

# Trade Rules, Intellectual Property, and the Right to Health

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## FULL TEXT

While the inaccessibility of lifesaving medicines in developing countries has long presented a grave international health problem, current trade rules perpetuate and exacerbate this dilemma. I argue that by restricting access to essential medicines, trade rules violate core human rights to minimally adequate health care. Medicines are not simply commercial commodities, but basic human needs, fundamental human rights entitlements, and critical components of health care systems. Given the potential loss of life that such restrictions entail, the legitimacy and justification for trade-related intellectual property rules on medicines should be assessed not only in terms of trade law and intellectual property rights, but from the perspective of human rights standards. These standards require that international trade rules on medicines be justified to the fullest extent possible, and permitted only to the extent to which they can be justified. I argue further that human rights standards may offer practical tools for challenging and even reforming trade rules on medicines.

## GLOBAL ACCESS TO ESSENTIAL MEDICINES

The figures describing the limited access to essential medicines in developing countries are staggering: almost two billion people, one-third of the global population, lack regular access to essential medicines. In poorest Africa and Asia, this lack of regular access rises to affect half of the population. Access to essential medicines that treat the most prevalent diseases in developing countries is similarly low. AIDS statistics highlight the problem vividly: despite AIDS being the worst infectious pandemic in modern history, the majority of infected people lack access to lifesaving, antiretroviral therapies. In sub-Saharan Africa, where over two-thirds of all people with HIV are located, only 28 percent have access to antiretroviral treatments.<sup>3</sup> In developing countries two million people die from tuberculosis every year;<sup>4</sup> over one million people (mainly African children) died from malaria in 2002; and approximately three million people die each year from HIV/AIDS globally, with over two million of these deaths occurring in subsanaran Africa alone.<sup>5</sup> HIV/AIDS in particular is exacting a tremendous social and economic toll given that its primary demographic is young people who are economically and reproductively active, and whose deaths are resulting in the orphaning of millions of children. In Africa the epidemic is reversing the developmental gains of the past fifty years, including hard-won increases in child survival and life expectancy.<sup>6</sup>

The use of lifesaving medicines could significantly mitigate these death tolls. Estimates show that in sub-Saharan Africa, antiretroviral medicines, combined with effective prevention strategies, could save between 5.8 and 10.1 million lives over the next fifteen years.<sup>7</sup> The

potential impact of improved access to essential medicines on reducing death rates is not, however, limited to HIV/ AIDS. In 2001 the World Health Organization (WHO) Commission on Macroeconomics and Health estimated that expanding access to existing medicines, preventive technologies, and vaccines to prevent or treat infectious diseases, maternal and perinatal conditions, childhood diseases, and noncommunicable diseases could save up to 10.5 million lives per year, and that expanding access to medicines for infectious diseases alone could save almost 9 million lives a year.<sup>8</sup>

Numerous factors influence the extent of access to medicines in any given country. These include national health policies on medicines (and whether these promote rational use of medicines) and the existence of reliable health systems, as well as the affordability of medicines and the availability of sustainable financing.<sup>9</sup> Direct economic factors, however, disproportionately affect access to medicines in poor countries, where drug purchases consume large proportions of national health budgets and limited resources restrict the types of drugs that can be offered in the public sector. Inadequate public-sector provision of medicines also means that the majority of individual drug expenditure in developing countries is out-of-pocket.<sup>10</sup>

State autonomy to address the determinants of medicines access (namely, rational use, infrastructures, affordability, and financing) may be considerably constrained by the international trade rules and politics that determine global drug prices. While many of what the WHO defines as essential medicines are off-patent and therefore more affordable, many priority health needs in developing countries require treatment with medicines that are very costly, and thus out of reach for the majority in need of them. This is true of artemisinin-based antimalarial drugs,<sup>11</sup> tuberculosis treatments and reserve antibiotics,<sup>12</sup> and, until recently, HIV/AIDS drugs, which were prohibitively expensive until public pressure forced their prices down (although in many places these drugs remain prohibitively priced, and second-line drugs everywhere remain particularly expensive).<sup>13</sup> Drugs used to treat common medical conditions are similarly prohibitively priced, however, including those for hepatitis C, diabetes, and many cancers. For example, it costs \$30,000 per person per year to treat hepatitis C, an infectious liver disease affecting 170 million people worldwide.<sup>14</sup>

