

Every Minute Matters: Improving the Regulatory Response to Vaccine Development During a Public Health Emergency

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ABSTRACT

In recent months, our lives have been turned upside down by the novel coronavirus (COVID-19) emergency. With no cure or vaccine in sight, millions of people have contracted the virus, and the death toll has surpassed that of World War I in a fraction of the time. In fact, the past decade has been marked by a series of highly publicized public health emergencies, including the devastating Ebola and Zika virus global outbreaks. Some of this panic arose from a failure to manufacture and distribute vaccines in a timely fashion. This failure occurred despite having several viable vaccine candidates, adequate funding, and strong public support for the vaccines. This Article explains how these failures are the consequence of a complex network of existing regulatory pathways and insufficient incentives to produce affordable vaccinations during a public health emergency. Fortunately, there are several ways that both the U.S. Patent and Trademark Office and the U.S. Food and Drug Administration can improve and streamline the process of patenting, approving, manufacturing, and distributing a vaccination. The last decade has demonstrated that public health emergencies occur quickly, and affected communities cannot afford the delays and mishaps that characterized the vaccine response to COVID-19, Ebola, and Zika.

This Article explores three ways to facilitate the development and distribution of vaccinations during a public health emergency. First, the U.S. Patent and Trademark Office can establish a dedicated public health emergency patent pathway for vaccine technology developed specifically in response to a public health emergency. Second, the U.S. Food and Drug Administration can better process investigational new drug applications filed for qualifying vaccines by revising its Qualified Infectious Disease Product pathway to include biologics and by providing targeted incentives for qualifying applications that reduce some of the financial burdens of providing vaccinations at low cost. Finally, Congress can pass legislation allowing for the issuance of a compulsory license to manufacture and distribute the vaccination, if vaccine developers and manufacturers are unable to independently agree on a licensing transaction that will be financially feasible for the targeted population and for all

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parties involved. With improved regulatory pathways developed in advance of the next public health emergency, researchers and manufacturers will be better positioned to develop and distribute vaccines to affected communities in time for them to be effective.

INTRODUCTION

In March 2015, health officials in Brazil alerted the World Health Organization (WHO) about a curious viral infection that caused fevers and skin rashes in otherwise healthy adults.¹ Two months later, Brazil again alerted the WHO about forty-nine cases of Guillain-Barre syndrome, a devastating neurological disease that can cause paralysis.² Shortly after, health officials were horrified to see an increase in babies born with debilitating head and brain abnormalities.³ Within six months, what was thought to be a mild mosquito-borne infection had become a global public health emergency—the Zika epidemic.⁴ The sprint to develop a Zika vaccine began almost instantaneously.⁵ By March 2016, government officials were confident that a vaccine would soon be on the market, but that confidence soon turned to disappointment.⁶ Following a breakdown in a licensing agreement and funding streams, researchers found themselves returning to the drawing board to develop a new Zika vaccine, months after the virus had disappeared from the public eye.⁷ Today, several years after Zika first caught the attention of health officials in Brazil, there is still no Zika vaccine on the market.⁸

One of the unique challenges presented by an impending public health emergency is the ability to get biologic products, such as vaccinations, to affected populations as quickly as possible while simultaneously ensuring that the vaccinations are affordable for the affected population and financially feasible for vaccine researchers and manufacturers.⁹ This challenge is exacerbated when there is no coordinated plan to identify, develop, approve, and manufacture the required products, and is further compounded when the ability of a drug developer to recoup the costs of drug development is limited by the ability (or rather, inability) of the affected population to

¹ Siddhartha Mukherjee, *The Race for a Zika Vaccine*, NEW YORKER (Aug. 22, 2016), <https://www.newyorker.com/magazine/2016/08/22/the-race-for-a-zika-vaccine> [https://perma.cc/DDJ2-V23T].

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ Erika Check Hayden, *The Race is On to Develop Zika Vaccine*, NATURE NEWS (Mar. 28, 2016), <https://www.nature.com/news/the-race-is-on-to-develop-zika-vaccine-1.19634> [https://perma.cc/7B4E-D56U].

⁶ *Id.*

⁷ Lena H. Sun, *Scientists Don't Have a Decade to Find a Zika Vaccine. They Need Volunteers Now*, WASH. POST (Jan. 12, 2017), https://www.washingtonpost.com/national/health-science/three-volunteers-on-the-front-lines-of-zika-vaccine-testing/2017/01/12/9d0f1b76-bbff-11e6-ac85-094a21c44abc_story.html?utm_term=.f65d38eb4740 [https://perma.cc/T5XN-MTNW].

⁸ *Zika Virus Vaccines*, Nat'l Inst. for Allergies & Infectious Diseases (Aug. 16, 2018), <https://www.niaid.nih.gov/diseases-conditions/zika-vaccines> [https://perma.cc/KP8P-HKXM].

⁹ Rebecca Haffajee, Wendy E. Parmet & Michelle M. Mello, *What is a Public Health "Emergency,"* 371 N. ENGL. J. MED. 986, 986–87 (2014).

afford the product.¹⁰ The ineffective response to recent public health emergencies has highlighted the urgent need to develop a plan that balances pharmaceutical development costs with the need for the product to reach affected populations quickly and with limited financial burden to consumers.¹¹ Although there are several categories of products that experience challenges during public health emergencies, including drugs and medical devices, this Comment will focus specifically on the challenges of developing and distributing biologic products during a public health emergency.

Section 319 of the Public Health Service Act (PHSA) grants the Secretary of Health and Human Services the ability to declare a public health emergency in one of two situations: “1) a disease or disorder presents a public health emergency; or 2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.”¹² A public health emergency declaration allows the federal government¹³ to access reserve funds, mobilize resources, and otherwise expedite responses to the emergency.¹⁴ However, this declaration is of little use when the processes by which vaccinations and other medical countermeasures are developed, manufactured, or distributed are ill-equipped to meet the full scope of demands during that time.¹⁵

In 2018, Professor Ana Santos Rutschman coined the phrase “intellectual property preparedness” to describe the transactional steps that have been and should be taken to develop, market, and protect intellectual property developed in response to a potential public health emergency.¹⁶ Professor Rutschman’s primary concerns stem from the claimed mismanagement of vaccine manufacturing and distribution in response to the Ebola and Zika outbreaks, which led to delays in getting vaccinations and other biologic products to market.¹⁷

Professor Rutschman identified several problems with the current state of intellectual property preparedness. First, vaccines developed in response to public health emergencies have unique research and development costs, especially when a public health emergency quickly captures public attention (thus spurring a stream of

¹⁰ *Id.* at 987.

¹¹ *See infra* Section II.A.

¹² *Public Health Emergency Declaration Q&As*, U.S. DEP’T HEALTH & HUMAN SERVS.: PUBLIC HEALTH EMERGENCY, <https://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx> [https://perma.cc/DS69-QRBT] (last accessed Sept. 1, 2020).

¹³ Responses to public health emergencies are regulated at both the state and federal level. This Comment will focus on public health emergency responses at the federal level because the patent and regulatory pathways that vaccine developers need to utilize in order to get their product to affected populations quickly are overseen by federal agencies.

¹⁴ *See Public Health Emergency Declaration*, U.S. DEP’T OF HEALTH & HUM. SERVS.: PUBLIC HEALTH EMERGENCY (2018), <https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx> [https://perma.cc/QB7B-A42R]; *see* Haffajee et al., *supra* note 9, at 986–87.

¹⁵ *See infra* at II.A.

¹⁶ Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1200 (2018).

¹⁷ *Id.* at 1200, 1200–04. In particular, both Zika and Ebola vaccination candidates are undergoing clinical trials required for approval by the Food and Drug Administration, despite the fact that both the Zika and Ebola crises have come and gone from the public arena. *Id.* at 1247.

funding) and just as quickly fades away (resulting in the funding stream drying up).¹⁸ For a vaccine or other biologic product to successfully reach the market, the candidate biologic requires a substantial financial commitment, especially to sustain through the lengthy approval process proscribed for biologics by U.S. Food and Drug Administration (FDA).¹⁹ Second, as the COVID-19 outbreak demonstrates, it is difficult to predict what the next public health emergency will be, making it challenging for both private- and public-sector research entities to determine where to concentrate their limited resources.²⁰ If research and development efforts start from scratch only after a public health emergency has been identified, it is all but impossible for a useful vaccination or biologic product to reach the market in time to have any tangible difference.²¹ Third, the financial incentives for vaccine development in response to a public health emergency are generally lacking.²² In the last decade, many public health emergencies have been concentrated in regions of the world where the affected population cannot pay the high costs that would be required for a vaccine or biologic manufacturer to recoup all research, development, and manufacturing costs without supplemental funding.²³ Although incentives such as priority review vouchers exist for research entities to produce pharmaceutical products that address so-called “neglected diseases,”²⁴ they are not always the most effective at leading to further research and development that targets potential public health emergencies, nor do the incentives actually help the target product reach affected populations faster.²⁵

This Comment proposes three additional mechanisms by which vaccinations can reach targeted populations faster during a public health emergency, without sacrificing the incentives provided by a market-based patent system: first, a revised public health emergency patent designation at the U.S. Patent and Trademark Office (USPTO); second, a revised Qualifying Infectious Disease Product designation that leverages FDA’s existing Breakthrough Therapy designation; and third, a compulsory licensing scheme for instances where access to the biologic product is hampered and all other voluntary processes have failed. To do so, Part I surveys the biologics approval process and some of the unique research and regulatory barriers present in vaccine research and development, provides a summary of current incentives in place at the USPTO and FDA, and discusses previous attempts to introduce a compulsory licensing scheme in response to public health emergencies and other health crises. Part II provides an overview of three recent public health emergencies—Ebola, Zika, and COVID-19—and discusses three proposals that have been raised to address the intellectual property challenges in the public health emergency context: (1) dormant licensing, (2) exclusive federal government patenting proposal, and (3) public collaboration. Part III describes

¹⁸ *Id.* at 1206–07.

¹⁹ *See supra* Section I.A.

²⁰ *See* Rutschman, *supra* note 16, at 1207, 1209–10.

²¹ *See id.* at 1207.

²² *See id.*

²³ *See id.* at 1209; *see also* WORLD HEALTH ORG., NEGLECTED TROPICAL DISEASES, https://www.who.int/neglected_diseases/diseases/en/ [<https://perma.cc/4TMG-S2NK>] (noting that a substantial number of “neglected tropical diseases”—which included Zika and Ebola—were concentrated in 149 tropical countries) [hereinafter WORLD HEALTH ORG.].

²⁴ *See* WORLD HEALTH ORG., *supra* note 23.

²⁵ *See infra* Section I.B.

the three novel proposals discussed above and explains the benefits of each. Finally, Part IV anticipates and addresses criticisms that may be raised in response to these proposals.

I. BIOLOGICS DEVELOPMENT AND EXISTING INCENTIVES

FDA has an extensive and lengthy approval process for any drug or biologic product that is distributed in the United States. To incentivize drug and biologic development companies to produce certain types of products, FDA provides several incentives to reduce the burdens of product approval. This Part provides an overview of the FDA approval process, specifically focusing on the steps needed to get biologics approved by FDA, and the specific challenges posed by biologics (which includes vaccines) in the approval process. This Part will then discuss the current incentives provided by the USPTO²⁶ and FDA.²⁷ This review of the current incentives provided by the USPTO and FDA will set the foundation for a discussion of why the current incentives are insufficient to promote biologics development during a public health emergency.

A. Overview of Biologics Development and Approval at FDA

Any vaccination introduced into interstate commerce for human use in the United States must be licensed by FDA in accordance with the Public Health Service Act (PHSA).²⁸ Vaccines are considered biological products, or “biologics,” under the PHSA.²⁹ Unlike traditional synthetic drugs, biologics are derived from living organisms and include toxins, blood, proteins, vaccines, and allergenic products.³⁰ As such, they are more complex than drugs derived from non-living chemical components, are more difficult to replicate when attempting to create cheaper generic alternatives, and are subject to more stringent safety and efficacy standards.³¹

²⁶ The USPTO is the federal agency responsible for issuing patents on qualifying inventions. Patent examiners review patent applications to ensure that the invention meets certain qualifications laid out in 35 U.S.C. §§ 101–103 (2012). If approved, a patent is granted for a term of twenty years from the date of application. During the patent term, the patent holder has an exclusive right to make, use, sell, or license their patented invention. §§101–103, 271; *see also* U.S. PATENT AND TRADEMARK OFFICE, PATENT PROCESS OVERVIEW, <https://www.uspto.gov/patents-getting-started/patent-process-overview> [<https://perma.cc/Y8FU-BWR5>].

