed South Africa in the Section 301 Report as a result. Consequently, South Africa dropped its legislation.116 Additionally, after Thailand announced its intent to issue compulsory licenses, the United States listed the country in the 301 Report.117

4. Allowing developing countries to resell medications via parallel importation instead of dispersing the medicine to their citizens deprives the public of much needed medication.

The WTO adopted the Doha Declaration to provide access to medicine in low- to middle-income countries,118 yet studies show that parallel importing fails to result in a reduced price for the consumer. Instead, parallel importation obstructs the ability of the patent holders to engage in price discrimination across national markets, thereby preventing developing countries from receiving the lower priced medication that price discrimination creates.119

Additionally, parallel importing depletes the country’s pharmaceutical supply.120 For example, the widespread parallel importing in Spain has resulted in frequent drug shortages,121 and the Spanish people lack access to medicine because Spain’s medicine is resold to other European countries. Sellers make more money selling to other countries, and therefore, sell off a large part of Spain’s drug supply.122

5. Compulsory licensing and parallel imports provide dangerous substandard medicine and, therefore, violate the Doha Declaration’s commitment to improving public health.

The Doha Declaration recognized the protection of public health as a paramount principle123 that necessitates the facilitation of greater access to medicine.124 To advance access to medicine, the Doha Declaration promoted the flexibilities of the TRIPS Agreement, including compulsory licensing, and clarified that developing countries may issue a compulsory license to produce a drug domestically or may import generic drugs from other nations.125 However, these flexibilities have created a public health hazard because the medicine developing countries produce or receive is likely substandard, due to a lack of regulation, with the potential to result in fatal consequences and create drug-resistant viruses.126 Thus, the flexibilities provided in the Doha Declaration, which were intended to alleviate the problem of access to medicine and public health, have merely exacerbated it.

Central to the Doha Declaration’s promotion of public health is the use of the TRIPS Agreement’s flexibilities, notably compulsory licenses and parallel imports, to provide universal access to medicine.127 Yet major health concerns exist regarding the quality of the drugs acquired via compulsory licensing and parallel importing.128 Generic drugs domestically manufactured or imported into developing countries are typically of a lower quality than drugs produced by the larger pharmaceutical companies, and though developing countries may produce the drug for a lower cost, these countries generally cannot produce the same product as the patent holder. When drug manufacturers in developing countries fail to provide exact versions of the drug, they create ineffective medicines that promote the growth of drug-resistant viruses.129
Drug production requires adhering to stringent procedures to ensure quality, yet the smaller or lesser-known drug producers often lack the necessary quality assurances. The importance of pharmaceutical quality cannot be overemphasized; a sub-strength or improperly mixed formulation can kill a patient and create contagious drug-resistant viruses. In the 1980s and 1990s, contaminated medicines killed more than five hundred people in Argentina, Bangladesh, Nigeria, Haiti and India. In 1998, a locally made medication contaminated with diethylene glycol, a toxic solvent, killed thirty-three children in India.

The undisciplined use and misuse of pharmaceutical drugs in developing countries has led to resistance in such diseases as tuberculosis and malaria. Varying the manufacturing method alters the drug and makes even the safest drugs harmful. Many drugs are complicated to produce, and the involvement of multiple manufacturers may lead to different products.

Developing countries also lack the capacity to regulate drug manufacturing and are thus unable to monitor effectively the safety and potency of the drugs. Developing countries lack safety nets like the Food and Drug Administration and have difficulty enforcing pharmaceutical legislation. For instance, China and India have become major international suppliers of generic drugs, but quality-control inspections are rarely conducted. As these countries continue to carelessly manufacture more drugs, the risk to human health grows exponentially. Counterfeit drugs, many of which have expired and should be destroyed, are often sold as parallel imports and have thus become a problem.

Kenya allowed parallel imports until 1997, when it banned the practice after the market was flooded with unsafe counterfeit drugs of poor quality. Many African cities have “grass pharmacies”—makeshift pharmacies set up in the streets—which sell medicines touted as antibiotics. However, these drugs typically contain no antibiotic at all, and the authorities and domestic health organizations do not know the origin of these drugs. Thus, because of the many problematic consequences of parallel imports and compulsory licensing, simply flooding developing countries with less expensive drugs is reckless.

IV. Recommendations:
To provide sustainable, long-term access to quality medication, countries must look beyond compulsory licensing and parallel imports, and instead adopt measures that incentivize innovation and research and development. Preserving the integrity of the patent and protecting intellectual property rights serves as one way to protect the pharmaceutical patent holder’s investment in pharmaceutical production. Other options consider relaxing patent protections in exchange for adequate compensation to the pharmaceutical company. Preserving the incentive of the pharmaceutical company is vital to encouraging research and development. Doing so will promote progress in pharmaceutical innovation, provide greater access to medicine, and help WTO member countries achieve their goal of better public health.

