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We Need a Vaccine: Proposals for Regulating Innovation in a Pandemic

Kristen Osenga

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Proposals for Regulating Innovation in a Pandemic

Kristen Osenga*

Introduction

Spring 2020 began an unprecedented time for the United States, as well as globally. After initially stating in January that COVID-19 was a "public health emergency of international concern," the World Health Organization (WHO) upgraded COVID-19 to a pandemic on March 11, 2020.[1] Within the next few weeks, life as we knew it changed as schools and universities moved to online learning, restaurants were limited to curbside pickup, and state governments issued "stay-at-home" orders that were originally set to expire in April.[2] While early June saw a loosening of some these orders, as we moved through the fall and then winter holidays and now early into 2021, states are still imposing various levels of restrictions – in the forms of required facemasks, limited public gatherings, and other social distancing efforts.[3] One of President Biden's first executive orders imposed a federal mask mandate and challenged Americans to "100 Days Masking."[4] Vast differences in state restrictions and enforcement, detrimental effects on the economy and other aspects of health, inconsistencies and

* Austin E. Owen Research Scholar and Professor of Law, University of Richmond School of Law. Many thanks to Erika Lietzan, Ana Santos Rutschman, Patti Zettler, and the participants at the 2020 Research Roundtable on Regulation, Innovation, and Public Health at the C. Boyden Gray Center for the Administrative State, Antonin Scalia Law School, George Mason University. All errors are mine.

[1] *See* World Health Organization, *Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)*, (Jan. 30, 2020), *available at* https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov); World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020*, (Mar. 11, 2020), *available at* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[2] *See* Alicia Lee, *These states have implemented stay-a-home orders. Here's what that means for you*, CNN, (Mar. 23, 2020; updated Apr. 7, 2020), *available at* https://www.cnn.com/2020/03/23/us/coronavirus-which-states-stay-at-home-order-trnd/index.html.

[3] *See* Littler Mendelson, *Facing Your Facemask Duties – A List of Statewide Orders as of June 7, 2020*, LITTLER (June 7, 2020), *available at* https://www.littler.com/publication-press/publication/facing-your-face-mask-duties-list-statewide-orders. Littler Mendelson has been updating this site regularly as state regulations are changed; as of February 8, 2021, the site is updated as of February 2. *See id.*

[4] *See e.g.* Maggie Fox, *Biden's first executive order will require masks on federal property,* CNN.com (1/20/21, updated 8:50a), *available at* https://www.cnn.com/2021/01/20/health/biden-first-day-health-executive/index.html.

uncertainties in best practices for avoiding the spread of COVID-19, and news of an upcoming second (or third) wave and mutant strains appearing this winter continue to cause much confusion, concern and consternation among the American public.[5] Despite best efforts on all other fronts to mitigate and prevent the spread and effects of this disease, many commentators suggest that only one thing will allow life to get as close as possible back to normal and "quash" the pandemic…and that is a vaccine.[6]

There is, thankfully, good news on that front. As of mid-January 2021, two COVID-19 vaccines had been approved (Pfizer-BioNtech and Moderna) for widespread use in the United States and another three are in large-scale, Phase 3 clinical trials (AstraZeneca, Janssen, and Novavax).[7] Despite the extraordinarily rapid success in developing and these vaccines in 2020, vaccines are not easy to create. Vaccines are a type of biologic, made in living cells, and are more complex than typical pharmaceuticals.[8] Typical vaccines take eight to ten years to develop and test for safety and efficacy before being approved for use.[9] Because of the novel nature of the coronavirus responsible for the current COVID-19 pandemic, researchers working on these and other vaccines are starting somewhat behind the eight ball.[10] With this background, the successes of 2020 and into 2021 on the vaccine front are even more remarkable.

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[5] *See, e.g.,* Jonnelle Marte, *Fed's Harker says opening economy too soon risks second wave of coronavirus*, REUTERS BUSINESS NEWS(May 12, 2020, 10:12a), *available at* https://www.reuters.com/article/us-usa-fed-harker/feds-harker-says-opening-economy-too-soon-risks-second-wave-of-coronavirus-idUSKBN22O23H; Paris Martineau, *Which States are Reopening, Which Remain on Lockdown, and Why*, WIRED (May 6, 2020), *available at* https://www.wired.com/story/which-states-reopening-lockdown/; Erin Duffin, *Impact of the coronavirus pandemic on the global economy*, STATISTA (June 26, 2020), *available at* https://www.statista.com/topics/6139/covid-19-impact-on-the-global-economy/; Ciara Nugent, *A New Strain of COVID-19 Is Being Blamed for a Surge in Cases in Brazil. Here's What to Know,* TIME (Jan. 20, 2021, 1:52p), *available at* https://time.com/5931366/brazil-new-covid-19-strain/.

[6] *See* Holly Yan, *Here's where we stand on getting a coronavirus vaccine*, CNN (June 8, 1:45p), *available at* https://www.cnn.com/2020/06/08/health/covid-19-vaccine-latest/index.html. A more skeptical position on the power of a coronavirus vaccine is taken by Sarah Zhang, *A Vaccine Reality Check*, THE ATLANTIC (July 24, 2020), *available at* https://www.theatlantic.com/health/archive/2020/07/covid-19-vaccine-reality-check/614566/ ("The vaccine probably won't make the disease disappear. It certainly will not immediately return life to normal.")

[7] *See* Different COVID-19 Vaccines, CENTERS FOR DISEASE CONTROL & PREVENTION (updated Jan. 15, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html. The Oxford-AstraZeneca vaccine has already been approved for use in the UK. *See* James Gallagher & Nick Triggle, *Covid-19: Oxford-AstraZeneca Vaccine approved for use in UK*, BBC (Dec. 30, 2020), *available at* https://www.bbc.com/news/health-55280671. There are, unfortunately, supply and distribution issues. *See, e.g.,* Carolyn Y. Johnson, *Companies scramble to expand coronavirus vaccine supply*, WASHINGTON POST (Jan. 14, 2021), *available at* https://www.washingtonpost.com/health/2021/01/14/covid-vaccine-supply/.

[8] *See* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 754-55 (2019).

[9] *See* Holly Yan, *Here's where we stand on getting a coronavirus vaccine*, CNN (June 8, 1:45p), *available at* https://www.cnn.com/2020/06/08/health/covid-19-vaccine-latest/index.html.

[10] *See* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L.REV. 1200, 1208-09 (2018). Outbreak diseases are difficult to predict and previous research on similar diseases may be of little use given unknown strains and mutations. *See id.*

Against this backdrop of breathtaking invention and innovation in the fight against the COVID-19 virus is another story – that of the war on intellectual property. Although this battle is not new, the pandemic has provided additional narratives of entry. Ranging from calls for innovators to either "voluntarily" forgo obtaining or exercising their legal patent rights on COVID-19 technology to calls for governments to simply take the rights to these patented inventions without permission, it is clear that intellectual property is under attack. Because these calls are coming from powerful groups such as Doctors Without Borders (Medecins Sans Frontieres/MSF) to the World Intellectual Property Organization (WIPO) to a novel organization known as the Open COVID Pledge, a group now stewarded by Creative Commons and naming IBM, Amazon, and Microsoft among its founding pledgors,[11] it is difficult to not feel pushback against innovators' legally-obtained rights. While many of these calls spring from a genuine desire to alleviate the overwhelming medical, economic, and social issues streaming from the pandemic, proposals that in effect devalue, or even disallow, intellectual property rights may have the opposite effect. Indicators point to intellectual property as spurring innovation – that is, in fact, one of the primary reasons we give intellectual property rights.[12] Additionally, there is evidence that a lack of intellectual property, or even a weak intellectual property system, impedes or harms innovation.[13] Faced with the uncertainty inherent in the development of vaccines and the costs associated not just with research but also to achieve the rapidity required to move promising vaccines through the extensive testing necessary for approval, the companies facing these risks and expenses must be incentivized – ideally with something more tangible than goodwill.[14] Because we need a vaccine, we also need to have the ability to grant and allow to be enforced intellectual property on that new technology.

Although some of the companies associated with approved and promising vaccines continued to press their development and testing efforts even in the face of these calls to devalue their intellectual property, and some have even eschewed profits that might be gained from the exploitation of these rights or declined to exercise these rights,[15] there are significant issues if this becomes the rule, rather

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[11] *See* Section II.B. *infra* for more information about these various calls. For information on the stewardship, membership, and supporters of Open Covid Pledge, *see* https://opencovidpledge.org/.

[12] *See, e.g.* Hon. Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 103 HARV. J. L. & TECH. 125-127 (2016) (noting a relationship between patent rights and research and development spending, economic growth, technological advancement, and business success as consistent with the notion that patents spur innovation).

[13] *See id.*

[14] *See, e.g.,* OECD, *Treatments and a vaccine for COVID-19: The need for coordinating policies on R&D, manufacturing, and access*, OECD (May 29, 2020), *available at* http://www.oecd.org/coronavirus/policy-responses/treatments-and-a-vaccine-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/ (explaining why vaccine development must be incentivized and suggesting some non-patent related incentive programs); Daniel Hemel & Lisa Larrimore Oullette, *Pharmaceutical Profits and Public Health are Not Incompatible*, NYT (April 8, 2020), *available at* https://www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html (making similar arguments regarding incentives).

[15] *See, e.g.,* Sir Menelas Pangolas, *Statement Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Pathway to a Vaccine: Efforts to Develop a Safe, Effective, and Accessible COVID-19*

than the exception. First, although these calls to devalue intellectual property rights have been present since near the beginning of the pandemic, they are getting louder and more insistent as time goes on. No longer are the calls able to be attributed as a natural reaction to a very scary situation that few understood. Second, even as these calls grow louder and more insistent, the intellectual property landscape continues to change. At some point, the idea that these vaccine companies will be able to unfairly and opportunistically exploit their intellectual property rights becomes more difficult to believe when there are myriad competitors willing to step in.[16] Third, there is evidence that when companies are faced with choices such as this, they have in the past abandoned this line of industry altogether. For these reasons, it is overly simplistic to say that the very existence of multiple vaccines in this case prove that the efforts to devalue intellectual property have not negatively affected the situation.

In contrast to the above-mentioned attacks on innovators' rights, there have been some regulatory efforts to incentivize research and development for COVID-related inventions by enhancing intellectual property and other laws. In May 2020, the United States Patent and Trademark Office (Patent Office) announced a free, expedited program that would allow certain types of businesses, specifically small and micro-entities, to obtain patents covering coronavirus-related inventions in as little as six months, rather than the two-plus years it typically takes receive an issued patent.[17] The Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC), the primary competition authorities in the United States, issued a Joint Statement, also in May 2020, explaining that "unprecedented cooperation" will be required to solve the pandemic and signaling some activities, such as collaboration between competitors, should be seen as potentially procompetitive and are not likely to be found in violation of antitrust laws.[18]

When the most insistent calls have been those seeking to devalue intellectual property rights, the actions of the Patent Office and of the DOJ and FTC are a breath of fresh air. However, while these

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Vaccine (July 21, 2020), *available at* https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Pangalos%2020200721_0.pdf (stating that AstraZeneca would make a certain number of doses of its vaccine available at a cost that "will provide no profit for AstraZeneca); Moderna, *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic*, (October 8, 2020), *available at* https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19 ("Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic . . . [and] upon request, [Moderna is] willing to license [its] intellectual property for COVID-19 vaccines to others for the post-pandemic period.").

[16] *See, e.g.,* Mark Schultz, *IP System Has Brought Light to the Tunnel*, CODEBLUE (Feb. 2, 2021), *available at* codeblue.galencentre.org/2021/02/02/ip-system-has-brought-light-to-the-tunnel-mark-schultz (*citing* Emily Field, head of European pharmaceutical research at Barclays).

[17] *See, e.g.,* U.S. PTO, *Covid-19 Prioritized Examination Pilot Program*, *available at* https://www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot; Susan Decker & Ian Lopez, *Covid-Related U.S. Patents Get Fast Track for Small Business*, BLOOMBERG (May 8, 2020, 3:01pm), *available at* https://news.bloomberglaw.com/ip-law/covid-related-u-s-patents-to-be-fast-tracked-for-small-business.

[18] *See* Joint Antitrust Statement Regarding COVID-19, *available at* https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19.

are steps in the right direction, they are shortsighted. While small companies may get a boost from the Patent Office program, the hurdles required to develop a vaccine, obtain regulatory approval, and then mass-market and distribute inventions of this type are generally well beyond the scope of small firms. Large firms that have the requisite research and regulatory wherewithal and access to necessary manufacturing resources, on the other hand, are excluded from taking advantage of the Patent Office's expedited program. Additionally, collaborative efforts, which have also been demonstrated to speed up and otherwise enhance the innovation process, such as in standards development organizations, and which have been presumptively blessed by the Joint Statement issued by the DOJ and FTC, would similarly be unable to utilize the expedited process because of the Patent Office's definition of a small entity. These baby steps by the Patent Office and competition authorities are insufficient to cover the great distance required, especially during a pandemic, to get us to a vaccine more quickly.