### The **WTO** TRIPS Agreement

Patents, the primary factor determining drug prices, are protected internationally under the World Trade Organization's (**WTO**) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS also extends protection to other forms of intellectual property, such as trademarks and copyrights. TRIPS requires twenty-year patents for pharmaceuticals, which give exclusive rights to holders to prevent nonconsensual use and which are subject to extensive domestic and international enforcement, including the **WTO's** formal mechanism for settling disputes related to **WTO** agreements. Today, all **WTO** members except least-developed countries (which are not obliged to implement TRIPS until January 1, 2016) are bound by TRIPS. Within less than nine years, however, this agreement will apply to all **WTO** members, including the poorest countries.

TRIPS does allow certain exceptions to patenting and limitations on exclusivity in the interests of public health and social welfare, including permitting parallel imports and compulsory licensing.<sup>15</sup> Parallel importing allows countries to import cheaper versions of patented medicines without any restrictions. Compulsory licensing authorizes governments to manufacture generic versions of patented medicines without corporate consent in certain circumstances.<sup>16</sup>

TRIPS globalizes drug patents at a strong, and for many countries unprecedented, level. Before TRIPS, more than forty countries did not patent medicines, many others (such as

India) only patented drug processes, and others provided shorter patent terms. Introducing patents where there were previously none drives up drug prices by enabling monopoly pricing and excluding cheaper generic alternatives. Given how price-sensitive drug access is in poor countries, higher prices can significantly limit access for the poor. This is illustrated in India, which introduced drug product patents in 2005 that are expected to significantly increase drug costs. A case study of the impact of introducing patents on four domestic antibiotics estimated that the total annual welfare losses to the Indian economy from the resulting price increases and access limits would be around \$305 million (most of which derives from the loss of consumer welfare), or about 50 percent of the sales of the entire systemic antibacterial segment in 2000.<sup>18</sup>

The price impact of excluding access to generic medicines is particularly acute, since generic competition is a critical factor in reducing drug prices. It is indicated, for instance, that pharmaceutical product prices fall sharply when generic entry occurs following the expiration of patents.<sup>19</sup> One study shows that "over time patents are a major factor in sustaining high drug prices; the appearance of generic competition results in prices of these drugs being much closer to the marginal production costs than those of brand name companies."<sup>20</sup>

Moreover, the introduction of global drug patents has a systemic impact on the manufacture and export of generic medicines globally. As TRIPS is implemented, it will eventually phase out the generic manufacture of patented medicines in totality, unless this is done under compulsory licensing. This will limit domestic manufacture of generic medicines, particularly in India, which has been a primary source of generic antiretroviral drugs for other developing countries.<sup>21</sup> The full implementation of TRIPS by 2016 will especially affect countries that depend on importing generic versions of currently patented medicines.<sup>22</sup>

#### Inadequate Solutions: The Doha Declaration and the Compulsory Licensing Amendment

Foreign and corporate contestation of the use of TRIPS flexibilities motivated developing countries at the Doha round of **WTO** trade negotiations in November 2001 to advocate for a Ministerial Declaration to clarify the TRIPS legality of compulsory licensing and parallel import. Accordingly, the declaration states:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health ... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of a **WTO** member's right to protect public health and, in particular, to promote access to medicines for all.<sup>23</sup>

The declaration confirms that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."<sup>24</sup> In particular:

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/ AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.<sup>25</sup>

The declaration also confirmed that members were free to establish their own regimes for parallel importation without challenge. Notably, Doha identified the problem posed by the TRIPS requirement that compulsory licensing shall be "predominantly for the supply of the domestic market." As such, in paragraph 6, the Doha Declaration called for an expeditious solution to the problem faced particularly by the least-developed countries without local manufacturing capacity. In August 2003, after protracted negotiations, the **WTO** General

Council released its decision on this problem, which was later formalized as an amendment to TRIPS Article 31.

