I. INTRODUCTION

Each year more than eighteen million human lives end in death from poverty-related causes, fully one-third of all human deaths globally. This amounts to fifty thousand deaths per day from causes such as respiratory infections, HIV/AIDS, tuberculosis, malaria, measles, and tropical diseases. Many of these are treatable, if not curable,
conditions. The numbers are overwhelming and mandate an examination of the barriers to accessing medicines in developing countries, where the majority of these deaths occur. Admittedly this is an immense and complicated issue, and the economics behind pharmaceutical innovation and access is but one facet of a complete understanding of the problem. This paper describes the context of the problems surrounding access to medicines, highlighting the tremendously complicated web of issues that prevent medicines from reaching the world’s poorest. The following sections provide a bit of background on pharmaceutical patents, international intellectual property law, the pharmaceutical industry perspective, and the complicated elements that come together to create the most significant barriers to pharmaceutical access. While the international patent system is obviously flawed and in need of improvement, it is overly simplistic to blame drug patents and the global pharmaceutical industry for the access problem. The reality surrounding the challenges of access to medicines is more nuanced. In the debate over barriers to access, the culprits include corruption, poverty, taxes and tariffs, and pharmaceutical counterfeiting. Section two presents the fundamentals of the global pharmaceutical market. Section three introduces the challenges surrounding access to medicines. Section four provides analysis, and section five concludes.

II. FUNDAMENTALS OF THE GLOBAL PHARMACEUTICAL MARKET

The HIV/AIDS pandemic and an increasing awareness of global diseases have brought heightened scrutiny to the international pharmaceutical industry and the structure of international trade. Both industry representatives and public health advocates are fiercely focused on the role of pharmaceutical patents in the development of new therapies and the availability of medical technologies to the world’s most vulnerable populations. The industry perspective is a supply-side story in which patents are seen as essential to protecting and preserving innovation on a global scale. In contrast, public health advocates argue that patents amount to a principal barrier to affordable medicines for consumers in developing countries, a demand-side story. Not surprisingly, both perspectives are incomplete and exaggerated.

The pharmaceutical industry is at the heart of the debate over access to medicines, and understanding the industry’s position requires an examination of the competitive forces in the global market place and, in turn, on the importance of intellectual

3 This perspective is well represented in Harvey E. Bale, Jr., IP and Pharmaceuticals: A Decade of Progress, in MANAGING INTELLECTUAL PROPERTY 4 (Pharmaceuticals Supp. 1994).

4 Consider, for example, the words of Dr. Eric Goemare: “I have seen children covered with scars due to AIDS-related dermatitis, unable to sleep for the pain. I knew that all of them could have been helped with antiretroviral therapy, but the cost of the patented drugs was the only barrier.” MSF and Patents, MEDECINS SANS FRONTIERES (July 2011), http://www.msfaccess.org/content/msf-patents [hereinafter MSF and Patents].
property (IP) rights protection. Fundamentally, the global pharmaceutical market is one of the world’s largest and most profitable markets. Sales in 2011 are estimated to reach $880 billion dollars. Figure 1 below depicts pharmaceutical sales by region. While North America comprises the lion’s share of the global pharmaceutical market, it is important to note that the U.S. market alone makes up ninety-four percent of the North American market.

**Figure 1: Pharmaceutical Sales by Region, 2007**

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6 See Press Release, IMS Health, IMS Health Reports Global Prescription Sales Grew 6.4 Percent in 2007, to $712 Billion (Apr. 15, 2008), available at http://imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d24d88cef5305210VgnVCM100000ed152ca2RCRD (noting that in 2007 the United States was the largest single market at $286.5 billion and that North American sales were $304.5 billion).

7 IMS HEALTH, GLOBAL PHARMACEUTICAL SALES BY REGION – 2007 1 (2008), available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StatusBar/Top_Line_Data/GlobalSalesbyRegion.pdf (information is as of February 26, 2008). These figures exclude “unaudited markets, and Russia, Ukraine and Belarus audited data. Sales cover direct and indirect pharmaceutical channel pharmaceutical wholesalers and manufacturers. The figures above include prescription and certain over-the-counter data and represent manufacturer prices.” Id.
The markets of the United States, Europe, and Japan together represent more than eighty percent of global sales. Importantly, the majority of European nations and Japan are characterized by government price controls on pharmaceuticals and periodic price reviews. In contrast, in the United States, the world's largest and most lucrative pharmaceutical market, there are no direct price controls for non-government pharmaceutical sales. Accordingly, the returns from the U.S. market are tremendously important to the industry and to continued investment in pharmaceutical innovation.

