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

Ana Santos Rutschman*

INTRODUCTION

In late 2019 and early 2020, a new strain of coronavirus, a family of pathogens causing serious respiratory illness, began infecting populations across the globe. A quick uptick in COVID-19, the disease caused by the novel pathogen, prompted the World Health Organization to declare the outbreak a Public Health Emergency of International Concern on January 30, 2020.¹ By mid-February 2020, with 26 countries reporting cases of COVID-19 infection, the global case count had surpassed 50,000, and had resulted in over 1,500 deaths.² The World Health Organization elevated the status of the outbreak to a pandemic in mid-March.³ As of early April 2020, the number of countries with reported cases of COVID-19 infection has grown to over 175, with the global case count surpassing 1.9 million and deaths nearing 120,000.⁴ No vaccine is available at this point, nor is one like-

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1. *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. (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> [https://perma.cc/CW2A-GHMK].

2. WORLD HEALTH ORG., CORONAVIRUS DISEASE 2019 (COVID-19), at 1 (Feb. 15, 2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200215-sitrep-26-covid-19.pdf?sfvrsn=a4cc6787_2 [https://perma.cc/E8Q8-BKUZ].

3. Jamie Ducharme, *World Health Organization Declares COVID-19 a 'Pandemic.' Here's What That Means*, TIME (Mar. 11, 2020), <https://time.com/5791661/who-coronavirus-pandemic-declaration/> [https://perma.cc/PJJ7-E7XB].

4. *COVID-19 Coronavirus Pandemic*, WORLDOMETER, <https://www.worldometers.info/coronavirus/> [https://perma.cc/FMU3-VNLS]; *World Map*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/locations-confirmed-cases.html#map> [https://perma.cc/KKU6-A4KZ].

ly to become available for months, if not years, to come.⁵ Yet, as soon as the seriousness of COVID-19 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 COVID-19.⁶

This story is not new. While the 2019–2020 coronavirus outbreak presents idiosyncratic challenges to local and international public health systems,⁷ the absence of fully developed vaccines has been a constant in recent transnational, large-scale outbreaks of infectious diseases. It happened with Zika in 2015–2016 and Ebola in 2014–2016.⁸ Similarly, globalized outbreaks throughout the early twenty-first century have prompted a race to develop vaccine candidates among multiparty 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 family.⁹ 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.¹⁰ In a world in which infectious diseases like Ebola and COVID-19 are poised to travel faster and wider,¹¹ the approval of Ervebo has been regarded as a victory for public health.¹²

5. See Robert Kuznia, *The Timetable for a Coronavirus Vaccine is 18 Months. Experts Say That's Risky*, CNN (Apr. 1, 2020, 2:14 PM), <https://www.cnn.com/2020/03/31/us/coronavirus-vaccine-timetable-concerns-experts-invs/index.html> [https://perma.cc/LCQ6-D5SB].

6. See, e.g., Catherine Lai, *Scientists Race to Develop Vaccine for New Coronavirus*, MEDICAL XPRESS (Feb. 9, 2020), <https://medicalxpress.com/news/2020-02-scientists-vaccine-coronavirus.html> [https://perma.cc/SGS9-EBCL].

7. See, e.g., Lawrence O. Gostin, *What Questions Should Global Health Policy Makers Be Asking About the Novel Coronavirus?*, HEALTH AFF. (Feb. 3, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200203.393483/full/> [https://perma.cc/8DB4-XT43].

8. See *Ebola Vaccines*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, <https://www.niaid.nih.gov/diseases-conditions/ebola-vaccines> [https://perma.cc/H5CZ-R5HG]; *Zika Virus Vaccines*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, <https://www.niaid.nih.gov/diseases-conditions/zika-vaccines> [https://perma.cc/A3K9-2SJJ].

9. News Release, 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> [https://perma.cc/JWC8-83L5].

10. See generally Claire Sykes & Miriam Reisman, *Ebola: Working Toward Treatments and Vaccines*, 40 PHARMACY & THERAPEUTICS 521, 521–24 (2015) (describing the increasing field of vaccine development in 2015 in response to the unprecedented Ebola outbreak).

