Article

The Morality of Compulsory Licensing as an Access to Medicines Tool

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INTRODUCTION

Patents and drug products seem to go hand in hand.[1] The right to exclude granted by a patent is widely considered essential to pharmaceutical investment and development.[2] Moreover, the deadweight losses that patents create are generally considered justifiable for pharmaceuticals, as companies need to price above marginal cost to recoup significant fixed development expenses.[3]

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1. *See, e.g.*, Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCI. 3, 4 (2017) ("Policy mechanisms to promote biopharmaceutical innovation often focus on fortifying incentives for firms to develop new products. Biopharmaceutical firms favor exclusionary rights [such as patents] that defer competition, allowing them to profit by charging higher prices prior to generic entry.").

2. *See, e.g.*, Chandra Mohan et al., *Patents—An Important Tool for Pharmaceutical Industry*, 2 J. PHARMACEUTICS & NANOTECH. 12, 13 (2014).

3. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECONS. 20, 21 (2016); *see also* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 88, 92 (2008) (distinguishing between the value of patents in the chemical and pharmaceutical areas from all other technological areas). Bessen and Meurer further note:

> The canonical example of the free-riding problem is traditional drug development. . . . About 70 percent of this [research and development] cost is incurred during the clinical trials necessary to obtain government approval. Generic drug manufacturers are not required to

However, these exclusionary rights translate to soaring drug prices in both rich and poor countries,[4] despite global calls for access to affordable medicines.[5] Yet efforts by governments to reduce costs, using mechanisms like compulsory licenses, routinely meet with censure at the hubris of even considering harm to the patent goose that lays the golden eggs of new medical breakthroughs.[6]

> repeat these same clinical trials, so their R&D costs are far less than those of the original manufacturer.

Id. Similarly, John Duffy argues:

> Intellectual property is a special case of a good with declining average cost. The fixed costs of producing the intellectual property are the costs of . . . developing an innovation. Once the intellectual property has been created, the marginal cost of using it an additional time is very low; in fact, in most cases, it is essentially zero.

John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37, 40 (2004).

4. *See, e.g.*, Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX: J.L.-MED. 139, 159 (2015); Zaheer Ud Din Babar et al., *Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia*, 4 PLOS MED. 466, 467 (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1831730/pdf/pmed.0040082.pdf; Sharon Begley, *Cancer Drugs, Though Cheaper, in the Developing World, Remain Unaffordable*, STAT (June 6, 2016), https://statnews.com/2016/06/06/cancer-drug-prices-developing-world; *Essential New AIDS Drugs Unaffordable for Developing Countries*, IRIN (July 25, 2007), http://www.irinnews.org/news/2007/07/25/essential-new-aids-drugs-unaffordable-developing-countries.

5. For example, Goal 3.B of the United Nations Sustainable Development Goals 2030 includes the targets of supporting "the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries" and providing "access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health." *Sustainable Development Goal 3, Good Health and Well-Being*, UNITED NATIONS, http://www.un.org/sustainabledevelopment/health (last visited June 18, 2018); *see also* UNITED NATIONS, REPORT OF THE UNITED NATIONS SECRETARY GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 7 (Sept. 2016), http://z.umn.edu/UNAccessToMedicines ("Over the last few decades, medical innovation has dramatically improved the lives of millions of people across the globe. . . . Despite this noteworthy progress, millions of people continue to suffer and die from treatable conditions because of a lack of access to health technologies.").

6. *See, e.g.*, William W. Fisher III and Talha Syed, INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT, ch. 6 (Stanford University Press, forthcoming 2017), https://cyber.harvard.edu/people/tfisher/Infection.htm (noting several reasons for the infrequent use of compulsory licenses despite the strong need for cheaper drugs, including that "the pharmaceutical firms disadvantaged by compulsory licenses and the governments of the countries in which those firms are based sometimes retaliate (or threaten to retaliate) against the countries that use them"); Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An*

Through compulsory licensing, a nation allows a third party to practice a patented invention without the patent owner's permission, and requires that third party to pay a government-specified royalty to the patent owner.[7] A compulsory license does not require the patent owner to do anything except sit back and receive the royalties from the third party. But it does prevent the patent owner from stopping that third party from practicing the patented invention.

Viewed from a property perspective, criticizing compulsory licenses might seem quite justified, as the right to exclude is the paradigmatic feature of private property. However, the very definition of patents as property remains a contested issue; as Bessen and Meurer note, "[l]awyers and legal scholars . . . tend to speak of patents not as a form of property, but as *analogous* to other forms of property. Some argue that the analogy might not be appropriate, others that the analogy is long-standing."[8] This is because patents and other forms of intellectual property (IP) lack some attributes of property, despite sharing others. For example, patented subject matter is nonrivalrous (can be used by multiple parties simultaneously without limit); lacks clear boundaries; provides minimal notice; and includes the right to exclude, not the right to use.[9] Thus it should not be surprising that governments would choose to employ, via a compulsory license, a liability rule (the patent owner is entitled to

Analysis of Arguments, 3 INT'L J. SOC. SCI. & HUMAN 254, 254–55 (2013) (cataloging arguments against compulsory licenses).

7. CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 127 (2011). *See also* Jatinder Mann & Dinesh Kumar, *Product Patent in Pharmaceuticals and Compulsory Licensing*, *in* PATENT LAW AND INTELLECTUAL PROPERTY IN THE MEDICAL FIELD, 113 (Rashmi Aggarwal & Rajinder Kaur eds., 2017) (noting that the royalty may be "far less than the patent owner could obtain in a free market").

8. BESSEN & MEURER, *supra* note 3, at 6 (internal citations omitted). They further note that "[t]oday there is vigorous debate among intellectual property law scholars between those who generally approve of the *propertization* of intellectual property law, and those who do not." *Id.* at 30.

9. *Id.* at 6, 8, 54; *see also* MARK A. LEMLEY ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE, at I-2 (2016). The authors argue:

> The fact that the possession and use of ideas is largely "nonrivalrous" is critical to intellectual property theory because it means that the traditional economic justification for tangible property does not fit intellectual property. In the state of nature, there is no danger of overusing or overdistributing an idea, and no danger of fighting over who gets to use it. Everyone can use the idea without diminishing its value.

Id.

compensation for use of the invention) and not a property rule (the patent holder can preclude use of the invention) for patent infringement in certain circumstances.[10] Patent rights are not absolute.

The legitimacy of compulsory licenses under international law is not truly in question. The United States and several European countries have issued numerous explicit and de facto compulsory licenses in various technological areas over the years.[11] Moreover, the 1995 World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) ultimately requires[12] all member countries, most of

10. *See, e.g.*, Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972); Sean Flynn et al., *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 184–85 (2009).

11. *See, e.g.*, James Love, *Written Comments and Notice of Intent to Testify at the Special 301 Public Hearing Monday, February 24, 2014 at the Offices of USTR*, KNOWLEDGE ECOLOGY INT'L (Feb. 7, 2014), https://www.keionline.org/wp-content/uploads/KEI_2014_Special301_7Feb20014_FRComments.pdf. As Love explains:

> [T]he United States itself is [a] major user of compulsory licenses. . . . [This includes] the extensive non-voluntary uses of patents and copyrights under [28 U.S.C. § 1498 (2012)], such as the compulsory licenses benefiting contractors for NASA . . . and the growing number of compulsory licenses granted by federal judges, when they forgo the granting of injunctions in patent infringement cases, in favor o[f] forward looking royalties as a remedy for infringement [per] *eBay*[,] *Inc. v. MercExchange*. . . . These include a number of medical inventions. . . . [The] USTR also intervened recently to permit Apple Computer to import mobile computing devices and iPADs that infringed on Samsung patents. In recent comments . . . USTR has used linguistic gymnastics to deny that our USA style nonvoluntary uses of patent inventions are "compulsory licenses." But denying the obvious does not make the obvious invisible to the world.

Id. See also James Packard Love, *Recent Examples of Compulsory Licensing of Patents*, KNOWLEDGE ECOLOGY INT'L (Mar. 8, 2007), https://www.keionline.org/book/publications-and-research-notes/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents (describing the issuance or threat of issuance of compulsory licenses by a variety of countries).

12. *See* Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, WTO Doc. IP/C/73 (Nov. 6, 2015), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/73.pdf (discussing how least developed country members are not required to provide patents on pharmaceutical products until 2033). Least developed countries (LDCs) are United Nations–designated low-income countries confronting severe structural impediments to sustainable development. *List of Least Developed Countries (as of June 2017)*, UNITED NATIONS (June 2017), https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf.

which are low and middle-income countries (LMICs), to eventually provide patents on pharmaceutical products while also explicitly allowing compulsory licenses under certain conditions.[13] Nevertheless, the moral "rightness" of countries in the global south issuing compulsory licenses for pharmaceuticals seems very much in question, with such tools often being labeled as theft and otherwise mischaracterized as expropriation.[14]

Theft rhetoric in patent law is not new but has a particularly pernicious effect in this context. Theft rhetoric tends to constrain policy choices and government actions, overly extending the boundaries of the patent grant beyond the social bargain for products that can mean life or death to millions of individuals, especially those in LMICs.

13. Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299, 313–14 [hereinafter TRIPS]; *see also* Ellen F.M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 J. PHARMACEUTICAL POL'Y & PRACT. no. 10:19, 2017, at 6 ("The right of governments to grant compulsory licences, including for public non-commercial use, is acknowledged in international law, including in TRIPS.").

14. *See also* Letter from Livia Leu, Swiss Ambassador, to Dr. Carolina Gomez, Adviser, Colombian Ministry of Health and Social Protection (May 26, 2015), https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closing-arguments.pdf (criticizing Columbia's plan to issue a compulsory license on the cancer drug Gleevic). Leu makes the following argument:

> While compulsory licenses are permissible under the WTO TRIPS Agreement on the condition of compliance with the terms and conditions set out in its Art. 31, they are also considered a policy tool of last resort. A compulsory license is tantamount to an expropriation of the patent owner and constitutes a deterrent to future research and development of innovative medicines and their placing on the market in Columbia. Accordingly, it is our view that . . . all other options are [to be] exhausted before the issuing of a compulsory license is being contemplated.