Though innovation is the lifeblood of the industry, it does not come easily. Pharmaceutical research and development is increasingly costly and uncertain. Recent estimates of the cost of developing a new chemical entity are approximately $1.3 billion. While these numbers are highly controversial, pharmaceutical innovation is unquestionably an expensive undertaking. It is also a process that is risky and lengthy. New drug development takes an average of ten to fifteen years with no guarantee of success. Figure 2 below details the drug development process. In essence, transforming a new chemical entity into a successful therapeutic medicine requires both a lot of time and a tremendous financial investment.

Fundamentally, without the protection provided by the patent system, innovators would have little incentive to invest in new technologies that could easily be replicated and sold by their competitors. Such free riding on the initial investment constitutes a market failure that would stymie most innovation. Patents correct this market failure, providing the innovative firms with a limited period of market exclusivity to both incentivize the investment required for innovation and to make public the knowledge gained in the process. In essence, in exchange for granting the innovator a limited period of monopoly power (a temporary, static loss) society gains complete knowledge of the innovation, a permanent, dynamic gain. Through this tradeoff, the existing patent system corrects the market failure, though there are clearly problems with the current mechanism.

Although innovation is difficult, risky, and expensive, firms continue to invest. The market works, and the only place where the free market is truly in place for

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8 Gilbert Ross asserts that while such price controls in Europe, Japan, and Canada benefit consumers in the short run, the long run consequence is the decline of pharmaceutical research and development. Gilbert Ross, *Drugs from Overseas Can be Cheap, Which Is Part of the Problem*, WASHINGTON EXAMINER, Aug. 13, 2009, reprinted at Health Issues, AM. COUNCIL ON SCI. AND HEALTH (Aug. 13, 2009), http://www.acsh.org/healthissues/newsID.1823/healthissue_detail.asp.


11 In 2010, research and development investments by U.S. biopharmaceutical companies reached record levels, totaling $67.4 billion. Press Release, Pharmaceutical Research and
pharmaceuticals is the United States. This explains why medical innovation is more robust in the United States than in any other country. Innovation is incentivized here. Innovation is profitable here, and innovation happens here. Figure 3 describes


12 Id.


the number of medicines in development by country. The figures for the United States outstrip the total of all other regions.

While pharmaceutical research and development (R&D) is difficult and expensive, the industry faces other challenges as well. Importantly, the competitive nature of the global pharmaceutical industry has intensified with the rapid launch of competing molecules within a therapeutic class\textsuperscript{16} and with the aggressive introduction of generics immediately upon patent expiry.\textsuperscript{17} A recent study reveals that the time between approvals of the first and second drugs within a therapeutic class declined from 10.2 years in the 1970s to 2.5 years in the 2000–2003 period, and the average time between first and second follow-on drugs fell from a median of 16.1 years in the 1960s to 1.1 years in the period between 2000–2003.\textsuperscript{18} Increasingly aggressive competition from generic versions has further intensified the competitive nature of the industry. In a study of eighteen patented brand-name drugs, Grabowski and Vernon found that generics gained close to half of the market share within two years of entry.\textsuperscript{19} Recent

\textsuperscript{15} U.S. Market Drives Global Development of Medicines, supra note 14.
\textsuperscript{19} Henry Grabowski & John Vernon, A New Look at the Returns and Risks of Pharmaceutical R&D, 36 MGMT. SCI. 804, 806 (1990).
years have seen even more dramatic change. Between 1984 and 2008, generics’ share of the U.S. prescription market increased from 18.6 percent to 63 percent.\textsuperscript{20}

The ability of innovative firms to capture the returns to research and development is ever more elusive and further challenged by shorter effective patent lives and the increasing complexity of clinical trials. A recent study from the Tufts Center for the Study of Drug Development found that, during the last decade, clinical trial procedures and requirements have become increasingly intricate, necessitating more staff, time, and effort.\textsuperscript{21} Between 1999 and 2005, the median number of procedures per trial protocol grew from 96 to 158, an increase of 65 percent.\textsuperscript{22} In the period between 1999–2002 and 2003–2006, the length of clinical trials increased by 69.9 percent, from 460 to 780 days.\textsuperscript{23} Between 1999 and 2002, the clinical-trial participant retention rate decreased by 21 percentage points.\textsuperscript{24} All of these changes increase the cost and difficulty of clinical trials.

