2019

Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health

Govind Persad
Assistant Professor, University of Denver Sturm College of Law

Follow this and additional works at: https://digitalcommons.law.yale.edu/yjhple

Part of the Health Law and Policy Commons, and the Legal Ethics and Professional Responsibility Commons

Recommended Citation
Available at: https://digitalcommons.law.yale.edu/yjhple/vol18/iss2/4

This Article is brought to you for free and open access by Yale Law School Legal Scholarship Repository. It has been accepted for inclusion in Yale Journal of Health Policy, Law, and Ethics by an authorized editor of Yale Law School Legal Scholarship Repository. For more information, please contact julian.aiken@yale.edu.
Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health

Govind Persad*

ABSTRACT

Advocates, activists, and academics have criticized pharmaceutical intellectual property ("pharma IP") rights as obstacles to access to medicines for the global poor. These criticisms of pharma IP holders are frequently exceptionalist: they focus on pharma IP holders while ignoring whether others also bear obligations to assist patients in need. These others include holders of other lucrative IP rights, such as music copyrights or technology patents; firms, such as energy companies and banks, that do not rely on IP; and wealthy private individuals. Their resources could be used to aid patients by providing direct medical assistance, funding prizes or biomedical research, or purchasing pharmaceutical patents and granting rights to the disadvantaged.

After identifying this exceptionalism, this Article evaluates several arguments in its defense. These are that pharma IP holders are unique in (1) owning what poor patients need, (2) being in special proximity to these patients, (3) being able to assist at low cost to themselves, (4) having a professional duty to help these patients, or (5) being implicated by their past conduct in these patients’ plight. It concludes that none of these arguments are compelling: while IP holders have a duty to help, this duty is not fundamentally different from the duties others owe.

Even though this project criticizes exceptionalism, it does not absolve pharma IP holders of duties to help the sick. Rather, it argues that spreading the costs of aiding patients in need across a greater number of market actors, via publicly funded "pull" programs like prizes and patent buyouts or "push" programs like grants, would be preferable. So would allowing pharmaceutical firms to seek contribution from others who are able to help. However, if others cannot be held to account, imposing burdens on pharma IP holders can be justified in order to promote global health: treating wealthy firms arbitrarily is preferable to ignoring the urgent needs of the global poor.

* Assistant Professor, University of Denver Sturm College of Law. JD, PhD, Stanford University. An early draft of this article was selected for the 2018 American Society for Law, Medicine, and Ethics BioIP Scholars Workshop at Georgia State University; I am grateful to my workshop commentators Erin Fuse Brown, Cynthia Ho and Kevin Outterson, as well as to Sam Halabi, Patti Zettler, Yaniv Heled, Deepa Varadarajan, Nicholson Price, Joe Miller, Sarah Conly, Scott Sehon, Matthew Stuart, Aaron Kesselheim, Ameet Sarpatwari, Leslie Wolf, Shubha Ghosh, Rebecca Wolitz, an audience at Bowdoin College, and the staff of the Yale Journal of Health Policy, Law, and Ethics for their suggestions and Kira Case for research assistance.
INTRODUCTION .................................................................................................................................159

I. IP-FOCUSED SOLUTIONS TO GLOBAL HEALTH NEEDS ..........................................................161
   A. CRITICISMS OF IP HOLDERS ......................................................................................................161
      1. THE UNITED NATIONS: HIGH LEVEL PANEL AND SPECIAL RAPPORTEURS ..................161
      2. ACADEMICS .........................................................................................................................165
      3. ACTIVISTS ............................................................................................................................166
   B. IP-FOCUSED LAW AND POLICY PROPOSALS ....................................................................167
      1. ELIMINATION OF IP IN SOME OR ALL HEALTH TECHNOLOGIES ........................................167
      2. IP-FOCUSED TAXES AND REGULATORY MANDATES ......................................................168
      3. IP-FOCUSED SOCIAL RESPONSIBILITY AND ETHICAL CONSUMERISM INITIATIVES ......170

II. EVALUATING THE JUSTIFICATIONS FOR IP-FOCUSED PROPOSALS .....................................171
   A. OWNERSHIP OF WHAT PATIENTS NEED ..................................................................................172
   B. INTERACTION WITH PATIENTS ..............................................................................................174
   C. ABILITY TO ASSIST AT LOWER BURDEN TO ONESELF ....................................................176
   D. PROFESSIONAL OBLIGATIONS ...............................................................................................177
   E. PAST CONDUCT .......................................................................................................................178

III. CAN WE MEET GLOBAL HEALTH NEEDS WITHOUT EXCEPTIONALISM? ............................182
   A. FUNDING ACCESS TO MEDICINES .........................................................................................182
   B. CONTRIBUTION .......................................................................................................................184
   C. AN EXPEDIENCY-BASED CASE FOR PHARMACEUTICAL EXCEPTIONALISM ......................186

CONCLUSION ......................................................................................................................................189
EXAMINING PHARMACEUTICAL EXCEPTIONALISM

INTRODUCTION

This Article examines and criticizes what it dubs pharmaceutical exceptionalism in debates over intellectual property ("IP") and health. Pharmaceutical exceptionalists regard IP rights in medicines as a major impediment to global health, and therefore argue for eliminating IP protections or imposing greater obligations on IP holders. It agrees with exceptionalists that IP protections can impede global health goals. But it contends that exceptionalists err by focusing narrowly on IP holders and ignoring other actors whose resources could be harnessed to improve access to medicines and to improve global health more generally.

To see how a variety of actors might owe obligations to people in medical need, consider the following vignette. Phumeza Tisile is a South African patient who contracted extensively drug-resistant tuberculosis (XDR-TB). Her diagnosis was delayed because the diagnostic device for XDR-TB was not available in South Africa. Linezolid, the recommended treatment for XDR-TB, cost US $67 per pill in the South African private sector market. A patent was preventing market entry of a generic that would have cost under $8 per pill. Because Phumeza could not afford linezolid, she took other medications that had serious side effects.

Who should have helped Phumeza? The United Nations Secretary-General’s High-Level Panel on Access to Medicines focuses its analysis and criticism on holders of IP rights, such as the firm holding the patent rights to linezolid. But other firms and individuals could have helped as well. Some—like retailers selling linezolid and wholesalers generating the raw materials for it—could have helped by reducing their contribution to the final price. Other pharmaceutical companies could have helped by developing competing treatments that drive down the price of the patented intervention. Furthermore, Phumeza’s difficulty in affording linezolid reflects not merely its price but also her limited financial resources. Actors outside the medical sector, including individuals, corporations, civil society organizations, and national governments, could have helped her by lowering prices for other goods, increasing her wages, providing her with affordable insurance, or simply transferring money to her. Other actors could also have helped Phumeza by ameliorating the underlying social conditions that contributed to her contracting XDR-TB.

2. Id.
In Part I, this Article reviews a variety of exceptionalist assertions that IP holders are acting wrongly by failing to promote global health, as well as proposals to impose legal duties on IP holders or encourage private actors to hold them to account. In Part II, the Article evaluates five potential bases for the core exceptionalist claim that IP holders have a special duty to assist patients like Phumeza over and above the duties other firms or individuals might have. These are that pharma IP holders are unique in (1) owning what poor patients need, (2) being in special proximity to these patients, (3) being able to assist at low cost to themselves, (4) having a professional duty to help these patients, or (5) being implicated by their past conduct in these patients’ plight. It concludes that none of these arguments are compelling: while IP holders have a duty to help, it is dubious that their duty is stronger than the duties owed by others.

In Parts III.A and III.B, the Article considers two strategies for moving beyond pharmaceutical exceptionalism. The first would promote access to medicines through public funding financed by broad-based taxes and giving. The second, modeled on the doctrine of contribution in tort law, would empower pharmaceutical IP holders to seek compensation from other actors who are also in a position to promote global health. In Part III.C, it argues that pharmaceutical exceptionalist laws can be a legitimate strategy for promoting global health even when they do not align with firms’ moral obligations, but that pharmaceutical exceptionalism is a strategy rather than a goal in itself.

Because debates around pharmaceutical IP and global health have been so charged, situating this Article in the existing debate is crucial. This Article challenges the frequently advanced claim that holders of IP rights owe uniquely strong moral duties to patients like Phumeza in need of patented medicines. It argues that the lens of global health advocacy should be broadened beyond concerns about pharmaceutical IP. But—unlike scholarship that seeks to exempt pharmaceutical IP holders from global health responsibilities—the Article does not conclude that imposing uniquely strong legal duties on holders of IP rights would be wrong. Instead, it concludes that while the morally ideal solution would be a division of burdens among all who can help, it is acceptable to assign stricter legal duties to pharmaceutical IP holders than to others who have moral duties to assist. When others cannot be held to account, imposing burdens on pharmaceutical IP holders can be justified in order to promote global health: as Part III.C argues,

---

4. E.g. William W. Fisher & Talha Syed, Global Justice in Healthcare: Developing Drugs for the Developing World, 40 U.C. DAVIS L. REV. 581, 647 (2007) (discussing pharmaceutical patents through a lens of ethical obligation); Debora Halbert, Moralized Discourses: South Africa’s Intellectual Property Fight for Access to AIDS Drugs, 1 SEATTLE J. SOC. JUST. 257, 282–83 (2002) (“Gradually, a viable international consensus on the importance of access to medication and affordable prices has developed and this access has been linked to health as a human right. Within this framework, actions taken by the pharmaceutical industry to protect their patents seem increasingly immoral.”).
underinclusiveness and arbitrariness are preferable to ignoring the urgent needs of the disadvantaged.

