PATENT RESPONSIBILITY

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The protection of strong rights under patent law is intended to incentivize investment in innovation. Beyond this protection, should patent law also impose responsibilities upon patent holders? The COVID-19 pandemic has revealed that the power patent law confers upon technology companies far exceeds any responsibilities these companies have assumed. This asymmetry of rights and responsibilities has undermined collaborative efforts to develop testing methods, medicines, and vaccines to contain the virus.

This article presents the first comprehensive theoretical study of patent holders' responsibilities. Examining COVID-19-related innovations, it shows how the prevailing rights-focused patent law fails to reflect the social nature of invention. The article argues for reform of patent law so that it not only protects patent holders' exclusive rights but also enforces their responsibilities. Based on ethics and political theory, it proposes that patent holders be required to reciprocate public contributions, fulfill innovators' role responsibility, and confront injustices created by patent protection. To enforce these three responsibilities, the article suggests ways in which limitations on patent rights such as the disclosure requirement, experimental use defense, and compulsory licensing scheme should be reshaped, and recommends the creation of a scheme entitled the Patent Philanthropy Initiative.

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INTRODUCTION

In June 2020, Gilead Sciences shocked the international community by pricing its patented medicine remdesivir at $3,120 per course of treatment for COVID-19 patients with private insurance in the United States (U.S.).[1] Thereafter, public interest groups and activists accused Gilead Haochen: followed this

1. *See Gilead's Remdesivir Will Cost $3,120 for Patients with Private Insurance*, CBS

suggestion with a minor change] of overcharging in "an offensive display of hubris and disregard for the public,"[2] and raised serious concerns that global efforts to contain the pandemic were effectively at the mercy of medical patent owners.[3] Even after the World Health Organization (WHO) declared COVID-19 a pandemic in March 2020, Labrador Diagnostics attempted to block any testing that used its patents through "the most tone-deaf IP suit in history."[4] In the face of a deadly pandemic, Gilead, Labrador, and other pharmaceutical companies have sought to capitalize on their patents and maximize private commercial interests at the expense of the interests of the public.[5]

The U.S. government turned a deaf ear to increased public demand for the responsible exercise of patent rights. In March 2021, the United States joined a group of developed countries to block a patent waiver request submitted to the World Trade Organization by India and South Africa, which would have expedited manufacture of vaccines in developing countries so as to alleviate the worsening COVID-19 pandemic.[6] It was only after global pressure intensified that the Biden administration gave its support to the waiver.[7] Amid the race to patent

NEWS (Jun. 29, 2020), https://perma.cc/GF28-QCMM.

2. *See e.g.*, Peter Maybarduk, *Gilead's Remdesivir Price Is Offensive*, PUB. CITIZEN https://perma.cc/FGE9-DCEV ("In an offensive display of hubris and disregard for the public, Gilead has priced at several thousand dollars a drug that should be in the public domain."); David Lazarus, *Is Gilead Ripping Us Off with a COVID-19 Treatment Topping $3,000?*, L.A. TIMES (June 29, 2020), https://perma.cc/5NF6-JEQH("In absolute terms, the price for remdesivir seems pretty expensive. . . . They seem to be pricing it as aggressively as they can.") (quoting Victoria Perez).

3. For example, the Institute for Clinical and Economic Review warned that "Gilead has the power to price remdesivir at will in the U.S., and no governmental or private insurer could even entertain the idea of walking away from the negotiating table." *See* Gina Kolata, *Remdesivir, the First Coronavirus Drug, Gets a Price Tag*, N.Y. TIMES (June 29, 2020), https://perma.cc/KBA7-K4ZJ.

4. Timothy B. Lee, *Firm Wielding Theranos Patents Asks Judge to Block Coronavirus Test*, ARS TECHNICA (Mar. 17, 2020), https://perma.cc/QDJ5-GLSX ("As Stanford patent scholar Mark Lemley puts it, 'this could be the most tone-deaf IP suit in history.'"). Labrador announced soon thereafter that it would grant royalty-free licenses to companies developing COVID-19 tests. *See* Gordon E. Runté, *Labrador Diagnostics Will Grant Royalty-free Licenses for COVID-19 Testing*, BUSINESS WIRE (Mar. 17, 2020), https://www.businesswire.com/news/home/20200316005955/en/Labrador-Diagnostics-Will-Grant-Royalty-free-Licenses-for-COVID-19-Testing.

5. *See* Brook Baker, *Drug Companies are Running Scared – Let's Make Them Run Faster*, HEALTH GAP (Mar. 30, 2020), https://perma.cc/R3JK-FTCK ("Government-granted monopolies to biopharmaceutical and medical devices companies are the most irresponsible barriers to erect in the middle of a global pandemic threatening millions of lives.").

6. *See* Matthew Kavanagh and Madhavi Sunder, *Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That.*, WASH. POST (Mar. 11, 2021), https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/.

7. *See* Andrea Shalal et al., *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, REUTERS (May 7, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/.

coronavirus-related medicines, vaccines, and testing methods,[8] and without any examination of the potential negative effects of doing so, the U.S. Patent and Trademark Office (USPTO) adopted the COVID-19 Prioritized Examination Pilot Program in May 2020.[9] The program's aim was to accelerate the timeline for granting coronavirus-related patents to as little as six months.[10] Meanwhile, despite the fact that Gilead received $70 million in public funds to develop remdesivir, the Department of Health and Human Services purchased close to Gilead's entire supply of the drug at a non-negotiable price and with no concern for any social responsibility that Gilead should assume.[11]

What drives pharmaceutical companies to exploit patent protection amid a global health emergency? And why does the U.S. government support their efforts to do so? In this article, I argue that U.S. patent law encourages the irresponsible exercise of patent rights through its asymmetric allocation of rights and responsibilities. Patent law protects a bundle of strong exclusive rights that entitle patent holders to set product prices as high as they choose.[12] Yet it imposes very weak responsibilities upon patent holders in return, setting a low patent information threshold and enfeebling the experimental use exception and compulsory licensing as limitations on patent rights.[13] The asymmetry in patent law has emboldened patent holders to abuse their rights and legitimized governmental condoning of such exploitation.[14]

As conventional wisdom has long taught us, great power comes with great responsibility.[15] Technology companies own countless patents and are among

8. *See, e.g.*, Press Release, Aquavit Pharmaceuticals, Inc., *Aquavit Files For New COVID-19 Self-Administrable Vaccine Delivery Method and Technology Patent Through Fast-track Prioritized Examination*, BIOSPACE (Aug. 18, 2020), https://perma.cc/3HWF-9PBR; Cynthia Koons, *The Vaccine Scramble Is Also a Scramble for Patents*, Bloomberg (12 August 2020 https://www.bloomberg.com/features/2020-covid-vaccine-patent-price/ ("Inside the race to develop a vaccine for the coronavirus is another contest worth keeping a close eye on: the rush to patent any discoveries.").

9. *COVID-19 Prioritized Examination Pilot Program*, U.S. PAT. & TRADEMARK OFF. (2020), https://perma.cc/YKW3-K6LN.

10. *Id.* (stating that "the USPTO believes it can achieve final disposition in six months if applicants provide more timely responses to notices and actions from the USPTO").

11. *See* Gina Kolata, *Remdesivir, the First Coronavirus Drug, Gets a Price Tag*, N.Y. TIMES (June 29, 2020), https://perma.cc/H25R-HA3A ("Remdesivir . . . will be distributed under an unusual agreement with the federal government that establishes *nonnegotiable* prices and prioritizes American patients. . ..."); Judy Stone, *US Buys World Supply of Remdesivir for Coronavirus—What Does That Mean for Public Health and Our Future?*, FORBES (July 2, 2020), https://perma.cc/8H6V-SLMP.

12. *See infra* Part I.B.1; *see also*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003) ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.").

13. *See infra* Part I.B.2.

14. *See infra* Part I.B.2.

15. *See, e.g.*, Kimble v. Marvel Entm't, LLC, 576 U.S. 446, 478 (2015) (citing Stan Lee & Steve Ditko, *Spider–Man!*, AMAZING FANTASY , Aug. 1962, at 13 ("[I]n this world, with

the world's richest and most politically powerful corporate institutions.[16] The COVID-19 pandemic has revealed that the responsibilities patent law imposes upon these companies are far from proportionate to the power that these companies are granted through patent law. Through the lens of the COVID-19 pandemic, this article reveals two serious social problems associated with such an asymmetrical arrangement of rights and responsibilities.

First, prioritizing the protection of patent rights is hostile to global efforts to combat the COVID-19 pandemic. The Open COVID Pledge and COVID-19 Technology Access Pool represent attempts to require patent holders to responsibly share their patented technologies in the public interest.[17] At the same time, widespread public involvement in the creation of COVID-19-related medicines, vaccines, testing, and contact-tracing technologies exposes the truth that patent holders do not always make the sole contribution to the development of their inventions[18] and demonstrates that public contributions should be reciprocated.

Second, by downplaying patent holders' responsibilities, contemporary patent law has failed to recognize innovation as a social process. In the context of COVID-19-related innovation, this article considers how patented inventions emerge through a process of sequential and combinatorial evolution, drawing upon existing knowledge and technologies.[19] The article further considers how social innovation has gained currency through various forms of private-public collaborative efforts to fight COVID-19, calling for the fair distribution of technological benefits in the public interest. [20]

Drawing on ethical and political theories of responsibility, I propose that patent law should be reformed to usher in three new responsibilities. First, patent holders should be required to reciprocate public contributions to the creation of their patents by faithfully disclosing sufficient patent information and taking proactive measures to benefit the users of patents developed through public funding.[21] Second, patent holders should be encouraged to take their innovator role seriously, accommodating invocation by the public of the experimental use limitation.[22] Third, patent holders should be made to confront the social injustices caused by patent protection. For example, they could address unaffordability of patented medicines by participating in the proposed Patent Philanthropy Initiative, and by cooperating with governments to implement compulsory licensing

great power there must also come—great responsibility.")).

16. *See* Stephen Johnston, *Largest Companies 2008 vs. 2018, a Lot Has Changed*, MILFORD (Jan. 31, 2018), https://perma.cc/BT3V-6KQT ("Technology companies not only dominate our daily lives (how many times have you checked your iPhone today?) but also the ranking of world's biggest companies.").

17. *See infra* Part II.A.

18. *See infra* Part II.B.

19. *See infra* Part III

20. *See infra* Part III.A.

21. *See infra* Part IV.A.

22. *See infra* Part IV.B.

orders.[23]

Presenting the first comprehensive theoretical study of patent holders' responsibilities, this article makes three original contributions to the literature on patent law and the public interest.[24] First, it explores patent law's new function in promoting responsible-use patents. Conventional wisdom treats the protection of exclusive rights as the major function of patent law.[25] Therefore, U.S. patent law has been structured as a legal system that grants a bundle of strong exclusive rights. By examining the problems with this conventional mode of patent protection, the article argues that the recognition and enforcement of patent holders' responsibilities should be deemed another major function of patent law. Drawing on both theory and practical examples from research tackling COVID-19, the article further considers the nature and scope of the responsibilities that patent holders should assume.

Second, the article offers a new perspective on the social nature of innovation and patents. Leading patent scholars have rejected the notions of individualistic innovation and sole creation, suggesting instead that inventions usually emerge in a social setting involving the contributions of others.[26] However, these scholars have largely applied the idea of the social nature of invention to justify patent right protection and consider how adjustments to such protection should be made. For instance, Professor Mark Lemley argues that the social nature of invention leads to patenting races, and therefore that strong patent rights should be granted to promote such races to create new solutions to technical problems.[27] This article take a different theoretical path by applying the social nature of inventions to justify the imposition of responsibilities upon patent holders. It first provides a more robust examination of the social nature of inventions through the lens of sequential, combinatorial, and social forms of innovation. The article

23. *See infra* Part IV.C.

24. Professor Srividhya Ragavan's article has briefly explored patent holders' obligations on the basis of the law of contracts. *See* Srividhya Ragavan, *Correlative Obligation in Patent Law: The Role of Public Good in Defining the Limits of Patent Excusivity*, 6 NYU J. INTELL. PROP. & ENT. L. 47, 83-89 (2016). *See also*, Jeremy De Beer, *The Rights and Responsibilities of Biotech Patent Owners*, 40 U.B.C. L. REV. 343, 363 (2007) ("Responsibilities are simply an inherent aspect of rights, including IP rights such as patents.").

25. *See* Peter Lee, *Toward a Distributive Agenda for U.S. Patent Law*, 55 HOUS. L. REV. 321, 323 (2017) ("As commonly understood, the U.S. patent system is a utilitarian regime that utilizes *exclusive rights* and market incentives to promote the generation of new technologies.") (emphasis added).

26. *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 711 (2011) ("Invention appears in significant part to be a social, not an individual, phenomenon."); Laura Pedraza-Fariña, *Patent Law and the Sociology of Innovation*, 2013 WIS. L. REV. 813, 838-39 (concluding that discovery is "inherently relational, emerging from a complex, interactive back-and-forth among researchers, often in different communities of practice or social worlds").

27. *See* Lemley, *supra* note 26, at 712 ("Patent rights encourage patent races. . . . This new 'patent racing' theory turns the traditional incentive story on its head, ironically granting strong exclusive rights in order to promote competition, not monopoly.").

then considers why three major responsibilities should be imposed upon patent holders in order to reshape patents in a manner conducive to the development of these forms of innovation.

Third, drawing upon patent holders' responsibilities, the article presents a new avenue for promoting social justice through patent law. Scholars, policy-makers, and judges have explored the ways in which strong patent protection results in social injustice.[28] The impact of high patented drug prices on public health is but one example.[29] This article shows that the imposition and enforcement of certain responsibilities on patent holders could effectively alleviate social injustices caused by patent protection. For example, a responsibility to promote universal and affordable access to patented medicines would reinforce patent holders' cooperation with the government in implementing compulsory licensing orders amid public health crises.

The remainder of the article proceeds as follows. Examining the negative effects of Gilead's high-priced patented medicine, Part I reveals that U.S. patent law strongly protects a bundle of patent rights, yet imposes very weak associated responsibilities. Through the lens of patent pledges and public contributions devoted to creating and sharing innovations, Part II suggests that the COVID-19 pandemic has exposed problems with the law's downplaying of patent holder responsibilities. Drawing upon further examples of the creation of COVID-19-related innovations, Part III considers how rights-centered patent law has failed to reflect the social nature of inventions. Part IV seeks to tackle the asymmetry between patent rights and responsibilities. By applying ethical and political theories, it proposes three responsibilities that future patent law reforms should impose upon patent owners.

28. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66, 92 (2012) (stating the exclusivity of patent rights "can impede the flow of information . . . rais[e] the price of using the patented ideas once created, [and] require[] potential users to conduct costly and time-consuming searches of existing patents and pending patent applications. . . . "); Haochen Sun, *Can Louis Vuitton Dance with Hiphone? Rethinking the Idea of Social Justice in Intellectual Property Law*, 15 U. PA. J.L. & SOC. CHANGE 389, 391 (2012) ("IP law itself, however, has progressed without due attention to its effects on social justice, where reducing inequality is seen as essential for humanity and civilization."); Joseph E. Stiglitz, *How Intellectual Property Reinforces Inequality*, N.Y. TIMES (July 14, 2013), https://perma.cc/9LV6-KLAB (arguing that "intellectual property regimes that create monopoly rents that impede access to health both create inequality and hamper growth more generally"); Colleen Chien, *The Inequalities of Innovation*, 4-5 Santa Clara Univ. Legal Studies Research Paper No. 2018-03 (2018), https://perma.cc/KZG5-6GYD (arguing that patent protection "can both intensify as well as alleviate the inequalities of innovation").

29. *See generally*, William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 646 (2006); ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 1-25 (2017).

I. STRONG PATENT RIGHTS BUT WEAK RESPONSIBILITIES

A. Patents, Pharmaceutical Companies, and COVID-19

Remdesivir, a broad-spectrum anti-viral medication researched as a potential treatment first for hepatitis C and then for Ebola, has also been found effective in treating COVID-19.[30] Following its patent filing in 2014, remdesivir developer Gilead Sciences decided to pursue broad protection to preclude competitors from producing and selling the medicine.[31] In June 2020, Gilead announced its decision to price remdesivir at $520 or $390 per vial and $3,120 or $2,340 per treatment course for U.S. patients with private insurance and government-sponsored insurance, respectively.[32] The company argued that such prices were below the drug's value and necessary to help maintain future innovation capacity.[33] Later that month, the U.S. government bought more than 500,000 treatment courses at a reported price of around $3,200 each.[34]

Gilead's pricing decisions have drawn fierce criticism for a number of reasons. First, medical experts have pointed out that is inexpensive to produce remdesivir. One study estimated that it could be produced for only a few dollars per treatment course, and an approved manufacturer in India announced that it would price its generic equivalent at just $71 per vial.[35] Although private companies by nature seek to maximize revenue, in the circumstances of a pandemic, it is difficult to frame Gilead's conduct as anything other than exploitation, as governments and hospitals have been left with no option but to accept its terms.[36]

Second, the U.S. government contributed at least $70.5 million of public funding to remdesivir's development.[37] Even though they are effectively stakeholders in remdesivir, U.S. citizens receive no financial benefit from their stake

30. Gilead, *Development of Remdesivir*, https://perma.cc/A7DX-T5QY (archived Apr. 20, 2021).

31. Anders Heebøll-Nielsen & Michael Bech Sommer, *What Patent Protection Does Gilead's COVID-19 Treatment Remdesivir Have?*, LEXOLOGY (Apr. 30, 2020), https://perma.cc/P5VD-U9PU ("By filing three PCT applications, Gilead obviously had a clear strategy to obtain broad protection, and their strategy can be inferred from the patent registers.").

