

2020

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Recommended Citation

Ana Santos Rutschman. The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks. Michigan Law Review Online 2020.

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THE INTELLECTUAL PROPERTY OF VACCINES:
TAKEAWAYS FROM RECENT INFECTIOUS DISEASE OUTBREAKS

Ana Santos Rutschman*

This Essay examines the ways in which intellectual property regimes influence incentives for the development of new vaccines for infectious diseases. Charting the tension between market forces and public health imperatives, the Essay considers an emerging solution to the long-standing problem of insufficient incentives for vaccine research and development: the rise of public-private partnerships in the health space. The Essay provides a short case study on CEPI, a large-scale public-private partnership dedicated exclusively to funding research on vaccines for infectious diseases. In exploring how the interaction between intellectual property rules and practices affect vaccine innovation, the Essay offers illustrations from recent outbreaks of infectious diseases, including the 2019 novel coronavirus, Zika, and Ebola.

INTRODUCTION

In late 2019, a new strain of coronavirus, a family of viruses causing serious respiratory illnesses, infected several people at a seafood market in Wuhan, a large city in China. The pathogen, known as 2019-nCoV, quickly spread across the globe, prompting the World Health Organization to declare the outbreak a Public Health Emergency of International Concern on January 30, 2020.¹ At this point, the global case count was approaching 10,000, resulting in over 200 deaths.² No vaccine is—or will be—available during the duration of the outbreak. Yet, as soon as the seriousness of 2019-nCoV infection became apparent, several research institutions, pharmaceutical companies, public-private partnerships and governmental actors announced funding for, and immediate work on, the development of vaccines targeting 2019-nCoV.³

This story is not new. While the 2019-2020 coronavirus outbreak presents idiosyncratic challenges to local and international public health systems, the absence of fully developed vaccines has been a constant in recent transnational, large-scale outbreaks of infectious diseases. It happened with Zika in 2015-16 and Ebola in 2014-16. Similarly, globalized outbreaks throughout the early 21st century have prompted a race to develop vaccine candidates among multi-party research and development (R&D) cohorts. The most recent product of such a race is a landmark vaccine, Ervebo, which was approved in December 2019 by the U.S. Food and Drug Administration (FDA) and is the first commercially available vaccine targeting a virus in the Ebola

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¹ WORLD HEALTH ORG., *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-Ncov)*, (Jan. 30, 2020), <https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-%282005%29-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-%282019-ncov%29>.

² U.S. CTRS. DISEASE CONTROL & PREVENTION, CONFIRMED 2019-NCOV CASES GLOBALLY, <https://www.cdc.gov/coronavirus/2019-ncov/locations-confirmed-cases.html#map>; WORLDOMETER, WUHAN CORONAVIRUS OUTBREAK (last accessed Jan. 30, 2020), <https://www.worldometers.info/coronavirus/> (last accessed Jan. 30, 2020).

³ See e.g. Shawn Radcliffe, *How Long Will It Take to Develop a Vaccine for Coronavirus?*, HEALTHLINE, <https://www.healthline.com/health-news/how-long-will-it-take-to-develop-vaccine-for-coronavirus>.

family.⁴ Efforts to bring the first Ebola vaccine to market gained momentum in 2015, as the deadliest Ebola outbreak on record ravaged West Africa and triggered a wave of international concern. In a world in which infectious diseases like Ebola and COVID-2019 are poised to travel faster and wider, the approval of Ervebo has been regarded as a victory for public health.

However, while constituting milestones in public health preparedness, the development—and eventual approval—of vaccines as a response to infectious disease outbreaks also hides a troubled history of R&D, (mis)articulation between the public and private sectors, and shortcomings of intellectual property (IP) regimes, all of which expose significant limitations in current legal and policy regimes designed to promote innovation. Using examples drawn from the current vaccine development landscape, this Essay explores the ways in which law and policy have been designed to support the development and commercialization of new vaccines, and how they often fail to achieve that goal. In Part I, the Essay focuses on the default regime aimed at spurring biopharmaceutical innovation—the patent system—and describes the misalignment between patent-based incentives to R&D and the characteristics of markets for vaccines targeting infectious diseases like the novel coronavirus, Zika and Ebola. In Part II, the Essay analyzes an emerging solution for the current incentives problem in the field of vaccines: the growing role of newly created public-private partnerships working directly and solely in the vaccine R&D space.

I. IP THEORY APPLIED TO VACCINES FOR INFECTIOUS DISEASES

A recurring trope in utilitarian IP narratives is that patent regimes are necessary for the promotion of socially desirable innovation, particularly in chronically underfunded areas of science and technology. According to some strands of these narratives, the need for patents is especially pressing in the case of biopharmaceutical innovation, where heightened R&D costs and risk of failure may drive would-be investors away if no form of market exclusivity is offered.⁵ While this view has been progressively nuanced in literature and practice, part of this ethos remains at the core of current embodiments of the patent bargain.