11. See *Emerging Infectious Diseases*, BAYLOR C. MED., <https://www.bcm.edu/departments/molecular-virology-and-microbiology/emerging-infections-and-biodefense/emerging-infectious-diseases> [https://perma.cc/E25W-SBR4].

12. See, e.g., News Release, U.S. Food & Drug Admin., *supra* note 9.

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. Patents function as a system of incentives to R&D in the form of a period of exclusivity during which inventors may exclude competitors from the market.¹³

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.¹⁴ 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.¹⁵

Even within the biopharmaceutical-innovation ecosystem, there is an important subject matter differentiation: some forms of technology and certain diseases traditionally attract more attention and funding streams, while others struggle to capture them, often irrespective of their public-health toll.¹⁶ Taken as a whole, the field of vaccines is one that tends to disproportionately populate the latter group.¹⁷

13. See U.S. CONST. art. I, § 8, cl. 8.

14. See, e.g., WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 316 (2003).

15. See, e.g., W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611, 1614–18 (2017).

16. Stanley A. Plotkin et al., *Establishing a Global Vaccine-Development Fund*, 373 NEW ENG. J. MED. 297, 298 (2015).

17. See *id.* at 297–98 (listing vaccine-preventable diseases for which no vaccines have yet been developed).

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.¹⁸ Moreover, they are widely regarded as instrumental in furthering related public health goals, such as the lessening of inequality among impoverished populations.¹⁹ From both an innovation-policy and a public-health 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 for several reasons.

First, as commodified goods, vaccines are often regarded as unappealing investment prospects. This is attributable to several factors.²⁰ The goal of vaccine deployment is eminently preventative. Success in this field translates into a nonevent, or 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.²¹ Moreover, these savings—to multiple individual and institutional players across health systems—do not translate into direct economic returns for vaccine developers.²²

Moreover, unlike several other biologic products, which require multiple doses or even lifelong use,²³ many vaccines deliver long-term immunity through a single use, while many others require a very limited number of uses.²⁴ 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.”²⁵ Because contemporary IP is largely animated by the prospect of nontrivial economic returns, such a limitation on

18. F.E. Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequality Worldwide*, 86 BULL. WORLD HEALTH ORG. 140, 142 (2008).

19. *Id.* at 143.

20. 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, 751–58 (2019).

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

22. See *id.*

23. Insulin, for example, is a biologic that requires lifelong use. *What Are Biologics?*, BIOSIMILARS RES. CTR., <https://www.biosimilarsresourcecenter.org/faq/what-are-biologics/> [<https://perma.cc/X3HC-V8KJ>].

24. See, e.g., *Varicella Vaccine Effectiveness and Duration of Protection*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/vpd-vac/varicella/hcp-effective-duration.htm> [<https://perma.cc/KJ9R-6CJT>] (indicating that live vaccines generally offer long-lasting immunity and that vaccines for varicella can offer protection for up to ten to twenty years after vaccination).

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

the size of the market further conditions the investment appeal of most vaccines.²⁶

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 a cold chain.²⁷ 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.²⁸ 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 late, in both the South and the North, rates of vaccine confidence have started to plummet.²⁹ The phenomenon is especially pronounced across Europe, Central Africa, and North America, where the percentages of people who agree 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.³⁰ Severe measles outbreaks in Washington State in 2019 and in New York State in 2018–2019, which set records for measles infection in the United States in the twenty-first century, have been linked to a decrease in herd immunity within the affected localities.³¹ 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 accentuates 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 fifty licensed vaccine manufacturers in the United States; by the late 1990s the number had fallen below

26. See Plotkin, *supra* note 16, at 297.

27. See Umit Kartoglu & Julie Milstien, *Tools and Approaches to Ensure Quality of Vaccines Throughout the Cold Chain*, 13 EXPERT REV. VACCINES 843, 844–45 (2014).

28. See *id.* at 844, 848.

29. GALLUP, WELLCOME GLOBAL MONITOR 106 (2019), <https://wellcome.ac.uk/sites/default/files/wellcome-global-monitor-2018.pdf> [<https://perma.cc/AZZ6-VBBS>].