32. *An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences*, GILEAD SCI. (June 29, 2020) [hereinafter *An Open Letter*], https://perma.cc/E6A3-VZP9.

33. *Id.* ("We also balanced that with our longer-term responsibilities: to continue with our ongoing work on remdesivir, to maintain our long-term research in antivirals and to invest in scientific innovation that might help generations to come.").

34. Barbara Mintzes & Ellen 't Hoen, *The US Has Bought Most of the World's Remdesivir. Here's What It Means for the Rest of Us*, THE CONVERSATION (July 3, 2020), https://perma.cc/UE5A-9LRQ.

35. Vidya Krishnan, *How Secret Deals Could Keep a COVID-19 Drug Out of Reach for Millions*, L.A. TIMES (July 1, 2020), https://perma.cc/VFR3-UV2P.

36. Rohan Chalasani, *The US Is Paying Way Too Much for Remdesivir*, WIRED (July 17, 2020), https://perma.cc/Q9BK-LM6T.

37. *The Real Story of Remdesivir*, PUBLIC CITIZEN (May 7, 2020),

and must pay whatever Gilead charges.[38]

Third, Gilead timed its price announcement in June 2020 so as to maximize profits. Research into the effects of remdesivir on COVID-19 was still ongoing, leading to media speculation that Gilead was hoping to maximize profits before any data challenging the drug's efficacy could be published.[39] Moreover, with countries around the world concurrently working on a vaccine, Gilead potentially had only a limited period in which to generate profits from remdesivir.[40]

Last but not least, the special licensing agreements that Gilead has entered into with a number of developing countries may jeopardize attempts to combat COVID-19 elsewhere. Critics have noted that such agreements prevent generic drugs from being distributed in dozens of countries, making low-cost alternatives unavailable to nearly half the world's population.[41] The countries excluded by the agreements include some of the hardest hit, including the U.S., Brazil, Britain, and Peru, leading many to argue that Gilead is intending to exploit the pandemic by charging the most desperate countries higher prices for access to the brand-name version of the drug.[42]

Although Gilead's aggressive patent strategies have caused public outcry, other pharmaceutical companies have followed in its footsteps. In May 2020, NellOne Therapeutics announced that it had filed a provisional patent application for use of the NELL1 signaling protein for the treatment of tissue damage and inflammation caused by COVID-19.[43] In the same month, Annovis Bio filed a patent application in the U.S. for a method of inhibiting, preventing, or treating COVID-19 neurological injuries.[44] In June 2020, the Salzman Group filed a provisional patent application for the preventative and therapeutic use of a particular compound in relation to COVID-19-caused pneumonia and acute lung injury.[45] The pharmaceutical companies Sunshine Biopharma,[46] Radient Technologies,[47]

https://perma.cc/H6HR-XFCR.

38. *See* Lazarus, *supra* note **Error! Bookmark not defined.** (pointing out that the U.S. government "allow[s] drug companies to charge as much as they please").

39. Lazarus, *supra* note **Error! Bookmark not defined.**.

40. *Id*.

41. Krishnan, *supra* note 35.

42. *Id*.

43. Press Release, NellOne Therapeutics Inc., *NellOne Therapeutics Files COVID-19 Treatment Patent*, PR NEWSWIRES (May 18, 2020), https://perma.cc/H48L-NJKJ.

44. Press Release, *Annovis Bio Files Patent Application for Method of Inhibiting, Preventing, or Treating Neurological Injuries Due to Viral and Other Infections Including COVID-19*, ANNOVIS (May 27, 2020), https://perma.cc/E8H8-JDJR.

45. Press Release, *Kalytera Announces Filing of Provisional Patent Protecting Use of R-107 for Treatment of Coronavirus and COVID-19 Associated Pneumonia*, KALYTERA June 2, 2020), https://perma.cc/6URU-ZWV8.

46. Press Release, *Sunshine Biopharma Files a Patent Application for a New Coronavirus COVID-19 Treatment*, SUNSHINE BIOPHARMA INC. (June 1, 2020), https://perma.cc/WYG5-Y2HV.

47. Press Release, *Radient Technologies Inc. Announces Collaboration on the Develop-*

BriaCell Therapeutics,[48] Bioneer Corporation,[49] and Dimerix[50] have all filed patent applications for medicines that can treat or alleviate COVID-19 symptoms.

Pharmaceutical companies have also filed for patent protection for other COVID-19-related innovations, ranging from vaccines, personal protection equipment, testing methods, and portable ventilators to pandemic management platforms. In addition, they have launched or threatened to launch patent litigation associated with COVID-19. For instance, Labrador initiated a lawsuit in the U.S. in March 2020 in an attempt to block COVID-19 testing that uses its patents.[51] In the same month, volunteers in Italy producing 3D-printed valves for use in life-saving ventilators were threatened by the valve patent owner with legal action for manufacturing the valves without permission.[52]

B. The Asymmetry between Strong Patent Rights and Weak Responsibilities

When announcing remdesivir prices, Gilead's CEO emphasized no fewer than six times his company's responsibility to combat the pandemic.[53] However, as revealed above, Gilead has in reality attempted to maximize the economic value of patent rights while minimizing its corresponding responsibilities. One consequence is that health advocacy groups and the medical humanitarian organization Doctors Without Borders have urged the Indian government to rescind its remdesivir patents.[54]

In this section, I argue that by creating asymmetry between rights and responsibilities, patent law has facilitated irresponsible acts by technology companies like Gilead. While the law protects strong patent rights, it imposes very weak responsibilities upon patent holders and lacks effective legal mechanisms to enforce them.

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ment of AntiViral Products and Files Patent Application Covering Cannabinoid Based Compositions for the Mitigation and Protection from Viruses, RADIENT (May 19, 2020), https://perma.cc/3P8B-K7EE.

48. Press Release, BriaCell Therapeutics Corp, *BriaCell Files Patent Application for Novel Immune Therapies for Multiple Disease Indications*, GLOBENEWSWIRE NEWS ROOM (May 20, 2020), https://perma.cc/8U4M-EQS6.

49. Si-gyun Kim & Minu Kim, *Bioneer Files for Patent Application of Candidate COVID-19 Therapeutics*, PULSE (May 26, 2020), https://pulse-news.co.kr/view.php?year=2020&no=538207

50. *Global REMAP-CAP Platform Trial Protocol to Include DMX-200 in COVID-19 Patients*, DIMERIX (June 4, 2020), https://perma.cc/23NT-YWPY.

51. *See* Lee, *supra* note 4.

52. Chloe Kent, *Covid-19: start-up that saved lives with 3D-printed valve may face legal action*, MED. DEVICE NETWORK (Mar. 18, 2020), https://perma.cc/VR9H-EANC.

53. *See An Open Letter, supra* note 32 ("In making our decision on how to price remdesivir, we considered the full scope of our responsibilities.").

54. Zeba Siddiqui, *Health Groups Ask India to Rescind Gilead's Patents for COVID-19 Drug Remdesivir*, REUTERS (May 14, 2020), https://perma.cc/8XCA-PTV2.

1. Strong Patent Rights

Patent law grants the right to make, use, sell, offer for sale, or import a patented invention for the term of the patent.[55] These rights are protected as a bundle of strong exclusive rights according to the scope of patent claims. Patents, as characterized by Justice Joseph Story in 1824, are private property rights entitling patentees to "absolute enjoyment and possession."[56] The Supreme Court supports this characterization.[57] Patent rights safeguard the value of patents[58] and penalize free-riders who make unauthorized use of them.[59] The scope of patent rights is generally broader than that of the rights protected by other intellectual property laws.[60] Through the doctrine of equivalents, patent law prohibits the production and sale of non-exact copies that are functionally equivalent to the invention concerned.[61] Judge Learned Hand championed the cause of this doctrine as being "to temper unsparing logic and prevent an infringer from stealing the benefit of the invention."[62]

This structure of strong patent rights is predominantly justified by utilitarian theory.[63] Given the nonrivalrous and nonexclusive nature of intellectual property as a public good,[64] absent any way of extracting value from the supply of a public

55. 35 U.S.C. § 154 (a)(1).

56. *Ex parte* Wood, 22 U.S. 603, 608 (1824) (stating that patent law "intended to give [a patentee] the absolute enjoyment and possession").

57. *See* United States v. Am. Bell Tel. Co., 167 U.S. 224, 243 (1897) (ruling that "a patent was issued to the telephone company . . . [and] was the property of the telephone company"). In *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, the Supreme Court ruled that a patent should be deemed "a public franchise" granted by the USPTO. But it also stated that this opinion did not contradict established case law that regards patents as private properties. See 138 S. Ct. 1365, 1375 (2018).

58. *Wood*, 22 U.S. at 608 (ruling that "[t]he inventor has . . . a property in his inventions; a property which is often of very great value. . .").

59. *See* Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (asserting that "let the [patent] damages be estimated as high, as they can be, consistently with the rule of law on this subject, if the plaintiff's patent has been violated; that wrong-doers may not reap the fruits of the labor and genius of other men.").

60. *See* Colleen Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1851 (2016) ("Patent law provides protection that is in many ways stronger and broader than trade secrecy or copyright: it can be enforced against independent inventors and non-exact copies.").

61. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 38 (1997) (ruling that the doctrine centers on the question about "substantially the same function in substantially the same way to obtain the same result") (quoting Machine Co. v. Murphy, 97 U.S. 120, 125 (1877)).

62. Royal Typewriter Co. v. Remington Rand, Inc., 168 F.2d 691, 692 (2d. Cir. 1948).

63. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1597 (2003) ("To a greater extent than any other area of intellectual property, courts and commentators widely agree that the basic purpose of patent law is utilitarian: We grant patents in order to encourage invention.").

64. *See* WILLIAM W. FISHER III, PROMISES TO KEEP: TECHNOLOGY, LAW, AND THE FUTURE OF ENTERTAINMENT 199 (2004); JAMES BOYLE, THE PUBLIC DOMAIN: ENCLOSING THE COMMONS OF THE MIND 3 (2008).

good or preventing free riding, market players have little incentive to produce that public good—a situation that, over time, results in undersupply, harming innovation and industrial progress.[65] Therefore, inventors should be rewarded with strong patent rights over their inventions in order to incentivize the disclosure of those inventions.[66] The Supreme Court has elaborated as follows.

> The patent laws promote [technological] progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens. In return for the right of exclusion—this 'reward for inventions,'—the patent laws impose upon the inventor a requirement of disclosure.[67]

According to this view, patent rights serve economic policy because the more patented knowledge is made publicly available, the better the promotion of technological progress and knowledge growth. Central to the realization of such policy is incentivizing invention through the granting and protection of strong patent rights.

Apart from this incentive-oriented utilitarianism, strong patent rights are also justified by the conventional wisdom that invention emerges from an inventor's individual contribution.[68] This traditional narrative envisions lone inventors relying on their own labor, talents, and ideas to develop extraordinary inventions and advance industrial progress.[69] The lone inventor narrative is reflected in both the philosophical foundations and distinct features of patent law.[70] By requiring protectible inventions to be both novel and non-obvious, patent law presupposes that a given invention would not have been invented (or disclosed) without the

65. *See* Dan L. Burk, *Law and Economics of Intellectual Property: In Search of First Principles*, 8 ANN. REV. L. & SOC. SCI. 397, 400 (2012).

66. *See* Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 25–26 (1950).

67. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974).

68. *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 710 (2011) ("[T]he very theory of patent law is based on the idea that a lone genius can solve problems that stump the experts, and that the lone genius will do so only if properly incented by the lure of a patent.").

69. *See* Christopher A. Cotropia, *The Individual Inventor Motif in the Age of the Patent Troll*, 12 YALE J.L. & TECH. 52, 54 ("The individual inventor story generally goes as follows: A lone individual toils in her limited free time-evenings after work and perhaps the weekend-to come up with an amazing breakthrough that turns out to be incredibly beneficial to society.").

70. *See id*. at 55 ("The patent system has traditionally taken the individual inventor motif to heart and seen patents as a vehicle to both fuel individual inventors and protect them from large corporations").

issue of a patent to the inventor.[71] To provide an economic incentive for innovation, there is a need to identify individuals to whom exclusive rights can be granted.[72] Therefore, patent law presumes that the source of an invention or innovation is a discrete and identifiable individual.[73] This presumption is a practical consequence of the property rights approach that patent law takes to incentivize innovation, whereby exclusive property rights are granted to individuals who have been incentivized to invent by the lure of a patent. Alternatively, it can be said that property rights are granted to individuals who are best placed to engage in private ordering.[74] The presumptions of patent law as to the source of innovation are fueled by a belief that a given invention would not have been invented but for the entirely original idea of a single creator.[75]

2. Weak Patent Responsibilities

While patent law protects strong exclusive rights, it imposes two categories of weak legal responsibilities upon patent holders. It first requires them to take responsibility for the sufficient disclosure of technical information. By carving out limitations on patent rights such as experimental use and compulsory licensing, patent law also imposes upon patent holders a responsibility to accommodate the public's unauthorized uses of their inventions within the ambit of these limitations. However, both responsibilities are very weak in terms of their legislation and enforcement in practice, as the following discussion reveals.

a. Disclosure

A bundle of patent rights is granted in exchange for patent holders' public disclosure of inventions that might otherwise remain trade secrets.[76] Therefore, patent disclosure is "the *quid pro quo* of the right to exclude."[77] The Patent Act

71. *See* Lemley, *supra* note 68, at 736 ("Patent law focuses on extraordinary inventions—things that could not be done by people having ordinary skill in the art.").

72. *See* Peter Lee, *Social Innovation*, 92 WASH. U. L. REV. 1, 27 (2014) ("This focus on individual inventorship directly reflects the mechanism by which the patent system achieves its policy objectives; it allocates private property rights to enable incentives to invent and innovate.").

73. *See id*. at 26.

74. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 269 (1977).

75. *See* Cotropia, *supra* note 69, at 57–58 (pointing out that "one of the main goals of the patent system should be to assist, and in some ways protect, the individual inventor").

76. *See, e.g*., Brenner v. Manson, 383 U.S. 519, 534 n.21 (1966) ("As a reward for inventions and to encourage their disclose, the United States offers a . . . monopoly to an inventor who refrains from keeping his invention a trade secret.") (quoting Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944))

77. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001)(quoting Kewanee Oil Co., v. Bicron Corp, 416 U.S. 470, 484 (1974)).

establishes three independent conditions for the sufficient disclosure of the invention contained within a patent: a written description of the invention, enablement, and best mode.[78] Failure to meet these requirements could lead the courts or USPTO to invalidate the patent. The disclosure responsibility benefits society at large by requiring patent holders to supply relevant technical information.[79] First, disclosure facilitates cumulative invention. Second, it clarifies the boundaries of an invention, enabling others to invent a non-infringing alternative.[80]

However, many patent holders irresponsibly avoid making a sufficient disclosure of information when filing patent applications. One way they do so is by using language that is difficult to decipher. The patentees of information technology inventions, for instance, are notorious for producing patents that contain very little information about the nature of technical solutions the patents encompass,[81] thereby creating an "indeterminate zone of potential … infringement for third parties to traverse."[82] The Supreme Court conceded in *Brenner v. Manson*[83] that the patent system has resulted in "the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible."[84]

Furthermore, there is a wealth of important information that is necessarily absent from patent documents. Some commentators have pointed out the importance of subsequent ancillary disclosures, licensing agreements, and post-grant challenges, for example, which can enhance the technical teaching within a patent document.[85] More specifically, it has been suggested that the enablement doctrine's failure to adequately consider validating follow-on research favors patents "grounded in early, irreproducible data."[86] Therefore, the doctrine's narrow and retrospective focus on the patent document has ultimately led inventors to disclose the minimum information necessary to obtain patent protection.[87] One survey of nanotechnology researchers found that 86% of those who do not read

78. 35 U.S.C. § 112 (2006).

79. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 331 (1945) ("[The patent law's] inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure."); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) ("'In consideration of [the fulfillment of] disclosure and the consequent benefit to the community, the patent is granted.'") (quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933)).

80. *See* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 407-408 (2012).

81. *See* Ben Klemens, *The Rise of the Information Processing Patent*, 14 B.U. J. SCI. & TECH. L. 1, 35 (2008) (concluding that "patents on software and other information-processing technologies [are] virtually useless for disclosure purposes.").

82. Devlin, *supra* note 80, at 410.

83. 383 U.S. 519 (1966).

84. *Id*. at 534.

85. *See* Chien, *supra* note 60, at 1869-77.

86. Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 911 (2017).

87. *See id*. at 847-49.

patents simply do not believe that patents contain useful information.[88]

b. Experimental Use

Patent law exempts an unauthorized use of an invention from infringement liability where the user is deemed to have engaged in experimental use. This exemption stems from the opinion of Justice Story in the 1813 *Whittemore v. Cutter* decision that the legislature could never have intended to punish those who use an invention "merely for philosophical experiments" or to ascertain "the sufficiency of the machine to produce its described effects."[89] Several judicial rulings have upheld experimental use as a common law doctrine according to which "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement."[90] Therefore, the experimental use exemption encourages experimentation and innovation that might otherwise be stifled by patent law's granting of limited monopolies to inventors.[91]

However, the Federal Circuit has significantly weakened the experimental use exemption since its establishment in 1982.[92] In *Roche Prod. Inc. v. Bolar Pharm.*,[93] the Federal Circuit ruled that Bolar's testing of a patented drug in preparation for Food and Drug Administration (FDA) approval of its generic drug constituted patent infringement. It rejected Bolar's experimental use defense, holding this exemption "to be truly narrow"[94] and therefore unable to accommodate Bolar's use of the drug for its commercial purpose. Congress, however, hoping to foster a generic drug industry, introduced through the 1984 Hatch-Waxman Act a specific statutory exemption (the Bolar exemption) that allows experimental use in order to develop information for submission to the FDA for prescription drug and medical device approval.[95]

88. *See* Ouellette, *supra* note **Error! Bookmark not defined.**, at 571.

89. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

90. Peppenhausen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1862) (No. 11,279).

91. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 225(1987) ("Without an experimental use defense, it is possible that no one would be able to build on the inventor's discovery until the patent expired."); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 83 (2004) (suggesting that "a well-designed experimental-use exemption from infringement liability can promote faster cumulative technological progress without significantly diminishing incentives to invest in the original invention"); Kris J. Kostolansky & Daniel Salgado, *Does the Experimental Use Exception in Patent Law Have a Future?*, COLO. LAW., Jan. 2018, at 36.

92. *See* Rochelle Cooper Dreyfuss, *Reconsidering Experimental Use*, 50 AKRON L. REV. 699, 702 (2016) ("Justice Story's carefully constructed exception began to crumble soon after the establishment of the Federal Circuit in 1982.").

93. 733 F.2d 858 (Fed. Cir. 1984).

94. *Id.* at 863.

95. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282).

Despite Congress's approval of the Bolar exemption, the Federal Circuit has continued to take an overly narrow approach to the experimental use exemption. For instance, in *Embrex, Inc. v. Service Engineering Corp.*,[96] the defendant had attempted to design around an existing patent through using it in the course of its experiments. The Federal Circuit held that the defendant's acts did not fall within the ambit of the experimental use exemption, because they were performed expressly for commercial purposes and were merely disguised as scientific inquiries.[97] In his concurring opinion, Judge Randall Rader even asserted that "the Patent Act leaves no room for any de minimis or experimental use excuses for infringement."[98]

The most notable limitation of the experimental use exemption came in *Madey v. Duke University*.[99] In this case, researchers at Duke University had used a patented laser technology in the belief that pure academic research and teaching were exactly what the experimental use exception was designed to protect.[100] The Federal Circuit disagreed, holding that the researchers' use of the laser during teaching was in keeping with Duke University's commercial goal of attaining sufficient status to attract students and lucrative research grants.[101] Therefore, such use did not "qualify for the very narrow and strictly limited experimental use defense."[102] Although this decision has not eliminated the experimental use exception entirely, many now consider the exception to be "essentially useless" for research universities and suggest that its demise could significantly inhibit innovation.[103]

The 2011 America Invents Act (AIA)[104] did not revive the experimental use exemption.[105] In part, this was due to an absence of data suggesting that research had been impeded by the exception's limitation, although that may have been the result of researchers ignoring patents or patentees ignoring scientists.[106] However, the main factor was opposition from the biotechnology industry. At the time of enactment of the AIA, biotechnology industry stakeholders opposed the experimental use exemption as a threat to the industry's business model, concerned that it would interfere with the industry's ability to earn revenue from the

96. 216 F.3d 1343 (Fed. Cir. 2000).

97. *Id.* at 1349.

98. *Id.* at 1352 (Rader, J., concurring).

99. 307 F.3d 1351 (Fed. Cir. 2002).

100. *Id.* at 1352-53.

101. *Id.* at 1362.

102. *Id.* at 1362.

103. Kostolansky & Salgado, *supra* note 91, at 37 (quoting Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018, 1019 (2003)).

104. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 15, 28, 35, 42, and 51 U.S.C.).

105. *See* Dreyfuss, *supra* note 92, at 701 (pointing out "the AIA's failure to revive this defense legislatively").

106. *Id.* at 706.

licensing of its innovations.[107]

c. Compulsory Licensing

In patent law, compulsory licensing entitles a governmental agency to authorize third-party manufacture of a patented product or the practice of a patented process without the consent of the patent holder in exchange for adequate remuneration.[108] Grounds previously asserted for compulsory licensing worldwide include circumstances of national emergency, vital public health needs, strong societal interest in access to an invention, abuse of economic power by a patent owner, and situations where multiple patents are blocking a potential new technology.[109]

The potential for compulsory licensing is recognized in U.S. patent law under 28 U.S.C. § 1498, which allows the government to use a patented invention for any reason and patent holders to sue only to recover reasonable compensation.[110] However, the U.S. patent system has generally proved hostile to the application of this provision.[111] The Bayh-Dole Act provides the government with "march-in rights," which in theory allow third parties to apply for compulsory licenses of patented inventions created using government funds.[112] Under 35 U.S. Code § 203, this form of compulsory license may be granted on reasonable terms where it is necessary to meet health or safety needs.[113]

During a public health crisis, a country can use compulsory licenses to ensure provision of lifesaving drugs to its citizens.[114] If the patent owner produces insufficient quantities of such a drug or sells it at a price a government cannot reasonably afford, the government can grant compulsory licenses enabling third parties to produce the drug. The Bayh-Dole Act's "march-in rights" serve a similar purpose. The Act's aim is to incentivize innovation by allowing universities to partner with private companies in the production of patented inventions, and § 203 protects the public against the non-use or unreasonable use of inventions that have received public funding.[115] This protection provides the government with another important tool when faced with unreasonable drug costs. Although compulsory licensing has traditionally been used by low-income countries, in

107. *Id*. at 707.

108. Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicine Tool*, 102 MINN. L. REV. 2463, 2465 (2018).

109. Justin Culbertson & Jason J. Jardine, *Compulsory Patent Licensing in the Era of Pandemic*, INT'L. BAR ASS'N (June 30, 2020), https://perma.cc/3UD4-K446.

110. *See* Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, SSRN 1, 8 (2020), https://ssrn.com/abstract=3636456.

111. *See* Culbertson & Jardine, *supra* note 109.

112. 35 U.S.C. § 203(a).

113. *Id*.

114. World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November 2001 ¶ 5.b, WTO Doc. WT/MIN(01)/ DEC/2, 41 I.L.M. 755 (2002).

115. Kumar, *supra* note 110, at 13.

response to COVID-19 higher-income countries including Canada, Israel, and E.U. member states are using or looking into the use of compulsory licensing as a tool to aid the production of drugs.[116]

The U.S., however, remains opposed to compulsory licensing on broadly three grounds. First, many patent holders and commentators have framed compulsory licensing as theft of intellectual property rights. It is "morally wrong" because it forces patent owners to bear costs.[117] Second, many patent holders and commentators take the view that compulsory licenses destroy innovation by removing the monopoly incentive.[118] Third, patent holders and commentators frequently assert that developing countries can get better drug prices from international procurement markets than from compulsory licensing.[119]

During past public health emergencies, the U.S. government avoided making use of the § 1498 compulsory license. In response to fears of potential anthrax attacks in the early 2000s, the government considered using the statute to secure Bayer's ciprofloxacin antibiotic at a cost lower than the prices offered to it by Bayer.[120] It was only able to negotiate a better price only after Canada issued a compulsory license to a domestic company, creating a threat to Bayer.[121] In 2016 and 2018, the government outright opposed calls for use of the § 1498 compulsory license in response to suggestions made by several scholars and elected officials that it should be used to lower the cost of hepatitis C antiviral drugs and other drugs covered by Medicare and Medicaid.[122]

Making use of the Bayh-Dole Act's "march-in rights" to obtain a compulsory license is difficult in part because of the complex and lengthy administrative process involved. This includes a fact-finding hearing that affords the patent owner an opportunity to appear with counsel and provide witnesses to oppose the license-seeker, and the license cannot proceed until the patent owner has exhausted all appeals.[123] Despite third-party requests, the government has not exercised its march-in rights to issue any compulsory licenses thus far.[124] For example, a shortage of Genzyme's Fabrazyme beginning in 2009 led to drug rationing

116. *Id*. at 4, 26-29.

117. Bagley, *supra* note 108, at 2472, 2474

118. *Id*. at 2474 (pointing out that some commentators argue "compulsory licenses will harm innovation and society will not get the new drugs it needs").

119. *See* Reed F. Beall, et. al., *Compulsory Licensing Often Didn't Produce Lower Prices for Antiretrovirals Compared to International Procurement*, 34 Health Affairs 493 (2015), https://pubmed.ncbi.nlm.nih.gov/25732501/.

120. *See* Kumar, *supra* note 110, at 10.

121. *Id*. at 10.

122. *See, e.g.*, Amy Kapczynski & Aaron Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFAIRS 791, 792 (May 2016) (proposing that the federal government should utilize § 1498 to lower the price of hepatitis C drugs), https://pubmed.ncbi.nlm.nih.gov/27140984/.

123. Kumar, *supra* note 110, at 13-14.

124. *Id*. at 13 ("To date, however, the government has never directly exercised its march-in rights.")

that resulted in disability and death for patients with Fabry disease.[125] Despite such harm to consumers and the pharmaceutical company in question repeatedly missing production targets, the Obama administration resisted compulsory licensing on the grounds that it would take too long to approve another manufacturer.[126]

Internationally, the U.S. approach has contributed to resistance to compulsory licensing issued by other countries. Compulsory licenses are permitted under Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[127] provided that they "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner."[128] However, when South Africa passed legislation to lower the cost of medicines through compulsory licensing during the peak of the AIDS epidemic, trade group Pharmaceutical Research and Manufacturers of America asked the U.S. Trade Representative to place the country on the Special 301 Watch List on the grounds that the legislation violated the TRIPS Agreement.[129] The U.S. backed down only after a public outcry and support for South Africa from the E.U. and WHO, among others.[130] The U.S. government's resistance to international compulsory licensing not only limits its own patent system's ability to effectively balance the incentive of monopoly rights against public health interests, but also the ability of the TRIPS Agreement to do so regionally and internationally.

II. THE COVID-19 PANDEMIC'S CHALLENGES TO THE CONVENTIONAL NOTION OF PATENT RIGHTS

As revealed in Part I, companies have rushed to file COVID-19-related patent applications and lodge lawsuits in order to maximize their private interests. Contrasting initiatives and efforts, however, have emerged that allow the exploration of avenues through which COVID-19-related patents can be exploited in a more socially beneficial manner. These initiatives and efforts, as this Part will demonstrate, emphasize the social dimension of innovation and the public interest implications of patent protection. Rather than supporting reliance on patent rights to maximize private interests, they encourage patent holders to take greater

125. *See* Andrew Pollack, *Genzyme Drug Shortage Leaves Users Feeling Betrayed*, N.Y. TIMES (Apr. 15, 2010), https://www.nytimes.com/2010/04/16/business/16genzyme.html.

126. *See* Kumar, *supra* note 110, at 36-37.

127. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 213999 (1994) [hereinafter TRIPS Agreement], https://perma.cc/C27A-6G8X.

128. *Id*. at art. 30.

129. *See* Kumar, *supra* note 110, at 14-15.

130. *Id*. at 15 ("President Clinton issued an executive order stating that the U.S. government will not seek the revocation of any policy of a sub-Saharan African country that expands access to HIV/AIDS drugs for impacted areas.").

responsibility for freely sharing the benefits of innovation progress.

A. Patent Pledges

1. Altering Patent Licensing: The Open COVID Pledge

In response to the pandemic, an international group of scientists, engineers, lawyers, and entrepreneurs launched the Open COVID Coalition.[131] Its primary concern is that intellectual property rights are unduly impeding efforts to contain the COVID-19 pandemic by limiting access to the relevant research and manufacturing technologies.[132] To address this concern, the Coalition created the Open COVID Pledge (OCP) in April 2020.[133]

Under the OCP, a patent holder or "pledgor" commits to making some or all of its patents available for the purpose of mitigating, managing, and ending the impact of COVID-19. The pledgor adopts one of three categories of license: an Open COVID License (OCL) drafted by the Coalition; a license deemed by the Coalition to be OCL compatible; or a license that mirrors the intent and effect of the OCP.[134] The OCL grants to individuals and entities, for free and without encumbrances, a license to use the pledgor's patents.[135]

The OCP carries legal effect. Licensees are entitled to rely on it to use the pledgor's patents to start researching, manufacturing, supplying, providing, or selling goods and services for permitted COVID-19-related uses without having any direct contractual relationship with the pledgor. It encourages the sharing and pooling of patents, limits the transaction costs required to negotiate individual licensing agreements, and reduces the uncertainties surrounding the ownership and use of patents. Thus, the OCP promotes temporary access to a wide array of research and manufacturing outputs, including diagnostics, medical equipment, pharmaceuticals, software, contact tracing, and manufacturing capabilities. The OCP functions to protect the public interest in achieving the timely development of, and affordable access to, essential technologies to combat the COVID-19 pandemic.

2. The COVID-19 Technology Access Pool

International organizations have called for expeditious scientific and technical cooperation at the global level.[136] In April 2020, the UN Committee on

131. *About Us*, OPEN COVID PLEDGE, https://perma.cc/9CCM-MCGL.

132. Mark A Lemley, *Stanford's Mark Lemley on Effort to Make IP Available to End COVID-19 Pandemic*, STAN. L. SCH. (Apr. 1, 2020), https://perma.cc/DG8Q-3S2Q

133. *Id*.

134. *About the Licenses*, OPEN COVID PLEDGE (July 29, 2020), https://perma.cc/K87S-HVQF.

135. *Id*.

136. Katrina Perehudoff & Jennifer Sellin, *COVID-19 Technology Access Pool (C-*

Economic, Social and Cultural Rights stated that "[i]f a pandemic develops, sharing the best scientific knowledge and its applications, especially in the medical field, becomes crucial to mitigate the impact of the disease, and to expedite the discovery of effective treatments and vaccines."[137]

Subsequently, the World Health Organization (WHO) launched the COVID-19 Technology Access Pool (C-TAP) in May 2020 to accelerate and broaden global access to vaccines, treatments, and diagnostics. The WHO outlined five priorities for C-TAP in order to create "a one-stop shop for scientific knowledge, data and intellectual property to be shared equitably by the global community."[138] They include ensuring transparency in the publication of clinical trial results; tying public research funds to affordable and equitable distribution; and licensing patents from promising discoveries to the established and UN-backed Medicines Patent Pool so that they can be produced at scale by generic manufacturers.[139]

The WHO also announced the Solitary Call to Action, which sets out the actions necessary to advance the pooling of knowledge, intellectual property, and data.[140] According to this call to action, governments should formulate legal and policy measures to promote innovation and remove barriers to ensure access to COVID-19 technologies for everyone.[141] Research funders should ensure that the outcomes of their COVID-19-funded research and the resulting health products are accessible and affordable by inserting clauses in funding contracts with pharmaceutical companies and research institutes that stress equitable publication, distribution, and access to information and products necessary for combatting COVID-19.[142] Intellectual property holders should share their rights in COVID-19 treatments, diagnostics, vaccines, or other health technologies through voluntary licensing schemes,[143]and researchers should publicly disclose COVID-19 virus genetic sequence information.[144]

C-TAP particularly seeks to ensure the equitable distribution of COVD-19-related supplies so that developing countries are not left behind. The pandemic

TAP): A Promising Human Rights Approach, HEALTH & HUM. RTS. J. (June 4, 2020), https://www.hhrjournal.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach.

137. U.N., Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rts., Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights 5, U.N. Doc. E/C.12/2020/1 (Apr. 17, 2020).

138. *International Community Rallies to Support Open Research and Science to Fight COVID-19*, WORLD HEALTH ORG. (May 29, 2020), https://www.who.int/news-room/detail/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19.

139. *See id*.

140. *See id*.

141. *Id*. (stating that "[g]overnments and other funders are encouraged to include clauses in funding agreements with pharmaceutical companies and other innovators about equitable distribution, affordability and the publication of trial data").

142. *Id*.

143. *Id*.

144. *Id*.

is exacerbating the health vulnerabilities of poor people in countries with limited health system capacity and other risk factors such as chronic malnutrition and poor air quality,[145] which may not be able to afford patented medicines without assistance from wealthy countries.[146] C-TAP is intended to help developing countries gain timely, equitable, and affordable access to COVID-19 health technologies and medical products through voluntary licenses granted by pharmaceutical companies and research institutes.[147] It will allow vaccines and treatments to be shared globally, with the potential manufacture of generic versions in developing counties, and will also facilitate the sharing of information such as trial data between research institutions, potentially speeding up the COVID-19 vaccine creation process.[148]

3. Summary

The COVID-19 pandemic reinforces the need of socially responsible exercise of patent rights. In such an unprecedented global public health crisis, one of the public policy priorities is to ensure that technology companies would take adequate responsibilities to swiftly and expansively benefit the public with their medical innovations in the COVID-19 research. In doing so, they should attach less importance to their existing or potential patent rights over those innovations. Further, public involvement in COVID-19-related innovation reveals that the lone inventor thesis exaggerates the individual contributions made by patent holders. Such involvement thus raises questions about patent holders' responsibility to reciprocate through the exercise of their exclusive rights.

However, major technology companies in the medical sector have failed to react to the global call for responsibility. For the purpose of containing the pandemic, the OCP and C-TAP urge patent holders to responsibly share their patented technologies in the public interest by altering their dedication to exclusive right protection. As the key institutions vital to bring an end to the pandemic, major pharmaceutical companies have not taken part in both initiatives at all. The OCP has engaged many companies such as IBM, Facebook, and Uber[149] and has obtained over 250,000 pledged patents.[150] Nevertheless, none of the major

145. LARS JENSEN & GEORGE GRAY MOLINA, United Nations Dev. Programme, COVID 19 AND HEALTH SYSTEM VULNERABILITIES IN THE POOREST DEVELOPING COUNTRIES 3-5 (2020), https://perma.cc/NY3Y-74R7.

146. *See* Robert Malley & Richard Malley, *When the Pandemic Hits the Most Vulnerable*, FOREIGN AFFS. (Mar. 31, 2020), https://perma.cc/SP42-QGWN.

147. David Knight & Joshua Marshall, *The Covid-19 Technology Access Pool: Sharing is Caring?*, EUR. PHARM. MFR. (July 2, 2020), https://www.epmmagazine.com/opinion/the-covid-19-technology-access-pool-sharing-is-caring.