Although it is beyond the scope of this paper to solve the vast divide between the calls to devalue and the efforts to enhance intellectual property rights, this paper suggests the efforts to enhance intellectual property rights are important and could be tweaked to make them more effective. Thus, this paper argues for a multi-layered regulatory approach to enrich intellectual property protection in an effort to support and encourage the level of innovation likely to solve this –and importantly, future—pandemics. First, the expedited patent examination program at the Patent Office must be made available to entities of all sizes, small and large. Second, in recognition of the heightened innovative capacity of collaborative efforts, any patent application submitted by a collaboration should receive an even further expedited process. This could be as simple as moving the collaboration's patent application to the front of the already-expedited line. Third, these expedited Patent Office reviews should be made a permanent fixture within the Patent Office, available anytime the World Health Organization or Centers for Disease Control declare a global pandemic or national health emergency. This would alleviate the need to reinvent the wheel in the seemingly likely event of future situations. Finally, the guidance released by the DOJ and FTC related to COVID-19 research and development should be amended to specially reference, and generally find procompetitive, any pandemic-related collaborative effort that is then submitted to the Patent Office for patenting, as well as specifically permitting the legal enforcement of any patent thereafter obtained.

Section I of this paper will discuss pandemics and vaccines. First, the role of vaccines in solving pandemics will be considered, followed by an explanation of how vaccines are developed and approved. Finally, this section will explore the role of collaboration in vaccine development and innovation more generally, as well as why collaboration is particularly critical during difficult times such as pandemics. Section II of this paper will discuss the role of patents in incentivizing innovation, and especially for the innovation of vaccines. After explaining how patents are critical to incentivize patents, this section will also address why other efforts, especially those that devalue intellectual property, including prizes, pledges, and government intervention, are problematic in this arena. Finally, Section III will discuss options for regulating and encouraging pandemic-times innovation within the patent and competition spaces. Specifically, this section will look at the incentives offered by the Patent Office and the U.S. competition authorities during the COVID-19 pandemic and explain why these incentives should be broadened, as described above, and made permanent to address future pandemics and other widespread health emergencies yet to come. After all, in the end, we need a vaccine.

I. Pandemics and Vaccines

Naturally, a problem that is sufficiently serious to be deemed a global pandemic is going to present a challenging and complex issue to solve. While COVID-19 is not the only pandemic in recent history, it is one of the more widespread and most harmful,[19] and it has proven rather difficult to slow down and prevent the spread of the virus.[20] Biomedical research into vaccines and cures is expensive and time-consuming in the best of times.[21] Pandemics are clearly not the best of times.[22]

Despite the everyday use (at least now) of the terms "pandemic" and "vaccine," a general understanding of these terms is likely incomplete. This section explains pandemics, as well as the role that vaccines play in pandemic-times. Next, this section will describe how vaccines are developed and approved, as well as the difficulties of creating and deploying vaccines in the midst of a pandemic. Finally, this section will discuss the role of collaborative efforts for innovation more generally, as well as in the context of vaccines.

A. Role of Vaccines in Pandemics

A pandemic, although difficult to define, is generally a public health crisis characterized by a number of features including extensive geographic involvement, rapid and widespread transmission, high attack rates and infectiousness, and minimal existing immunity, often due to the novel nature of the cause.[23] Captured by these criteria is the notion of explosive spread, where a multiple cases appear over a very short time frame due to a dangerous combination of a highly contagious disease, exposure to a common source, and a short incubation period.[24] Additionally, the severity of the disease may be

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[19] *See, e.g.,* Hilary Brueck & Shayanne Gale, *How the coronavirus death toll compares to other pandemics, including SAR, HIV, and the Black Death*, BUSINESS INSIDER (May 22, 2020, 12:21p), *available at* https://www.businessinsider.com/coronavirus-deaths-how-pandemic-compares-to-other-deadly-outbreaks-2020-4. At that time (May 2020), there were over 333,000 coronavirus-related deaths worldwide, putting the current pandemic ahead of only ebola, SARS, and MERS. *See id.* As of early February 2021, the worldwide death toll associated with the coronavirus pandemic is over 2.33 million and rising. *See* https://www.worldometers.info/coronavirus/.

[20] *See, e.g.,* Sarah Kaplan, William Wan, & Joel Achenbach, *The coronavirus isn't alive. That's why it's so hard to kill.*, WASHINGTON POST (Mar. 23, 2020, 11:36a), *available at* https://www.washingtonpost.com/health/2020/03/23/coronavirus-isnt-alive-thats-why-its-so-hard-kill/.

[21] *See* Section I.B., *infra*.

[2222] *See, e.g.,* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L.REV. 1200, 1207 (2018) (noting that the "lengthy and costly traditional model for developing vaccines and therapies is ill-suited" during pandemics and other outbreaks).

[23] *See, e.g.,* David M. Morens, Gregory K. Folkers, and Anthony S. Fauci, *What is a Pandemic?*, 200 J. INFECTIOUS DIS. 1018, 1018-20 (2009). *See also* Centers for Disease Control & Prevention, *Influenza (Flu): Pandemic Basics*, *available at* https://www.cdc.gov/flu/pandemic-resources/basics/index.html (defining a pandemic as a public health crisis that happens when a new virus emerges that easily infects and spreads amongst humans).

[24] *See* Morens, et al., *supra* note 23, at 1019.

considered, with fatal or severe diseases being more readily classified as a pandemic.[25] The COVID-19 or novel coronavirus has lived up to these characteristics, and then some.[26]

Despite the fact we have been living under the shadow of the current pandemic for a year now, pandemics are not common. The most recent pandemic declaration prior to 2020 was the 2009 H1N1 outbreak (otherwise known as "swine flu").[27] Pandemics of the twentieth century include the 1918 influenza pandemic that killed an estimated 675,000 Americans,[28] as well as influenza pandemics in 1957 and 1968.[29] Although only the swine flu rose to the level of pandemic, several other significant health threats (often grouped with pandemics) have occurred over the last twenty years, including SARS, MERS, Ebola, and the avian flu.[30] Many scientists believe that we will be facing more pandemics in the foreseeable future, due to the global nature of the economy, the ease of travel, and the world's changing relationship with nature.[31]

Beyond the death toll and health effects directly related to the COVID-19 virus, there are additional negative impacts attributable to the coronavirus and efforts to mitigate it. On the health front, there is evidence that patients have eschewed or received delayed care for non-coronavirus related issues.[32] Additionally, much has been written about the mental health issues associated with the

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[25] *See id.* at 1019-20.

[26] *See, e.g.,* Catharine I. Paules, Hilary D. Marston, and Anthony S. Fauci, *Coronavirus Infections – More Than Just the Common Cold*, 323 JAMA 707, 707-708 (2020); Jamie Ducharme, *World Health Organization Declares COVID-19 a 'Pandemic.' Here's What That Means*, TIME (Mar. 11, 2020, 12:39p), *available at* https://time.com/5791661/who-coronavirus-pandemic-declaration/.

[27] *See, e.g.,* Ducharme, *supra* note 26; Centers for Disease Control and Prevention, *Past Pandemics*, *available at* https://www.cdc.gov/flu/pandemic-resources/basics/past-pandemics.html.

[28] *See, e.g.,* Centers for Disease Control and Prevention, *1918 Pandemic (H1N1 virus)*, *available at* https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html.

[29] *See, e.g.,* Edwin D. Kilbourne, *Influenza Pandemics of the 20th Century*, 12 J. EMERGING INFECTIOUS DIS. 9 (2006); Eileen M. Kane, *Preparing for Pandemic Influenza: Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L.REV. 1137, 1139 (2009).

[30] *See, e.g.,* Leslie Reperant & Albert D.M.E. Osterhaus, *AIDS, Avian flu, SARS, MERS, Ebola, Zika … What Next?*, 35 VACCINE 4470, 4471 (2017).

[31] *See id.* at 4472-73; Jon Hilsenrath, *Global Viral Outbreaks Like Coronavirus, Once Rare, Will Become More Common*, WSJ (Mar. 6, 2020, 5:30a ET), *available at* https://www.wsj.com/articles/viral-outbreaks-once-rare-become-part-of-the-global-landscape-11583455309; Victoria Gill, *Coronavirus: This is not the last pandemic*, BBC NEWS (June 6, 2020), *available at* https://www.bbc.com/news/science-environment-52775386 (citing Professor Matthew Baylis: "And [the current coronavirus] is not the last pandemic we are going to face …").

[32] *See, e.g.,* Julius Chen & Rebecca McGeorge, *Spillover Effects of the COVID-19 Pandemic Could Drive Long-Term Health Consequences for Non-COVID-19 Patients*, HEALTH AFFAIRS BLOG (Oct. 23, 2020), *available at* https://www.healthaffairs.org/do/10.1377/hblog20201020.566558/full/.

pandemic and its lockdowns.[33] Beyond health, the economic concerns related to the pandemic are troubling[34] and it is unclear yet how the effects of closing down schools for an extended period of time, from preschools to universities, will impact the education and socialization skills of the younger generation, not to mention their caregivers' careers.[35] Some, but not all, of these losses may be ameliorated by widespread vaccination.

Vaccines have been described as "the single most important pharmaceutical during a pandemic."[36] Some vaccines prevent recipients from getting ill, while others also prevent the immunized patient from infecting others, known as a sterilizing vaccine.[37] Studies have shown that if a sterilizing vaccine that protects 80% of those immunized has been given to 75% of the population, the pandemic would largely be ended without further public health measures such as social distancing.[38] This concept is often called "herd immunity."[39] While a sterilizing vaccine (that inhibits transmission) would be ideal for curbing the pandemic, even a non-sterilizing vaccine would have significant impact. The common flu vaccine, for example, is a non-sterilizing vaccine that provides a noticeable level protection to the population.[40] In the case of the pandemic, non-sterilizing vaccines would not result in

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[33] *See, e.g.,* Alison Abbott, *COVID's mental-health toll: how scientists are tracking a surge in depression*, NATURE (Feb. 3, 2021), *available at* https://www.nature.com/articles/d41586-021-00175-z.

[34] *See, e.g.,* Lora Jones, Daniele Palumbo & David Brown, *Coronavirus: How the pandemic has changed the world economy*, BBC NEWS (Jan. 24, 2021), *available at* https://www.bbc.com/news/business-51706225; Anne Sraders & Lance Lambert, *Nearly 100,000 establishments that temporarily shut down due to the pandemic are now out of business*, FORTUNE (Sept. 28, 2020), *available at* https://fortune.com/2020/09/28/covid-buisnesses-shut-down-closed/.

[3535] *See, e.g.,* Nicola Fuchs-Schudeln, et al., *The long-term effects of school closures*, VOX EU CEPR (Nov. 12, 2020), *available at* https://voxeu.org/article/long-term-effects-school-closures; Emma Garcia & Elaine Weise, *Covid-19 and student performance, equity, and U.S. education policy*, ECON. POLICY. INST. (Sept. 10, 2020), *available at* https://www.epi.org/publication/the-consequences-of-the-covid-19-pandemic-for-education-performance-and-equity-in-the-united-states-what-can-we-learn-from-pre-pandemic-research-to-inform-relief-recovery-and-rebuilding/; Jillian Berman, *Here's how much school closures will cost parents in lost wages, reduce GDP — and negatively impact the nation's education system*, MARKET WATCH (July 28, 2020, 7:24a), available at https://www.marketwatch.com/story/heres-how-much-school-closures-will-cost-parents-in-lost-wages-reduce-gdp-and-negatively-impact-the-nations-education-system-11595587585.

[36] U.S. Gov't Accountability Office, Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions 2 (2008), available at http://www.gao.gov/new.items/d08671.pdf.

[37] *See* Stacey McKenna, *Vaccines Need Not Completely Stop COVID Transmission to Curb the Pandemic*, SCIENTIFIC AMERICAN (Jan. 18, 2021), *available at* https://www.scientificamerican.com/article/vaccines-need-not-completely-stop-covid-transmission-to-curb-the-pandemic1/.

[38] *See id.* (citing a paper published in the American Journal of Preventive Medicine).

[39] *See* World Health Organization, *Herd Immunity, Lockdowns, and COVID-19*, WHO (updated Dec. 31, 2020), *available at* https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19.

[40] *See id.*

an abrupt end and would likely require public health measures, at some level, to continue for a number of years.[41]

To understand how vaccines achieve these ends, it is helpful to know the basics about how vaccines work. Vaccines are used to train the immune system to recognize and fight pathogens by introducing antigens into the body.[42] These antigens often include a weakened or dead version of either the virus in question or a vector virus (a different virus that includes genetic materials from the virus at issue).[43] When a vaccinated person is exposed to these antigens a second time, from exposure to a virus or bacteria, the body will remember and attack the antigens before the pathogens can spread and cause illness.[44]

Vaccines are important, even beyond the pandemic context. Many vaccines have been around for quite a long time.[45] The early 1900s has been called the "golden age of vaccines."[46] From a starting point of zero licensed vaccines and zero licensed vaccine manufacturers in 1902, until a high of over 60 licensed, commercialized vaccines and 52 manufacturers in 1940, vaccine development in this period flourished.[47] By the late 1950s, most children in developed countries were receiving a variety of routine vaccinations.[48] There are a number of vaccines recommended to be given to babies and children in the United States to fight against many once-common, and previously severe or fatal, illnesses.[49] These

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[41] *See, e.g.,* Amos Zeeburg, *Will the vaccine end the pandemic? This question must be answered first*, DISCOVER MAG. (Dec. 29, 2020, 5:25p), *available at* https://www.discovermagazine.com/health/will-the-vaccine-end-the-pandemic-this-question-must-be-answered-first.