30. See *Herd Immunity (Herd Protection)*, VACCINE KNOWLEDGE PROJECT, <https://vk.ovg.ox.ac.uk/vk/herd-immunity> [<https://perma.cc/A6MC-L9BA>]; Jamie Ducharme, *Most People Worldwide Trust That Vaccines Are Safe—But the Number Who Don't Is Concerning*, TIME (June 19, 2019), <https://time.com/5609984/vaccine-trust-worldwide/> [<https://perma.cc/43B3-NYGZ>].

31. See Aimee Cunningham, *How Holes in Herd Immunity Led to a 25-Year High in U.S. Measles Cases*, SCIENCE NEWS (Apr. 29, 2019, 4:04 PM), <https://www.sciencenews.org/article/holes-herd-immunity-led-25-year-high-us-measles-cases> [<https://perma.cc/FBT8-CYHZ>].

ten.³² Market exodus appears to have been driven by a mix of liability-related concerns—which the 1986 National Childhood Vaccine Injury Act sought to address³³—and economic considerations.³⁴ These considerations encompassed both rising regulatory costs associated with vaccine development and approval³⁵ and the perceived unprofitability of vaccines.³⁶

To put things in perspective, consider how sales of vaccines fare when compared with sales of other pharmaceutical products. In the wake of the 2018–2019 measles outbreaks, sales of MMR vaccines (measles-mumps-rubella) increased by 58 percent in the United States as compared to the previous year, generating a total of \$675 million.³⁷ By contrast, Januvia, a drug used in the treatment of diabetes, generates close to \$6 billion a year.³⁸ The drug is manufactured by Merck, which is also the sole manufacturer of MMR vaccines in the United States.³⁹ 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.⁴⁰

It is important to underscore that the MMR vaccine is one of the best-selling vaccines currently on the market when considering its relative unprofitability. Perhaps the most well-known example of a commercially successful vaccine is Gardasil, a vaccine also manufactured by Merck that targets human papillomavirus (HPV). Gardasil generated over \$3 billion in 2018, an increase by a factor of 3.7 compared to the average growth registered in the preceding three years.⁴¹

32. See Rutschman, *supra* note 20, at 740–41 (presenting data on manufacturer entrance and attrition in the United States vaccine market).

33. See 42 U.S.C. §§ 300aa-21 to -23 (1988).

34. Rutschman, *supra* note 20, at 740–41.

35. *Id.* at 743.

36. See, e.g., Jon Cohen, *U.S. Vaccine Supply Falls Seriously Short*, 295 SCIENCE 1998, 1998 (2002).

37. See Berkeley Lovelace Jr., *U.S. Measles Outbreak Helps Boost Merck's Vaccine Sales in Second Quarter*, CNBC (July 30, 2019, 11:33 AM), <https://www.cnbc.com/2019/07/30/nasty-us-measles-outbreak-helps-boost-merck-vaccine-sales-in-q2.html> [<https://perma.cc/N2QN-4WK9>].

38. *Merck Announces Fourth-Quarter and Full-Year 2017 Financial Results*, MERCK (Feb. 2, 2018), <https://investors.merck.com/news/press-release-details/2018/Merck-Announces-Fourth-Quarter-and-Full-Year-2017-Financial-Results/default.aspx> [<https://perma.cc/M2KW-NF3A>].

39. See Lovelace, *supra* note 37.

40. Josh Nathan-Kazis, *Merck's Keytruda Will Become Best-Selling Drug Worldwide, Research Group Says*, BARRON'S (Oct. 4, 2019, 11:55 AM), <https://www.barrons.com/articles/mercks-keytruda-will-become-best-selling-drug-worldwide-research-group-says-51570204530> [<https://perma.cc/6M54-Y6FQ>].

41. Trefis Team, *Merck's \$3 Billion Drug Jumped to 4x Growth over Previous Year*, FORBES (Oct. 4, 2019, 4:30 AM), <https://www.forbes.com/sites/greatspeculations/2019/10/04/mercks-3-billion-drug-jumped-to-4x-growth-over-previous-year/#4e4113de6294> [<https://perma.cc/UNK6-X9EV>].