²⁷ The Food and Drug Administration is responsible, among other things, for regulating drugs and biologics for interstate commerce in the United States. FDA’s Center for Drug Evaluation and Research oversees an extensive process by which pharmaceutical developers must demonstrate that their candidate drug or biologic is both safe for use in humans and effective for its intended use. *See generally Drug and Biologic Approval and IND Activity Reports*, U.S. FOOD & DRUG ADMIN. (Oct. 17, 2019), <https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/drug-and-biologic-approval-and-ind-activity-reports> [<https://perma.cc/64UQ-L9NJ>] (last visited Jan. 13, 2019); *see also Investigational New Drug (IND) or Device Exemption (IDE) Process (CBER)*, U.S. FOOD & DRUG ADMIN. (Mar. 24, 2020), <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-drug-ind-or-device-exemption-ide-process-cber> [<https://perma.cc/B2WP-PYMT>].

²⁸ *Vaccine Development – 101*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblprocess/ucm133096.htm> [<https://perma.cc/5C64-5TVR>] (last visited Nov. 23, 2018); *see also* 42 U.S.C. § 262 (2019).

²⁹ 42 U.S.C. §262(i)(1) (2019).

³⁰ *Id.*; *see also* Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 142 (2015).

³¹ *Id.* at 142–43.

In a non-emergency situation, the process for receiving a biological license for a vaccination can take ten to fifteen years, from identifying the initial components of a vaccination through the required clinical trials.³² Once a candidate vaccine has been developed, researchers conduct a series of laboratory tests to establish that the candidate vaccination is safe for human testing.³³ At this stage, researchers can submit an investigational new drug (IND) application to proceed with clinical trials in humans that is largely focused on convincing FDA officials that the candidate vaccine is safe for use in human clinical trials.³⁴ FDA can then permit clinical trials to proceed or can place the study on hold if the information contained in the IND does not sufficiently establish that the candidate vaccine will be safe for human testing.³⁵ If permitted to proceed, clinical testing occurs in three phases.³⁶ Phase I trials are designed to gather information about the safety of the candidate vaccine and include testing for adverse reactions to the vaccine as well as general information about immune responses.³⁷ Phase II trials continue to monitor the safety of the candidate drug, as well as collect results that indicate whether the vaccination is effective.³⁸ Phase III trials continue to look at the effectiveness of the candidate vaccination in a larger study population, as well as the consistency of vaccination results between and across multiple vaccine lots.³⁹

Once clinical trials have been completed, researchers can submit a biologics license application (BLA) to introduce the vaccination into interstate commerce.⁴⁰ The Center for Biologics Evaluation and Research at FDA will evaluate the safety and efficacy information contained in the BLA and will weigh the risks and benefits of the candidate vaccine to decide whether a biologics license should be granted.⁴¹ Once a biologics license is granted, FDA will continue to evaluate the safety of the vaccine, including but not limited to monitoring the manufacturing process for the vaccination and post-approval clinical trials (also known as Phase IV clinical trials).⁴² The Department of Health and Human Services also maintains the Vaccine Adverse Event Reporting System (VAERS) to allow members of the public to report adverse reactions to vaccinations.⁴³

³² Paul Offit, *Vaccine Development, Testing, and Regulation*, COLLEGE OF PHYSICIANS OF PHILA. (Jan. 17, 2018), <https://www.historyofvaccines.org/index.php/CONTENT/articles/vaccine-development-testing-and-regulation> [<https://perma.cc/W3PB-MUVZ>].

³³ Valerie Marshall & Norman W. Baylor, *Food and Drug Administration Regulation and Evaluation of Vaccines*, 127 PEDIATRICS S23, S26 (2011).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* This is unique to many biologics, because the size and complexity of biologics renders them susceptible to denaturing or instability that could result in adverse effects in clinical study participants.

⁴⁰ 21 C.F.R. § 601.20; Marshall & Baylor, *supra* note 33, at S27.

⁴¹ 21 C.F.R. § 601.20; *see Vaccine Development – 101, supra* note 28.

⁴² *See Vaccine Development – 101, supra* note 28.

⁴³ *Report an Adverse Event to VAERS*, DEP'T OF HEALTH AND HUM. SERVS.: VACCINE ADVERSE EVENT REPORTING SYSTEM, <https://vaers.hhs.gov/reportevent.html> [<https://perma.cc/2UJH-TBW4>] (last accessed Nov. 25, 2018). Vaccine manufacturers are required to report adverse reactions to VAERS. *Id.*

During a public health emergency, the vaccination approval process can be expedited or bypassed in whole or in part under the Pandemic and All-Hazards Reauthorization Act of 2013, which amends Section 564 of the Federal Food, Drug and Cosmetic Act (FDCA) to allow the Commissioner of the FDA greater flexibility in ensuring that necessary medical countermeasures are available during a public health emergency.⁴⁴ FDA can grant approval based on “adequate and well-controlled clinical trials” that the vaccination “is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit.”⁴⁵ Researchers can also leverage information gathered from already-existing clinical trials and apply that information toward the development of new candidate vaccinations.⁴⁶ Furthermore, several organizations conduct surveillance to collect information about potential public health emergencies in order to identify and study the pathogen that could cause a widespread outbreak.⁴⁷

One obstacle to vaccine development during public health emergencies is the difficulty in developing “generic” vaccines—termed “biosimilars” by FDA—that could reduce costs to consumers in the same way that generic drugs do.⁴⁸ In 2009, President Barack Obama signed into law the Biologics Price Competition and Innovation Act (BPCIA) in order to spur biosimilars research and development.⁴⁹ However, there are several challenges to this process, both from a practical standpoint and a regulatory standpoint. From a practical standpoint, biologics are derived from living organisms and are often large molecule drugs that are more difficult to replicate than smaller synthetic compounds.⁵⁰ Furthermore, many biologics, including proteins and blood-based compounds, are prone to breaking down if developed or stored in conditions that fall outside of a narrow ideal range. As such, there may be variations in safety and efficacy, not only between a reference biologic and its biosimilar, but also between multiple batches of the same reference biologic.⁵¹ FDA also requires that biosimilars meet heightened clinical requirements, including that the reference product and the candidate biosimilar utilize the same mechanisms for the conditions of use

⁴⁴ 42 U.S.C. § 300hh; *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> [<https://perma.cc/595T-GLSR>] (last visited Nov. 21, 2018); *Summary of PAHPRA’s MCM Provisions*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm346195.htm> [<https://perma.cc/9BH5-KK5B>] (last accessed Nov. 21, 2018). During a public health emergency and other emergency situations, FDA-regulated products such as drugs, vaccines, and medical devices are considered “medical countermeasures.” See *What are Medical Countermeasures?*, U.S. FOOD & DRUG ADMIN. (June 1, 2020), <https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures> [<https://perma.cc/7RZ5-995Q>] (last accessed Nov. 25, 2018).

⁴⁵ 21 C.F.R. § 601.41.

⁴⁶ Michelle L. Rose & Claudia K. Fehling, *How to Speed Up Drug and Vaccine Development During a Public Health Crisis*, STAT (2017), <https://www.statnews.com/2017/11/09/drug-vaccine-development-public-health/> [<https://perma.cc/KHT6-RBTT>].

⁴⁷ See, e.g., *Public Health Surveillance*, WORLD HEALTH ORG., https://www.who.int/immunization/monitoring_surveillance/burden/vpd/en/ [<https://perma.cc/F8D8-JV4W>] (last accessed Nov. 25, 2018).

⁴⁸ See Kasey E. Koballa, *The Biologics Price Competition and Innovation Act: Is a Generic Market for Biologics Attainable?*, 9 WM. & MARY BUS. L. REV. 479, 487 (2018).

⁴⁹ See *id.*

⁵⁰ See *id.*

⁵¹ See Shepherd, *supra* note 30, at 149.

prescribed and that the route of administration, dosage form, and strength are the same.⁵² Because of the heightened requirements for biosimilars, very few biosimilar products have entered the market since the BPCIA was signed into law.⁵³

B. FDA Pathways to Expedite Drug Approval and Distribution

As discussed above, FDA provides several incentives to drug and biologics developers to reduce the financial burden of clinical testing or to expedite the process. This section will review FDA's several options for expediting the review of investigational new drug applications in the hopes of getting certain types of drug products to market faster. These include (1) priority review vouchers, (2) Fast Track designation, (3) Breakthrough Therapy designation, and (4) Qualified Infectious Disease Product pathway. Although a grant of any of these designations might suggest that the candidate drug or biologic is promising, none of the designations guarantees that the candidate drug or biologic will be approved.

I. Priority Review Vouchers

FDA offers priority review vouchers in exchange for the development of specific types of drugs, including those targeting neglected tropical diseases.⁵⁴ The priority review voucher program began in September 2007 to address neglected tropical diseases.⁵⁵ Under this process, a drug development entity, such as a pharmaceutical company, would invest in developing a drug or biologic product aimed at preventing or treating a designated neglected tropical disease⁵⁶ in exchange for a voucher that could be "redeemed" for priority review for a more profitable drug in the future.⁵⁷ Although FDA does not guarantee approval, or approval within a specific timeframe, the goal of a priority review voucher is to get ninety percent of products using a priority review voucher approved and on the market within six months.⁵⁸ Theoretically, the expedited review (and earlier entry into the marketplace) would allow the drug

⁵² 42 U.S.C. § 262(k)–(l) (2019). Non-biologic drugs do not have these same requirements and can also show similarity through means less burdensome and expensive than clinical trials, such as blood tests.

⁵³ See Koballa, *supra* note 48, at 479, 487.

⁵⁴ *Tropical Disease Priority Review Vouchers: Guidance for Industry*, U.S. FOOD & DRUG ADMIN., (July 15, 2020), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program> [<https://perma.cc/YJ63-DMW8>] [hereinafter *Tropical Disease Priority Review Vouchers*]. FDA also provides priority review vouchers for products that target pediatric conditions and products that are designed to combat bioterror attacks. As those are outside the scope of this Comment, those vouchers will not be discussed here.

⁵⁵ Kyle Wamstad, *Priority Review Vouchers—A Piece of the Incentive Puzzle*, 14 VA. J. L. & TECH. 127, 127 (2009).

⁵⁶ As of November 25, 2018, the list of neglected tropical diseases includes malaria, Zika virus, tuberculosis, Chagas disease, and rabies. The list of what constitutes a neglected tropical disease has received some criticism—in particular, the inclusion of malaria on the list. For example, the first priority review voucher was awarded to the pharmaceutical company Novartis for the development of Coartem to treat malaria, but over 200 million doses of Coartem have been administered worldwide. This has been considered an undue windfall to some. See Wamstad, *supra* note 55, at 128; Tatum Anderson, *Novartis Under Fire for Accepting New Reward for Old Drug*, 373 LANCET 1414 (2009).

⁵⁷ See Wamstad, *supra* note 55, at 127. The priority review voucher does require a user fee. For FY 2019, the user fee is approximately \$2.4 million. Fee for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2019, 83 Fed. Reg. 48,437 (Sept. 25, 2018).

⁵⁸ See *Tropical Disease Priority Review Vouchers*, *supra* note 54. For comparison, a standard (non-priority) review is conducted within approximately ten months. *Id.*

development entity to recoup the costs of development for the product targeting the neglected tropical disease, which might not be administered to as large a population.⁵⁹ Under Section 524(b)(2) of the FDCA, an entity that holds a priority review voucher can transfer that voucher to another entity.⁶⁰ Because of the scarcity of the voucher and the voucher's ability to help drug developers beat competitors to market, priority review vouchers are in high demand. For example, Sanofi and Regeneron Pharmaceuticals purchased a priority review voucher from voucher recipient BioMarin for \$67.5 million, which allowed them to beat competitor Amgen to market for a new cholesterol drug, even though Amgen had filed an application for the same drug with FDA first.⁶¹

2. *Fast Track Designation*

FDA describes the Fast Track designation as one “designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet need. The purpose is to get important new drugs to the patient earlier.”⁶² Although the program does not aim to get designated drugs on the market within a specific time, the benefits offered by the designation have been estimated to shorten the approval process by approximately one year.⁶³ Instead, the Fast Track designation includes several benefits that are correlated with expedited approval and distribution.⁶⁴ The benefits include more frequent meetings with FDA officials in order to identify and address issues in the drug approval process earlier; eligibility for priority review and accelerated approval; and the ability to undergo “Rolling Review” by submitting sections of an IND or BLA for targeted periodic review, rather than waiting for a completed application before beginning the review process.⁶⁵ Several vaccinations have received Fast Track designation, including Merck's vaccine Gardasil to treat HPV⁶⁶ and Takeda's Zika vaccine candidate.⁶⁷

⁵⁹ See Wamstad, *supra* note 55, at 128.