Id. Compulsory licenses are not tools of last resort; as the WTO Doha Declaration on TRIPS and Public Health makes clear, countries have the right to determine when compulsory licenses are necessary. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc WT/MIN(01)/DEC/2, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. Moreover, expropriation is the government taking of private property with little or no compensation; compulsory licenses under international law require, at a minimum, adequate or reasonable compensation. *See* TRIPS, *supra* note 13, at art. 31(h). *See also*, Letter from Dr. Deborah Gleeson et al. to Juan Manuel Santos, President of the Republic of Colombia (May 16, 2016), https://www.keionline.org/wp-content/uploads/5-16-2016-letter-to-colombia-santos-imatinib-license.pdf (letter from 122 health, intellectual property, and trade experts defending Colombia's right to issue a compulsory license).

This Article contemplates the validity of theft rhetoric in relation to the right of countries to grant compulsory licenses from an unconventional perspective; that of biblical teachings on what it means to steal.[15] Part I describes the use of theft rhetoric in relation to IP infringement broadly and drug-patent compulsory licenses in particular. Part II challenges the contention, suggested by theft rhetoric, that compulsory licenses are morally wrong as a form of stealing, by considering the meaning of theft in the context of its Judeo-Christian origins. Part III considers the cogency of the accusation that the issuance of compulsory licenses in developing countries destroys pharmaceutical-company innovation incentives. Part IV concludes that expanding, as the Bible does, the definition of theft to include the possibility that a property owner may be stealing from the poor, can help us to properly evaluate the morality of drug-patent compulsory licenses.

I. PATENTS, DRUGS, AND THE LANGUAGE OF EXPROPRIATION

Through the patent mechanism, a government grants an inventor the right to exclude others from making, using, selling, offering to sell, or importing a patented invention into a country for the patent term, approximately twenty years from the filing date.[16] Patent rights are territorial, so inventors must apply in each country or region where they desire protection and the

15. While not common, other legal scholars have applied biblical insights to legal questions as diverse as environmental ethics, capital punishment, dispute resolution, and professionalism. *See, e.g.*, Jennifer Gerarda Brown, *For You Also Were Strangers in the Land of Egypt: How Procedural Law and Non-Law Enable Love for "Strangers" and "Enemies*,*"* 28 QUINNIPIAC L. REV. 667, 670 (2010) (discussing professional responsibility and dispute resolution); Patrick M. Laurence, Note, *He Beareth Not the Sword in Vain: The Church, the Courts, and Capital Punishment*, 1 AVE MARIA L. REV. 215, 219–20 (2003) (discussing capital punishment); Lucia A. Silecchia, *Environmental Ethics from the Perspectives of NEPA and Catholic Social Teaching: Ecological Guidance for the 21st Century*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 659, 675 (2004) (discussing the environment). I, too, have previously used insights from biblical parables to illuminate issues relating to patents and self-replicating technologies. *See* Margo A. Bagley, *Grant Me Justice Against My Adversary: What Parables Can Teach Us About* Organic Seed Growers & Trade Assoc. v. Monsanto Co., *in* DIVERSITY IN INTELLECTUAL PROPERTY 211 (Irene Calboli and Srividyha Ragavan eds., 2015); Margo A. Bagley, *The Wheat and the (GM) Tares: Lessons for Plant Patent Litigation from the Parables of Christ*, 10 U. ST. THOMAS L.J. 683 (2013).

16. TRIPS, *supra* note 13, arts. 28 and 33.

resulting patent is only valid in that territory.[17] Moreover, because patent laws differ by country, an inventor may obtain a patent in one country and not in another on the same invention.

Broadly speaking, when a third party makes, uses, sells, or offers to sell an invention in a country, or imports a patented invention into that country, without the patent owner's permission, that third party has engaged in patent infringement.[18] Garden variety patent infringement is a strict liability offense; no particular mental state is required to violate a patent owner's rights.[19] Nevertheless, enhanced damages may be awarded for willful infringement, and, controversially, some countries even provide criminal remedies for patent infringement.[20] Thus it is perhaps unsurprising that patent infringement is sometimes characterized as theft. Consider the following examples:

> "What makes *patent theft* so attractive is that *infringement* is not a criminal act and those found guilty face no jail time."[21]
>
> "The theft (or 'infringement') of a patent . . . is typically handled as a civil matter."[22]
>
> "Licensing is simply a legitimate cost of doing business. Not paying that cost is *theft*."[23]

17. Paris Convention for the Protection of Industrial Property art. 4, Mar. 20, 1883, 828 U.N.T.S. 305, 319 (1979).

18. *See, e.g.*, 35 U.S.C. § 271 (2012).

19. *See, e.g.*, *id.* § 271(a) (containing no scienter requirement for direct infringement).

20. *See* J.W. BAXTER ET AL., WORLD PATENT LAW AND PRACTICE, App. 2A.00 (providing a list of countries with criminal penalties for patent infringement as of September 2017). *See generally* Irina D. Manta, *The Puzzle of Criminal Sanctions for Intellectual Property Infringement*, 24 HARV. J.L. & TECH. 469 (2011) (discussing criminal penalties in IP law).

21. Pat Choate, *Patent Theft as a Business Strategy*, HUFFINGTON POST (May 23, 2010), https://www.huffingtonpost.com/pat-choate/patent-theft-as-a-busines_b_508780.html (emphasis added).

22. Richard Stim, *Intellectual Property Crimes*, NOLO: INTELLECTUAL PROPERTYLAWFIRMS.COM, http://www.intellectualpropertylawfirms.com/intellectual-property/ip-crimes.htm (last visited June 18, 2018).

23. John Wiley, *Patent Infringement Is Theft, Plain and Simple*, WASH. POST (Nov. 17, 2015), https://www.washingtonpost.com/news/in-theory/wp/2015/11/17/patent-infringement-is-theft-plain-and-simple. Moreover, President Donald Trump recently tweeted: "The U.S. is acting swiftly on Intellectual Property theft. We cannot allow this to happen as it has for many years!" President Donald J. Trump (@realDonaldTrump), TWITTER (Mar. 7, 2018, 10:38 AM), https://twitter.com/realDonaldTrump/status/971409845453762560.

The use of theft framing is not new to IP. Trade secret misappropriation is often labeled as theft,[24] and in copyright and trademark law, criminal penalties are available for counterfeiting, which also involves a close link with the notion of theft.[25] The ubiquitous FBI notices that appear at the beginning of copyright protected movies have long linked copyright infringement and piracy, a form of theft.[26] On some level, infringement does involve third-party unpermitted use of something to which a government-granted right attaches, and certainly some of the types of infringement being characterized in this way are more egregious than others.

The notion that theft is wrong, that it is even immoral, derives, at least in part, from the Judeo-Christian roots of the Ten Commandments and their injunction against stealing.[27] The Ten Commandments, or Decalogue, is known as "the moral law,"[28] and the violation of many of its tenets, such as those against adultery, lying, and stealing, are actions widely deemed immoral or wrong in the United States even today. One striking example of linking IP infringement to violation of a biblical precept is found in *Grand Upright Music Ltd. v. Warner Bros. Records, Inc.*, where the defendant was accused of sampling a small portion from one of the plaintiff's recordings.[29] The opinion begins as follows:

24. In fact, a few years ago, Congress passed the Theft of Trade Secrets Clarification Act of 2012, Pub. L. No. 112-236, 126 Stat. 1627 (codified as amended at 18 U.S.C. § 1832 (2012)).

25. 18 U.S.C. § 2320(b)(1) ("Whoever commits an offense under subsection (a) [by counterfeiting]—if an individual, shall be fined not more than $2,000,000 or imprisoned not more than 10 years, or both.").

26. *See Anti-Piracy Warning Seal*, FBI, https://www.fbi.gov/investigate/white-collar-crime/piracy-ip-theft/fbi-anti-piracy-warning-seal (last visited June 18, 2018) (providing a seal containing the phrase "FBI ANTI-PIRACY WARNING" that owners of a copyright, in works to which criminal penalties for infringement attach, may use adjacent to the following language: "'The unauthorized reproduction or distribution of a copyrighted work is illegal. Criminal copyright infringement, including infringement without monetary gain, is investigated by the FBI and is punishable by fines and federal imprisonment.").

27. "Thou shalt not steal." *Exodus* 20:15 (King James).

28. *See* John A. Eidsmoe, *The Use of the Ten Commandments in American Courts*, 3 LIBERTY U. L. REV. 15, 43–44 (2009). Professor Eidsmoe identified 515 cases mentioning the Ten Commandments and a further 331 cases referencing the Decalogue. *Id.* at 15. He notes that "these case citations cover a time span from the early 1800s to the present time, demonstrating an unbroken tradition of looking to the Ten Commandments as the moral foundation of [U.S.] law." *Id.* at 18–19.

29. 780 F. Supp. 182 (S.D.N.Y. 1991).

> *"Thou shalt not steal"* has been an admonition followed since the dawn of civilization. Unfortunately, in the modern world of business this admonition is not always followed. . . . The conduct of the defendants herein, however, violates not only the *Seventh Commandment*, but also the copyright laws of this country.[30]

When a judge begins his decision with the line, "Thou shalt not steal," it is a pretty safe bet that things will not turn out well for the defendant, and the defendant was found to have infringed the copyright in that case. Importantly, the judge explicitly classified copyright infringement as a violation of the biblical commandment against stealing, a moral wrong. This is not an isolated occurrence; references to the Ten Commandments have appeared in at least 846 cases since the early 1800s. As John Eidsmoe notes, "These usages demonstrate how thoroughly ingrained into our culture the Ten Commandments have become, to the point that the usage of this terminology lends instant recognition and moral authority to the injunctions they describe."[31]

A surprising number of theft-of-property cases, dealing with tangible and intangible property, mention the Seventh Commandment (or Eighth, depending on which version of the Bible is used).[32] While many of these cases are old, some are rather new. And while the courts are not explicitly relying on the Commandment as the basis for the decision, invoking the biblical admonishment is doing some work for the judge; a link is being made between the moral law and theft. In *Edgenet, Inc. v. Home Depot USA, Inc.*, the court also alluded to modern IP laws as being derived from the Seventh Commandment:

> The ancient admonition "thou shalt not steal" expresses a value that is basic to and underlies the law of property: one cannot freely appropriate to him or herself what has been produced by the labor, efforts, or capital of another. While the plaintiff . . . did not formally allege that the defendants . . . contravened the Seventh

30. *Id.* at 182 (emphasis added).