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.⁴² As a consequence, vaccine R&D has been significantly underfunded, particularly from the mid-twentieth century onwards.⁴³

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 2014–2016 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.⁴⁴ Unlike immunization against measles, mumps, and rubella, which is part of Centers of Disease Control and Prevention’s immunization schedules,⁴⁵ 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.⁴⁶ A variation of this lack of commercial appeal was observable during the first months of the 2019–2020 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 experienced difficulties at first in finding a large private-sector firm interested in partnering to develop a vaccine candidate.⁴⁷ The director of the National Institute of Allergy and Infectious Diseases, an NIH institute, summarized the lack of commercial interest as follows: “Companies that have the skill to be able to do [vaccine manufacturing] are not going to just sit around and have a warm facility, ready to go for when [the public sector] need[s] it.”⁴⁸

42. See, e.g., *A Smarter Jab*, *ECONOMIST* (Oct. 14, 2010), <https://www.economist.com/business/2010/10/14/a-smarter-jab> (on file with the *Michigan Law Review*).

43. See generally Rutschman, *supra* note 20, 738–44 (surveying the arc of vaccine R&D in the United States throughout the twentieth century).

44. 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> [<https://perma.cc/Rf4V-RPK2>].

45. *Table 1. Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2020*, *CTRS. FOR DISEASE CONTROL & PREVENTION*, <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html> [<https://perma.cc/7GPP-EKFE>]; *Table 1. Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2020*, *CTRS. FOR DISEASE CONTROL & PREVENTION*, <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> [<https://perma.cc/3FLQ-EL55>].

46. See Grady, *supra* note 44.

47. See Nicholas Florko, *Major Drug Makers Haven’t Stepped Up to Manufacture NIH Coronavirus Vaccine, Top U.S. Health Official Says*, *STAT* (Feb. 11, 2020), <https://www.statnews.com/2020/02/11/major-drug-makers-havent-stepped-up-to-manufacture-coronavirus-vaccine-top-u-s-health-official-says/> [<https://perma.cc/H4GG-GU36>].

48. *Id.*

Incentives regimes anchored predominantly in IP function prospectively: funders tend to invest in R&D in goods for which they anticipate economic returns. These regimes thus fail to account for the specificities—and the 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.⁴⁹ 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,⁵⁰ face a similar predicament. However, unlike the drugs or biologics likely needed to address orphan diseases (or nonvaccine preventable conditions), most vaccine technology currently in use is relatively simple.⁵¹ Moreover, in the case 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 2015–2016 outbreak, they adapted existing vaccine technology and produced a vaccine candidate in roughly three months.⁵²

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 stabilizers⁵³—should, in principle, counterbalance the pervasive lack of preoutbreak 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.

49. See Rutschman, *supra* note 20, at 756–57.

50. *Orphan Products: Hope for People with Rare Diseases*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases> [<https://perma.cc/ZQ4Y-GF97>] (defining orphan diseases as those affecting fewer than 200,000 in the United States).

51. This 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 U.S. Dept. Health & Human Servs., *Vaccine Types*, VACCINES.GOV, <https://www.vaccines.gov/basics/types> [<https://perma.cc/226S-TU8A>] (listing the four existing types of vaccines).

52. Annette M. Boyle, *Army Research Produces Zika Vaccine Candidate in Record Time*, U.S. MED. (Aug. 5, 2016), <https://www.usmedicine.com/agencies/department-of-defense-dod/army-research-produces-zika-vaccine-candidate-in-record-time/> [<https://perma.cc/A28P-A994>].

53. U.S. Dep’t Health & Human Servs., *Vaccine Ingredients*, VACCINES.GOV, https://www.vaccines.gov/basics/vaccine_ingredients# [<https://perma.cc/QH79-8R8H>].

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 prescription for innovation policy across different technology domains.⁵⁴ 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.⁵⁵ In practice, an important change occurred in the early 2000s, when several nonprofit 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, the Drugs for Neglected Diseases Initiative, which focused many of its early efforts on malaria R&D.⁵⁶ 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 2014–2016 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 outbreaks of infectious diseases.⁵⁷ Importantly, in January 2020 CEPI entered into agreements to provide financial support for the development of three different types of vaccines for COVID-19.⁵⁸ The financial commitment came less than two weeks after Chinese scientists first made a sequence of COVID-19 available through a public database.⁵⁹

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

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

56. *DNDi Achievements*, DRUGS FOR NEGLECTED DISEASES INITIATIVE (2008), <https://www.dndi.org/achievements/> [<https://perma.cc/YWJ4-FX3M>].