⁶⁰ 21 U.S.C. § 360n(b)(2) (2017).

⁶¹ Peter Loftus, *Drug Makers Buy Pricey Vouchers to Speed Products to Market*, WALL ST. J. (Nov. 1, 2015), https://www.wsj.com/articles/drug-firms-buy-pricey-vouchers-to-speed-products-to-market-1445333403#_=_ [<https://perma.cc/2BBJ-J8Y6>].

⁶² *Fast Track*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm> [<https://perma.cc/JTN8-AZGX>] (last accessed Nov. 24, 2018).

⁶³ Melissa Healy, *FDA's Program to Speed Up Drug Approval Shaved Nearly A Year Off the Process*, L.A. TIMES (Dec. 5, 2017), <https://www.latimes.com/science/sciencenow/la-sci-sn-fda-expedited-drugs-20171205-story.html> [<https://perma.cc/KEY2-AB9E>].

⁶⁴ See *Fast Track*, *supra* note 62.

⁶⁵ *Id.*

⁶⁶ Lucija Tomljenovic & Christopher A. Shaw, *Too Fast or Not Too Fast: The FDA's Approval of Merck's HPV Vaccine Gardasil*, 40 J. L. MED. & ETHICS 673, 674 (2012).

⁶⁷ *Takeda's Zika Vaccine Candidate Receives U.S. FDA Fast Track Designation*, TAKEDA (Jan. 29, 2018), <https://www.takeda.com/newsroom/newsreleases/2018/takedas-zika-vaccine-candidate-receives-u.s.-fda-fast-track-designation/> [<https://perma.cc/LE2T-QC7Z>].

3. Breakthrough Therapy Designation

Breakthrough Therapy designation is FDA's newest expedited pathway, established by the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012.⁶⁸ In order for a drug or biologic product to obtain Breakthrough Therapy designation, the drug developer must present preliminary clinical evidence that the candidate drug not only treats a serious condition, but also that the candidate drug may demonstrate substantial improvement in effectiveness or safety over other available therapies.⁶⁹ A Breakthrough Therapy designation includes all of the benefits of a Fast Track designation, with the added benefits of increased involvement by senior officials at FDA, and intensive guidance beginning as early as Phase I clinical trials.⁷⁰ Having early involvement by senior officials and guidance beginning during Phase I trials will allow for FDA officials and researchers to work together to develop clinical trials that will pass muster with FDA, likely avoiding the costs and delays associated with having to supplement a BLA with additional clinical trials or having to repeat trials. In 2019, seventy-nine applications for Breakthrough Therapy designation were approved, including a candidate treatment for cystic fibrosis and a candidate treatment for postpartum depression.⁷¹ Similar to the Fast Track designation, the Breakthrough Therapy designation reduces the approval time by approximately one year.⁷²

4. Qualified Infectious Disease Product (QIDP) Designation

In January 2018, FDA released draft guidance regarding the incentives for a designated qualified infectious disease product (QIDP) under the *Generating Antibiotic Incentives Now* (GAIN) provision in Section 505E of the FDCA.⁷³ GAIN was enacted to incentivize the creation of drug products that diagnose, prevent, or treat "serious or life threatening conditions" caused by "an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens."⁷⁴ The primary incentive of a QIDP designation is a five-year exclusivity extension if the qualifying drug product is approved under Section 505⁷⁵ of the FDCA and both a fast-track designation and priority review for the first application submitted for approval for a

⁶⁸ *Fact Sheet: Breakthrough Therapies*, U.S. FOOD & DRUG ADMIN., (Mar. 28, 2018), <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/fdasia/ucm329491.htm> [<https://perma.cc/43A5-7XUW>].

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Breakthrough Therapy Approvals*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/nda-and-bla-approvals/breakthrough-therapy-approvals> [<https://perma.cc/BUQ2-KVJV>].

⁷² See Healy, *supra* note 63.

⁷³ See U.S. FOOD & DRUG ADMIN., QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION: QUESTIONS AND ANSWERS GUIDANCE FOR INDUSTRY (Jan. 2018), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualified-infectious-disease-product-designation-questions-and-answers> [<https://perma.cc/7HFN-T68Y>] [hereinafter QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION].

⁷⁴ *Id.* Examples of qualifying pathogens include methicillin-resistant *Staphylococcus aureus* (commonly known as MRSA), pathogenic strains of *E. coli*, and multi-drug resistant tuberculosis. 21 U.S.C. § 355f(1) (2018).

⁷⁵ 21 U.S.C. § 355f. This is important because biologics, including vaccinations, are *not* approved under Section 505 of the FDCA; rather, biologics, discussed *supra* at Section I.A, are approved under Section 351 of the FDCA and are subject to more intense scrutiny. See Shepherd, *supra* note 30, at 142.

QIDP.⁷⁶ However, the current QIDP designation only addresses drugs approved under Section 505 of the FDCA, which applies to small-molecule non-biologic drugs.⁷⁷ The draft guidance specifically indicates that biologics, which includes vaccinations, are not entitled to a QIDP designation.⁷⁸ This exclusion did not go unnoticed during the public comment period. The Biotechnology Innovation Organization specifically indicated that the exclusion of biologics from QIDP designation and incentives represented a “missed opportunity to spur innovation” of critical biologic products, including vaccines and monoclonal antibodies.⁷⁹ As proposed in Section IV.B below, the QIDP framework, particularly the option for multiple “layers” of expedited review and targeted attention to study development, could be applied to the development of vaccinations in response to a public health emergency while also providing necessary market protections and incentives to enable vaccine developers to invest in vaccine research.⁸⁰

C. Intellectual Property Incentives at the USPTO

In addition to the drug approval process, researchers can elect to seek a patent over any biologic product or its individual components. Patenting a biologic product is not required in order to get the product approved, but researchers overwhelmingly seek patent protection for their products. The following section will discuss the options currently available at the USPTO to expedite the patent and drug approval process, respectively. This includes the current “Track One” pathway at the USPTO and the “Patents for Humanity” program that the USPTO oversees to grant priority review vouchers as awards for humanitarian technologies.

1. USPTO “Track One”

The USPTO currently has one general “fast track” option for any patent application regardless of subject matter, named the USPTO Prioritized Patent Examination Program, or “Track One.”⁸¹ Established in 2011, this track allows patent applicants to pay an additional fee⁸² to have the examination of their patent application expedited.⁸³ The USPTO has an annual cap on Track One patents, limiting this option to the first 10,000 patent applications received and requested that year. The process for patent applicants is fairly simple—applicants submit a “Certification and Request for

⁷⁶ 21 U.S.C. §§ 355f, 356(b)(1), 360n-1; *see* QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION, *supra* note 73, at 2.

⁷⁷ QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION, *supra* note 73, at 4.

⁷⁸ *Id.*

⁷⁹ U.S. FOOD & DRUG ADMIN, COMMENT FROM BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) (Apr. 10, 2018), <https://www.regulations.gov/document?D=FDA-2017-D-7001-0005> [<https://perma.cc/3LNV-LUFU>].

⁸⁰ *See infra* Section III.B.

⁸¹ USPTO’s Prioritized Patent Examination Program, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program> [<https://perma.cc/Z95G-BMRR>].

⁸² The fee is \$4,000 for “non-small entities” and \$2,000 for “small entities.” *See id.*

⁸³ *Id.*

Prioritized Examination under 37 CFR 1.102(e)” along with their application.⁸⁴ In return, the USPTO aims to provide a final disposition of the patent application within twelve months, without adding any expedited deadlines for the patent applicant to request appeals or to amend or supplement their application.⁸⁵ Users can track how many Track One patent applications have been filed; approximately 8,300 applications were filed in 2019 and early 2020.⁸⁶ Track One is available to all patent applications, regardless of the subject matter of the patents.

2. Humanitarian Patent Program

The USPTO has previously attempted—and failed—to implement separate fast track options for humanitarian patents or patents addressing a critical social need. In September 2010, the USPTO began seeking comments about a proposed pilot program that would grant a priority review voucher for patent re-examination to patentees who sought to patent a humanitarian invention.⁸⁷ In particular, USPTO identified treatments for tropical diseases⁸⁸ as a target of the humanitarian pilot program.⁸⁹ The USPTO proposed two pathways for patentees to qualify their technology under the humanitarian pilot program: making their technology available for humanitarian use directly to affected populations or making their technology available to researchers who are already working on developing humanitarian products.⁹⁰

In the initial proposal by the USPTO, the patentee would receive a voucher for a priority *ex parte* patent re-examination in exchange for a humanitarian patent designation.⁹¹ The voucher would allow the patentee to effectively jump to the front of a patent examiner’s queue, with the goal of review being six months or less.⁹² The

⁸⁴ See REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(E), U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/sites/default/files/forms/aia0424.pdf> (last accessed Oct. 14, 2018).

⁸⁵ *USPTO’s Prioritized Patent Examination Program*, *supra* note 81.

⁸⁶ See *Patent Special Program Data August 2020*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/dashboard/patents/special.html> [<https://perma.cc/8WBD-X484>].

⁸⁷ Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261 (Sept. 20, 2010) (not codified); Press Release, USPTO Launches Effort to Incentivize Humanitarian Technologies, U.S. Patent & Trademark Off. (Sept. 20, 2010) (on file with author), <https://www.uspto.gov/about-us/news-updates/uspto-launches-effort-incentivize-humanitarian-technologies> [<https://perma.cc/EUT4-9QZ2>].

⁸⁸ Discussed *infra* at Section I.B.1. The list of neglected tropical diseases included both Ebola and Zika, as well as other diseases that impacted large populations of people, such as malaria.

⁸⁹ Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261; Press Release, USPTO Launches Effort to Incentivize Humanitarian Technologies, *supra* note 87.

⁹⁰ *Id.*

⁹¹ See Public Comment, Request to Federal Register Notice Docket No. PTO-P-2010-0066 Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System (Nov. 19, 2010), https://www.uspto.gov/sites/default/files/patents/law/comments/humanitarian_f_hollinger2010_nov19.pdf [<https://perma.cc/E23Z-G5MX>]; Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261; *USPTO Launches Effort to Incentivize Humanitarian Technologies*, *supra* note 87.

⁹² See *id.* Expedited patent review is highly beneficial to a patentee, because a patent term issues from the date that a patent application is filed, not the date that the patent application is actually approved. Currently, a patent is valid for twenty years after it has been filed, 35 U.S.C. § 154 (2015), but the patent validity post-approval can often be several years shorter, depending on delays during the patent examination

USPTO's rationale for a priority re-examination voucher was that technologies that undergo *ex parte* re-examination are often the most valuable, and as such, the re-examination voucher would be more valuable to inventors.⁹³ Similar to priority review vouchers at FDA,⁹⁴ which provide an expedited approval process for any target drug or biologic to which the voucher is applied, the proposed priority re-examination vouchers could be sold on the open market.⁹⁵

In 2012, the USPTO launched the "Patents for Humanity" program, which differed from the proposed pilot program in several substantial ways.⁹⁶ Rather than being open to any prospective humanitarian patent applicant, the program functions as a competition, in which winners in five categories—Medicine, Nutrition, Sanitation, Household Energy, and Living Standards—are awarded a non-transferable voucher that must be used within twelve months.⁹⁷ The vouchers can be used to accelerate a patent application, a patent re-examination, or an *ex parte* appeal, and those who receive an honorable mention receive one non-transferable voucher to accelerate a patent application (but not other proceedings).⁹⁸ In addition, the number of awards granted is limited; in 2018, only nine awards were granted.⁹⁹

Notably, the National Institute of Allergies and Infectious Diseases, one of the National Institutes of Health, received an award "for creating a low-cost, temperature tolerant rotavirus vaccine for use in developing countries, with 3.8 million doses ordered by the government of India's childhood immunization program."¹⁰⁰ This particular award suggests that a humanitarian patent pathway is feasible to incentivize the development of vaccines, and that the humanitarian pilot program can be expanded and utilized to address vaccine development during public health emergencies, as discussed below.¹⁰¹

D. Compulsory Licensing

If developers, manufacturers, and regulatory bodies are unable to voluntarily coordinate efforts to produce a vaccine during a public health emergency, Congress could legislate an alternate pathway to compel vaccine production. This section will discuss a legislative option, compulsory licensing, which is used in limited contexts in the United States but has not been successfully implemented for public health

process. See also Scott E. Yackey, *To the Front of the Line: Spurring Biotech Collaboration Through Patent Fast-Track Examination Vouchers*, 5 ST. L. J. HEALTH L. & POL'Y 341, 367 (2012).