Even within the biopharmaceutical innovation ecosystem, there is an important subject matter differentiation: some forms of technology and certain diseases have traditionally attracted more attention and funding streams, while others struggle to capture them, often irrespective of their public health toll. Taken as a whole, the field of vaccines is one that tends to disproportionately populate the latter group.⁶

At first blush, this should not be the case. Vaccines constitute relatively economical means of preventing or reducing the burden of disease, disability and death. Moreover, they are widely regarded as instrumental in furthering related public health goals, such as the lessening of inequality among impoverished populations.⁷ From both an innovation policy and a public health

⁴ U.S. FOOD & DRUG ADMIN., FIRST FDA-APPROVED VACCINE FOR THE PREVENTION OF EBOLA VIRUS DISEASE, MARKING A CRITICAL MILESTONE IN PUBLIC HEALTH PREPAREDNESS AND RESPONSE (DEC. 19, 2019), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>.

⁵ See e.g. WILLIAM W. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW*, HARVARD UNIVERSITY PRESS (2003), at 316.

⁶ See Stanley A. Plotkin et al., *Establishing a Global Vaccine-Development Fund*, 373 *NEW ENGL. J. MED.* 297 (2015) (listing vaccine-preventable diseases for which no vaccines have yet been developed).

⁷ See F.E. Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, *BULL. WORLD HEALTH ORG.*, (<https://www.who.int/bulletin/volumes/86/2/07-040089/en/>).

perspective, vaccines are extremely cost-effective products whose development should attract adequate funding and resources. However, the specific properties of vaccines as a form of biotechnology, together with the economics of vaccine markets, make them a poor match for contemporary, IP-driven innovation regimes.

As commodified goods, vaccines are often regarded as unappealing investment prospects. This is attributable to several factors.⁸ The goal of vaccine deployment is eminently preventative. Success in this field translates into a non-event, or in the lessening of characteristics associated with a particular event—an outbreak. As several commentators have pointed out, the quantification of the savings generated by the effective deployment of vaccines is hard to perform, if not virtually impossible.⁹ Moreover, these savings—to multiple individual and institutional players across health systems—do not translate into direct economic returns for vaccine developers.

Unlike several other biologic products, which require multiple doses or even life-long use, many vaccines deliver long-term immunity through a single use, while many others require a very limited number of uses. This feature limits the possibilities of monetization of vaccines in significant ways. As commentators have noted, “[t]he longer the efficacy [of a vaccine], the smaller the demand.”¹⁰ Because contemporary IP is largely animated by the prospect of non-trivial economic returns, such a limitation on the size of the market further conditions the investment appeal of most vaccines.

Even within existing markets for vaccines targeting infectious pathogens, the successful deployment of vaccines faces practical hurdles. Unlike conventional drugs (although similarly to other biologics), preserving the efficacy of a dose of vaccine requires the maintenance of cold chain.¹¹ Some types of vaccines—such as live virus vaccines—are particularly sensitive to temperature changes, a feature that poses enhanced problems in reaching vaccine markets in remote areas of the Global South. While in isolation these characteristics are not enough to lessen the profitability of vaccines from the perspective of a would-be investor, they add to the distinctiveness of vaccines as biopharmaceutical products and, by extension, to the complexities that mire vaccine markets.

As of lately, in both the South and the North, rates of vaccine confidence have started to plummet.¹² The phenomenon is especially pronounced across Europe, Central Africa and North America, where the percentages of people who agree with the proposition that vaccines are safe are far below the percentages generally required to maintain immunity to certain vaccine-preventable diseases within communities, also known as herd immunity.¹³ Severe measles outbreaks in Washington State in 2019 and in New York State in 2018-19, which set records for measles infection in the United States in the twenty-first century, have been linked to a decrease

⁸ For an expanded analysis of the specifics of vaccines and vaccine markets, see Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 751-758 (2019).

⁹ See e.g. Rino Rappuoli et al., *The Intangible Value of Vaccination*, 297 SCI. 937 (2002).

¹⁰ Patricia M. Danzon et al., *Vaccine Supply: A Cross-National Perspective*, 24 HEALTH AFF. 706, 707 (2005).

¹¹ Umit Kartoglu & Julie Milstien, *Tools and Approaches to Ensure Quality of Vaccines Throughout the Cold Chain*, 13 EXPERT REV. VACCINES 843 (2014).

¹² Jamie Ducharme, *Most People Worldwide Trust That Vaccines Are Safe—But the Number Who Don't Is Concerning*, TIME MAGAZINE (Jun. 19, 2019), <https://time.com/5609984/vaccine-trust-worldwide/>.

¹³ VACCINE KNOWLEDGE PROJECT, HERD IMMUNITY (HERD PROTECTION), <https://vk.ovg.ox.ac.uk/vk/herd-immunity>.

in herd immunity within the affected localities.¹⁴ To date, there is no data suggesting that the rise of vaccine mistrust might result in a decline of investment in vaccine R&D. However, a vaccine-specific property (herd immunity), combined with the recent decline in vaccine confidence, further accentuate the idiosyncrasies of vaccines as instruments for the promotion of public health.