57. *Why We Exist*, CEPI, <http://cepi.net/about/whyweexist/> [<https://perma.cc/4VZB-QGJT>].

58. *CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV-2019*, CEPI (Jan. 23, 2020), https://cepi.net/news_cepi/cepi-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/ [<https://perma.cc/78QC-9YE7>].

59. See Jon Cohen, *Scientists Are Moving at Record Speed to Create New Coronavirus Vaccines—But They May Come Too Late*, SCIENCE (Jan. 27, 2020, 6:30 AM), <https://www>

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 coexist 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.⁶⁰ The landscape changed dramatically in the early 2000s, with heterogeneous institutions entering into collaborative agreements.⁶¹ In the biopharmaceutical arena, these partnerships tend to assume one of two models: access partnerships and product development partnerships.⁶²

Access partnerships operate mainly by pulling together resources to guarantee the purchase and subsequent distribution of biopharmaceuticals.⁶³ The focus of these partnerships is to bring “existing drugs to underserved markets.”⁶⁴ The most prominent example in the field of vaccines is Gavi, a nonprofit, international public-private partnership created in 2000 to “improv[e] access to new and underused vaccines” in the Global South.⁶⁵ Gavi is supported by a broad network of institutional players, 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 tech-

.sciencemag.org/news/2020/01/scientists-are-moving-record-speed-create-new-coronavirus-vaccines-they-may-come-too [https://perma.cc/T8GR-EJSG].

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

61. *Id.* at 7, 17 (finding that, as of 2005, half of the existing public-private partnerships in the field were under five years old).

62. *See id.* at 2.

63. *Id.* (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”).

64. *Id.*

65. *About Our Alliance*, GAVI, <https://www.gavi.org/our-alliance/about> [https://perma.cc/73KD-3RRA]; *see also* GAVI, THE VACCINE ALLIANCE 2015 ANNUAL FINANCIAL REPORT 7 (2016), <https://www.gavi.org/sites/default/files/sites/default/files/document/evaluations/financial-reports/GAVI%20Alliance%202015%20Annual%20Financial%20Report.pdf> [https://perma.cc/JQ4Y-4HF6].

nical health institutes.⁶⁶ Gavi relies on long-term financial support from donors as well as on increasing cofinance of vaccine acquisitions by countries that benefit from Gavi-purchased vaccines.⁶⁷ The partnership currently supports thirteen vaccines targeting hepatitis B, rotavirus, polio, human papillomavirus, measles, and rubella, among other infectious agents.⁶⁸

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.⁶⁹ Such partnerships are widely used in areas where traditional R&D models strain to produce new drugs, as recently exemplified by the Cancer Moonshot.⁷⁰ They can be “general-purpose” partnerships, funding the discovery and development of drugs in multiple areas, like the Innovative Medicines Initiative in Europe;⁷¹ partnerships that target specific areas, like CARB-X, sponsoring R&D on antibacterial products;⁷² or disease specific, like the TuBerculosis Vaccine Initiative, which has formed a fifty-party consortium to discover and develop new tuberculosis vaccines.⁷³

The number of new public-private partnerships launched per year in the biopharmaceutical arena has grown exponentially since the turn of the century.⁷⁴ In 1995, only 1 partnership entered the market.⁷⁵ In 2000, there were 4 new partnerships.⁷⁶ But it is what happened from 2006 onwards that changed the landscape of multiparty biopharmaceutical R&D. Between 2006 and 2013, 310 new biopharmaceutical public-private partnerships entered the market, an average of nearly 40 per year.⁷⁷ In 2012 alone, 63 new part-

66. *Gavi's Partnership Model*, GAVI, <https://www.gavi.org/our-alliance/operating-model/gavis-partnership-model> [<https://perma.cc/FQN4-55YW>].

67. *Funding*, GAVI, <https://www.gavi.org/investing-gavi/funding> [<https://perma.cc/33KA-W7N7>].

68. *Vaccine Support*, GAVI, <https://www.gavi.org/support/nvs/> [<https://perma.cc/6JSM-JHXJ>].

69. See MERZ, *supra* note 60, at 2 (defining product development partnerships as “non-profit 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”).

70. *Cancer Moonshot*, NAT'L CANCER INST., <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative> [<https://perma.cc/DUV9-8UMU>].