I. IP-FOCUSED SOLUTIONS TO GLOBAL HEALTH NEEDS

Commentators have criticized pharmaceutical IP holders for aggressive enforcement of intellectual property rights under current treaties; for seeking expanded intellectual property protections as part of new international trade agreements; and for resisting the use of procedures such as compulsory licensing. Some of the most broadly criticized IP rights are those found in the Agreement on Trade-Related Aspects of Intellectual Property Rights (generally referred to as the “TRIPS” agreement), which has been excoriated for undermining access to lifesaving medicines for patients in developing countries. More recent international agreements and proposed agreements, such as the Trans-Pacific Partnership, have been similarly criticized. So have bilateral treaties such as the recent Korea-United States free trade agreement. This Part reviews arguments that pharmaceutical IP holders are failing in their global health responsibilities, and also reviews proposals to impose greater responsibilities on pharmaceutical IP holders.

A. Criticisms of IP Holders

1. The United Nations: High Level Panel and Special Rapporteurs

The United Nations Secretary-General’s 2016 High Level Panel on Access to Medicines identified a variety of obstacles to access to medicines. Some were non-

5. See, e.g., Peter K. Yu, Virotech Patents, Viropiracy, and Viral Sovereignty, 45 ARIZ. ST. L.J. 1563, 1567 (2013) (“[S]ince the TRIPS Agreement entered into force in January 1995, it not only has taken away the wide policy space less developed countries once enjoyed at the international level, but it has also resulted in needless deaths and suffering to patients that have acquired either the human immunodeficiency virus (“HIV”) or the Acquired Immune Deficiency Syndrome (“AIDS”).”); see also Burcu Kilic, Defending the Spirit of the Doha Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines, 12 LOY. U. CHI. INT’L L. REV. 23, 30 (2014) (“To a great extent, the patent regime has been linked to rising healthcare costs and problems regarding access to medicine. Many developing countries, especially the least developed ones, were faced with public health crises. These countries have experienced the difficulties related to the increasing prices of medicines. It became evident that patents substantially delayed market entry of generic medicines, raising costs and reducing access. As a result, the Agreement has come under fierce criticism.”).

6. Alexander Stimac, The Trans-Pacific Partnership: The Death-Knell of Generic Pharmaceuticals?, 49 VAND. J. TRANSNAT’L L. 853, 874–75 (2016) (“Rohit Malpani, the director of policy and analysis at the MSF Access Campaign, has stated that ‘[t]he TPP is the most damaging trade agreement we have ever seen in terms of access to medicines for poor people.’”).

IP barriers to access, such as "[r]egulatory inefficiencies, poor health education, unavailability of health insurance and insufficient financial protection for those who have to pay for some or all of their treatment," as well as "fees, profits, taxes and tariffs along the supply chain"; the Panel also observed that millions of patients remain unable to access essential off-patent medicine. However, it focused most of its analysis on pharmaceutical IP. This may reflect the nature of the Panel's mandate: the Panel was tasked with addressing tension between the "justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies," rather than "analyzing all the reasons why health technologies are not available [n]or affordable."

The Panel concluded that pharmaceutical IP rights can obstruct access to medicines. It began by observing that "the obligation to grant patents on medicines and other health technologies would affect the availability and affordability of health technologies," and "had a clear potential to strain national budgets and to place health technologies out of the reach of those in need." This emphasis on the access-constricting effects of IP continues throughout the report. The Panel goes on to assert that there is a "misalignment between public health objectives and trade and intellectual property protection" and that "the application of patent protections . . . can conflict with the right to health in rich and poor countries alike." The report also explicitly endorses the primacy of health claims over property rights, stating that "[t]ensions between ministries responsible for the promotion of trade and the protection and enforcement of intellectual property on the one hand and those responsible for public health should not result in the prioritization of trade over health," and that "[t]he very nature of fundamental human rights requires that they outweigh private interests under national law." The Panel ultimately, however, elected to reaffirm the importance of the TRIPS Agreement and the flexibilities it includes, rather than rejecting pharmaceutical IP rights in medicines.

Some members of the Panel would have gone further and eliminated IP rights over a subset of essential medicines, and potentially over all health technologies. In a commentary annexed to the report, Jorge Bermudez, Winnie Byanyima and Shiba Phurailatpam, three members of the Panel, describe "the current R&D and access system – based on intellectual property (IP) protection as embodied in the WTO's TRIPS Agreement and aggravated by free trade and investment

8. REPORT ON ACCESS, supra note 1, at 15-16.
9. Id. at 4.
10. Id.
11. Id. at 17.
12. Id. at 21.
13. Id.
14. Id. at 24.
agreements and treaties” as a “systemic failure.” In a separate commentary, Bermudez and Byanyima argue that, instead, “medicines on national lists or on the WHO Model List for Essential Medicines should be exempted from IP protection,” a proposal they assert was supported by two-thirds of the Panel but excluded from the final report. They likewise argue that the UN should examine how “IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.” Underscoring their belief that IP and pricing constitute the crucial barriers to access, they criticize the Panel’s claim that unavailability of health insurance constitutes a barrier to access, stating that “insurance does not protect people from the high cost of medicines nor does it guarantee access to the medicines they need even in high income countries.” In an individual commentary, Phurailatpam underscores his view that the pricing of patented medicines, rather than the resources available to patients to purchase medicines, should be the focus of critical attention.

The two most recent former United Nations Special Rapporteurs on the Right to Health, Paul Hunt and Anand Grover, have similarly argued that uniquely strong duties apply to pharmaceutical IP holders. In one article, Grover and his co-authors argue that “[t]ransnational pharmaceutical companies, along with states, play the largest role in determining whether medicines are equitably available and accessible,” and then go on to assert that

[M]any medicines currently available on the market are simply too expensive for millions around the world to afford. Many medicines available in the developing world are only available to a small percentage of the population due to economic inequities. The profit-seeking behavior of pharmaceutical companies exacerbates this problem. In most cases, the price reductions required to make drugs affordable to a broader class of people in

15. Id. at 53.
16. Id. at 61.
17. Id. at 61-62.
18. Id. at 55.
19. Id. at 63 (“Several people who put pressure on the work of the Panel accused it of ignoring the role of health systems in limiting access. In the case of patented medicines - it is my own personal experience and that of the multitude of patients in need of patented medicines - that the cascade of misery that we endure in being pushed from pillar to post, in navigating public and private healthcare systems and complicated health coverage and ultimately facing death or destitution, starts with or is certainly made far worse, by the pricing and restricted availability of those patented medicines.”).
the developing world are not offset by the resultant increase in sales volume. Simply stated, in most of the developing world, it is more profitable to sell drugs to the very wealthy at high prices than it is to sell cheaper drugs to a greater number of people. As a result, medicines remain unaffordable for the vast majority of people in many parts of the world. While this might be an acceptable outcome for certain commodities, such as luxury goods, it is completely unacceptable for life-saving medicines. Therefore, in order to effectively address the global lack of access to medicines, the role pharmaceutical companies play in the international intellectual property regime must be critically examined.\(^{22}\)

Grover et al. appear to place a special responsibility for providing access to medicines on pharmaceutical companies and focus in particular on pharmaceutical companies’ conduct with respect to intellectual property rights. They also argue that IP holders who do not do what they need to do should be subject to external constraints.\(^{23}\)

Another former Special Rapporteur, Paul Hunt, took a similar position in a 2012 article. Hunt and Joo-Young Lee argue that:

[S]ociety has a legitimate expectation that the patent holder of a life-saving medicine will not only enjoy the privileges arising from the patent but also fulfill the corresponding responsibilities. The crucial right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model. As soon as the new medicine is marketed at higher prices (usually in high-income countries), the patent holder has a right-to-health responsibility to put in place a range of mechanisms, such as differential pricing between and within countries, to enhance access for those who cannot afford those prices. Also, the patent holder has a right-to-health responsibility to develop formulations for children, the elderly, pregnant and lactating women, and extremes of climate. For the duration of the patent, only the patent holder is authorized (with limited exceptions) to take these steps. Thus, the agreement between society and patent holder includes a

\(^{22}\) Id.