31. Eidsmoe, *supra* note 28, at 43–44.

32. *See, e.g.*, Fountain v. State, 109 So. 463, 464 (Fla. 1926) (noting that the meaning of the word steal "has been pretty thoroughly understood since the [E]ighth [C]ommandment was brought down from Sinai, or at least since it was translated into English"); Rochon v. Iberia Par. Sch. Bd., 601 So. 2d 808, 809–10 (La. Ct. App. 1992) ("One of the commandments is 'Thou shalt not steal.' Stealing and theft are synonymous and are criminal acts. . . . So, this Court holds that theft (especially of these funds) is an immoral act."); State v. Jim, 508 P.2d 462, 465 (Or. Ct. App. 1973) (quoting Cameron v. Hauck, 383 F.2d 966, 971 (5th Cir. 1967) ("Theft is a synoptic concept: the Eighth Commandment condemns theft without explaining every possible nuance and contrivance in its accomplishment.")).

> Commandment, [the Plaintiff] has accused the defendants of violating nearly every modern derivation of the biblical edict.[33]

It is unlikely that courts and commentators link the moral law and IP infringement unconsciously or even thoughtlessly, especially in light of the increasing domestic and international efforts to criminalize IP infringement.[34] However, such rhetoric is particularly concerning when compulsory licensing of drug patents is characterized as theft. With a compulsory license, national and international law allows a third party to use a patented invention without the permission of the patent owner, who is entitled to receive adequate compensation for such use.[35] Theft rhetoric in relation to compulsory licensing employs moral overtones, and it seems uniquely designed to counter what might otherwise appear to be a moral obligation to save lives when it will not harm one to do so. Consider the following examples.

A few years ago, *The Wall Street Journal* published an op-ed castigating the Thai government's issuance of compulsory licenses on two HIV/AIDS drugs and a heart-disease drug. According to Boston University School of Law Dean Emeritus Ronald Cass, Thailand had engaged in "theft":

> The European Union's trade commissioner . . . recently joined the U.S. in protesting Thailand's effective theft of pharmaceutical companies' intellectual property. . . . [T]here is growing appreciation that trampling patents to allow a middle-income nation to cut its spending on drugs seriously threatens the world's system of protections for innovation.[36]

Though Thailand is considered a middle-income nation, its per capita gross national income was a mere $5,640 in 2016.[37] One of the op-ed's striking aspects was the characterization of Thailand as both ripping off drug companies and harming

33. Edgenet, Inc. v. Home Depot USA, Inc., No. 09-CV-747, 2010 WL 148389, at *1 (E.D. Wisc. Jan. 12, 2010), *aff'd*, 658 F.3d 662 (7th Cir. 2011).

34. *See* Christopher Buccafusco & Jonathan S. Masur, *Innovation and Incarceration: An Economic Analysis of Criminal Intellectual Property Law*, 87 S. CAL. L. REV. 275, 276–79 (2014) (observing an "expansion of the use of criminal sanctions to deter IP violations" but arguing against the use of those sanctions in most cases).

35. Because the government generally determines what comprises adequate or reasonable compensation, there may be disagreement regarding whether that standard is met in a given case. *See generally* JOHN R. THOMAS, CONG. RESEARCH SERV., R43266, COMPULSORY LICENSING OF PATENTED INVENTIONS (2014) (discussing compulsory licensing laws in the United States and several other countries).

36. Ronald A. Cass, *Patent Remedy*, WALL ST. J. (Aug. 28, 2007), https://www.wsj.com/articles/SB118824874547610202.

37. *Data for Upper Middle Income: Thailand*, WORLD BANK, https://data.worldbank.org/?locations=XT-TH (last visited June 18, 2018).

innovation, when it was in fact complying with its international obligations. The license was for the Thai public-health system and thus constituted "public non-commercial use" within the meaning of TRIPS Article 31(b).[38] Also, as Jill Johnstone and James Love noted, the public health reasons for the licenses were quite legitimate:

> In 2006, Thailand had an average per capita income of $8.19 per day. For the bottom 80 percent of the income distribution, the average was $5.22 per day. To illustrate the Thai concerns regarding affordability of products, it is useful to note that the pre-compulsory licensing price for the heart disease drug Plavix was $2 per day, or nearly 40 percent of the average income of the bottom 80 percent of the population.[39]

Like Cass, other commentators have used theft language to describe compulsory licenses, including the CEO of pharmaceutical giant Bayer AG, who characterized a different compulsory license as "essentially . . . theft."[40] The Indian government granted the compulsory license on a cancer drug that Bayer had priced so high in India that it was available to only two percent of the patients who needed it.[41]

38. *See* HO, *supra* note 7, at 134.

39. Letter from James Love, U.S. Co-Chair, and Jill Johnstone, European Co-Chair, Trans Atlantic Consumer Dialogue Working Group on Intellectual Property, to Susan C. Schwab, Ambassador and U.S. Trade Representative, and Peter Mandelson, European Commissioner for International Trade (Mar. 17, 2008), http://test.tacd.org/wp-content/uploads/2013/09/TACD-IP-2008-Letter-To-S.-Schwab-and-P-Mandelson-on-Compulsory-Licensing.pdf; *see also* Inthira Yamabhai et al., *Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts*, 7 GLOBALIZATION & HEALTH, no. 28, 2011, at 9, 11 (concluding that Thailand's compulsory licenses resulted in increased access to the medicines, with no appreciable decline in exports or foreign direct investment).

40. Ketaki Gokhale, *Merck to Bristol-Myers Face More Threats on India Patents*, BLOOMBERG (Jan. 28, 2014), https://www.bloomberg.com/news/articles/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-drug-patents; *see also* Editorial, *Theft, Extortion, and AIDS*, CHI. TRIB. (July 6, 2005), http://articles.chicagotribune.com/2005-07-06/news/0507060005_1_compulsory-licensing-drugs-called-protease-inhibitors-brazilian-congress ("No matter how you package it, Brazil's campaign against patents held by U.S. pharmaceutical firms amounts to international thievery and extortion."); Nirmal Ghosh, *Battle Rages over Thai Actions on AIDS Drugs*, STRAITS TIMES, May, 28, 2007 (Sing.), 2007 WLNR 9967069 (noting that a U.S. lobbying group "accused Bangkok of 'stealing' American and European innovation"); Merrill Matthews, *Miracle Drugs Ripped Off*, GEELONG ADVERTISER, Dec. 9, 2008, at 15 (Austl.), 2008 WLNR 23639900 ("In Thailand and Brazil, politicians have decided to reward inventors of medical miracles not with accolades, but with compulsory licenses. This is a fancy name for simple theft.").

41. Shamnad Basheer, *Bayer's Nexavar, Patent Working and Compulsory Licensing: Mind the (Information) Gap!*, SPICYIP (Apr. 27, 2015), https://

When using this theft rhetoric or framing, commentators generally send two related but distinct messages: (1) compulsory licenses are morally wrong because stealing is morally wrong; and (2) compulsory licenses will harm innovation and society will not get the new drugs it needs.[42]

They thus appeal both to moral outrage and understandable self-interest. Each message will be considered in turn.

II. COMPULSORY LICENSES: MORALLY WRONG OR MORALLY RIGHT?

First, if compulsory licenses are morally wrong because it is morally wrong to steal, and the moral wrongness of theft derives in some measure from the Judeo-Christian moral law embodied in the Ten Commandments, then it may be instructive to take a closer look at the meaning of theft under that moral law.

Accusing someone of stealing is a serious matter. In the Bible, theft is a sin, a violation of a command that is sacred in Judeo-Christian traditions. However, the Ten Commandments

www.spicyip.com/2015/04/bayers-nexavar-patent-working-and-compulsory-licensing-mind-the-information-gap.html.

42. *See* Phil Kerpen, Editorial, *Time to Get Tough on India for Stealing All of Our Stuff*, BAXTER BULL., Apr. 21, 2014, at A4, 2014 WLNR 37483767. Kerpen states:

> Quite simply, from pharmaceuticals to motion pictures . . . India is stealing our stuff. . . . Strong protections for [IP] rights of innovators are absolutely critical to raise the capital and justify investing it in developing new cures. The greatest threat to innovation globally now comes from India's policies.

Id. (emphasis added); Jasson Urbach, *State Will Undercut Itself with New IP Policy*, BUS. DAY, Feb. 28, 2014 (S. Afr.), 2014 WLNR 5917470 ("Compulsory licences allow the government to break a patent and give a licence to a local manufacturer to produce a drug. This amounts to *state-sanctioned theft of property*. . . . [I]f we weaken drug patents, we will *discourage companies and investors from developing the next generation of medicines*." (emphasis added)). A more subtle argument by pharmaceutical companies and their governments is that countries issuing compulsory licenses will not receive significant foreign direct investment, an assertion that is also not substantiated, as many factors go into foreign direct investment decisions and IP protection is only one. *See* Lee Branstetter et al., Has the Shift to Stronger Intellectual Property Rights Promoted Technology Transfer, FDI, and Industrial Development? 9 (unpublished manuscript), http://www.people.hbs.edu/ffoley/BFSWIPO.pdf (last visited June 18, 2018) ("[T]he poorest countries attract little FDI, and a change in the IPR regime may do relatively little to induce large FDI flows simply because the degree of IPR protection is only one of many determinants of inward FDI."); *see also* Nitya Nanda, Editorial, *This Isn't Case of Tech Theft*, PIONEER (Mar. 18, 2016), http://www.dailypioneer.com/columnists/oped/this-isnt-case-of-tech-theft.html ("The developed nations' argument that compulsory licensing in India will scare foreign investors, is bogus.").

do not exist in isolation, but rather as part of a larger and richer context that both prohibits actions and prescribes affirmative duties to humankind. As such, the Ten Commandments are far more than just a bunch of thou shalt nots.