A final element that sets vaccines apart from most other fields of biotechnology is the historical evolution and concentration on the supply side of the market. In the mid-1940s there were over 50 licensed vaccine manufacturers in the United States; by the late 1990s the number had fallen below ten.¹⁵ Market exodus appears to have been driven by a mix of liability-related concerns—which the 1986 National Childhood Vaccine Injury Act sought to address¹⁶—and economic considerations. These considerations encompassed both rising regulatory costs associated with vaccine development and approval,¹⁷ as well as the perceived unprofitability of vaccines.¹⁸

To put things in perspective, consider how sales of vaccines fare when compared with sales of other pharmaceutical products. In the wake of the 2018-19 measles outbreaks, sales of MMR vaccines (measles-mumps-rubella) increased by 58% in the United States when compared to the previous year, generating a total of \$675 million.¹⁹ By contrast, Januvia, a drug used in the treatment of diabetes, generates close to \$6 billion a year.²⁰ The drug is manufactured by Merck, which is also the sole manufacturer of MMR vaccines in the United States. Merck's Keytruda, a biologic used in oncology which is projected to become the company's best-selling drug over the next few years, is expected to surpass the yearly mark of \$20 billion.²¹

In considering the relative unprofitability of vaccines like MMR, it is important to underscore that this is one the best-selling vaccines currently on the market. Perhaps the most well-known example of a commercially successful vaccine is the case of Gardasil, a vaccine also manufactured by Merck that targets human papillomavirus (HPV), and which generated over \$3 billion in 2018, an increase by a factor of 3.7 when compared to the average growth registered in the preceding three years.²²

¹⁴ Aimee Cunningham, *How Holes in Herd Immunity Led to a 25-year High in U.S. Measles Cases*, SCIENCE NEWS (Apr. 29, 2019), <https://www.sciencenews.org/article/holes-herd-immunity-led-25-year-high-us-measles-cases>.

¹⁵ Rutschman, *The Vaccine Race*, *supra* note 8, at 740-41 (presenting data on manufacturer entrance and attrition in the United States vaccine market).

¹⁶ 42 U.S.C. §§ 300aa-21–300aa-23 (1988).

¹⁷ Rutschman, *The Vaccine Race*, *supra* note 8, at 743.

¹⁸ See e.g. Jon Cohen, *U.S. Vaccine Supply Falls Seriously Short*, 295 SCI. 1998 (Mar. 15, 2002).

¹⁹ See Berkely Lovelace Jr., *US Measles Outbreak Helps Boost Merck's Vaccine Sales in Second Quarter*, CNBC (Jul. 30, 2019), <https://www.cnbc.com/2019/07/30/nasty-us-measles-outbreak-helps-boost-merck-vaccine-sales-in-q2.html>.

²⁰ MERCK, *Merck Announces Fourth-Quarter and Full-Year 2017 Financial Results* (Feb. 2, 2018), <https://investors.merck.com/news/press-release-details/2018/Merck-Announces-Fourth-Quarter-and-Full-Year-2017-Financial-Results/default.aspx>.

²¹ Josh Nathan-Kazis, *Merck's Keytruda Will Become Best-Selling Drug Worldwide, Research Group Says*, BARRON'S (Oct. 4, 2019), <https://www.barrons.com/articles/mercks-keytruda-will-become-best-selling-drug-worldwide-research-group-says-51570204530>.

²² Trefis Team, *Merck's \$3 Billion Drug Jumped To 4x Growth Over Previous Year*, FORBES (Oct. 4, 2019), <https://www.forbes.com/sites/greatspeculations/2019/10/04/mercks-3-billion-drug-jumped-to-4x-growth-over-previous-year/#4e4113de6294>.

While the examples of MMR and Gardasil help illustrate the relative scale of revenue streams generated by vaccines, it is important to note that these are outliers in the vaccine market landscape. As a whole, and largely due to the characteristics surveyed above, the field of vaccines is considered unprofitable and unattractive to most players in the biopharmaceutical arena.²³ As a consequence, vaccine R&D has been significantly underfunded, particularly from the mid-twentieth century onwards.²⁴

These limitations are especially salient in the case of vaccines targeting infectious diseases that are not traditionally endemic to the Global North. The ongoing development of vaccines targeting different strains of Ebola illustrates this difference. Until the 2014-16 outbreak, the only existing vaccine candidate was languishing in storage, having failed to attract a private-sector sponsor for clinical trials and the later stages of the regulatory approval process.²⁵ Unlike immunization against measles, mumps and rubella, which is part of Centers of Disease Control and Prevention's immunization schedules,²⁶ there was no foreseeable market for an Ebola vaccine and therefore, from an economic point of view, no incentive for private companies to engage in the costliest stages of R&D. A variation of this lack of commercial appeal was observable during the first months of the 2019-20 coronavirus outbreak: even though the U.S. National Institutes of Health (NIH) quickly initiated R&D on the new coronavirus strain—and in spite of the escalating morbidity and mortality toll of the virus—the agency was [at first] unsuccessful in finding a large private-sector partner interested in partnering to develop a vaccine candidate.²⁷

Incentives regimes anchored predominantly in IP thus fail to account for the specificities—and relatively limited prospects of revenue generation—of vaccines targeting infectious diseases that have very limited markets, if any, in the United States or the Global North.²⁸ To be sure, vaccines are not the only field of biotechnology that is routinely underfunded and fails to attract the attention of major players in the private sector. For instance, diseases affecting very small segments of the population, the so-called orphan diseases,²⁹ face a similar predicament. However, unlike the drugs or biologics likely needed to address orphan diseases (or non-vaccine preventable conditions), most vaccine technology currently in use is relatively simple.³⁰ Moreover, in the case

²³ See e.g. *A Smarter Jab*, *The Economist* (Oct. 14, 2010), <https://www.economist.com/business/2010/10/14/a-smarter-jab>.