⁹³ *USPTO Launches Effort to Incentivize Humanitarian Technologies*, *supra* note 87.

⁹⁴ See *infra* Section I.C.1.

⁹⁵ *USPTO Launches Effort to Incentivize Humanitarian Technologies*, *supra* note 87.

⁹⁶ *Patents for Humanity*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patent/initiatives/patents-humanity/learn-more> [<https://perma.cc/LX6F-QMA7>]; see also Press Release, Patents for Humanity: Five Years of Global Reach, Baker Botts (Dec. 7, 2017), <https://bakerbotts.com/thought-leadership/publications/2017/12/patents-for-humanity> [<https://perma.cc/9GSP-JU87>].

⁹⁷ See *Patents for Humanity: Five Years of Global Reach*, *supra* note 96.

⁹⁸ *Id.*

⁹⁹ *2018 Award Recipients: Patents for Humanity*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patent/initiatives/patents-humanity/2018-award-recipients> [<https://perma.cc/X7EU-B5RY>].

¹⁰⁰ *Id.*

¹⁰¹ See *infra* Section III.A.

emergencies despite previous attempts to create such a provision. Compulsory licensing allows the federal government to “compel a patent holder to license the patent, allowing for production and distribution of patented products to the public.”¹⁰² Compulsory licensing can also take the form of simply allowing a third party to practice a patent without permission, in exchange for a royalty payment set by the federal government.¹⁰³

Compulsory licensing in response to public health risks occurs more frequently abroad.¹⁰⁴ This can be at least partially attributed to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹⁰⁵ and the Doha Declaration on the TRIPS Agreement, combined with the considerably stronger patent protections granted to patent holders in the United States.¹⁰⁶ Article 31(b) of TRIPS “waives the need to obtain authorization from the [patent right] holder . . . to use that product” during times of national emergencies.¹⁰⁷ The Doha Declaration provides that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”¹⁰⁸ Furthermore, the Doha Declaration grants signatories the ability to determine what constitutes “a national emergency or other circumstances of extreme urgency.”¹⁰⁹ TRIPS Article 31(b) and the Doha Declaration have their criticisms and ambiguities that merit consideration, but that discussion is outside the scope of this Comment.¹¹⁰

Generally, compulsory licensing in the United States is disfavored by legislators and patent holders alike.¹¹¹ There are certain statutory provisions that allow for limited compulsory licensing that serve the public interest. For example, the Atomic Energy Act and the Clean Air Act both have provisions allowing for limited compulsory

¹⁰² Kimberly M. Thomas, *Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in the Absence of an Experimental Use Exception*, 23 SANTA CLARA COMP. & HIGH TECH. L. J. 347, 348 (2007).

¹⁰³ Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicines Tool*, 102 MINN. L. REV. 2463, 2465 (2018).

¹⁰⁴ See Thomas, *supra* note 102, at 348.

¹⁰⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; see, e.g., Dawn Dziuba, *TRIPS Article 31(b) and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?*, 20 IND. INT'L & COMP. L. REV. 195, 196 (2010).

¹⁰⁶ Ministerial Declaration of Nov. 14, 2001, WORLD TRADE ORG. WTO Doc. WT/MIN(01)/Dec 1,41 ILM 746, ¶5 (2002).

¹⁰⁷ See Dziuba, *supra* note 105, at 197.

¹⁰⁸ See *supra* note 106.

¹⁰⁹ *Id.*

¹¹⁰ See Dziuba, *supra* note 105, at 199–201 (discussing different scholars' interpretations of what constitutes a national emergency or a public health exception); Caroline Manne, *Pharmaceutical Patent Protection and TRIPS: The Countries That Cried Wolf and Why Defining “National Emergency” Will Save Them From Themselves*, 42 GEO. WASH. INT'L L. REV. 349, 351 (2010) (“The lack of a concrete definition for the phrase ‘national emergency’ allows nations to manipulate the system by issuing compulsory pharmaceutical licenses after declaring a ‘national emergency’ despite the availability of alternate products and remedies.”).

¹¹¹ Joseph A. Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1278 (2001).

licensing.¹¹² However, other attempts to secure limited compulsory licensing, even in times of public health necessity, have failed. For instance, Congress was unable to secure a compulsory licensing provision in the proposed Affordable Prescription Drug Act.¹¹³ Much of the opposition to compulsory licensing, particularly in the pharmaceutical sphere, points to the incredible expenditures and investments made by pharmaceutical developers to bring drugs to market.¹¹⁴ The United States has a complex and expensive regulatory system for approving drugs, with estimates as high as \$2.6 billion needed for approval of an innovative new drug.¹¹⁵ Nevertheless, the U.S. government has considered compulsory licensing in extreme situations. For example, in the wake of the anthrax scare in 2001, then-Attorney General John Ashcroft wanted the government to sanction the development of a generic version of ciprofloxacin, an antibiotic needed to treat anthrax that at the time was under a patent held by Bayer AG.¹¹⁶ Supporters of compulsory licensing, particularly in the context of accessing medications that would otherwise be unaffordable, have pointed out that patent rights are created by the government for the public good, and as such, compulsory licensing should be part of the trade-off that is involved in getting a patent.¹¹⁷ The existence of compulsory licensing provisions in other statutes suggests that such a framework during a public health emergency, though controversial, would not be unreasonable. Legislators would not need to reinvent the wheel in order to create such a provision, and the provision could be narrowly tailored to ensure that it is truly a measure of last resort.¹¹⁸

II. IMPACT OF FAILED INTELLECTUAL PROPERTY INCENTIVES, AND SOLUTIONS PROPOSED THUS FAR

The recent Ebola, Zika, and COVID-19 outbreaks demonstrate the shortcomings of current intellectual property incentives and how existing incentive options failed to

¹¹² 42 U.S.C. § 2183 (allowing for the U.S. Atomic Energy Commission to license an “affected patent” and allowing for any person to apply to the Commission for a nonexclusive license, in exchange for a reasonable royalty fee that is set by the Commission); 42 U.S.C. § 7404 (permitting the Administrator of the Clean Air Act to “acquire secret processes, technical data, inventions, patent applications, patents, licenses” in furtherance of avoiding air pollution).

¹¹³ H.R. 2927, 106th Congress (1999). Several bills to follow also failed to pass. For example, the Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, 108th Cong. (2001), and the Public Health Emergency Medicines Act, H.R. 4102, 109th Cong. (2005), both included compulsory licensing measures, and both failed to pass. See Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 176–77 (2003).

¹¹⁴ Bruce A. McDonald, Vladislav Ugryumov & Denis Kolesnikov, *Compulsory Licensing of Pharmaceutical Patents in the Russian Federation Threatens Foreign & Domestic Drug Developers*, 46 AIPLA Q. J. 1 (2018).

¹¹⁵ *Id.*; see also Wayne Winegarden, *Valuing Innovative Drugs Based on Their Cost of Manufacturing Will Prolong the Covid-19 Pandemic*, FORBES (Aug. 14, 2020), <https://www.forbes.com/sites/waynewinegarden/2020/08/14/valuing-innovative-drugs-based-on-their-cost-of-manufacturing-will-prolong-the-covid-19-pandemic/#7ca6fd961d69> [https://perma.cc/JX7N-5JC5].

¹¹⁶ See Lee, *supra* note 113, at 175.

¹¹⁷ See Bagley, *supra* note 103, at 2480–81 (“Making sure the poor have access to the drugs they need in order to live, in a way that does not harm the patent holder, should be viewed as part of the social bargain inherent in the patent system and deemed morally right, not morally wrong.”).

¹¹⁸ See *infra* Section III.C.

produce affordable vaccine products quickly. This Part will summarize vaccine development in response to the Ebola, Zika, and COVID-19 outbreaks, and why those responses failed. This Part will also survey solutions that have been proposed in response to the failed vaccine development process, and the benefits and drawbacks of each proposed solution.

A. *The Ebola Crisis: Defined by Delays*

In August 2014, the World Health Organization declared Ebola a Public Health Emergency of International Concern, with 1,711 reported cases and 932 reported deaths, largely concentrated in West Africa.¹¹⁹ Because of prior research that had been done regarding Ebola in response to prior outbreaks, the initial response to Ebola was more organized than other public health emergencies, but was not without its faults.¹²⁰ The Iowa-based pharmaceutical company NewLink Genetics obtained a patent on the candidate Ebola vaccine in 2003 but struggled to attract any private-sector interest in the vaccine until the 2014 outbreak.¹²¹ Ultimately, the vaccine candidate, developed jointly by Canadian research institutes and the United States Army Medical Research Institute for Infectious Diseases (USAMRIID), became the leading candidate following an outpouring of interest and financial support for vaccine development.¹²²

In 2014, shortly after the public health emergency was declared, NewLink licensed the patent to the Government of Canada and quickly received funding from the U.S. Department of Defense and from BARDA.¹²³ NewLink also entered into a licensing agreement with the U.S.-based pharmaceutical company Merck, at which point clinical trials for the rVSV-ZEBOV vaccination were expedited. As of mid-2017, the rVSV-ZEBOV vaccine is currently undergoing clinical trials.¹²⁴ The transfer of IP rights from NewLink to Merck took approximately three months and cost Merck approximately \$50 million.¹²⁵ This three-month delay, given that the public attention (and thus, motivation for funding) lasted less than two years, was not insignificant.¹²⁶

B. *The Zika Crisis: A Failed Exclusive Licensing Agreement*

Unlike Ebola, where there had been some pre-existing research conducted on the pathogenicity of the virus, the response to Zika exemplifies the challenges of responding to a public health emergency involving a pathogen that is relatively

¹¹⁹ See *Ebola Virus Disease Update – West Africa*, WORLD HEALTH ORG. (Aug. 6, 2014), www.who.int/csr/don/2014_08_06_ebola/en [https://perma.cc/42MP-78GQ].

¹²⁰ See Rutschman, *supra* note 16, at 1228.

¹²¹ See *id.* at 1227–28.

¹²² *Id.* at 1221.

¹²³ Bioprotection Systems Corp., *Sole Licensing Agreement for Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers* (Apr. 30, 2007), http://www.sec.gov/Archives/edgar/data/1126234/000104746911009169/a2206169zex-10_67.htm [https://perma.cc/8UHB-ZGKQ]. See also Amir Attaran & Jason Nickerson, *Is Canada Patent Deal Obstructing Ebola Development?*, 384 LANCET e61, e61 (2014).

¹²⁴ See Rutschman, *supra* note 16, at 1226.

¹²⁵ See *id.*; *NewLink, Merck Deal Boosts Prospects for Ebola Vaccine*, CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY, UNIV. OF MINN. (2014), <http://www.cidrap.umn.edu/news-perspective/2014/11/newlink-merck-deal-boosts-prospects-ebola-vaccine> [https://perma.cc/M6QK-3XL6].

¹²⁶ See Rutschman, *supra* note 16, at 1254.

unknown. The World Health Organization declared Zika a public health emergency in February 2016,¹²⁷ when the global public health community was still reeling from the Ebola epidemic. Unlike Ebola, very little research had been done on Zika at the time it became a cause for public concern.¹²⁸ This led to a sudden spike in academic publications, research efforts, and most notably, at least forty entities that were involved in developing a vaccine.¹²⁹ One of the leading vaccine candidates, ZPIV, was developed in January 2016 by three federal government institutes: the Walter Reed Army Institute for Research (WRAIR) in collaboration with the National Institute for Allergies and Infectious Diseases (NIAID) and the Biomedical Advanced Research Development Authority (BARDA).¹³⁰ In a timeline that can only be described as breathtaking by FDA standards, clinical trials for ZPIV began in November 2016, less than a year after the vaccine was first developed; at the same time, the Army had two patents pending on the ZPIV vaccine.¹³¹

In December 2016, the Army announced its intent to license the ZPIV vaccine exclusively to the French pharmaceutical company Sanofi Pasteur.¹³² The decision to license the patent to a private pharmaceutical company is not uncommon for government-developed biologics. While government research facilities have the resources to research and develop new biologics, the government does not have the capacity to manufacture and distribute such products, leading to licensing of the biologic to a pharmaceutical company that has the manufacturing capacity.¹³³ Sanofi received a \$43 million contract from BARDA for continued development of the vaccine.¹³⁴ However, the downfall in this particular exchange was that the U.S. Army granted an *exclusive* license for its patent in the midst of a public health emergency, without any indication of a contingency plan, should the sole manufacturer responsible for the production of the vaccine fail to deliver.

In August 2017, BARDA stopped funding Zika research and development, focusing instead on disease surveillance throughout the United States in regions affected by the

¹²⁷ WORLD HEALTH ORG., ZIKA STRATEGIC RESPONSE PLAN 8 (2016).