The "export solution" is intended to permit least-developed and other countries to import generic medicines made under compulsory licensing according to strict conditions. For example, both importing and exporting countries must issue compulsory licenses; eligible importing members other than least-developed countries must establish insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question; such medicines are limited to the amount necessary to meet the needs of the importing country, and must be imported in their entirety to the member; the medicines must be clearly identified as produced under this system through labeling, distinguished by packaging and/or shaping and coloring; and importing countries must take reasonable measures to prevent reexportation of products.<sup>26</sup>

While growing numbers of countries (including Malaysia, Indonesia, Zambia, Zimbabwe, and Mozambique) have recently successfully issued compulsory licenses for antiretroviral medicines, to date not a single country has exported medicines produced under compulsory license. Several factors account for this, including persistent corporate and governmental threats of legal or economic sanctions and the complexity, cost, and limited duration and scope of the rules themselves. Thus, despite its TRIPS legality, the generic manufacture and export of patented medicines to poor countries is simply not occurring. In the absence of generic versions of patented medicines, drug prices remain at patent monopoly levels, and this restricts access in resource-constrained settings.

#### A TRIPS-Plus World: Bilateral Agreements and Corporate Contestation

The intellectual property rules in TRIPS are considerably less stringent than the rules developing countries are increasingly adopting in free-trade agreements with the United States and other Western governments. These "TRIPS-plus" agreements place greater restrictions on the use of TRIPS flexibilities. For example, many free-trade agreements make it much more difficult for generic drugs to enter the market upon patent expiration and extend patent periods beyond twenty years.<sup>27</sup> Moreover, they limit compulsory licensing and prohibit parallel imports. The United States has concluded bilateral and regional trade agreements containing TRIPS-plus standards with over sixty countries, many of which are developing countries with extremely high disease burdens, including HIV/AIDS.

At the same time, countries that try to use such flexibilities as compulsory licensing and parallel importing often face the threat of trade sanctions or corporate litigation (which often come as a single combined assault) from both pharmaceutical companies and Western governments. This has been the case for Thailand, Mexico, Chile, Brazil, Indonesia, Bolivia, Colombia, Ecuador, Peru, Venezuela, South Korea, and South Africa. Despite the confirmation of the legality of compulsory licensing and parallel imports in the **WTO's** Doha Declaration on Public Health, corporate and governmental challenges continue. In 2002, for example, the U.S. government pressured South Korea to refuse a compulsory license for Gleevec, a leukemia drug that costs around \$27,000 per year per person. In 2006, Pfizer sued a Philippine company and government officials in their private capacity to prevent parallel importing of a generic version of Norvasc, a hypertension drug.<sup>29</sup>

Given the adverse health impacts of the intellectual property protections contained in these free-trade agreements, why do countries consent to entering them at all? On the one hand, it is not surprising that governments may favor economic growth over critical health investments, especially considering how routinely health systems are underfinanced and how access to health care for marginalized and poor populations is so often neglected in both rich and poor countries.<sup>30</sup> Governments may also assume that the aggregate

economic benefits of these trade agreements outweigh and indeed justify any restrictions in access to medicines that they may cause. At the same time, trade negotiators may simply lack knowledge of the health implications of higher levels of intellectual property protection. There is, however, a degree of coercion that may accompany the finalization of these agreements. Peter Drahos suggests that developing countries have little room to refuse bilateral agreements, as trade negotiations take place alongside actual or threatened unilateral trade sanctions.<sup>32</sup>

Debates about the economic benefits of trade aside, from a human rights perspective sacrificing access to essential medicines for the poorest (those who most assuredly will be affected) in the service of broader economic growth is not an acceptable trade-off. Nor should it be a necessary trade-off. In Peru recently, largely due to the advocacy of Paul Hunt, the UN Special Rapporteur on Health, the government conducted an assessment of the potential impact of a free-trade agreement being negotiated with the United States. The assessment indicated that the agreement would limit access to medicines for approximately 700,000 people, and the government accordingly recommended implementing a fund from industries that would profit from the agreement to supplement this shortfall.<sup>33</sup> While the Peruvian experience suggests that governments can mitigate the restrictive impact of trade rules on medicines access at the domestic level, impact assessments cannot directly challenge the injustices inherent in the current trade regime on medicines. Free-trade agreements and corporate and governmental challenges effectively turn TRIPS rights into powerful corporate entitlements that can be only rarely limited. This not only perpetuates the inaccessibility of present medicines but excludes poor people from accessing new therapeutic advances.