²⁴ Rutschman, *The Vaccine Race*, *supra* note 8, 738-744 (surveying the arc of vaccine R&D in the United States throughout the twentieth century).

²⁵ See Denise Grady, *Ebola Vaccine, Ready for Test, Sat on the Shelf*, *N.Y. TIMES* (Oct. 23, 2014), <https://www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html>.

²⁶ U.S. CTRS. DISEASE CONTROL & PREVENTION, *CHILD AND ADOLESCENT IMMUNIZATION SCHEDULE (2020)*, <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>; ID., *RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER (2020)*, <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>.

²⁷ Note to Editors: information to be updated as close as possible to publication.

²⁸ *Supra* note 6.

²⁹ U.S. FOOD & DRUG ADMIN., *ORPHAN PRODUCTS: HOPE FOR PEOPLE WITH RARE DISEASES (2018)*, <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases> (defining orphan diseases as those affecting fewer than 200,000 in the United States).

³⁰ The Essay does not focus on more complex forms of vaccine technology currently under development, but not commercially available, such as DNA vaccines or vaccines targeting certain types of cancer (excluding HPV). See also DPT. HEALTH & HEALTH SERV., *VACCINE TYPES*, <https://www.vaccines.gov/basics/types> (listing the four existing types of vaccines).

of the pathogens at the root of recent infectious disease outbreaks—and likely to originate future outbreaks—R&D often takes place on an extremely compressed timeline. For instance, when U.S. Army scientists decided to develop a Zika candidate during the early stages of the 2015-16 outbreak, they adapted existing vaccine technology and produced a vaccine candidate in roughly three months.³¹

Shorter R&D timelines and reliance on relatively straightforward, well-known processes—the killing or weakening of viral matter and combining it with enhancers and stabilizers³²—should in principle counterbalance the pervasive lack of pre-outbreak incentives to R&D, particularly if a public health crisis in the form of an outbreak alters the incentives landscape. Yet, vaccines targeting diseases like Zika or coronaviruses offer prospective investors truncated markets on multiple levels: quantitative (overall number of patients indicated to receive a vaccine); geographical (incidence of outbreaks in “hubs” across the globe, as opposed to the near-global demand for blockbuster drugs dealing with cardiovascular or oncology diseases); and temporal (relative shortness of outbreaks, following which demand for vaccines declines). Against this backdrop, even a spike in funding generated by an outbreak is likely to be ephemeral.

Until recently, there were very few vaccine-specific responses to the problems posed by the misalignment between IP incentives frameworks and actual investment in vaccine R&D. At the conceptual level, scholars of incentives theory have long recommended the pairing of IP with non-IP incentives such as prizes, grants, tax credits or reimbursement schemes as a general prescription³³ for innovation policy across different technology domains. Scholars focused on the specific impact of IP regimes on vaccine R&D have directed their attention to themes adjacent to, but not centered on, the problem of incentives.³⁴ In practice, an important change occurred in the early 2000s, as several non-profit organizations began forming around selected underfunded diseases, to support disease-specific R&D on a range of drugs or treatments (although not specifically vaccines): for example, this was the case of the Drugs for Neglected Diseases Initiative, which focused many of its early efforts on malaria R&D.³⁵ The recent wave of international outbreaks of infectious diseases, however, has underscored the need for solutions tailored to the idiosyncrasies of vaccine markets.

The Essay now turns to the current embodiment of the first large-scale, vaccine-specific response to the problem outlined above—a response that is aimed directly at counterbalancing the structural limitations of IP-based incentives regimes, and which was prompted by the shortcomings in funding for vaccine R&D observed before and during the 2014-16 Ebola outbreak. It presents a short case study on the Coalition for Epidemic Preparedness Innovations (CEPI), a public-private partnership focused on selecting and funding vaccine R&D projects in an effort to prevent

³¹ Annette M. Boyle, *Army Research Produces Zika Vaccine Candidate in Record Time*, U.S. MED. (Aug. 2016), <https://www.usmedicine.com/agencies/department-of-defense-dod/army-research-produces-zika-vaccine-candidate-in-record-time/>.

³² DPT. HEALTH & HEALTH SERV., VACCINE TYPES, <https://www.vaccines.gov/basics/types> (listing the four existing types of vaccines).

³³ See generally Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L. J. 544 (2019).

³⁴ See Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017) (addressing instances of vaccine innovation outside IP frameworks); Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018) (focusing on solutions for transactional problems arising during licensure of IP-protected vaccine technology).