\(^{23}\) Id. at 236 ("It is increasingly clear that the structure of the international intellectual property regime must be modified and that reasonable constraints be placed on the behavior of pharmaceutical companies in order to allow for adequate levels of industry competition.").
EXAMINING PHARMACEUTICAL EXCEPTIONALISM

responsibility on the patent holder to take these steps, expeditiously and effectively, by way of deliberate, concrete, and targeted measures. If the patent is worked without these steps being taken (i.e., without a range of mechanisms being put in place to enhance access, and without steps being taken to develop formulations for children, etc.), then the patent holder is in breach of its right-to-health responsibilities. Of course, the success of the patent holder’s actions will sometimes depend upon States, donors, and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it reasonably can.24

While Lee and Hunt note that other actors also have responsibilities, their focus is on the IP holder, who “has a right-to-health responsibility to do what it reasonably can.”25

2. Academics

Many academic commentators have condemned pharmaceutical IP holders for depriving the global poor of essential medicines. A representative example is Chuan-Feng Wu, who asserts that

the cavalier conduct of [transnational pharmaceutical corporations] is . . . the primary cause of right-to-health violations, especially the right to access medicines. For example, because pharmaceutical leaders employ strategies, such as patent protection, to maximize profits and returns on investments to benefit the corporation and its shareholders, they are responsible for the high prices charged for life-saving drugs. Studies also show that the poor’s healthcare needs are barely met in patent-based pharmaceutical markets because patent holders (i.e., pharmaceutical corporations), who are entitled to control the prices on all sales of their products, sometimes abuse their power of market dominance by charging excessive prices.26

Other commentators similarly assert that intellectual property protections “have a particularly debilitating effect on how lower income countries provide

25. Id.
their citizens access to life-saving medication”²⁷, that “[p]rohibitive drug prices are often the result of strong intellectual property protection”²⁸, and that “[i]n many parts of the world, overly restrictive intellectual property regimes place essential medicines beyond the reach of those who need them.”²⁹

Some commentators have not only criticized pharmaceutical IP holders but provided specific proposals that would impose burdens on them. Lisa Forman echoes the arguments made by Bermudez, Byanyima, and Phurailatpam, contending that because “existing policy initiatives have failed to adequately respond to the impact of trade-related intellectual property rights on access to medicines . . . bolder measures are required, including suspending the application of trade-related intellectual property rights to essential drugs for low- and middle-income countries.”³⁰ Talha Syed and Terry Fisher, meanwhile, argue that “international institutions, such as . . . the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’) in particular . . . must be reformed so as to eliminate their complicity in unjustifiable harms to the residents of developing countries.”³¹

3. Activists

A poster tweeted by Melinda St. Louis, the Director of International Campaigns at Public Citizen’s Global Trade Watch, states a pharmaceutical exceptionalist view in particularly striking form: “Pfizer+Obama’s TPP=Death for People with AIDS.”³² This poster refers to the Trans-Pacific Partnership (TPP), a proposed international trade agreement, and alleges that the TPP would permit

³¹ Fisher & Syed, supra note 4, at 662; see also Ruth Lopert & Deborah Gleeson, The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines, 41 J.L. Med. & Ethics 199, 199 (2013) (“The proliferation of post-TRIPS bilateral and regional ‘free’ trade agreements (FTAs) has been characterized by a progressive ‘ratcheting up’ of IP protections for pharmaceuticals, with provisions intended to prolong monopolies, support high prices and frustrate market entry of generic medicines -- all of which undermine access to affordable medicines”).
³² Melinda St. Louis (@MelindaGTW), TWITTER (July 3, 2015, 3:00 AM), https://twitter.com/MelindaGTW/status/616682828521025536; see also Margaret Flowers, Stopping The Trans-Pacific Partnership Essential To Universal Health Care, POPULAR RESISTANCE (Sept. 4, 2013), https://popularresistance.org/stopping-the-trans-pacific-partnership-essential-to-universal-health-care/ (using the same image).
pharmaceutical firms like Pfizer to worsen access to medicines for people living with AIDS. Medecins Sans Frontieres, meanwhile, referred to pharmaceutical companies’ attempts to limit compulsory licensing (a patent law doctrine that permits governments to grant licenses without the patent-holder’s consent) in South Africa as “one of the most stark acts of corporate inhumanity.”

B. IP-Focused Law and Policy Proposals

The claims in Part I.A that pharmaceutical IP holders are wrongfully impeding global health has prompted proposals to either weaken IP holders’ rights or to impose correlative responsibilities. This Subpart reviews these proposals.

1. Elimination of IP in some or all health technologies

A contribution to the High Level Panel’s deliberations by the legal academic Brook Baker and several advocacy groups argues that intellectual property protections for health technologies should be completely eliminated. Baker and his co-submitters call for “eventually exempting all health technologies for all health conditions from IP protections in international, regional, bilateral, and national law,”34 “an explicit exemption of medical technologies from patent, copyright, and data protections in the WTO TRIPS Agreement, in trade agreements, and in national legislation,”35 and “unenforceability of investor rights concerning health technologies.”36 They also provide a detailed proposal that would revise the TRIPS agreement to eliminate IP rights. In support of this proposal, they claim that IP rights are inefficient at driving innovation and that “global, regional, bilateral, and national IP regimes adversely affect universal, equitable, and affordable access to health technologies, which should be treated as a global public good.”37 While they


34. Brook Baker and Health GAP, Contribution to the United Nations Secretary-General’s High-Level Panel on Access to Medicines, February 26, 2016, http://www.unsgaccessmeds.org/inbox/2016/2/26/z73kpodxk4jw96mhqe2tivq0sd1g3v

35. Id.
36. Id.
37. Id.
acknowledge that their proposal may be difficult to implement politically, they argue that it is preferable to incremental reforms. Their proposal is also endorsed by other contributors to the Panel’s deliberation.38

Other contributors offer the more limited suggestion that IP rights in essential medicines should be eliminated or severely restricted. As previously mentioned, Bermudez, Byanyima, and Phurailatpam propose the complete elimination of IP rights in relation to essential medicines. Less drastically, Chandni Raina, from the Center for WTO Studies at the Indian Institute of Foreign Trade, argues that patents in medicines that are essential for treating a disease should be subject to mandatory licensing, which would allow any pharmaceutical company to produce such medicines after paying a reasonable royalty.39

2. IP-focused taxes and regulatory mandates

Rather than weakening property rights in IP, some contributors to the High Level Panel, as well as some of the members themselves, argue for imposing correlative responsibilities on holders of IP. One such proposal, offered by the Treatment Action Campaign (TAC) and endorsed by other organizations, would require “compliance with a research mandate as a condition for maintaining intellectual property rights on medical products.”40 Their mandate would have the following structure:

- For a company in possession of any pharmaceutical patents to maintain the rights to those patents it must, on an annual basis, file information confirming the following:


That over the last 12 months the company spent a minimum of 30% of revenue on R&D and

Spending on R&D over the last 12 months was at least double the combined spending on marketing and advertising over the same period and

Spending on R&D over the last 12 months was at least double the company’s profits.

For the purpose of this mechanism investment on R&D must include direct contributions made to approved medical R&D grant-making institutions at the national level or as part of a UN agency or a partnership with a UN agency. A minimum of 20% of the patent holder’s R&D investment must be contributed to such institutions. Such institutions should be obliged to invest these funds in R&D relating to areas of greatest medical need.

In cases where fewer than four companies hold a license or licenses to market a specific patented medical product, these provisions will apply to all license holders in exactly the same way as it applies to the original patent holder.41

In its contribution, TAC also reviewed a variety of other proposed R&D mandates on pharmaceutical IP holders. These include a proposed Brazilian “tax on pharmaceutical profits that would go toward an R&D fund . . . used only for R&D on medicines and vaccines that address public health needs of developing countries”42 and a 1996 proposal by then-Rep. Bernie Sanders that would impose “minimum R&D requirements on companies that sell drugs in the United States,”43 with the requirements depending on “patent protection, orphan drug status, and the magnitude of sales.”44 They also discussed mandates that fund pharmaceutical R&D by taxing antibiotic use or mineral resource exploitation.45

Fisher and Syed, whose work is discussed in Part I, submitted a contribution advocating a regulatory approach similar to TAC’s, but which focuses on outcomes achieved as a result of the firm’s products rather than on R&D spending. They advocate requiring all pharmaceutical firms to “demonstrate compliance, annually, with a ‘social-responsibility index,’ which index would consist of the

41. Id.
42. Id.
43. Id.
44. Id.
45. Id.
ratio between (1) the total number of Disability Adjusted Life Years (DALYs) saved as a result of the consumption of the firm’s products during the year and (2) the firm’s global gross revenues during the year.”46 They would allow a “cap-and-trade” system for DALYs, where a firm whose products saved insufficient DALYs could buy them from another firm.47

Finally, Grover et al. proposed a UN framework convention on global health that would incorporate a tax on pharmaceutical companies. Grover et al.’s proposed convention would establish a “judicial committee with the authority to issue binding judicial decisions enforceable under international law”48; the committee would have the authority to hear complaints that pharmaceutical companies have violated the right to health, and provide remedies including “compensation for victims, guarantees of non-repetition, commitments to research and development priorities for neglected diseases, and the granting of compulsory licenses.”49 These remedies would be financed by “taxes levied on pharmaceutical companies by the state in which they are domiciled,”50 and “based upon the companies’ compliance with the obligations in the framework convention; companies with poor records would be required to pay more taxes than those who fare better under review by the convention body.”51