[42] *See* Centers for Disease Control and Prevention, *Understanding How COVID-19 Vaccines Work*, (updated Jan. 13, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html; World Health Organization, *How Vaccines Work*, VACCINE SAFETY BASICS: E-LEARNING COURSE, *available at* https://vaccine-safety-training.org/how-vaccines-work.html.

[43] *See id.* The COVID-19 vaccination research has added another possibility to these modes of activity – mRNA technology. *See* notes 54-57 and accompanying text.

[44] *See id.*

[45] There are between 80-90 approved vaccines for a variety of diseases. The list of FDA approved vaccines is available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. More on the approval, or licensing, process can be found at Section I.B., *infra*.

[46] *See id.* at 739.

[47] *See id*. at 739-40.

[48] *See, e.g.,* Brian Greenwood, *The contribution of vaccination to global health: past, present, and future*, 369 PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY B (2014), *available at* https://doi.org/10.1098/rstb.2013.0433.

[49] *See* Centers for Disease Control, *2020 Recommended Vaccinations for Infants and Children (birth through 6 years) Parent-Friendly Version*, *available at* https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html#vpd; Centers for Disease Control, *2020 Recommended Vaccinations for Children (7-18 years old) Parent-Friendly Version*, *available at* https://www.cdc.gov/vaccines/schedules/easy-to-read/adolescent-easyread.html.

illnesses include chicken pox, diphtheria, hepatitis A and B, HPV, measles, mumps, pertussis, polio, rubella, and tetanus.[50] While these vaccines have made significant inroads in addressing these childhood diseases (and even eradicating smallpox and rinderpest),[51] other diseases and strains thereof require constant development of new vaccines – such as the annual flu vaccine. Seasonal flu vaccines protect against the viruses and strains that research indicates will be the most prevalent during an upcoming season.[52]

Vaccines for COVID-19 do not utilize a weakened or dead version of the specific coronavirus, instead using either mRNA technology or vector viruses.[53] Some vaccines, such as the Pfizer-BioNTech vaccine and the Moderna vaccine, for COVID-19 use mRNA technology.[54] Instead of triggering an immune response by injecting a weakened or inactivated germ, mRNA vaccines teach the body's cells to make a protein, or piece of a protein, producing antibodies.[55] Essentially, these vaccines instruct our cells to make a "spike protein," similar to that found on the surface of the COVID-19 virus.[56] After the cells make the protein piece, the body's immune system recognizes that the protein does not belong in the body and mounts an immune response.[57] This process teaches the body to protect against future exposures to this protein.[58] Other vaccines, such as the one developed by Johnson & Johnson, are viral vector vaccines. These work by using a modified version of a different, harmless virus to produce the spike protein, triggering our bodies' immune response.[59]

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[50] *See id.*

[51] *See, e.g.,* Angel Corona, *Disease Eradication: What does it take to wipe out a disease?*, AMER. SOC'Y MICROBIOLOGY (Mar. 6, 2020), *available at* https://asm.org/Articles/2020/March/Disease-Eradication-What-Does-It-Take-to-Wipe-out *(*discussing eradication of small pox and rinderpest, as well as factors that lead to eradication, including the presence of a vaccine).

[52] *See* Centers for Disease Control, *Key Facts About Seasonal Flu Vaccine*, *available at* https://www.cdc.gov/flu/prevent/keyfacts.htm.

[53] *See* Centers for Disease Control, *Understanding How COVID-19 Vaccines Work* (updated Jan. 13, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.

[54] *See id.* Although mRNA technology for vaccines has been studied for a few decades now, the COVID-19 vaccines are the first approved uses of the technology. *See, e.g.,* Anthony Komaroff, MD, *Why are mRNA vaccines so exciting?*, HARVARD HEALTH BLOG (Dec. 10, 2020) *available at* https://www.health.harvard.edu/blog/why-are-mrna-vaccines-so-exciting-2020121021599.

[55] *See* Centers for Disease Control, *Understanding mRNA COVID-19 Vaccines*, (updated December 18, 2020) *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html.

[56] *See id.*

[57] *See id.*

[58] *See id.*

[59] *See* Centers for Disease Control and Prevention, *Understanding Viral Vector COVID-19 Vaccines*, (updated Jan. 5, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html.

While the development and approval of these vaccines will not end the pandemic overnight, or even in short order as discussed above, it is an important first step.[60] Specifically, questions remain about how long immunity granted by the approved vaccines will last, whether the vaccines simply protect the injected person from illness or will prevent viral transmission to others, and whether the logistics puzzles inherent in a global immunization program can be solved.[61] These questions, however, were merely theoretical until there was a successful vaccine.

B. How Vaccines are Innovated and Approved

Vaccine development is a lengthy and costly effort, followed by what is usually a long and expensive approval process. To get a vaccine from early stage development to approval is a lengthy and expensive, often lasting ten to fifteen years and involving an array of private and public actors.[62] Both the research and development side, as well as navigation of the regulatory requirements, are rife with uncertainty.[63] Moreover, because the very nature of vaccines is to prevent disease with just one or a few doses, the ability to recoup these development and approval expenses is constrained in ways unlike conventional pharmaceuticals.[64] Add to that the extra difficulties of developing a vaccine during a pandemic and you might wonder why any company would choose this path.

Vaccine development begins with basic laboratory research to identify natural or synthetic antigens, such as weakened viruses or bacteria, virus-like particles, or other pathogenic substances that might be used to prevent a disease.[65] This process often lasts two to four years.[66] Other ingredients for the vaccine are also identified, including preservatives, surfactants to keep the vaccine ingredients blended, and stabilizers to prevent chemical reactions from happening within the vaccine.[67] The vaccine is subject to pre-clinical studies using tissue or cell culture systems and animal testing to determine if

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[60] *See* The Lancet Microbe, *Covid-19 vaccines: the pandemic will not end overnight*, THE LANCET MICROBE (December 18, 2020), *available at* https://doi.org/10.1016/S2666-5247(20)30226-3.

[61] *See id.*

[62] *See Vaccine Development, Testing, and Regulation*, THE HISTORY OF VACCINES, *available at* https://historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation.html.

[63] *See, e.g.,* Gail Dutton, *Past Vaccine Failures May Reduce COVID-19 Vaccination Rates*, BIOSPACE (June 10, 2020), *available at* https://www.biospace.com/article/past-vaccine-failures-may-reduce-covid-19-vaccination-rates-/ (describing failure rates at various stages of vaccine development).

[64] *See* Rutschman, *supra* note 8, at 756.

[65] *See, e.g., Vaccine Development, Testing, and Regulation*, THE HISTORY OF VACCINES, *available at* https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation (*hereinafter* Vaccine Development, Testing & Regulation).

[66] *See id.*

[67] *See, e.g., How are vaccines developed?*, WORLD HEALTH ORGANIZATION (Dec. 8, 2020), *available at* https://www.who.int/news-room/feature-stories/detail/how-are-vaccines-developed.

the vaccine produces the desired immune response and is safe.[68] The pre-clinical stage often lasts one to two years and many vaccine candidates never progress further because they do not produce the desired immune response.[69] If a successful vaccine candidate emerges at this point, an application for the vaccine is then submitted to the U.S. Food and Drug Administration, beginning the regulatory approval process.[70]

Because vaccines are considered intended to prevent disease, they are classified as "drugs" under the Federal Food, Drug, and Cosmetic Act, as well as "biological products" under the Public Health Service Act.[71] As such, vaccines must be approved by the Food and Drug Administration (FDA).[72] This process is handled by the FDA's Center for Biologics Evaluation and Research.[73] Vaccine approval requires that the vaccine is "safe, pure, and potent" or "safe and effective" and that it can be manufactured at a facility with "current good manufacturing practices."[74] Arriving at these determinations follows a process similar to other new drugs, including preclinical testing (before the application is submitted), followed by several phases of clinical testing, designed to provide proof of effectiveness and safety.[75] Finally, the FDA must decide that the data collected thus far show that the drug's benefits outweighs risks when used as intended.[76]

Showing a vaccine is safe and effective involves exploratory and pre-clinical stages, followed by clinical review phases.[77] The clinical stage generally, but not always, includes three phases – phase I

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[68] *See* Vaccine Development, Testing & Regulation, *supra* note 65.

[69] *See id.*

[70] *See id.*

[71] *See* 42 U.S.C.S. §262(i)(1).

[72] Because vaccine manufacturers must secure approval of a biologics license application, often it is said that vaccines are "licensed" rather than "approved." *See* Erika Lietzan, *Vaccine Approval 101*, OBJECTIVE INTENT BLOG (Feb. 29, 2020), *available at* objectiveintent.blog/2020/02/29/vaccine-approval-101/. For simplicity, this paper will simply refer to the processes as "approval."

In the European Union, the European Medicines Agency supervises vaccines; the World Health Organization makes recommendations on vaccines internationally. *See Vaccine Development, Testing, and Regulation*, THE HISTORY OF VACCINES, *available at* https://historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation.html.

[73] *See* 21 C.F.R. § 601.2; U.S. Food & Drug Admin., *Biologics License Application Process (CBER)* (current as of 1/27/2021), *available at* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

[74] *See* 42 U.S.C.S. § 262(a)(2)(C).

[75] *See* 21 C.F.R. § 601.2.

[76] *See id.*

[77] *See* Centers for Disease Control & Prevention, *Development of New Vaccines*, *available at* https://www.cdc.gov/vaccines/basics/test-approve.html [CDC, *New Vaccines*].

where small groups of people receive the vaccine, phase II where the vaccine is given to an expanded group, including people who have characteristics common to those for whom the vaccine is intended, and phase III, focused on efficacy and safety as the vaccine is given to thousands of patients.[78] Even after approval, many vaccines continue to be studied for their safety and efficacy.[79] While vaccines have better odds of being approved than other drugs, the failure rate is still very high; vaccines in Phase I trials have a success rate of 22%, rising to 62% if the vaccine reaches Phase III.[80]

Effectiveness of a vaccine is shown if it reduces the incidence of a disease.[81] The best proof of efficacy is a randomized, controlled, double-blinded study showing a reduction in incidence of disease for the vaccinated group as compared to the un-vaccinated group.[82] However, it would be unethical to administer a placebo to a group of people and then expose them to a dangerous disease.[83] To avoid this, vaccine trials can be performed in areas where a disease is spreading, and outcomes for those who received the vaccine are compared to those who did not.[84]

In a public health emergency, the FDA is authorized flexibility to ensure that medical countermeasures, such as vaccines and pharmaceuticals are available.[85] In particular, the FDA commissioner may allow unapproved products or unapproved uses of products during the emergency when there are no adequate, approved, or available alternatives.[86] A number of Emergency Use Authorizations (EUAs) have been issued during the current pandemic, including for diagnostics, personal protective equipment, and the Moderna and Pfizer/BioNTech vaccines.[87]

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[78] *See id.*

[79] *See id.*

[80] *See* Gail Dutton, *Past Vaccine Failures May Reduce COVID-19 Vaccination Rates*, BIOSPACE (June 10, 2020), *available at* https://www.biospace.com/article/past-vaccine-failures-may-reduce-covid-19-vaccination-rates-/.

[81] *See, e.g.,* Natasha S. Crowcroft & Nicola P. Klein, *A framework for research on vaccine effectiveness,* 36 VACCINE 7286 (2018), *available at* https://doi.org/10.1016/j.vaccine.2018.04.016; Rene F. Najera, *Randomized Clinical Trials for Vaccine Safety, Efficacy and Effectiveness*, THE HISTORY OF VACCINES (April 21, 2019), *available at* historyofvaccines.org/content/blog/vaccine-randomized-clinical-trials.

[82] *See* Najera, *supra* note 81.

[83] *See id.*

[84] *See id.* (discussing case-control studies in outbreak investigations).

[85] *See, e.g.,* 42 U.S.C. § 300; U.S. Food & Drug Admin, *Emergency Use Authorization, available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[86] *See id.*

[87] *See id.*

Erika Lietzan provides a nice overview of the licensing process and the types of data submitted in support of a recently approved vaccine, specifically the December 2019 approval of a vaccine for the prevention of *Zaire ebolavirus* in individuals 18 and older.[88] In summary, the application submitted included data studies in a variety of animals, followed by a series of clinical studies involving nearly 16,000 subjects over eight Phase 1 studies and four Phase 2/3 studies.[89] The process took nearly six years from the start of the recent Ebola outbreak in 2013 until approval in 2019.[90]

The process, from start to finish, is rife with uncertainties. At every step, a vaccine developer faces a substantial risk that it will fail-- from finding the proper antigen that provokes the desired immune response to successful navigating pre-clinical and clinical trials to show safety efficacy to ensuring that the vaccine does not have negative side effects that outweigh its benefits. These risks include sunk costs in research, development, and the regulatory aspects of licensing, as well as (somewhat limited) exposure for negative outcomes. The incentive to encourage the vaccine developer to face these risks is, quite naturally, financial. However, the financial incentives for vaccine are also somewhat problematic.