148. *Id*.

149. *See See* Charlotte Kilpatrick, *Tech Companies Promote Benefits of Open Covid Pledge*, Sept. 24 2020, https://perma.cc/6JHL-NCN4

150. *See* Michael S. Horikawa, *The Open COVID Pledge – Don't Say "I Do" Till You Think It Through*, PILLSBURY (June 24, 2020), https://perma.cc/3GRV-HJ4H

pharmaceutical companies have pledged their patents to the OCP,[151] a gridlock that has led some commentators to caution companies should actively take initiative to devote their patents to the OCP.[152] Since its inception, the C-TAP has not yet started to function because "no technology or treatments have been shared."[153] None of the pharmaceutical companies have volunteered to join the C-TAP as of March 2021.[154] Worse still, some of the major pharmaceutical companies have even condemned it as "nonsense" and being "dangerous."[155]

B. The Public Role in Developing Inventions

The public interest insofar as COVID-19 is concerned is fairly obvious. Research institutions and commercial entities have been open with respect to their motivations to respond to COVID-19, whether owing to the exigencies of the crisis, out of genuine altruism, or in response to considerable public pressure and scrutiny. Additionally, there exists immense pressure, for both humanitarian and pragmatic reasons, to ensure that any treatment and vaccine are universally accessible.[156]

1. Free Information Sharing

A number of research institutions and corporations have launched information sharing initiatives to disseminate data and intellectual property rights relating to COVID-19. These initiatives have made information about potential treatments and vaccines, infection rates, and clinical observations, as well as patient data, publicly available.

A number of the innovations that have emerged in the wake of the pandemic

151. *Id*. ("However, the Pledge has not yet seen wide adoption in certain key industries. For example, it does not appear that the Open COVID Pledge has been embraced by the pharmaceutical or medical device industries.").

152. *Id*. (cautioning that "it is especially important for companies to carefully consider the impacts of being an early (or sole) adopter in an industry").

153. Michael Safi, *WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began*, GUARDIAN (Jan. 22, 2021), https://perma.cc/HPZ4-2Q6Z.

154. Selam Gebrekidan and Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. TIMES (March 21, 2021), https://perma.cc/Z5UG-3U5N ("Not a single vaccine company has signed up [for the C-TAP].").
https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/

155. Sarah Newey, *WHO Patent Pool for Potential Covid-19 Products Is 'Nonsense', Pharma Leaders Claim*, THE TELEGRAPH (May 29, 2020), https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/.

156. *See, e.g*., Matthew S. Schwartz, *In Christmas Message, Pope Francis Urges Coronavirus 'Vaccines for All'*, NPR (Dec. 25, 2020), https://perma.cc/K2EE-5SMF; Philip Pullella, *In Christmas Message Curbed by COVID, Pope Calls on Nations to Share Vaccines*, REUTERS (Dec. 25, 2020), https://perma.cc/2VAK-CR3S.

contain features of social innovation motivated by protection of the public interest. They include the sharing of information on the promotion and adoption of personal protective equipment, hygiene and cleaning practices, quarantine and social distancing protocols, testing and diagnostics, and tracking and tracing software and methodologies. What these innovations have in common is that they are all potentially low-cost innovations, require mass behavioral changes in society, involve novel implementations of existing ideas, are legacies of past pandemics (SARS and MERS) and the experience gleaned, and were developed with the aim of responding to a public health crisis.

Crowdsourcing platforms have been used to contribute to social innovation in COVID-19 information sharing. InnoCentive is one such platform.[157] It provides a two-sided market in which information seekers can post problems and information providers can choose problems to work on in return for a fixed prize. Thus far, challenges have been posted relating to protective films, transmission prevention, and ventilators.[158]

2. Developing Treatments and Vaccines

The process of developing COVID-19 treatments and vaccines also highlights the public role in innovation development. In a race against time to curb the spread of COVID-19, private sector collaborations have speeded up the development process to which the public sector has already made substantial contributions.

The treatment development process has entailed extensive public involvement through clinical trials. For example, Gilead's remdesivir trials involved a large number of patients.[159] The Solidarity Trial, a clinical trial program for COVID-19 treatments operated by the WHO, has enrolled around "12,000 patients in 500 hospital sites in over 30 countries."[160] The Trial collects data from patients on their underlying condition, treatments given, the commencement of any ventilation or intensive care, date of discharge, date of death, and cause of death.[161] Patient and hospital involvement, access to treatments, and the sharing of results are critical to the Trial's success. Other drug and clinical research trials also involve a high degree of patient recruitment.[162]

157. *See* DAVID BURKUS, THE MYTHS OF CREATIVITY: THE TRUTH ABOUT HOW INNOVATIVE COMPANIES AND PEOPLE GENERATE GREAT IDEAS 78–79 (2014).

158. *COVID-19 Challenges*, INNOCENTIVE, https://perma.cc/J7CQ-PCX2.

159. Press Release, *Gilead Announces Results From Phase 3 Trial of Remdesivir in Patients With Moderate COVID-19,* GILEAD SCIENCES (June 1, 2020), https://perma.cc/F55E-ST46.

160. *"Solidarity" Clinical Trial for COVID-19 Treatments*,30 WORLD HEALTH ORG., https://perma.cc/AB9A-4JF5.

161. *Id*.

162. *See COVID-19 Clinical Research Trials*, CENTERWATCH, https://www.centerwatch.com/clinical-trials/listings/condition/1097/covid-19.

Vaccine development also requires extensive patient involvement in clinical trials.[163] For example, the phase three study of Moderna's COVID-19 vaccine involved more than 30,000 participants.[164] Likewise, Pfizer and BioNTech enrolled more than 40,000 participants in their phase three study to test the efficacy of their COVID-19 vaccine.[165] What is distinct in the COVID-19 pandemic is the mass availability of human subjects and widespread public interest in the rapid development of a widely accessible treatment and/or vaccine. The COVID-19 pandemic and resulting public health crisis have thrown into sharp focus the involvement of patients in the development of treatments and vaccines and the importance of the data and results derived.

3. Testing and Contact Tracing

Testing is crucial to combating COVID-19. As many current COVID-19 tests are built upon existing technologies and methods, innovation centers not on novel testing methodologies but on efficiency in terms of speed, required supervision, accuracy, cost, and/or portability. Much of the development appears to be reflected in open source journal articles.[166] Previous diagnostic studies on the related coronaviruses SARS and MERS are also relevant in the development of tests for COVID-19.[167] Analogous to pharmaceutical research and development, the development of COVID-19 testing and diagnostics reveals the incremental and social nature of innovation.

Contact tracing has also proven crucial to containing the spread of COVID-19. In February 2019, a business method patent was granted to Blyncsy, Inc. for "tracking proximity relationships and uses thereof."[168] Since then, Blyncsy has launched a website for companies wishing to request licensing for its method of

163. *See* Alice Yan, *Take a Shot, Isolate at Hotel: Chinese Volunteer 048 Describes Vaccine Trial,* S. CHINA MORNING POST (May 25, 2020), https://perma.cc/HBV4-WT6A; Laura Zhou, *Chinese Military Scientists Record Promising Results From Coronavirus Vaccine Trial*, S. CHINA MORNING POST (May 23, 2020), https://perma.cc/83DF-CFD6; Nsikan Akpan, *A COVID-19 Vaccine Has Passed Its First Human Trial. But Is It the Frontrunner?*, NAT'L GEOGRAPHIC (May 31, 2020), https://perma.cc/QS4X-N5WB.

164. Press Release, *Moderna Announces Publication of Results from the Pivotal Phase 3 Trial of the Moderna COVID-19 Vaccine in The New England Journal of Medicine*, MODERNA (Dec. 31, 2020), https://perma.cc/M9DN-BJFF.

165. Press Release, *Pfizer and Biontech Conclude Phase 3 Study of Covid-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints*, PFIZER (Nov. 18, 2020), https://perma.cc/KJ6J-SG49.

166. *See, e.g.*, Linda J. Carter et al., *Assay Techniques and Test Development for COVID-19 Diagnosis*, 6 ACS CENT. SCI. 591, 591-92 (2020).

167. *Id.* at 600.

168. U.S. Patent No. 10,198,779 B2 (filed Feb. 5, 2019) (capitalization altered); *see* Benjamin Henrion, *COVID-19 Tracing Apps Threatened by Blyncsy Software Patent,* FFII (May 12, 2020), https://perma.cc/NR8Z-N8UF.

contact tracking.[169] At the same time, other companies, including Apple and Alphabet, have provided contact tracing apps.[170] Another mobile application developer, Twenty, claims to have developed a contact tracing app, Healthy Together, independently of Blyncsy.[171] It is evident that contact tracing applications are built upon and made possible by pre-existing software and technological platforms, i.e., mobile electronic devices, tracking software, surveillance technology, and GPS, and the concept of tracking a contagion is not novel either, having been around at least since the 1800s.[172]

Clearly, contact tracing is an inevitable incremental development. Although no litigation or challenges in relation to Blyncsy, Inc.'s patent have been initiated at the time of writing, developments in this area of COVID-19-related innovations illustrate the public interest nature of innovation.

III. THE SOCIAL NATURE OF INNOVATION AND PATENTS

As the preceding has demonstrated, many technology companies have not adequately fulfilled their responsibilities associated with their COVID-19-related innovations and patents even at the tipping points of the pandemic. In this part of the article, I shift from the pandemic periods of crisis management responsibilities to consider patent holders' responsibilities under the normal circumstances of innovation. I argue many technology companies have also failed to scrutinize their responsibilities required by the social nature of innovation.[173] Responding to the fact that innovation is by nature a social process, we must challenge the conventional focus of patent law on the protection of patent holders' rights and call for a patent law reform intended to impose greater responsibilities on patent holders. Analyzing COVID-19-related innovation, I first demonstrate the process of sequential and combinatorial evolution from which technologies and inventions are drawn and developed and then examine the function of social innovation in promoting distributive justice and public welfare.

169. *Contact Tracing*, BLYNCSY, INC., https://perma.cc/PD9Q-W3J2 (archived Apr. 18, 2021).

170. Tripp Baltz & Susan Decker, *Startup Risks Clash with Apple, Google Over Virus-App Royalties*, BLOOMBERG L. (May 7, 2020, https://perma.cc/6NKD-54W3.

171. *Id*.

172. Kathleen Tuthill, *John Snow and the Broad Street Pump: On the Trail of an Epidemic*, CRICKET MAG., Nov. 2003, at 23, 23-31, *reprinted in* UCLA, FIELDING SCH. OF PUB. HEALTH, https://perma.cc/9MAK-2VXQ; Baltz & Decker, *supra* note 170.

173. *See* BRIAN W ARTHUR, THE NATURE OF TECHNOLOGY: WHAT IT IS AND HOW IT EVOLVES 2 (2011) ("[New] technologies were not 'inventions' that came from nowhere. . . . [They] were created—constructed, put together, assembled—from previously existing technologies. Technologies in other words consisted of other technologies, they arose as combinations of other technologies. "); *See also* DAVID BURKUS, THE MYTHS OF CREATIVITY: THE TRUTH ABOUT HOW INNOVATIVE COMPANIES AND PEOPLE GENERATE GREAT IDEAS 60 (2014) ("Inventors, marketers, and artists all utilize the raw materials of existing ideas to create new works").

A. Sequential Innovation

Sequential innovation often occurs in communicative and interactive contexts.[174] Individuals build on prior art, often working in groups and interacting with one another or working independently but in parallel.[175] Accordingly, innovation may involve multiple teams and individuals developing and honing a single idea or exploring different approaches and solutions to a problem in a form of complementary innovation, increasing the likelihood of a solution being found.[176]

Teamwork and collaboration are often involved in the process of innovation, irrespective of whether the result is marketed under an individual's name.[177] In scientific research labs and experimentation, social interactions at the conference table have a significant impact on whether and how the innovative solutions that emerge are analyzed.[178] Social interactions between individuals from diverse backgrounds are particularly conducive to innovation and discovery,[179] and open environments characterized by interaction and collaboration better promote innovation than closed environments characterized by patent rights and secrecy.[180]

The sequential nature of innovation also involves incremental and cumulative improvements on existing technologies and inventions.[181] New innovations

174. *See* Lee, *supra* note 72, at 28; Pedraza-Fariña, *supra* note 26, at 839 (concluding that innovation is "inherently relational, emerging from a complex, interactive back-and-forth among researchers, often in different communities of practice or social worlds").

175. *See* Lemley, *supra* note 68, at 750 ("Invention is social phenomenon, not one driven by lone geniuses. Inventors are working in groups, interacting with each other and building on the prior work of others. But even where they work independently, they are often working in parallel to solve identified problems or to improve existing technology.").

176. *See* James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation*, 40 RAND J. ECON. 611, 612 (2009) (describing complementary innovation as the situation where "each potential innovator takes a different research line and thereby enhances the overall probability that a particular goal is reached within a given time").

177. *See* BURKUS, *supra* note **Error! Bookmark not defined.**, at 105–24.

178. *See* Kevin Dunbar, *How Scientists Really Reason: Scientific Reasoning in Real-World Laboratories*, *in* THE NATURE OF INSIGHT 365, 385 (Robert J. Sternberg & Janet E. Davidson eds., 1995).

179. *See* Pedraza-Fariña, *supra* note 26, at 855.

180. *See* STEVEN JOHNSON, WHERE GOOD IDEAS COME FROM: THE NATURAL HISTORY OF INNOVATION 232 (2010) ("All of the patterns of innovation we have observed in the previous chapters—liquid networks, slow hunches, serendipity, noise, exaptation, emergent platforms—do best in open environments where ideas flow in unregulated channels. In more controlled environments, where the natural movement of ideas is rightly restrained, they suffocate.").

181. *See* Lemley, *supra* note 68, at 713–15; *see also* Bessen & Maskin, *supra* note 176, at 612 (describing sequential innovation as the situation where "each successive invention builds on the preceding one, in the way that the Lotus 1-2-3 spreadsheet built on VisiCalc, and Microsoft's Excel built on Lotus"); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 881 (1990) ("In industries like those producing automobiles, aircraft, electric light systems, semiconductors and computers, technical advance is cumulative, in the sense that today's advances build on and interact with many

tend to build upon and be limited by available ideas, technologies, and resources,[182] and history shows that as a new technology becomes available, further innovation inevitably follows. Electric batteries, for instance, were invented almost simultaneously by two different parties in 1745 and 1746, and oxygen was independently isolated by two scientists between 1772 and 1774.[183] These concurrences of innovation were possible only because prior discoveries and inventions had made new experiments suddenly possible.[184]

The development of the Internet epitomizes sequential innovation. Without previous innovations in data transmission speeds and the development of Adobe Flash video capability, such Internet-related innovations as social networking platforms, online transactions, and digital maps would not have been possible.[185] Each Internet innovation is built upon technological platforms that are themselves a collection of existing innovations.[186] Scholars have noted that sequential innovation is also typical in other research areas such as molecular genetics, DNA, and evolutionary psychology.[187] Hence, it is widely accepted that sequential innovation is vital to major technological developments because the pace and trajectory of innovation are dependent on the technologies and inventions existing within society at a given point in time.

The development of remdesivir as a candidate for COVID-19 treatment demonstrates the importance of sequential innovation. Originally developed as a potential treatment for hepatitis C and later Ebola, although ultimately found ineffective for these viral infections, subsequent research discovered that it might produce potent effects against coronaviruses.[188] Based on laboratory and animal studies showing it to be active against other coronaviruses, remdesivir was tested against COVID-19 in January 2020 at the start of the outbreak in China.[189] Since then, laboratory studies and clinical trials have provided signs that remdesivir is a promising treatment for COVID-19, one being that it can reduce hospitalization time.[190] In May 2020, the FDA issued emergency use authorization for

other features of existing technology.").

182. *See* JOHNSON, *supra* note 180, at 25-42 (applying the concept of "adjacent possible," a term coined by Stuart Kauffman, to the context of innovation).

183. *Id*. at 34.

184. *Id*. at 35.

185. *Id*. at 34, 39-40 ("Had Hurley, Chen, and Karim tried to execute the exact same idea for YouTube ten years earlier, in 1995, it would have been a spectacular flop, because a site for sharing video was not within the adjacent possible of the early Web.").

186. *See id*. at 189-90.

187. *See id*. at 190.

188 . Bret Stephens, *The Story of Remdesivir*, N.Y. TIMES (Apr. 17, 2020), https://www.nytimes.com/2020/04/17/opinion/remdesivir-coronavirus.html.

189. Joseph Walker, *Gilead Sciences Offers Experimental Drug for Coronavirus Treatments, Testing*, WALL ST. J. (Jan. 31, 2020), https://perma.cc/JL2M-T2R9; Denise Grady, *China Begins Testing an Antiviral Drug in Coronavirus Patients*, N.Y. TIMES (Feb. 6, 2020), https://perma.cc/5M8T-JSVS.

190. Andrew Dunn & Lydia Ramsey Pflanzer, *Gilead Turned a Failed Ebola Drug Into the First Effective Coronavirus Treatment. Here's Everything You Need to Know About*

remdesivir, allowing its distribution and use in treating hospitalized patients with severe COVID-19.[191] In July 2020, the U.S. bought more than 90% of the world's supply of the drug for the next three months.[192]

The successful development of remdesivir cannot be attributed solely to its patent holder, the biopharmaceutical company Gilead Sciences. Both its development and clinical trials benefited significantly from approximately $70.5 million in public funding through grants to various universities and contributions from the U.S. government.[193] Although Gilead claims the discovery of the original compound,[194] remdesivir's development was a collaboration between Gilead and a group of scientists drawn from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Centers for Disease Control and Prevention (CDC).[195] Research conducted by USAMRIID, CDC, and Gilead scientists found remdesivir to have a broad-spectrum antiviral effect against certain RNA viruses, including coronaviruses.[196]

B. Combinatorial Innovation

New innovations can arise when existing inventions are applied outside their original context, expanding the application of an existing technology.[197] This combinatorial aspect of innovation has driven cutting-edge technological growth

Remdesivir, BUS. INSIDER (July 6, 2020), https://perma.cc/PYX4-YLA6.Latest studies show that remdesivir is not very effective in treating Covid-19 infection, but it does block Coronavirus activity. *See* JV Chamary, *The Strange Story of Remdesivir, A Covid Drug That Doesn't Work*, FORBES (Jan. 31, 2021), https://perma.cc/5NRM-5P5K.