3. **IP-focused social responsibility and ethical consumerism initiatives**

Several organizations have proposed campaigns that leverage market mechanisms and consumer power to pressure pharmaceutical IP right-holders to promote global health. One such campaign is the Global Health Impact scorecard, proposed by Nicole Hassoun, which would label products made by firms that hold IP rights according to those firms’ contribution to global health.52 Hassoun submitted a contribution to the High Level Panel arguing that this approach should

47. Id.
48. Grover et al., supra note 20, at 246.
49. Id.
50. Id.
51. Id.
52. Nicole Hassoun, *Individual Responsibility for Promoting Global Health: The Case for A New Kind of Socially Conscious Consumption*, 44 J.L. MED. & ETHICS 319, 323 (2016) (proposing the use of “the Global Health Impact rating system for pharmaceutical companies’ key impacts on global health to incentivize positive change” via “a Global Health Impact certification and labeling campaign” within which “the best companies, in a given year, will be given a license to use a Global Health Impact label on all of their products - everything from lip balm to food supplements”).
be part of the Panel’s efforts.\textsuperscript{53} A similar proposal has been advanced by Nir Eyal.\textsuperscript{54}

Another campaign, focused on universities rather than pharmaceutical manufacturers, is the Universities Allied for Essential Medicine (UAEM) scorecard, which evaluates universities by how well their IP licensing proposals promote access to medicines.\textsuperscript{55} UAEM has also developed what it calls an Equitable Access License, which requires IP licensees to grant their exclusive rights in the drugs they produce using that IP back to the university.\textsuperscript{56} A number of universities, as well as the American Association of Medical Colleges, the National Institute of Health, and the Centers for Disease Control, have endorsed a commitment to promoting access to university-held IP in developing countries.\textsuperscript{57}

\section*{II. Evaluating the Justifications for IP-Focused Proposals}

An implicit premise of the IP-focused proposals above is that pharmaceutical IP holders have a greater responsibility to promote global health than other firms or individuals do. This premise requires defense, as we can see by examining Fisher and Syed’s proposal discussed in Part I.B. If Fisher and Syed’s proposal applied to all firms, Coca-Cola (as an example) would have a \textit{negative} social responsibility index, since consuming its products does not avert DALYs and arguably causes them.\textsuperscript{58} Many other firms, like Gucci, would at best have a zero social responsibility index. Yet Fisher and Syed’s proposal would impose

\begin{itemize}
\item \textsuperscript{54} Nir Eyal, \textit{Global-Health Impact Labels}, in \textit{GLOBAL JUSTICE IN BIOETHICS} 241-78 (Ezekiel J. Emanuel & Joseph Millum eds. 2012).
\item \textsuperscript{55} See Ian Ayres & Lisa Larrimore Ouellette, \textit{A Market Test for Bayh-Dole Patents}, 102 CORNELL L. REV. 271, 318 (2017) (discussing the “establishment of the activist group Universities Allied for Essential Medicines (UAEM), which has pushed universities to consider how their patent policies affect global health, and which helped craft—and convince universities to sign—two licensing policy statements related to the dissemination of medical technologies,” and observing that “UAEM now issues an annual report card that grades universities on their global health impact in an effort to increase transparency about university policies”).
\item \textsuperscript{57} Lisa Larrimore Ouellette, \textit{How Many Patents Does It Take to Make A Drug? Follow-on Pharmaceutical Patents and University Licensing}, 17 MICH. TELECOMM. & TECH. L. REV. 299, 310 (2010) (describing commitment signed by AAMC that “[u]niversities have a social compact with society” that gives them “a responsibility... to share the fruits” of their inventions with “the world’s poor,” and also describing endorsement by the CDC and NIH of the 2009 Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies, which contains similar language).
\item \textsuperscript{58} See Gitanjali M. Singh et al., \textit{Estimated Global, Regional, and National Disease Burdens Related to Sugar-Sweetened Beverage Consumption in 2010}, 132 CIRCULATION 639, 639 (2015).
\end{itemize}
obligations on pharmaceutical firms but not on Coca-Cola or Gucci. This is so even though Coca-Cola and Gucci could both improve global health for patients like Phumeza by, for instance, donating profits to enable the global poor to purchase medicines or to obtain needed surgeries. An identical critique applies to taxes and regulatory mandates, like Grover’s proposal, that fall exclusively on pharmaceutical firms. And a similar critique applies to the proposals for eliminating IP — Coca-Cola and Gucci could improve the financial circumstances of the global poor tremendously if they granted the poor access to the lucrative IP they control.

UAEM’s “University Report Card,” which assigns failing global health grades to the University of Cincinnati and Wake Forest University, but assigns no grade at all to universities without global health programs, faces a similar criticism. Wake Forest spends money promoting global health goals, even though it may spend less than the top-scoring universities, whereas these other universities do not spend on global health at all. Castigating Wake Forest as a failure for doing too little while ignoring universities that do nothing at all requires defense.

This Part will examine five potential justifications for focusing on holders of pharmaceutical IP rather than on other firms or wealthy individuals. These justifications are that pharmaceutical IP holders, unlike other firms or individuals:

a) own what patients need;
b) interact with patients;
c) can help without incurring significant costs;
d) have a professional responsibility to help; and/or
e) have caused patients’ plight by creating barriers to access.

I argue that none of these justifications succeed in differentiating IP holders from others who can help.

A. Ownership of what patients need

Grover et al. claim that “unlike in many other forms of intellectual property . . . the chemical compounds that constitute drugs are necessary to protect the health and the human rights of millions of people.” They use this claim as a justification for IP-focused policies.

59. See Ayres & Ouellette, supra note 55.
60. See Wake Forest School of Medicine, Global Health Funding, https://school.wakehealth.edu/About-the-School/Global-Health/Funding.
61. Grover et al., supra note 20, at 236.
This argument cannot justify the broad elimination of all IP rights in health technologies that Baker and others defend, because many health technologies are not necessary to protect health or human rights. Some are “me too” drugs that provide only marginal benefits. Others are drugs for conditions like baldness, treatments which are not essential to human rights.

Even when deployed in defense of proposals to remove IP rights over medicines that do protect health and human rights, this argument faces three additional problems. First, many pharmaceuticals represent an additional treatment option without being necessary for improving health. As an example, both older and newer medications can treat HIV, although older medications are often less effective or more toxic. Similarly, older, off-patent antipsychotic drugs can be as effective as patented treatments.

Second, property other than pharmaceutical IP can also be harnessed to protect health and human rights. Within the pharmaceutical supply chain, retailers could sell pharmaceuticals more cheaply and raw material producers could lower their prices. Outside the pharmaceutical supply chain, wealthy firms and individuals could transfer their property rights in non-pharmaceutical IP, money, or real property to the global poor to enable them to purchase patented drugs or improve their health in other ways.

Third, there can be compelling reasons to recognize property rights in essential goods—not only essential medicines, but also food, water, housing, and non-pharmaceutical health care. Where individuals lack the ability to pay, recognizing and enforcing a collective responsibility to assist is typically preferable to abrogating property rights for specific essential goods. Abrogating property rights in essential goods would create perverse incentives. For instance, if food could not be owned but inessential goods like Gucci handbags could, there would be an incentive to produce handbags instead of food. It would also produce dubious distributive outcomes, as wealthier consumers in developed countries would receive essential goods at low or no cost. This parallels the problem with using price caps, rather than financial assistance, to ensure that poorer consumers

62. Michael A. Carrier & Steve D. Shadowen, Product Hopping: A New Framework, 92 NOTRE DAME L. REV. 167, 183 (2016) (“In a recent five-year period, 67% of the ‘new’ drugs approved by the FDA were ‘me-too’ drugs — drugs that are slight chemical variants of their predecessor and that produce essentially the same medical results in patients”).
63. Cynthia M. Ho, Unveiling Competing Patent Perspectives, 46 HOUS. L. REV. 1047, 1063 (2009) (discussing the exemption of “lifestyle” drugs, such as those to treat baldness, acne, or erectile dysfunction” from some access to medicines proposals).
65. Francis Collins, Opportunities for Research and NIH, 327 SCIENCE 36 (2010).
66. This does not imply anything about retailers’ or producers’ relative contribution to prices.
can access essential goods like food, water, or electricity.\textsuperscript{67} Last, abrogating property rights in essential goods would lead to a misalignment between aid and needs: if a firm has IP rights in essential medicines, but poor patients need off-patent drugs, it would be preferable to have the firm transfer cash to the poor rather than transferring or not enforcing its IP rights.

\textbf{B. Interaction with patients}

The suggestion that interacting with poor patients can generate duties to assist is familiar from other contexts, such as clinical research conducted by pharmaceutical firms abroad,\textsuperscript{68} and is therefore worth examining as a basis for the claim that pharmaceutical IP holders owe special duties to the poor. In the law, friendly interaction with others, or participation in a common undertaking, can sometimes generate obligations to assist.\textsuperscript{69} However, there is no obvious tie of friendship between pharmaceutical IP holders and poor patients, nor are the two involved in a common venture. The law of unjust enrichment also indicates that reciprocity can be a basis for duties to assist;\textsuperscript{70} but pharmaceutical IP holders are not attempting to profit substantially from the global poor.