Although vaccines are critical for public health, their development is often not a high priority for private companies because the "unlikelihood of a return on investment."[91] Even where funding is available for early stage, or discovery, research, there is, what is called, a "valley of death" in the transition from early stages to commercialization, in the form of preclinical and clinical trials.[92] Additionally, unlike other pharmaceutical inventions, vaccines ideally confer lifelong, or at least long term, immunity with just a few doses.[93] These features render vaccine development less profitable than other avenues of biologic and pharmaceutical research.

The vaccine market is often lumped in with the pharmaceutical market; despite the similarities there are significant differences.[94] While the global pharma market is a trillion-dollar industry, the global vaccine market has estimated revenues of $50 billion.[95] Clinical trials for vaccines also differ; because vaccines focus on preventing, rather than curing, a disease, the primary study population is healthy individuals.[96] To determine whether the vaccine is effective, the investigators cannot look for

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[88] *See* Lietzan, *supra* note 72.

[89] *See id.*

[90] *See id.*

[91] *See* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L.REV. 729, 752 (2019).

[92] *See id.* at 752-3.

[93] *See id.* at 756.

[94] *See* Qiwei Claire Xue & Lisa Larrimore Ouelette, *Innovation policy and the market for vaccines*, 7 J.L. BIOSCI. 1, (June 1, 2020).

[95] *See id.*

[96] *See id.*

elimination of symptoms, but instead must either look for differences in disease rates or for a particular immune response, such as antibody level.[97] Moreover because these trials are occurring in healthy individuals, there is little tolerance for side effects and Phase III trials must often be larger than for drugs to detect rare side effects.[98] Finally, vaccine manufacturing plants are expensive and the decision to build or fit a facility to produce the vaccine is often made many years in advance.[99]

Developing a vaccine during a pandemic adds an additional layer of complexity onto this already complicated analysis that companies must make when deciding to develop a vaccine. In some respects, the pandemic makes things easier – there is a known need and a clear market for the vaccine and there is ready access to transmission information and subjects for clinical testing. Moreover, public attention to the pandemic may spur a stream of funding to aid with research and development costs.[100] On the other hand, as noted above, vaccine developers are unlikely to have been developing antigens for this specific outbreak, as is the very nature of a pandemic.[101] Also, the pandemic may pose logistical challenges for research, development, and approval due to lock-downs and other mitigation efforts imposed to stem the growth of the pandemic. Finally, depending on whether the vaccine is a sterilizing type, the useful lifespan of the vaccine may be limited if the vaccine is successful; it is a bit of a perverse incentive – the best vaccine would eradicate the pandemic-causing virus, but would obviate the need for the vaccine to continue to be made and sold.

C. Collaborative Efforts in Difficult Times

Collaborative efforts have been made easier with today's technology and are allowing for a growing amount of collaboration, especially across disciplinary and organizational boundaries.[102] In fact, studies have shown that some of the best innovative research is being produced by diverse collaborations.[103] Collaboration has significant benefits for innovation, particularly in the case of developing vaccines during a pandemic. This section will discuss collaboration more generally before turning to collaborative vaccine development.

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[97] *See id.*

[98] *See id.*

[99] *See id.*

[100] *See* Rutschman, *supra* note 10, at 1206-07.

[101] *See id.* at 1207, 1209-10.

[102] *See, e.g.,* Liza Vertinsky, *Boundary-Spanning Collaboration and the Limits of the Joint Inventorship Doctrine*, 55 HOUSTON L. REV. 401, 407 (2017).

[103] *See id.* at 410-11 (*citing* Jonathan Adams, *Collaborations: The Rise of Research Networks*, 490 NATURE 335, 336 (2012) and Stefan Wuchty, Benjamin F. Jones & Brian Uzzi, *The Increasing Dominance of Teams in Production of Knowledge*, 316 SCI. 1036, 1036 -37 (2007)).

Collaboration is an activity that can occur at any stage of innovation, from research and development to manufacturing and beyond, and may take a number of different forms.[104] It has long been part of scientific research in the form of sharing data.[105] Collaboration has been called "a critical aspect" in areas "dominated by complex problems, rapidly changing technology, dynamic growth of knowledge, and highly specialized areas of expertise," all of which define most areas of innovation today.[106] Collaborative efforts can be found in many industries, from high tech to manufacturing to pharmaceuticals.[107] Through collaboration, researchers have access to resources, expertise, tools, and knowledge that may not be available to them individually or within their organization.[108]

An example of extraordinary innovation in a collaborative environment is seen in standards development organizations (SDOs).[109] SDOs are groups of firms – large and small, often competitors – that work collaboratively to solve technological problems.[110] SDOs are able to innovate at high levels because various members bring their developed technology to the table to be combined with other members' contributions, allowing for a sharing of resources, and also because the various members compete and collaborate within the SDO to achieve an optimal collection of technology.[111] Collaborative innovation is also common in health care.[112]

Although the first vaccine in history is credited to the work of a single doctor, and later stories trumpet the successes of a single researcher, the vaccine development tale going forward will be one of collaborative efforts. In 1796, British physician Edward Jenner introduced a sample of an animal virus

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[104] *See, e.g.,* Talya Ponchek, *Does the Patent System Promote Scientific Innovation? Empirical Analysis of Patent Forward Citations*, 25 ALB. L.J. SCI. & TECH. 289, 300 (2015).

[105] *See id*. at 301-02.

[106] Noriko Hara et al., *An Emerging View of Scientific Collaboration: Scientists' Perspectives on Collaboration and Factors that Impact Collaboration*, 54 J. AM. SOC'Y INFO. & TECH. 952, 952 (2003).

[107] *See, e.g.,* Jorge L. Contreras & Liza S. Vertinsky, *Pre-Competition*, 95 N.C. L.REV. 67, 69 (2016).

[108] *See id.*; Ponchek, *supra* note 104, at 304.

[109] *See, e.g.,* Joshua D. Wright, *SSOs, FRAND and Antitrust: Lessons from the Economics of Incomplete Contracts*, 21 GEO. MASON L.REV. 791, 792 (2014) ("SSOs have long played a crucial role in our innovation-driven economy, and this fundamental role has only intensified over the last few decades."); *see also* Kristen Jakobsen Osenga, *Ignorance over Innovation: Why Misunderstanding Standard Setting Organizations Will Hinder Technological Progress*, 56 U. LOUISVILLE L.REV. 159 (2018). Standards development organizations (SDOs) and standard setting organizations (SSOs) are often terms used interchangeably; the author prefers to use SDOs.

[110] *See id.*

[111] *See, e.g.*, Alan Devlin, *Standard-Setting and the Failure of Price Competition*, 65 N.Y.U. ANN. SURV. AM. L. 217, 229 (2009).

[112] *See, e.g.,* Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L.REV. 1992 (2018) (discussing collaborative efforts among health-related agencies, including NIH, FDA, and the Centers for Medicare and Medicaid Services); Dennis C. Liotta, et al., *North-South Collaborations to Promote Health Innovation in Africa*, 67 EMORY L.J. 619 (2018) (discussing collaborations between high-income developed nations (north) and low-to-middle income developing countries (south) to address disease).

related to smallpox (cowpox) into the system of a healthy child, triggering an immune reaction in the child.[113] Jenner's reports of this, and similar, experiments began the work that underlies today's vaccines. Another researcher considered via conventional wisdom to be a solo researcher is Maurice Hilleman, who with his team at Merck, developed over forty vaccines, including for measles, mumps, chicken pox, rubella, hepatitis, and meningitis, including eight of the fourteen vaccines given routinely to American children.[114] While these innovators star in a romanticized view of vaccine development, today's reality is that vaccine development is the realm of big firms and collaborations, either between private and public institutions or between multiple private institutions.

Prior to the 1990s, there were few public-private partnerships in the pharmaceutical space.[115] Starting in the 2000s, these collaborative partnerships became more common.[116] Between 2006 and 2013, over three hundred new biopharmaceutical public-private partnerships were created.[117] Some partnerships sponsor research and development, often for underfunded diseases.[118] Examples of these types of partnerships include the Cancer Moonshot, and the TuBerculosis Vaccine Initiative.[119] Other partnerships focus on post-development and bring together resources to ensure that existing pharmaceuticals are made available to underserved markets.[120] One of the most prominent partnership of this type is Gavi, created in 2000 to improve access to vaccines in the Global South.[121] Another, quite relevant partnership is the Coalition for Epidemic Preparedness Innovations (CEPI), founded in 2017 in part because of the lack of Ebola vaccines during the Ebola outbreak in 2014-15.[122] According to the World Health Organization, these partnerships are "an effective way to capitalize on the relative

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[113] *See* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 735 (2019).

[114] *See* Thomas H. Maugh II, *Maurice R. Hilleman, 85; Scientist Developed Many Vaccines that Saved Millions of Lives*, L. A. TIMES (April 13, 2005), *available at* https://www.latimes.com/archives/la-xpm-2005-apr-13-me-hilleman13-story.html.

[115] Jon F. Merz, World Health Organization, INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS 17 (2005).

[116] *See id.* at 2.

[117] *See* Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L.REV. ONLINE 170, 180 (Apr. 2020).

[118] *See* Merz, *supra* note 115, at 2.

[119] *See* Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L.REV. ONLINE 170, 180 (Apr. 2020) (describing a variety of development partnerships).

[120] *See* Merz, *supra* note 115, at 2.

[121] *See* Rutschman, *supra* note 119, at 179-80.

[122] *See* CEPI, *Why We Exist*, *available at* https://cepi.net/about/whyweexist/.

strengths of the public and private sectors to address problems that neither could tackle adequately on its own."[123]

Collaborations between private entities in the pharmaceutical space is also on the rise.[124] This has been attributed to rising costs, decreasing resources, and growing scientific resources.[125] Governments and policymakers have encouraged these collaborations to accelerate pharmaceutical developments while lowering costs.[126] Some examples of these promoted collaborations include the Accelerating Medicines Partnership, a collaboration among pharmaceutical firms and the National Institutes of Health to identify drug targets for certain diseases, and the Critical Path Initiative, launched by the FDA to encourage members to collaborate as part of improving the way FDA-regulated products were developed, evaluated, and manufactured.[127]

Perhaps now, more than ever before, we have seen that an extraordinary problem requires extraordinary solutions. In particular, pandemics of this type will require rapid, collaborative efforts to solve, as we saw in 2020.[128] While other health emergencies, such as the HIV/AIDS crisis in the 1990s, spurred extensive international collaboration, today's technology and means of sharing information make these efforts easier and more fruitful.[129] The proof is, as they say, in the pudding.

Part of the success in arriving at a COVID-19 vaccine as quickly as was done in 2020 is owed to collaborative efforts, both public-private partnerships and collaborations between private companies. CEPI, the vaccine development consortia sponsored by multiple governments as well as private funding, established the Access to COVID-19 Tools Accelerator to speed the development, production, and distribution of diagnostics, therapeutics, and vaccines related to the coronavirus.[130] The United States Biomedical Advanced Research and Development Authority (BARDA) provided funding to a number of

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[123] *Public-Private Partnerships (PPPs)*, WORLD HEALTH ORG., *available at* https://www.who.int/intellectualproperty/topics/ppp/en/ [https://perma.cc/DCL7-ZNPH].

[124] *See* Contreras & Vertinsky, *supra* note 107, at 77.

[125] *See id.*

[126] *See id.* at 79.

[127] *See id.* at 79-80.

[128] *See, e.g.,* Matt Apuzzo & David D. Kirkpatric, *Covid-19 Changed How the World Does Science, Together*, N.Y. TIMES (Apr. 1, 2020), *available at* https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html ("While political leaders have locked their borders, scientists have been shattering theirs, creating a global collaboration unlike any in history. Never before, researchers say, have so many experts in so many countries focused simultaneously on a single topic and with such urgency.").

[129] *See id.*

[130] *See, e.g.,* Judith Kulich, et al., *COVID-19 vaccines: How pandemic partnerships may accelerate vaccine development*, VS INSIGHTS (June 10, 2020), *available at* https://www.zs.com/insights/covid-19-vaccines-how-pandemic-partnerships-may-accelerate-vaccine-development. CEPI is funded in part by the United Kingdom, Canada, Belgium, Norway, Switzerland, Germany, and the Netherlands. *See id.*

pharmaceutical companies and partnerships working on vaccine development.[131] Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) is organized by the National Institutes of Health in the United States and is joined by at least eighteen of the leading biopharmaceutical companies, as well as American and European agencies.[132] In April 2020, over sixty research and development deals between pharmaceutical companies were announced to work on therapies and vaccines related to COVID-19.[133] For example, Pfizer agreed to pay BioNTech up to $748 million for their partnership that has resulted in one of the earliest approved vaccines in the United States.[134] Whether public-private or between companies, these joint efforts include many of the very biggest players in this space. For example, Sanofi and Glaxo-Smith Kline announced in April 2020 a partnership that "brings together two of the world's largest vaccine companies" to "combin[e] … scientific expertise, technologies, and capabilities."[135]

II. Patents vs. Prizes, Pledges, and Other Options

Because of the costs and uncertainties associated with vaccine development, it is important to provide adequate incentives for companies to invest in the effort.[136] However, ensuring that research and development of vaccines is viable for innovative companies needs to be balanced with the notion that the developed vaccines are affordable and can be sufficiently produced and distributed to the affected population[137]…in this case, basically the entire world. This section will explain the role that patents play in vaccine development, before turning to the various efforts that have been suggested as ways to speed innovation during the pandemic that have the effect of devaluing patent rights. This section will further explain why, even as innovative companies are continuing to invest in research and development in the face of these calls to devalue patent rights, we should not expect these companies to continue to do so over the long term.