A. Patent protection must be fortified with data exclusivity or cost-sharing.
In many developing countries, when a company submits data to the state’s drug regulatory agency for the approval and registration of a new drug, the regulatory agency enables other companies to use this data to reproduce and market the same drug. Consequently, the later registrant may free ride on the research and development of the initial registrant and may market the drug without having to replicate any of the prior testing performed by the initial registrant. Because the absence of data protection disincentivizes drug developers from marketing their product in these countries, data exclusivity has been touted as a possible solution.

Data exclusivity refers to the process by which drug regulatory authorities keep marketing approval data confidential for a set period to prevent generic knockoffs. Without data exclusivity, drug developers have insufficient incentive to undergo the costly trials and clinical research for drug production and marketing approval because of the high probability that a generic producer will recreate and sell the drug for much less. Generic producers use the registration data to reverse engineer their own products and need only demonstrate that their product is the therapeutic equivalent to the original drug (bio-equivalency), thereby avoiding spending billions of dollars in research and development. However, the generic replication of drugs impedes drug developers from recouping their billion-dollar investment in the drug. Consequently, data exclusivity is a favorable option for drug developers because it keeps the marketing approval data private and prevents generic knockoffs, thus enabling drug producers to recoup their investment.

However, developing countries, in particular, argue against the adoption of data exclusivity and explain that without the ability to rely on the drug developer’s marketing approval data, generic drugs cannot be produced. The inability to produce generic drugs eliminates competition and creates expensive, and thus inaccessible, drugs. Another option focuses on using a “cost sharing” approach, which allows follow-on firms (“later registrants”) to use the marketing approval data of the initial registrant in exchange for adequate compensation for the costs of testing. The cost-sharing model prevents the creation of a monopoly period as well as duplicative testing. After paying adequate remuneration to the initial registrants, later registrants could begin marketing their products as soon as they proved bioequivalence. This cost-sharing approach provides competition to consumers, which may lower prices. This method also provides a way for the pharmaceutical manufacturer to recoup some of their investment in the product. Consequently, cost-sharing is particularly effective because it addresses the concerns of both drug developers and developing countries.

B. Prize funds preserve the pharmaceutical patent holder’s incentive to conduct research and development for new medications.
Prize funds serve as another viable option to promote innovation and incentivize drug development. Prize funds provide large monetary prizes, paid for by industrialized nations, to the company
that develops new medications and vaccines for diseases that affect the developing world. The remuneration amount varies depending on the health priority of the disease, the number of people the disease affects, whether the cure or vaccine affects a neglected disease, and whether the drug is an alternative treatment for an already existing drug. Drug developers are reluctant to develop drugs for diseases in developing countries whose markets do not provide an adequate return on the drug developer’s investment. Prize funds create the incentive, which combined with patent protection and price regulation, supplants the revenue that drug development companies lose when they develop medicine for the developing world. The prize system separates the cost of innovation from the subsequent higher price tag that a patent requires, thereby allowing new generic medicines that can be immediately placed in the market.

C. Utilizing price differentiation would provide access to medicine in developing countries.

Another approach to providing medication to developing countries at lower prices involves amending the TRIPS Agreement to include a tiered pricing system based on the income level and economic prosperity of member countries. Under this system, drug developers would market drugs at a lower price in developing nations than in developed nations. Also known as differential pricing, this system provides developing countries with cheap medicines while enabling pharmaceutical producers to recoup the cost of their investments. Though drug companies may initially lose money by selling their drug at the lower cost to the developing nation, they make up for the loss via the higher prices that they charge the developed nations. Thus, the differential pricing system reduces the financial barriers that prevent access to medicine in developing countries.

D. Individual governments must accept greater responsibility in protecting the public health of their citizens.

Developing countries will not progress in their access to medicine unless the countries themselves make health care a priority. More than 90 percent of the drugs on the World Health Organization’s (WHO) List of Essential Drugs lack patent protection and have low price tags. However, because many developing nations have an extremely low per capita spending on medicine, they cannot afford to purchase the drugs, even at discounted rates. Developed countries can continue to provide aid, and pharmaceutical companies can continue to donate medicine, but until the countries themselves develop domestic legislation that spends more on adequate health care and creates regulatory agencies to promote the public health, all efforts will prove futile.

V. Conclusion

In summary, the Doha Declaration cannot promote public health and access to medicine in developing countries. Compulsory licenses and parallel imports provided by the Doha Declaration fail to offer a sustainable answer to the access to medicines problem and create more problems than they solve. Additionally, without patent protection, pharmaceutical producers lack an incentive to invest in research and development for new pharmaceuticals targeting the diseases that afflict the developing world. To advance public health and access to medicine, WTO countries must either protect patents or provide the pharmaceutical companies with adequate profits. Otherwise, public health in developing countries will remain stagnant, and access to medicine will continue to be impeded.

1 See Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases, Medicus Sans Frontieres (2001), available at http://www.doctorswithoutborders.org/publications/reports/2001/fatal_imbalance_short.pdf (lamenting the fact that until recently, the only treatment for people suffering from sleeping sickness, which afflicts hundreds of thousands of people each year, involved a painful arsenic-based medicine).