Probably the most illuminating way to think about their true meaning is through the explanation Jesus gave when, asked by an expert in the law which was the greatest commandment, He said:

> "Love the Lord your God with all your heart and with all your soul and with all your mind." This is the first and greatest commandment. And the second is like it: "Love your neighbor as yourself." All the Law and the Prophets hang on these two commandments.[43]

In other words, Jesus explains that the Ten Commandments, perhaps surprisingly, are about love. Love for God in the first four, and love for your neighbor in the last six.

We show love to God by not putting other gods before him,[44] by not bowing down to idols,[45] by not taking His name in vain,[46] and by choosing to spend His Sabbath with Him.[47] In terms of

43. *Matthew* 22:37–40. Jesus's answer is also repeated in *Mark*, where it is footnoted as referring to *Deuteronomy* 6:4–5 and *Leviticus* 19:18. *See Mark* 12:28–34. It also appears, in the context of the lawyer answering Jesus, and Jesus affirming his answer, in *Luke* 10:25–28, and serves as a prelude to the parable of the Good Samaritan. That Jesus is indeed referring to the Ten Commandments can be further seen in a comparison of *Luke* 10:25–28 and *Luke* 18:18–23, in which a rich young ruler also asks Jesus what he must do to inherit eternal life, and Jesus responds by rattling off the last six commandments relating to love for one's neighbor. Then, when the young man states that he has kept all of those commandments since his youth, Christ tells him: "You still lack one thing. Sell everything you have and give to the poor, and you will have treasure in heaven. Then come, follow me." *Luke* 18:18–23. Upon hearing this, the young man became very sad and went away, because he loved money and his possessions (his idols) more than he loved God. *Id.*

44. *See Exodus* 20:2–3 ("I am the Lord your God. . . . You shall have no other gods before me.").

45. *See id.* at 20:4–5 ("You shall not make for yourself an idol in the form of anything. . . . You shall not bow down to them or worship them; for I, the Lord your God, am a jealous God.").

46. *See id.* at 20:7 ("You shall not misuse the name of the Lord your God, for the Lord will not hold anyone guiltless who misuses his name.").

47. *See id.* at 20:8–11. *Exodus* further states:

> Remember the Sabbath day by keeping it holy. Six days you shall labor and do all your work, but the seventh day is a Sabbath to the Lord your God. On it you shall not do any work, neither you, nor your son or daughter, nor your manservant or maidservant, nor your animals, nor the alien within your gates. For in six days the Lord made the heavens and the earth, the sea, and all that is in them, but he rested on the seventh day. Therefore the Lord blessed the Sabbath day and made it holy.

Id.

our love for, or duty to, our neighbor, dishonoring our parents is not loving,[48] neither is murder,[49] nor cheating on our spouses.[50] Nor is lying about our neighbor,[51] or coveting our neighbor's possessions. And stealing is definitely not loving.[52]

Perhaps because of that love orientation and the context of duties and obligations, there are explicit instructions in the Bible regarding a variety of actions that would otherwise be considered stealing.[53] And some of those actions, embodied in the Jewish concept of *pe'ah*,[54] provide an interesting and useful analogy that can inform the way we think about compulsory licenses on pharmaceutical patents. The descriptions of *pe'ah* can be found in *Leviticus* chapters 19 and 23, and in *Deuteronomy* chapter 24: "When you reap the harvest of your land, . . . [d]o not go over your vineyard a second time or pick up the grapes that have fallen. Leave them for the poor and the alien. I am the Lord your God."[55] The instructions apply not only to vineyards but to other crops: "When you reap the harvest of your land, do not reap to the very edges of your field or gather the gleanings of your harvest. Leave them for the poor and the alien. I am the Lord your God."[56] Similarly, *Deuteronomy*

48. *See id.* at 20:12 ("Honor your father and your mother, so that you may live long in the land the Lord your God is giving you.").

49. *See id.* at 20:13 ("You shall not murder.").

50. *See id.* at 20:14 ("You shall not commit adultery.").

51. *See id.* at 20:16 ("You shall not give false testimony against your neighbor.").

52. *See id.* at 20:17 ("You shall not covet your neighbor's house. You shall not covet your neighbor's wife, or his manservant or maidservant, his ox or donkey, or anything that belongs to your neighbor.").

53. *See id.* at 20:15 ("You shall not steal."). To be sure, the Bible does condemn ordinary theft, and it even requires restitution when someone steals because they are hungry. *See, e.g.*, *id.* 21:16 (dealing with kidnapping, which is stealing someone's freedom); *Id.* 22:1–4 (dealing with stealing livestock); *Hosea* 12:7 (referring to fraud by merchants); *Proverbs* 6:30–31 (saying one should not despise a thief who steals because he is hungry, but that he should still be punished for his crime).

54. In Hebrew, *pe'ah* means corner or side. *See Strong's Concordance*, BIBLE HUB, http://biblehub.com/hebrew/6285.htm (last visited June 18, 2018). As Jeffrey Spitzer explains: "The Bible's model of tzedakah (social justice and support) included a variety of agricultural gifts. Grain and produce that were left or forgotten during the harvest were available for the poor to glean. The corners of the fields (*pe'ah*) were also designated for the poor." Jeffrey Spitzer, *Pe'ah: The Corners of Our Fields*, MY JEWISH LEARNING, https://www.myjewishlearning.com/article/peah-the-corners-of-our-fields (last visited June 18, 2018).

55. *Leviticus* 19:9–11.

56. *Id.* 23:22. It also is interesting to note that, just as in this verse, God uses the phrase "the Lord your God" in each of the first four commandments of

provides: "When you beat the olives from your trees, do not go over the branches a second time. Leave what remains for the foreigner, the fatherless and the widow."[57] *Deuteronomy* further provides: "When you are harvesting in your field and you overlook a sheaf, do not go back to get it. Leave it for the alien, the fatherless and the widow, so that the Lord your God may bless you in all the work of your hands."[58]

In these examples, the poor have the right to enter onto the land of a property owner and harvest the leftovers from the crop. These are not leftovers after the workers have cleaned every scrap of salvageable fruit or grain. The property owner is instructed not to do too good a job in harvesting the crop so that some portion of the crop is left for the poor and the immigrant foreigner. In fact, these examples illustrate that loving one's neighbor is so important that not only are the poor *not* stealing (nor even trespassing), the landowner is *enjoined* from harvesting to the edges of his field. *Or* going back to get the forgotten sheaf in the field. *Or* making a second sweep to pick up missed grapes in his vineyard or missed olives in his olive groves. What is left *does not belong* to the landowner *and it will not harm him to let the poor have it*. It seems God wanted people to trust Him, not wealth, to supply their needs.

These overarching concepts are also reflected in Christian thought and tradition. For example, the Catholic catechism recognizes the universal destination of goods as being provided by God for the benefit of the *whole* human race,[59] and it also forbids unjustly taking or keeping the goods of one's neighbor or wronging him in any way with respect to his goods.[60] Thus, while it affirms the importance of respect for private property, it also considers as theft "forcing up prices by taking advantage of the . . . hardship of another."[61] And as Baptist theologian Gary

the Decalogue (love for God) but not in the last six (love for neighbor). The use of this phrase in these gleaning texts suggests that love for God also should motivate us to love others.

57. *Deuteronomy* 24:20.

58. *Id.* at 19.

59. *Catechism of the Catholic Church* para. 2402, http://www.vatican.va/archive/ccc_css/archive/catechism/p3s2c2a7.htm (last visited June 18, 2018).

60. *Id.* para. 2409.

61. *Id.* The Catholic Church set forth this position even more forcefully in a 2001 submission to the World Intellectual Property Organization:

> All men and women of all nations are entitled to have whatever they need for their subsistence and personal advancement, taking it from all the resources available at any given time in history. The provisions protecting private property cannot therefore ever lose sight of the

Gunderson notes, "At the core of every major faith tradition stands an explicit commitment to be with the sick, the poor, the alienated, the marginal, the wounded, and the dying. The commitments are very old, but the implications are forever new and increasingly radical because of remarkable changes in health science."[62]

Now to be clear, neither the United States nor any other Western country is a theocracy, and this Article is not positing that the Ten Commandments, or even some portion of them, are the foundation of U.S. law.[63] Nor is it suggesting the adoption of Levitical approaches to dealing with current day legal issues. Rather, this Article is: (1) an invitation to consider another perspective on the meaning of theft, drawn from a text widely considered as sacred; and (2) an argument that current uses of theft rhetoric in patent law, to the extent they aim to resonate with Judeo-Christian notions of morality, are incomplete, dangerous, and a misapplication of Biblical scripture.

Such uses are incomplete because they do not take account of the full definition of theft in that Judeo-Christian moral context, a definition which includes the possibility of the property owner stealing from the poor. These uses represent a misapplication of scripture because when one invokes the power of the Commandment against stealing, one must also import the

> common destiny of all goods, so much so that it has to be said that all private property is subject to a social encumbrance. Consequently, should there be an institutional conflict between acquired private rights and overriding community demands, it is for the public authorities to set about resolving it with active involvement on the part of individuals and social groups.

World Intellectual Property Organization, *Document Submitted by the Holy See on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore for the First Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, at 4, WIPO/GRTKF/IC/1/7 (Apr. 26, 2001).