¹²⁸ Rutschman, *supra* note 16, at 1254.

¹²⁹ *Id.* at 1235–36, Table 2 at 1238–39. One obvious problem with having as many as forty competing Zika vaccinations in development is the inability to coordinate a response or to concentrate resources towards a couple of vaccinations. These vaccinations would all ultimately need to go through FDA approval process, discussed *supra* Section I.C., further back-logging the FDA approval pipeline.

¹³⁰ *Zika Virus Purified Inactivated Vaccine (ZPIV) Accelerated Vaccination Schedule Study (Z001)*, U.S. NAT'L LIBR. MED. (2017), <https://clinicaltrials.gov/ct2/show/NCT02937233>.

¹³¹ *See id.* For reference, it can sometimes take as long as ten to fifteen years for a vaccination to be approved, especially if the vaccination contains any live components of the pathogen it is designed to protect against.

¹³² Intent to Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89,087 (December 9, 2016). The important part of this exchange was that the U.S. Army granted an *exclusive* license to a manufacturer.

¹³³ *See* Rutschman, *supra* note 16, at 1250.

¹³⁴ *Timeline of U.S. Army & Sanofi Zika Vaccine Collaboration*, KNOWLEDGE ECOLOGY INT'L (2017), <https://www.keionline.org/book/government-funded-inventions/zika-resources-on-2016-2017-army-exclusive-patent-license-to-sanofi/timeline-of-u-s-army-sanofi-zika-vaccine-collaboration> [<https://perma.cc/GY34-4R3V>]. One of the primary controversies of this licensing decision was the use of U.S. taxpayer dollars to fund a French pharmaceutical company's research efforts. *See* Knowledge Economy Int'l, Comment Letter RE Army Intent to Grant Exclusive License (Mar. 10, 2017), https://www.keionline.org/wp-content/uploads/2017/03/KEI-March_10_2017-3rd-Comments-Zika.pdf.

infection.¹³⁵ Without its primary financial incentive, Sanofi stopped developing the vaccine.¹³⁶ By this time, many of the other entities that had been researching other Zika vaccinations at the start of the outbreak had stopped doing so in light of the Army-Sanofi deal. At a critical time in the midst of the Zika outbreak, the United States was left without a promising candidate vaccine on its way to the market.¹³⁷

For several reasons, the Army-Sanofi deal was heavily criticized. By only having one licensee for the Army's patent, there was no other entity as part of the transaction that could continue vaccination development once Sanofi and BARDA backed out.¹³⁸ This criticism was so harsh because exclusive licensing of a federally funded patent is generally prohibited under Section 209 of the Patent Act unless absolutely necessary.¹³⁹ Section 209 provides in part that a federally funded invention shall only be exclusively licensed if it would promote the invention's utilization by the public, and if the licensee "makes a commitment to achieve practical application of the invention within a reasonable time" and provides the agency with a plan for developing the invention.¹⁴⁰ This section also requires public notice of an exclusive licensing agreement, which the Army did provide, but the Army did not provide any reasons supporting why it was necessary to enter into an exclusive licensing agreement, nor did it provide any indication that Sanofi was fully prepared to bring the candidate vaccine to market.¹⁴¹ In addition, it would have taken months to re-create a licensing agreement not only between the Army and another entity, but possibly also between Sanofi and another entity, to prevent a third entity from having to start vaccine development from scratch.¹⁴² When the Army and Sanofi entered into the licensing agreement, they signed a cooperative research and development agreement in order to divide the remaining steps in the drug development and approval process.¹⁴³ Starting over would have required re-negotiating the terms of how each entity involved would proceed, and more daunting, how the entities would split the costs.¹⁴⁴

¹³⁵ Press Release, Sanofi Statement on Zika Vaccine License, Sanofi Pasteur (Sept. 1, 2017), <http://www.news.sanofi.us/press-statements?item=991>.

¹³⁶ *Id.*

¹³⁷ As of this writing, there are now other Zika vaccinations undergoing clinical trials pursuant to FDA guidelines. However, Zika is largely removed from the public eye. Although it is wholly possible that Zika could result in another public health emergency, the public attention—which is often a financial incentive for pharmaceutical development during times of emergency—has come and gone.

¹³⁸ See Rutschman, *supra* note 16, at 1259.

¹³⁹ 35 U.S.C. § 209(a).

¹⁴⁰ 35 U.S.C. § 209(a)(1)–(3); § 209(f).

¹⁴¹ Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L. J. F. 651, 653 (2018) [hereinafter *Vaccine Licensure*].

¹⁴² See Rutschman, *supra* note 16, at 1263. Part of why the Army did not have to completely start from scratch in the case of the Zika vaccine candidate was because researchers could rely on the vaccination candidate developed to treat Japanese encephalitis, which has some similarities to Zika pathogenicity. See *Vaccine Licensure*, *supra* note 141, at 655.

¹⁴³ *Vaccine Licensure*, *supra* note 141, at 655 (citing Press Release, Testing of Investigational Inactivated Zika Vaccine in Humans Begins, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Nov. 7, 2016), <https://www.nih.gov/news-events/news-releases/testing-investigational-inactivated-zika-vaccine-humans-begins> [<https://perma.cc/KB96-RJEE>]).

¹⁴⁴ Of note, BARDA provided Sanofi with \$43.2 million in order to support Phase II clinical trials. See Press Release, Testing of Investigational Inactivated Zika Vaccine in Humans Begins, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (Nov. 7, 2016), <https://www.nih.gov/news->

C. COVID-19: An Improvised Response Without Regulatory Support

On December 31, 2019, the World Health Organization (WHO) learned of a novel respiratory virus—coined a “viral pneumonia”—in the Wuhan province in China.¹⁴⁵ Throughout January and February 2020, WHO continued to receive reports from other countries indicating that the virus was spreading through human-to-human contact.¹⁴⁶ The first case in the United States—a person who had traveled to the Wuhan province area—was reported on January 21, 2020, in Washington State.¹⁴⁷ And on February 26, 2020, the CDC confirmed the first COVID-19 case in a patient who had not traveled to an outbreak area.¹⁴⁸ And beginning in March, COVID-19 cases throughout the United States began to skyrocket.¹⁴⁹

One of the major challenges to developing the COVID-19 vaccine has been its novelty. Unlike Ebola,¹⁵⁰ where there had been other outbreaks historically, this was the first time scientists had to deal with a global coronavirus outbreak.¹⁵¹ FDA’s response to COVID-19 has been swifter than other global outbreaks, but they refused to establish any fast-track options to get a vaccine approved more quickly.¹⁵² Rather, FDA opted to grant “emergency use authorization” for certain medical devices, including specific types of personal protective equipment (PPE) and testing methods.¹⁵³ FDA had also granted emergency use authorization for anti-malarial drug hydroxychloroquine, but revoked that emergency use authorization after several patient deaths.¹⁵⁴

events/news-releases/testing-investigational-inactivated-zika-vaccine-humans-begins [https://perma.cc/KB96-RJEE].

¹⁴⁵ *Timeline of WHO’s Response to COVID-19*, WORLD HEALTH ORG. (June 29, 2020), <https://www.who.int/news-room/detail/29-06-2020-covidtimeline> [https://perma.cc/P4EZ-BN9U] (last visited Aug. 18, 2020).

¹⁴⁶ *Id.*

¹⁴⁷ Erin Schumaker, *Timeline: How Coronavirus Got Started*, ABC NEWS (July 28, 2020), <https://abcnews.go.com/Health/timeline-coronavirus-started/story?id=69435165> [https://perma.cc/6UEG-MG5B].

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *See supra* Section II.A.

¹⁵¹ Schumaker, *supra* note 147.

¹⁵² *Development and Licensure of Vaccines to Prevent Covid-19*, U.S. FOOD & DRUG ADMIN. (June 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19> [https://perma.cc/P9PZ-J8DX].

¹⁵³ *Coronavirus Disease 2019 (COVID-19) Emergency Use Authorization for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Aug. 3, 2020), <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices> [https://perma.cc/2BWV-EC4S].

¹⁵⁴ *Coronavirus Disease 2019 (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine*, U.S. FOOD & DRUG ADMIN. (JUNE 15, 2020) <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and> [https://perma.cc/C77T-SF46].

As of October 2, 2020, there are forty-nine candidate coronavirus vaccine candidates that have reached some phase of human testing.¹⁵⁵ Only two vaccines have been approved anywhere in the world: a coronavirus vaccine developed by Chinese company CanSino developed a vaccine that was approved by the Chinese military for limited use; and the “Sputnik V” vaccine that was approved by the Ministry of Health of the Russian Federation, despite significant concerns about the safety of the vaccine.¹⁵⁶ As of this writing, there are no vaccines approved for use in the United States.¹⁵⁷

III. CURRENT PROPOSALS TO ADDRESS INTELLECTUAL PROPERTY PREPAREDNESS

These failures of the intellectual property scheme that have led to delays and mishaps with vaccinations during public health emergencies did not go unnoticed. In response to these and other public health emergencies, several proposals for improved processes have been put forth. This section will discuss recent proposals to address portions of the problems experienced when trying to develop biologics and other drug products during public health emergencies. These proposals include (1) a dormant licensing and streamlined intellectual property framework; (2) a proposal to grant patents for products to be used during public health emergencies exclusively to the federal government; and (3) a proposal to incentivize collaboration, data, and information sharing between researchers.

A. *Dormant License Agreement and Streamlined Intellectual Property Framework*

Professor Rutschman proposed a dormant licensing agreement that would expedite the transfer of intellectual property by instituting a licensing agreement that was agreed upon and fine-tuned before the public health emergency began:

A public-sector institution develops outbreak-disease technology. When that technology is transferred to a private-sector company, the streamlined IP framework attaches to the transfer but only becomes applicable if the rights are re-transferred during a formal outbreak. The framework is a basic IP licensing agreement developed or adopted by the public-sector institution and previously agreed to by the initial licensee. When an outbreak occurs, if the licensee does not work the technology within a certain period of time and refuses to license it, then any entity ready to meet the terms of the framework would become the new licensee through notification to the public-sector institution.¹⁵⁸

¹⁵⁵ Jeff Craven, *Covid-19 Vaccine Tracker*, REGULATORY FOCUS (Oct. 8, 2020), <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker> [https://perma.cc/GC5T-NDPY].

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ Rutschman, *supra* note 16, at 1258–59. An important aspect of this licensing plan is that it is triggered by an “outbreak.” Rutschman does not explicitly define what would constitute an “outbreak,” but at other times throughout her paper, Rutschman conflates outbreak with the formal declaration of a public

Rutschman's primary contention is that by having many of the details of a licensing agreement settled upon before a potential outbreak, the actual transfer of intellectual property and other rights would be more efficient once a public health emergency was declared.¹⁵⁹ Furthermore, Rutschman's proposed plan includes a safeguard against a licensee backing out of the agreement by allowing a presumably swift transfer of rights to another licensee.¹⁶⁰ Turning to the delays in the transfer of rights for the NewLink Ebola vaccine,¹⁶¹ Rutschman's proposal aims to reduce delays caused by the transfer of IP rights by laying out the details and proposed plans up front.¹⁶²

The dormant license agreement that Rutschman proposed does not actually contain any sample language or suggestions for the specific rights or conditions to be covered in the license.¹⁶³ Rather, Rutschman claims that such a plan would work regardless of how narrowly or broadly defined the terms of the license were, although Rutschman argues that the framework would work best for a highly specified license agreement.¹⁶⁴

While Rutschman argues that a dormant license would be more efficient post-outbreak, she does acknowledge that this framework has the drawback of causing hesitation among manufacturers or other parties about committing to such an agreement *ex ante*.¹⁶⁵ In response, Rutschman points out that the appropriate candidates for this type of licensing agreement would be smaller pharmaceutical companies that might not be able to profit from manufacturing a vaccination nationwide, but who could develop a business strategy by further transferring rights to larger manufacturers post-outbreak, once the vaccine becomes more commercially viable and appealing.¹⁶⁶

Rutschman also argues that having a non-exclusive licensing model would promote competition if there is a limit to how many licensees are included in this type of agreement.¹⁶⁷ Given the Army–Sanofi dilemma, it would make sense on its face to have multiple licensees working on the vaccination, provided that the competitive field is not so crowded as to be a deterrent.

Rutschman's proposal addresses some, but not all, of the issues raised by a lack of intellectual property preparedness. For instance, as the spike in activity after Zika became publicly known shows, there could be heightened competition amongst potential licensors, which is not addressed in Rutschman's proposal. Even in a situation where one dormant licensing agreement only encompasses two or three competitor licensees, this qualification does not address a situation in which there are

health emergency. *See, e.g., id.* at 1262. It is important to note that there is not always a formal declaration of a public health emergency, even in situations where there *is* an active outbreak. In addition, the formal declaration of a public health emergency can sometimes come months after the outbreak has officially started. This could also lead to delays, particularly on the manufacturing and distribution front.