2 See Ending the R&D Crisis in Public Health: Promoting Pro-Poor Medical Innovation, Oxfam International (2008), available at http://www.oxfam.org.uk/resources/policy/health/bp122_crisis_public_health.html (noting that diseases which have been mostly controlled in the developed world, such as tuberculosis, continue to cause a health crisis within the developing world and despite the fact that neglected tropical diseases kill hundreds of thousands of people each year, between 1999 and 2004, only three new medicines were created to treat neglected diseases).


4 See Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS Agreement] (recognizing members may, but are not obligated to, implement more extensive protection than is required by the Agreement); see also Jamie Feldman, Compulsory Licenses: The Dangers Behind the Current Practice, 8 J. INT’L BUS. & L. 137, 141 (2009) (explaining that “[t]he goal of the TRIPS Agreement is to standardize the manner in which intellectual property rights are protected around the world”).

5 See Sara Germano, Note, Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low-and Middle-Income Countries, 76 UMKC L. REV. 273, 274 (2007) (explaining the concern that the TRIPS Agreement’s patent protections would increase the cost of medicine and thereby decrease access for those low-to-middle-income countries that could not afford the higher prices).

6 See Declaration on the TRIPS Agreement and Public Health, World Trade Org. (Nov. 14, 2001), available at http://www.wto.org/english/hc-e/minist_e/mn011_e/min11_trips_e.pdf [hereinafter Doha Declaration] (recognizing “the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,” and emphasizing “the need for the TRIPS Agreement to be part of the wider national and international action to address” problems with access to medicine and public health).

7 See id. at art. 3 (admitting that “intellectual property protection is important for the development of new medicines”).

8 See id. at arts. 4-5 (reaffirming “WTO members’ [right] to use, to the fullest extent, the provisions in the TRIPS Agreement, which provide flexibility” and include “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”).


10 See TRIPS Agreement, supra note 4, at Art. 31(f) (mandating that compulsory licenses be allowed for the domestic market of the Member country that authorized the compulsory license).

11 See Feldman, supra note 4, at 137 (explaining that Article 31 acted like a barrier for those countries who could not manufacture pharmaceuticals domestically because the provision only allowed for compulsory licenses if the product was to be used in the domestic market of the country producing the product). Thus, a country could not issue a compulsory license, produce it, and then export it to another country, which prevented countries in need
from receiving medicine.

12 See infra Part II (detailing the relationship between the TRIPS Agreement, Doha Declaration, and council Decision and discussing the role of patent protection in each).
13 See infra Part III (warning against the potential for decreased investment in research and development and overall access to medicine and questioning the quality of the medicines provided).
14 See infra Part IV (protecting the patent registrant’s data protects their monopoly power and preserves innovation).
15 See infra Part IV (finding that pharmaceutical patent holders can sustain innovation, research, and development as long as it is financially worthwhile to do so).
16 See infra Part IV (holding that pharmaceutical companies may charge developing countries less for medication if they charge developed countries more, thus enabling these companies to make a profit while also providing medicine to countries in need).
17 See infra Part IV (explaining that international aid will be fruitless until countries themselves invest in the public health of their people).
18 TRIPS Agreement, supra note 4; see, e.g., Marla L. Mellino, Note, The TRIPS Agreement: Helping or Hurting Least Developed Countries’ Access to Essential Pharmaceuticals?, 20 FORDHAM INT’L. PROFS. MEDIA & ENT. L.J. 1349, 1353 (2010) (explaining the tension the TRIPS Agreement created between pharmaceutical companies, who needed to earn a profit, and developing countries, who needed greater access to medicines).
19 See Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 CHI.-KENT L. REV. 1469, 1470 (2007) (explaining that the TRIPS Agreement established the first-ever minimum levels of patent rights on a global scale); see also Feldman, supra note 4, at 145 (noting that as the importance of intellectual property rights became more important to international trade, economic tension between countries arose due to the various levels of intellectual property protections). WTO member nations sought to ease this growing tension by creating minimum levels of international protection for intellectual property rights.
20 E.g., John H. Barton, TRIPS and the Global Pharmaceutical Market, 23 HEALTH AFFAIRS 146, 147-149 (2004) (explaining that pharmaceutical companies rely on patent protection for profits but that patent protection presents a problem for least developed countries who cannot afford the higher priced medicine that results from patenting a product).
21 See Feldman, supra note 4, at 146 (explaining that the broad text of the TRIPS Agreement includes Article 31 which authorizes the use of a patented product without the authorization of the patent holder).
22 See TRIPS Agreement, supra note 4, at art. 31 (stating that where the domestic legislation of the WTO member country allows for compulsory licenses, the TRIPS Agreement allows that country to issue the compulsory license without the authorization of the right holder). This includes use by the government or third parties authorized by the government; Cf. Germano, supra note 5, at 280 (detailing that, though the text of the TRIPS Agreement does not explicitly refer to compulsory licensing, it is inferred from the language).
23 See Anthony P. Valach, TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries, 4 CHI.-KENT J. INT’L. PROPS. 156, 158 (2005) (defining compulsory licensing as when a government enables either itself or a third party to reproduce a patented product or process without the patent owner’s authorization).
24 See TRIPS and Pharmaceutical Patents: Fact Sheet, WORLD TRADE ORG. (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_patmas_2006_e.pdf [hereinafter WTO Fact Sheet] (explaining that parallel importation occurs when the patent, trademark, or copyright owner or someone with the patent owner’s consent, markets the product in one country for a set price but the product is then imported and sold in another country without the approval of the patent owner).
25 See generally Feldman, supra note 4 (detailing how lesser patent protection is detrimental to the pharmaceutical patent holder and has adverse effects on the public health and economic welfare of the country).
26 See Ending the R&D Crisis in Public Health: Promoting Pro-Poor Medical Innovation, OXFAM INTERNATIONAL, (Nov. 2008), available at http://www.oxfam.org.uk/resources/policy/health/hp122_crisis_public_health.html (“[T]he WTO TRIPS Agreement [i.e.] provides monopolies to pharmaceutical companies that result in unaffordable prices for medicines.”).