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[131] *See id.* Among others, BARDA has funded Oxford/AstraZeneca, Moderna, Merck, Johnson & Johnson, and Sanofi.

[132] *See* Press Release, *NIH Director: Defeating COVID-19 requires unprecedented action and collaboration*, (May 18, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-director-defeating-covid-19-requires-unprecedented-action-collaboration.

[133] *See* Kulich et al., *supra* note 130.

[134] *See id.*

[135] Press Release, *Sanofi and GSK to join forces in unprecedented vaccine collaboration to fight COVID-19,* (April 14, 2020), *available at* https://www.sanofi.com/en/media-room/press-releases/2020/2020-04-14-13-00-00.

[136] To be sure, there may be other incentives for vaccine developers, whether in the form of other regulatory benefits or simply goodwill. The focus of this paper is on intellectual property, and particularly patent incentives.

[137] *See, e.g.,* Rebecca Haffajee, Wendy E. Parmet & Michelle M. Mello, *What is a Public Health "Emergency"*, 371 N.ENGL. J.MED. 986, 986-87 (2014).

A. Why Patents Are Necessary

Patents are the primary tool used to promote innovation.[138] By granting a limited period of exclusive rights in the invention, patents are used to incentivize inventors to invest in research and development, as well as to foster disclosure of new technology and facilitate commercialization of the invention.[139] Exclusivity may provide the patent owner with an opportunity to recoup some of their costs either by making or selling the invention himself or by licensing it to others.[140] Further relevant to this discussion, patents also may facilitate information sharing and collaboration.[141]

Patents are granted for useful, new, and non-obvious inventions.[142] The composition of vaccines, as well as the process of manufacturing them and devices for delivering the vaccines can all be protected by patent.[143] Patents are an important part of the incentive structure for the development of vaccines, and have been for a long time.[144] Incentive structures are required for vaccine development and production generally. Although difficult to develop, as described above, "profits in vaccine making are low" and vaccine manufacturers "are generally wary of developing vaccines for pandemics, not least because developing vaccines for diseases that then vanish is even less profitable."[145]

In the pharmaceutical and biologics industry, companies invest hundreds of millions of dollars in clinical trials before their products can be sold to the public.[146] Because generic rivals are exempted from many of the regulatory requirements and can enter the market at a much lower cost, patent

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[138] *See, e.g.,* W. Nicholson Price, *The Cost of Novelty*, 120 COLUM. L.REV. 769, 771 (2020); ("Patent law promotes innovations that are different from what the world already knows."); 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 ….).

[139] *See, e.g.,* Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

[140] *See, e.g.,* Rochelle Cooper Dreyfuss, *Dethroning* Lear: *Licensee Estoppel and the Incentive to Innovate*, 72 VA. L.REV. 677, 679 (1986).

[141] *See, e.g.,* Stephen Yelderman, *Coordination Focused Patent Policy*, 96 B.U. L.REV. 1565, 1567 (2016).

[142] *See* 35 U.S.C. §101 (utility), § 102 (novelty), and §103 (non-obvious). The invention must also be patent-eligible subject matter, a doctrine which is much less clear, but should encompass most vaccine-related inventions.

[143] *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L.REV. 303, 327-28 (2013).

[144] *See Patent Landscape Report on Vaccines for Selected Infectious Diseases*, WORLD INTELL. PROP. ORG. 60 (2012), *available at* https://www.wipo.int/edocs/pubdocs/en/patents/946/ wipo_pub_946_3.pdf (noting patent applications on vaccine technology filed as early as the 1920s and increasing from the 1960s to present). *See also* Rutschman, *Vaccine Race*, *supra* note 8, at 746-49 (describing the WIPO data).

[145] *Can the World Find a Good Covid-19 Vaccine Quickly Enough?,* ECONOMIST (April 16, 2020), *available at* https://www.economist.com/briefing/2020/04/16/can-the-world-find-a-good-covid-19-vaccine-quickly-enough; Ana Santos Rutschman, *The Intellectual Property of Vaccines*, *supra* note 117, at 173-174.

[146] *See, e.g.,* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L.REV. 503, 508 (2009).

protection is necessary to give pharmaceutical companies sufficient time to recoup their research and development investments.[147] There is no direct equivalent to a "generic" vaccine, because the regulatory process for second generation or follow-on products is still extensive.[148] Patents still, however, are important in encouraging research in vaccine development and, importantly, further investment in commercializing that research, such as the construction of manufacturing facilities or creation of distribution chains.[149]

To be sure, there are concerns that a patent can allow the patent holder to charge a higher price than otherwise would be possible.[150] However, often that harm is smaller than any injury that can be attributed to the invention never having been developed in the first place – particularly in the case of vaccines and pharmaceuticals.[151] Pharmaceutical firms have often stated that patent protection is necessary for their participation in the industry.[152] Moreover, these firms have indicated that their ability to license patents for free or sell drugs and vaccines at cost is "precisely because they know that their intellectual property will be protected. That's not a flaw in the system; it's how the system ensures that pharmaceutical research will continue to be funded."[153] Efforts to devalue these intellectual property rights raise concerns about future development in these very important areas of technology, especially during a pandemic.

B. Why Other Systems Are Problematic

Despite evidence that patents promote innovation and encourage companies to invest in uncertain and expensive research and development efforts, a number of proposals have been raised that suggest altering the usual intellectual property rights would provide a quicker solution to address the COVID-19 pandemic.[154] The premise of many of these proposals is that the cost of the exclusive

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[147] *See id.*

[148] *See, e.g.,* Aurelia Nguyen & Nina Schwalbe, *Apples and oranges? Can second generation vaccines become as low cost as generic medicines?*, 37 VACCINE 2910, 2911-12 (2019), *available at* https://doi.org/10.1016/j.vaccine.2019.04.016.

[149] *See* Roin, *supra* note 146, at 510.

[150] *See id.* at 513.

[151] *See id.*

[152] *See id.* (citing F.M. Scherer, THE POLITICAL ECONOMY OF PATENT POLICY REFORM IN THE UNITED STATES 6-8, 13 (Dynamics of Insts. & Mkts. in Eur., Intellectual Prop. Rights Working Paper No. 26, 2006), available at http://www.dime-eu.org/files/active/0/IPR-WORKING-PAPER-26 Scherer.pdf). *See also* Thomas Cueni, *The Risk in Suspending Vaccine Patent Rules*, N.Y. TIMES (Dec. 10, 2020), *available at* https://www.nytimes.com/2020/12/10/opinion/coronavirus-vaccine-patents.html ("Intellectual property rights underpin the system that gives us all new medicines, from psychiatric drugs to cancer treatments.").

[153] *See* Cueni, *supra* note 152.

[154] To be fair, many of these proposals are not new – nor is the tension between intellectual property rights and access. The current pandemic has just made some of these issues more visible.

rights afforded by intellectual property is simply too high, given the dire situation facing the nation and the world, and thus suggest altering the intellectual property rights available to and possessed by inventors working on pandemic-related technology. These proposals may be grouped into three categories: 1) offering something other than patent rights as a means of encouragement, such as prizes; 2) asking innovators to voluntarily forgo seeking or enforcing intellectual property rights, including the Open COVID Pledge; and 3) simply taking the technology covered by patent rights, either via compulsory licensing or other statutory schemes. This section describes these programs (and similar efforts) in more detail and explains none are likely to encourage the desired result – the much-needed vaccine.

1. Prizes & other incentives

Although patents are the usual incentive for innovation, other tools may be used to encourage research and development activity. Some of these tools include prizes and grants. Grants are used to directly fund research and development work and awarded ex ante, or before the results of the research and development activity are known.[155] Grants are often provided by the U.S. government for research in myriad areas.[156] Grants have been used extensively in supporting research into COVID-19 vaccinations and treatments. A significant amount of this funding is occurring as part of Operation Warp Speed and financed by supplemental appropriation acts. [157] This funding was this funding was then made available to accounts at the National Institutes of Health (NIH), Department of Defense, and the Public Health and Social Services Emergency Fund, the parent account for BARDA.[158] These organizations then offered grants to researchers.[159] Private organizations and companies have also offered grants to fund COVID-19 research.[160]

In addition to being awarded before the research is completed, and so act less as an incentive rather than an input resource, typically grants do not preclude patenting of the outcomes from the research. Specifically, the Bayh-Dole Act, passed in 1980, established that the results of government-funded research may be patented by the research institution, which may then license the technology.[161] Coupled with this ability for researchers to obtain and exploit patents for inventions made with federal

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[155] *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L.REV. 303, 308, 320 (2013).

[156] *See* Morten & Duan, *supra* note 201 (noting that the U.S. government provides over $100Billion in direct grants each year).

[157] *See* Kavya Sekar, *Funding for COVID-19 Vaccines: An Overview*, CONGRESSIONAL RESEARCH SERVICE INSIGHT (Dec. 15, 2020), *available at* https://www.hsdl.org/?view&did=848318.

[158] *See id.*

[159] *See, e.g.,* NIH, *Funding Opportunities Specific to COVID-19*, *available at* https://grants.nih.gov/grants/guide/COVID-Related.cfm.

[160] *See, e.g.,* Pfizer, *COVID-19 Vaccine Grants*, *available at* https://www.pfizer.com/purpose/independent-grants/covid-19-vaccine.

[161] Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212.

funding, the government reserved for itself the power to "march-in" on the patents and grant licenses, a power has been rarely used or even suggested.[162] March-in rights are discussed in more detail below.

A different type of incentive that has been suggested as an alternative to patents, and specifically in the case of COVID-19 research, are prizes. Typical prize situations involve an entity – or the government – promising a payment of a large amount of money to the first party to solve a particular problem.[163] Although several commentators suggested a prize system to incentivize development of a COVID-19 vaccine, no prize was ever offered.[164] Unlike grants, prizes often require the innovator to put the technology into the public domain and eschew patent protection.[165]

2. Pledges and promises

A second category of alterations to intellectual property rights in view of the pandemic is the notion that innovators can voluntarily forgo seeking and/or enforcing their intellectual property rights as a way to more quickly solve the pandemic. The Open COVID Pledge is one of the most visible efforts to separate intellectual property protection from pandemic-related technological innovation. Founded by law professors Mark Lemley and Jorge Contreras, among others, the language of the Pledge itself is rather simple: "We therefore pledge to make our intellectual property available for use in ending the COVID-19 pandemic and minimizing the impact of the disease, free of charge and without encumbrances."[166] The pledge is a promise between the intellectual property owner and the public; however, that promise may be found to have legal force if others reasonably rely on it and start making and selling their own products based on that intellectual property.[167]

The creators of the Open COVID Pledge provided not just a pledge statement for intellectual property owners, but also draft license language for companies to use to implement the pledge.[168] The purpose of the public license is to avoid the "slow and expensive" process typical of drafting and negotiating a license, allowing owners of COVID-related intellectual property to make a unilateral pledge saving "weeks or months at a time when a single day's delay in a cure, treatment, or prevention could

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[162] *See* 35 U.S.C. § 203(a).

[163] *See* Hemmel & Ouellette, *supra* note 155, at 317.

[164] *See* Daniel Hemel & Lisa Ouellette, *Want a Coronavirus Vaccine Fast? Here's a Solution*, TIME (Mar. 4, 2020) *available at* https://time.com/5795013/corona-virus-vaccine-prize-challenge). Hemel & Oulette proposed a prize of $500/person for a vaccine (amounting to about $165 billion, assuming it was given to all U.S. residents) to "ensure that a vaccine would be cheap—or even free" while still "giving the private sector powerful incentives to pour resources into vaccine research."

[165] *See, e.g.,* Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L.REV. 115, 120-21 (2003) (detailing a number of prize system proposals, most as an alternative to patenting).

[166] *See* Open COVID Pledge, *The Open COVID Pledge*, available at https://opencovidpledge.org.

[167] *See* Open COVID Pledge, *Frequently Asked Questions*, available at https://opencovidpledge.org/faqs/

[168] *See id.*

cost thousands of lives."[169] If an intellectual property owner uses the license set forth by the Open COVID Pledge (or otherwise drafts a license to effectuate the Pledge), the owner is granting a license to "make, use, sell, and otherwise exploit any technology that can be used in the fight against COVID-19" and includes diagnostics, vaccines, therapies, and medical equipment.[170]

The Open COVID website has entered pledges into a publicly searchable database and also promises to actively and publicly promote pledgors – and the list of companies that are identified as pledgors is impressive, including Facebook, Amazon, IBM, Microsoft, and more.[171] In August 2020, Creative Commons took on the leadership and stewardship of the Open COVID Pledge.[172] Creative Commons is "a nonprofit organization that helps overcome legal obstacles to the sharing of knowledge and creativity to address the world's pressing challenges."[173] In taking the reins of the Open COVID Pledge, Creative Commons plans to "continue working with large companies to unlock their intellectual property (IP) rights in the pursuit of saving lives" and to bring in smaller companies, universities, individual inventors, and others.[174] The Open COVID Pledge is clearly a high-profile and well-supported endeavor.