#### INTERNATIONAL HUMAN RIGHTS ON HEALTH

Since the global imposition and enforcement of stringent patent rights play a direct role in the high loss of life due to inaccessible medicines, such a system should be justifiable not simply from the perspective of intellectual property rights but from the perspective of human rights law. Access to essential medicines is a fundamental human rights claim under the rights to health and life.<sup>34</sup> In accordance with international human rights law, it should therefore be seen as a core human rights entitlement to receive minimally adequate health care. Under these rights, governments have a range of duties with regard to medicines, which include, inter alia, ensuring the affordability of essential medicines and preventing restrictions on access. In this light, government use of TRIPS flexibilities to provide access to lifesaving medicines should be seen as necessary to fulfill their duties under rights to health and life. In cases where the adoption of patent provisions in TRIPS-plus free-trade agreements will result in the loss of life due to limited access to lifesaving drugs, this action should be seen as a violation of these duties. Support for the idea that the enforcement of trade-related intellectual property rights may violate human rights is found in the work of Thomas Pogge. Pogge argues that those who uphold social rules, such as trade and economic policies, can violate human rights when these rules 'foreseeably and avoidably deprive human beings of secure access to the objects of their human rights.'<sup>35</sup> Pogge argues that the present international patent system fulfills these conditions.

While Pogge's argument that current trade rules violate the human right to health rests on ethical and not legal grounds, I suggest that the legal basis of this claim is increasingly well established. Certainly this statement must contend with common arguments disputing the legal force of a "right to health." Perceptions that such a right would create limitless entitlements and place indeterminate duties on governments are somewhat reinforced by the international law formulation of this right as an entitlement to "the highest attainable standard of health," with state duties limited to progressive realization to the maximum of available resources.<sup>36</sup>

There have been, however, authoritative international definitions of the right to health that clarify both the scope of the entitlement under this right and the nature of duties it places on governments. The most important of these is a general comment on the right to health released by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) in 2000. According to the comment, the right to health includes a right to adequate and affordable health care, and imposes minimum core duties on governments. These are a baseline of obligations below which the committee asserts no state should drop irrespective of its resources, and for which countries should be held to strict account for failures to comply. Minimum core duties under the right to health are roughly consistent with essential primary health care, and include providing essential drugs as defined by the WHO.

Yet the committee's indication that minimum core obligations should not be limited under any circumstances may present a paradox for poor countries that lack the ability to fully realize their core duties to provide essential medicines, or whose governments believe that public interests are better served by investment in, for example, physical infrastructure or broadening educational opportunities than by increased health expenditures. Governments are not required to perform the impossible, however. Instead, states should be held to strict account in domestic and international legal fora for policies and laws that fail to meet minimum core duties, and should be required to provide persuasive justifications for failures to comply.<sup>37</sup>

The comment also defines the specific duties that the right to health (and the duty to provide essential medicines) places on states and other social actors. For example, domestic governments hold threefold duties not to interfere with the enjoyment of this right, to prevent interference in the right by third parties, and to provide health care where people cannot secure access to goods on their own.

This implies that the duty to provide medicines requires states to prevent corporations from obstructing access, including through prohibitive pricing. Indeed, CESCR indicates that these duties extend to ensuring that international agreements do not adversely impact the right to health either domestically or in other countries, and that a failure to do so violates the right. This implies that states must use TRIPS flexibilities to fulfil their duties under the right to health, and that they must negotiate less restrictive intellectual property rights in bilateral free-trade agreements. Yet while governments are the primary duty holders under international human rights law, they are not the only actors obligated to ensure the realization of this right. All members of society, including the private business sector, have responsibilities regarding the realization of the right to health. In addition, states hold international obligations with regard to the right to health, which the committee suggests include duties not to obstruct this right in other countries, to prevent corporations from violating it elsewhere, and to ensure that international agreements do not adversely impact the right to health.<sup>40</sup>