62. GARY GUNDERSON, DEEPLY WOVEN ROOTS: IMPROVING THE QUALITY OF LIFE IN YOUR COMMUNITY 5 (1997).

63. *See* HAROLD J. BERMAN, LAW AND REVOLUTION: THE FORMATION OF THE WESTERN LEGAL TRADITION 589 (1983) ("[N]either Jewish thought nor Jewish law seems to have had any substantial influence on the legal systems of the West, at least so far as the surviving literature shows."). This is not to say that the Ten Commandments and other biblical provisions, as well as the body of Jewish law that developed around the Torah, has not influenced the common law; the case law references identified by Professor Eidsmoe attest to that. *See* Eidsmoe, *supra* note 28. However, the influence has not always been explicit. *See* Michael J. Broyde, *The Hidden Influence of Jewish Law on the Common Law: One Lost Example*, 57 EMORY L.J. 1403, 1403–04 (2008) (providing an example of the hidden influence of Jewish law on the common law of bailments).

underlying norms and values embodied in that Commandment. Such uses are also dangerous because they delegitimize a government's moral obligation to provide for the health and well-being of its citizens. When governments are threatened with sanctions for issuing compulsory licenses based on theft framing, they may be reluctant to issue such licenses to alleviate problems with access to medicines, and some people may die as a result of not getting medicines they should have received.

It is perhaps worthwhile to remember that patent rights are limited property rights at best, and that their contours and scope are constantly being adjusted through judicial, legislative, and administrative action. Every court or United States Patent and Trademark Office (USPTO) tribunal invalidation of a patent based on obviousness is an indictment of an absolute-rights stance. Governments grant patents to meet utilitarian societal goals and governments decide the subject matter, scope, and duration of patents. Two inventors in the same country may independently work countless hours and develop the same invention; however, only one of them will receive a patent claiming that exact invention from that country's patent office.[64] The United States Constitution authorizes, but does not require, Congress "to promote the Progress of Science and useful Arts, by securing for *limited Times* to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[65] Moreover, an inventor does not have a natural right to a patent. As Thomas Jefferson eloquently stated:

> Stable ownership is the gift of social law, and is given late in the progress of society. It would be curious then, if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. . . . Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.[66]

64. In rare cases, a patent office may inadvertently issue two patents on the same invention, but one would be invalid. In the United States, federal law provides for a civil action to determine which inventor has priority and is entitled to the patent. 35 U.S.C. § 291(a) (2012).

65. U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

66. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* 13 THE WRITINGS OF THOMAS JEFFERSON 326, 333–34 (Andrew A. Lipscomb & Albert Ellery Bergh eds. 1905). *But see* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent Privilege in Historical Context*, 92 CORNELL L. REV. 953, 1011–12 (2007) (arguing that natural rights philosophy undergirded the grant of patents in early America).

Thus, for example, in *eBay v. MercExchange*, the United States Supreme Court concluded that having a right to exclude does not mean the remedy for the violation of that right is an injunction. Rather, the statute makes the grant of injunctions discretionary resulting in many de facto compulsory licenses where injunctive relief was denied and an adjudged infringer was able to continue practicing the invention by paying an ongoing royalty.[67] The same Court's conclusion that isolated genomic DNA is not patent eligible is also not theft, even though that decision likely invalidated thousands of patent claims.[68] The fact that there may be important reasons for creating property rights to allow owners to internalize externalities does not mean that the owner should be able to internalize *all* of the positive externalities.[69] Allowing the public to absorb some beneficial spillovers without positively harming the property owner can be a virtuous policy choice.

In fact, protecting pharmaceutical products by patent is a relatively recent phenomenon, even in many highly developed countries. For example, Germany did not introduce drug patents until 1968, Italy until 1978, Spain until 1992, and many developing countries not until 2005 as a result of the WTO TRIPS Agreement.[70] Because governments create patent rights, governments can impose appropriate limitations on those rights without such limitations being theft. Making sure the poor have access[71] to the drugs they need in order to live, in a way that

67. eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 392–93 (2006); *see also* Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1316 (Fed. Cir. 2007) (Rader, J., concurring) ("[C]alling a compulsory license an 'ongoing royalty' does not make it any less a compulsory license.").

68. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013); *see also* Subhashini Chandrasekharan et al., *Do Recent US Supreme Court Rulings on Patenting of Genes and Genetic Diagnostics Affect the Practice of Genetic Screening and Diagnosis in Prenatal and Reproductive Care?*, 34 PRENATAL DIAGNOSIS 921, 921, 925 (2014).

69. *See* Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 348–49 (1967).

70. *See* Ellen 't Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, J. INT. AIDS SOC. at 2, 4 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/pdf/1758-2652-14-15.pdf (discussing Italy and Spain); Bhavan N. Sampat, *Intellectual Property Rights and Pharmaceuticals: The Case of Antibiotics* 5 (World Intellectual Prop. Org., Econ. Research Paper No. 26, 2015), http://www.wipo.int/edocs/pubdocs/en/wipo_pub_econstat_wp_26.pdf (discussing Germany).

71. Of course, having low-cost drugs produced does not guarantee patient access to those drugs. There may be several factors at play that impact whether drugs actually reach needy people. *See* Lucie White, *Getting Real About Essential Medicines: "The Last Kilometer,"* 31 MARYLAND J. INT'L. L. 79 (2016)

does not harm the patent holder, should be viewed as part of the social bargain inherent in the patent system and deemed morally right, not morally wrong.

III. THE FALLACY OF COMPULSORY LICENSES AS DESTROYERS OF INNOVATION

Regarding the second message, that compulsory licenses will harm innovation resulting in society not getting the drugs it needs,[72] and that the poor would not have received those drugs without the patent incentive, two points bear mentioning: (1) we already are not getting many of the drugs we need; and (2) the ones we get we often cannot afford. These points arise because drug companies are incentivized, but not in the ways one might think.

A. PHARMACEUTICAL COMPANY INCENTIVES: NOT DRUGS FOR THE GLOBAL SOUTH

It is instructive to consider big pharma's profitability and decisional inputs. The pharmaceutical industry has long been one of the top five, often top two, most profitable industries in the world. The numbers are astounding:

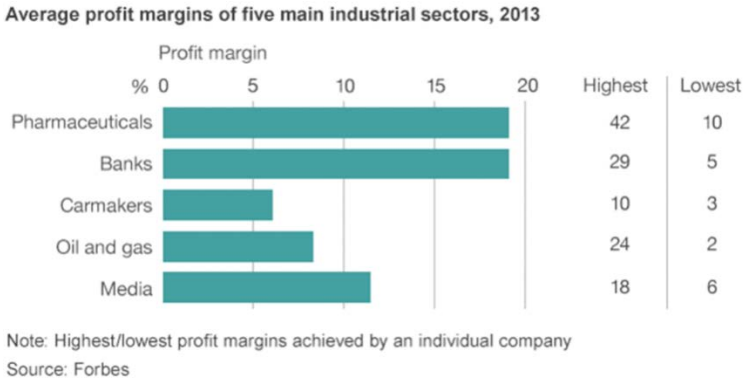
(exploring the complex barriers that may exist to getting drugs the last mile, or last kilometer, to the patients who need them).

72. This argument/threat from pharmaceutical companies arises in relation to other kinds of price-reduction proposals as well. As Sachs and Frakt recount:

> The response from the pharmaceutical industry [to reduced drug prices] has been the same: Even if these proposals improve access to medicines today, they will have a negative effect on innovation in the future. If the government limits manufacturers' ability to recoup the costs of risky research and development, including investments that fail to lead to marketable drugs, they will simply reduce their investment in developing new drugs. This could harm all of us. The drugs we need in the future may not be available.

Rachel E. Sachs & Austin B. Frakt, *Innovation-Innovation Tradeoffs in Drug Pricing*, 165 ANN. INTERN. MED. 871, 871 (2016).

Figure 1: Pharmaceutical Profits, 2013[73]



The ability to obtain such profits is, not surprisingly, what drives big pharma drug development decisions because their goal, as for-profit corporations, is to maximize shareholder value.[74] They are not charitable institutions and we should not expect them to be.

The costs of bringing a drug to market are high and doing so involves significant risk.[75] But innovator companies sell most

73. Richard Anderson, *Pharmaceutical Industry Gets High on Profits*, BBC (Nov. 6, 2014), http//www.bbc.com/news/business-28212223.

74. *See* Jia Lynn Yang, *Maximizing Shareholder Value: The Goal That Changed Corporate America*, WASH. POST. (Aug. 26, 2013), https://www.washingtonpost.com/business/economy/maximizing-shareholder-value-the-goal-that-changed-corporate-america/2013/08/26/26e9ca8e-ed74-11e2-9008-61e94a7ea20d_story.html ("Driving this change is a deep-seated belief that took hold in corporate America a few decades ago and has come to define today's economy—that a company's primary purpose is to maximize shareholder value."); *see also* Anneta Konstantanides & Khaleda Rahman, *Pharmaceutical Entrepreneur Who Jacked up AIDS Pill Price by 5,000% Says He Should Have Charged Even More*, DAILY MAIL (Dec. 5, 2015), http://www.dailymail.co.uk/news/article-3347441/Martin-Shkreli-said-raised-price-Daraprim-more.html (quoting Martin Shkreli, who hiked the price of Daraprim by 5000% overnight, as saying "[m]y investors expect me to maximize profits, not to minimize them, or go half, or go 70 percent, but to go to 100 percent of the profit curve that we're all taught in MBA class").