There are at least two criticisms on the use of pledges and other promises – one general and one specific to the COVID-19 pandemic (and likely other public health emergencies). First, there is scholarly literature that suggests that pledges have hidden costs on innovation.[175] Some of these costs include enhancing opportunities for patent-holdup, foreclosing alternative technologies, and raising barriers to entry.[176] While there are ways to mitigate these costs, these costs can have a hidden negative impact on innovation and so pledges may have a very different net effect on innovation than is understood when these pledges are designed and made.

Second, and more insidious, is that during a health emergency especially, these pledges may not be what they seem. Despite the fact that the Open COVID Pledge and similar efforts are billed as "voluntary," companies that own patents covering COVID-19 related technology have already faced backlash. In March, a company that had acquired patents from now-disgraced Theranos sparked an outcry after it sued a company developing COVID-19 tests, leading this company to pledge to offer

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[169] *See id.*

[170] *See id.*

[171] *See id. See also* Pledgors, *available at* https://opencovidpledge.org/partners/.

[172] *See* Diane Peters & Eric Steuer, *Creative Commons Is Now Leading the Open COVID Pledge – Here's What That Means*, CREATIVE COMMONS BLOG (Aug. 27, 2020), *available at* https://creativecommons.org/2020/08/27/cc-ocp/.

[173] *See* Creative Commons, *What We Do*, available at https://creativecommons.org/about/.

[174] *See* Diane Peters & Eric Steuer, *Creative Commons Is Now Leading the Open COVID Pledge – Here's What That Means*, CREATIVE COMMONS BLOG (Aug. 27, 2020), *available at* https://creativecommons.org/2020/08/27/cc-ocp/.

[175] *See, e.g.,* Liza Vertinsky, *Hidden Costs of Free Patents*, 78 OHIO ST. L.J. 1379, 1384 (2017).

[176] *See id.*

royalty-free licenses for pandemic-related uses.[177] Gilead Sciences then abandoned its bid for "orphan drug" status for an experimental COVID-19 treatment, which could have provided the company with seven years of exclusivity of sales and tax credits, after critics accused the company of trying to profit from the pandemic.[178] To be clear, voluntary pledges to not obtain or enforce patent rights are very different from compulsory licensing or other involuntary losses of intellectual property rights – even if the voluntary action is taken in response to peer or public pressure. However, voluntary does not necessarily mean freely and cheerfully given. While these cases represent unique situations, companies may certainly think twice before enforcing patents covering COVID-19-related technologies, particularly as Open COVID Pledge and others gain momentum.

3. Government Intervention

While pledges may be optional or voluntary, the third category of changes to intellectual property rights that has received much attention during the COVID-19 pandemic are requests for governments to step in and make use of patented technology without the patentee's permission, thereby devaluing those intellectual property rights.[179] Modalities to do this include compulsory licensing and the exercise of Section 1498. Each of these options, as well as the negative impact that may arise, will be described below.

a. Compulsory Licenses

Compulsory licensing is the notion that a government can use patented technology, without the patent holder's permission, in instances of public health emergencies.[180] Compulsory licensing is expressly permitted under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).[181] Article 31 allows member states to use patents without permission "in the case of a national emergency or other circumstances of extreme urgency."[182] The member state must first try to obtain permission

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[177] *See* Ryan Davis, *How COVID-19 Could Shake Up Patent Strategies*, LAW360 (April 6, 2020, 9:26pm), *available at* https://www.law360.com/articles/1260795/how-covid-19-could-shake-up-patent-strategies.

[178] *See id.*

[179] Relatedly, there are also calls for governments to deny patent or other intellectual property protection to technology related to the coronavirus. Specifically, in October 2020, India and South Africa asked the World Trade Organization to allow countries to choose to not grant or enforce intellectual property related to COVID-19-related technology during the pandemic. *See, e.g.,* Manvi Rathod & Keiya Barot, *India & South Africa's COVID Vaccine Proposal to the WTO: Why Patent Waiver Must Be Considered Over Compulsory Licensing*, IP WATCHDOG (Jan. 2, 2021), *available at* https://www.ipwatchdog.com/2021/01/02/india-south-africas-covid-vaccine-proposal-wto-patent-waiver-must-considered-compulsory-licensing/id=128652/. However, this section will focus on the government's use of patented technology.

[180] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994), Art. 31(b) (hereinafter TRIPS Agreement).

[181] *See id.*

[182] *See id.*

from the rights holder, but if the government moves forward without permission, it must pay "adequate remuneration in the circumstances of each case."[183]

Compulsory licensing was used most notably in the 1990s during the HIV/AIDS epidemic, when many developing countries took advantage of the procedure to obtain important pharmaceuticals.[184] More recently, developed nations have also begun to use compulsory licensing in a variety of ways. For example, in 2004, Canada created an Access to Medicines Regime that allowed Canadian generic drug manufacturers to supply drugs and vaccines to poor countries.[185] As a different example, France amended its patent laws in 2004 to allow for compulsory licensing in response to high costs of breast cancer (BRCA) testing.[186]

Given the pandemic, many countries have again looked toward compulsory licensing to alleviate potential drug and vaccine shortages.[187] In April 2020, Canada passed the COVID-19 Emergency Response Act, which facilitates the government's issuing of compulsory licenses to prevent and treat the coronavirus, regardless of whether the patent holder is capable of making the patented invention itself.[188] European countries have also demonstrated an interest in using compulsory licensing in the recent past and are again imposing it during the current pandemic. In March 2020, France passed an emergency law allowing the Prime Minister to control the prices of products and services to fight the virus; the Prime Minister has indicated that he may utilize compulsory licensing to do so.[189] Germany and the Netherlands have made similar adjustments.[190]

The United States, on the other hand, has been generally opposed to compulsory licensing, to the point of retaliating via trade restrictions against countries who have exercised this right.[191] For example, the U.S. Trade Representatives (USTR) put South Africa on the Special 301 Watch List claiming its use of compulsory licensing for HIV medications violated patent law.[192]

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[183] *See id.*

[184] *See, e.g.,* Heinz Klug, *Access to Medicines and the Transformation of the South African States,* 37 L. & DOC. INQUIRY 297, 314 (2012) (discussing an act passed by South Africa to improve access to HIV/AIDS medicines).

[185] *See e.g.,* Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. MED. ETHICS 247 (2009).

[186] *See id.* at 21.

[187] *See, e.g.,* Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, at 4 (Jan. 28, 2021), *draft available at* https://ssrn.com/abstract=3636456.

[188] *See id.* at 26.

[189] *See id.* at 28-29.

[190] *See id.* at 29-30.

[191] *See id.* at 7-8, 15-16.

[192] *See id.*

Compulsory licensing has come under attack for a number of additional reasons. Innovative companies argue that compulsory licensing should be "strictly limited (if allowed at all) because overriding patents would destablilize investor expectations and reduce future investment" in research and development.[193] Moreover, because developed countries, as well as developing countries can make use of the provisions, it is viewed as being used unfairly to subvert the intellectual property rights of innovative companies in these countries. Some commentators have gone so far to label compulsory licensing as theft.[194]

Worse still, compulsory licensing raises these concerns on the incentive side but may not do so with the benefits that are attributed to it. For example, upon deciding to issue a compulsory license, it took nearly four years for AIDS medication to reach Rwanda, with some of those years being spent settling the level of adequate remuneration and other logistical and contract issues.[195] Countries that have exercised these rights risk facing retaliation from pharmaceutical companies as well.[196]

b. Government Use

Beyond, compulsory licensing, there have been multiple calls for the United States government to use statutory march-in rights to used patented technology without permission. Specifically, various government leaders have been considering whether the march-in rights, afforded by the Bayh-Dole Act, or Section 1498(a) rights might be used to take the intellectual property that would otherwise belong to the vaccine developer.[197] Bayh-Dole march-in rights apply to inventions that are developed with the support of funding from the federal government and are intended to be used in extremely rare circumstances, and only when the patent holder is unable or unwilling to commercialize or license their

[193] *See* Abbott & Reichman, *supra* note __ (citing Harvey E. Bale, Jr., *Patent Protection for Pharmaceuticals: A Platform for Investment, Markets, and Improved Health in the Americas*, paper presented to Workshop ID, Cartagena, March 1996; Elaine Ruth Fletcher, *Pharma Under the Microscope in the COVID-19 Crisis*, HEALTH POLICY WATCH (May 19 2020), *available at* https://healthpolicy-watch.org/pharma-under-the-microscope-in-the- covid-19-crisis/); Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 1, 2 (2008) (compulsory licensing "disrupts the investment-based expectation of the property right").

[194] *See, e.g.,* Elizabeth Wright, *Compulsory Pharmaceutical Licensing is Little More than Government Theft*, THE HILL (Aug. 4, 2018), *available at* https://thehill.com/opinion/healthcare/400415-compulsory-pharmaceutical-licensing-is-little-more-than-government-theft.

[195] *See* Rathod & Barot, *supra* note 179.

[196] *See id.* (noting that Thailand faced retaliation from pharmaceutical companies after exercising compulsory licensing with respect to HIV/AIDS medications).

[197] *See, e.g.*, Charles Sauer, *Government May Attempt to Steal COVID Vaccine,* REAL CLEAR HEALTH (June 17, 2020), *available at* https://www.realclearhealth.com/articles/2020/06/17/government_may_attempt_to_steal_covid_vaccine_111060.html.

invention.[198] Section 1498 allows the government to do so, regardless of whether federal funding supported the invention of the technology.[199]

Section 1498 allows the government the power to manufacture and use any patented invention at "reasonable [cost] and entire compensation for such use and manufacture."[200] Multiple calls have issued for the U.S. government to invoke § 1498 during the COVID-19 pandemic.[201] Although often associated with wartime,[202] use of the provision in public health emergencies had been contemplated well before the current pandemic.[203] Notably, use of § 1498 was suggested during the anthrax scare in 2001 as a way to procure ciprofloxacin.[204]

The Bayh-Dole Act, via its march-in rights provision, also allows the government to use patented inventions.[205] Specifically, § 203 permits a federal agency to exercise march-in rights where the patent holder "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application" of the invention.[206] Further, march-in rights can be utilized if "necessary to alleviate health or safety needs which are not reasonably satisfied" by the patent holder or if a compulsory license is requested.[207]

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[198] *See id.*

[199] *See id.*

[200] 28 U.S.C. § 1498 (a). "Whenever an invention described in or covered by a patent of the United States is used or manufactured by or for the United States without the license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

[201] *See, e.g.,* Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 4-5 (2020); Michael Liu, et al., *March-in Rights and Compulsory Licensing – Safety Nets for Access to a COVID-19 Vaccine*, HEALTH AFF. BLOG (May 6, 2020), *available at* https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/; Amy Kapczynski, Paul Biddinger & Rachel Walensky, *Remdesivir could Be in Short Supply. Here's a Fix*, N.Y. TIMES (July 29, 2020), https://nytimes.com/2020/07/28/opinion/remdesivir-shortage-coronavirus.html.

[202] *See* Morten & Duan, *supra* note 201 at 8-11.

[203] *See id.*; Dennis D. Crouch, *Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic*, 39 SETON HALL L. REV. 1125, 1126 (2009); Amanda Mitchell, *Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents*, 95 CAL. L.REV. 535, 557-58 (2007).

[204] *See* Morten & Duan, *supra* note 201, at 26-28.

[205] 35 U.S.C. §203(a).

[206] *Id.*

[207] *See, e.g.,* Gerald Barnett, *Bayh-Dole Basics, 8: Reasonable Terms*, RES. ENT. (May 29, 2019), *available at* https://researchenterprise.org/2019/05/29/bayh-dole-basics-8-reasonable-terms; Kumar, *supra* note 187, at 12.

Despite calls from multiple fronts for the United States to devalue patent rights through any one of these paths, other commentators have remarked on how these provisions will harm future innovation.[208]

C. The Problem with Devaluing Patents

The problem with patent pledges, compulsory licensing, or march-in rights is in that, in each case, the underlying intellectual property is devalued. While in the short-term, the unfettered access to COVID-19 related technology may seem like a boon, there are questions about the long-term impacts of these moves on innovation going forward.[209] Intellectual property rights are considered critical to incentivizing the research and development necessary to achieve innovation; without patent protection, innovation may be hindered.[210] Particularly in cases where the innovation is ongoing – as it is in efforts to solve the COVID-19 pandemic – the absence of intellectual property may stall efforts. This is particularly true where, as here, the pandemic seemed to be accompanied by a financial depression or recession on the horizon. In the face of economic uncertainty and a possible inability to recoup the costs of this research and development, some companies may be led to decide to spend their limited resources elsewhere.

Moreover, opening the floodgates by using these little-known and rarely used provisions in this circumstance will simply make the choice to opt for them in the future that much easier. Compulsory licensing and other government interventions in patent rights have not been widely used, even in cases of previous medical emergencies, in part because of how negatively these provisions are viewed. Doing so now would confer a sort of blessing on these provisions, essentially ensuring they would be called for and perhaps even used in emergencies, and maybe even non-emergencies, going forward. This is a slippery slope argument, to be sure, but there is a reason the phrase exists.