³⁵ DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://www.dndi.org>.

outbreaks of infectious diseases.³⁶ Importantly, in January 2020 CEPI entered into agreements to provide financial support for the development of three different types of vaccines for the Wuhan coronavirus.³⁷ The financial commitment came less than two weeks after Chinese scientists first made a sequence of COVID-19 available through a public database.³⁸

In addition to providing an overview of CEPI—and an insight into how public-private partnerships can play a role in progressively detaching vaccine R&D from IP incentives molds—the next section highlights how collaborative R&D models can co-exist with IP rights associated with the development of new vaccines and vaccine technology.

II. SOLVING THE INCENTIVES PUZZLE FOR VACCINES: THE RISE OF PUBLIC-PRIVATE PARTNERSHIPS

A. Global Health Public-Private Partnerships in Context

Until the 1990s, there were barely any public-private partnerships operating in the drug development space.³⁹ The landscape changed dramatically in the early 2000s, with heterogeneous institutions entering into increasingly larger collaborative agreements.⁴⁰ In the biopharmaceutical arena, these partnerships tend to assume one of two models: access partnerships and product development partnerships.⁴¹

Access partnerships operate mainly by pulling together resources to guarantee the purchase and subsequent distribution of biopharmaceuticals.⁴² The focus of these partnerships is to bring “existing drugs to underserved markets.”⁴³ The most prominent example in the field of vaccines is Gavi, a non-profit, international public-private partnership created in 2000 to “improve access to new and underused vaccines” in the Global South.⁴⁴ Gavi is supported by a broad network of funders, including the Bill & Melinda Gates Foundation, governments, international organizations like the World Health Organization, UNICEF and the World Bank, the biopharmaceutical industry, civil society organizations, and research and technical health institutes.⁴⁵ Gavi relies on long-term

³⁶ COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (hereinafter CEPI), CEPI MISSION, <http://cepi.net/mission>.

³⁷ CEPI, CEPI TO FUND THREE PROGRAMMES TO DEVELOP VACCINES AGAINST THE NOVEL CORONAVIRUS, nCoV-2019 (Jan. 23, 2020), https://cepi.net/news_cepi/cepi-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/.

³⁸ See Jon Cohen, *Scientists Are Moving at Record Speed to Create New Coronavirus Vaccines—But They May Come Too Late*, SCIENCE (Jan. 27, 2020) <https://www.sciencemag.org/news/2020/01/scientists-are-moving-record-speed-create-new-coronavirus-vaccines-they-may-come-too>.

³⁹ Jon F. Merz, INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS, WORLD HEALTH ORG. (2005), at 17 (reporting that, as of 2005, there were only two public-private product development partnerships that had been created before the 1990s).

⁴⁰ *Id.*, *ib.* (finding that, as of 2005, half of the existing public-private partnerships in the field were under five years old).

⁴¹ *Id.*, at 2.

⁴² *Id.*, *ib.* (defining access partnerships as “entities concerned primarily with expanding access by pulling together manufacturers, funding agencies (such as GAVI, USAID) and developing countries to enable the purchase and distribution of existing drugs, vaccines, and other medical products”).

⁴³ *Id.*, *ib.*

⁴⁴ GAVI, GAVI’S MISSION, <https://www.gavi.org/about/mission/>.

⁴⁵ GAVI, GAVI’S PARTNERSHIP MODEL, <https://www.gavi.org/about/gavis-partnership-model/>.

financial support from donors, as well as on increasing co-finance of vaccine acquisitions by countries that benefit from Gavi-purchased vaccines. The partnership currently supports 13 vaccines targeting hepatitis B, rotavirus, polio, human papillomavirus, measles and rubella, among other infectious agents.⁴⁶

In contrast to access partnerships, product development partnerships are entities that operate at the opposite end of the R&D pipeline, sponsoring early to mid-stage R&D on otherwise underfunded diseases.⁴⁷ Such partnerships are widely used in areas where traditional R&D models strain to produce new drugs, as recently exemplified by the Cancer Moonshot.⁴⁸ They can be “general-purpose” partnerships, funding the discovery and development of drugs in multiple areas, as is the case of the Innovative Medicines Initiative in Europe;⁴⁹ partnerships that target specific areas, like CARB-X, sponsoring R&D on antibacterial products;⁵⁰ or disease-specific, like the TuBerculosis Vaccine Initiative, which has formed a 50-party consortium to discover and develop new tuberculosis vaccines.⁵¹

The number of new public-private partnerships launched per year in the biopharmaceutical arena has grown exponentially since the turn of the century.⁵² In 1995, only one partnership entered the market.⁵³ In 2000, there were four new partnerships.⁵⁴ But it is what happened from 2006 onwards that changed the landscape of multi-party biopharmaceutical R&D. Between 2006 and 2013, 310 new biopharmaceutical public-private partnerships entered the market, an average of nearly 40 per year. In 2012 alone, 63 new partnerships were launched. These numbers speak to the buoyancy of large-scale collaborative partnerships as the current preferred model to counter imperfect incentives to biopharmaceutical research.