75. *See, e.g.*, Rhona Finkel, *The 5 Most Profitable Medications Ever Produced*, DRUGS INFO. & SIDE EFFECTS DATABASE (May 24, 2014), http://www.drugsdb.com/blog/the-5-most-profitable-medications-ever-produced.html. Finkel makes the following argument:

> It is certainly true that—from the outside—it looks like drug companies live on easy street . . . but the reality is that they invest billions of dollars every year into research and development. However . . . only one out of every 5,000 to 10,000 compounds that the companies study in preclinical trials actually makes its way to market. . . . And of

drugs so far above marginal cost that the prices more than make up for the costs of drug development, as their annual profits clearly show.[76] As described in a World Health Organization submission, "Launch prices as set by companies are not based on research and development investment or production costs, but on the outcomes of economic calculations that aim to identify the highest possible profit margin the market will tolerate."[77] Also, a recent United States Government Accountability Office Study notes that:

> About 67 percent of all drug companies saw an increase in their annual average profit margins from 2006 to 2015. Among the largest 25 companies, annual average profit margin fluctuated between 15 and 20 percent. For comparison, the annual average profit margin across non-drug companies among the largest 500 globally fluctuated between 4 and 9 percent.[78]

Consider for example, imatinib, also known as Gleevec, a treatment for chronic myeloid leukemia (CML), a disease which used to be a death sentence but has been turned into a chronic condition.[79] According to an article by 100 CML experts, imatinib was originally priced at $30,000 per year of treatment in 2001, and there were 30,000 patients in the United States, which would generate $900 million per year.[80] At that rate, the developer would recoup the costs of development in its first few

> those, very, very few ever become blockbusters. You don't have to cry for them—but it is more complicated than it initially appears.

Id.; *see also* Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B*, SCI. AM. (Nov. 24, 2014), https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b ("CSDD's finding, a bellwether figure in the drug industry, is based on an average out-of-pocket cost of $1.4 billion and an estimate of $1.2 billion in returns that investors forego on that money during the 10-plus years a drug candidate spends in development.").

76. *See* BESSEN & MEURER, *supra* note 3, at 88 ("The higher prices that pharmaceutical firms charge while they are still 'on patent' allow them to earn above-normal profits or 'rents,' that more than recoup their development investments.").

77. WORLD HEALTH ORG., SUBMISSION TO THE UN SG HIGH LEVEL PANEL ON ACCESS TO MEDICINES 5 (2016), http://z.umn.edu/WHOSubmission (citing ED SCHOONVELD, THE PRICE OF GLOBAL HEALTH (2011)).

78. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (Nov. 2017), https://www.gao.gov/assets/690/688472.pdf.

79. *See, e.g.*, Maggie Fox, *Cancer Pill Gleevec Keeps Patients Alive and Well for a Decade*, NBC NEWS (Mar. 9, 2017), https://www.nbcnews.com/health/cancer/cancer-pill-gleevec-keeps-patients-alive-well-decade-n730951.

80. *The Price of Drugs for Chronic Myeloid Leukemia (CML) Is a Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts*, 121 BLOOD 4439, 4440 (2013).

years on the market, and generate profits after that.[81] The drug was far more successful than anticipated at prolonging life for CML patients; the ten-year survival rate increased from twenty percent to eighty percent.[82] However, the price of imatinib increased over time from $30,000 annual to $92,000 in 2012, even though all research costs were accounted for in the original price, new indications were developed, and the patient population increased dramatically.[83]

Despite having made tremendous profits from sales of imatinib, when the government of Colombia announced it was considering granting a compulsory license on the drug in 2015, Novartis, the owner of several patents on the drug, engineered the assertion of significant negative pressure on Colombia.[84] Two sources of the pressure were Switzerland (home to Novartis, the patent holder) and the United States.[85]

High profits also reinforce the minimization of risk that comes from seeking approval for, and introducing new chemical entities. As a result, pharmaceutical companies have focused much of their marketing and development efforts on either drugs for rare indications for which exorbitant prices can be charged,[86] or for me-too drugs with the same mechanism of action as a prior blockbuster drug and with the same active ingredient, except now it may be in a different form, dosing regime, et cetera.[87] According to the U.S. GAO, in 2006, sixty percent of new FDA approvals were for me-too drugs.[88]

81. *Id.* at 4439.

82. *Id.*

83. *Id.*

84. *See* Associated Press, *Colombia Is Threatening Novartis over This Cancer Drug's High Price*, FORTUNE (May 18, 2016), http://fortune.com/2016/05/18/colombia-novartis-cancer-drug-price.

85. *See* Leu, *supra* note 14; Letter to President Santos, *supra* note 14.

86. *See* Sara Jane Tribble & Sydney Lupkin, *High Prices for Orphan Drugs Strain Families and Insurers*, NPR (Jan. 17, 2017), https://www.npr.org/sections/health-shots/2017/01/17/509507035/high-prices-for-orphan-drugs-strain-families-and-insurers.

87. *See* Rosanne Spector, *Me-Too Drugs: Sometimes They're Just the Same Old, Same Old*, STAN. MED. MAG. (Summer 2005), http://sm.stanford.edu/archive/stanmed/2005summer/drugs-metoo.html.

88. U.S. GOV'T ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 17 (2006), https://www.gao.gov/new.items/d0749.pdf.

Neglected tropical diseases affect more than a billion people each year.[89] Almost 200,000 people die from these diseases annually.[90] Millions more are so incapacitated by disease that they cannot work, care for themselves, or care for their children.[91] These diseases predominantly affect the poorest people in the least-developed countries.[92] Yet as Figure 2 from the European Patent Office shows, pharmaceutical research and development disproportionately focuses on chronic, non-communicable diseases, even though many more disability-adjusted life years are lost for infectious diseases.[93] Thus, we as a global community are already not getting the best mix of drugs that we need.[94]

89. *See Neglected Tropical Diseases*, WORLD HEALTH ORG., http://www.who.int/neglected_diseases/diseases/en (last visited June 18, 2018).

90. *The U.S. Government and Global Neglected Tropical Disease Efforts*, HENRY J. KAISER FAM. FOUND. (Nov. 3, 2017), https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-neglected-tropical-diseases/#footnote-241667-7.

91. *See Neglected Tropical Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/globalhealth/ntd/index.html (last visited June 18, 2018) (explaining that these diseases' "disfiguring, debilitating, and sometimes deadly impact" cause significant social stigma as well).

92. Suerie Moon, *Powerful Ideas for Global Access to Medicines*, 376 NEW ENGLAND J. MED. 505, 505 (2017), http://www.nejm.org/doi/full/10.1056/NEJMp1613861. In her article, Moon states:

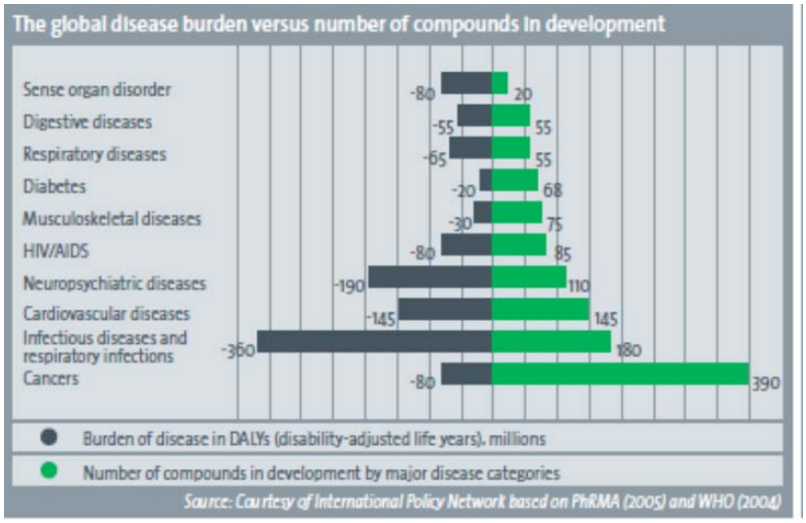
> Whether low- and middle-income countries (LMICs) are struggling to treat millions of people living with HIV or to immunize refugee children against pneumonia, unaffordable prices mean that many people simply go without. Meanwhile, despite billions of public and private dollars invested in pharmaceutical research and development, urgent needs for new antibiotics and tools for other public health priorities go unmet.

Id.

93. EUROPEAN PATENT OFFICE, SCENARIOS FOR THE FUTURE 77 (2007), http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/EPO_scenarios_bookmarked.pdf.

94. Moon, *supra* note 92, at 505; *see also* REPORT OF THE U.N. SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 13 (2016), http://z.umn.edu/UNAccessToMedicines.

Figure 2: The Global Disease Burden Versus Number of Compounds in Development[95]



Above: R&D follows the money, not the disease High-profile diseases afflicting Western countries tend to attract the highest levels of research (as measured by the number of compounds in development). There is a particularly disproportionate level of research into cancers, diabetes and musculoskeletal diseases compared to their impact. Infectious diseases, which are particularly prevalent in the developing world and cause by far the highest disease burden, ranks a distant second to cancers in terms of R&D.

In 2014, a whopping forty percent of new drugs approved by the FDA targeted rare diseases for which high prices and generous profit margins are common.[96] In 2012, such specialty drugs represented a tiny one percent of prescriptions nationwide, "but accounted for twenty-five percent of the $263.3 billion spent on all prescription drugs."[97] With many of the other approvals being for me-too drugs, we arguably are not getting enough of the kinds of drug innovations we need for the myriad diseases currently afflicting patients due to the current system's skewed incentives.[98]

95. EUROPEAN PATENT OFFICE, *supra* note 93, at 77.

96. John Jenkins, *CDER Approved Many Innovative Drugs in 2014*, FDA: FDA VOICE (Jan. 14, 2015), https://blogs.fda.gov/fdavoice/index.php/2015/01/cder-approved-many-innovative-drugs-in-2014.

97. Laura Fegraus & Murray Ross, *Sovaldi, Harvoni, and Why It's Different This Time*, HEALTH AFFAIRS (Nov. 21, 2014), https://www.healthaffairs.org/action/showDoPubSecure?doi=10.1377%2Fhblog20141121.042908&format=full.

98. *See generally* GAO, *supra* note 88 (explaining the factors contributing to this dearth of drugs even while pharmaceutical R&D costs have increased).