71. *Strategic Research Agenda*, INNOVATIVE MEDS. INITIATIVE, <https://www.imi.europa.eu/about-imi/strategic-research-agenda> [<https://perma.cc/439A-3M9N>].

72. *About CARB-X*, CARB-X, <https://carb-x.org/about/overview/> [<https://perma.cc/SAP9-9YG5>].

73. *TBVI at a Glance*, TUBERCULOSIS VACCINE INITIATIVE, <http://www.tbvi.eu/about-us/tbvi-at-a-glance/> [<https://perma.cc/W5JM-6W88>].

74. See Mark D. Lim, Commentary, *Consortium Sandbox: Building and Sharing Resources*, SCI. TRANSLATIONAL MED., June 25 2014, at 1, 2.

75. *Id.*

76. *Id.*

77. *Id.*

nerships were launched.⁷⁸ These numbers speak to the buoyancy of large-scale collaborative partnerships as the current preferred model to counter imperfect incentives to biopharmaceutical research. As the WHO has put it, “[p]ublic-private partnerships are seen as an effective way to capitalize on the relative strengths of the public and private sectors to address problems that neither could tackle adequately on its own.”⁷⁹

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.⁸⁰ It is funded primarily by the governments of Norway, Japan, and Germany; the Bill & Melinda Gates Foundation; and the Wellcome Trust⁸¹ and subsidiarily by several other institutions.⁸² As of January 2020, CEPI has over seventy partners, including research institutions, large pharmaceutical companies, regulatory agencies, and nonprofits.⁸³

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,⁸⁴ was the inexistence of Ebola vaccines during the 2014–2015 Ebola crisis.⁸⁵ Yet, as a whole, the partnership was created with much broader goals than merely addressing the problems posed by recent outbreaks.⁸⁶ The partner-

78. *Id.*

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

80. *Why We Exist*, *supra* note 57.

81. *See* CEPI, *FUNDING AND EXPENDITURE 2* (2018), https://cepi.net/wp-content/uploads/2019/03/050319-Funding-and-Expenditure-Final_V3.pdf [<https://perma.cc/W3TD-WVG8>]. The Wellcome Trust is a U.K. nonprofit organization, and one of the largest funders of global biomedical R&D. *See About Us*, WELLCOME TRUST, <https://wellcome.ac.uk/about-us> [<https://perma.cc/T7YD-DT2Q>].

82. These include the governments of Belgium, Canada, and Australia; the European Union; and Australia’s Medical Research Future Fund. *See A Global Coalition for a Global Problem*, CEPI, <https://cepi.net/about/whoweare/> [<https://perma.cc/8F2K-8YEA>].

83. *Id.*

84. *See* Professor John-Arne Røttingen, Interim CEO, CEPI, Presentation to the WHO: Coalition for Epidemic Preparedness Innovations (July 21, 2017) [hereinafter Presentation], <https://www.who.int/medicines/ebola-treatment/TheCoalitionEpidemicPreparednessInnovations-an-overview.pdf> [<https://perma.cc/WD5W-BTEK>].

85. *See* John-Arne Røttingen et al., *New Vaccines Against Epidemic Infectious Diseases*, 376 *NEW ENG. J. MED.* 610, 610–11 (2017); *see also* Børge Brende et al., Comment, *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”).

86. *Putting Shots in the Locker*, *ECONOMIST* (Sept. 1, 2016), <https://www.economist.com/science-and-technology/2016/09/01/putting-shots-in-the-locker> (on file with the *Michigan Law Review*) (noting that “part of the inspiration for CEPI’s creation

ship was designed to play the role of gap filler⁸⁷ for lacking R&D on vaccines targeting infectious diseases:

CEPI wants to galvanize the development of new vaccines against diseases that we know could cause the next devastating epidemic. It aims to do this by creating an innovative partnership between public, private, philanthropic and civil organisations to tackle the barriers to epidemic vaccine development, advancing safe, effective, and affordable vaccines to contain outbreaks at the earliest possible stage.⁸⁸

CEPI's initial goals, for projects developed between 2017 and 2021, are for the partnership to "tackle the barriers" in vaccine R&D and ensure that collaborations between partners will result in "affordable vaccines."⁸⁹ 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."⁹⁰

Between 2017 and 2021, CEPI is funding R&D on pathogens chosen from the World Health Organization's list of "priority diseases."⁹¹ Unlike Ebola, for which there was ongoing R&D before the 2014–2015 outbreak, many of these pathogens have weak R&D pipelines.⁹² CEPI's initial projection is that the partnership will invest in vaccine projects targeting up to three priority pathogens.⁹³ 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 2021.⁹⁴ At that point, CEPI will facilitate partnerships with

was not the failure to deliver an Ebola vaccine in time for it to be useful, but how close that project came to success").