¹⁵⁹ *Id.* at 1258–59.

¹⁶⁰ *Id.* at 1260.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 1260–61.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 1261.

¹⁶⁷ *Id.* at 1263. Rutschman does not define what constitutes too many licensees; presumably, this determination is to be made on a case-by-case basis.

multiple competing licensing agreements. Consider a situation in which there are four competing vaccinations from four public sector institution for the same pathogen, each with its own patent and its own dormant licensing agreement. If each licensor has three licensees that have agreed to further develop and manufacture the vaccination, there will suddenly be twelve licensees who are competing for a space in the same market. There were initially at least forty competing vaccinations either on the market or under development for Zika at the time the outbreak began.¹⁶⁸

Furthermore, the dormant licensing plan does not address the initial costs that a potential licensor will need to incur to get licensing rights over a product through the patent system. In order for a licensor to get a utility patent for a potential vaccination, the licensor will need to satisfy all of the conditions for patentability.¹⁶⁹ Furthermore, the patent review process is wrought with its own delays: getting a patent can take multiple years, especially if the patentee needs to appeal a rejection.¹⁷⁰ When combining the initial costs that licensors must undertake in order to secure a patent on their biologic product with the possibility that not all licensees with manufacturing and development capacity would be willing to undergo a dormant licensing agreement *ex ante*, there is a possibility that such a dormant licensing system might actually be unattractive to licensors, especially because there is the risk that the public health emergency for which the licensor has prepared a biologic might not materialize for years. Rutschman's proposal seems best-suited for a post-outbreak situation or a situation like the current coronavirus outbreak, where public health officials have deemed that a particular public health emergency is imminent (or in present times, painfully present), and where the motivation for entering into licensing agreements is higher.

B. Exclusive Government Patents for Public Health Emergencies

Rachel Morowitz and Doug Lichtman have proposed a means of addressing IP challenges pre-outbreak. This proposal involves exclusively awarding patents to the federal government for materials related to public health emergencies, in the hopes that an alternate pathway for government patents can circumvent the current barriers in the patent system that have been problematic for private sector research institutions.¹⁷¹ The proposal identifies three barriers to a timely response: (1) the first-to-file system imposed by the American Invents Act could lead to a less-than-ideal

¹⁶⁸ *Id.*

¹⁶⁹ See 35 U.S.C. § 102, 112.

¹⁷⁰ See *Patent Process Overview: Step 6*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patents-getting-started/patent-process-overview#step6> [https://perma.cc/JZ8V-A7ZV]; see also *How Long Does it Take to Get a Patent?*, ERICKSON LAW GROUP, PC, <http://www.ericksonlawgroup.com/law/patents/patentfaq/how-long-does-it-take-to-get-a-patent/> [https://perma.cc/DZP2-EYGR]. The possibility of delays is heightened when a biologic product is the subject of the patent. Following the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013), there has been confusion and controversy regarding how "altered" a naturally derived product needs to be in order to satisfy the "patentable subject matter" requirement of 35 U.S.C. § 101.

¹⁷¹ Rachel Morowitz, *Overcoming Barriers Created by the Patent System to Develop an Effective and Timely Response to Public Health Emergencies*, 25 FED. CIR. B. J. 621, 622 (2016).

patent holder; (2) the backlog at the USPTO; and (3) the confusion about what constitutes patentable subject matter under 35 U.S.C. § 101.¹⁷²

Morowitz argues that the new first-to-file system under the America Invents Act, which replaced the first-to-invent system under the 1952 Act, can lead to problems if the first-to-file is not a suitable patent holder.¹⁷³ In particular, Morowitz identifies non-practicing entities as one example of a non-suitable patent holder, and as a particularly high risk in the context of patents for biologics developed during public health emergencies, which would result in a significant number of patent infringement suits, with little to no development of the patented product by the patent troll.¹⁷⁴ Morowitz discusses the confusion regarding patentable subject matter under 35 U.S.C. § 101, especially in light of the Supreme Court's holding in *Association for Molecular Pathology v. Myriad Genetics*.¹⁷⁵ Morowitz also points out the current USPTO backlog, leading to an average wait time of 23.6 months for patent prosecution.¹⁷⁶ Morowitz claims that the primary concern for the backlog goes beyond the physical wait time and also concerns the resources that government researchers must use in order to defend their patents.¹⁷⁷

Morowitz's proposal is to grant patents for products developed during public health emergencies exclusively to the federal government, rather than to private entities.¹⁷⁸ Morowitz argues that privately held patents encourage expensive licensing, citing to *Myriad's* treatment of institutions who wanted to produce tests for the BRCA1 and BRCA 2 genes.¹⁷⁹ Morowitz also claims that the federal government can be given an "alternate patent prosecution process" when seeking a patent during times of public health emergencies.¹⁸⁰ Although Morowitz does not go into the details of this alternate plan, presumably it would allow the federal government to "jump the line" and have an expedited review of any patents that the federal government seeks. Once the federal government has received a patent, Morowitz proposes that the government can

¹⁷² *Id.*

¹⁷³ *Id.* at 632. For example, if the first-to-file is not committed to further developing, manufacturing, and bringing the vaccination to market either themselves or via licensing, a challenging situation is created in which there is no way forward for the vaccination to end up in the stream of commerce without infringing the patent.

¹⁷⁴ *Id.* As Morowitz describes, "patent trolls are companies who buy patents for the sole purpose of finding infringers and suing them. These companies are not using the patents for their utility as claimed, but rather as tools to litigate and collect damages." *Id.*; see also Kristen Osenga, *Formerly Manufacturing Entities: Piercing the "Patent Troll" Rhetoric*, 47 CONN L. REV. 435, 442–44 (2014).

¹⁷⁵ 133 S. Ct. 2107 (2013). In *Myriad*, the Supreme Court rejected a holding by the Federal Circuit that isolated genes could be patented. The patent holders in this case held patents over the isolated BRCA1 and BRCA2 genes and filed an infringement lawsuit against institutions who were using the genes as the basis for breast cancer tests. The Supreme Court held that simply isolating a gene did not constitute an "invention" because the gene was found in nature. This holding was a limitation of the Court's holding in *Diamond v. Chakrabarty*, where the Court upheld a patent on a modified bacterium that had been engineered to break down crude oil and had been sufficiently altered in order to constitute something beyond the bacterium found in nature. *Diamond v. Chakrabarty*, 477 U.S. 303 (1980).

¹⁷⁶ Morowitz, *supra* note 171, at 625; see *Patents Data, at a Glance August 2020*, U.S. PATENT & TRADEMARK OFF. (2020), <https://www.uspto.gov/dashboard/patents/> [<https://perma.cc/4DW8-QLG6>].

¹⁷⁷ *Id.* at 625.

¹⁷⁸ *Id.* at 622.

¹⁷⁹ *Id.* at 631–32.

¹⁸⁰ *Id.* at 634.

incentivize the public and private sector through grants or prizes for additional development.¹⁸¹

Morowitz is correct to identify that the federal government has opportunities to incentivize vaccination and biologic development through less financially prohibitive means, and the concerns about patent trolls are particularly heightened when it comes to subject matter that needs to be developed during a public health emergency. However, this proposal only addresses a subset of the problems. First, the concerns raised in *Myriad* about patentable subject matter will not disappear solely because it is the federal government that is going through the patent application process. The limitations of 35 U.S.C. § 101 exist for all applicants and will pose a problem for certain types of biologics regardless of whether it is the government or a private entity that is applying for the patent.¹⁸² Second, the system of grants and prizes that Morowitz proposes can be achieved—and already is achieved—even when the government does not hold a patent.¹⁸³ The National Institutes of Health and a variety of other federal entities provide research grants for researchers who are hoping to develop vaccines and biologics, and the federal government does so without holding a patent on the underlying technology.¹⁸⁴

The concerns Morowitz raises in her proposal were also raised in Doug Lichtman's response to Professor Rutschman's dormant licensing proposal.¹⁸⁵ Professor Lichtman argues that the patent system is ill-equipped to address the unique needs of research, development, and manufacturing of biologics during public health emergencies. Because the market-based system that patents encourage is contrary to the need to produce biologics at a price that makes them accessible to those who most need them, Lichtman argues that using patents as an incentive to develop new biologics simply does not allow for the developed product to reflect and match the true "social value" of the product.¹⁸⁶ Lichtman then briefly discusses a "prize system" by which the federal government can award the first entity to develop a much-needed biologic product during a public health emergency.¹⁸⁷ Implicit in this system is an assumption that the cash prize would result in lowering prices for the consumers of the newly developed product, rather than going straight into the pockets of the entity. But clearly, one cannot assume that a pure cash prize for the first-to-invent would automatically translate into lower prices for consumers—simply removing the patent system from the equation does not remove the market forces that drive how pharmaceutical

¹⁸¹ *Id.* at 636.

¹⁸² As *Myriad* describes, inventions need to go beyond a naturally derived discovery, and it is unclear at this point just how much an inventor needs to "invent" beyond the natural discovery in order to meet the requirements of § 101.

¹⁸³ See, e.g., Press Release, Funding Opportunity Focusing on Innovative Vaccine Research, Nat'l Inst. of Allergies & Infectious Diseases (May 17, 2017), <https://www.niaid.nih.gov/grants-contracts/funding-opportunity-focuses-innovative-vaccine-research> [<https://perma.cc/Q3NN-VVZU>].

¹⁸⁴ *How to Apply for Funding*, NAT'L INSTS. OF HEALTH, <https://prevention.nih.gov/funding/how-apply-funding> [<https://perma.cc/R6P4-VGHC>].

¹⁸⁵ Doug Lichtman, *The Central Assumption of Patent Law: A Response to Ana Santos Rutschman's IP Preparedness for Outbreak Disease*, 65 UCLA L. REV. 1268 (2018).

¹⁸⁶ *Id.* at 1275.

¹⁸⁷ *Id.*

manufacturers make decisions and set prices. The misdirection of current incentive programs clearly demonstrates this phenomenon.¹⁸⁸

C. *Incentivizing Collaboration and Sharing of Data*

Scott Yackey proposed a mechanism for data collaboration and research tool sharing, based largely on the mechanisms used by the Alzheimer's Disease Neuroimaging Initiative (ANDI).¹⁸⁹ Beginning in 2003, several biomedical research entities, including the NIH and FDA, engaged in an "unprecedented collaborative effort to find the biological markers that show the progression of Alzheimer's disease in the human brain."¹⁹⁰ This proposal is based on an exploration of the phenomenon "tragedy of the anticommons," in which privatization of resources and simultaneous rights of exclusivity effectively prevent anyone from accessing the resource.¹⁹¹ In the biomedical context, it is argued that having multiple overlapping patents impedes future research, because researchers need access to multiple patented inventions in order to create a new product, and inventors are unwilling to license their developments due to fears of whether that transaction would be cost-effective.¹⁹²

Yackey's proposal, as applied to the biotechnology context, involves researchers agreeing to give up all intellectual property rights on

processes, methods, products . . . that were developed during research. This would include any research data, cell lines, novel processes to develop cell lines, novel data extraction and analysis techniques, or any other patentable subject matter that resulted from the search . . . that was the aim of the collaboration.¹⁹³

Yackey further proposes that researchers and outside developers could maintain intellectual property rights in any resulting drugs or therapies.¹⁹⁴ To offset the loss of intellectual property rights, Yackey proposes an alternative USPTO priority review voucher program, allowing any researchers or organizations participating in qualified research organizations to apply a priority review voucher to any drug or therapy that resulted from their research or from any other collaborative or non-collaborative research.¹⁹⁵ This proposal would allow researchers to forego patent rights on a collaborative research effort in exchange for a fast track examination on another research effort.¹⁹⁶

¹⁸⁸ See *supra* Section I.C.

¹⁸⁹ Yackey, *supra* note 92, at 341. Although Yackey's proposal does not focus on public health emergencies, the discussion is relevant based on calls for more collaboration between research entities in response to public health emergencies.

¹⁹⁰ *Id.* at 341–42 (quoting Dr. John Q. Trojanowski ("[W]e all realized that we would never get biomarkers unless all of us parked our egos and intellectual-property noses outside the door and agreed that all of our data would be public immediately.")).

¹⁹¹ *Id.* at 349.

¹⁹² *Id.* at 350.

¹⁹³ *Id.* at 368.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 369.