191. *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, U.S. FOOD & DRUG ADMIN. (May 1, 2020), https://perma.cc/EHE3-DP8P.

192. Mia Jankowicz, *The US Bought Up 90% of the World's Supply of Remdesivir for the Next 3 Months, and Patents Mean Many Countries Won't Be Able to Get Any*, BUS. INSIDER (July 1, 2020), https://perma.cc/S633-Q4LH.

193. *The Real Story of Remdesivir*, *supra* note 37.

194. Christopher Rowland, *Taxpayers Paid to Develop Remdesivir but Will Have No Say When Gilead Sets the Price*, WASH. POST (May 26, 2020), https://perma.cc/7487-KXBF.

195. *See* Ed Silverman, The U.S. government contributed research to a Gilead remdesivir patent — but didn't get credit, https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/; Justin Hughes & Arti K. Rai, *Acknowledging the Public Role in Private Drug Development: Lessons from Remdesivir*, STAT (May 8, 2020), https://perma.cc/5UWG-TF85 ("As detailed by the nonprofit Knowledge Ecology International, the public role in the development of remdesivir is undeniable. Our own review of the drug's development indicates that one or more government researchers should probably have been listed as inventors on key patents for remdesivir.")

196. *Id*.

197. *See* JOHNSON, *supra* note 180, at 152–53 (discussing the concept of exaptation); M. L. Weitzman, *Recombinant Growth*, 113 Q.J. ECON. 331, 332-33 (1998); *see generally* JOSEPH A. SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT: AN INQUIRY INTO PROFITS, CAPITAL, CREDIT, INTEREST, AND THE BUSINESS CYCLE (1934) (writing about economic development more generally as involving new combinations of existing resources and means of production).

through the appropriation and aggregation of various existing technologies and knowledge.[198] Whether in biotechnology, computing, or chemistry, there is a core of knowledge providing individuals with technical insight to call upon in pursuit of further innovation.[199] The rise of digital technologies and explosion of online information have catalyzed this model of innovation, with new combinations limited only by our inability to process such information at sufficient speeds.[200]

The printing press combined a number of pre-existing technologies, including ink, paper, and movable type.[201] Similarly, many electronics are an assortment of existing technologies. The smartphone is not an invention, instead comprising a wealth of existing digital innovations ranging from central processors, memory, communications, navigation, messaging, applications, and transistors to Internet technologies.[202] Combinatorial innovation is of vital importance to data-driven technologies. This is to be expected as emerging technologies such as artificial intelligence (AI), which thrive on the study of digital data, are inherently capable of working well with other new digital technologies.[203] For instance, Internet of Things devices using AI, cognitive computing, and virtual and augmented reality technologies to process data collected by smart objects are able to offer consumers remarkably intelligent and practical services.[204]

Examining U.S. patent records, scholars have concluded that contemporary innovation consists predominantly of combinatorial evolution[205] rather than the introduction of truly novel technological platforms.[206] A potential explanation

198. ERIK BRYNJOLFSSON & ANDREW MCAFEE, THE SECOND MACHINE AGE: WORK, PROGRESS, AND PROSPERITY IN A TIME OF BRILLIANT TECHNOLOGIES 82 (2014) (defining combinatorial innovation as "an innovation-as-building block view of the world, where both the knowledge pieces and the seed ideas can be combined and recombined over time").

199. *Google and Combinatorial Innovation*, FARNHAM ST., https://perma.cc/9PV8-NDZJ.

200. Matt Clifford, *5 Things I Learned from The Second Machine Age*, MEDIUM (Aug. 3, 2015), https://perma.cc/J854-54GD.

201. *See* JOHNSON, *supra* note 180, at 152–53.

202. Mehmet Yildiz, *Combinatorial Innovation*, MEDIUM (Mar. 14, 2020), https://medium.com/dataseries/combinatorial-innovation-16e6cefd6163.

203. Rajesh Kandaswamy, *Combinatorial Digital Innovation Will Become Vital to Make the Most of Digital in the Next Decade*, GARTNER (Nov. 25, 2019), https://perma.cc/PK3X-DUK4.

204. *See* Yildiz, *supra* note 202.

205. *See* Hyejin Youn, Deborah Strumsky, Luis M. A. Bettencourt & José Lobo, *Invention as a Combinatorial Process: Evidence from US Patents*, J. ROYAL SOC'Y. INTERFACE 4 (2015).

206. *See id*. at 7 ("The introduction of new technological functionalities plays a minimal role in fuelling invention once the system is mature. Instead, 'refinements', which here means the reuse of existing technology codes or of existing combination of codes to identify the novelty of a patented invention, are very important in pushing invention forward"). This is reflected in a study which found that patenting increases correlated with new combinations made previously and created a statistical model for innovation suggesting that a rise in expected affinity for pairs led to an increase in expected patent grants. The study concluded that the

for this outcome is that pairs or combinations of existing technologies are more likely to produce effective inventions, which are in turn more likely to be successfully patented. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court decided that inventions derived from combinatorial innovation are non-obvious if they yield more than predictable results.[207]

Combinatorial innovation has created a new pathway for fighting the COVID-19 pandemic. Commentators have suggested that the combination of data, machine learning, and cloud technologies are now the driving force of innovation, and it is therefore unsurprising to see this reflected in so many novel approaches for combating the pandemic.[208] For example, such combinations have been used to track the coronavirus, to model the effect of lifestyle changes on halting its spread, and to produce sociological forecasts predicting its impact on hospitals and the economy.[209] Researchers at Penn State have combined machine learning with quantum physics with the aim of accelerating the screening of billions of chemical compounds in order to find drug candidates that might help in the treatment of COVID-19.[210]

C. Social Innovation

Innovation also has a distributional dimension, which tackles how the benefits of technological progress should be distributed fairly in a society. Innovations have both market and social value.[211] Traditionally, markets determine, on the basis of ability to pay, access to innovations and the kinds of innovation that are developed and distributed.[212] Patent law allocates resources to innovations of high market value, irrespective of their social value,[213] and rewards market actors

prospect of innovation is greatest after initial research has produced a set of building blocks and begun to establish elements with high affinity, but only if exploratory research continues to ensure that ideas do not become exhausted and lead to a decrease in productivity. Matthew S. Clancy, Combinatorial Innovation, Evidence from Patent Data, and Mandated Innovation 45, 46, 92 (2015) (Ph.D. dissertation, Iowa State University), GRADUATE THESES & DISSERTATIONS 14671.

207. 550 U.S. 398, 415-16 (2007).

208. David Vellante, *Breaking Analysis: Big Data in the Fight Against COVID-19*, WIKIBON (Mar. 31, 2020), https://perma.cc/2N7A-8BJ9.

209. *Id.*

210. Joe Devanesan, *Could Quantum Machine Learning Hold the Key to Treating COVID-19?*, TECHWIRE ASIA (May 8, 2020), https://perma.cc/7Z6T-UHTF.

211. *See* Lee, *supra* note 72, at 26 ("Although innovation in the patent paradigm focuses on individual inventors, social innovation reveals that many creations arise more collectively from communal efforts.").

212. *See id.* at 69; Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2823 & n.4 (2006).

213. *See* Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1051 (2005); *see also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1714–15 (1996).

for developing potentially profitable rather than socially beneficial inventions. The law legally enables patent holders to distribute technological benefits as they wish through voluntary market transactions. They have the exclusive rights to permit others to use their patented technologies contingent on royalties.[214] Researchers are prevented from using results and data generated by companies undertaking research and development (R&D) until patents are filed.[215] At the same time, for companies that draw upon the public domain in the R&D process, even where there is no intention to file a patent, relationships between commercial entities are characterized by confidentiality and secrecy. Hence, the extent to which members of the public can use a technological benefit often hinges upon how much they can pay the patent holder concerned.

The rise of social innovation, however, challenges patent law's market value-oriented distribution of technological benefits. It serves the public interest by increasing social value and inducing social and behavioral changes.[216] Social value can be defined as "the creation of benefits or reduction of costs for society . . . in ways that go beyond the private gains and general benefits of market activity."[217] In many ways, innovations traditionally covered by patent law do offer social value beyond the private value they offer to their creators. For instance, pharmaceuticals save lives, computers increase productivity, learning, and creativity, and cars simultaneously provide independence and promote contact between people who live apart.[218] However, they cannot be considered social innovations because, with regard to the motives underlying their creation, the balance is tipped toward private value and individual gain rather than social value and the public interest.[219] Public interest encapsulates substantive human needs and includes social welfare, public health, and safety.[220] It is the motivation to serve the public interest rather than obtain financial gain that distinguishes social innovations from normal commercial activities.

Examination of examples of social innovation reveals that in addition to being social in that they serve the public good, many are also social in that they

214. *See* ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY, at xi (2011) (IP rights let inventors "leverage their creative work, turning their effort into saleable assets. This not only enhances their income, it buys freedom.").

215. Jonathan Alan King, *Protecting Public Health Requires COVID-19 Treatments to Be Patent-Free*, TRUTHOUT (May 19, 2020), https://perma.cc/AJX6-TF4Y.

216. *See* Lee, *supra* note 68, at 8–11; CAROL YEH-YUN LIN & JEFFREY CHEN, THE IMPACT OF SOCIETAL AND SOCIAL INNOVATION: A CASE-BASED APPROACH 64 (2018) (arguing that social innovation's goal is to produce actions that are "socially valuable and good for many") (internal quotation marks omitted).

217. James A. Phills Jr., Kriss Deiglmeier & Dale T. Miller, *Rediscovering Social Innovation*, STAN. SOC. INNOVATION REV., Fall 2008, at 34, 39 (2018).

218. *Id.*

219. *Id.*

220. *See* Lee, *supra* note 72, at 9; Phills Jr. et al., *supra* note 217, at 36 (defining social innovation as "[a] novel solution to a social problem that is more effective, efficient, sustainable, or just than existing solutions and for which the value created accrues primarily to society as a whole rather than private individuals").

arise collectively from communal efforts.[221] This is certainly the case when describing innovation at high levels of abstraction such as in feminism or environmentalism and in broad technological fields such as semiconductors.[222] It is also true in the case of more specific innovations. For example, although Aaron Beck and Albert Ellis are recognized for their role in developing cognitive behavioral therapy, the field has much broader origins, and its development owes a lot "to the merger of behaviorism and the cognitive revolution."[223] Similarly, in the field of microfinance, Grameen Bank founder Muhammad Yunus alone is often credited, when in reality he would best be described as the articulator of a communal innovation.[224]

Owing to their nature, social innovations are not always protected by patents.[225] Nonetheless, they are immensely important. In this regard, social innovations may take the form of a public good. They are often low-tech, cheap, and easy to implement, as in the case of a set of recommended best practices, for example.[226] By extension, patent pools, information sharing initiatives, and new implementations of existing inventions fall within the definition of social innovation. Because access is a key consideration, social innovations are not necessarily inconsistent with the exclusivity granted by patents, although by implication affordability and pricing are important factors.

The COVID-19 pandemic has demonstrated the crucial importance of social innovation. By developing medicines and vaccines in the public interest, such innovation addresses the serious problems with the profit-driven, patent-oriented pharmaceutical industry. While for-profit private companies assert that strong patent protection offers the most effective incentive for pharmaceutical innovation[227] and leads to the development of new medicines to cure life-threatening diseases,[228] in reality these claims pose two serious problems.

One problem is that private pharmaceutical companies have largely failed to develop medicines and vaccines for deadly infectious diseases that create only limited market demand. When innovation is driven by the market, as in a pandemic, private companies frequently fail to act quickly enough because, until the

221. *See* Lee, *supra* note 72, at 26-27.

222. *Id*. at 28.

223. *Id*. at 27.

224. *Id*. at 27-28.

225. *See id*. at 6.

226. *See id*. at 22 (using the example of the best practices for preventing MRSA in hospitals).

227. *See* Tom Wilbur, *IP Explained: Myth vs. Fact About Strong Patent Protections in the Biopharmaceutical Industry*, PHRMA: THE CATALYST (May 2, 2019), https://perma.cc/6XD4-82SE (broadly claiming that that strong patent protection "is the most effective tool to reward and incentivize innovation").

228. *See* Mark Grayson, *5 Reasons Why Biopharmaceutical Patents Are Different*, PHRMA: THE CATALYST (Sept. 10, 2015), https://perma.cc/562Q-YCTH.

pandemic has created sufficient demand, directing resources toward the development of vaccines is antithetical to market incentives.[229] The case of Ebola shows how obstructive the market approach can be to the creation of social value. After Canada's National Microbiology Laboratory had developed and produced in 2005 a vaccine for Ebola that was highly effective in animals, a small private company licensed it for $200,000, failing to take the vaccine any further before sublicensing it to Merck for $50 million in 2014 after the Ebola outbreak in Africa.[230] Not only was the company's involvement unnecessary but it ultimately slowed down development of the vaccine, with Merck receiving approval for its vaccine only in 2019.[231]

Furthermore, despite patent rights frequently being cited by pharmaceutical companies as the necessary incentive for producing lifesaving drugs, the patent protection model has failed to drive effective research on infectious diseases such as coronaviruses.[232] Although emerging viruses present significant scientific challenges, in 2019, prior to the outbreak of COVID-19, there were only six active coronavirus clinical trials.[233] Had the potential risk driven companies to increase their coronavirus research, the medical community would likely have been better placed to address the challenges of the pandemic. However, market-oriented pharmaceutical companies do not proactively invest research effort in medical treatments and vaccines likely to yield low profits. Instead, they pursue only the most lucrative avenues of research. Some pharmaceutical companies have openly admitted that researching vaccines is not in their interest. Instead, they have chosen to fund treatments for chronic conditions, with cancer drugs being a favorite, as they command a high price despite often providing only marginal therapeutic improvements.[234]

By contrast, social innovation driven by nonprofit public institutions has

229. Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1222 (2018) ("Even today, during the inter-outbreak period following the largest and most lethal Ebola pandemic in recorded history, it is not clear that the vaccines currently in advanced clinical development will have a 'clear commercial market.'") (quoting CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY, COMPLETING THE DEVELOPMENT OF EBOLA VACCINES 25 (2017), https://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_team_b_report_3-011717-final_0.pdf); Juliana Broad, *Coronavirus and Ebola Show We Can't Leave Vaccine Development to Big Pharma*, TRUTHOUT (Mar. 9, 2020), https://perma.cc/22N3-LWE9.

230. *See* Broad, *supra* note 229; Zain Rizvi, *Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model*, PUB. CITIZEN (Feb. 19, 2020), https://perma.cc/A8GL-35FF.

231. *See* Broad, *supra* note 229.

232. Rivzi, *supra* note 230.

233. *Id*.

234. *Id*. ("Out of the 20 largest pharmaceutical companies, only four have major vaccine programs. One of the remaining vaccine producers, GSK, has decided to curtail its epidemic response work. A senior executive noted, 'We do not want to have these activities compete with in-house programs. And our learnings from Ebola, from pandemic flu, from SARS previously, is that it's very disruptive and that's not the way that we want to do business going forward.'").

contributed tremendously to deadly infectious disease responses, primarily in the form of funding and grants. A recent report on the Ebola vaccine found that it was "almost entirely researched and developed using public money."[235] Following the COVID-19 pandemic outbreak, the U.S. government launched Operation Warp Speed with the aim of delivering over 300 million doses of a safe and effective vaccine by January 2021 through public investment in vaccine development, manufacturing, and distribution capabilities.[236] Examples of this public investment include $456 million in funds for Johnson & Johnson. Haochen: see the new footnote],[237] $955 million for Moderna, and up to $1.2 billion for AstraZeneca for their respective vaccine candidates.[238] The U.S. National Institutes of Health has issued over 1,500 grants for research into COVID-19.[239]

IV. CREATING PATENT RESPONSIBILITIES

Both the COVID-19 pandemic and the social nature of innovation, as Parts II and III show, run counter to the asymmetry of strong rights and weak responsibilities supported by patent law's utilitarian theory and the lone inventor thesis.[240] In this part, I argue that the lessons gleaned from the COVID-19 pandemic and the social nature of innovation support reform of patent law so as to require patent holders to take stronger responsibilities. Drawing on ethical and political theories of responsibility,[241] I propose three major responsibilities that patent holders should fulfill in order to promote innovation in the public interest.

235. *See* Broad, *supra* note 229; Matthew Herder, Janice E. Graham & Richard Gold, *From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*, J.L. & THE BIOSCIENCES 3-4 (2020) ("Public sources contributed over 73% (USD$758.8 million) of the USD$1.035 billion allocated to Ebola and other filovirus research from 1997 to 2015.").

236 . *Coronavirus: Operation Warp Speed,* U.S. DEP'T OF DEFENSE, https://perma.cc/QL37-VNUB.

237. *See* Noah Higgins-Dunn, *Johnson & Johnson Reaches Deal with U.S. For 100 Million Doses of Coronavirus Vaccine at More Than $1 Billion*, https://www.cnbc.com/2020/08/05/jj-reaches-deal-with-us-for-100-million-doses-of-coronavirus-vaccine-at-more-than-1-billion.html.