87. Karianne Johansen, Secretariat, CEPI, Regulatory Perspectives and Challenges for Development of CEPI EID Vaccines, https://www.unicef.org/supply/files/VIC_2017_SESSION_5_CEPI.pdf [<https://perma.cc/89SK-6DLF>].

88. Arnaud Bernaert & Dessislava Dimitrova, *Global Healthcare: The \$300 Billion Question*, WORLD ECON. F. (Nov. 17, 2017), <https://www.weforum.org/agenda/2017/11/the-300-billion-global-health-question/> [<https://perma.cc/238D-BJHZ>].

89. CEPI, PRELIMINARY BUSINESS PLAN 2017-2021, at 7 (2016) [hereinafter PRELIMINARY BUSINESS PLAN], https://cepi.net/wp-content/uploads/2019/02/CEPI-Preliminary-Business-Plan-061216_0.pdf [<https://perma.cc/FU2R-HJNG>].

90. *The Race to Develop an Ebola Vaccine*, GAVI, <https://www.gavi.org/vaccineswork/race-develop-ebola-vaccine> [<https://perma.cc/3ZFF-CUFF>].

91. PRELIMINARY BUSINESS PLAN, *supra* note 89, at 8; see *Prioritizing Diseases for Research and Development in Emergency Contexts*, WORLD HEALTH ORG., <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts> [<https://perma.cc/K7WD-ZYK7>] (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. See PRELIMINARY BUSINESS PLAN, *supra* note 89, at 17.

92. PRELIMINARY BUSINESS PLAN, *supra* note 89, at 14.

93. *Id.* at 9.

94. *Id.* at 28.

private-sector pharmaceutical companies to ensure “sufficient global vaccine development and manufacturing capacity.”⁹⁵

The CEPI initial budget for a five-year period was estimated between U.S. \$600 million and \$1 billion.⁹⁶ A year after it was launched, the partnership had reached \$625 million in multidonor contributions.⁹⁷ As CEPI produces the first deliverables, the goal is to move towards ten-year funding periods, which will enable the partnership to operate on an expanded timeline, as well as to fund larger R&D projects.⁹⁸ 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.⁹⁹

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.¹⁰⁰ Chief among these principles is “equitable access,” which translates into affordability and availability of CEPI-funded vaccines.¹⁰¹ Other principles include “shared benefits,” which relates to the allocation of potential revenue between parties involved in a project.¹⁰²

CEPI considers equitable access to be the most important principle governing its awards for vaccine R&D.¹⁰³ The Preliminary Business Plan 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

95. *Id.*

96. *Id.* at 47.

97. 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> [<https://perma.cc/53X5-PZD5>].

98. PRELIMINARY BUSINESS PLAN, *supra* note 89, at 50.

99. See Lisa M. Jarvis, *CEPI and Themis Partner for Vaccines*, CHEMICAL & ENGINEERING NEWS, Mar. 12, 2018, at 19; Mario Christodoulou, *CEPI Awards Contract Worth up to USD\$36 Million to Consortium Led by IDT to Develop MERS Vaccine*, CEPI (Aug. 20, 2018), https://cepi.net/news_cepi/cepi-awards-contract-worth-up-to-usd36-million-to-consortium-led-by-idt-to-develop-mers-vaccine/ [<https://perma.cc/YW6Z-XNJ6>]; *Coalition for Epidemic Preparedness Innovations Supports MERS & Lassa Enhanced DNA Vaccine Technology to Expedite Vaccine Development*, WISTAR INST. (Apr. 19, 2018), <https://wistar.org/news/press-releases/coalition-epidemic-preparedness-innovations-supports-mers-lassa-enhanced-dna> [<https://perma.cc/3NTJ-3SUN>].