This is because such monopolies prevent the use of generics, which excludes competition that would otherwise drive down costs. But see Amir Attaran, How Do Patents and Economic Policies Affect Access to Essential Medicine in Developing Countries?, 23 HEALTH AFFAIRS 155 (2004) (asserting that poverty, not patents, impose the greater limitation on access to medicine). See Feldman, supra note 4, at 137 (holding that the Doha Declaration was adopted in response to the TRIPS Agreement backlash that concerned the issue of access to medicine).
28 See id. at 148 (declaring that the Doha Declaration affirmed that the TRIPS Agreement should be interpreted in a way that supports WTO members’ right to protect the public health). The Doha Declaration also acknowledged that the TRIPS Agreement provided compulsory licenses and parallel imports for this purpose.
29 See cf., Barton, supra note 20, at 149 (stating that the Doha Declaration and its affirmation of compulsory licensing was seen as a defeat for the research-based pharmaceutical companies).
30 See Doha Declaration, supra note 6, at art. 5 (recognizing that the effect of the TRIPS Agreement is to leave each member country free to establish its own regime for the exhaustion of intellectual property rights). See Pharmaceutical Patents and the TRIPS Agreement, WORLD TRADE ORG. (Sept. 21, 2006), http://www.wto.org/english/tratop_e/trips_e/phrma_atc186_e.pdf (explaining that where a country’s domestic law holds that IP rights are exhausted, right holders cannot take action against parallel imports).
31 See Germano, supra note 5, at 281 (detailing how the Doha Declaration reaffirmed the rights of WTO Members to use the provisions in the TRIPS Agreement without actually changing any provisions within the TRIPS Agreement).
32 See Alan O. Sykes, TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution”, 3 C.H. INT’L L. 47, 63 (2002) (concluding that parallel importation undercuts the ability of the patent holder to engage in price discrimination across national markets and thereby prevents developing countries from gaining access to lower priced medicine).
33 See WTO Fact Sheet, supra note 24, at 5 (explaining that the Doha Declaration clarifies the TRIPS Agreement so that members may chose for themselves whether to allow exhaustion).
34 See Sykes, supra note 33, at 66 (noting that “exhaustion” prevents a patent holder from having a legal right to require nations in which it holds a valid patent to prevent parallel imports).
35 Id. at 62.
36 See id. (detailing how parallel importation policies erode patent holders’ profits).
38 Compare TRIPS Agreement, supra note 4, at art. 6 (asserting that it does not address the issue of the exhaustion) with Doha Declaration, supra note 6, at art. 5 (providing member countries with the ability to set up their own legislation regarding the exhaustion of intellectual property rights, thereby allowing parallel imports).
39 TRIPS Agreement, supra note 4, at art. 6.
40 See Peggy B. Sherman & Ellwood F. Oakley, III, Pandemics and Panaceas: The World Trade Organization’s Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs, 41 AM. BUS. L.J. 353, 374 (2004) (explaining that because TRIPS does not address the question of “exhaustion,” member nations are free to adopt laws that reflect international exhaustion of rights, and thus permit parallel importation).
41 Feldman, supra note 4, at 161.
43 Compare Doha Declaration, supra note 6, at art. 5 (explaining that each WTO member has the right to grant compulsory licenses and the freedom to determine when and why such licenses will be granted), with TRIPS Agreement, supra note 4, at art. 31 (dictating that the use of a compulsory license “may only be permitted if, prior to the use, the proposed user has attempted to obtain authorization from the right holder on reasonable
commercial terms and conditions and that these efforts have not been successful within a reasonable period of time.") However, in the cases of a national emergency or other extreme urgency or in cases of public non-commercial use, a member country may waive this requirement.