While the committee's interpretations do not constitute binding law, they represent important normative advances that may influence voluntary conduct by states and corporations as well as provide support for rights-based advocacy and litigation. Certainly less than universal acceptance of the right to health and UN interpretations persists, and not all governments will be persuaded of their human right duties under this right. It is significant, however, that considerably more countries have accepted the legality of this right than not. Two-thirds of all countries (153 of 192) have ratified the International Covenant on Economic, Social and Cultural Rights (ICESCR), for example; and the Convention on the Rights of the Child (CRC), which also contains a right to health, enjoys almost universal ratification.<sup>41</sup> Rights to health are also contained in several other broadly ratified international and regional treaties.<sup>42</sup> While treaty ratification is no guarantee of the effective implementation of human rights standards, similar rights are increasingly being

entrenched in domestic constitutions: according to a recent study, over two-thirds of all domestic constitutions have provisions regarding health and health care.<sup>43</sup> Moreover, human right claims for health care are increasingly being enforced at the domestic level, both through civil rights such as rights to life and equality (in India and Canada <sup>44</sup>) and as a direct justiciable right (in South Africa and numerous Latin American countries, including Argentina and Venezuela<sup>45</sup>). There is also a growing global jurisprudence where access to medicines has been successfully claimed under human rights protections. A recent study identified seventy-one cases from twelve countries where access to medicine was claimed as a human right, with 83 percent of these cases being successful. The study found that the consistent variables in successful cases were national ratification of the Social Rights Covenant and constitutional entrenchment of a right to health.<sup>46</sup> Legal claims based on the right to health have also been successfully employed against corporations to challenge medicine pricing under patents.<sup>47</sup> The right to health can therefore no longer be seen as an ineffectual "manifesto" right; it is a widely recognized legal right with tangible force and effect in claiming access to health care and medicines.

### Conflicts between International Human Rights and TRIPS

The provisions of TRIPS that require all **WTO** members to provide twenty-year patents for medicines appear to create a prima facie restriction of national capacities to realize core obligations to provide essential medicines. While it could be argued that there need not be such a conflict between TRIPS and right-to-health obligations if countries use TRIPS flexibilities, as I have indicated above, these flexibilities are being eroded in free-trade agreements and challenged by corporations and Western governments. As a result, in many countries TRIPS rights have become virtually absolute for the duration of patents. This poses prima facie conflicts with the right to health that need to be resolved both by domestic policy-makers and national judiciaries, and by global policy bodies addressing TRIPS and public health.

The first step toward resolving this problem is to establish a legal relationship between human rights and TRIPS obligations at both a practical and theoretical level. Doing so should provide a strong justificatory framework to empower poor states to resist patent-related provisions in TRIPS-plus agreements. It is notable that the vast majority of **WTO** members hold concurrent right-to-health obligations: 81 percent of current **WTO** members (122 out of 149 countries) have ratified the ICESCR, and 97 percent (145 out of 149 countries) have ratified at least one human rights treaty containing a health right (such as the CRC, the Convention on the Eradication of All Forms of Racial Discrimination, or the Convention on the Elimination of All Forms of Discrimination Against Women).<sup>49</sup>

There is also support in international law and international consensus documents for the primacy of human rights over trade obligations.<sup>50</sup> The primacy argument is based on the principle that the human rights of the most vulnerable and poor should be prioritized when they conflict with trade and intellectual property interests. However, the primacy argument also raises an important question: Should primacy be understood to require that human rights always trump trade and intellectual property rights? While the seriousness of the human rights claims at stake may well suggest that this is the case, most human rights can be justifiably limited to protect collective interests, such as national security, public health, or the rights of others.<sup>51</sup> These restrictions must, however, be both necessary and proportional, meaning that they should be the least restrictive alternative for achieving a particular aim.<sup>52</sup>