¹⁹⁶ *Id.*

Yackey's proposal does address one need that was not fully addressed by Rutschman or Morowitz: the need for collaboration and joint efforts in pursuit of a common goal (in this case, the "common goal" was identifying Alzheimer's biomarkers).¹⁹⁷ However, one overlooked aspect of this proposal would be the patenting of collaborative research efforts by third parties. The ANDI proposal that is relied upon involves not just collaborative efforts between multiple research institutions, but *publicizing* collective research findings for the common good.¹⁹⁸ When applied to the public health emergency context, it is not difficult to imagine a scenario in which a non-collaborating entity uses public collaborative research findings, files and receives a patent on a critical component required for vaccine or biologic development, and thus revives the anticommons problem that the researchers were trying to avoid. This is even more concerning considering Morowitz's discussion of patent trolls, which have proliferated in light of the new "first-to-file" system under the America Invents Act.¹⁹⁹

IV. UTILIZING EXISTING PATHWAYS IN A NOVEL FASHION: THREE WAYS TO IMPROVE VACCINE DEVELOPMENT DURING A PUBLIC HEALTH EMERGENCY

The previously discussed proposals have a common theme: current incentives, whether through FDA or through the USPTO, are ineffective at getting affordable biologic products produced in response to a public health emergency on the market quickly and with limited research or transactional obstacles or delays.²⁰⁰ This Comment proposes three methods by which some of these residual concerns can be addressed. The first proposal is a public health emergency patent program that provides an expedited review of a patent for any invention that is directly related to a public health emergency. This voucher can then be used for priority review of any other patent, and an extended patent term, in exchange for making the product readily available to affected populations and for agreeing not to enter into exclusive licensing agreements for manufacturing and distribution. The second proposal is a drug approval-based priority review that combines aspects of FDA's Breakthrough Designation pathway with FDA's proposed Qualified Infectious Disease Product Designation. This proposal would mirror the current FDA infrastructure for drugs that qualify for Breakthrough Designation but include additional methods to expedite the clinical trial process for qualifying biologics. The third proposal—which should be enacted only if all voluntary patent or regulatory pathways are ineffective—is to pass a law that enables the U.S. government to issue compulsory licenses and oversee the manufacturing and distribution process until the public health emergency is no longer a threat to public health and safety.

¹⁹⁷ *Id.* at 368.

¹⁹⁸ *Id.* at 342.

¹⁹⁹ *See supra* Section II.C.2; Morowitz, *supra* note 171, at 624.

²⁰⁰ *See supra* Section I.A. I acknowledge that some of these issues are attributed to the lack of incentives, and others can be attributed to a lack of resources to sufficiently address potential incentives. I do not focus on that distinction in this Article, but it is worth exploring. The financial elements of developing, marketing, and distributing a vaccine are exceptionally challenging.

A. *A Specific Public Health Emergency Patent Designation*

This section discusses a “revised” public health emergency patent designation for biologics produced during public health emergencies. This proposal blends the previously proposed USPTO “humanitarian voucher” with the current “fast-track” option that currently exists at the USPTO. In addition, this proposal offers a variety of incentives to the patentee in exchange for an agreement to refrain from nonexclusive licensing agreements, to be applied narrowly to a vaccine that specifically treats a current public health emergency as declared under Section 319 of the PHSA.

As discussed above, in 2010, the USPTO requested comments for a proposed fast-track “humanitarian voucher” program.²⁰¹ The proposed program would have allowed for patent applicants demonstrating “humanitarian use” or “humanitarian research” to be granted a voucher for expedited re-examination of a patent within six months.²⁰² Re-examinations to which the voucher is applied would have been given the highest priority, directing the patent examiner to treat the application as though it were next in line.²⁰³ Although this proposal was ultimately not adopted, it did receive considerable public support.²⁰⁴ Instead, the USPTO’s only fast-track option until recently was Track One, through which a patent applicant can pay an extra fee in order to have their application expedited.²⁰⁵

The first part of this Article’s proposal involves utilizing the current fast track option at the USPTO, which allows for up to 12,000 grants to receive priority review and charges \$4,000 for non-small entities and \$2,000 for small entities.²⁰⁶ However, this proposal would specifically address products developed during a public health emergency²⁰⁷ and that directly relate to that specific public health emergency in some capacity, whether it be monitoring and surveillance, testing, or reactive or prophylactic treatment. These products should not count towards the 12,000 grants that the USPTO permits per year²⁰⁸ and should be able to draw from the public health emergency reserve funds (which can be used broadly) held by the CDC if the entity that is seeking patent protection is unable to pay the patent application fee. Given that these two incentives would be a significant “highway” to approval in comparison to other patent

²⁰¹ Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261 (Sept. 20, 2010).

²⁰² *Id.* at 57,262. This proposal modeled FDA’s current priority review vouchers. *See Yackey, supra* note 92, at 368.

²⁰³ *See Yackey, supra* note 92, at 367.

²⁰⁴ *See, e.g.,* Public Comment, Request to Federal Register Notice Docket No. PTO-P-2010-0066 Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System (Nov. 19, 2010), https://www.uspto.gov/sites/default/files/patents/law/comments/humanitarian_f_hollinger2010_nov19.pdf [<https://perma.cc/E23Z-G5MX>].

²⁰⁵ *See* Section I.B.1.

²⁰⁶ *See USPTO’s Priority Patent Examination Process*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program> [<https://perma.cc/VV64-BPEG>] (last accessed Oct. 14, 2018).

²⁰⁷ Although a declaration of a formal public health emergency would certainly qualify, there need not be a formal declaration of a public health emergency in order for this proposal to go into effect.

²⁰⁸ Admittedly, this requirement may not be necessary. Between January and August 2020, the USPTO has received over 8,400 Track One applications, suggesting that this limit would easily permit the accommodation of public health emergency patents. *See Patent Special Program Data August 2020, supra* note 86.

applicants who seek priority review, the conditions under which a patent can qualify as a public health emergency patent should be narrowly construed and limited only to patent applications for biologics or other products that are directly addressing a current public health emergency.²⁰⁹

The second part of this Article's proposal involves utilizing the previously proposed humanitarian voucher system as an additional incentive by granting a voucher to an applicant who successfully receives a patent on a product that was produced for and in response to a public health emergency. The priority review voucher would act as the 2010 proposal stated—it would allow the holder of the voucher to seek priority review on another patent application in the future if the patent enters re-examination proceedings. Further, this voucher could be transferable in the same manner as FDA priority review vouchers. If publicly requested, the proposed humanitarian voucher can have some limitations that further the goals of encouraging inventions with humanitarian aims or purposes (not necessarily limited to public health emergencies); however, such a limitation would render this voucher less of an incentive.

The third part of this proposal would be to subject the humanitarian patent to a similar non-exclusive licensing provision that is currently found in Section 209 of the Patent Act, which generally prohibits federally held patents from being transferred through a non-exclusive license.²¹⁰ A licensing agreement need not be provided alongside the patent application, but this provision should go further than Section 209 in explicitly prohibiting exclusive licensing agreements. This part of the proposal directly addresses the concerns brought about by the failed Zika vaccine licensing agreement.

This proposal has two primary benefits. First, it clearly addresses the challenges to the patent system raised by Rutschman and Morowitz regarding delays in the patent office. By having a narrowly defined scope of which patents would qualify for a public health emergency fast-track, it is unlikely that there would be a significant influx of patent applications to further backlog the system, because presumably there would be some patent applications that are tangentially related to the public health emergency, but not enough to trigger the specialized humanitarian patent designation. Furthermore, in light of an established public health emergency, the USPTO would have flexibility in allotting enough patent examiners. While there might be concerns about the fee structure, the combination of the USPTO having independent control over its own budget, the ability to access reserve funds for public health emergencies, and the limited number of patent applications that would qualify for this designation, it is unlikely that this proposal would have a burdensome financial impact on the USPTO's regular operating procedures.

Second, this proposal addresses the lack of financial incentives through vouchers and possible waived filing fees from the USPTO. The combination of a fast-track

²⁰⁹ One immediate concern would involve patenting biologics or other products addressing a potential future public health emergency. The exact methodology for predicting a future public health emergency is outside the scope of this Article; however, the Centers for Disease Control and Prevention, in conjunction with other domestic and international organizations, actively monitor potential public health emergencies, in response to both pathogenic and environmental health hazards. *See, e.g.*, Dale A. Rose, Shivani Murthy, Jennifer Brooks & Jeffrey Bryant, *The Evolution of Public Health Emergency Management as a Field of Practice*, 107 AM. J. PUB. HEALTH S126, S126 (2017). This proposal can be refined in order to address patents seeking to address a public health emergency with enough evidentiary support to be considered a credible future emergency.

²¹⁰ 35 U.S.C. § 209(a).

option and a humanitarian voucher would allow the inventor to reap the benefits of patent exclusivity for longer and reap the benefit again for a humanitarian purpose. Having a voucher system that is limited to future humanitarian patent applications serves the purpose of encouraging the development of inventions that directly address humanitarian patent applications, not limited to patent applications in response to a public health emergency.²¹¹

In 2020, the USPTO created a COVID-19 Prioritized Examination Pilot Program for up to 500 qualifying patent applications that addressed the COVID-19 outbreak, which waived certain fees for applicants that qualified as small or micro entities.²¹² This program is certainly a step in the right direction, but it would be beneficial for the USPTO to create a more permanent process that applicants can rely on, rather than a reactive and temporary pathway.²¹³ The creation of this program is a strong example of why the USPTO needs to have pathways in place that can allow applicants to quickly access the patent approval process during a public health emergency.²¹⁴

B. A Revised QIDP Pathway for Biologics

In addition to the proposal discussed above, FDA should establish a QIDP designation specifically for biologics developed during a public health emergency. Such a designation is necessary because the current QIDP designation does not include biologics, nor is the current QIDP designation designed for use during a public health emergency.

The first part of this proposal involves applying the equivalent to a Breakthrough Therapy designation to a biologic that is developed during a qualifying public health emergency. Like the humanitarian patent designation, what constitutes a qualifying biologic and a qualifying public health emergency should be narrowly defined and narrowly construed. By applying this designation, the candidate vaccine would receive both priority review and involvement of dedicated senior officials at FDA to evaluate the candidate vaccine. Because of the complex nature of many biologics, it is imperative that senior officials at FDA are involved in the application process, not only to identify and address potential problems arising in clinical trial data, but also to advise the applicant in how to most efficiently proceed with clinical trials to proceed through the process more quickly. To offset the cost of the priority review, supplemental funding or grants should be made available from the CDC public health emergency reserve funds.

The second part of this proposal involves granting either a waived application fee²¹⁵ or a priority review voucher²¹⁶ if the vaccine manufacturer agrees to forego market

²¹¹ The 2010 proposal includes a more streamlined definition of what constitutes a humanitarian patent application. This definition is sufficient for the present proposal. If this system were adopted, the USPTO can and should consider the use of public comments to further define what would qualify as a “humanitarian patent application.”

²¹² *COVID-19 Prioritized Examination Pilot Program*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot> [<https://perma.cc/XG4V-ABRR>].

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ Should FDA need to recoup the costs of the waived application fee, the emergency reserves at the CDC can be made available.

²¹⁶ This proposal specifically calls for a non-transferable priority review voucher to avoid a windfall to a vaccine manufacturer and to ensure that the two incentives are roughly matched in price. The priority

exclusivity. One of the unique challenges of vaccine development is the difficulty in producing a biosimilar vaccine, which would reduce approval and marketing costs.²¹⁷ The barriers to biosimilar development are daunting,²¹⁸ and it is even less likely that they can be overcome during a public health emergency when time is of the essence. By foregoing market exclusivity and requiring that vaccine manufacturers engage in cooperative non-exclusive agreements to manufacture and distribute the candidate vaccine, FDA and other public and private health entities could ensure that the candidate vaccine reaches target populations as quickly as possible.

This proposal has two primary benefits. First, because a QIDP designation already exists for antibacterial and antifungal drugs, the agency can avoid the problem of having to reinvent the wheel by developing and implementing a new designation. Breakthrough Therapy designation has also been in effect and has been utilized for several qualifying products—including vaccines²¹⁹—, meaning that the process of simultaneously having priority review by senior officials along with accelerated approval has been tried and tested. The inclusion of senior FDA officials has the added benefit of maximizing the safety and efficiency of clinical trials and the process of getting an approved candidate vaccine to market.