The most plausible basis for the idea that pharmaceutical IP holders have a special relationship with the global poor involves their intervention in countries where the global poor live in order to assert their IP rights. When an IP holder goes into court in South Africa or India to assert its rights, its interaction with that nation might appear to be a basis for assigning it a special obligation. In contrast, a wealthy private individual or a firm that makes its money purely or primarily via domestic commerce (think of Shake Shack or a local taxi company) would not have similar special obligations.

Appeals to mere interaction, however, faces two of the problems discussed in the prior Subpart. First, others—such as pharmaceutical retailers and non-pharmaceutical firms that do business in developing countries—interact more with patients than pharmaceutical IP holders do, and would be subject to equally strong duties to assist. More importantly, allowing interaction to generate a special responsibility will produce a perverse incentive to avoid interaction. To see how

\begin{footnotesize}
\begin{enumerate}
\item[] 67. \textsc{Joseph Heath}, \textit{Economics Without Illusions}, ch. 7 (2010) ("[F]iddling with the price of electricity is a terrible way of addressing the underlying problem of distributive justice, simply because the benefits of low prices are available to everyone, not just those who are in need.").
\item[] 70. \textit{Id}. at 1187.
\end{enumerate}
\end{footnotesize}
making responsibility contingent on interaction can provide perverse incentives, consider the following example discussed by Alan Wertheimer and Thomas Pogge:

A filmmaker wishes to produce a documentary about behavior of fishermen whose boats are in distress. He believes that the film will help others avoid counterproductive panic-induced behavior. A successful film requires that the fishermen not be rescued until it is too late. The film crew flies to a location off the coast of a poor country and waits for a radio signal of a ship in distress. When it receives a distress signal, the film maker radios back with the following proposal. If the fishermen agree, the filmmaker will flip a coin. If it comes up heads, the filmmaker’s crew will fly by helicopter and save them. If it comes up tails, it will fly by helicopter and film them and make no effort to save them, but will remain in the area until another ship is in distress and it will then save those fishermen. Because the fishermen have no better option, they readily agree.\textsuperscript{71}

Unlike pharmaceutical IP holders, the filmmaker in this case is not only interacting with the fishermen, but potentially benefiting substantially from his interaction with them. Nonetheless, examining this case is useful because if the filmmaker lacks an obligation to aid even though he potentially benefits from the interaction, pharmaceutical IP holders—who merely interact without substantially benefiting—will also lack a special obligation to aid.

Wertheimer and Pogge evaluate the above example in opposing ways. Pogge recognizes that imposing a duty to assist on the filmmaker once he interacts with the fishermen (regardless of how the coin lands) would produce a strong incentive to avoid interacting, but elects to bite the bullet, stating that duties sometimes produce perverse incentives and that “morality cannot plausibly be purged of such counterproductivity entirely.”\textsuperscript{72} In contrast, Wertheimer argues that “this is not the sort of counterproductivity that we have come to expect of a sensible morality.”\textsuperscript{73} He goes on to assert that

In the case at hand, the moral requirement to save the fishermen does not serve to protect the fishermen from being sacrificed for the benefit of others; it leads to the preventable deaths of the

\begin{footnotesize}
\begin{enumerate}
\item WERTHEIMER, supra note 68, at 245-46 (paraphrasing Thomas Pogge, Testing Our Drugs on the Poor Abroad, in EXPLOITATION AND DEVELOPING COUNTRIES 116 (Jennifer Hawkins & Ezekiel J. Emanuel eds, 2008)).
\item Pogge, supra note 71, at 122.
\item WERTHEIMER, supra note 68, at 247.
\end{enumerate}
\end{footnotesize}
fishermen themselves. If it is hard to have confidence in a morality that allows that allows filmmakers to deliberately refrain from rescuing fishermen in distress, it is also hard to have confidence in a morality that renders it certain that the fishermen will not be rescued.  

If we find Wertheimer's reasoning plausible in the fisherman example, the case for rejecting interaction-based duties is even stronger in the case of IP holders who—unlike the fisherman—do not derive a benefit from their interactions with the global poor. We can see the counterproductive results Wertheimer identified in the context of Fisher and Syed's suggestion, where a pharmaceutical company that is judged to under-contribute to global health would receive a lower "social responsibility rating" than a firm like Coca-Cola that does not contribute to global health at all. On this approach, a firm producing multiple products would have an incentive to divest its pharmaceutical division, or stop producing pharmaceuticals: such activities expose the firm to a "moral rescue burden" it would not otherwise have faced.

C. Ability to assist at lower burden to oneself

The capacity to forestall a harm at low cost to oneself is a recognized basis for moral and legal obligations. One way that pharmaceutical IP holders could be able to forestall harm at a lower cost than other property holders involves the non-rival nature of IP: allowing patients to access a patented drug does not prevent the patent-holder from selling or manufacturing medicines, whereas allowing poor patients to access money or real property does prevent others from using that money or property.

This argument faces two problems. First, it does not explain why pharmaceutical IP holders have a greater responsibility to assist than holders of non-pharmaceutical IP, which is equally non-rival. Allowing patients to access other forms of IP could free patients to purchase medicines or health care that they need. The pharmaceutical exceptionalist needs to explain why requiring

74. Id.
75. Cf. Pogge, supra note 71, at 122 (acknowledging that "[t]he filmmaker has no earthly reason to be near the ocean with his radio equipment and helicopter if this can win him no exciting filming opportunity, but can only slap him with a moral rescue burden.").
76. See Rebecca E. Wolitz, A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications, 94 IND. L.J. 1163 (2019); Wilder Corp. of Delaware v. Thompson Drainage & Levee Dist., 658 F.3d 802, 806 (7th Cir. 2011) ("[L]iability for inflicting a harm should come to rest on the party that could, at the lowest cost, have prevented the harm in the first place").
EXAMINING PHARMACEUTICAL EXCEPTIONALISM

pharmaceutical companies to share their IP rights with the global poor is more justified than requiring firms like Coca-Cola to share their lucrative IP.

The nonrivalry argument might also fail to differentiate pharmaceutical IP from some forms of real property, because the technically rivalrous use of some real property imposes little cost on the better-off. Historically, the poor were permitted to enter land they did not own, glean crops that would otherwise go unused, and doctrines like adverse possession are often understood as resting on the benefits of allowing access to unused property. In the health context, an example of non-rivalrous use might be the use of medical equipment or expired but still usable pharmaceuticals that are currently thrown out rather than being made available for reuse.

Second, it does not acknowledge that even though IP is non-rival, allowing patients to bypass IP rights could create a disincentive to innovate. Robert Merges argues that the view that "there is no need for property where goods are non-rivalrous" ignores the role of IP in stimulating new contributions. While completely eliminating IP rights in medicines would not prevent researchers and corporations from manufacturing and selling the medicines they discover, it could reduce the incentive to engage in discovery.

Another argument would appeal to the great wealth of some pharmaceutical firms. While this argument does make some pharmaceutical IP holders more appropriate targets for responsibility than many other actors, such as the governments of less developed countries, it also fails to establish that pharmaceutical IP rightsholders should be the unique object of duties. Firms like Coca-Cola and Gucci also are very wealthy—wealthier than many holders of pharmaceutical IP, such as startup firms and university researchers.

D. Professional obligations

Another potential basis for special obligations involves the fact that some individuals who work for pharmaceutical companies are members of professions who owe special obligations to meet the health needs of the global poor. For

78. Randall Bezanson & Andrew Finkelman, Trespassory Art, 43 U. Mich. J.L. Reform 245, 284 (2010) (“The common law also deprived a landowner of a remedy for a trespass when use of private resources benefited the public without harm to the landowner. Blackstone, for example, wrote that the “common law and custom of England” held that it was no trespass for the poor to enter another’s land after harvest to glean another’s grounds.”).


80. See Persad, supra note 64, at 571-76.

81. ROBERT MERGES, JUSTIFYING INTELLECTUAL PROPERTY 37 (2011).


177
instance, if pharmaceutical companies employ physicians and nurses to carry out clinical trials, these physicians and nurses may owe a professional ethical duty to poor patients, a duty whose fulfillment requires the provision of professional services rather than through the provision of other goods.83 This could be a basis for imposing greater obligations on pharmaceutical IP holders than on Coca-Cola or Gucci. Even if pharmaceutical firms’ employees are not directly interacting with the global poor, they are departing from their duty to focus on healing the sick when they work as pharmaceutical employees. In contrast, it might be argued, designers at Gucci do not have role-based professional duties to the global poor, and so Gucci does not have obligations to serve the needs of the global poor.

This argument faces several problems. First, it is contentious whether the duties of professionals should take the specific form of providing professional services. It is plausible that professionals instead have duties to serve the public good, but that these professional duties can be fulfilled in other ways.84 Second, many—probably most—employees of pharmaceutical firms are not physicians or nurses, and so do not have the specific role-based obligations to the global poor that physicians do. Last, even physicians and nurses at pharmaceutical firms do not have a permission to set back the firm’s economic position in order to fulfill their professional duties to promote global health, just as they do not have a permission to set back the corporation’s economic position in order to fulfill other special responsibilities they might have. (Analogously, in-house lawyers are limited in their ability to provide pro bono services on company time, and such services must typically be authorized.85)

E. Past conduct

Another way to support the claim that pharmaceutical IP holders owe a distinctive obligation to patients like Phumeza is to look to their past conduct. If pharmaceutical IP holders’ conduct has brought about the bad health outcomes that


84. See WILLIAM MACASKILL, DOING GOOD BETTER 77 (2015) (arguing that physicians can often save more lives by “earning to give” — i.e. donating a portion of their salaries to effective charities -- than by providing pro bono services).