Are there any compelling public interests that may justify restricting the right to essential medicines? The arguments in support of international trade rules on intellectual property, which effectively limit access to essential medicines in service of patents, make precisely

this claim, holding that patents are essential to promote the innovation of new medicines and to enable authors to profit from their work. Certainly I do not dispute the right of authors to profit from their work, whether they are individuals or corporations. Yet as I indicate below, strong intellectual property law is used as a justification for pricing that dramatically exceeds marginal cost. Moreover, there is no parity in the nature of human rights to essential medicines and intellectual property rights, which are better understood as legal entitlements (albeit serving a positive public function) than as fundamental human rights. For example, the Committee on Economic, Social and Cultural Rights comments that

human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.<sup>53</sup>

The committee suggests that if intellectual property rights are to be appropriately balanced with other rights, they can be subjected to necessary and proportional limitations that do not unduly favor the private interests of authors and give due consideration to the public interest in enjoying broad access to their productions.<sup>54</sup> In particular, this means that state parties should ensure that their legal or other regimes protecting this right do not impede their ability to comply with their core obligations under rights to food, health, and education. The implications of such a balancing for government policies regarding medicine pricing is made explicit: "Ultimately, intellectual property is a social product and has a social function. State parties thus have a duty to prevent unreasonably high costs for access to essential medicines."<sup>55</sup>

#### Does the Innovation and Reward Argument Justify Limiting Access to Medicines?

The pharmaceutical industry argues that strict global patent protection is critical in order to recoup the massive resources drug companies invest on research and development (R&D), which they claim is around \$800 million per medicine, and to provide them with the incentive to spend more on R&D to produce new medical innovations. The industry claims that such exceptions as compulsory licensing and parallel imports threaten the viability of the medical innovation system.<sup>57</sup> Proponents of strict intellectual property rules maintain that the patent system serves a vital public health function by enabling the production of new medicines, and that this justifies the short-term welfare loss that patent rights will inevitably cause through increased medicine costs.

Patents unquestionably play an important role in financing the pharmaceutical industry and in stimulating R&D. There are, however, important qualifications to the industry's arguments both about the scale of profits necessary to recoup R&D expenditure and about the necessity of patents in poor countries to recoup profits. Evidence suggests that pharmaceutical companies spend considerably less than \$800 million to develop each new drug. Studies have shown, for instance, that this amount includes not just actual expenditure but opportunity costs, which are not actual expenditures but instead reflect what the money could have earned elsewhere if it had not been spent on R&D.<sup>58</sup> The vast majority of the global pharmaceutical industry is located in the United States and, to a lesser extent, Western Europe. In the United States, companies receive extensive tax breaks on R&D, sometimes recouping up to 50 percent of the cost of clinical trials.<sup>59</sup> Moreover, many therapeutic drugs sold by private companies were actually researched and developed by government-funded public institutions. Studies indicate that in the United States, "between 60 and 75 percent of innovative new drugs developed in the last few decades would not have been developed, or would have been delayed significantly, absent public sector research." In light of these factors, it is estimated that on average



pharmaceutical companies actually spend closer to \$100 million per drug, over 75 percent less than what the industry claims.<sup>61</sup>

Moreover, the industry's assumed high-cost and high-risk status is not reflected in its spending on marketing, which far outstrips what it spends on R&D.<sup>62</sup> These figures cast doubts on the necessity of high prices to recoup R&D, as opposed to maintaining the industry's incredible profit margins. Indeed, the industry's R&D costs are the basis on which it justifies its pricing structures in all markets. It is notable, however, that the private industry persistently fights efforts to ensure disclosure of its R&D costs.<sup>63</sup> Thus, while no one could dispute the industry's legitimate commercial interests, there are valid questions about the extent to which the industry seeks to maximize profitability at the expense of its social function as a producer of critical health products.

If governments are providing a significant proportion of R&D funding, a converse argument may be that strict intellectual property rights enable governments to recoup their R&D costs through taxation of pharmaceutical company profits, and that this accordingly incentivizes their continued funding of medicine research. There is a significant difference, however, between corporations, which are necessarily profit-driven entities, and governments, which in addition to ensuring economic growth are also tasked with more broadly ensuring social welfare. This means that even in the absence of a clear relationship between state expenditure in R&D and economic returns, social welfare considerations will likely motivate states to continue investment in the research of new medicines. Moreover, as the industry's profit levels suggest, governments are in any event recouping their investments in R&D.