45 Doha Declaration, supra note 6, at art. 5.

46 See Sisule F. Musunungu & Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?, COMM’N ON INT’L. PROP. RTS, INNOVATION AND PUB. HEALTH 15 (2005), available at http://www.who.int/Intellectualproperty/studies/TRIPSFLLEXI.pdf (touting one of the benefits of compulsory licensing to be the production of generic medicine which provides greater access to medicine); see also Mandy Wilson, Pharmaceutical Patent Protection: More Generic Favorited Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation, 90 Ky. L. J. 495, 496 (2001) (holding that generic pharmaceuticals may cost less than patented versions and thus will be accessible to more of the general population)—did not see textual support for this parenthetical (e-mailed about it). But see Amir Attaran & Lee Gillespie-White, Do Patents on Antiretroviral Drug Constrain Access to AIDS Treatment in Africa?, 286 JAMA 1886, 1891 (2001) (testing the hypothesis that patents are a leading barrier to widespread AIDS treatment in Africa and concluding that patents do not act as a barrier to antiretroviral treatment in Africa).

47 Trips Agreement, supra note 4, at art. 31.

48 See Feldman, supra note 4, at 137 (explaining that article 31 was essentially useless to the countries that were in need of compulsory licenses the most because it prevented those countries that lacked manufacturing capabilities from issuing a compulsory license).

49 E.g., Mellino, supra note 18, at 1359-60 (pointing out that a compulsory license provides little help for a country that does not have the manufacturing ability to make use of the license).

50 See Germano, supra note 5, at 282 (declaring that the TRIPS language prevented countries with a domestic generics industry from exporting drugs to countries that lacked industrial capacity).

51 See Mellino, supra note 18, at 1359-60 (highlighting that a country lacking adequate manufacturing capacity could not utilize compulsory licenses under Article 31(f) and a country that could utilize the compulsory license could only produce the licensed technology for its domestic use and could not import the products to other countries).

52 Doha Declaration, supra note 6, at art. 6 (recognizing that WTO members with insufficient or no manufacturing capacity cannot effectively utilize compulsory licensing under the TRIPS Agreement’s language).

53 Id. at 851.

54 See generally Feldman, supra note 4, at 147-48 (explaining the different portions of article 31 that the council Decision waived, including the requirement that products produced under compulsory license be utilized solely for domestic supply).

55 See Germano, supra note 5, at 283 (noting that on December 6, 2005 the WTO members approved an amendment to TRIPS that would make the council’s decisions permanent but two-thirds of the WTO members must approve the amendment before it may be incorporated into the TRIPS Agreement and so far, this requirement has not been met).

56 See Council Decision, supra note 9 (“. . . exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products.”).

57 See Henry Grabowski, Patents, Innovation and Access to New Pharmaceuticals, 5 J. INT’L. ECON. L. 849, 856 (2002) (noting that the patent system has played a crucial role in incentivizing R&D investment for global diseases like AIDS, but pointing out that neglected diseases such as tuberculosis and malaria lack R&D investment partly because of the lack of patent protection).

58 Id. at 851.

59 Id. at 850; see also Claude Barfield & John E. Calfee, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 18-19 (AEI Press, 2007) (discussing the fact that even the most promising drugs, some of which cost up to a billion dollars, have failed before even reaching the market place, while others which do reach the market place, prove unreliable despite favorable market predictions).


61 See Wilson, supra note 46, at 496 (reiterating that the time prior to the induction of a drug is increasingly complex and costly). Companies do not make money during this time and instead spend exorbitant sums on research and development for new drugs.

62 See id. at 496 (emphasizing that companies also rely on these “blockbuster” drugs to not only pay off the cost of the drug, but to recoup the losses of the drugs that failed either before or after making it onto the market).

63 See id. at 497 (citing a Congressional Budget Office Study that conducted calculations on sixty-seven new drugs; of those products, the top six earned $1 billion in total, however only one third of the drugs earned enough money to cover the costs of research and development for a single drug).

64 See id. at 496 (emphasizing that patent protection is also important to predicting profitability of a developing drug).

65 Barfield & Calfee, supra note 59, at 66.

66 See Wilson, supra note 46, at 496 (observing that pioneer companies, the inventors of the drug, spend extensive amounts of money and time on research and development, while generic manufacturers are able to copy the drug at very little cost).

67 Id. at 496.

68 Id.

69 See id. (emphasizing that for pioneer companies to recover their expenses and produce a profit, an adequate patent term is vital; thus, the risk of shorter patent terms is likely to decrease the incentive to pay the costs of research and development).

70 See Sykes, supra note 33, at 60 (noting a widely-cited study by Edwin Mansfield that found that 65% of innovations in the pharmaceutical industry would never have been created without patent protection; cf. Barfield & Calfee, supra note 59, at 27 (contrasting the patent-dependent pharmaceutical industry with other industries and finding that product innovation for no other industry was more than 18% dependent on patent protection).


72 See TRIPS Agreement, supra note 4, at preamble.

73 Compare id. at art. 28 (authorizing that a patent confer on its owner the right to prevent third parties who lack the owner’s consent, from using, offering for sale, selling, or importing the product), with Doha Declaration, supra note 6, at art. 4 (declaring that the TRIPS Agreement should be interpreted in such a way as to promote compulsory licensing which the WTO Ministerial Conference feels will protect public health); see cf. Sykes, supra note 33, at 56 (exclaiming the paradox of the Doha Declaration which essentially dismantles the patent protection that the TRIPS Agreement creates).