85. See Ronald T. Y. Moon, Access to Civil Justice: Is There A Solution?, 88 JUDICATURE 155, 157 (2005) (“Survey results of corporate legal departments indicated 40 percent in-house pro bono participation with another 40 percent indicating plans to start in-house pro bono programs. Of those reporting active in-house pro bono participation, 83 percent permit counsel to perform pro bono legal services on company time.”).
produce the need for health care, this could support the imposition of obligations. The legal academic Kevin Outterson and the medical sociologist Donald Light argue that pharmaceutical IP constitutes an affirmative barrier placed in the way of access to health care.\textsuperscript{86}

\begin{quote}
[T]he patent-based drug companies are not strangers to the global access to medicines problem; nor are they innocent bystanders who happen upon a tragedy by chance. They cannot rely on libertarian arguments to absolve themselves of responsibility. They helped create the global system of intellectual property law that stands as a barrier to generic production for the poor . . . The patent-based drug companies are among the chief architects and beneficiaries of this global system, and thus bear enhanced responsibility for its effects on the poor, even in the absence of fault or negligence. They are active participants in the creation of the problem rather than innocent bystanders. The patent-based drug companies actively work to prevent rescue by others. Generic production and distribution of patented drugs for low- and medium-income country populations is possible, as demonstrated by the actions of generic drug companies such as Cipla Ltd of India and charities such as Médecins Sans Frontières. But the drug companies can use patent law to block generic production of the best available medicines and to drive “unreasonable bargains” on pricing . . . Patent law gives companies the right to block generic production for poor countries during the patent period, but exercising it transforms the companies from innocent bystanders into entities claiming the legal right to prevent rescue.\textsuperscript{87}
\end{quote}

I agree with Outterson and Light that pharmaceutical IP holders who assert their rights are placing a barrier in the way of access to medicines. But so are holders of rights to real property or to money. When a pharmaceutical retailer—as opposed to an IP holder—refuses to let an impoverished parent bring home a prescription for her child without paying, the retailer is also asserting the “legal right to prevent rescue.” The same is true when the bank next door locks its vaults, or wealthy customers in the store close their wallets and refuse to pay for needy patients’ medicines. While Outterson and Light assert that “[t]he drug company’s status is . . . unique because of the patent law’s ability to block the activities of

\begin{footnotesize}
\begin{enumerate}
\item Kevin Outterson & Donald W. Light, \textit{Global Pharmaceutical Markets}, in \textit{A Companion to Bioethics} 417 (Helga Kuhse & Peter Singer eds., 2009).
\item \textit{Id.} at 418.
\end{enumerate}
\end{footnotesize}
others,"88 this assertion of uniqueness does not survive scrutiny. Property and contract law prevent rescue just as surely as patent law does.89 As such, Outterson and Light's attempt to distance themselves from ethicists who would more generally "find positive duties on the rich to care for the needy" is unavailing.90

Thomas Pogge has also argued that pharmaceutical firms are affirmatively harming the global poor. As Glenn Cohen summarizes,

Pogge begins with the idea that all people have rights to a "minimally worthwhile life" and therefore require a share of minimum levels of basic goods, including health care, that are essential to a decent life — he terms such goods "human rights." According to Pogge's theory, citizens of one state have an obligation to avoid "harming" citizens of another state by imposing "deficits" on their access to these human rights; that is, he argues that "[w]e are harming the global poor if and insofar as we collaborate in imposing" a "global institutional order . . . [that] foreseeably perpetuates large-scale human rights deficits that would be reasonably avoided through foreseeable institutional modifications."91

While Pogge's claim that everyone has a right to a minimally decent life is plausible and is consistent with human rights documents,92 his claim that the global international order is affirmatively harming the poor, rather than failing to provide them with fair benefits, has been vigorously and persuasively challenged by Norman Daniels and others who point out that describing the international order

88. Id. at 419.
89. See Ronald H. Coase, The Federal Communications Commission, 2 J.L. & ECON. 1, 27 (1959) ("All property rights interfere with the ability of people to use resources. What has to be insured is that the gain from interference more than offsets the harm it produces."); James Sterba, From Liberty to Welfare, 105 ETHICS 65, 70 (1994) (observing that property rights interfere with "the liberty of the poor not to be interfered with in taking from the surplus possessions of the rich what is necessary to satisfy their basic needs").
90. Outterson & Light, supra note 86, at 420.
91. I. Glenn Cohen, Medical Tourism, Access to Health Care, and Global Justice, 52 VA. J. INT'L L. 1, 43 (2011) (quoting THOMAS W. POGGE, WORLD POVERTY AND HUMAN RIGHTS (2002)). While this Article cites Pogge's work because of its influence on the debate, it also acknowledges the numerous charges of sexual misconduct against Pogge. See Colleen Flaherty, Separating the Philosophy from the Philosopher, INSIDE HIGHER ED., Aug. 3, 2016, https://www.insidehighered.com/news/2016/08/03/philosophers-move-limit-alleged-harassers-influence-within-discipline (reporting numerous allegations that Pogge has harassed women students, and discussing efforts to respond, including syllabus and citation boycotts).
92. See Persad, supra note 64, at 603-06 (discussing conceptions of the right to health as a right to a decent minimum)
as inflicting harm requires adopting a tendentious definition of harm. More importantly, even if we grant its correctness for the sake of argument, Pogge’s view — like Outterson and Light’s — is unable to support pharmaceutical exceptionalism. Firms like Coca-Cola and Gucci also rely on and lobby for international trade rules, and are embedded in networks of global commerce.

Activists’ more provocative suggestion that pharmaceutical IP holders who enforce their rights actively kill patients in need faces the same problem. Even if the IP holder could be described as killing the poor by depriving them of medicines, the same is true of the retailer and the fellow customer. It is more plausible to say that all three fail to aid the poor than to say that some kill the poor while others merely fail to help.

Some have instead argued that pharmaceutical IP holders owe special obligations to the global poor because they benefit from publicly funded research investments by universities and governments. The case for such duties appears normatively compelling, particularly where universities and governments provide the fruits of their research below cost or for free, and would differentiate at least some pharmaceutical IP from many types of non-pharmaceutical IP. However, this argument does not support the IP-focused policies discussed in Part I.B. Only pharmaceutical IP holders who benefited from such investments would owe duties. More importantly, these duties would be owed to universities and developed world governments, not directly to the global poor: the extent to which these universities and governments should direct pharmaceutical IP holders to assist the global poor,

93. See Cohen, supra note 91, at 44 (citing NORMAN DANIELS, JUST HEALTH 337-40 (2008)); see also Mathias Risse, Do We Owe the Global Poor Assistance or Rectification? 19 ETHICS & INT’L AFF. 9, 9 (2005) (arguing that the “global order does not harm the poor according to the benchmarks of comparison used by Pogge”); Debra Satz, What Do We Owe the Global Poor?, 19 ETHICS & INT’L AFF. 47, 53-54 (2005) (agreeing that the global status quo is unjust, but rejecting Pogge’s “specific argument that the advantaged citizens of the affluent countries actively cause most of the severe poverty in the world” and suggesting that this argument relies on an “understanding of causation” that “erodes the distinction between harming and failing to remedy”).


95. I am grateful to Ameet Sarpatwari for suggesting that I examine this argument. See Lissett Ferreira, Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations, 71 FORDHAM L. REV. 1133, 1142 (2002) (“[D]evelopment of new drugs frequently is subsidized heavily by the taxpayer’s money and performed in publicly-funded laboratories. Thus, critics…argue that it is unfair for drug companies to reap huge profits from the inflated prices they charge for products developed using taxpayer money.”); see also Outterson & Light, supra note 86, at 423.

96. This argument could be understood as appealing to ideas of unjust enrichment; see Moore, supra note 69, at 1187.
rather than to assist the domestic poor or to invest in scientific research, is a complex question.

A final argument would point to egregious misconduct by pharmaceutical IP holders, such as false advertising, anticompetitive conduct, and the funding of misleading clinical trials. Scholars have identified compelling evidence of such misconduct. But this misconduct likewise does not support the proposals in Part I.B. Rather, it supports efforts to enforce greater clinical trial transparency, to regulate advertising, and to ensure competition. A focus on corporate misconduct would also sweep more broadly than pharmaceutical firms, given the many non-pharmaceutical firms and wealthy private individuals who hamper global health aims through egregious misconduct like pollution, tax evasion, and the sale of harmful products.