Ultimately all of these factors matter because innovative firms must be profitable in order to continue to invest in future pharmaceutical research. Fundamentally, this is an industry whose future, whose existence, whose survival depends upon innovation. Innovation is essential to the industry and is the source of both profits and growth for the pharmaceutical industry. As a result, patent protection is disproportionately more important for ensuring that the researcher appropriates the returns to R&D to the pharmaceutical industry than virtually any other. Building on the 1987 “Yale Survey,”\textsuperscript{25} Wesley M. Cohen and his co-researchers found that while “patents are unambiguously the least central of the major appropriability mechanisms overall . . . reflecting their subordinate role in the preponderance of industries” the drug industry regards them as strictly more effective than alternative mechanisms.\textsuperscript{26}

Their study reexamines the effectiveness of various means of appropriating intellectual property, finding that there are tremendous differences in the effectiveness of various appropriability mechanisms, both among industries as well as within...


\textsuperscript{23} Growth Protocol Design Complexity Stresses, supra note 21.

\textsuperscript{24} Id.


them. Relative to other industries, the study confirmed the industry’s high propensity to patent both product innovations (overall highest propensity at ninety-six percent) and process innovations (sixth highest propensity at forty-two percent). This reliance on intellectual property and its strong importance to the chemical and pharmaceutical industries is confirmed in numerous other studies.

Despite the protection provided by patents, it is important to note that even when research and development efforts are successful and a safe and effective drug is developed, it may not necessarily be profitable. Recent studies show that only two in ten new drugs are profitable, with lifetime sales that exceed average R&D costs. Figure 4 below graphically depicts these values, further emphasizing the risk associated with drug development. While blockbuster innovations may be highly profitable, their discovery is the exception.

Pharmaceutical innovation is motivated by potential profits. As such, the diseases endemic to developing nations and the limited purchasing power of these consumers hold little appeal. Sadly, global health research spending is characterized by a 10/90 gap. Specifically, less than ten percent of global health research expenditures are dedicated to conditions that account for more than ninety percent of preventable

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27 See id. at 5–14, tbls.1–2.
28 Id. at 49, tbl.A1.
30 The “10/90 gap” was coined by the Global Forum for Health Research to capture the imbalance between the disease burden born by the world’s poor and “the resources devoted to
Figure 4: Lifetime Sales Compared to Average R&D Costs (reproduced from John A. Vernon et al.)

mortality. Consider that “of the 1,556 new drugs approved between 1975 and 2004, only 21 (1.3%) were specifically developed for tropical diseases and tuberculosis, even though these diseases account for 11.4% of the global disease burden.” Notably, five of these thirteen drugs emerged from veterinary research. Unfortunately the absence of a profitable market for these diseases directs research efforts and resources to other endeavors.

In the midst of an increasingly exigent environment, the global pharmaceutical industry continues to bring innovative therapies to patients. As of February 2011, U.S. research-based firms “have a record 460 medicines in late-stage development for the prevention or treatment of rare diseases.” The industry invested in these innovations despite a development process that is progressively more costly, uncertain, and complex, with growing competition from follow-on molecules and the ever more


33 Pogge, supra note 1, at 197–98.

rapid entry of generic versions. Given the increasing number of challenges faced by the innovative pharmaceutical industry, its reliance on intellectual property protection and pharmaceutical patents to safeguard continued investment in innovation is both understandable and judicious.