There has been an extraordinary amount of innovation occurring, even in the midst of these calls to devalue patent rights. No vaccine developer has spoken favorably about compulsory licensing or government intervention and the pharmaceutical industry generally has lobbied against these devaluing actions.[211] And innovation has continued, not because of these efforts, but rather in spite of the risks that their intellectual property will be devalued. Some companies have even preemptively ceded their

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[208] *See e.g.,* Fred Reinhart, *Exercising Bayh-Dole march-in rights would handicap Covid-19 innovation*, STAT (May 4, 2020), *available at* https://www.statnews.com/2020/05/04/bayh-dole-march-in-rights-handicap-covid-19-innovation/; Matt Rizzolo, Brendan McLaughlin, & Ryan Sullivan, *What If Gov't Allows Patent Infringement for COVID-19 Drugs?*, LAW 360 (April 1, 2020) (Under either Bayh-Dole or § 1498, "the government should tread lightly, lest its actions have a chilling effect on biopharmaceutical innovation right when such innovation is so sorely needed.").

[209] *See id.*

[210] *See e.g.,* Elizabeth Wright, *Compulsory Pharmaceutical Licensing is Little More than Government Theft*, THE HILL (Aug. 4, 2018), available at https://thehill.com/opinion/healthcare/400415-compulsory-pharmaceutical-licensing-is-little-more-than-government-theft (arguing that the use of compulsory licensing would result in "fewer miracle drugs being researched and developed").

[211] *See, e.g.,* Cueni, *supra* note 152(identifying himself as director general of the International Federation of Pharmaceutical Manufacturers and Associations).

rights to profit or enforce their patents.[212] While goodwill is certainly part of these gestures, another reason is that these companies are playing the long game. For example, Moderna holds several patents and patent applications directed towards mRNA-vaccine technology.[213] With the approval of mRNA COVID-19 vaccines, Moderna and other companies are hoping that the way is now paved for other uses for this technology and, in allowing other companies to use the technology during the pandemic, the viability of technology becomes more apparent.[214] Aggressively interfering with patent rights during a pandemic may change the innovation calculus in unexpected ways.

Finally, the circumstances of the pandemic seem to be changing on a daily basis. In one respect, the calls to devalue patent rights of innovative companies are getting louder and more insistent as time goes on. On the other hand, the intellectual property landscape and the innovation sphere are also very much in flux. There are over 200 vaccine projects around the world, with over fifty being in clinical trials; at least seven different vaccines have been approved in various countries worldwide.[215] This situation is beginning to look less and less like an emergency in which patent rights need to be devalued, and more like a competitive marketplace.[216] The innovation system seems to be working exactly as it should, and we are getting the vaccines we need.[217]

III. Regulating Innovation within the Patent System

An alternative to devaluing patent rights would be enhancing the intellectual property system to better serve during a pandemic. In the early months of the current pandemic, the Patent Office set forth a pilot prioritized examination program to speed up the issuance of patents on COVID-19-related technology. The FTC and the DOJ issued a joint statement acknowledging the extraordinary level of cooperation required to solve a pandemic, allowing for broader collaborations between competitors. Both of these actions are positive steps, but they do not go far enough. This section will first the Patent Office's pilot program and the FTC/DOJ joint statement discuss in more detail, before turning to four specific recommendations to improve on these regulatory actions to aid in solving this and, importantly, future pandemics.

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[212] *See* note 15, *supra*.

[213] *See* Daniel Shores, *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?*, IP WATCHDOG (Nov. 11, 2020).

[214] *See id.*

[215] *See* Cueni, *supra* note 152.

[216] *See id.;* Schultz, *supra* note 16.

[217] At least these vaccines are being developed and approved; logistics in getting these vaccines into the public have proved more troublesome and are not within the scope of this paper.

A. Patent Office Incentives during COVID-19

On May 8, 2020, the US Patent and Trademark Office announced its COVID-19 Prioritized Examination Pilot Program.[218] The program suggests a final disposition of a patent application could occur within twelve months (although the Patent Office will endeavor for six months if the patent applicant responds promptly to communications from the Patent Office).[219] This is a much quicker than the current average pendency of nearly two years.[220] This is similar to other prioritized examination routes available to certain patent applicants but it also waives fees related to the expedited examination for firms that meet the two primary qualifications.[221] First, the claimed invention "must cover a product or process that is subject to U.S. Food and Drug Administration (FDA) approval for use in the prevention and/or treatment of COVID-19."[222] Second, the applicant must quality as a small or micro entity.[223] A small entity is an individual inventor, a small business concern (meaning having 500 or fewer employees) that has not conveyed its rights to an entity that would not qualify as a small entity, or a non-profit organization (again, that has not conveyed its rights to a non-small entity).[224] A micro entity is a small entity that 1) has not been named as an inventor on more than four previously filed patent applications and 2) whose gross income does not exceed three times the median household income as set by the IRS.[225] The Pilot Program began accepting requests for prioritized examination on July 13, 2020, and will continue until the Patent Office has accepted 500 requests, at which time it may extend the Pilot Program or terminate it.[226]

At the end of 2020, the Patent Office provided an update on the program thus far. Specifically, the Patent Office noted that 251 requests for prioritized examination had been granted and that 33

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[218] *See* USPTO, Press Release, *USPTO announces COVID-19 Prioritized Examination Pilot Program for small and micro entities*, (May 8, 2020), available at https://www.uspto.gov/about-us/news-updates/uspto-announces-covid-19-prioritized-examination-pilot-program-small-and.

[219] *See id.*

[220] *See* USPTO, *Patents Data, at a Glance, June 2020*, available at https://www-byr-dgr.uspto.gov/dashboard/patents/ (noting a 23.1 month average for traditional total pendency and a 15.9 month average pendency before receiving a first office action).

[221] *See* ___, *infra* for more information about other expedited patent examination programs.

[222] *See* Press Release, *supra* note 218.

[223] *See id.*

[224] *See* 37 C.F.R. 1.27 (definition of small entities).

[225] *See* 37 C.F.R. 1.29.

[226] *See* COVID-19 Prioritized Examination Pilot Program, 85 Fed. Reg. 28932 (May 14, 2020).

patent applications had been allowed (or issued as patents).[227] Of those requests, the Patent Office stated that most are directed towards medical treatments, diagnostics, and vaccines.[228]

To be sure, the Patent Office's efforts to provide accelerated examination of patent applications directed to COVID-19-related inventions could provide incentives for firms to research and develop a vaccine or treatment for the virus. While this may seem like a small, perhaps even insignificant, benefit in view of the extraordinary expenses that are associated with vaccine development and testing – speed of issuance does have appreciable value, especially in a pandemic. In the case of a successful, sterilizing vaccine, its value is largely realized during initial periods of vaccination. That is, the innovative company will be able to profit from the vaccine so long as the vaccine is being given. Unlike the MMR or chicken pox vaccine, where the vaccine will likely be given for many decades to come, the COVID-19 vaccine could become irrelevant within a decade or less if the virus can be eradicated. Even if the vaccine will need to be given over a number of decades, the height of its value will be in the initial inoculation with a long tail of decreasing value following that. Thus, it is important for patent rights to granted as quickly as possible for pandemic-related technology, to allow for the innovator to have a reasonable opportunity to exploit those rights before the pandemic has been mitigated. Moreover, patent rights facilitate licensing, which is also most critical during the early years of a public health emergency when the need for pandemic-related technology may require the efforts of multiple manufacturers.

The Patent Office's prioritized examination pilot program, while providing a real incentive for research and development into COVID-19 related technology, is far too narrow to truly be effective. First, as noted above, vaccine development is an expensive and time-consuming process. Because of this, rarely are vaccines developed by solo inventors or small firms; smaller firms or inventors affiliated with universities are often collaborating with other, larger institutions. Thus, the incentive being offered by the Patent Office for small and micro-entities is aimed at inventors who will be unlikely working in the spaces where the innovation is most desired. Second, as also described above, the COVID-19 pandemic is unlikely to be the last pandemic in our lifetime; by limiting this program to COVID-19 prevention or treatment and also limiting, at least on a pilot basis, the number of applicants who can take advantage of this program, the Patent Office is ensuring that this program is of limited value for future pandemics. To better serve as an incentive, this program must be expanded in scope and time.

B. Related Competition Authority Incentives during COVID-19

On May 1, 2020, the Antitrust Division of the Department of Justice and the Bureau of Competition of the Federal Trade Commission (collectively "the Agencies") issued a joint antitrust statement regarding COVID-19.[229] Recognizing that "[a]ddressing the spread of [COVID-19] will require unprecedented cooperation," the Agencies indicated a number of ways in which they planned to react. First, the Agencies indicated they "will aim to respond expeditiously" to requests for guidance regarding

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[227] *See, e.g.,* Donald Zuhn, *USPTO Provides Update on COVID-19 Prioritized Examination Pilot Program*, PATENT DOCS (Jan. 3, 2021), *available at* https://www.patentdocs.org/2021/01/uspto-provides-update-on-covid-19-prioritized-examination-pilot-program.html.

[228] *See id.*

[229] *See* DOJ/FTC, *Joint Antitrust Statement Regarding COVID-19* (May 1, 2020), *available at* https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19.

proposed business conduct in cases related to COVID-19. Second, the Agencies would also expeditiously process filings with respect to proposed joint ventures. And third, the Agencies explained that many activities related to the pandemic are presumptively procompetitive, including collaborative research, sharing of technical knowhow, joint purchasing agreements leading to procurement efficiencies, and lobbying "addressed to the use of federal emergency authorities."[230] On the flipside, the Agencies also indicated that they "stand ready to pursue civil violations of antitrust laws" including price fixing, bid rigging, and market allocation.[231]

In recognizing the importance of joint ventures and collaborative efforts, the Agencies are attuned to how today's vaccines are being developed, mass-manufactured, and delivered (along with other critical supplies during pandemic times, like personal protective equipment and testing materials). However, the same collaborative behavior that is being blessed by the Agencies is counterbalanced by the Pilot program of the Patent Office that is limited to small and micro-entities. Moreover, again because this statement is limited to COVID-19, it will need to be restated, as it were, every time a new pandemic arises.

C. Adjusting These Incentives For The Current – and the Next -- Pandemic

Avoiding calls and efforts to devalue intellectual property would be a good first step to ensure innovative companies have sufficient incentive to invest in developing vaccines and other pandemic-related technology. The longstanding conflict between intellectual property and access, however, is beyond the scope of this paper's solution. Instead, this article suggests modest proposals that will serve as better pandemic-time incentives than the current programs and guidance offered by the Patent Office, as well as the FTC and DOJ. This section sets forth four potential adjustments that could be made by those agencies that would make the current programs more productive and available for this, and future, pandemics. These adjustments include 1) making expedited examination available to firms of all sizes; 2) incentivizing collaborative efforts by providing a further examination boost; 3) making these programs permanent and available for any future pandemics or health emergencies; and 4) finding collaborative efforts related to the pandemic that result in the filing of a patent application to be presumptively pro-competitive. The contours, reasons, and implementations of each of these adjustments is described below.

1. Expand the Pilot Program

The Expedited Examination Pilot Program for COVID-19 related technology should be expanded to be available to all firms, regardless of size. The Patent Office's effort to expedite examination for patent applications related to COVID-19 filed by small and micro-entities is a step in the right direction, but it is far too small a step. As discussed above, the nature of vaccine development is such that the greatest progress is likely to come out of a collaborative effort and the firms with the capacity to withstand the extensive testing procedures are likely to fall outside of the small entity definition. Further, in view of the collaborative efforts most likely to achieve results in the development of

[230] *See id.*

[231] *See id.*

vaccines, having an incentive program that effectively is unavailable for joint ventures provides little benefit.

To its credit, the Patent Office also recently a rule change to encourage individuals, small businesses, and non-profits to collaborate with the Federal Government while still maintaining their small entity status for purposes of obtaining discounted patent fees.[232] As a general rule, the U.S. government is considered a large entity, and so in collaborating with the government, the joint venture loses its ability to claim small entity status.[233] The rule creates a number of exceptions that permits an otherwise qualifying small or micro-entity from losing that status due to federal collaboration.[234] However, this new rule does not save most of the collaborative efforts occurring during the current pandemic, which involve at least one firm that would not qualify as a small entity, or efforts that are being done solely by large firms.

Prioritized examination allows a patent application to jump ahead of patent applications that were filed prior to it, upon meeting certain conditions – in this case, upon a granted request made by a small or micro-entity for technology related to the pandemic. Usually, patent applications are taken up for examination by the assigned examiner in the order in which they have been filed. Currently, the average length of time between filing and receiving a First Office Action (that is, the first response from the Patent Office that provides information about what is and is not patentable in the application) is about 15.6 months; the average length of time between filing and issuance of a patent is just shy of two years. A prioritized examination program that strives to complete examination within a year, or ideally six months, by jumping ahead of other applications in line represents significant timesavings.

As discussed above, having a patent sooner than later on a product that is intended to treat or prevent a pandemic does provide a not-insignificant benefit to the patent holder. Patents cannot be enforced until they are issued; moreover, issued patents are more valuable for negotiating and executing licensing as they provide greater certainty than patent applications. Although there are many other hurdles that vaccine developers must jump through, giving them property rights in their inventions over a year earlier than usual is a noticeable advantage. Opening this incentive to large firms, as well as collaborations that include at least one large firm – that is, opening the program to entities that are currently shut out of the program due to its limitation of small and micro-entity status would mean that the benefit would be available to the very types of firms that are making progress in this area. Further, small and micro-entities, working either independently or with the U.S. government, would still be eligible to participate in the program and receive prioritized examination.