III. CAN WE MEET GLOBAL HEALTH NEEDS WITHOUT EXCEPTIONALISM?

Part II’s conclusion is that assigning special responsibility to pharmaceutical IP holders is difficult to defend. However, pharmaceutical IP holders retain the same responsibilities to assist patients in need, like Phumeza, that others who are equally well-off and equally well placed to aid do. This Part will consider two strategies for assisting patients like Phumeza that do not focus narrowly on the elimination or weakening of IP rights. It will then argue that while non-exceptionalist strategies for helping poor patients are the best option, it is acceptable to employ pharmaceutical exceptionalist policies when doing so is the most attainable way of achieving important global health goals.

A. Funding Access to Medicines

Access to medicines can be achieved via routes other than IP, such as “pull” programs that reward the development of medicines and “‘push” programs that encourage research. A prominent example of a pull program is a prize system, which would offer a prize to firms or other actors who develop drugs that have certain desirable outcomes. These desirable outcomes can be overall

---

improvements in health or can be more specific subcategories of improvements such as new antibiotics. These prizes would incentivize research in these areas, just as the monopoly granted to patent recipients is supposed to incentivize research. However, unlike with IP, the prizewinning intervention would then enter the public domain and be producible by generic manufacturers, enabling its provision at a lower cost.\footnote{100} In fact, as Amy Kapczynski notes, patients like Phumeza may benefit more from pull programs than from limitations on IP rights.\footnote{101} Another type of pull program is a patent buy-out, in which the patent rights to drugs that poor patients need would be bought out to enable generic production.\footnote{102} “Push” programs, meanwhile, include grants that fund research.\footnote{103}

Unlike IP systems, which incentivize innovation by granting monopolies, grants, prizes and patent buy-outs all need to be paid for in advance.\footnote{104} This makes them more politically challenging, but also more able to surmount pharmaceutical exceptionalism because paying for them requires identifying revenue sources. Push or pull programs could be funded by a variety of actors, including governments, international organizations, and NGOs. These actors could exhort wealthy firms like Gucci and Coca-Cola, as well as wealthy private individuals, to donate. Or, if politically feasible, governments or international organizations could impose taxes or fees that reach a variety of actors who have the ability to pay. Two such proposals are a financial transactions tax and a global wealth tax. Thomas Piketty has recently proposed a global wealth tax as a way of rectifying economic inequality.\footnote{105} However, such a tax could also be used to promote access to global health for the global poor. Unlike pharmaceutical-exceptionalist policies, a global wealth tax would treat pharmaceutical IP identically to other forms of property. It would align the burdens of the duty to assist with individuals’ capacity to assist. Another possibility would be a financial transactions tax, which imposes a small

\footnotesize{100. Kapczynski, supra note 99, at 973 (“[A] government offers a financial reward to anyone who creates a desired invention—say, a vaccine. The inventor enjoys the benefit of the reward, and the government puts the information it has purchased in the public domain.”).}

\footnotesize{101. Id. at 998-99 (“It is no accident that the global access to medicines campaign and its focus on addressing patent barriers to medicines arose out of the HIV/AIDS movement. A large enough community of people living with HIV in wealthy countries existed to attract investment into new medicines to treat HIV. No similar interest exists in developing treatments for conditions such as extensively drug-resistant tuberculosis (TB)—the largest impact of which is felt in South Africa. No patent exception can give patients with this form of TB better access to simple and fast-acting medicines, because such medicines do not exist.”).}


\footnotesize{103. W. Nicholson Price, Grants, 34 BERKELEY TECH. L.J. 1 (2019).}

\footnotesize{104. Wisser, supra note 98, at 273.}

fee on stock trades and other transactions involving financial instruments.\textsuperscript{106} Such a tax would not track ability to assist perfectly, as it would impose greater burdens on financial transactors than on wealthy individuals or firms who simply sit on their assets. However, it would be more equitable than pharmaceutical-exceptionalist approaches.

\textbf{B. Contribution}

A more modest way of moving away from pharmaceutical exceptionalism would be to continue imposing duties to aid on pharmaceutical IP holders, while creating a mechanism for them to seek contributions from those who hold other forms of property. This approach would resemble the right of contribution in the common law of torts, which permits a tortfeasor who is jointly liable for a harm to seek contribution from other tortfeasors. As a recent article explains,

Contribution arose as an equitable rule to ameliorate the perceived unfairness of holding one joint tortfeasor jointly and severally liable for all of an indivisible harm caused by multiple parties. The common law of contribution provides such a joint tortfeasor with a cause of action "to collect from others responsible for the same tort after the tortfeasor has paid more than his or her proportionate share." A common law contribution plaintiff can recover if she proves a common liability with defendants and a payment to resolve that liability in excess of her equitable share.\textsuperscript{107}

While early common law did not provide for a right to contribution, most jurisdictions now do.\textsuperscript{108} One prominent justification for permitting contribution is fairness — that it is inequitable to impose the full cost of a harm on only one among many parties who are jointly responsible for causing it.\textsuperscript{109} The Supreme Court has recognized this fairness principle when discussing contribution.\textsuperscript{110} The imposition of responsibilities on pharmaceutical IP holders is arguably a case of liability for


\textsuperscript{109} Id. at 1059-63.

EXAMINING PHARMACEUTICAL EXCEPTIONALISM

nonfeasance, rather than liability for misfeasance. Dividing liability for nonfeasance among multiple nonfeasant parties, however, is a recognized challenge. Essentially, if holders of IP are responsible for the health deficits the global poor face, as the authors discussed in Part I argue, they should be permitted to seek contribution from others who are also failing to contribute to the realization of the right to health.

The contribution-based approach could be implemented by allowing pharmaceutical IP holders to obtain contributions from others who share joint responsibility for global health deficits. This contribution could take the form of monetary transfers and could be obtained via traditional legal channels. Another way of implementing this contribution-based approach would be to permit pharmaceutical IP holders whose rights are abrogated to in turn abrogate the IP of other similarly situated actors. So, for instance, if both Gucci and a pharmaceutical IP holder have a duty to alleviate the problems of the global poor, but only the latter is facing the imposition of legal duties to aid, the pharmaceutical IP holder would in turn have a (potentially transferable) right to use Gucci’s IP. Even if this sort of IP cascade is inefficient, it could serve as a penalty default that motivates a move toward a prize system or some other way of improving health care access for the global poor that distributes the burden of doing so more equitably.

I use Gucci, of course, only as an example, and not to suggest that Gucci is uniquely deficient in its contribution to global health. A detailed analysis of how responsibility for global health deficits should be apportioned is beyond this Article’s scope. However, the two most relevant factors in assigning responsibility to help are an actor’s (a) affirmative contribution to deficits, and (b) its capacity to remedy deficits. Actors who affirmatively contribute to global health deficits might include, for instance, polluting industries and marketers of unhealthy foods or tobacco. Actors with the capacity to remedy deficits, meanwhile, will be those with substantial resources—whether fungible, like money, or non-fungible, like food or medicines. Gucci’s substantial capacity to remedy deficits can justify imposing more substantial duties on it than on, for instance, a local fast food restaurant or trucking business, even if the latter two businesses make more obvious contributions to health deficits.

111. Harold F. McNiece & John V. Thornton, Affirmative Duties in Tort, 58 YALE L.J. 1272, 1288 (1949) (“Suppose A is in danger and fifty men are at hand to rescue him. Must all attempt the rescue under pain of liability?”).

112. Cf: Liam Murphy, Beneficence, Law, and Liberty: The Case of Required Rescue, 89 GEO. L.J. 605, 623 (2001) (“If all fifty fail to rescue the one, then . . . they are all liable (though in this case we would add that the plaintiff can recover only once and that the enforced-against tortfeasor may seek contribution from the others”).

C. An Expediency-Based Case for Pharmaceutical Exceptionalism

If neither broad-based funding for push and pull programs nor contribution prove politically feasible, we face the question of whether pharmaceutical exceptionalism is an acceptable, even if nonideal, policy approach. This Subpart will argue that pharmaceutical exceptionalist policies can be acceptable, but should be recognized as creatures of practical expediency rather than as fundamentally required by justice.

Why might pharmaceutical exceptionalism be more politically attractive than broad-based funding for access to medicines? One reason is that the legal incidence of exceptionalist policies falls on a small and unpopular set of actors (pharmaceutical IP holders), rather than middle-class taxpayers.\(^{114}\) Another is that pharmaceutical exceptionalist policies provide in-kind benefits to poor patients that can neither be misspent nor redirected to other social priorities.\(^{115}\) These factors make pharmaceutical exceptionalism analogous to other policy choices, such as the preference for regulatory mandates rather than taxes, that are criticized as inefficient by scholars and “policy wonks” but frequently implemented in practice.\(^{116}\) One analogue for pharmaceutical exceptionalism is the effort to improve housing affordability via inclusionary zoning requirements imposed on developers, rather than via taxpayer-subsidized housing vouchers. Commentators have criticized inclusionary zoning for treating developers unfairly and for creating perverse incentives:

If people knew that landowners had to bear the cost of providing affordable housing, the policy might be considered unfair or even a taking because landowners have no more responsibility to pay the full cost of social policies than anyone else. If people knew that market-rate home buyers had to bear the cost of providing affordable housing, the policy also might be considered counterproductive because rather than creating more affordable

---

114. Cf. Edward J. McCaffery & Jonathan Baron, The Political Psychology of Redistribution, 52 UCLA L. Rev. 1745, 1761, 1782 (2005) (hypothesizing and confirming that people prefer “hidden” taxes that initially fall on a third party (e.g. corporate taxes) to taxes that initially fall on individuals).