74 Cf. Sykes, supra note 33, at 55 (exclaiming that the TRIPS Agreement offered periods of protection in which patent holders could recover the cost of their investment but that, by promising compulsory licensing, the Doha Declaration would obliterate the chance to earn back the costs incurred).

75 See Doha Declaration, supra note 6, at art. 3 (recognizing that the development of new medication relies on intellectual property protection but also noticing the concern that patents lead to higher priced medicine).

76 See Doha Declaration, supra note 6, at art. 4-5 (asserting that WTO member countries should interpret the TRIPS Agreement in a way that promotes their right to protect public health, specifically, universal access to medicine). To further that objective, WTO members may use, to the full, the provisions of the TRIPS Agreement which include compulsory licenses and the exhaustion of intellectual property rights.

77 Doha Declaration, supra note 6, at art. 5.

78 See Sykes, supra note 33, at 57 (contemplating that patent rights give the patent holder a period of monopoly rents that enables the recoupment of
research and development costs). 79 See Valach, supra note 23, at 158 (emphasizing that patent holders typically dislike compulsory licenses because it enables the government of another country to strip a patent-holder of the patent’s protections); cf. Sykes, supra note 33, at 63 (contending that parallel imports reduce the return on holding a patent).

See Sykes, supra note 33, at 66-67 (arguing that if a patent holder’s invention may be copied and sold by competitors, the price of the drug is driven down to the marginal price of whatever it costs the generic producer to manufacture the drug and thus does not account for the expense that the patent holder paid for research and development). As a result, inventors will not be able to recoup their costs of innovation; thus, potential inventors, knowing this, will be unwilling to incur the costs of research and development and thus innovation will be stifled.

See Feldman, supra note 4, at 149 (arguing that the TRIPS Agreement language is too broad, that the wording is too flexible, and that it lacks objective guidelines). This fosters compulsory license abuse and misuses of this strong governmental right will have detrimental consequences.

See generally id. at 151-2 (detailing the controversial compulsory licenses issued by Thailand, Brazil, and Rwanda, and noting this unlimited scope of compulsory licensing will cause pharmaceutical companies to decrease investment in drugs for fear that they will not earn profits); see also Aileen M. McGill, Compulsory Licensing of Patented Pharmaceuticals: Why A WTO Administrative Body Should Determine What Constitutes A Public Health Crisis Under the Doha Declaration, 10 Wake Forest Intell. Prop. L.J. 69, 96 (2009) (concluding that the terms of the Doha Declaration are too broad, allowing countries to issue compulsory licenses for medications that do not treat life-threatening illnesses, such as Viagra and Plavix). Many countries have seen a dramatic drop in Foreign Direct Investment (FDI) as a result of extensive compulsory licensing of patented pharmaceuticals, making least developed countries hesitant to invoke the terms of the Doha Declaration for fear of similar losses in FDI.

Feldman, supra note 4, at 152.

Id. at 151-2.

Id. at 151.

Id. at 151-2.

See Doha Declaration, supra note 6, at art. 5 (emphasizing that each member country has the freedom to decide the grounds upon which a compulsory license may be granted and also may determine what constitutes a national emergency). Public health crises, count as national emergencies for which a compulsory license may be granted.

See Doha Declaration, supra note 6, at art. 5.

Sykes, supra note 33, at 66.

See Grabowski, supra note 57, at 851 (asserting that it takes an extensive amount of money, time, and resources to discover and create a new medicine and without patent protection, imitators may free ride on the innovator’s clinical data and create duplicate drugs for a fraction of what it cost the innovator).

Id.; see also Feldman, supra note 4, at 142 (holding that if compulsory licenses are too easily obtainable funding for innovation will erode). The “monopoly power pharmaceutical companies obtain over their patented medicines induces invention. Therefore, future investment in pharmaceuticals will be viewed as a risk without this monopoly power.”

See Doha Declaration, supra note 6, at art. 5 (holding that each member is free to establish its own regime for the exhaustion of intellectual property rights); see also WTO Fact Sheet, supra note 24, at 5 (explaining that the Doha Declaration attempts to enable member countries to formulate their domestic policy objectives in a way that supports public health).

See Sykes, supra note 33, at 63-4 (noting that as long as the price of the drug covers the marginal cost of making and delivering the drug, the pharmaceutical patent holder can sell the drug for an extremely discounted price).

Id. at 64.

Id.

Id.

See Graham Dutfield, Delivering Drugs to the Poor: Will the Trips Amendment Help?, 34 Am. J.L. & Med. 107, 120 (2008) (describing the many multifaceted requirements that must be met before a compulsory license actually delivers the needed medication).
European Commission, effectively kept most governments from issuing compulsory licenses.

See Mellino, supra note 18, at 1369 (explaining that the United States Trade Representative created the Special 301 Report to list and give notice to countries that it believes committed trade violations).