238. *See* Berkeley Lovelace Jr. & Nate Rattner, *Coronavirus Vaccine Frontrunner Pfizer Delivers Key Trial Data – Here's Where the Other Vaccines Stand*, CNBC (Nov. 9, 2020),

239 . Search Results, NIH RSCH. PORTFOLIO ONLINE REPORTING TOOLS (2020), https://perma.cc/C49U-TL9V (last visited Apr. 5, 2021).

240. *See* text accompanying *supra* notes 63-75231.

241. This discussion about reciprocity, role responsibility, and social justice is a modified version of my previous analysis of these ideas published in the *University of Miami Law Review*. *See* Haochen Sun, *Corporate Fundamental Responsibility: What Do Technology Companies Owe the World?*, 74 U. MIAMI L. REV. 898, 923-25, 929-32, 937-41 (2020).

A. Responsibility to Reciprocate

1. Reciprocity

The ethical norm of reciprocity requires that we return proportionately the positive actions of others,[242] overcoming our selfish impulses to consider how we can act in their interest in return.[243] Using friendship to illustrate the importance of reciprocity, Aristotle characterized a positive friendship as one in which two persons treat each other as equals and are willing to reciprocate admiration and good deeds.[244] Otherwise, a negative friendship develops because the two persons involved care only about their own utility or pleasure.[245] Cicero regarded reciprocity as the bedrock of all ethical norms, emphasizing that "there is no more essential duty than that of returning kindness received" and that "to omit the returning of kindness is impossible for a good man."[246] Reciprocity provides us with the expectation that the recipient of our kindness will ultimately respond positively,[247] and, through the repetition of reciprocal actions, we become more willing to both initiate and respond to positive deeds.[248] Thus, reciprocity has intrinsic value in stabilizing interpersonal relationships and societal institutions and, as a result, is *universally* accepted and practiced.[249]

Reciprocity involves two specific responsibilities. First, we have a responsibility to appreciate positive actions done for us by others.[250] Instead of showing indifference, we should be willing to recognize benefits received and identify the ways in which those benefits have promoted our well-being. Second, motivated by the process of appreciation for benefits received, we have a responsibility to act in return. That act may involve, for example, the repayment of a debt owed according

242. *See* LAWRENCE C. BECKER, RECIPROCITY 3 (1986); FRANCIS FUKUYAMA, TRUST: THE SOCIAL VIRTUES AND THE CREATION OF PROSPERITY 11 (1995) ("Law, contract, and economic rationality . . . must as well be leavened with reciprocity, moral obligation, duty toward community, and trust . . . . The latter are not anachronisms in a modern society but rather the sine qua non of the latter's success.").

243. *See, e.g.*, Alvin W. Gouldner, *The Norm of Reciprocity: A Preliminary Statement*, 25 AM. SOC. REV. 161, 170 (1960).

244. ARISTOTLE, NICOMACHEAN ETHICS bk. VIII, at 147, 149 (Roger Crisp ed. & trans., Cambridge Univ. Press 2000) (c. 384 B.C.E.) ("[I]t is bad people who will tend to be friends for pleasure or utility . . . . But good people will be friends for each other's sake . . . .").

245. *Id.* at 149.

246. MARCUS TULLIUS CICERO, *De Officiis*, *in* ETHICAL WRITINGS OF CICERO 32 (Andrew P. Peabody, trans., Little, Brown, & Co. 1887).

247. *Id.*

248. *See* GEORG SIMMEL, THE SOCIOLOGY OF GEORG SIMMEL 387 (Kurt H. Wolff ed. & trans., The Free Press 1950) (concluding that social equilibrium and cohesion only exist because of "the reciprocity of service and return service").

249. *See* Gouldner, *supra* note 243, at 171–76; *see* DAVID SCHMIDTZ, THE ELEMENTS OF JUSTICE 79 (2006) (arguing that reciprocity induces cooperation and "enables people to live together in mutually respectful peace").

250. *See, e.g.*, SCHMIDTZ, *supra* note 249, at 76 ("The art of reciprocity is partly an art of graciously acknowledging favors.").

to a contract,[251] the expression of appreciation verbally or in writing, or the provision of assistance or care.[252]

On the basis of reciprocity, I argue in the two following sections that patent holders should assume two major responsibilities: the *ex ante* responsibility to reciprocate the grant of patent rights by faithfully fulfilling the patent disclosure requirement and the *ex post* responsibility to reciprocate public funding for their innovations by lowering the prices of their patented products or their amount of patent royalties.

2. Responsibility for Patent Disclosure

Redefining the nature of the patent disclosure requirement is a sensible way of dealing with the major problems with that requirement discussed in Part I. Conventionally, patent law has treated insufficient disclosure as a legal basis for rejecting or invalidating the grant of a patent. Accordingly, the law places the inadequate disclosure burden of proof on the patent examiner rather than on the patent applicant to show adequate disclosure.[253] A 2003 report by the Federal Trade Commission summarizes the major problem with that rule for the burden of proof:

The *ex parte* nature of the [examination] proceeding leaves the examiner on his or her own to evaluate and challenge applicants' assertions. Because the courts have placed the burden on the PTO to demonstrate grounds for rejecting a patent, rather than on the applicant to demonstrate that it meets the statutory criteria, difficulties in assembling responsive evidence work in favor of patent applicants.[254]

The conventional characterization of patent disclosure has therefore rendered patent examiners and courts reluctant to reject or invalidate patents on the ground that they lack an enabling disclosure.[255] In addition, confusingly drafted

251. *See* SIMMEL, *supra* note 248, at 387 (commenting that "[a]ll contacts among men rest on the schema of giving and returning the equivalence").

252. *See, e.g.*, IRIS MARION YOUNG, INCLUSION AND DEMOCRACY 30 (2000) ("The conditions of equal opportunity to speak and freedom from domination encourage all to express their needs and interests. The equality condition also requires a reciprocity such that each acknowledges that the interests of the others must be taken into account in order to reach a judgement.").

253. *See* Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 1015 (2013) (contending that the nature of patent disclosure has actually required examiners to make affirmative rejections, which creates a presumption of patentability that they must rebut in order to reject patent applications).

254. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8 (2003), https://perma.cc/4ZHG-N4YK.

255. *See* Chien, *supra* note 60, at 1862-63 ("[A]ccording to a study of patent applications, of all grounds of rejection, enablement was the least used ground for rejection among bioinformatics applications and the second-to-least used by examiners among data-processing applications. Based on an analysis of published district court decisions from 2008 to 2009, enablement and written description were among the least asserted grounds for invalidity during litigation.").

and scientifically limited patents offer little help to researchers hoping to put the information therein into practice. In a survey of nanotechnology researchers looking to patents for technical information, 60 percent indicated that they found useful information, but only 38 percent indicated that the information found was reproducible.[256] This outcome is significant because "[w]hen specifications fail to teach how protected technologies operate, they subvert the disclosure function of patent law."[257]

Following the ethical norm of reciprocity, I argue that patent disclosure should be redefined as an *ex ante* responsibility that patent holders should faithfully fulfill in return for the grant of patent rights and others' contributions to sequential and combinatorial innovation, as discussed in Part III.[258] First, the patent holder should bear the burden of proving sufficient disclosure in judicial proceedings challenging a USPTO denial of a patent application. The court could order the patent holder to supply evidence showing that the written description and extra specifications filed with the PTO constituted sufficient information disclosure by demonstrating that they provide information in sufficient detail that a "person having ordinary skill in the art" (PHOSITA) will be able to practice the invention.[259] To meet this enablement responsibility, the patent holder must explain how a PHOSITA would be able to make and use the invention without "undue experimentation."[260]

Second, the patent holder needs to prove that he or she has disclosed information in the best mode possible; that is, he or she has described the best way of making the invention that he or she knew of at the time of the application.[261] More specifically, the patent holder should demonstrate possession of the best mode for practicing the invention and disclose it to the PTO to enable a PHOSITA to practice it.[262] Although patents may no longer be invalidated for a failure to disclose the best mode under the AIA, best mode disclosure is still considered a requirement for receiving a patent.[263]

Third, Congress should enforce the *ex ante* responsibility for information disclosure by introducing new civil and criminal liabilities for patent holders who willfully withhold disclosable patent information. At present, the only legal consequence for a failure to disclose is revocation of the registered patent. Absent other penalties, patent holders may still have a financial incentive to disclose insufficient patent information in the hope that the patent examiners will be unable to detect it. For instance, patent holders could withhold patent information

256. *See* Ouellette, *supra* note **Error! Bookmark not defined.**, at 560-562, 576.
257. *See* Devlin, *supra* note 83, at 411.
258. *See supra* Part III.A & B.
259. Chien, *supra* note 60, at 1856.
260. *Id*.
261. *Id*. at 1857.
262. *Id*.
263. *See* Ouellette, *supra* note **Error! Bookmark not defined.**, at 552.

in order to accumulate a portfolio of patents and exclude competitors in the marketplace.[264] The introduction of civil penalties such as fines and even criminal penalties for fraudulent acts would likely deter the willful non-disclosure of patent information by patent holders.

3. Responsibility for Public Funding

In addition to their *ex ante* responsibility for disclosure, patent holders should also assume an *ex post* responsibility for the public funding they have received. A great deal of public funding has supported essential research, especially the development of life-saving drugs. In the case of the Ebola vaccine, for example, Canadian government scientists were responsible for development from the laboratory bench to a commercial grade product ready for clinical trials, whereas private companies waited for an Ebola outbreak to undertake this process.[265] A number of pharmaceutical companies, including AstraZeneca, Johnson & Johnson, and Moderna, have received public funding to develop COVID-19 vaccines.[266]

A major problem with public funding is that many patent holders fail to reciprocate in the form of benefits to the public. As discussed in Part I, for example, despite public funding support, Gilead overcharges for its patented medicine remdesivir.[267] In addition, the company also charges $20,000 for a one-year course of the patented drug Truvada, approved to prevent H.I.V. infection, even though it too was developed with government funding.[268] In response to such irresponsible pricing, experts have urged the U.S. government to consider why so many patented medicines developed using public funding still "remain unaffordable for millions of Americans."[269]

Similar practices have been seen with respect to patents developed by U.S. universities with the support of public funding. Before 1980, patents resulting from publicly funded research were owned by the U.S. government.[270] The 1980 Bayh-Dole Act,[271] however, triggered a significant increase in patent applications by universities because it entitles U.S. universities to elect to retain title to inventions arising from federally funded research or contract programs and to

264. Devlin, *supra* note 83, at 427-430.

265. *See* Herder et al., *supra* note 235, at 2.

266. *See* U.S. DEP'T OF DEFENSE, *supra* note 236.

267. *See supra* Part I.A.

268. *See* Donald G. McNeil Jr. and Apoorva Mandavilli, *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*, N.Y. TIMES (Nov. 8, 2019), https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html

269. *Id*.

270. Adam Hayes, *When Universities Patent Their Research*, IP WATCHDOG, https://www.ipwatchdog.com/2017/11/20/universities-patent-research/id=90200/.

271. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

license them to firms under certain conditions.[272] The Act was intended to motivate increased investment in the development of patent inventions into commercial products and to encourage technology transfers,[273] as commercial opportunities are seen as a sustainable way of maintaining high-quality, profitable research and innovation at universities in the long run.[274]

Greater levels of patent ownership have also increasingly emboldened elite universities to launch patent litigation. From 2000 to 2009, universities joined their licensees in suing another party for patent infringement in 139 cases. In another 51 cases, universities brought patent infringement suits on their own.[275] Instead of using patents in the public interest to reciprocate for public funding, many universities have adopted "overly litigious" tactics, which effectively makes them patent trolls aiming to extract large damage awards.

A positive way to deal with this dilemma would be to rely on the ethical norm of reciprocity to impose *ex post* responsibility on patent holders. Such responsibility would require patent holders to proactively reciprocate for public funding. First, inventions developed through public funding should be deemed social innovations devoted to promoting the public interest, as shown in Part III.[276] Second, given the social innovation status of such inventions, patent holders should reduce the prices of their patented products or the amount of royalties they receive for licensing those patents. For example, pharmaceutical companies that have received public funding for COVID-19 vaccine development ought to make those vaccines available at a relatively low price. Doing so would make the vaccines available to as many people as possible and would also induce other vaccine developers to follow suit.

To enforce this responsibility to reciprocate, the government should require patent holders to agree to assume such responsibility when submitting funding

272. *See id*.

273. *See* Charles R. McManis & Sucheol Noh, *The Impact of the Bayh-Dole Act on Genetic Research and Development*, *in* PERSPECTIVES ON COMMERCIALIZING INNOVATION 436-37 (F. Scott Kieff & Troy A. Paredes eds., 2012).

274. Peter Lee, *Patent and The University*, 63 DUKE L.J. 1, 32 (2013) (pointing out that "[i]n addition to legislative reforms, scientific advances and the academic patenting"). For example, biotechnology generated enormous enthusiasm on university campuses, as it promised significant therapies and large revenues for academic patentees. Biotechnology also reveals a shift in the nature of research: a trend in moving beyond the passive observation to actively manipulate the basic building blocks of life. This proactive way of research enables more fruitful researches.

275. *Id*. at 42 ("Empirical work by Professor Christopher Holman found that from 2000 to 2009, there were 139 cases in which a university joined a licensee in suing another party for patent infringement and 51 cases in which universities brought patent infringement suits on their own "). Universities participating in lawsuits are in a significant upward trend. There were only 11 lawsuits filed by the universities while 8 cases of universities' participation in 2000. The figure rose to 43 such lawsuits and 22 such cases in 2012 respectively. *See* Jacob H. Rooksby, *Innovation and Litigation: Tensions between Universities and Patents and How to Fix Them*, 15 YALE J.L. & TECH. 312, 338 tbl.1. (2013).

276. *See infra* Part III.C.

applications. If patent holders then fail to fulfill the responsibility faithfully, the government can demand repayment or even sue them for their misuse of public funding.

B. Innovators' Role Responsibility

1. Role Responsibility

Another ethical norm, role responsibility, requires individuals to take responsibility for the specific roles they choose to adopt, such as sea captain, husband, or clerk. These interpersonal roles put the individual in a special position in relation to others whose interests are affected by the performance of certain assigned functions or the fulfillment of assigned goals.[277] In this context, expectations are cast upon the individual to take responsibility for the functions or goals attached to his or her role.[278] As H.L.A. Hart points out, "whenever a person occupies a distinctive place or office in a social organization, to which specific duties are attached to provide for the welfare of others or to advance in some specific way the aims or purposes of the organization, he is properly said to be responsible for the performance of these duties, or for doing what is necessary to fulfil them. Such duties are a person's responsibilities."[279]

Role responsibility triggers accountability toward people whose interests may be affected either directly or indirectly. A sea captain, according to Hart, is responsible for the safety of the ship for the sake of its passengers, and is supposed to exercise due care throughout the journey.[280] A judge is responsible for the impartial adjudication of a given case[281] and must make every effort to fulfill this role responsibility for the parties involved.[282]

To fulfill the accountability triggered by role responsibility, an individual must engage in ethical deliberation about the nature of his or her role, the corresponding responsibilities attached to it, and the ways in which he or she can fulfill those responsibilities. This deliberative function is of critical importance. Hart asserts that "[a] responsible person is one who is disposed to take his duties seriously; to think about them, and to make serious efforts to fulfil them. To behave responsibly

277. H. L. A. HART, PUNISHMENT AND RESPONSIBILITY: ESSAYS IN THE PHILOSOPHY OF LAW 212 (2d ed. 2008)

278. *See* Robin Zheng, *What is My Role in Changing the System? A New Model of Responsibility for Structural Injustice*, 21 ETHICAL THEORY & MORAL PRAC. 869, 874-75 (2018).

279. HART, *supra* note 277, at 212 ("A sea captain is responsible for the safety of his ship, and that is his responsibility, or one of his responsibilities. A husband is responsible for the maintenance of his wife; parents for the upbringing of their children; . . . a clerk for keeping the accounts of his firm.").

280. HART, *supra* note 277, at 212.

281. *See, e.g.*, Lon L. Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 365 (1978).

282. *See id.*

is to behave as a man would who took his duties in this serious way."[283]

There are two key steps in conducting ethical deliberation.[284] First, individuals in specific personal or professional roles must consider the private or societal interests that might be affected by their performance of those roles. For instance, doctors need to be aware of their responsibility to receive adequate medical ethics education.[285] Second, such individuals must consider how to perform their personal or professional roles so as to promote the private or societal interests involved.[286] This process normally requires "care and attention over a protracted period of time,"[287] and failure to do so triggers legal liability or moral blame.[288]

2. Patent Holders' Role as Innovators

As innovators, patent holders should assume a role responsibility to promote innovation. Technology companies play the role of innovators by generating new intellectual properties. In 2019, the top 50 recipients of registered patents were technology companies. IBM topped the ranking, with 9,262 patent applications approved by the USPTO.[289] For many researchers, technology companies provide the means to create, operationalize, and commercialize their inventions, and so they are willing to sign contracts that grant ownership of their employment-related inventions to those companies.

Technology companies are the most forceful drivers of innovation in part because they have institutional capacities to recognize market needs and recruit competent people for R&D,[290] as well as the departments to nurture these capacities. In market research, personnel are specialized in discovering unmet consumer needs, preferences, and desires. R&D department personnel are familiar with existing related technologies, and are able to create new ones according to the needs/preferences/desires identified by the market research team. Financial support for projects, meanwhile, is secured by the finance department.

283. HART, *supra* note 277, at 213.

284. *See* Haochen Sun, *Copyright and Responsibility*, 4 HARV. J. SPORTS & ENT. L. 263, 295–96 (2013) (analyzing the role of moral deliberation).

285. *See* ARISTOTLE, *supra* note 120, at 3 (pointing out that "the end of [the medical art] is health").