III. CHALLENGES SURROUNDING ACCESS TO MEDICINES

Beyond drug development, getting drugs to those who need them remains a significant challenge. The difficulties surrounding access to medicines are especially important in developing countries. In the context of access, pricing policies are widely recognized as a crucial issue. Patent protection and the market exclusivity it guarantees also provide the firm with some control over price and the ability to segment distinct markets and charge different prices. The challenge for the industry is finding a balance between providing for continued investment in innovation and assuring broad access to affordable medicines. Obviously national markets differ, and differences in incomes and preferences will lead to differential prices across countries. Economic theory has established that this is most effectively done through Ramsey pricing, the most efficient mechanism for recovering shared (global) R&D costs by charging different consumers different prices based on their price elasticity of demand (price sensitivity). Specifically, consumers who are relatively insensitive to price changes will be charged a larger markup over marginal cost than consumers who are more price sensitive (based on income, preferences, etc.). The result is the set of prices that generates sufficient revenue to cover the shared development cost and generates the highest level of consumer welfare.

IV. ANALYSIS

While Ramsey pricing may be the most efficient mechanism for recovering R&D expenditures, it is clearly not enough. The striking numbers presented in the introduction are a stark reminder of this fact. At the center of the access to affordable medicine debate is the issue of pharmaceutical patents. Given this, one must ask whether patents truly are the barrier to access some contest. At the same time, if patents work to incentivize innovation as others believe, why is this market not

35 See, e.g., MSF and Patents, supra note 4.
36 Patricia M. Danzon, Making Sense of Drug Prices, 23 REGULATION 56, 61 (2000), available at http://www.cato.org/pubs/regulation/regv23n1/danzon.pdf. Ramsey pricing has been widely utilized in the regulation of utilities. The mechanism “covers all costs by charging lower prices to price-sensitive buyers than to price-insensitive buyers” and results in a pricing structure under which “[c]onsumers on the whole are better off with Ramsey pricing than they would be with uniform pricing.” Id.
37 See MSF and Patents, supra note 4.
working in developing countries? What are the factors that are keeping drugs from getting to patients in these nations?

While a definitive answer remains elusive, recent studies shed some light on contributing factors. In a 2001 study, Attaran and Gillespie-White examine the patent status of antiretroviral (ARV) drugs in African nations and attempt to determine if patent protection limits access to treatment. Their analysis considers the patent status of fifteen ARV drugs patented by eight pharmaceutical firms in fifty-three African countries. They calculate that of the possible 795 patents only 172, or 21.6 percent, actually exist. Attaran and Gillespie-White thus conclude that patents do not limit access to antiretroviral drugs in Africa because such a small percentage of the possible patents for antiretroviral drugs exist in these countries. Given this, they argue that other factors must be to blame: ubiquitous poverty, lack of political will, poor medical care and infrastructure, inefficient regulatory procedures, and high tariffs and taxes. It may be that these conclusions are exactly right, but a more informative figure would adjust for infection rates, drug utilization, and income levels in calculating the true barrier created by pharmaceutical patents. In particular, it would be helpful to know if the majority of HIV/AIDS sufferers are found in countries where most of the drugs are on-patent. If so, then patents may, in fact, be a serious obstacle to the treatment of these people. Clearly access is and was a problem, but patent protection is not extensive in the African nations included in the study. Despite the opportunity to patent ARVs in these nations, the patents were not sought by the innovative pharmaceutical companies indicating both that patents may not be the primary barrier to access and that such protection may not be as ubiquitously essential as claimed.

In another effort to determine whether patents are a barrier to access, Attaran considers the relationship between patents and access to the World Health Organization’s (WHO) essential medicines. The study finds that patenting is rare. In the sixty-five low- and middle-income countries studied, only 19 of the 319 products on the WHO’s essential medicines list are patentable, though frequently they are not actually patented. Admittedly, the WHO’s list focuses on cost-effective drugs and

39 Id. at 1887.
40 Id.
41 Id. at 1890.
42 Id.
43 See id. at 1889–91.
45 See id. at 157–58.
therefore features a majority of off-patent medicines and treatments; however, in those few cases where patents were available, innovative firms only sought patents thirty-one percent of the time.\textsuperscript{46} Attaran finds that patents and patent applications exist for only 1.4 percent of all essential medicines in the sixty-five studied countries (300 instances out of possible 20,735 cases, combinations of medicines and nations).\textsuperscript{47} Again, this suggests that patents may not be as crucial as sometimes described by the industry. Nevertheless, since access is clearly a problem even in the absence of patents, the results suggest that something beyond patents prevents access. While these two studies may be flawed, they do point to an important phenomenon that bears exploring.