116. Cf. Thomas Merrill & David M. Schizer, Energy Policy for an Economic Downturn: A Proposed Petroleum Fuel Price Stabilization Plan, 27 YALE J. ON REG. 1, 27 (2010) (“Given . . . infrastructural and political realities, there is no mystery why command and control strategies succeed politically while Pigouvian taxes fail. The costs of regulations are not explicitly tied to the regulatory mandate, but instead are quietly passed on by manufacturers in the form of higher prices or lower wages and investment returns[.]”).

186
Despite these criticisms, inclusionary zoning is popular and widely used. Its popularity likely reflects the fact that it can be implemented without imposing visible burdens on taxpayers.

Assuming that pharmaceutical exceptionalism is politically tenable, three concepts are useful in assessing its desirability: vertical equity, horizontal equity, and efficiency. Vertical equity is achieved by appropriately responding to different actors’ economic circumstances, and is often associated with policies that impose lesser burdens on the disadvantaged. Horizontal equity is achieved by treating like actors alike. Efficiency is achieved by enlarging the total sum of societal resources. While these concepts are most familiar in tax policy, they have also been used to analyze, inter alia, real estate regulation and health policy.

Pharmaceutical exceptionalist policies typically advance vertical equity, because they transfer entitlements from wealthier pharmaceutical firms to the global poor. However, as Part II argued, they violate horizontal equity, because


118. Keaton Norquist, Local Preferences in Affordable Housing: Special Treatment for Those Who Live or Work in A Municipality?, 36 B.C. ENVTL. AFF. L. REV. 207, 208 (2009) (stating that "[o]ne of the most popular and effective solutions" to lack of affordable housing "has been the enactment of inclusionary zoning ordinances requiring residential developers to set aside a specified percentage of new units — often ten to fifteen percent — which must be sold or rented at prices deemed affordable to low- and moderate-income households"); Cecily T. Talbert et. al., Recent Developments in Inclusionary Zoning, 38 URB. LAW. 701, 706 (2006) (similar).

119. See Paul Boudreaux, Infill: New Housing for Twenty-First-Century America, 45 FORDHAM URB. L.J. 595, 632 (2018) (observing that inclusionary zoning is "perhaps the most popular mechanism to ensure the creation of permanent new low-cost housing," and that its popularity may reflect its implementability without "financial expenditures by the government, in contrast to techniques such as subsidies, tax breaks, and duties to provide fair shares" because "[t]he expenses of providing low-cost housing are borne by housing developers.").


121. Robert C. Ellickson, Suburban Growth Controls: An Economic and Legal Analysis, 86 YALE L.J. 385, 415 (1977) ("Horizontal equity requires government to treat like persons alike.").

122. Randall, supra note 120, at 165.

123. See Ellickson, supra note 121; Randall, supra note 120.

187
there is no compelling basis for treating pharmaceutical IP holders as more responsible for the plight of poor patients than other firms or wealthy individuals are. Pharmaceutical exceptionalism’s effects on efficiency, meanwhile, are unclear: although exceptionalist policies create perverse incentives to avoid investment in pharmaceutical research, current intellectual property law contains its own suboptimal incentives.  

When vertical and horizontal equity conflict, it can be acceptable to violate horizontal equity in order to achieve vertical equity. To the extent that it can genuinely improve vertical equity, pharmaceutical exceptionalism represents this sort of allowable violation. In taking this position, this Article parts company with recent commentators who worry about unfairness to pharmaceutical firms. For example, Rebecca Wolitz has worried that

Without additional argument, it seems unfair to single out biopharmaceutical companies to sacrifice their profits or products to rescue others. Why not say that other groups... have an obligation of rescue to pitch in and pony up? Why effectively impose a moral tax on a particular industry merely qua that industry being that industry?

Other commentators assert that society should not require pharmaceutical companies to help the poor unless everyone with comparable ability to pay is also required to do so. These objections go wrong by allowing the perfect to be the


125. Cf. Liam Murphy & Thomas Nagel, The Myth of Ownership: Taxes and Justice 170-72 (2002); Zachary Liscow, Reducing Inequality on the Cheap: When Legal Rule Design Should Incorporate Equity As Well As Efficiency, 123 Yale L.J. 2478, 2501 (2014) (“Arguing for the unimportance of horizontal equity is the idea that the government should take the opportunity to distribute an entitlement to the poor at a low efficiency cost because the poor need the money... [C]riticizing aiding some of the poor but not others amounts to holding the desperately needed aid for the poor hostage to the desire to help all of the poor.”).

126. Wolitz, supra note 76, at 1204.

127. Anita Ho, Global Health Disparity and Pharmaceutical Companies’ Obligation to Assist, in PHILOSOPHICAL ISSUES IN PHARMACEUTICS 29, 36 (Dien Ho ed., 2017) (suggesting that “holding only pharmaceutical companies responsible without calling upon other industries to assist under the duty of rescue is going too far and unfair to drug companies”); Pepe Lee Chang, Who’s in the Business of Saving Lives?, 31 J. Med. & Phil. 465, 476 (2006) (“If we do not require other types of corporations to save lives then we should not require drug companies to do so.”).
EXAMINING PHARMACEUTICAL EXCEPTIONALISM

enemy of the good. Just as "[t]here would be nothing unfair . . . in a tax on chocolate ice cream but not on vanilla, though it would be arbitrary," there similarly is nothing fundamentally unfair about taxing pharmaceutical IP holders while not taxing others who have equal ability to pay. (Although — as Part II argues — there is also nothing fundamentally just about taxing pharmaceutical IP holders either.) Courts are rightly reluctant to find that violations of horizontal equity constitute violations of the right to equal protection.129 Instead, courts typically find that governments are permitted to tax and regulate in overinclusive or underinclusive ways, so long as there is a rational relationship between the objective and the means selected to achieve that objective.130 Even though pharmaceutical exceptionalism is often suboptimal from both fairness and efficiency perspectives, it can be justified where fairer or more efficient policy options are politically or practically impossible.

CONCLUSION

I have reviewed the arguments for and against pharmaceutical exceptionalism and found much to doubt in both. Ultimately, this Article disagrees with pharmaceutical exceptionalism’s most vehement advocates, but also with its most vehement critics. Pharmaceutical IP holders — like developers subjected to inclusionary zoning requirements — have no special moral obligation to assist the disadvantaged: their duties are the same as those of anyone else who can help, including firms like Gucci and Coca-Cola. But — as with developers — even though pharmaceutical IP holders have no special moral obligation to help, it can be acceptable to task them with a special legal obligation to do so. The imposition of such a legal obligation is analogous to the creation of other civil obligations that track no antecedent moral rule.131

Whether it is wise to require pharmaceutical IP holders to assist poor patients depends on what the available alternatives are, and what the consequences of

128. MURPHY & NAGEL, supra note 125, at 170.
130. Williamson v. Lee Optical, Inc., 348 U.S. 483, 489 (1955) ("[R]eform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind . . . The legislature may select one phase of one field and apply a remedy there, neglecting the others." (citing Semler v. Oregon State Board of Dental Examiners, 294 U.S. 608 (1935) and Am.Fed’n of Labor v. Am. Sash & Door Co., 335 U.S. 538 (1949)).
131. See, e.g., H.L.A. HART, THE CONCEPT OF LAW 68 (2d ed. 1994) ("There can be legal rights and duties which have no moral justification or force whatever.").
imposing such an obligation would be. While the arbitrary treatment of pharmaceutical IP holders is not a sufficient reason to reject pharmaceutical exceptionalism, decreases in long-term innovation and ensuing losses for future patients would be. The risk of such an outcome can only be determined by empirical analysis.

This Article's conclusion, then, is that pharmaceutical exceptionalism should neither be reviled nor exalted, but instead should be recognized as resting on pragmatic and contingent, rather than principled, foundations. It is, fundamentally, a kludge. As with any other kludge, we should recognize and examine the short-term risks of eliminating it, but also investigate whether some more elegant alternative will serve us better in the long run.

132. See D. Casey Flaherty, Copy, Paste, Repeat . . . No More, ACC ASS’N OF CORP. COUNS. DOCKET, Sept. 2014, at 128, 128 (“A kludge is a crude workaround, an assortment of poorly matching parts that form a sub-optimal but serviceable whole. A kludge is often the outcome of jury-rigging -- in the nautical, rather than the courtroom, sense — a semi-functional contrivance made from materials that happen to be on hand.”); Mark A.R. Kleiman, Is “Medical Marijuana” an Idea Whose Time has Come — and Gone?, 13 CONN. PUB. INT. L.J. 173, 175 (2014) (“Allowing for medical use of an otherwise-banned drug that has not passed through the usual drug-approval process is no doubt a regulatory kludge, but it is arguably the “least-bad” of the politically and operationally available options.”).