Leaving aside the question of the amount of industry outlays on R&D, the necessity of patents in poor countries to recoup R&D and incentivize further R&D is debatable. The global pharmaceutical market is telling in this regard, since over 86 percent of the global drug market lies in North America, Europe, and Japan.<sup>64</sup> The remainder is spread over the rest of the world, including Asia, Africa, Latin America, and Eastern Europe, with each of these vast regions consuming a tiny percentage of patented medicines. For instance, in 2005, Africa accounted for just over 1 percent of the global market for pharmaceuticals.<sup>65</sup> It is notable that both the majority of the world's population and the majority of the global disease burden lie in these regions, and that the drug consumption figures in these regions largely reflect use by elites and not by the poor. To get a relative sense of the profits that sales in these regions generate, it has been estimated that poor countries purchase patented medicines in such comparably minute amounts that twenty-year patents in poor countries would be equivalent to extending patents in developed countries by two weeks.<sup>66</sup>

While there is certainly some profit to be made in poor countries, these profits simply do not stimulate innovation for the primary disease burden in developing countries. This is reflected most egregiously in the "10/90 gap," which articulates the fact that an estimated 90 percent of global health R&D is spent on conditions that affect only 10 percent of the world's population, with priority conditional upon ability to pay.<sup>67</sup> Indeed, a recent study showed that between 1975 and 1999, only 0.1 percent (16 out of 1,393) of new chemical entities produced were for tropical diseases and tuberculosis.<sup>68</sup>

Given the concerns about the efficacy and ethics of the current incentive system, in 2003 the WHO appointed a Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) to review evidence on how effective this system is for diseases that are prevalent in developing countries and that predominantly affect poor people.<sup>69</sup> The CIPRH released its final report in April 2006, which held that "where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market."<sup>70</sup>

If patents in poor countries do not serve valid public health purposes or contribute to pharmaceutical innovation, they cannot be seen as justifiable limitations of core rights to life and medicines; and their adoption and imposition should in fact be seen as serious violations of human rights. The strong evidence and growing consensus that pharmaceutical patents in poor countries serve no public interest or innovative function suggest fundamental flaws in the justifications for the current global patent system, particularly considering the disproportionate regional loss of life that results from the stringent enforcement of patents for essential medicines. Corporate fears of reimportation in the absence of strict global controls appear to be significantly overblown: If products from generic industries in India and Thailand did not flood Western markets in the years prior to TRIPS, there is little reason to believe that they would now. In any event, rather than allowing fears of reimportation to quash efforts to remedy the deficiencies of the present system, measures to prevent reimportation into wealthy countries could be implemented. At a minimum, the TRIPS agreement's patent protections should be scaled back to the extent necessary to ensure that they do not violate the right to health. Any alternative that does not assure this allows the current system to turn the human right to life and health into a vigorously policed, limited, and contested exception to an inviolable property right.

This is not to argue that the current innovation system should be revoked in toto. It functions relatively well for wealthy markets.<sup>71</sup> As I indicate above, however, the system does not appear to work for developing countries. The increased use of TRIPS flexibilities and the exclusion of lower-income countries from providing drug patents could help avoid many preventable deaths in developing countries without harming innovation or significantly reducing inventors' rewards.

#### PRACTICAL APPROACHES TO LIMITING RESTRICTIONS ON ACCESS TO ESSENTIAL MEDICINES

The limited extent of pharmaceutical innovation and reward through poorcountry patenting motivated the WHO CIPIH to make over sixty recommendations aimed at improving the international intellectual property system. These include recommendations that countries increase use of TRIPS flexibilities and that companies avoid filing patents in low-income developing countries.<sup>72</sup> These recommendations may be realized through broader political acceptance, since an intergovernmental working group at the WHO is developing a global strategy and plan of action to realize them. Alternative approaches to promoting innovation have also been proposed. For example, a proposed Medical Research and Development Treaty (MRDT) would create a new global framework for medical research and development based on equitable sharing of its costs and incentives to invest in research and development in areas of public interest.<sup>73</sup> These kinds of advances could considerably expand the autonomy of poor countries seeking to improve access to affordable medicines and facilitate international political support for such measures.