Fundamentally, those who argue that pharmaceutical patents create a barrier to access claim that the absence of patents would generate generic competition and, in turn, dramatically lower drug prices.\textsuperscript{48} A recent study on developing country markets casts doubt on these claims. In a June 2011 study, Danzon, Mulcahy, and Towse analyze pharmaceutical prices in emerging markets, focusing on the importance of income, competition, and procurement efforts:\textsuperscript{49}

\begin{quote}
Within-country income inequality contributes to relatively high prices in MLICs [middle and low income countries]. The number of therapeutic and generic competitors only weakly affects prices to retail pharmacies, plausibly because uncertain quality leads to competition on brand rather than price. Tendered procurement attracts multi-national generic suppliers and significantly reduces prices for originators and generics, compared to prices to retail pharmacies.
\end{quote}

This indicates that generic competition may not be the route to lower prices for developing nation consumers as assumed. As such, we must look beyond pharmaceutical patents for the factors inhibiting access to medicines.

\begin{footnotes}
\item[46] Id. at 156, 158.
\item[47] Id. at 158.
\item[50] Id. at abstract.
\end{footnotes}
In reality, there are a host of other complicating factors that work against patients in the developing world. The most significant of these is likely poverty. Close to half of the world’s population lives on less than two dollars per day. That is more than three billion people who are locked out of the market and unable to purchase the medicines that they need. In Africa, annual drug spending is estimated to be two dollars per person or less. In an economic context, demand is defined as the quantity that consumers are willing and able to purchase over a specified period of time. Developing-nation consumers are foiled by their inability to afford treatment. Poverty is truly the most significant barrier to access. Even at cost, even at pennies per dose, many consumers in developing nations are unable to purchase the drugs they need. As explained by Musgrove and Hotez, in terms of access, “extreme poverty is universally the most important determinant. This is true both for individuals and for countries too poor to fund control efforts fully, still less to undertake needed research.”

Unfortunately poverty is not the only barrier faced by developing country patients. Remarkably, pharmaceutical prices are frequently inflated due to their own government’s tax and tariff policies. In many nations local price inflators (LPIs) are significant contributors to pharmaceutical prices. These include tariffs, sales and value added taxes (VAT), port charges, importer’s margins, pre-shipment inspection, clearance and freight, and central, regional and local government taxes. The impact of local price inflators is presented in Table 1 below. In a study of fifty-three low-income countries, Bate, Tren, and Urback find that when all duties and taxes are accounted for, the cost of medical treatments and equipment can be inflated by over 51 percent.  


54 See Philip Musgrove & Peter J. Hotez, Turning Neglected Tropical Diseases into Forgotten Maladies, 28 Health Aff., 1691, 1694 (2009).


56 Id. at 6.

57 See generally id.
thirty percent.\textsuperscript{58} Local price inflators are a function of government intervention and are widely utilized to both protect local industry through high import barriers and raise government revenue.\textsuperscript{59} As shown below, these price increases can exceed eighty percent.

**Table 1: Local Pharmaceutical Price Inflators (LPIs) (reproduced from Benedict Irvine)\textsuperscript{60}**

<table>
<thead>
<tr>
<th>Country</th>
<th>LPI (percentage increase over base price)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armenia</td>
<td>87%</td>
</tr>
<tr>
<td>Brazil</td>
<td>82%</td>
</tr>
<tr>
<td>Kosovo</td>
<td>74%</td>
</tr>
<tr>
<td>South Africa</td>
<td>74%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>74%</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>64%</td>
</tr>
<tr>
<td>Mauritius</td>
<td>59%</td>
</tr>
<tr>
<td>Kenya</td>
<td>54%</td>
</tr>
<tr>
<td>Nepal</td>
<td>48%</td>
</tr>
</tbody>
</table>

Of the LPIs studied, tariffs are a particularly important factor. According to a 2003 study by the European Commission that considered drugs for the treatment of communicable diseases, total taxes and duties vary widely, from a low of 0.01 percent in Malaysia to a striking 60 percent in India, with a global average of 18 percent.\textsuperscript{61} Details on these rates are presented below in Table 2.