B. The Coalition for Epidemic Preparedness Innovations

The Coalition for Epidemic Preparedness Innovations (CEPI) was launched at Davos in early 2017 and its sole focus is to fund vaccine R&D on infectious diseases. It is funded primarily by the governments of Norway, Japan and Germany, the Bill & Melinda Gates Foundation and the

⁴⁶ GAVI, VACCINE SUPPORT, <https://www.gavi.org/support/nvs/>.

⁴⁷ See Merz, INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS, *supra*, note **Error! Bookmark not defined.**, at 2 (defining product development partnerships as “nonprofit entities that sponsor others to perform or directly perform themselves at least one of the following R&D activities: basic research (such as target identification, validation and proof of concept), animal, preclinical and clinical testing, licensing, and manufacturing”).

⁴⁸ NATIONAL CANCER INSTITUTE, CANCER MOONSHOT, <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>.

⁴⁹ INNOVATIVE MEDICINES INITIATIVE, ABOUT IMI, <https://www.imi.europa.eu/about-imi>.

⁵⁰ COMBATING ANTIBIOTIC-RESISTANT BACTERIA BIOPHARMACEUTICAL ACCELERATOR (CARB-X), ABOUT CARB-X, <https://carb-x.org/about/overview/>.

⁵¹ TUBERCULOSIS VACCINE INITIATIVE, TBVI AT A GLANCE, <http://www.tbvi.eu/about-us/tbvi-at-a-glance/>.

⁵² See Mark D. Lim, *Consortium Sandbox: Building and Sharing Resources*, 242 SCIENCE TRANSL. MED. 1, 2 (2014).

⁵³ *Id.*

⁵⁴ *Id.*

Wellcome Trust,⁵⁵ and subsidiarily by several other institutions.⁵⁶ As of January 2020, CEPI has over 70 partners, including research institutions, large pharmaceutical companies, regulatory agencies and non-profits.⁵⁷

Part of the impetus for the formation of a large-scale public-private partnership in this field, and one of the reasons it came together so quickly,⁵⁸ was the inexistence of Ebola vaccines during the 2014-15 Ebola crisis.⁵⁹ Yet, as a whole, the partnership was created with much broader goals than merely addressing the problems posed by recent outbreaks.⁶⁰ The partnership was designed to play the role of “gap-filler”⁶¹ for lacking R&D on vaccines targeting infectious diseases:

CEPI wants to galvanize the development of new vaccines against diseases we know could cause the next devastating epidemic. We will achieve our vision by creating an innovative partnership between public, private, philanthropic and civil organizations. It is ambitious both in its scope and in the breadth of organizations involved. CEPI will take an end-to-end approach – we won’t take on discovery research or vaccine delivery, but we will work through all the steps in between. We will stay abreast of new discoveries and technologies, and we’ll work with other organizations to make sure any vaccines that are developed reach those who need them.⁶²

CEPI’s initial goals, for projects developed between 2017 and 2021, are for the partnership to “tackle barriers” in vaccine R&D and ensure that collaborations between partners will result in “affordable vaccines.”⁶³ An additional long-term goal, for work to be done after 2021, is to draw on the “capabilities and partnerships” developed during the first stage and extend the business model “to cover endemic diseases and other medical interventions.”⁶⁴

⁵⁵ The Wellcome Trust is a U.K. non-profit organization, and one of the largest funders of global biomedical R&D. See WELLCOME TRUST, ABOUT US, <https://wellcome.ac.uk/about-us>.

⁵⁶ These include the governments of Belgium, Canada and Australia, the European Union and Australia’s Medical Research Future Fund. See CEPI, PARTNERS, <http://cepi.net/partners>.

⁵⁷ *Id.*

⁵⁸ Interview with CEPI Senior Consultant (on file with author).

⁵⁹ See John-Arne Røttingen et al., *New Vaccines Against Epidemic Infectious Diseases*, 376 *NEW ENG. J. MED.* 610, 610 (2017); Børge Brende et al., *CEPI—A New Global R&D Organisation for Epidemic Preparedness and Response*, 389 *Lancet* 233, 233 (2017) (arguing that “[e]valuations of the Ebola response highlight that the global community must rethink how vaccines, diagnostics, and drugs for emerging infections are developed given their lack of commercial profitability”).

⁶⁰ CEPI, SUMMARY, at 5 (noting that “the coalition [CEPI] was created not because of the failure to deliver an Ebola vaccine in time for it to be useful, but because of how close that project could have come to success”).

⁶¹ CEPI, CEPI’S END-TO-END GAP-FILLING ROLE: A SUSTAINABLE PARTNERSHIP APPROACH, http://cepi.net/sites/default/files/CEPI_Gap_Filling_Role.pdf.

⁶² CEPI, APPROACH, <http://cepi.net/approach>.