286. *See, e.g.*, JUSTIN OAKLEY & DEAN COCKING, VIRTUE ETHICS AND PROFESSIONAL ROLES 74 (2001) (arguing that "a professional role is . . . importantly determined by how well that role functions in serving the goals of the profession, and by how those goals are connected with characteristic human activities").

287. HART, *supra* note 277, at 213.

288. *Id*. at 215–22.

289 . IFI CLAIMS Patent Services, *2019 Top 50 US Patent Assignees*, https://www.ificlaims.com/rankings-top-50-2019.htm. (updated Jan. 8, 2020).

290. *See* Barishnikova O.E. & Nevzorova M.N., *Development of Innovation*, 6 EUR. J. NAT. HIST. 53, 53 (2015) ("Information technology and changing business processes and management style can produce a work climate favorable to innovation . . . .").

Certain limitations on patent rights function to promote innovation. For instance, the experimental use exemption encourages experimentation and innovation that might otherwise be stifled by patent law's granting of limited monopolies to inventors.[291] Although monopolies provide an incentive for the investment in innovation, they undermine patent law's broader goal of promoting the progress of science and technology if they prevent researchers from applying patented inventions in new and useful areas.[292] The experimental use exemption has helped to alleviate this strain on innovation, and has proved important for research institutions.[293]

As discussed in Part I,[294] the *Madey v. Duke University* ruling has led to the near demise of the experimental use exemption. However, Judge Newman has opposed such demise, stating that "the [Federal Circuit] disapproves and essentially eliminates the common law research exemption. This change of law is ill-suited to today's research-founded, technology-based economy."[295] This position has received significant support from the broader research community and many legal scholars. For example, Professor Rochelle Dreyfuss cautions that the demise of the experimental use defense "could lead to research arbitrage, brain drain, and—ultimately—the loss of U.S. technological dominance."[296]

3. Responsibility for Accommodating Limitations on Patent Rights

To fulfill their role responsibility as innovators, patent holders should assume a responsibility to accommodate limitations on patent rights such as experimental use. I suggest that Congress should legislate a general statutory experimental use exemption as a means of ascribing and enforcing patent holders' role responsibility as technology innovators. While this statutory exemption would require patent holders to allow members of the public to make experimental use of their patents, it treats uses for non-commercial and commercial purposes differently. With respect to an experimental use for non-commercial purposes, the user does not need pay any remuneration to its rights owner. However, the exemption would require the user who uses a patented invention for commercial purposes to pay remuneration to its rights owners on fair, reasonable, and non-discriminatory (FRAND) terms.

This statutory exemption would promote the public interest primarily in three ways. First, it does not necessarily rule out experimental uses that are made

291. *See* text accompanying *supra* notes 91-**Error! Bookmark not defined.**.

292. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1075 (1989).

293. *See* Dreyfuss, *supra* note 92, at 717.

294. *See supra* Part I.B.2.

295. Integra Lifesciences I, LTD. v. Merck KgaA, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part), *vacated*, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

296. *See* Dreyfuss, *supra* note 92, at 701.

for commercial purposes. As shown in Part I,[297] the Federal Circuit has categorically invalidated experimental uses for commercial purposes. Some scholars and judges have rejected this judicial ruling as arbitrary and one that does not take full account of the social benefits generated by such uses. For instance, Judge Newman urged courts to distinguish between experimenting with a patent invention in the public interest and experimenting on a patented invention for the user's private financial gain.[298] The former falls within the ambit of experimental use because its purpose is *research* aimed at benefiting the public by improving the patented invention, finding new uses for it, or designing around it.[299] The latter does not because it leads to *development and commercialization* of the patent invention primarily in the user's private interests.[300] The on-going COVID-19 pandemic has also called into question the categorial ban on any experimental use with a commercial purpose. If a pharmaceutical company experiments with a patented vaccine to test whether it can immunize people against all existing and future COVID mutants better than the patent vaccine, such an experimental use has a commercial character and would be invalidated according to the Federal Circuit's reasoning (assuming the company will sell its vaccine in the marketplace.) Nevertheless, this experimental use promotes public health by finding the most effective means of combating COVID mutants, and should be therefore be deemed non-infringing.

Second, the proposed statutory exemption creates a new avenue for promotion of scientific progress by encouraging patent holders to fulfill their role responsibility as technology innovators. Conventionally, experimental use is deemed a defense to the allegation of patent infringement.[301] A liberal understanding of experimental use has treated it as a right enjoyed by members of the public.[302] By contrast, the proposed statutory exemption is intended to redefine

297. *See* text accompanying *supra* notes 92-103.

298. *See* Integra Lifesciences I, LTD. v. Merck KgaA, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) ("[T]he patent system both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology."); Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NW. J. TECH. & INTELL. PROP. 61, 74 (2005). ("Drawing a distinction between research and development, Judge Newman reasoned that research with a patented invention will fall within the exemption while research on an invention (development and commercialisation) will not.").

299. *See id*. at 875 ("The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it.").

300. *See id*. at 875 ("[T]he patent is infringed by and bars activity associated with development and commercialization of infringing subject matter…").

301. *See* Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (stating how a use of a patent can qualify for "the very narrow and strictly limited experimental use defense"); Sonya J. Bible, *Does the Experimental-Use Defense to Patent Infringement Still Exist*, 13 SMU SCI. & TECH. L. REV. 17, 19 (2010) ("Since the early 1800s, the recognition of experimental use as a defense to patent infringement has continually evolved ….").

302. *See* Integra Lifesciences I, LTD. v. Merck KgaA, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) ("The right to conduct research

experimental use as a responsibility imposed on patent holders given their role responsibility to promote innovation in the public interest. So redefined, it would require patent holders to accommodate experimental uses that produce this positive effect regardless of whether they are made for commercial purpose or not.

Third, the proposed statutory exemption safeguards patent holders' private interests through the FRAND terms. Professor Eisenberg has suggested that experimental use may permit researchers to use patents without obtaining rights holders' authorization. But in certain types of cases, users should be charged a "reasonable royalty" after they develop new inventions so as to compensate for patent holders' initial investment.[303] Professor Dreyfuss has proposed that patents should be licensed for experimental use on reasonable and nondiscriminatory licensing (RAND) terms as "a feasible way of ensuring the accessibility of materials that are needed to facilitate [such use]."[304] Similarly, the proposed statutory exemption is intended to appropriately compensate patent holders whose patents are used for commercial purposes, but applies a different approach to providing compensation. Under the exemption, researchers can first use patents for experimental purposes without the patent holders' authorization, but they need to pay a reasonable amount of royalties on FRAND terms if they obtain financial gains through this use. The introduction of FRAND terms legalizes unauthorized experimental use, at the same time ensuring that patent holders receive a fair share of financial gains from users' inventions.

In the following discussion, I focus on how patent holders should be remunerated on FRAND terms for experimental uses conducted for commercial purposes. I will first examine the nature and scope of the FRAND terms and then consider how their application can contribute to a revival of the experimental use limitation on patent rights.

a. FRAND Terms

Standard essential patents (SEPs) are foundational patents required for devices to be interconnectable and interoperable on the same standard or network.[305] Standardization can bring many benefits to manufacturers and consumers. Compliance with a standard enhances the value of a manufactured product because it allows other manufacturers to produce related compatible devices.

Licensing SEPs on FRAND terms ensures that interoperability actually occurs without undue influence from market monopoly and patent hold-up.[306] It is

to achieve such knowledge need not, and should not, await expiration of the patent.").

303. *See* Eisenberg, *supra* note 292, at 1078.

304. *See*. Dreyfuss, *supra* note 92, at 719.

305. *See generally,* Doris Johnson Hines & Ming-Tao Yang, *Worldwide activities on licensing issues relating to standard essential patents*, https://www.wipo.int/wipo_magazine/en/2019/01/article_0003.html.

306. *Microsoft Corp. v. Motorola Inc.*, 696 F.3d 872, 876 (9th Cir. 2012) (finding that

also in the interests of the public to ensure that potential competitors are actually able to compete and innovate. Without FRAND terms, SEP holders could monopolize the market by creating an essentially infinitely high barrier to entry.[307] On the other hand, the FRAND commitment enables the SEP holder to get fair compensation from licensing its SEPs.[308]

The meanings of FRAND terms are often ambiguous because standard setting organizations sometimes adopt vague language in their IP policies, leaving the terms to the courts for interpretation.[309] While scholars and practitioners continue to debate what it means for terms to be fair, reasonable, and non-discriminatory,[310] this does not preclude us from understanding the core features of FRAND terms. The underlying licensing terms must be fair to both licensors and licensees. Borrowing a concept from antitrust law, a fair term is a term that does not have the object or effect of harming competition. Examples of unfair anticompetitive contractual obligations are tying, bundling, and exclusive dealing. Reasonableness of the terms concerns licensing rates. It is generally accepted by the courts that the SEP holder should be awarded a reasonable royalty based on the incremental value of the SEP added to the end product,[311] but there is no consensus on how the royalty is calculated.[312]

The non-discriminatory term requires the SEP holder to license its patent to all parties if they are willing to pay the FRAND rate.[313] However, it does not impose an obligation on the SEP holder to license its patent on identical terms to every licensee as their circumstances may not be equivalent. They may have different backgrounds, levels of goodwill and assets, desires and needs that justify differential treatment. The SEP holder is only obliged to offer similar terms to

an SEP could give the patent holder disproportionate market power and permit him or her to "extract unreasonably high royalties from suppliers [and users] of standard-compliant products and services").

307. *See* Benjamin C. Li, *The Global Convergence of Frand Licensing Practices: Towards "Interoperable" Legal Standards*, 31 BERKELEY TECH. L.J. 429, 434-35 ("Many SSOs have . . . adopted FRAND policies to prevent SEP holders from exercising this type of unjustified post-adoption leverage.").

308. Kirti Gupta, *Technology Standards and Competition in the Mobile Wireless Industry*, 22 GEO. MASON L. REV. 865, 868 (2015).

309. *See, e.g.*, Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CALIF. L. REV. 1889, 1913 (2002).

310. Richard Li & Richard Li-dar Wang, *Reforming and Specifying Intellectual Property Rights Policies of Standard-Setting Organizations: Towards Fair and Efficient Patent Licensing and Dispute Resolution*, 2017 U. ILL. J.L. TECH. & POL'Y 1, 15 (2017).

311. *See, e.g.,* Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1226 (Fed. Cir. 2014) ("The essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product.").

312. Li, *supra* note 307, at 432.

313. *See, e.g.,* Microsoft Corp. v. Motorola, Inc., 795 F.3d 1024, 1031 (9th Cir. 2015) ("Under [FRAND] agreements, an SEP holder cannot refuse a license to a manufacturer who commits to paying the [F]RAND rate.").

similarly situated prospective licensees. Non-discrimination is an important requirement because it ensures that market participants, including new entrants, are on a level playing field and able to compete in the same technology area. It also ensures that no one is unfairly excluded from opting in to the standard.

b. Licensing Patents for Experimental Use

As I have suggested, the proposed statutory exemption would require that patent holders license their patents for experimental use on FRAND terms should such use be conducted for commercial purposes. Akin to SEP licensing, the proposed application of the FRAND terms for experimental use would promote the public interest in stimulating *sequential, combinatorial,* and *social* innovations as discussed in Part III in a healthily competitive environment and sharing knowledge with the public at lower cost. To license such patents on FRAND terms, a patent holder should proactively take the following measures.

First, patent holders should make their inventions available for experimental use on FRAND terms to any and all interested parties. By sharing inventions with companies that can commercialize them to benefit society at large, patent holders can maximize return on research dollars. In contrast, a patent holder that abuses their bargaining power by unfairly extracting large royalties from licensing patents undermines the utilization of its inventions.

Second, patent holders should not discriminate in making available their patents by category, industry, or location in the supply chain. Not all private businesses should be treated as patent holders' competitors. Patent holders should not exclude any party from having access to their inventions as long as the party agrees to accept FRAND terms.

Third, patent holders should set an appropriate FRAND royalty base for licensing its patents for experimental use. The base should be calculated based on the smallest saleable patent practicing unit to account for royalty stacking considerations. Moreover, the base should further exclude any value associated non-patented features and contributions and innovations of others. Patent holders should make the calculation process transparent by publicizing the relevant information such as the amount of FRAND royalties.

C. The Responsibility to Confront Injustices Created by Patent Protection

1. Social Injustice

All human beings are equal in dignity and freedom, a status legally recognized in both international human rights treaties and national constitutions.[314]

314. For example, Article 1 of the Universal Declaration on Human Rights states that, "[a]ll human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." G.A.

However, injustice is a part of every society. The unjust distribution of social resources is causing increasing disparities in income,[315] while status injustices caused by discrimination based on race, gender, and sexual orientation still exist in the U.S. and in many other countries.

Social justice is widely regarded as a fundamental value intended to minimize the impacts of the unequal distribution of resources and status discrimination, and has been called the "first virtue of social institutions."[316] By nature, social justice centers on how to allocate responsibilities for distributing resources and social status. Rawls captures the essence of this responsibility-based notion of social justice as follows.

> This conception [of justice] includes what we may call a *social division of responsibility*: society, the citizens as a collective body, accepts the responsibility for maintaining the equal basic liberties and fair equality of opportunity, and for providing a fair share of the other primary goods for everyone within this framework, while citizens (as individuals) and associations accept the responsibility for revising and adjusting their ends and aspirations in view of the all-purpose means they can expect, given their present and foreseeable situation.[317]

The foregoing statement shows that central to social justice is the distribution of responsibilities among citizens. Rawls further argues that "the principles of social justice . . . provide a way of assigning rights and duties in the basic institutions of society and they define the appropriate distribution of the benefits and burdens of social cooperation."[318]

2. Social Injustices and Patent Protection

Strong patent protection can cause two major social injustices in enjoying the benefits of technological progress. It first gives rise to the concern that technology companies have not adequately fulfilled their social justice responsibility to promote affordable access to technological benefits accrued from inventions.

Res. 217 (III) A, Universal Declaration of Human Rights, art. 1 (Dec. 10, 1948).

315. *See generally* THOMAS PIKETTY, CAPITAL IN THE TWENTY-FIRST CENTURY 430–32 (Arthur Goldhammer trans., 2014) (surveying the growing inequality in distribution of resources); Ilyana Kuziemko & Stefanie Stantcheva, *Our Feelings About Inequality: It's Complicated*, N.Y. TIMES (Apr. 21, 2013), https://opinionator.blogs.nytimes.com/2013/04/21/our-feelings-about-inequality-its-complicated ("Since the 1970s, income inequality in the United States has increased at a historic rate. In 1970, the richest 1 percent of Americans enjoyed 9 percent of total national pre-tax income. In 2011, by contrast, that share had risen to 19.8 percent.").

316. JOHN RAWLS, A THEORY OF JUSTICE 3 (Harvard Univ. Press rev. ed. 1999) [hereinafter RAWLS, A THEORY OF JUSTICE]. Rawls also points out that "[a] theory however elegant and economical must be rejected or revised if it is untrue; likewise laws and institutions no matter how efficient and well-arranged must be reformed or abolished if they are unjust." *Id*.

317. JOHN RAWLS, *Social Unity and Primary Goods* (1982), *reprinted in* COLLECTED PAPERS 359, 371 (Samuel Freeman ed., Harvard Univ. Press 1999) (emphasis added).

318. RAWLS, A THEORY OF JUSTICE, *supra* note 316, at 4.

With the set of strong exclusive rights, patent holders can maximize their profits by charging prices as high as possible, so long as their inventions have viable market demands from those who are financially capable.[319] Their patent power, however, exclude those who are financially unable to afford their inventions from benefiting from the technological progress they created. Pharmaceutical inventions epitomize this worsening social injustice, which frequently causes matters of life or death. For instance, most patented medicines developed for curing cancers are too expensive for many patients to afford. Just over a decade' time, prices of such life-saving medicines have virtually doubled in the U.S.[320] Eleven of the twelve cancer medicines approved by the U.S. Food and Drug Administration in 2012 were each "priced above US$ 100,000 per year."[321]

Another major social injustice that technological companies have not made efforts to correct is the development of technologies for those neglected population. Given the profits-driven incentives created by strong patent protection, pharmaceutical companies typically invest in the research and development of new medicines that can yield high market returns. [322] However, most of them do not develop medicines for neglected diseases that affect comparatively small proportions of the relevant populations. It has been revealed that patenting of medicines for neglected diseases is quite limited. The total number of filed patents for cardiovascular diseases or cancer is at least 200 times larger than neglected diseases.[323]

The ongoing COVID-19 pandemic has also exposed the conflict between patent protection and social justice. Private pharmaceutical companies do not guarantee universal affordable access to medicines and vaccines for deadly infectious diseases. The control granted by intellectual property allows these companies to set exorbitant prices, delay competition, and, in the process, minimize the role of taxpayer investments in the development of important medical treatments.[324] The privatized nature of pharmaceutical production has slowed pandemic relief measures at the expense of the clear public interest in fast and affordable access

319. *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* 21 (2016) ("IP rights confer patent monopolies on the right holder, who in turn often charges whatever price the market will bear."); Blasi, A. (2012) An ethical dilemma: Patents & profits v. access & affordability. Journal of Legal Medicine, 33(1), pp.115-128.

320. *Report of the United Nations Secretary-General's High-Level Panel on Access to* Medicines, *id*. at 21.

321. *Id*. at 21.

322. *Id*. at 8; *see* text accompanying *supra* notes 229-231.

323. Folahanmi Tomiwa Akinsolu et al., *Patent landscape of neglected tropical diseases: an analysis of worldwide patent families*, 13 Global Health 2017; 13: 82., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5686799/ ("The gap between patenting NTDs and cardiovascular diseases/cancers is striking; the number of filed patents for cardiovascular diseases or cancer is at least 200 times larger than NTDs.").