B. PHARMACEUTICAL COMPANY INCENTIVES: EXPENSIVE "TREATMENTS" FOR THE GLOBAL NORTH

But the adverse effects of the pharmaceutical industry's skewed incentives manifest in ways beyond a lack of cures for the Global South. Throughout the world, even in high-income countries, companies are incentivized to develop compounds that turn deadly diseases into chronic conditions so that people can live longer and keep taking the drug. Pharmaceutical companies have few incentives to develop cures for diseases.[99] This is not to say that they never develop cures; sometimes they do, but mostly they develop treatments because cures are problematic for drug companies.[100] Cures generate a one-time payment, not a revenue stream.[101] If developers price cures too high, they may encounter significant resistance and censure in the marketplace. The controversial blockbuster Sovaldi® provides a timely example of this phenomenon.

Sovaldi—one of the most expensive drugs in history—sells for $1000 per pill.[102] It provides a treatment and, in up to ninety-five percent of cases, a cure, for hepatitis C (also called HCV), which is estimated to affect more than 100,000,000 people worldwide.[103] In fact, deaths from HCV outnumbered those from HIV/AIDS in the United States for the first time in 2007.[104] Gilead purchased the startup Pharmasset, in 2011 for eleven billion dollars in order to acquire sofosbuvir, the active ingredient in Sovaldi.[105] Gilead then finished the FDA approval process and launched the drug in 2013, following up with the

99. *See* Finkel, *supra* note 75 (quoting Martin Kuehne, University of Vermont chemist: "Pharmaceutical companies don't like cures. Really, they don't—that's the sad thing. They like treatment. Something for cholesterol or high blood pressure that you take for years and years, every day. That's where the profit is.").

100. *See id.*

101. *See id.*

102. *See* STAFF OF SENATE COMM. ON FIN., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM, S. REP. NO. 114-20, at 129 (2015) [hereinafter S. REP. NO. 114-20].

103. *Id.*; Jason Millman, *The New $84,000 Hepatitis C Treatment Is Losing Momentum for Now*, WASH. POST (Sept. 18, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/09/18/the-new-84000-hepatitis-c-treatment-is-losing-momentum-for-now.

104. *See* Kathleen N. Ly et al., *The Increasing Burden of Mortality from Viral Hepatitis in the United States Between 1999 and 2007*, 156 ANNALS INTERNAL MED. 271, 273 (2012).

105. *See* S. REP. NO. 114-20, *supra* note 102, at 1, 3.

same active ingredient in a different formulation in a drug called Harvoni in 2014.[106]

In its first full year on the market, Gilead made nearly thirteen billion dollars in net product sales, on the two drugs and over thirteen billion dollars on Sovaldi and Harvoni during the first nine months of 2015.[107] So the company earned twenty-six billion dollars on a product it acquired for eleven billion dollars, in less than two years.[108]

A 2015 Senate committee report details the story of how Sovaldi and Harvoni came to be priced so high, and the answer is disturbing. The report concluded that:

> Gilead asserted that its primary concern in developing and marketing Sovaldi was to treat the largest number of HCV patients possible. . . . In reality, Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more patients to be treated. . . . Significantly, when confronted with the widespread initiation of access restrictions, Gilead refused to offer substantial discounts and did not significantly modify its contracting strategy to improve patient access. . . . [F]ederal healthcare programs . . . have little to no policy levers at their disposal to significantly impact the price of a single source innovator drug.[109]

106. *See id.* at 3, 9.

107. *See id.* at 2.

108. Ly et al., *supra* note 104, at 273. Sovaldi is a treatment for a disease that primarily affects poor people, and as such, seemingly should not exist. However, there is a logical explanation for its development. There are different genotypes of the HCV virus and interestingly, they differ by geographic region. So genotypes 1, 2 and 3 are common in the United States, and genotypes 4 and 5 are common in Africa and Asia. S. REP. NO. 114-20, *supra* note 102, at 6. Not surprisingly, Pharmassett focused on developing a drug to target genotypes prevalent in the United States and Europe where they could maximize revenue. *See id.* Surprisingly, Sovaldi ended up being a broad-spectrum treatment that is effective, in combination with other drugs, against *all* HCV genotypes. *See id.* at 10. Thus, in light of the fact that Gilead has so much more than made up for its R&D costs and garnered abundant profits with more to come in the United States and other wealthy countries, what should be the global response when LMICs, like Malaysia, conclude they cannot afford the treatment price and decide to use a compulsory licensing mechanism?

109. S. REP. NO. 114-20, *supra* note 102, at 117, 120 (emphasis added). It is beyond the scope of this paper to address the situation in the United States, where access to drugs is also becoming a very serious problem for reasons including, but not limited to, patents. Having compulsory-licensing discussions in the United States adds a further complexity due to the fact that R&D decisions are based, in large part, on the U.S. market. *See* Michael Edwards, *R&D in Emerging Markets: A New Approach for a New Era*, MCKINSEY & CO. (Feb. 2010), https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/r-and-38d-in-emerging-markets-a-new-approach-for-a-new-era. Nevertheless, it is worth noting that when United

So what does this mean for compulsory licenses in developing countries? They are often both necessary and justifiable.[110] Pharmaceutical companies are not incentivized to base their research and development decisions on the possibility of generating profits in developing countries. They are basing their decisions on the needs of the United States, Europe, and other highly developed markets where the bulk of their revenue originates.[111] The following chart, showing pharma revenue by region, illustrates this point, showing almost eighty percent of global pharmaceutical market revenue coming from North America, Europe, and Japan.[112]

States Senator Bernie Sanders proposed a bill to put Sovaldi under compulsory license after the Veteran's Administration (VA) ran out of funding for HCV treatment and was unable to put any more patients on Sovaldi, Gilead reduced the VA's price to $600/pill in response. *See* Patricia Kime, *VA, DoD Spend More Than $450M on Costly Hepatitis Drug*, USA TODAY (Jan. 8, 2015), https://www.usatoday.com/story/news/politics/2015/01/08/government-hepatitis-drug-costs/21462363.

110. As a Malysian HCV report notes:

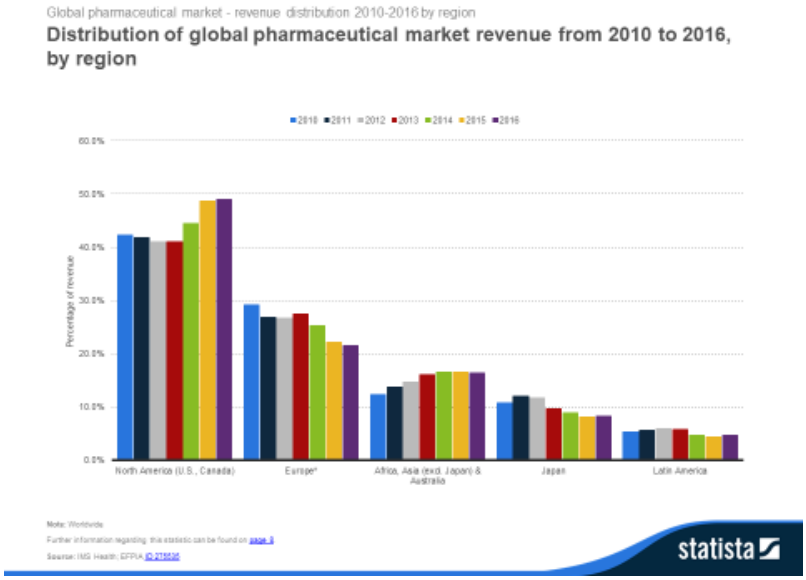
> Sofosbuvir . . . is patented in Malaysia, which means it must be sold at the originator companies' proposed Malaysian price (USD $12,000 for twelve weeks of treatment). Given that it is estimated that the drug can be produced at USD $171–360 for twelve weeks of treatment, at volume, pricing is likely to be based on maximisation of profit margins rather than any rational stratification based on country developmental levels (as claimed by pharmaceutical companies).

FIFA RAHMAN ET AL., AT THE EDGE OF A MIRACLE: THE HEPATITIS C VIRUS (HCV) EPIDEMIC IN MALAYSIA 5 (2017), https://aidsdatahub.org/sites/default/files/publication/At_the_edge_of_a_miracle_HCV_epidemic_in_Malaysia_2017.pdf.

111. According to Statista, in 2015, global pharmaceutical-market revenues were $950 billion, up from $712 billion in 2008. *Global Pharmaceutical Market Revenue from 2008 to 2015 (in Billions of U.S. Dollars)*, STATISTA, https://www.statista.com/statistics/266039/global-pharmaceutical-market-revenues (last visited June 18, 2018). Moreover, "In 2016, the United States was still the largest single pharmaceutical market, generating almost 450 billion U.S. dollars of revenue. Europe was responsible for generating around 200 billion U.S. dollars." *Global Pharmaceutical Sales from 2014 to 2016, by Region (in billion U.S. Dollars)*, STATISTA, https://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region (last visited June 18, 2018).

112. *See Distribution of Global Pharmaceutical Market Revenue from 2010 to 2016, by Region*, STATISTA, https://www.statista.com/statistics/275535/distribution-of-global-pharmaceutical-market-revenue (last visited June 18, 2018).

Figure 3: Global Pharmaceutical Market Revenue



When decisions are made about where to invest R&D dollars, they are made based on wealthy markets. Whatever drug companies earn in poor countries is largely gravy. Bayer CEO Marijn Dekkers confirmed this, after calling the Nexavar® compulsory license "essentially . . . theft," when he explained: "Is this going to have a big effect on our business model? . . . No, because we did not develop this product for the Indian market, let's be honest. We developed this product for Western patients who can afford this product, quite honestly."[113]

This is not to suggest that the relatively small percentage of revenue is not a meaningful sum which companies would not wish to lose. Such concerns are arguably why companies that voluntarily participate in access vehicles like the Medicines Patent Pool (MPP), as Gilead did with certain HCV patents, often exclude middle-income countries from the advantageous

113. Gokhale, *supra* note 40; *see also* Love, *supra* note 11, at 4 ("The Bayer CEO's reaction to the Indian compulsory license describes the current reality for the majority of the world's population. Many companies find it acceptable to price products out of reach for the majority of persons living in developing countries.").

pricing deal.[114] However, this potential loss of revenue does not justify pressuring countries to forego compulsory licensing using theft rhetoric. In both the Thai and Indian compulsory license examples, the drugs were going to poor people who would not be able to buy them at the price the originator pharmaceutical company was charging.[115] These were not lost sales; these sales never would have been made by the patent owner.

Moreover, in situations where the compulsory license is for public noncommercial use, such as the licenses granted in Thailand and Malaysia, the generic drugs would only be supplied to patients in the public health system; rich Thai and Malay citizens would continue to buy the expensive branded drugs sold by the patent owner.[116] This is important because LMICs tend to have high income inequality, a factor that pharmaceutical firms count on in pricing their drugs.[117] As Flynn et al. explain in an example involving South Africa, where the richest ten percent of the population earn fifty-eight percent of the income:

> The [pharmaceutical company] maximizes its sales in South Africa by selling at the price that only the top 10% can afford. At this price, the firm makes $814.6 million in total revenue. If the firm lowers its price to be able to make sales to 20% of the affected individuals (at $396 per patient), then it will sell twice as many medicines at a price less than half of the profit-maximizing price, earning substantially less ($435.6 million). As the monopolist continues to cut prices and raise production, revenues fall further at almost every level of output and corresponding price. In other words, the firm will maximize its profits by setting a price unaffordable for at least 90% of people in need.[118]

114. *See* MEDICINES PATENT POOL, https://medicinespatentpool.org (last visited June 18, 2018) (describing the mission and vison, model, partners and strategy of MPP); *see also* Catherine Saez, *Malaysia Grants Compulsory Licence For Generic Sofosbuvir Despite Gilead Licence*, INTELLECTUAL PROP. WATCH (Sept. 15, 2017), https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence (noting that threat of a compulsory license by Malaysia led to the middle-income country being offered MPP pricing by Gilead for Sofosbuvir).

115. *See supra* notes 34–40 and accompanying text.

116. *See* HO, *supra* note 7, at 168. The impact of such licenses can be profound. The public noncommercial use-license issued in Malaysia in 2003 for HIV/AIDs drugs resulted in an 81% reduction in the average cost of treatment per month-per patient (from $315 to $58) and an increase in government treatment capacity from 1500 to 4000 patients. *See* FIFA RAHMAN, *supra* note 110, at 30.

117. *See* CHRISTOPHER HOY ET AL., MIDDLE-INCOME TRANSITIONS AND INEQUALITY: IS THERE A LINK? 13 (2016), https://www.odi.org/sites/odi.org.uk/files/resource-documents/10383.pdf.

118. Flynn et al., *supra* note 10, at 189 (emphasis added).

Because wealthy patients in LMICs can still be expected to purchase the originator pharmaceutical company's products, compulsory licenses are not likely to meaningfully affect even that further twenty to twenty-five percent of revenue in LMICs. This also shows that there is little incentive for pharmaceutical companies to lower their prices in LMICs despite the vast numbers of people in need of access to their medicines.

This precise scenario resulted in the catastrophic loss of life on the African continent due to the pricing of HIV/AIDS drugs out of the reach of millions of poor people in the late 1990s and early 2000s. As vividly described in the movie *Fire in the Blood*, the entire continent of Africa accounted for only one percent of originator pharma HIV/AIDS drug sales.[119] As noted by James Love in the movie, the entire continent was "a rounding error," yet the companies took a hard line, keeping their prices at $10,000 to $15,000 per patient-per year in Africa, just as in the United States, and fought against the introduction of generic drugs while millions of lives were lost.[120]

C. THE MORAL "RIGHTNESS" OF COMPULSORY LICENSING

Thus it is worth asking: if the incentive to develop new drugs is not meaningfully[121] affected by developing country markets, should a country allow such a drug patent (one most likely obtained by a foreign entity) to result in lost or impaired lives? Should we watch people die when it costs nothing, or very little, to let them live?[122] Or, to put it in the context of *pe'ah*, shouldn't

119. *See* FIRE IN THE BLOOD (Sparkwater India 2013); *see also* FIRE IN THE BLOOD, http://www.fireintheblood.com (last visited June 18, 2018) [hereinafter FIRE IN THE BLOOD, http://www.fireintheblood.com].

120. *See* FIRE IN THE BLOOD, http://www.fireintheblood.com, *supra* note 119.

121. This is not to say that there is no possible effect on innovation. Compulsory licensing makes it even less likely that companies will develop drugs to treat conditions prevalent in such countries. Nevertheless, as Flynn et al. note:

> [F]or markets in which firms can expect demand to be highly convex—which is likely to be true in markets for medicines in most developing countries—the patent system will be ineffectual in delivering much innovation. . . . Ultimately, the problem of finding an adequate and equitable mechanism to fund research and development for medicines in developing countries must be found elsewhere.

Flynn et al., *supra* note 10, at 192 (2009).

122. There is also a self-interest argument for compulsory licenses in the infectious-disease context. We are living in a world where we are increasingly seeing global pandemics. *See* Meera Senthilingam, *Seven Reasons We're at More Risk than Ever of a Global Pandemic*, CNN (Apr. 10, 2017), https://www.cnn.com/2017/04/03/health/pandemic-risk-virus-bacteria/index.html. SARS, H1N1,

the poor have a right to needed drugs when such use of the patented invention will not harm the patent holder?

Moreover, is it possible that a government has a duty to allow a third party to provide a drug, via compulsory license or some other mechanism, to its citizens in a way that will not harm the patent owner? Certainly. When we consider the broader meaning of theft illuminated by the biblical concept of *pe'ah*, we should be more willing to conclude that a LMIC issuing a compulsory license is not engaging in theft and its action should not be characterized as such. We also should be able to recognize that the poor do have a right to free or low-cost life-saving drugs, where providing such drugs does not unduly harm the drug developer.

Issuing a compulsory license in accordance with TRIPS is not a morally culpable action, and is far removed from theft. It is not even defined as stealing under international law and involves compensation to the patent owner. Yet it is too often characterized as theft in a way that appears to give pharmaceutical companies the moral high ground and allows them to play the victim in terms of public relations and inciting governmental action against offending countries. In fact, it may be more appropriate to turn the tables and label, from a moral perspective, the pharmaceutical companies trying to keep needed drugs from the poor as thieves.

The patent system was never designed to be a guarantee of maximum profits, rather it is supposed to have a positive impact on society. As described by the U.S. Supreme Court:

> The possession and assertion of patent rights are "issues of great moment to the public." A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the "Progress of Science and useful Arts." At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market.[123]

If, to some extent, our notions of the moral wrongness of stealing derive from the Ten Commandments, we should not look at those commandments in isolation, but should consider also

MERS, bird flu, swine flu, Ebola, Zika, the list keeps growing. These diseases cross borders and oceans. As such, the health of the developing world affects us all. To the extent more people in the developing world are immune compromised or lack treatment, there may be a greater spread of such diseases, or the development of mutations that may affect the ability of HICs to fight these pandemics when they reach their shores.

123. Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 815–16 (1945).

the contextual limitations on that concept. As Professor Gnuse explains:

> Though the gleaning laws are not extensive, they provide us with significant insight into the command against theft. What the modern mind might call theft was not so defined in the Old Testament. . . . Human need had a right of access to the basic essentials of life. . . . For the poor to take food from another person's land was not theft, but it was wrong for the more affluent person to withhold it.[124]

Using the label of theft to describe a particular set of actions and simultaneously playing the innovation card effectively erects a barrier that may limit a government's ability to appropriately utilize compulsory licensing to meet pressing societal needs. So the hard questions regarding who really is stealing from whom do not get asked. This theft framing has no correlation to the most productive innovation, nor to providing optimal innovation; rather, it is employed to produce optimal profit.[125] In view of the access-to-medicines crisis occurring in countries across the globe, it is critically important for us to tear down that barrier.

CONCLUSION

The misapplication of a Biblical precept in the context of access-to-medicines tools like compulsory licenses in the Global South is profoundly disturbing, especially in light of the deafening silence that prevails with respect to the use of compulsory licenses in the Global North. When we consider the biblical analogy of *pe'ah*, it allows us to begin to reframe the discussion and ask who is stealing from whom. Are our policies out of balance such that the poor are being robbed of what they are due? These are not easy issues to address, and there are no risk-free solutions, no clear way to know exactly how to optimize access and innovation at the same time. But we may be better able to get to win-win outcomes if we open our eyes to other ways of viewing competing interests, and allow our legal discussions to be enlightened by analogies from important traditions that have in the past informed our constructions of right and wrong, and of morality itself.

The value of human life is what makes the production of essential medicines important and worthy of powerful incentives

124. ROBERT GNUSE, YOU SHALL NOT STEAL: COMMUNITY AND PROPERTY IN THE BIBLICAL TRADITION 29 (1985).

125. Ramsi Woodcock, *Property, Efficiency, the Commons, and Theft*, *in* RESEARCH HANDBOOK ON POLITICAL ECONOMY AND LAW 531, 561 (Ugo Mattei & John D. Haskell eds., 2015).

because they may improve the duration and quality of human life. But without proper controls, patents and other incentives may produce harms, which is why the patent system has always included various limits and safety valves on the scope of the patent grant. If we consider a just law to be one that improves the lives of human beings, then drug compulsory licenses issued in accordance with international law are not only legal, but they are also moral, and just. Governments have a moral obligation to provide access to life-saving treatments for their citizens and the use of incomplete and dangerous theft rhetoric to stigmatize and denigrate such efforts undermines that duty in profoundly important ways.

Both patent law and the biblical Commandment against stealing exist within larger systems of rights and obligations. Recognizing this allows us to put together, as Christ did, the two phrasings: thou shalt not steal and thou shalt love thy neighbor as thyself. Blending these two phrasings of the commandment together allows us to view theft in relation to pharmaceutical patents in its proper light. We can seek and develop appropriate exceptions to patent rights that do not eviscerate protection, but provide the balance society needs to enhance access to essential medicines.