100. Initially, CEPI addressed “shared benefits” and “intellectual property management” separately, but already regarding both as a means of ensuring equitable access to vaccines. See Interview with CEPI Senior Consultant (on file with the *Michigan Law Review*).

101. Presentation, *supra* note 84.

102. CEPI, CEPI POLICY DOCUMENTATION 2 (2017) [hereinafter POLICY DOCUMENTATION], https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf [<https://perma.cc/YJS8-YBQL>].

103. *Id.* at 2 (“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.” (emphases omitted)).

Middle Income Countries (LMICs).¹⁰⁴ 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 deployment."¹⁰⁵ 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.¹⁰⁶

It should be noted that, although awards have been made, CEPI's equitable access policy is still evolving.¹⁰⁷ The initial policy was drafted for a one-year trial and will continue to be refined after CEPI further analyzes the comments received during a period of public consultation, which ended in August 2018.¹⁰⁸

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.¹⁰⁹ In fact, CEPI has made it explicit that "[c]ontracts should include reasonable royalty payment provisos for products or patents."¹¹⁰ This is part of a broader policy designed both to promote fairness and attract commercial partners.¹¹¹ CEPI's interim CEO 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."¹¹² 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.¹¹³

"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 developers should be propor-

104. PRELIMINARY BUSINESS PLAN, *supra* note 89, at 12.

105. POLICY DOCUMENTATION, *supra* note 102, at 4 (emphasis omitted).

106. *Id.*

107. Interview with CEPI Senior Consultant, *supra* note 100.

108. See Brenda Hueycutt et al., *CEPI Revises its Equitable Access Policy*, 38 VACCINE 2144, 2144–48 (2020).

109. See POLICY DOCUMENTATION, *supra* note 102, at 3–4 (noting that CEPI will not take ownership of IP); Interview with CEPI Senior Consultant, *supra* note 100; Presentation, *supra* note 84.

110. Presentation, *supra* note 84.

111. See *id.*

112. *Id.*

113. See *supra* note 103 and accompanying text.

tionate to the level of risk undertaken and to the nature of the R&D, infrastructure, IP or other contributions a developer has made.¹¹⁴

If commercial benefits arise, both CEPI and the awardee(s) are entitled to recoup costs proportional to their investment in the project.¹¹⁵ CEPI's ability to recoup costs is limited to licensed vaccines or other foreground¹¹⁶ intellectual property, and it comes with an obligation to return all commercial benefits to CEPI's funding pool.¹¹⁷

The general rule is that both background and foreground intellectual property belong to the recipient of a CEPI grant.¹¹⁸ In order to build a degree of flexibility into the negotiation process, specific intellectual-property terms are dealt with on a case-by-case basis.¹¹⁹ 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.¹²⁰

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."¹²¹ In such cases, the license regulating the transfer of intellectual property must be a "non-exclusive, royalty-free, sub-licensable, worldwide license."¹²²

Keeping in line with CEPI's goal of promoting vaccine innovation, CEPI requires awardees to comply with other knowledge-disseminating obligations.¹²³ These requirements include sharing clinical trial data and results through a publicly available platform, timely publication of results, and publication of negative results.¹²⁴

CEPI also enforces an open access-publication model.¹²⁵ Any publication resulting from CEPI funding must be made available for free immediately and must provide "unrestricted access free of charge, with maximum opportunities for re-use, and including the underlying data."¹²⁶

114. PRELIMINARY BUSINESS PLAN, *supra* note 89, at 12.

115. POLICY DOCUMENTATION, *supra* note 102, at 8.

116. 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 preexisting rights covering technology that a party brings to a collaborative R&D project. *See id.* at 12.

117. *Id.* at 8.

118. *Id.* at 3 (noting that "CEPI's preferred approach is not to take ownership of IP" (emphasis omitted)).

119. *See id.* at 10.

120. *See id.* at 2-4.

121. *Id.* at 10.

122. *Id.*

123. *Id.* at 3.

124. *Id.*

125. *Id.*

126. *Id.*

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 CEPI's role and operating principles, the Essay has illustrated how IP rights associated with the development of new vaccines can be managed within collaborative R&D models.