⁶³ *Id.*

⁶⁴ *Id.*

Between 2017 and 2021, CEPI is funding⁶⁵ R&D on pathogens chosen from the World Health Organization’s list of “priority diseases.”⁶⁶ Unlike Ebola, for which there was ongoing R&D before the 2014-15 outbreak, many of these pathogens have “weak R&D pipelines.”⁶⁷ CEPI’s initial projection is that the partnership will invest in vaccine projects targeting up to three priority pathogens.⁶⁸ The boost in funding, allied with the combined expertise of a plurality of parties involved in each project, is expected to lead to the development of between four and six vaccine candidates ready for phase III trials by 2021.⁶⁹ At this point, CEPI will facilitate partnerships with private-sector pharmaceutical companies to ensure “sufficient global vaccine development and manufacturing capacity.”⁷⁰

The CEPI initial budget for a five-year period was estimated between U.S. 600 million and 1 billion.⁷¹ A year after it was launched, the partnership had reached \$625 million in multi-donor contributions.⁷² As CEPI produces the first deliverables, the goal is to move towards 10-year funding periods, which will enable the partnership to operate on an expanded timeline, as well as to fund larger R&D projects.⁷³ Between March and August 2018, CEPI has awarded three contracts funding vaccine R&D on Middle East Respiratory Syndrome coronavirus (MERS), Nipah virus and Lassa fever.⁷⁴

CEPI’s awards, both current and future, are guided by a set of core principles aimed at guaranteeing the ultimate availability of CEPI-sponsored vaccines.⁷⁵ Chief among these principles is “equitable access,” which translates into affordability and availability of CEPI-funded vaccines.⁷⁶ Other principles include “shared benefits,” which relates to the allocation of potential revenue between parties involved in a project.⁷⁷

⁶⁵ CEPI, PRELIMINARY BUSINESS PLAN, 2017-2021 (November 2016) (hereinafter PRELIMINARY BUSINESS PLAN) (on file with author).

⁶⁶ See WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS (2017) (listing nine groups of pathogens). The pathogens chosen for CEPI’s first stage were Lassa fever, Middle East Respiratory Syndrome Coronavirus (MERS), and Nipah virus.

⁶⁷ CEPI, PRELIMINARY BUSINESS PLAN, *supra* note 65.

⁶⁸ *Id.*, at 9.

⁶⁹ *Id.*, at 28.

⁷⁰ *Id.*, *ib.*

⁷¹ *Id.*, at 47.

⁷² See Catherine Cheney, *CEPI, A Year In: How Can We Get Ready for the Next Pandemic?*, DEVEX (Feb. 5, 2018), <https://www.devex.com/news/cepi-a-year-in-how-can-we-get-ready-for-the-next-pandemic-91987>.

⁷³ CEPI, PRELIMINARY BUSINESS PLAN, *supra* note 65, at 50.

⁷⁴ See CEPI, CEPI AWARDS CONTRACT WORTH UP TO USD\$36 MILLION TO CONSORTIUM LED BY IDT TO DEVELOP MERS VACCINE (Aug. 20, 2018), <http://cepi.net/news/cepi-awards-contract-worth-usd36-million-consortium-led-idt-develop-mers-vaccine>; WISTAR INST. PRESS RELEASE, COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS SUPPORTS MERS & LASSA ENHANCED DNA VACCINE TECHNOLOGY TO EXPEDITE VACCINE DEVELOPMENT, (Apr. 19, 2018), <https://wistar.org/news/press-releases/coalition-epidemic-preparedness-innovations-supports-mers-lassa-enhanced-dna>; Lisa M. Jarvis, *CEPI and Themis Partner for Vaccines*, 96 CHEM. & ENGINEERING NEWS 19 (Mar. 12, 2018) <https://cen.acs.org/articles/96/i11/CEPI-Themis-partner-vaccines.html>.

⁷⁵ Interview with CEPI Senior Consultant, *supra* note 58. Initially CEPI addressed “shared benefits” and “intellectual property management” separately, but already regarding both as a means of ensuring equitable access to vaccines; see *infra* note 78, and accompanying text.

⁷⁶ CEPI, PRESENTATION TO THE WHO (Jul. 21, 2017) (on file with author).

⁷⁷ CEPI, POLICIES, <http://cepi.net/cepi-policies>

CEPI considers equitable access to be the most important principle governing its awards for vaccine R&D.⁷⁸ Policy documentation circulated in 2017 provided a tentative definition of the principle, stating that “[g]lobal access arrangements will be negotiated in contracts between CEPI and vaccine developers to ensure affordability and availability in Low and Middle Income Countries.”⁷⁹ Further clarification can be found in CEPI’s Preliminary Business Plan, which breaks down the principle into two components. First, in the case of an outbreak, it means “access to investigational vaccine stockpiles” for phase III trials and “emergency development.”⁸⁰ And second, if a CEPI-funded vaccine is approved by a national regulatory entity, it means “access to the licensed vaccine” in terms that guarantee that the vaccine is affordable and that it is made available to populations in need.⁸¹

It should be noted that, although awards have been made, CEPI’s equitable access policy is still evolving.⁸² The initial policy was drafted for a one-year trial, and will be refined after CEPI analyzes the comments received during a period of public consultation, which ended in August 2018.⁸³

Even though the policy is not finalized, CEPI has established that equitable access is not incompatible with proprietary rights over CEPI-funded vaccines, and that position is very unlikely to change, given the underlying business model of the partnership.⁸⁴ In fact, CEPI has made it explicit that “[c]ontracts should include reasonable royalty payment provisos for products or patents.”⁸⁵ This is part of a broader policy designed both to promote fairness and attract commercial partners. The interim CEO of CEPI has referred to this as the idea of “no loss,” in the sense that “vaccine developers should be reimbursed for their direct and indirect costs.”⁸⁶ These goals are embodied in CEPI’s second core principle, shared benefits, which has been framed by CEPI as a means to promote equitable access.⁸⁷