See Bess-Carolina Dolmo, Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example, 7 BUFF. HUM. RTS. L. REV. 137 (2001) (explaining that the HIV/AIDS crisis in South Africa prompted the government to enact Section 15(c) of the South African Medicines and Medical Devices Regulatory Act (SAMMDRA), which authorized parallel imports and compulsory licensing with the objective of allowing easier access to affordable drugs).

See Melino, supra note 18, at 1377 (holding countries are mindful of the effects that compulsory licensing can have on foreign direct investments because placement on watch lists like the Section 301 Report can lead to trade sanctions).

Id. at 1376.

See Germano, supra note 5, at 274 (explaining that concern regarding access to affordable medicine in developing countries led to the Doha Declaration).

See infra Part III (describing the benefits of price discrimination in terms of providing access to medicine).

See Sherman & Oakley, supra note 41, 375 (noting that parallel importing decreases the need for countries to establish domestic drug manufacturing).

Id.

Id. at 1376.

See Doha Declaration, supra note 6, at art. 4, 5 (agreeing that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health, such as compulsory licensing).

See Sherman & Oakley, supra note 41, at 367 (affirming that the Doha Declaration held that the TRIPS Agreement can and should be interpreted and implemented in a manner that supports WTO members’ right to protect public health and, in particular, to promote access to medicines for everyone).

See id. (reaffirming that the Doha Declaration grants to WTO members the right to use the provisions in the TRIPS Agreement to the fullest, which the Doha Declaration believes promotes its goals of access to medicine); see also Feldman, supra note 4, at 160 (explaining that the Doha Declaration clarifies that developing nations unable to domestically manufacture drugs are authorized to import generic drugs from nations with manufacturing capabilities).

See Feldman, supra note 4, at 160 (explaining that developing are likely to import drugs from the unregulated plants and that these contaminated and ineffective generics are very difficult to track down).

See id. at 148 (affirming that the Doha Declaration held that the TRIPS Agreement must be implemented in a manner supportive of public health and that its flexibilities, which include compulsory licenses and the exhaustion of intellectual property rights, may be utilized to promote public health).

See Sherman & Oakley, supra note 41, at 401 (emphasizing that imitation drugs of poor quality contain contaminants that may harm or kill people).

See Denise Grady, Generic Medicine for AIDS Raises New Set of Concerns, N.Y. TIMES, APR. 24, 2001, at F1 (proclaiming that different manufacturing techniques will change the way the body absorbs an AIDS drug which would diminish the potency of the drug); see id. (detailing a conversation with the past president of the International AIDS Society, who explained it would be “far superior” for developing countries in Africa if drugs were provided by companies other than the generic companies, particularly those generic companies who lack a proven track record on quality).

See id. (highlighting The Bulletin of the World Health Organization which warned that developing countries faced a growing threat from substandard medicines and that the problem was largely underestimated).

See Sherman & Oakley, supra note 41, at 353, 402 (warning that scientists have already noted drug resistance among some strains of HIV).

See Grady, supra note 129.


See id. (noting a test of seven generic forms of Lasis, a diuretic used to treat high blood pressure and heart failure). The generics were made in Western Europe, Eastern Europe and Africa and though some dissolved at almost the same rate as the brand-name drug, one drug “was very different” due to solubility differences of the raw material used.

Id.; see also Sherman & Oakley, supra note 41, at 401 (affirming that developing countries have poor regulation of generic drug manufacturing). CIPLA, a generic drug manufacturer in India, is certified by the U.S. FDA, but many other generic drug manufacturers in India have not had a similar quality control check. Even though these generics are heavily discounted, many in the developing world do not want to buy them due to quality concerns.

See Grady, supra note 134 (asserting the vulnerability of developing countries in the world drug market because of their lack of a developed infrastructure to provide for adequate and safe drug development); see also Sherman & Oakley, supra note 41, at 401 (holding that India hosts around 22,000 drug companies, but there is very little regulation).

Marc Kaufman, FDA Scrutiny Scant in India, China as Drugs Pour into US, WASHINGTON POST, June 17, 2007, available at http://www06/16/AR2007061601295.html (noting that the US had 1,222 quality-assurance inspections conducted in one year, while India had only a handful).

Id. (noting that medicines from China and India pose the risk of being contaminated, counterfeit, understrength, and ineffective).

See Sherman & Oakley, supra note 41, at 401 (holding that these drugs may also contain inadequate instructions, or information in another language, both of which escalate the potential for improper and dangerous usage of the drug).

Id. at 402 (pointing out that Kenya, consequently, changed its laws to prohibit parallel imports because there was no regulation of the drugs they were receiving).


Id.

See id. (insisting that developing countries lack the ability to properly monitor pharmaceutical products and further illustrates this point with the fact that diethylamino glycol, a deadly toxin well known throughout the world since the 1930’s, continuously surfaces in pharmaceutical products sold the developing world).

See Sherman & Oakley, supra note 41, at 401.

Id. at 404-08.