C. A “Last Resort” Compulsory License Provision

This proposal is designed to be a last resort, only to be used when all other voluntary means of producing and distributing a vaccination have failed. As discussed previously, there is a general aversion to compulsory licensing in the United States, given the importance of the patent system as an incentive for innovation and the costs of bringing a new candidate drug or vaccine to market.²²⁰ Additionally, previous attempts to authorize compulsory licensing during public health emergencies have failed to pass both houses of Congress.²²¹ This proposal calls for the passage of a bill similar to the 2005 Public Health Emergency Medicines Act, which would have allowed the Secretary of Health and Human Services to issue a compulsory license without the patent holder’s consent during a public health emergency, in exchange for a reasonable royalty.²²² The relevant portions of the proposed bill are as follows:

(a) . . . In the case of any invention relating to health care the Secretary of Health and Human Services shall have the right to authorize use of the subject matter of the patent without authorization of the patent holder or any licensees of the patent holder if the Secretary makes the determination that the invention is needed to address a public health emergency.

review voucher would not be limited to public health emergency biologics, but could be used on a traditionally profitable drug, biologic, or medical device, produced by the same drug development entity.

²¹⁷ See Koballa, *supra* note 48, at 487.

²¹⁸ See *supra* Section I.A.

²¹⁹ Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *The FDA Breakthrough-Drug Designation—Four Years of Experience*, 378 NEW ENGL. J. MED. 1444, 1446 (2018) (identifying two candidate meningococcal vaccinations—one developed by GlaxoSmithKline, and another developed by Pfizer, among the list of Breakthrough Designation recipients).

²²⁰ See *supra* Section I.B.

²²¹ See Public Health Emergency Medicines Act, H.R. 4102, 109th Cong. (2005).

²²² *Id.*

(b) . . . In exercising the right . . . to authorize other use of the subject matter of a patent, the right holder shall be paid reasonable remuneration for the use of the patent. In determining the reasonableness of remuneration for the use of a patent, the Secretary of Health and Human Services may consider—

- (1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;
- (2) evidence of the efficacy and innovative nature and importance to the public health of the invention or products using the invention;
- (3) the degree to which the invention benefited from publicly funded research;
- (4) the need for adequate incentives for the creation and commercialization of new inventions;
- (5) the interests of the public as patients and payers for health care services;
- (6) the public health benefits of expanded access to the invention²²³

However, considering concerns raised by drug manufacturers that compulsory licensing could be harmful to innovation and result in manufacturers being unable to recoup the costs of research, development, and manufacturing, this proposal calls for a compulsory license provision to be used as a “last resort,” when all attempts to establish and enter into voluntary licensing agreements have failed to occur within a designated period of time.

For example, if a compulsory licensing provision had been available during the Ebola crisis, the federal government could have stepped in to permit compulsory licensing of the NewLink candidate vaccine²²⁴ once it was clear that NewLink’s licensing negotiations were being delayed. Even if the federal government did not immediately exercise a compulsory licensing scheme, the availability of that as an option could have spurred NewLink to act quicker to address the impending emergency needs in the United States and abroad.

This proposal has two primary benefits. First, section (b) of the Public Health Emergency Medicines Act allows for the consideration of numerous factors in determining a reasonable royalty rate, including the costs of innovation and other commercial costs. As such, the concern of vaccine developers expending resources that cannot be recouped is diminished, although it will take further economic analysis to determine whether these provisions alone would allow developers to fully recoup all research and development costs. Second, by having this provision as one of last resort, patent holders can still exercise their property rights over intellectual property during public health emergencies as long as this exercise does not prevent the development and dissemination of vaccinations during public health emergencies.

²²³ *Id.*

²²⁴ Discussed *supra* Section II.A.

V. ADDRESSING POTENTIAL CHALLENGES TO THE PROPOSALS

This section anticipates and addresses challenges to the proposals discussed above. First, this section continues the discussion of aversion to compulsory licensing in the United States and explores the reasons for maintaining a compulsory license option as a last resort during a public health emergency. As discussed above, there is no general compulsory licensing provision in the patent statute, and attempts to legislate a compulsory licensing option in response to bioterror incidents have failed. Second, this section discusses why current pathways at FDA are not suitable for public health emergencies and justifies why FDA needs to dedicate a pathway specifically for biologics developed in response to public health emergencies. In particular, this section focuses on why the fast-track options for neglected tropical diseases, which includes both Ebola and Zika, is not sufficient for an emergency response.

A. *Compulsory Licensing*

As discussed above,²²⁵ compulsory licensing has not been a popular solution in the United States, even in light of significant bioterror threats such as the anthrax cases in 2001.²²⁶ The grant of a patent is often characterized as a contract between the federal government and an inventor, allowing the inventor to exercise certain exclusive rights, particularly the right to make and sell the invention, in exchange for disclosure of the invention to the public through the patent application process.²²⁷ Compulsory licensing has thus been seen as an infringement on these exclusive rights by the same entity that granted them.²²⁸

In an ideal setting, a compulsory license would not be necessary because the patent owner would seize the opportunity to make and use their invention by manufacturing and distributing it themselves or granting a license voluntarily to another commercial entity that has the ability to manufacture and distribute the invention on a larger scale. However, the greatest risk to *not* having a compulsory licensing scheme for public health emergencies is that the patent holder for a vaccination (or other critical invention at the time) would not take the steps necessary to ensure that the vaccine was distributed to affected populations. For example, pharmaceutical non-practicing

²²⁵ See *supra* Section I.D.

²²⁶ Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 176 (2003) (characterizing a bill that would have authorized compulsory licensing as “an attempt to capitalize on the threat of bioterrorism.”).

²²⁷ *Id.* at 177. For a patent application to be approved, the inventor must disclose the invention in its entirety, including a portion of the application dedicated to enabling a person having ordinary skill in the art to make and use the invention. 35 U.S.C. § 112.

²²⁸ *Id.*

entities,²²⁹ or “patent trolls,” have recently become a cause for concern.²³⁰ By using a patent as a weapon to prevent others from using the invention in any way, either by refusing to practice the patent or charging prohibitive licensing fees to utilize the patented invention, non-practicing entities block the path forward for pharmaceutical development.²³¹

In the context of a public health emergency where the patent for a vaccine (or a component of a vaccine) was held by a non-practicing entity, the actions (or rather, inaction) of the entity would be paralyzing because the only way to get the vaccination to market would be by infringing the patent, or, if the non-practicing entity agrees, paying an exorbitantly high licensing fee that could be raised in the context of a public health emergency.²³² This cost could be catastrophic to the infringing developer or manufacturer.²³³ Furthermore, FDA’s extensive regulatory process, which requires a brand new application for any change to a drug’s formulation, makes it difficult to “invent around” the blocked invention.²³⁴

Permitting the government to issue a compulsory license in the context of a qualifying public health emergency, for a qualifying vaccination, would sidestep the obstacles posed when attempting to manufacture a vaccine on a larger scale. As a point of emphasis, this proposal is suggesting that compulsory licenses be issued *only* in instances where there is a clear public health emergency and when the involved parties are unable to independently come to an agreement about how to manufacture and distribute the vaccination. Before issuing a compulsory license, the federal agency overseeing the compulsory licensing process must verify that there has been absolutely no progress made towards a licensing agreement. A compulsory license would not, for instance, come into play when there is only an exclusive license agreement and would not come into play even when outside parties believe that the licensing agreement made might be inadequate. Furthermore, a compulsory license is not a full-scale takeover of a patent holder’s rights, particularly in terms of financial gain. Compulsory licensing schemes involve the issuance of a “reasonable royalty” to compensate the patent owner for the use of the invention.²³⁵ Thus, the patent holder during a public health emergency would still be compensated for the use of their patented invention,

²²⁹ A “non-practicing entity” in the patent context is someone who holds a patent for an invention but does not take steps to exercise any of the patent rights that she is granted. If someone else attempts to practice the patented invention, the non-practicing entity can file a patent infringement lawsuit, often dissuading the infringing party from pursuing the invention. Thus, litigation becomes the primary means of capital for patent trolls, rather than actually producing the patented invention. This leads to a situation in which the patented invention is not practiced by anyone, and the patent that the non-practicing entity holds becomes a barrier to future innovation. See generally *Patent Trolls*, ELECTRONIC FRONTIER FOUND., <https://www.eff.org/issues/resources-patent-troll-victims> [<https://perma.cc/768T-AU8B>] (last visited Jan. 13, 2019).

²³⁰ Robin Feldman & W. Nicholson Price II, *Patent Trolling—Why Bio & Pharmaceuticals Are at Risk*, 17 STAN. TECH. L. REV. 773, 778–85 (2014).

²³¹ See *id.*

²³² See *id.* at 779.

²³³ See *id.*

²³⁴ See *id.* at 792.

²³⁵ See, e.g., 42 U.S.C. § 2183 (a provision of the Atomic Energy Act granting the Commissioner the ability to authorize a compulsory license and providing for a reasonable royalty for the patent holder).

and any obstacles preventing large-scale manufacturing and distribution would be avoided.²³⁶

B. Shortcomings of Current FDA Pathways

As discussed above, FDA already provides several pathways that biologics developers can use to get their product into the stream of commerce faster, and some of those pathways already include financial incentives, such as a priority review voucher.²³⁷ For example, both Ebola and Zika qualify as neglected tropical diseases and could proceed with drug development under the Orphan Drug Act.²³⁸ The Orphan Drug Act provides several incentives for pharmaceutical companies that pursue development of drugs that target so-called “orphan diseases.”²³⁹ These incentives include tax credits to help recoup the costs of clinical testing, fast-track review at FDA, extended periods of market exclusivity, and priority review vouchers that can be applied to more profitable drugs or sold on the open market.²⁴⁰ Why, then, is the Orphan Drug Act pathway not sufficient for public health emergencies?

First, on its face, the Orphan Drug Act is not designed to act in an emergency setting—its primary purpose was to address diseases that were otherwise not financially feasible to address.²⁴¹ The Orphan Drug Act does not include a way to mobilize as many resources as possible at FDA to get a candidate vaccine on the market as quickly as possible. Second, not all potential public health emergencies would qualify under the Orphan Drug Act. For example, Ebola was not included among the list of neglected tropical diseases until 2014.²⁴² Finally, the Orphan Drug Act does not explicitly target biologics, which often have a higher cost of production and for which the incentives are not sufficient.²⁴³

Given the panicked environment that can often accompany the declaration of a public health emergency, it is critical that there is a regulatory pathway in place *specifically* for the development of vaccines and other biologics during a public health emergency. Pathways for non-biologic pharmaceuticals, such as the current QIDP, are not sufficient because they do not account for the higher cost of development for biologics, nor do they factor in the more complicated clinical trial designs that may require more FDA involvement and resources.²⁴⁴ Because many of the components of the revised qualified infectious disease pathway proposed above already exist, scattered across multiple pathways, the act of bringing these components together into

²³⁶ Naturally, a compulsory license alone would not be sufficient to ensure that the entirety of the targeted population receives a necessary vaccine at a reasonable cost. The license would need to be granted to an entity that could meet these requirements, and ideally, multiple manufacturers, in case one manufacturer backs out, as happened with the Zika vaccine.

²³⁷ See *supra* Section I.B.

²³⁸ See Cameron Graham Arnold & Thomas Pogge, *Improving the Incentives of the FDA Voucher Program for Neglected Tropical Diseases*, 21 BROWN J. WORLD AFFAIRS 223, 225 (2015).

²³⁹ Also known as neglected tropical diseases, these are rare infectious diseases that independently do not have a large enough population to justify the high costs of drug development. Neglected tropical diseases include rabies, leprosy, and leishmaniasis. NEGLECTED TROPICAL DISEASES, *supra* note 23.

²⁴⁰ See Arnold & Pogge, *supra* note 238, at 225.

²⁴¹ See *id.*

²⁴² *Id.* at 230.

²⁴³ *Id.*

²⁴⁴ See *supra* Section I.B.

a single framework dedicated to research and development during a public health emergency will not be difficult—in fact, it is necessary to have a coordinated response during times of emergency. The critical component of this proposal is in recognizing that there is a need for a coherent plan that addresses vaccine development during a public health emergency—from patenting, to development, to manufacture and distribution.

CONCLUSION

These three proposals are not intended to be an answer to every problem that the current regulatory scheme poses to the vaccine development process during a public health emergency. Instead, these proposals aim to address three specific regulatory and legislative shortcomings that, if adopted, could enhance the ability of domestic vaccine developers and manufacturers to overcome the time and financial barriers to expedient vaccine distribution.

When evaluating the response to the Ebola, Zika, and COVID-19 outbreaks, it is clear that the current regulatory framework available for faster vaccine development is not suitable for public health emergencies, which pose both a time and a financial barrier. Without addressing the shortcomings of the current regulatory framework and proactively preparing an improved process for vaccine patenting, approval, and distribution, the domestic response to the next public health emergency could once again fall short, leaving affected populations vulnerable to whatever the next outbreak may be.