\textsuperscript{58} Id. at 16–18 tbl.2.
\textsuperscript{59} Id. at 12.
\textsuperscript{60} BENEDICT IRVINE, INTERNATIONAL POLICY NETWORK, DEATH AND TAXES: THE IMPACT OF TAXES AND OTHER GOVERNMENT BARRIERS TO ACCESS 2 tbl.2 (2004).
Table 2: Duties and Taxes on Retail Medicines (reproduced from Benedict Irvine)  

<table>
<thead>
<tr>
<th>Country</th>
<th>Combined Total Duties and Taxes</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>55%</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>40%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>34%</td>
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<tr>
<td>Pakistan</td>
<td>33%</td>
</tr>
<tr>
<td>Bolivia</td>
<td>32%</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>29%</td>
</tr>
<tr>
<td>China</td>
<td>28%</td>
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<tr>
<td>Jamaica</td>
<td>27%</td>
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<tr>
<td>Morocco</td>
<td>25%</td>
</tr>
<tr>
<td>Georgia</td>
<td>25%</td>
</tr>
<tr>
<td>Mexico</td>
<td>24%</td>
</tr>
</tbody>
</table>

Many vulnerable populations are denied efficacious treatments by their own governments through other means as well. While government tariff and taxation policy raise the prices of pharmaceutical therapies, government corruption also creates a barrier to access. “In South Africa almost 50% of the pharmaceuticals entrusted to the government itself are stolen.” In a study of missing malaria drugs, Bate claims that “the vast majority of diversion (80 percent, or 24 million treatments) takes place directly from government-run storage and distribution facilities--with the support of

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62 IRVINE, supra note 60, at tbl.2.
local government officials, or at least without their interference.64 Starting in July 2001, millions of doses of GlaxoSmithKline’s Combivir® and Epivir®, used to treat HIV/AIDS, were shipped to Africa at reduced prices and later intercepted in the supply chain in the Netherlands and France.65 Due to the high value of pharmaceuticals, corruption and resale are widespread.66 Unfortunately, the temptation is greatest where the need is greatest and discounted prices are most crucial.

In the context of barriers to access to medicines, corruption takes other forms as well. Most sinister of these is pharmaceutical counterfeiting. First, a definition:

a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.67

African health officials have noted that “counterfeit medicines are a greater public health threat than AIDS or malaria.”68 Although reports on counterfeiting incidents are abundant, the magnitude of the problem is difficult to estimate. “Pharmaceutical

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64 Roger Bate, Do Aid Agencies Want to Know When Their Medicines Go Missing?, 2010 AM. ENTERPRISE INST.’S HEALTH POL’Y OUTLOOK SERIES 3.
67 General Information on Counterfeit Medicines, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/services/counterfeit/overview/en/index.html (last visited Nov. 12, 2011). Even defining a counterfeit drug is surrounded by controversy. The definition utilized here, provided by the World Health Organization, is the one most frequently cited. The definition found in the U.S. Food, Drug and Cosmetic Act (1938) is similar, though more elaborately defined. “A drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.” 21 U.S.C.S § 321 (g)(2) (LexisNexis 2011).
counterfeiting is a pervasive problem, impacting nations of every size and income level and drugs of every description.\textsuperscript{69} Given that medicines are very high value products relative to their bulk and in very high demand, the problems of patent infringement\textsuperscript{70} and counterfeiting have assumed enormous proportions.\textsuperscript{71} No company is untouched. No drug is invulnerable. No country is immune. Counterfeiting is a significant and growing barrier and threat to public health. In a 2006 statement, Peter Pitts, former Associate Commissioner of the Food & Drug Administration and President of the Center for Medicine in the Public Interest (CMPI), projects global counterfeit drug sales to reach $75 billion in 2010, a 92 percent increase from the 2005.\textsuperscript{72} That figure exceeds the annual GDP of two-thirds of all the world’s nations (131 of the 193 listed by the World Bank) and is equivalent to the combined annual GDP of the 24 poorest Sub-Saharan African Nations.\textsuperscript{73} This threat is particularly acute in developing nations, where regulatory and enforcement efforts are often inadequate. Given the size and profitability of this market, it is not surprising, but it is discouraging. Counterfeiters victimize the most vulnerable patients. Those with the least to lose are frequently the ones who lose the most.