See id. (arguing that this prevents wasteful repetition of tests and facilitates greater access to medicine by putting generics on the market faster).

See id. (asserting that to prevent generic manufacturers from gaining access to their regulatory data, drug developers have turned to Data Exclusivity for protection of their research findings).

See id. (reiterating that because generic manufacturers do not produce the research and development data that is necessary for the production of the drug, they are unfairly benefiting from the work of the initial registrant).

Id.

See Fellmeth, supra note 147, at 446-47 (reemphasizing that without access to this data, generic producers must either wait the specified time limit for the data exclusivity to expire (the US has a five year term of data exclusivity for new drug registrants while the EU has six to ten years of data exclusivity) or to replicate the studies themselves).

Id. at 447

But see id. at 444 (arguing that the lack of competition is not the main obstacle to facilitating access and distribution of necessary drugs in the developing world). The fact that developing countries lack access to many inexpensive and off-patent drugs argues against the theory that increased
competition and compulsory licensing would substantially ameliorate the lack of access to drugs in the developing world.

155 See Fellmeth, supra note 147, at 481 (highlighting that under the cost sharing approach, later registrants would not have to repeat the initial registrant’s data testing so long as they paid an equal portion of the costs of the test). To determine the amount of compensation owed, the total costs associated with gaining market approval are divided by the number of registrants and each later registrant reimburses the initial registrant for that amount.

156 See id. (noting that as soon as competing drug manufacturers proved bioequivalence to the initial registrant’s data, they could begin marketing the product in developing countries and thereby provide competition to consumers).

157 Id.

158 See Fellmeth, supra note 147, at 481 (explaining that consumers would benefit from the competition in the drug market due to the lower prices competition is expected to provide and that drug developers would benefit due to the remuneration for their research and development).

159 See Joseph Stiglitz, Give Prizes Not Patents, NEW SCIENTIST, Sept. 17, 2006, available at http://www.newscientist.com/article/dn10090-innovation-a-better-way-than-patents.html (noting that the Prize System includes a fund in which governments would contribute large sums of money and every year the funds would be allocated to firms that bring new products to the market); see also Tim Hubbard & James Love, A New Trade Framework for Global Healthcare R&D, 2 PLOS BIOLOGY 147 (2004), available at http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.0020052 (highlighting that this payment to the innovative firm would provide the proper remuneration to incentivize drug producers to develop new drugs while also enabling the introduction of generic competition).

160 See James Love, Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D, 40 U.C. DAVIS L. REV. 679, 700-01 (2006) (allowing greater rewards for innovative products and less for “me too” products that work no better than existing products, proves more rational than the existing system).

161 See Grabowski, supra note 57, at 856 (asserting there is a low potential for sales in the markets of developing countries and the fact that the governments of these developing countries invest almost nothing to combat disease and make medicine more accessible further exacerbates the problem of access).

162 See Ester Ferrara, Access to Medicine: Patent, Price Regulation and Prizes, 1 ILSP LAW JOURNAL 13, 18 (2007) (arguing that prize funds incentivize drug developers to produce medicine for the diseases in the developing world that, for economic reasons, do not attract research and development).

163 See James Love & Tim Hubbard, The Big Idea: Prizes to Stimulate R&D for New Medicines, 82 CHI.-KENT L. REV. 1519, 1528 (2007) (explaining that a patent allows patent holders to recoup the cost of investment and development but prevents competition which drives down prices).

164 See Immunization Financing Options: A Resource for Policymakers, GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION, 9 [hereinafter GAVI Options], available at http://www.who.int/immunization_financing/options/00_briefcase_Eng.pdf (explaining that Tiered Pricing means that different classes of buyers are charged different prices for the same product).


166 Id. at 639–40.

167 See GAVI Options, supra note 164, at 9 (illustrating that vaccines in developing countries are frequently priced at less than 10 percent of the price of those vaccines in richer countries, and thus more people have access).

168 See WHO Secretariat, More Equitable Pricing for Essential Drugs: What Do We Mean and What are the Issues?, WORLD HEALTH ORG., 9 (2001), available at http://www.who.int/fratop_fripts_f/who_background_e. doc (recognizing the government of developing countries as the stewards of each country’s health system and one of the major actors, with particular responsibility, in promoting access to drugs).

169 See Grabowski, supra note 57, at 856 (touting this as an argument against the inaccessibility of medicines due to patent protection). Other factors must be to blame if the majority of medicine for essential diseases are not patented yet are still inaccessible.

170 See id. at 857 (commenting on the fact that the governments of developing countries dedicate minimal amounts to promoting health care in their countries).

171 See Amir Attaran & Lee Gillespie-White, Do Patents for Antiretroviral Drugs Constrains Access to AIDS Treatment in Africa?, 286 JAMA 1886, 1890 (2001) (recognizing that a comprehensive treatment access plan is pivotal in order to overcome the non-patent barriers that prevent access to medicine). Such barriers include the insufficient finances to purchase drugs, the lack of political will among countries, the lack of medical care and infrastructure, and the inefficient drug regulatory procedures. Id.