“Shared benefits” operates in cases in which CEPI-funded vaccines generate revenue, a prospect that is taken as unlikely:

It is anticipated that vaccines developed with CEPI support will not be profitable. In the event that a vaccine developed with CEPI support does develop economic value, agreements between CEPI and the vaccine developer will ensure either that CEPI’s investment is reimbursed or that the economic value is shared through royalties or other risk sharing agreements. Any rewards that accrue to vaccine

⁷⁸ CEPI, CEPI POLICY DOCUMENTATION (2017) (on file with author) (“Equitable access is CEPI’s most important principle; the policies on shared risks/shared benefits and management of IP support CEPI’s aim of achieving equitable access to CEPI-supported vaccines”), at 2.

⁷⁹ *Id.*, at 12.

⁸⁰ CEPI, PRELIMINARY BUSINESS PLAN, *supra* note 65, at 12.

⁸¹ *Id.*, *ib.*

⁸² Interview with CEPI Senior Consultant, *supra* note 58.

⁸³ CEPI, INVITATION TO COMMENT ON CEPI’S POLICY REGARDING EQUITABLE ACCESS, http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf.

⁸⁴ Interview with CEPI Senior Consultant, *supra* note 58 (noting that CEPI is “IP-neutral”).

⁸⁵ CEPI, PRESENTATION TO THE WHO, *supra* note 65.

⁸⁶ *Id.*

⁸⁷ See *supra* note 78, and accompanying text.

developers should be proportionate to the level of risk undertaken and to the nature of the R&D, infrastructure, IP or other contributions a developer has made.⁸⁸

If commercial benefits arise, both CEPI and the awardee(s) are entitled to recoup costs proportionally to their investment in the project.⁸⁹ CEPI's ability to recoup costs is limited to licensed vaccines or other foreground⁹⁰ intellectual property, with an obligation to return all commercial benefits to CEPI's funding pool.⁹¹

The general rule is that both background and foreground intellectual property belong to the recipient of a CEPI grant.⁹² In order to build a degree of flexibility into the negotiation process,⁹³ specific intellectual property terms are dealt with on a case-by-case basis.⁹⁴ This takes into account the different capabilities and internal policies of diverse R&D partners. It also enables expedited transfers of technology during situations of public health crisis.⁹⁵

Background or foreground intellectual property used in a CEPI-funded project may be made available to third parties to "foster broader research efforts and innovation of vaccines for emerging infectious diseases that lack market potential."⁹⁶ In such cases, the license regulating the transfer of intellectual property must be a "non-exclusive, royalty-free, sub-licensable and worldwide license."⁹⁷

Keeping in line with CEPI's goal of promoting vaccine innovation, CEPI awardees are required to comply with other knowledge-disseminating obligations.⁹⁸ The requirements include sharing clinical trial data and results through a publicly available platform; timely publication of results; and publication of negative results.⁹⁹

CEPI also enforces an open access publication model.¹⁰⁰ Any publication resulting from CEPI funding must be made available for free, immediately and providing "unrestricted access free of charge, with maximum opportunities for re-use, and including the underlying data."¹⁰¹

⁸⁸ CEPI, PRELIMINARY BUSINESS PLAN, *supra* note 65, at 12.

⁸⁹ CEPI POLICY DOCUMENTATION, *supra* note 58, at 8.

⁹⁰ Foreground intellectual property refers to new rights arising out of a collaborative R&D project, as opposed to background intellectual property, which refers to the pre-existing rights covering technology that a party brings to a collaborative R&D project.

⁹¹ CEPI POLICY DOCUMENTATION, *supra* note 78, at 8.

⁹² *Id.*, at 13 (noting that "CEPI's preferred approach is not to take ownership of IP").

⁹³ Interview with CEPI Senior Consultant, *supra* note 58.

⁹⁴ CEPI POLICY DOCUMENTATION, *supra* note 78, at 10.

⁹⁵ Interview with CEPI Senior Consultant, *supra* note 58.

⁹⁶ CEPI POLICY DOCUMENTATION, *supra* note 78, at 10.

⁹⁷ *Id.*, *ib.*

⁹⁸ *Id.*, at 6.

⁹⁹ *Id.*, *ib.*

¹⁰⁰ *Id.*, *ib.*

¹⁰¹ *Id.*, *ib.*

CONCLUSION

As vaccine-preventable pathogens spread faster in an increasingly globalized world, the development of new vaccines remains a critical public health priority. This Essay has highlighted the disconnect between IP regimes heavily centered on incentives narratives and the challenges posed by markets for vaccines targeting infectious diseases. The emergence of new public-private partnerships focusing on vaccine technology constitutes a much-needed addition to an otherwise severely underfunded R&D landscape. In examining the role and operating principles of CEPI, the Essay has illustrated how IP rights associated with the development of new vaccines can be managed within collaborative R&D models.