The challenges surrounding access to medicines are significant and include ubiquitous poverty, lack of political will, high tariffs and taxes, inefficient government regulatory procedures, and counterfeiting. The most important of these is likely poverty, and this challenge has been addressed on the global stage through the TRIPS Agreement and the Doha Declaration, which provide legal flexibilities for nations to grant compulsory licenses to patents given that certain conditions are met.\textsuperscript{74} Article 31 of

\textsuperscript{69} Lybecker, supra note 17, at 511.

\textsuperscript{70} It is important to specify that the term “patent infringement” is only correct if the developing country in which counterfeiting occurs has pharmaceutical patent protection legislation in place.

\textsuperscript{71} See Bate, supra note 64, at 4.

\textsuperscript{72} Peter Pitts, President, Center for Medicine in the Public Interest, Written Testimony for the U.S.-China Economic and Security Review Commission (June 7, 2006) (transcript available at http://www.uscc.gov/hearings/2006hearings/written_testimonies/06_06_07wrtc/06_06_7_8_pitts_peter.php).


the TRIPS Agreement seeks to enhance access to essential medicines by the world’s poor while simultaneously preserving the incentives to innovate. 75

Specifically, Article 31(b) of the TRIPS Agreement allows for use without authorization of the rights holder if

prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. 76

At the same time, the scope of its use is limited, and the licenses are non-exclusive and non-assignable. 77 While Article 31(f) specifies the compulsory license must be predominantly for the supply of the domestic market, 78 the Doha Declaration, Paragraph 6 establishes a temporary waiver of this stipulation. 79 Finally, the TRIPS Agreement specifies that the nation must pay adequate remunerations for its use, accounting for the economic value of the authorization. 80 The allowance of compulsory licenses within the context of the TRIPS Agreement aims to alleviate the barriers of patent protection and insufficient manufacturing capacity when a legitimate public health need arises. While this effort enhances access, considerable challenges remain when it comes to securing medicines for the world’s poorest.

V. CONCLUSION

While it is easy to point to patents and blame the industry and international trade law for barriers to access to medicines in developing nations, the reality of the situation is more nuanced and not nearly so straightforward. Patents serve a purpose and have incentivized medicines that have enhanced and extend lives on a global scale. This innovation necessitates protection, and this protection necessitates a tradeoff. Patents provide that tradeoff, market exclusivity in exchange for continued investment in innovation. Admittedly room for improvement exists, and access is certainly a

75 Id. at 333.
76 Id.
77 Id.
78 Id.
80 TRIPS Agreements, supra note 74, at 333.
priority. However, it is imperative that we preserve the incentives to innovate and ensure that the future R&D pipeline will continue to yield the innovative medicines that treat the world’s sick and suffering.

Moreover, in the debate over barriers to access, the focus must be broadened to include other important factors such as poverty, taxes and tariffs, corruption, and pharmaceutical counterfeiting. Each of these elements inhibits access to medicines through financial challenges, higher prices, shortages, and spurious products. For the most vulnerable populations it is essential to address all of the key barriers to access and improve procurement and monitoring systems. Without a wider focus and a solution to these problems, it is unlikely that efforts to improve access will succeed.

As we consider the challenges to getting medicines to developing nations, the numbers quickly become overwhelming. $1.3 billion. That is the estimated cost of developing a new drug. 81 Admittedly it is a very controversial number, but even if it is one-half or a third of that figure, it is still a tremendous amount of money. Twelve years. That is the number of years of effective patent life that innovative pharmaceutical firms have to recoup their investment. 82 After discovery, development, clinical testing, and regulatory approval, twelve years is all that remains of the twenty-year patent life. 83 Two dollars per day. For half of the world’s population living on less than two dollars per day, even pennies per dose for the drugs they need is too costly. 84 The economics behind the debate over access to medicines should shed some light on the complexity of this issue, the magnitude of the problem, and the importance of a solution.

81 DiMasi & Grabowski, supra note 9, at 469.
82 Id. at 853.
83 Id.
84 CHEN & RAVALLION, supra note 51, at 20.