I argue further that the recognition that TRIPS and associated rules and agency potentially violate human rights could guide practical approaches at the domestic and international levels to ensure better integration of trade and human rights concerns by judicial decision-makers and governmental policymakers in all sectors. This would ensure that international human rights standards and interpretations are realized by governments and courts when considering the impact of intellectual property rights on access to essential medicines. For example, **WTO** dispute settlement panels, which adjudicate disputes between members over the implementation of **WTO** agreements, could interpret TRIPS provisions according to human rights standards contained in international human rights treaties.<sup>74</sup> If member states are challenged on the use of TRIPS flexibilities, they could precipitate this kind of interpretation by invoking right to health treaty duties. Another strategy to ensure that trade does not negatively affect health is to work toward greater coherence in government

policies on health and trade. For example, it has been proposed that trade negotiations and implementation not take place without addressing the health impacts of the trade policies. The UN Special Rapporteur on the Right to Health recommends that governments use right-to-health impact assessment mechanisms to evaluate the potential and actual impact of trade rules on medicine access. While this idea is yet to be implemented and does not provide a complete solution, the Peruvian experience mentioned above shows its potential utility.

Civil society's mobilization of human rights standards against governments and corporations is probably the most powerful locus of action for enforcing human rights claims, irrespective of the legal or political nature of the country in question. Indeed, this is evident in experiences in South Africa both before and after the demise of apartheid. Domestic and international mobilization using human rights standards was a primary factor in the demise of the apartheid state itself.<sup>75</sup> South Africa's post-apartheid constitutional democracy provides additional illustrations of how to challenge corporations and governments using human rights arguments and public opinion to great effect. For example, between 1997 and 2001, the U.S. government and forty pharmaceutical companies banded together to challenge legislation that enables parallel imports and generic substitution of medicines in South Africa, which has one of the worst HIV epidemics in the world.<sup>76</sup> Human rights advocates joined the case, bringing strong human rights arguments and staging extensive civil society protests, which attracted global media attention and in the process provoked an international outrage so great that the United States withdrew its diplomatic and trade pressures and the pharmaceutical companies withdrew their legal action.

This example illustrates how public opinion can enable powerful reputational impacts that can create economic incentives for companies to alter their conduct. Linking corporate restrictions on medicines with growing consumer preferences for more socially just corporate practices offers a practical way of pushing drug companies in the direction of more human-rights-protective conduct when it comes to medicines.<sup>77</sup> The effectiveness of organized public opinion in forcing the United States to withdraw its trade pressures against South Africa illustrates a similar utility when it comes to governments.

There is also considerable scope for direct legal enforcement of human rights norms against governments and companies with regard to medicines. For example, in South Africa a national advocacy group sued GlaxoSmithKline and Boehringer Ingelheim using national competition law, arguing that their pricing of antiretroviral drugs was anticompetitive and violated constitutional and international rights to life and health. After the case cleared the first hurdle at the Competition Commission, the companies settled out of court and issued voluntary licenses<sup>78</sup> on the drugs in question to generic manufacturers, at vastly reduced prices.<sup>78</sup>

## CONCLUSION

The CIPIH report states that "the economic problem is the lack of effective demand for health products needed by developing countries."<sup>79</sup> This statement effectively illustrates the fatal flaw in the current global patent system, where medical needs, unmatched by money, simply are not seen to constitute demands. It demonstrates why using purely economic criteria to allocate medicines globally is inappropriate, and why the present system is so blind to the needs of the global poor. Human rights provide a critical corrective by transforming human needs into legal entitlements and by placing a nonmaterial value on them that demands action from social institutions and agents. Certainly, the force of human rights in this respect also arises from the fact that law, irrespective of the extent to which it is complied with by states, is intimately linked to power. To this extent law can be seen as an important terrain of struggle for a more humane trade system. Human rights therefore

not only hold the potential to alter the behavioral incentives currently driving the system but, as law intimately linked to social design, may provide a mechanism capable of reforming the system itself.

#### **FOOTNOTE**

#### NOTES

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