Implementation of this proposal is simple, particularly because it is merely expanding an already existing pilot program. Further, the Patent Office has significant experience in operationalizing prioritization of examination given the multiple methods that already exist, allowing an applicant to "skip ahead" in line and have a patent application taken up out of turn. These methods include petitions to make special, patent prosecution highway (PPH), and prioritized (Track One) examination, and

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[232] *See* 85 Federal Register 82917-923 (Dec. 21, 2020) (amending 37 C.F.R. 1.27(a), effective Jan. 21, 2021).

[233] *See id.*

[234] *See id.*

accelerated examination. Each of these demonstrate the Patent Office's ability to implement a prioritized examination program that does not turn on the small or micro-entity classification of the applicant.

The petition to make special provision allows for applications from certain categories of applicants and applications on certain types of important technologies to be examined out of turn and ahead of other applications.[235] Petitions to make special may be filed without a fee if the applicant is 65 or older or in poor health, if the invention will "enhance the quality of the environment" or contribute to the conservation of energy resources, or is useful in countering terrorism.[236] While this option is cheap, the circumstances in which petitions to make special are available are fairly narrow and, perhaps worse, the petitions themselves often take months to be granted before the patent application is taken up out of turn.

The patent prosecution highway, or PPH, is available for patent applications that have counterpart applications filed in foreign patent offices.[237] In the PPH, participating patent offices agree that when an applicant receives a final ruling from one of the participating offices that allow at least one claim, the applicant can then seek fast-tracked examination of the corresponding claim(s) in other participating offices.[238] Not every foreign patent office participates, but many of the more popular patent offices do, including USPTO, EPO, JPO, Australia, Canada, China, Mexico, Russia, and the UK.[239] While this option does not speed up the initial examination, it does advance prosecution after at least one participating patent office has had the opportunity to act on an application.

"Track One Prioritized Patent Examination Program" allows a patent applicant to pay for a quicker examination of a patent application.[240] This program is limited to 12,000 patent applications yearly and promises a final disposition within about twelve months.[241] The fee associated with prioritized examination is $4000 on top of other examination fees.[242] Additionally there is a limit on the number of claims permitted in the patent.[243] While this process to speed up examination is not limited

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[235] *See* 37 C.F.R. 1.102 (c).

[236] *See id.*

[237] *See, e.g.,* USPTO, *Patent Prosecution Highway (PPH) – Fast Track Examination of Applications*, *available at* https://www.uspto.gov/patents/basics/international-protection/patent-prosecution-highway-pph-fast-track.

[238] *See id.*

[239] *See id.*

[240] USPTO, *USPTO's Prioritized Patent Examination Program*, available at https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program.

[241] *See id.*

[242] *See* 37 C.F.R. 1.17(c). The fee is $2000 for a small entity and $1000 for a micro entity. *See id.*

[243] *See id.*

to type of applicant or technology, it levees a fairly hefty premium on top of already expensive prosecution fees.

The long-term existence of these various prioritized examination programs demonstrates the ability of the Patent Office to implement and administer them without much issue. Moreover, data from these programs helps address the primary opposition to this proposal – i.e., if the prioritized examination program is open to a larger range of applicants, the Patent Office will be overwhelmed. Given how well the Patent Office has handled the number of applicants availing of existing expedited programs, it is unlikely that this proposal would put more burden on the Patent Office than it can handle. Based on Patent Office Data, 2090 electronic petitions to make an application special on grounds of age or health were filed in the 12 months preceding December 2020, as well as 1634 non-electronic petitions for the same.[244] Approximately 1100 Track One applications are filed each month, with the time to first office action being 1.8 months and the pendency from granting of the Track One petition to final disposition being 6.2 months.[245]

The Patent Office can be creative when setting up an expedited or accelerated examination program. While previous programs may be limited in time or scope, the variety of programs available and the ability of the Patent Office to readily handle those availing of these programs demonstrate that limiting the COVID-19 Prioritized Examination Program to only small micro-entities is not necessary. It is further unlikely that opening prioritized examination for firms of all size would overwhelm the Patent Office and its examining corps – the proposal simply reorders the applications from the order in which they were received to take up for examination. Thus, in order to best incentivize innovation in the COVID-19 prevention and treatment space, the provision limiting the expedited program to small and micro entities should be removed. Any application filed that is related to COVID-19 prevention and treatment, regardless of applicant size, should be able to move ahead in the line for prosecution.

2. Add a Collaboration Booster

While opening the Prioritized Examination Program to firms of all sizes would be a good first step, the incentivizing nature of this program could be further enhanced by recognizing the heightened innovative capacity of collaborative efforts. Specifically, patent applications covering technology related to COVID-19 may request prioritized examination regardless of the size of the firm, but the program should be enhanced by permitting "priority-priority" examination to patent applications submitted on behalf of a collaborative effort—effectively a bump to the head of an already expedited line.

As discussed above, the bulk of vaccine research and development for COVID-19 is being done via collaborative efforts, as is likely true of other future efforts, specifically during a pandemic. The vaccines that have been approved for use in the United States and the UK are all products of significant collaborations: Moderna and the National Institutes of Health (NIH); BioNtech and Pfizer and Fosun

[244] *See* USPTO, *Petition Data December 2020*, *available at* https://www.uspto.gov/dashboard/patents/petitions.html. These petitions were decided in 0 days for electronic petitions and an average of 22 days for non-electronic petitions. *See id.*

[245] *See* USPTO, *Patent Special Program Data December 2020*, *available at* https://www.uspto.gov/dashboard/patents/special.html.

Pharmaceuticals; and Astrazeneca and the University of Oxford.[246] Over half of the other potential vaccines that are in Phase 2 trials are being developed through collaborative efforts.[247]

The reason for this proposal is a recognition of the value that collaborative endeavors add to innovation, as discussed above. By pooling resources and intellectual capital, as well as putting the problem in front of a larger number of smart people, collaborations have the ability to provide an even better solution than may be available based on individual efforts. The benefits of prioritized examination would be just as advantageous to a collaboration as for an individual firm and thus this proposal seeks to entice even more collaborative efforts going forward.

This proprosal would not require any additional resources at the Patent Office beyond the already-implemented (although ideally expanded) prioritized examination pilot program. Instead, this proposal seeks simply to reorder those patent applications that are in line to be examined through that program. All qualifying patent applications could request to be prioritized and, if granted, those requests that are the product of collaborative inventive efforts would simply be moved to the head of the line. Moreover, if this program were indeed to incentivize collaborative efforts, the potential number of patent applications to be examined could be decreased.

There are, of course, some difficulties with preferencing patent applications based on collaborative effort. A primary objection would be that it could be easy for a large company to "game" the system – for example, one company could set up a sham collaboration with a subsidiary of itself or a shell company simply to get a boost to the front of the patent examination line. One way to alleviate this concern is to require that the companies verify their independence. There are options available from corporate law that could easily be used in this arena to ensure that collaborative efforts between independent companies are what they appear to be. Another objection is that this provision may overwhelm or clog up the expedited examination program for other, non-collaborating patent applicants. While that is a valid concern, it is unlikely that there will be so many collaborative patent applications requesting and granted prioritized examination that non-collaborating patent applicants would be overly disadvantaged. Moreover, the benefits that could be realized through a collaboration outweigh the slight inconvenience of shifting non-collaborative patent applications slightly backwards in the queue.

3. Make Permanent as Part of Patent Office Regulations

Priority examination for COVID-19 related patent applications, expanded to cover firms of any size and either with or without the extra-boost for products of collaboration, should be made a permanent feature within the Patent Office. Specifically, a prioritized examination program should be available whenever the World Health Organization or the Centers for Disease Control declare a global

[246] *See* https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html. It is worth noting that at least one of, if not both of, the parties in these collaborative efforts is also a large firm that would not qualify under the existing prioritized examination procedure due to their size.

[247] *See id.* Three of these eight are also the three identified as being in Phase 3 trials, as combined trials are being allowed at this point. *See id.*

pandemic or national health emergency and the window for priority examination should remain open until that pandemic or health emergency is declared "over."

Implementing this as a standing program allows the Patent Office to respond quickly in the case of the next pandemic, not by having to create yet another new program, but by immediately being able to move relevant patent applications to the front of the line. Further, making this prioritized examination program permanent has been done before to solve other important public health and safety issues, as well as to permit speedy examination for additional fees. The impact on the Patent Office in making this change is minimal. Yet, despite being an easy fix, it is an important one as we have seen during COVID-19, because pandemics have the potential to become rapidly and incredibly disruptive to everyday business and life. Rather than having to behave reactively, permanent regulations that cover legitimate public health issues would allow the Patent Office to be proactive, even if the world is working from home. Moreover, the knowledge that there is a standing expedited examination program for pandemic-related technology may incentivize firms to more quickly jump into research and development when the next pandemic occurs.

As described above, there is Patent Office precedent for making certain prioritized examination procedures permanent, including some that were introduced during a time of great need that has somewhat lessened in the meantime. Similarly, the prioritized examination procedure introduced to deal with COVID-19 is responsive to a great need, but the ability to quickly obtain intellectual property protection on pandemic-related inventions will remain important to the public for many years to come. For this reason, it is reasonable and a rather easy fix to enact permanent regulations to allow any pandemic-related (not just COVID-19-related) inventions to obtain expedited examination.

4. Find Collaborative Efforts Leading to Patenting Pro-Competitive

The joint statement from the FTC and the DOJ acknowledging the importance of collaborations for solving the current pandemic is an important first step. However, the statement could go even further and also be symbiotic and mutually reinforcing with one of the previously suggested proposals to amend the Patent Office's prioritized examination program. While collaborative efforts towards addressing COVID-19 are presumptively allowed, if the collaborative efforts result in a patent application being filed with the Patent Office, these efforts should be deemed generally procompetitive. Moreover, any patent that results from a collaborative effort should be viewed as generally enforceable by the collaborators or their assignees; the enforcement actions should be deemed generally procompetitive.

While a subtle distinction, this concept goes beyond recognizing that working together to solve the pandemic is likely to not be problematic. Instead, the frame of this statement would show that working together to solve the pandemic and availing of the Patent Office with pandemic-related technology that is the fruit of that collaboration is actually a positive for society. This framing recognizes that, beyond the benefits of collaboration that were described above, patent applications themselves provide benefits to the public in the form of published disclosures. The purpose of this second provision, presumptively permitting enforcement of any patent rights that arise from the collaboration, is to avoid the recent trend of using antitrust as a tool to avoid patent infringement claims; protecting these collaborations by allowing the enforcement of the patents that result from the collaborations would achieve this. Finally, the Agencies' position could be extended, like the Patent Office proposal, to be effective during any future declared pandemic or national health emergency.

To be sure, there could be anticompetitive collaborative efforts and anticompetitive enforcement actions related to collaboratively obtained patents; however, the blessing conferred by the stance proposed in this article is narrow (tied to COVID-19 or, perhaps better, to pandemics current or future) and the blessing is granted only when the companies in question have already committed to a course of research and development in a much-needed space. These activities are presumptively allowed until a patent application has been filed and then these collaborations are generally allowed. For this reason, finding these activities generally procompetitive is unlikely to result in anticompetitive behavior being missed nor is enforcement of competition laws prohibited by this guidance.

Conclusion

For many Americans, COVID-19 is the first major public health emergency that has affected our day-to-day lives. Given what scientists are saying, this pandemic may not be the last this generation sees. For this reason, it is important to be better prepared for the next pandemic. Having systems in place to more quickly address the next emergency is one step that can be taken now – including having an existing program of prioritized examination at the Patent Office for public health emergency-related technologies. While this pandemic showed us how quickly our lives can change in the face of an unknown virus, COVID-19 has also demonstrated what amazing innovation can occur when companies collaborate to fight the new disease. Celebrating these collaborative efforts and recognizing them via regulatory reform – by permitting collaborative efforts, even those where one party is a big company or organization, to avail of the prioritized examination program and further adding a collaboration booster to allow patent applications submitted by collaborative efforts to "jump the line" – makes sense when thinking not just about this pandemic, but also those to come. Furthermore, standing guidance that not only blesses these collaborative efforts as generally pro-competitive, but also ensuring that the patents that result from these collaborative efforts can be enforced acknowledges their value to society.

These proposed changes do not affect questions about regulatory approval, access, manufacturing, or distribution – all of which are legitimate concerns for fighting a pandemic. However, the intellectual property system is not the place to address those problems. Patents incentivize invention and innovation, provide disclosure of new technology, and facilitate collaborative efforts as well as licensing. Devaluing patents may have significant negative impacts on those fronts; addressing those issues through other means is likely a better approach and well beyond the scope of this article. Instead, this article suggests that if we are going to tweak the patent system to enhance pandemic-related innovation, we can do a better job. Making the proposed four simple changes suggested to the regulatory schemes of the Patent Office and the competition authorities has little down-side and much to appreciate, especially in our search for the next vaccine.