324. *See* Rizvi, *supra* note 230.

to essential medicine.[325] Experts have estimated that without significant policy changes to address the vastly unequal distribution of vaccines globally,[326] most poor countries will not be able to achieve mass vaccination against COVID-19 until 2024.[327]

The COVID-19 pandemic is likely to result in further conflict between private patent owners and national governments attempting to secure the drugs and treatments necessary to protect their citizens. To promote social justice by guaranteeing equal access to COVID-19-related drugs and vaccines, countries have utilized compulsory licensing. A few developed countries have revised their laws concerning compulsory licensing. Canada has long been a proponent of compulsory licensing, but until recent legislation was introduced circumstances constituting public health-related national emergencies were relatively narrow.[328] However, after amendments introduced by the COVID-19 Emergency Response Act, a compulsory license may be issued if the application includes a confirmation that the Chief Public Health Officer believes there to be a public health emergency of national concern.[329] Germany has traditionally been opposed compulsory licensing, largely because it is home to two of the world's largest pharmaceutical companies, but has softened its approach in recent years.[330] In response to COVID-19, the country went further by introducing legislation which empowers the state, in case of an epidemic situation of national importance, to order under § 13(1) of the Patent Act that medical inventions be used in the interest of public welfare.[331]

Other developed countries have issued compulsory licensing orders. In March 2020, Israel issued a compulsory license to import generic versions of AbbVie's antiretroviral drug Kaletra, after the Ministry of Health determined that it could be a possible treatment for patients with COVID-19.[332] Following

325. King, *supra* note 215.

326. Rajiv J. Shah, *The Choice for Rich Nations: Help Vaccinate the Developing World, Or Face A Prolonged Pandemic*, FORTUNE (Mar. 19, 2021), https://fortune.com/2021/03/19/rich-countries-covid-vaccine-developing-world-options/ ("Unfortunately, vaccination distribution has thus far been deeply inadequate and inequitable.").

327. Michael Safi, *Most Poor Nations 'Will Take Until 2024 to Aachieve Mass Covid-19 Immunisation'*, GUARDIAN (Jan. 27, 2021), https://www.theguardian.com/society/2021/jan/27/most-poor-nations-will-take-until-2024-to-achieve-mass-covid-19-immunisation.

328. *See* Kumar, *supra* note 110, at 25-26.

329. Patent Act, R.S.C. 1985, c P-4 §§ 19.4(1), 19.4(2) (Can.), amended by COVID-19 Emergency Response Act, S.C. 2020, c 5 § 51 (Can.).

330. *See* Kumar, *supra* note 110, at 28-29. ("Germany is home to two top-twenty pharmaceutical companies—Bayer and Boehringer Ingelheim. . . . In the 2017 case Merck Sharpe v. Shinogi, the Federal Court of Justice (FCJ) affirmed for the first time the Federal Patent Court's (FPC's) award of a § 24.1 compulsory license.").

331. Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen ('Act on the Prevention and Control of Infectious Diseases in Humans') §§ 5(1), 5(2)5 (2020).

332. Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, J. GLOB. HEALTH, http://www.jogh.org/documents/issue202001/jogh-10-010358.htm.

the decision AbbVie made a commitment to "take all steps necessary to remove any potential barriers" for generic manufacturers, a process that includes dedicating their intellectual property rights to the public.[333] Though the decision did not involve the introduction of any new legislation, it so far amounts to the strongest action taken yet by any government of a developed country.[334] It has been suggested AbbVie's swift and dramatic response could be to dissuade governments from feeling compelled to take similar action in the case of future global health crises.[335]

3. Responsibility for Facilitating Universal and Affordable Access to Patented Medicines

Patent holders should assume a responsibility to cooperate with the government in reducing the tension between social justice and patent protection. Specifically, they should provide reasonable support for governmental schemes to achieve universal and affordable access to patented medicines essential to protecting public health.[336] In this section, I argue that as patent holders of medical inventions, pharmaceutical companies should assume, among others, two major social justice responsibilities. One is to take proactive actions to share the benefits of the patented medical inventions through schemes such as technology transfer and medical donations. The other is to cooperate with the government in implementing compulsory licensing orders issued to contain public health crises.

With respect to the first social justice responsibility, the U.S. government should require pharmaceutical companies to devote resources to sharing the benefits of their patented medical inventions. I refer to this requirement as the Patent Philanthropy Initiative. According to the initiative, for each patent it acquires from the USPTO a pharmaceutical company would be required to make a corresponding contribution to a domestic or global social welfare program. A pilot initiative program could be administered by the USPTO with each pharmaceutical company required to contribute 1% of its annual post-tax sales volumes derived from its patented inventions. Pharmaceutical companies would be allowed to take various actions to fulfill this responsibility. For instance, they may transfer technology to a company located in a developing country to boost production and distribution of medicines for neglected diseases. They may donate medical products and equipment to a not-for-profit organization or a developing country

333. Ed Silverman, *AbbVie Will Allow Generic Copies of Its HIV Pill in Israel After the Government Approved a License*, STAT NEWS (Mar. 20, 2020), https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/.

334. *See* Kumar, *supra* note 110, at 28-29.

335. *See* Kumar, *supra* note 110, at 26.

336. *See* Ruth L. Okediji, *Does Intellectual Property Need Human Rights?*, 51 N.Y.U. J. INT'L L. & POL. 1, 43, 35 (2018) (arguing that "access to medicines remains a key and growing challenge in virtually all countries" and "medicines need to be available for all and not only for those who can afford them").

in dire need of them. Alternatively, they may deploy staff to train and boost the knowledge and skills of medical professionals in low-income regions in the U.S. or developing countries.

The COVID-19 pandemic has demonstrated the potential efficacy of the proposed initiative. Despite global calls that patent rights concerning COVID-19 vaccines be waived, many leaders and experts have pointed out it is more effective and urgent to capitalize on direct technology transfer associated with production of vaccines and donation of manufacture ingredients and equipment to ramp up the availability of vaccines in developing countries around the world.[337] In response to public health crises, the Patent Philanthropy Initiative would encourage pharmaceutical companies to increase technology transfer and donation of manufacture ingredients and equipment to boost the production and distribution of vaccines as well as medicines. After containment, the initiative would further promote in the long term the medical capacities of low-income regions in the U.S. and developing countries.

The USPTO should require each pharmaceutical company to submit an annual report detailing the nature, scope and effects of its actions taken in fulfillment of the responsibility attached to each of its medical inventions. I suggest that the USPTO should review those reports every five years with a panel consisting of its own administrators, independent patent experts, auditing professionals and public interest activists. The panel would decide whether a relevant pharmaceutical company has met its responsibility to devote 1% of its annual post-tax sales volumes derived from its patented inventions to social welfare programs. If the panel finds that a company has failed to fulfil the responsibility, it will make recommendations to the USPTO on expeditious actions the company should take to mitigate its shortcomings. Every 10 years, the USPTO should conduct a comprehensive review of the Patent Philanthropy Initiative, studying its efficacy and how it should be improved with new measures to boost social welfare and safeguards to protect pharmaceutical companies' interests. Therefore, the initiative would continue creating dynamic schemes reflective of social and technological developments.

A profound lesson from the COVID-19 pandemic is that it is time for the

337. *See* Katie Jennings Aayushi Pratap, *Waiving Patents On Covid-19 Vaccines Isn't Enough To Speed Up Production*, FORBES (May 4, 2021), https://www.forbes.com/sites/aayushipratap/2021/05/04/waiving-patents-on-covid-19-vaccines-isnt-enough-to-speed-up-production/?sh=201edacd14f9&fbclid=IwAR3rUHyVy5Z0FKQcQxuYCr8kIk2me4KXRgTB60dctPTWZEy0N4L2SbQruLI ("Patents and intellectual property rights are only one constraint in a much bigger and complex vaccine manufacturing global supply chain that requires technology transfers, equipment and trained personnel."); Hannah Kuchler, *Will a Suspension of Covid Vaccine Patents Lead to More Jabs?*, Financial Times (May 6 2021), https://www.ft.com/content/b0f42409-6fdf-43eb-96c7-d166e090ab99 ("Efforts to mass produce Covid-19 vaccines on an unprecedented scale have been constrained by various bottlenecks, including limited supplies of materials such as lipid nanoparticles and equipment such as bioreactor bags.").

U.S. to amend patent law to introduce a more effective compulsory licensing system. This amendment would create a moral mandate, requiring pharmaceutical companies to responsibly cooperate with the government to contain public health crises.[338] To this end, Congress should consider amending the Patent Act by ushering in a limited "public-health related working requirement." This would require the owner of a patent granted by the U.S. to practice the invention within the country or face the prospect of a compulsory license. Despite historic attempts to abolish a working requirement from international intellectual property treaties,[339] many countries retain a patent working requirement in some form, with importation usually sufficient to satisfy it.[340] Previous attempts to introduce such a requirement in the U.S have so far been unsuccessful.[341]

Proponents of the working requirement suggest that its introduction would violate the TRIPS Agreement, which contains no provision specifically addressing working requirements. They argue it is implied, but ultimately no binding interpretation of the issue exists.[342] Were the requirement to be introduced under the U.S. Patent Act, Article 31 of the TRIPS Agreement containing the minimum standards for compulsory licensing provisions would need to be satisfied. For instance, petitioners would need to show they had first attempted to negotiate a patent license except in the case of a national emergency.[343] Furthermore, any law would likely need to ensure that petitioners are capable of producing the drug and address FDA obstacles to new manufacturers producing drugs during shortages. Although the U.S. is largely against compulsory licensing, provided it is

338. *See* MADHAVI SUNDER, FROM GOODS TO A GOOD LIFE: INTELLECTUAL PROPERTY AND GLOBAL JUSTICE 187 (2012) (arguing that compulsory licensing is designed to "correct a moral failure, not a market failure").

339. *See* Kumar, *supra* note 110, at 16 ("Pharmaceutical industry groups argue that working requirements are prohibited under Article 27(1) [of the TRIPS Agreement], and force drug manufacturers to set up costly local facilities and to expend resources training local workers.")

340. Marketa Trimble, *Patent Working Requirements: Historical and Comparative Perspectives*, 6 U.C. IRVINE L. REV. 483, 493-496 (2016). ("During the 1911 Washington Conference, Germany and the United States both argued in favor of abolishing working requirements. However, the idea of a complete abolition of the requirement did not enjoy sufficient support among the other national delegations . . . . During the 1925 Hague Conference, only three countries opposed the abolishment of the working requirement.").

341. *See* Mark W. Lauroesch, *General Compulsory Patent Licensing in the United States: Good in Theory, But Not Necessary in Practice*, 6 SANTA CLARA HIGH TECH. L.J. 41, 42-43 (1990).

342. *See* Trimble *supra* note 340, at 696. ("[S]ome commentators have suggested that some of its provisions do affect working requirements, specifically, the provisions that prohibit discrimination based on the place of invention and based on whether the invention is manufactured locally or is imported. . . . [C]ommentators have inferred from the Agreement that countries must accept importation as satisfying the working requirement.").

343. *See* TRIPS Agreement, supa note 127, art. 31 (b) (stating that "such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time").

limited to public health crises such as the current COVID-19 pandemic the working requirement approach could be easier for opponents to accept. This is because it avoids market intervention until private companies making use of the U.S. patent system have failed to provide any medicine to the country. As evidenced by the COVID-19 pandemic, it is very unlikely large pharmaceutical companies would ignore the market offered by the U.S. in such times, but a working requirement could provide an essential safety measure for the U.S. government.

Congress should also guarantee that application of the "public-health related working requirement" will provide *fair* compensation to affected pharmaceutical companies. For example, 28 USC § 1498 entitles the patent holder to claim "compensation" when his or her patent is subject to a compulsory license. But the law does not make clear the nature of compensation. By creating the "public-health related working requirement," Congress should make clear in the amendment that fair compensation should be provided to the patent holder. The Spanish patent regime includes an especially aggressive provision allowing the state to take ownership of patents in circumstances of public interest and, in recognition of the severity, it is stated that compensation received by patent owners will be fair.[344] Although the proposed working requirement is not so aggressive, the provision of *fair* compensation would be an important concession.

There are many different perspectives on what amounts to fair compensation, especially between governments and pharmaceutical companies. For example, past government compulsory license royalty rates have ranged from 0.5% to 4%, whereas pharmaceutical companies have tended to reach agreements for royalties ranging from 4% to 5%.[345] Several royalty systems have been established across the globe which could provide a framework for the U.S. to consider. For instance, the United Nations Development Program's 2001 Guidelines set a base royalty rate of 4 percent which can be increased or decreased by up to 2 percent based on special factors such as whether the product is particularly innovative or whether the government has contributed to research and development.[346] Similarly, the Japanese Patent Office's 1998 Guidelines set a base rate of 2 to 4 percent which can be increased by 2 percent, creating a range of 0 to 6 percent.[347] A completely different approach is provided by the Tiered Royalty Method which, instead of calculating the royalty from generic product sales in the license issuing country, bases the royalty rate on the price of the product in the high income

344. *Compulsory License and New Provisions Affecting IP Holders During the Coronavirus Crisis in France and Globally*, CLIFFORD CHANCE (Apr. 2020), https://www.cliffordchance.com/content/dam/cliffordchance/briefings/2020/04/compulsory-licensing-and-new-provisions-affecting-ip-holders-during-the-coronavirus-crisis-in-france-and-globally.pdf.

345. Monika Shailesh, *Fair Remuneration for Compulsory Licensing*, MONDAQ (Aug. 3, 2017), https://www.mondaq.com/india/patent/616430/fair-remuneration-for-compulsory-licensing. ("For example Malaysia set a royalty rate of 4%; Mozambique establishes a 2% royalty; Zambia set a 2.5% royalty; and Indonesia arrived at 0.5% royalty.").

346. *Id*.

347. *Id*.

country where the product is patented, therefore more adequately sharing the actual cost of research and development.[348]

As a public policy matter, compulsory licensing for public health should be legally recognized because it can deter pharmaceutical companies from pricing their essential medicines at rates that are too high for the general public. Studies have shown that antibiotics protected by patents will often have a higher price than those unprotected.[349] However, other studies have shown that compulsory licenses are capable of countering this to provide dramatically lower drug costs. For example, in Brazil a compulsory license for the AIDS drug Efavirenz was issued in 2007. The patent owner Merck responded by offering a 30 percent price reduction but Brazil refused with the intention of proceeding with the compulsory license with a 1.5 percent royalty rate.[350] Ultimately Brazil did not proceed with the compulsory license as the chosen manufacturer lacked the capability to produce the drug, but the case demonstrates that the issuing of compulsory licenses can encourage patent owners to respond by lowering their prices.[351]

Absent actual compulsory licensing orders by the government, mere statutory adoption of compulsory licenses would serve as an effective deterrent against overly aggressive pricing of patented drugs. Prior to the compulsory license issued in 2007, Brazil had on other occasions threatened to adopt this approach.[352] Some commentators consider this conduct an important part of Brazil's celebrated response to the HIV/AIDS crisis in the early 2000s.[353] As mentioned previously, the U.S. has also benefitted from this approach to compulsory licensing. Following a scare in 2011 that terrorists might start using anthrax in attacks, the U.S was able to secure a better price for the drug ciprofloxacin after stating they were considering a compulsory license, while Canada made a similar threat.[354] Removing legal recognition of compulsory licenses

348. *Id*.

349. *Review of Existing Research on Patents and Access to Medical Products and Health Technologies*, THIRTY-FIRST SESSION WIPO STANDING COMMITTEE ON THE LAW OF PATENTS 2 (2019), https://www.wipo.int/edocs/mdocs/scp/en/scp_31/scp_31_5.pdf

350. Eric Bond & Kamal Saggi, *Compulsory Licensing, Price Controls, and Access to Patented Foreign Products* 5 (Vanderbilt University Department of Economics Working Papers, Paper No. 12-00006, 2012), https://ideas.repec.org/p/van/wpaper/vuecon-12-00006.html.

351. *Id*.

352. *Id*.

353. Tina Rosenberg, *Look at Brazil*, N.Y. TIMES (Jan. 28, 2001), https://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html ("While Brazil's ability to reach patients encourages other nations, far more important is its success in lowering the cost of medicine. . . . Since Brazil started making generics of AIDS drugs, their cost has plummeted. The price of AIDS drugs with no Brazilian generic equivalent dropped 9 percent from 1996 to 2000. The price of those that compete with generics from Brazilian labs dropped 79 percent. But just the credible threat of generic competition is enough to get manufacturers to lower their prices.").

354. Gorik Ooms & Johanna Hanefield, *Threat of Compulsory Licences Could Increase*

would therefore be unadvisable for any country, even the U.S. which is generally opposed to making use of them.

CONCLUSION

Justice Breyer has voiced concern that "sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection."[355] This is the fundamental problem explored in this article. It shows that the legal power granted technology companies by patent law far exceeds the responsibilities these companies have assumed. Amid the COVID-19 pandemic, this asymmetry of rights and responsibilities has seriously jeopardized global efforts to develop testing methods, medicines, and vaccines.

In response, this article proposes reforms of patent law to usher in new responsibilities requiring patent holders to reciprocate for public contributions, fulfill their innovator role responsibility, and confront the injustices created by patent protection. To enforce these responsibilities, the article recommends reshaping limitations on patent rights such as the disclosure requirement, experimental use defense, and compulsory licensing scheme, as well as creation of the Patent Philanthropy Initiative. Such reforms will make patent law more innovation-friendly, better able to serve the public interest and above all, in the view of the public, ethically justifiable.

Access to Essential Medicines, BMJ (May 28, 2019), https://www.bmj.com/content/365/bmj.l2098.

355. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting).