

Intellectual Property as a Determinant of Health

*Ana Santos Rutschman**

ABSTRACT

Public health literature has long recognized the existence of determinants of health, a set of socioeconomic conditions that affect health risks and health outcomes across the world. The World Health Organization defines these determinants as “forces and systems” consisting of “factors combin[ing] together to affect the health of individuals and communities.” Frameworks relying on determinants of health have been widely adopted by countries in the global South and North alike, as well as international institutional players, several of which are direct or indirect players in transnational intellectual property (IP) policymaking. Issues raised by the implementation of IP policies, however, are seldom treated as an integral part of analyses using these frameworks, even though IP bears direct effects on the dynamics of several determinants of health, such as access to health goods and health services.

This Article conceptualizes post-Trade-Related Aspects of Intellectual Property Rights (TRIPs) IP as a contributing element to the literature on the socioeconomic determinants of health. IP norms and policies have long been understood as playing a role in outcomes that closely align with determinants frameworks, but interventions inspired by institutions relying on determinants frameworks routinely fail to consider the role of international IP regimes. This Article explores two consequences of this dissociation: first, it argues that TRIPs-implemented IP materially affects several determinants of health, both at the social and economic levels; and second, it argues that IP should

* Assistant Professor of Law, Saint Louis University School of Law, Center for Health Law Studies, Center for International and Comparative Law. S.J.D., Duke Law School. For accompanying each step of this article and for their mentoring, I am grateful to Rochelle Dreyfuss, Maggie Chon, Gian Luca Burci, Judit Rius and Bhaven Sampat. I am also grateful to Christine Farley, Dmitry Karshtedt, Laura Pedraza-Fariña, Nicholson Price, Sarah Rajec, David Simon, Jayashree Watal and Joy Xiang for insightful comments on early drafts of this piece. Earlier versions of the article were presented and workshopped at the 2020 (virtual) annual meeting of the American Society of International Law as part of the Fifth Annual Detlev F. Vagts Roundtable: Conceptualizing Intellectual Property as a Social Determinant of Health, and the 2021 International Intellectual Property Roundtable organized by the Chicago-Kent College of Law.

be regarded on equal footing with other canonically recognized determinants of health. While taking steps towards the development of an IP framework that can be articulated with, and incorporated by, literature on the determinants of health, the Article presents three short case studies on pharmaceutical and agricultural technologies—HIV prophylactic drugs (*Truvada*); drugs and vaccines needed for epidemic and pandemic preparedness (*Ebola vaccines and COVID-19 treatments like remdesivir*); and genetically modified rice crops.

TABLE OF CONTENTS

I.	IP AND THE DETERMINANTS OF HEALTH: CURRENT PERSPECTIVES.....	414
	A. <i>The Framework for the Socioeconomic Determinants of Health.....</i>	414
	B. <i>The Interface Between Intellectual Property and the Determinants of Health</i>	418
II.	ILLUSTRATING THE INFLUENCE OF IP IN HEALTH RISKS AND OUTCOMES	424
	A. <i>A Case Study on Pharmaceuticals: Preventing HIV Infection in the Twenty-First Century</i>	424
	B. <i>A Case Study on Epidemic and Pandemic Preparedness: From Ebola to COVID-19 Vaccines and Treatments</i>	432
	C. <i>A Case Study on AgTech: Genetically Modified Crops</i>	440
III.	TOWARDS A FRAMEWORK FOR THE IP DETERMINANTS OF HEALTH	444
	A. <i>The Existing IP Framework.....</i>	444
	B. <i>Complementing the Toolkit of Determinants of Health Through IP</i>	448
IV.	CONCLUSION	457

I. IP AND THE DETERMINANTS OF HEALTH: CURRENT PERSPECTIVES

A. *The Framework for the Socioeconomic Determinants of Health*

Public health-oriented scholars, policymakers, and institutions have long recognized the existence of a series of nonclinical factors that affect the health of populations across the globe. Known as the determinants of health, these factors consist in a set of socioeconomic conditions that are likely to bear a significant impact on health risks and health outcomes.

Work around the determinants of health is anchored in the idea that there are profound “inequalities in health” within populations in the same country.¹ Within the United States, for instance, different literatures have repeatedly documented disparities in morbidity and mortality rates depending on a range of nonclinical factors that ultimately have an impact on the quality of life and health outcomes associated with certain populations.² These factors include race, ethnicity, gender, state of residency (or even zip code within a city),³ education, class,⁴ and income.⁵ Similar studies have arrived at comparable conclusions within other countries in the Global North⁶

1. Michael Marmot, *Social Determinants of Health Inequalities*, 365 LANCET 1099, 1099 (2005).

2. See, e.g., Allan S. Noonan, Hector Eduardo Velasco-Mondragon & Fernando A. Wagner, *Improving the Health of African Americans in the USA: An Overdue Opportunity for Social Justice*, PUB. HEALTH REV., Oct. 3, 2016, at 1, 3; NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2015: WITH SPECIAL FEATURE ON RACIAL AND ETHNIC HEALTH DISPARITIES (2015); U.S. CTRS. DISEASE CONTROL & PREVENTION, RACIAL AND ETHNIC DISPARITIES CONTINUE IN PREGNANCY-RELATED DEATHS (Sept. 5, 2019), <https://www.cdc.gov/media/releases/2019/p0905-racial-ethnic-disparities-pregnancy-deaths.html> [<https://perma.cc/33P7-FHZZ>] (archived Jan. 21, 2021) (collectively documenting race- and ethnicity-based disparities); see also Dovile Vilda Maeve Wallace, Lauren Dyer, Emily Harville & Katherine Theall, *Income Inequality and Racial Disparities in Pregnancy-Related Mortality in the US*, 9 SSM POPULATION HEALTH 1, 2 (2019) (focusing on income inequality); Keith P. Gennuso, Courtney K. Blomme, Marjory L. Givens, Elizabeth A. Pollock & Anne M. Roubal, *Deaths of Despair(ity) in Early 21st Century America: The Rise of Mortality and Racial/Ethnic Disparities*, 57 AM. J. PREVENTIVE MED. 585, 585–91 (2019) (focusing on diseases of despair); David Hartley, *Rural Health Disparities, Population Health, and Rural Culture*, 94 AM. J. PUB. HEALTH 1675, 1675–78 (2004) (focusing on rural disparities). For an overview of some of the legal and health policy problems affecting the overall functioning of the United States healthcare system, see generally ELIZABETH ROSENTHAL, *AN AMERICAN SICKNESS* (2017).

3. See Jay Bhatt, *Your Zip Code, Your Health*, AM. HOSP. ASS'N (May 16, 2018), <https://www.aha.org/news/insights-and-analysis/2018-05-16-your-zip-code-your-health> [<https://perma.cc/U49R-LAYM>] (archived Jan. 21, 2021); see also *Could Where You Live Influence How Long You Live?*, ROBERT WOOD JOHNSON FOUND., <https://www.rwjf.org/en/library/interactives/wherelyouliveaffects/howlongyoulive.html> (last updated Jan. 2020) [<https://perma.cc/U68F-RQMC>] (archived Jan. 21, 2021).

4. Stephen L. Isaacs & Steven A. Schroeder, *Class—The Ignored Determinant of the Nation's Health*, 351 NEW ENG. J. MED. 1137, 1140 (2004).

5. Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFF., Oct. 4, 2018, at 1, 1–6.

6. See, e.g., Johan P. Mackenbach, Ivana Kulhánová, Gwenn Menvielle, Matthias Bopp, Carme Borrell, Giuseppe Costa, Patrick Deboosere, Santiago Esnaola, Ramune Kalediene, Katalin Kovacs, Mall Leinsalu, Pekka Martikainen, Enrique Regidor, Maica Rodriguez-Sanz, Bjørn Heine Strand, Rasmus Hoffmann, Terje A. Eikemo, Olof Östergren & Olle Lundberg, *Trends in Inequalities in Premature Mortality: A Study of 3.2 Million Deaths in 13 European Countries*, 69 J. EPIDEMIOLOGY & CMTRY. HEALTH 207, 207–17 (2014); Churnrurtai Kanchanachitra & Viroj Tangcharoensathien, *Health Inequality Across Prefectures in Japan*, 390 LANCET 1471, 1471–73 (2017); Gavin Turrell, L. Stanley, Michael de Looper & Brian Frederick Oldenburg, *Health Inequalities in Australia: Morbidity, Health Behaviours, Risk Factors and Health Service Use*, 2 AUST. INST. HEALTH & WELFARE, Apr. 6, 2007, at 1.

and Global South.⁷ Moreover, these disparities are also detected through comparisons between analogous populations in different countries or geographical regions.⁸

An important characteristic of the global distribution of health disparities is that they have become systemically ingrained in economies of the Global South and the Global North alike.⁹ But even though they are heterogeneous in origin and kind, these inequalities have been found to share a common trait: they are “socially determined,” in the sense that they emerge from complex decision-making processes.¹⁰ The idea of social determination seeks to emphasize the fact that lack of access to vital goods and services, such as water or health care, is not merely attributable to the existence of infrastructural or technical shortcomings in the status quo. Rather, it is the product of a series of allocative decisions, often made by different actors and at different points in time, converging towards the ossification of structural inequalities and to the worsening of health outcomes within certain populations.¹¹

The concept of, and framework for, the determinants of health thus arose against this background, and current policy interventions relying on determinants frameworks embody this approach. The World Health Organization (WHO), which defines the social determinants of health as “the conditions in which people are born, grow, live, work and age,”¹² further notes that these conditions “are shaped by the distribution of money, power, and resources at global, national, and local levels. The social determinants of health are mostly responsible

7. See, e.g., Alba Llop-Gironés, Mireia Julià, Sergio Chicumbe, Janeth Dulá, Anita Aunda Pedro Odallah, Francesc Alvarez, Ivan Zahinos, Elisio Mazive & Joan Benach, *Inequalities in the Access to and Quality of Healthcare in Mozambique: Evidence from the Household Budget Survey*, 31 INT'L J. FOR QUALITY HEALTH CARE 577, 577–82 (2019); Nandini Oommen, Elizabeth Lule, Deborah Vazirani & Ritu Chhabra, *Inequalities in Health, Nutrition and Population*, WORLD BANK REP., June 2003, at 1; Celia Landmann-Szwarcwall & James Macinko, *A Panorama of Health Inequalities in Brazil*, 15 INT'L J. FOR EQUITY HEALTH 174 (2016). See generally Christopher Garimoi Orach, *Health Equity: Challenges in Low Income Countries*, 9 AFR. HEALTH SCI. (SPECIAL ISSUE 2) S49, S49–S51 (2009); Davidson R. Gwatkin, *Trends in Health Inequalities in Developing Countries*, 5 LANCET 371 (2017).

8. Marmot, *supra* note 1, at 1099; see, e.g., WORLD HEALTH ORG., FACT FILE ON HEALTH INEQUITIES, <https://www.who.int/sdconference/background/news/facts/en/> [<https://perma.cc/E98V-8YEB>] (archived Jan. 21, 2021) (noting, inter alia, a “36-year gap in life expectancy” between Malawi and Japan).

9. See, e.g., Ichiro Kawachi & Bruce P. Kennedy, *Socioeconomic Determinants of Health: Health And Social Cohesion: Why Care About Income Inequality?*, 314 BRIT. MED. J. 1037, 1037–40 (1997).

10. Marmot, *supra* note 1, at 1101.

11. See *id.*

12. *Social Determinants of Health*, WORLD HEALTH ORG., https://www.who.int/social_determinants/en/ (last visited Jan. 21, 2021) [<https://perma.cc/DFJ9-3Z2B>] (archived Jan. 21, 2021).

for health inequities—the unfair and avoidable differences in health status seen within and between countries.”¹³

It is important to note that current definitions of determinants of health are not homogenous. Several institutions distinguish between social and economic determinants; the latter category includes factors like income levels and income distribution—which are often recognized as some of the most powerful predictors of health risks and outcomes.¹⁴ Several other institutions, as well as commentators and policymakers, take a hybrid approach, speaking of socioeconomic determinants of health.¹⁵ For instance, in addition to providing the most diffused definition of social determinants of health,¹⁶ the WHO, in its framework for Health Impact Assessment methods,¹⁷ describes determinants of health as encompassing both “the social and economic environment,” and expands the concept to include “the physical environment,” as well as a “person’s individual characteristics and behaviors.”¹⁸

A number of other definitional approaches coexist. To give but one example, the U.S. Office of Disease Prevention and Health Promotion distinguishes between social and physical determinants of health.¹⁹ The former group includes many conditions long recognized as social determinants, from access to healthcare services to quality of education and job training, as well as conditions recognized elsewhere as economic determinants (e.g., poverty levels).²⁰ Physical

13. *Id.*

14. See, e.g., N.Z. NAT'L ADVISORY COMM. HEALTH & DISABILITY, THE SOCIAL, CULTURAL AND ECONOMIC DETERMINANTS OF HEALTH IN NEW ZEALAND: ACTION TO IMPROVE HEALTH 23 (1999); see also Yannish Naik, Peter Baker, Ian Walker, Taavi Tillmann, Kristin Bash, Darryl Quantz, Frances Hillier-Brown & Clare Bambra, *The Macro-Economic Determinants of Health and Health Inequalities—Umbrella Review Protocol*, 6 SYSTEMATIC REV. 222, 222 (2017).

15. See, e.g., Samantha Artiga & Elizabeth Hinton, *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity*, KAISER FAM. FOUND. ISSUE BRIEF (May 10, 2018), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/> [https://perma.cc/6FQ4-PTGJ] (archived May 12, 2021).

16. See *Social Determinants of Health*, *supra* note 12.

17. A Health Impact Assessment is a “combination of procedures, methods, and tools by which a policy, program, or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population.” See EUR. CTR. HEALTH POLICY, HEALTH IMPACT ASSESSMENT (1999), http://www.healthedpartners.org/ceu/hia/hia01/01_02_gothenborg_paper_on_hia_1999.pdf [https://perma.cc/H3EJ-96ES] (archived Jan. 22, 2021).

18. *Health Impact Assessment*, WORLD HEALTH ORG., https://www.who.int/health-topics/health-impact-assessment#tab=tab_1 (last visited Feb. 10, 2021) [https://perma.cc/AW45-V389] (archived Feb. 10, 2021).

19. U.S. OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION, SOCIAL DETERMINANTS OF HEALTH (2020), <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health> [https://perma.cc/N8VN-NCKM] (archived Ja. 21, 2021).

20. *Id.*

determinants include exposure to toxic substances, interaction with the built environment, and consequences of climate change.²¹

The unifying thread in how existing definitions of determinants of health are populated is that they are generally conceptualized as conditions that are external to healthcare systems.²² In this sense, a person's income, education, or exposure to harmful chemicals may contribute, directly or indirectly, to that person's interaction (or lack thereof) with a given healthcare system. These contributing factors, however, are nonclinical in nature, even if they might create the need for clinical interventions. Recent studies looking at premature death rates have underlined the relevance of nonclinical factors in health outcomes. Currently, only 10 percent of premature deaths in the United States are linked to issues arising in the context of clinical care; 30 percent of premature deaths are attributable to genetic factors; and 60 percent are attributable to social, environmental, and behavioral factors that fall under the general umbrella of socioeconomic determinants of health.²³

This Article uses the expression "socioeconomic determinants of health" in an expansive way, to include all types of nonclinical conditions that have been identified in the literature and in practice as bearing an impact on health risks and outcomes. Moreover, as detailed in the following Part, this Article seeks to articulate a connection between the canonical sets of determinants of health—as currently recognized in multiple literatures—and the impact of globally harmonized IP frameworks and norms.

B. *The Interface Between Intellectual Property and the Determinants of Health*

The impact of IP regimes on discrete fields of health-related innovation has been studied by scholars in legal and nonlegal fields alike. Since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) came into force in 1995,²⁴ commentators have noted a progressive but inexorable convergence of national and regional IP regimes towards higher levels of IP protection across the

21. *Id.*

22. See Jennifer Prah Ruger, *Ethics of the Social Determinants of Health*, 364 LANCET 1092, 1092 (2004).

23. Garth Graham & John Bernot, *An Evidence-Based Path Forward to Advance Social Determinants of Health Data*, HEALTH AFF. BLOG (Oct. 25, 2017), <https://www.healthaffairs.org/do/10.1377/hblog20171025.721263/full/> [https://perma.cc/62UW-GE5Z] (archived Jan. 21, 2021).

24. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement].

globe.²⁵ While this upwards harmonizing trend has been a general feature,²⁶ and not a specificity of the pharmaceutical and biotech domains, the TRIPs implementation battle over IP rights covering many of the technologies in these fields has been especially contentious.²⁷ As the ratcheting up of IP protection through tendentially harmonized regimes²⁸ has contributed to the divide between the Global North and South,²⁹ perhaps nowhere are escalating levels of patent protection as noticeable as in the field of health-related technological innovation.³⁰

Even under globalized and globalizing IP frameworks, there is room at the domestic level for the development of country-specific bodies of IP law and practices. With regard to pharmaceutical and biopharmaceutical technologies, lawmakers and law interpreters at the country level have experimented with different approaches, with varying degrees of success. India, for instance, availed itself of the transitional period granted by TRIPs.³¹ Even when compelled to apply the patent floors mandated by the Agreement, it carved out a patentability regime for pharmaceutical innovations that is

25. See, e.g., Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323 (2004); Ruth Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 125 (2004); Bryan C. Mercurio, *TRIPs-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM (Lorand Bartels & Federico Ortino eds., 2006); Susan K. Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, PROGRAM ON INFO. JUST. & INTELL. PROP., Oct. 1, 2010, at 1.

26. See, e.g., Denis Borges Barbosa, *Minimum Standards vs. Harmonization in the TRIPS Context: The Nature of Obligations Under TRIPS and Modes of Implementation at the National Level in Monist and Dualist Systems*, in 1 RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 52 (Carlos M. Correa ed., 2010).

27. See, e.g., Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT'L L. 123 (2004); Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the DOHA Declaration on the Trips Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613 (2004).

28. But see Sarah R. Wasserman Rajec, *The Harmonization Myth in International Intellectual Property Law*, 62 ARIZ. L. REV. 735 (2020) (challenging the centrality of harmonization concepts and vocabulary in TRIPs implementation narratives).

29. See Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2832 (2006); Rochelle Cooper Dreyfuss, *TRIPS—Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 21–22 (2004).

30. See, e.g., Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469 (2002).

31. See, e.g., Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITTS. L. REV. 491 (2007).

significantly less permissive of secondary patenting than most other countries.³²

However, the existence of strata of domestic patent law, lodged amidst tendentially overprotecting national and transnational IP regimes, is not enough to address the differentiated types of problems created by the (mis)application of current IP laws, norms, and philosophies to pharmaceutical and biopharmaceutical innovation. Part of the problem lies in the origins of contemporary IP. As Jerome Reichman and Rochelle Dreyfuss have put it, “[t]he domestic patent laws as currently practiced were largely formulated for the inventions of the Industrial Revolution, and these laws still reflect the technological premises and concepts of the creative sectors as they were then structured.”³³ The foundational IP treaties,³⁴ whose ethos and many a provision were absorbed by TRIPs,³⁵ predate the pharmaceutical and biotech industries, and the TRIPs-induced race to ratchet up levels of protection has done little to account for the nuances of innovative processes in these fields, on the one hand, and for the very specific characteristics of the consumers of the emerging goods, on the other. As such, individualized contemporary IP regimes may be able to provide an *ad hoc* fix for a particular malfunction—as India did with regard to secondary patenting of pharmaceuticals³⁶—through legislative, regulatory, or interpretive interventions. Nonetheless, they have proven incapable of tending to systemic problems rooted in modern embodiments of IP that render different types of drugs and biotech products unavailable to populations in need³⁷ or, in some cases, that make certain drugs unavailable across the globe.³⁸

This irresponsiveness of IP systems has a direct bearing on health outcomes and risks faced by different populations around the globe. Traditionally, the dynamics of IP and issues surrounding the availability and price of pharmaceutical and biotech products have been understood as separate from the sets of issues that make up the

32. See, e.g., Bhaven N. Sampat & Kenneth C. Shadlen, *Secondary Pharmaceutical Patenting: A Global Perspective*, 46 RESEARCH POL'Y 693 (2017); see also Ravinder Gabble & Jillian Clare Kohler, *To Patent or not to Patent? The Case of Novartis' Cancer Drug Glivec in India*, GLOBALIZATION & HEALTH, Jan. 6, 2014, at 693.

33. Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 92 (2007).

34. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583.

35. See TRIPs Agreement, *supra* note 24, §§ 2, 9.

36. See *supra* note 32 and accompanying text.

37. See *infra* Part II.A (case study on HIV prevention drugs in the United States).

38. See *infra* Part II.B (case study on drugs needed during outbreaks of infectious diseases such as the recent Ebola and Zika epidemics and the ongoing COVID-19 pandemic).

universe of determinants of health, at least as currently adopted for operational purposes.

Socioeconomic determinants of health are generally conceptualized as “health determinants outside the health-care system.”³⁹ This view portrays the determinants of health as upstream factors that may lead an individual to develop a condition that requires clinical care, thus prompting engagement between individuals and healthcare systems. By contrast, IP is normally associated with the provision of goods or services—in the form of drugs or treatments—that are made available to individuals once they engage with the healthcare system. In this sense, not only is there a conceptual divide between the domains of application of the determinants of health versus IP regimes, but IP is primarily regarded as relevant at the downstream level of healthcare provision.

As illustrated in the case studies in Part II, this separation is artificial and does not correctly account for the on-the-ground impact of IP laws and norms. Consider the following scenario: a company or institution foregoes the opportunity to develop a relatively simple vaccine or drug for a known pathogen likely to cause an outbreak; the decision is primarily based on a prospective lack of return-on-investment; an outbreak occurs. This sequence, which reflects what happened recently with regard to COVID-19 drugs and Ebola vaccines,⁴⁰ has profound implications from a public health perspective, as morbidity and mortality strain already-struggling health systems. But it is also umbilically tied to IP paradigms, and in particular to the incentives-providing function theorized under utilitarian IP approaches. From this perspective, IP becomes a contributing factor affecting health outcomes and health risks.

Although different in kind, another example of the direct impact of IP frameworks—or, if nothing else, of IP-informed choices—in public health outcomes and risks is provided by countless instances of excessive pricing of pharmaceutical products, which in recent decades has become a recurring feature of the United States drug pricing ecosystem.⁴¹ Part of this phenomenon is enabled by the proliferation of patents over pharmaceutical and biotech products, which can inhibit the entrance of generic drugs and, more broadly, competition.⁴² For

39. Ruger, *supra* note 22, at 1092.

40. See *infra* Part II.

41. See Inmaculada Hernandez, Chester B. Good, David M. Cutler, Walid F. Gellad, Natasha Parekh & William H. Shrank, *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, 38 HEALTH AFF. 76, 76–83 (2019).

42. See, e.g., Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, (Keith Maskus & Jerome H. Reichman eds., 2005).

instance, recent studies have shown that the manufacturers of the eight best-selling biologic drugs in the United States applied for an average of 151 patents for each individual biologic.⁴³ Through the articulation of patent rights, market exclusivities granted by the U.S. Food and Drug Administration,⁴⁴ and product hopping,⁴⁵ sponsors of these drugs estimate that follow-on competitors are not able to enter the market for periods ranging from thirty-one to forty-eight years.⁴⁶

Rising prices of pharmaceuticals and biologic drugs is likely not to be restricted to the Global North, as North-South bilateral and plurilateral agreements have become a tool for ratcheting up pharmaceutical and biotech IP rules and policies.⁴⁷ Recently, a strand of commentary has attempted to counter this narrative by suggesting that the proliferation of trade agreements in recent years has not increased the prices of pharmaceuticals in developing countries.⁴⁸ Kapczynski, Sampat, and Shadlen, however, have argued that there is insufficient empirical data documenting the actual impact that trade agreements have had on the prices of medicines across the developing world.⁴⁹

The manifold ways in which IP can have a direct bearing on access to drugs (or other biotech products, such as fortified foods) by populations in need have direct consequences for the health of individuals, communities, and health systems. For example, by laying out the legal-economic construct that allows firms to limit patients' access to HIV drugs, post-TRIPs patent law has a direct bearing on present and future health outcomes and health risks. At a time in which HIV epidemics ravage certain areas of the globe—and, importantly, in which patented drugs have been shown to be 99 percent effective in preventing infections among indicated populations—IP has provided the legal infrastructure on which certain players rely. In this sense, IP ought to be regarded as a determinant of the present status quo (and short-to-medium-term outlook) of the current HIV epidemic

43. See I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 2 (2018).

44. See, e.g., Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals — Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2011).

45. See, e.g., Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129 (2019).

46. See Hernandez, Good, Cutler, Gellad, Parekh & Shrunk, *supra* note 41.

47. See *supra* note 25 and accompanying text.

48. See Thomas J. Bollyky, *What Past Trade Deals Reveal About Drug Pricing*, FOREIGN AFFS. (Oct. 28, 2016), <https://www.foreignaffairs.com/articles/2016-10-28/what-past-trade-deals-reveal-about-drug-pricing> [https://perma.cc/2SQZ-F85J] (archived Feb. 12, 2021).

49. Amy Kapczynski, Bhaven N. Sampat & Ken Shadlen, *Trade Agreements, Patents, and Drug Prices: Continuing the Debate*, (Yale L. & Econ. Research Paper No. 572, 2017), <https://ssrn.com/abstract=2933574> [https://perma.cc/72NM-YNKG] (archived Jan. 21, 2021) (further documenting several flaws in the Bollyky study).

in the United States, on par with other determinants of health that are specific to this area, such as income or geography.

If it is true that the socioeconomic determinants of health reflect a concern with entrenched inequality and allocative imbalances, then another link between determinants of health and IP—particularly as implemented in the wake of the TRIPs Agreement—is the fact that the crystallization of a maximalist ethos in national and transnational IP regimes has profound distributional consequences. While exploring the multiple linkages between the evolution of IP regimes and equality, Margaret Chon has noted that not only are equality themes often absent from IP discourse, but the opposite is true as well.⁵⁰ The approach proposed in this Article—considering IP as a core contributor to health outcomes and risks on par with other determinants of health—seeks to connect IP-induced, distributional imbalances to discourses centered on health (in)equality.

Having sketched a possible relationship between the fields of IP and determinants of health, Part II turns to specific illustrations of the impact of IP regimes on health outcomes and risks through case studies on different forms of technology. As a note, the examples conveyed by the case studies are neither exhaustive within a certain domain of biotechnology, nor are these domains the only ones in which an interaction between IP and socioeconomic determinants of health can be discerned. Other possibilities include epidemiological or genomic data models (which may be hampered by the existence of proprietary rights over databases, for example)⁵¹ or the development of green technologies (which rely significantly on IP-based incentives frameworks).⁵²

Although the case studies in this Part cover different embodiments of biotechnologies used in innovations that have or may have an impact on the health of significant population groups, the point is not about the exceptionalism of biotechnology within IP, but rather about how several types of technology—in areas in which innovation has become primarily IP-driven—are being made available in ways that exclude, or may limit access to, swaths of indicated populations. One of the enabling factors for this exclusion is IP, through choices that are made at the beginning of, or during, the research and development (R&D) processes. The case studies thus seek to illustrate the impact of

50. See Margaret Chon, *Intellectual Property Equality*, 9 SEATTLE J. FOR SOC. JUST. 259, 261 (2010).

51. See, e.g., Stephen M. Maurer, *Across Two Worlds: Database Protection in the United States and Europe*, in INTERNATIONAL CONFERENCE ON INTELLECTUAL PROPERTY AND INNOVATION IN THE KNOWLEDGE-BASED ECONOMY 13-1 (Jonathan D. Putnam ed., 2001); Rebecca S. Eisenberg, *Intellectual Property Issues in Genomics*, 14 TRENDS BIOTECHNOLOGY 302, 302 (1996).

52. See generally RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND CLIMATE CHANGE (Joshua D. Sarnoff ed., 2016).

these choices on populations who are priced out of some inventions and populations who would benefit from relatively inexpensive medical technologies, which are not developed due to a (perceived) lack of incentives for R&D.

The case studies illustrate three different forms in which post-TRIPs IP regimes can produce these effects. The first one is via excessive pricing, in the context of access to HIV prevention drugs in the Global North. The second is via lacking incentives frameworks, in the Global South and Global North alike. And the third is via blocking patents—and more precisely about informational asymmetries arising in patent thicket situations—with primary effects on technologies needed to support nutritional health in the Global South.

II. ILLUSTRATING THE INFLUENCE OF IP IN HEALTH RISKS AND OUTCOMES

A. A Case Study on Pharmaceuticals: Preventing HIV Infection in the Twenty-First Century

As shown by Jerome Reichman and Rochelle Dreyfuss, progressive rounds of harmonization of international IP have had detrimental effects not only on populations in the Global South, but on populations in the Global North as well.⁵³ The case of access to HIV/AIDS drugs illustrates this point. While a significant portion of the foundational literature on access to medicines focuses on examples of these detrimental effects on countries in the Global South,⁵⁴ an emerging strand of commentary on responses to the ongoing HIV epidemic in the North has identified problems in access to drugs and treatments that are ultimately attributable to a malfunction in patent regimes. This case study focuses on the response to the late-twentieth century AIDS epidemic in the United States, which made a public health priority of R&D on drugs that could be used in the treatment and prevention of HIV/AIDS.⁵⁵

In the early 2000s, research demonstrated that a two-drug combo—emtricitabine and tenofovir disoproxil fumarate—which blocks an enzyme the virus needs in order to replicate itself within a human body, was effective in the treatment of HIV-positive patients.

53. Reichman & Dreyfuss, *supra* note 33, at 92.

54. See, e.g., WILLIAM W. FISHER III & CYRILL P. RIGAMONTI, THE SOUTH AFRICA AIDS CONTROVERSY: A CASE STUDY IN PATENT LAW AND POLICY (2005), <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf> [<https://perma.cc/X3WK-DX79>] (archived Jan. 21, 2021).

55. See generally Ronald Bayer, *The Medicinalization of HIV Prevention: New Opportunities Beset by Old Challenges*, 92 MILBANK Q. 434 (2014) (summarizing the overall response to the AIDS epidemic in the United States).

This new combo, which eventually came to the market under the brand name Truvada, gained FDA approval in 2004 as part of a treatment regimen for HIV infection in combination with other antiretrovirals.⁵⁶ Gilead—a large pharmaceutical company headquartered in California—sponsored the drug.⁵⁷

Additional research conducted in the mid to late 2000s showed that Truvada could also be used in the prevention of HIV infection.⁵⁸ In 2012, Gilead sought and obtained FDA approval to market Truvada for pre-exposure prophylaxis (PrEP), making it the first commercially available drug to be used in HIV prevention.⁵⁹ Even though Gilead started commercializing Truvada for PrEP as soon as it was licensed by the FDA, Gilead had initially decided not to promote Truvada as a prophylactic, fearing an association with the promotion of unsafe sexual practices.⁶⁰ Word of mouth, patient advocacy, and the eventual endorsement of PrEP from the Centers for Disease Control and Prevention in 2014⁶¹ led the company to shift its approach in 2016. Since then, it has invested heavily in marketing.⁶²

As brand recognition increased, so did the price of Truvada.⁶³ When the drug was initially approved in 2004, without prophylactic indications, it was priced at around \$650 a month.⁶⁴ In 2012—the year

56. U.S. FOOD & DRUG ADMIN., TRUVADA APPROVAL LETTER (2004), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_Truvada_Approval.pdf [https://perma.cc/G5TL-AJKQ] (archived Jan. 21, 2021).

57. GILEAD SCIS., <https://www.gilead.com> (last visited Jan. 21, 2021) [https://perma.cc/5TKW-A62R] (archived Jan. 21, 2021).

58. See Robert M. Grant et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*, 363 NEW ENG. J. MED. 2587, 2597 (2010); Jared M. Baeten et al., *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*, 367 NEW ENG. J. MED. 399, 407 (2012).

59. See Press Release, U.S. Ctrs. for Disease Control & Prevention, CDC Statement on FDA Approval of Drug for HIV Prevention (July 16, 2012), <https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html> [https://perma.cc/A9VV-6JKS] (archived Jan. 21, 2021); *Pre-exposure Prophylaxis (PrEP)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/risk/prep/index.html> [https://perma.cc/MX99-HSRW] (archived Jan. 21, 2021).

60. See *Switching Course*, *Gilead Markets HIV Drug for Prevention*, NBC NEWS (Nov. 30, 2016), <https://www.nbcnews.com/feature/nbc-out/switching-course-gilead-markets-hiv-drug-prevention-n690271> [https://perma.cc/5KGP-UVHT] (archived Jan. 21, 2021).

61. See Press Release, U.S. Ctrs. for Disease Control & Prevention, HIV PrEP Guidelines (May 14, 2014), <https://www.cdc.gov/nchhstp/newsroom/2014/PrEP-Guide-lines-Press-Release.html> [https://perma.cc/4273-6UUJ] (archived Jan. 21, 2021).

62. See *Switching Course*, *supra* note 60.

63. See Jason Rhode, *PrEP Drug Priced Out of Most People's Reach*, GA. VOICE (July 13, 2018), <https://thegavoice.com/news/national/prep-drug-priced-out-of-most-peoples-reach/> [https://perma.cc/Y8P8-EQTB] (archived Jan. 21, 2021).

64. Ed Silverman, *Gilead Loses Its Challenge to a Pair of U.S. Patents for an HIV Prevention Pill*, STAT (Feb. 5, 2020), <https://www.statnews.com/pharmalot/2020/02/05/gilead-hiv-patents-truvada-cdc/> (subscription required) [https://perma.cc/W9EW-AGZL] (archived Jan. 21, 2021).

Gilead obtained FDA approval to market Truvada for PrEP—the price tag increased to \$1,159 a month.⁶⁵ In 2017, it had reached \$1,500;⁶⁶ in 2018, it increased again to \$1,600.⁶⁷ In 2019, the price was \$1,750 a month, or \$21,100 a year.⁶⁸ The increase in price has taken place over a period during which the number of PrEP users in the United States has skyrocketed. In 2012, there were 8,768 users in the United States; by 2016, the year Gilead began promoting Truvada, the number had climbed to 77,120.⁶⁹ The combination of market expansion and price hikes transformed the drug into a reliable best-seller for Gilead. In 2016,⁷⁰ for instance, Truvada generated over \$2.3 billion in the United States market and over \$3.5 billion globally.⁷¹ In 2019, domestic sales were up to \$2.6 billion.⁷² Since 2004, Truvada has earned Gilead over \$36 billion.⁷³

Elsewhere in the world, generic versions of Truvada for PrEP are available at much lower price points. In France, for instance, the price of Truvada while on patent was around 400 euros (\$467) a month; through generic competition the drug is now available for approximately 190 euros (\$186) per month.⁷⁴ These prices are still

65. *Id.*

66. See Michael Mezher, *FDA Approves First Generic Version of Gilead's HIV Drug Truvada*, REGUL. AFFS. PROS. SOC'Y (June 9, 2017), <https://www.raps.org/regulatory-focusTM/news-articles/2017/6/fda-approves-first-generic-version-of-gilead-s-hiv-drug-truvada> [https://perma.cc/GA5C-Y6Q2] (archived Jan. 21, 2021).

67. See Shefali Luthra & Anna Gorman, *Rising Cost of PrEP to Prevent HIV Infection Pushes It Out of Reach for Many*, NPR (June 30, 2018), <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many> [https://perma.cc/MJ2T-CJND] (archived Jan. 21, 2021) (further noting that, for a period of time, Gilead waived up to \$4,800 in out-of-pocket expenses for patients with commercial insurance plans).

68. See Mark Terry, *Trump Administration Sues Gilead Over Truvada PReP for HIV Prevention*, BIOSPACE (Nov. 7, 2019), <https://www.biospace.com/article/trump-administration-sues-gilead-over-hiv-drug/> [https://perma.cc/4UPP-LSTK] (archived Jan. 21, 2021).

69. See Complaint at 46, *United States v. Gilead Sciences*, No. 19-2103-MN (D. Del. Nov. 6, 2019) [hereinafter Complaint].

70. 2016 was the year prior to FDA approval of the first generic competitor to Truvada in the United States market. See Mezher, *supra* note 66.

71. Press Release, Gilead Sciences, *Gilead Sciences Announces Fourth Quarter and Full Year 2016 Financial Results* (Feb. 7, 2017), <https://www.gilead.com/news-and-press/press-room/press-releases/2017/2/gilead-sciences-announces-fourth-quarter-and-full-year-2016-financial-results> [https://perma.cc/V8M3-EBKL] (archived Jan. 21, 2021).

72. Silverman, *supra* note 64.

73. See Christopher Rowland, *Americans Pay \$US2000 for Drug Costing Aussies Less Than \$6*, FIN. REV. (May 17, 2019), <https://www.afr.com/world/north-america/americans-pay-us2000-for-drug-costing-aussies-less-than-6-20190517-p51odk> (subscription required) [https://perma.cc/54DL-4944] (archived Jan. 21, 2021).

74. See EU Door Opens for Generic Version of AIDS Medicine Truvada, MED. EXPRESS (July 26, 2018), <https://medicalxpress.com/news/2018-07-eu-door-version-aids-medicine.html> [https://perma.cc/HF8J-WNHA] (archived Jan. 21, 2021).

higher than elsewhere in the Global North. In Australia, for example, PrEP currently costs around \$8 a month.⁷⁵

The cost of Truvada for PrEP in the United States has been identified as one of the major factors causing indicated HIV-negative patients not to take the drug.⁷⁶ This deterrent effect is especially problematic as current levels of HIV infection in the United States are considered epidemic.⁷⁷ Experts and public health-oriented agencies consider PrEP an especially effective way of addressing the epidemic, as data shows that regular use of PrEP reduces the risk of HIV by 99 percent in populations who do not use controlled substances, and at least 74 percent in those who do.⁷⁸

The consequences of price-based deterrence affect both patient populations and regions of the United States in different ways. Today, the geographical distribution of HIV infection is uneven across America, with rural areas in the South and Puerto Rico being disproportionately affected.⁷⁹ According to the latest available data, pertaining to 2017, Southern states reported 52 percent of new HIV diagnoses, with Western states a distant second at 19 percent followed by 16 percent in the Northeast and 13 percent in the Midwest.⁸⁰ However, even though the South registers more than half of new cases, studies mapping the use of PrEP suggest that fewer patients in this area have access to the drug than elsewhere in the country.⁸¹

Compounding the geographical disparities, new cases of HIV infection also affect certain populations in disproportional ways: 50 percent of all new reported infections occur among black, Latino, gay, and transgender populations.⁸² Among women—who account for

75. Rowland, *supra* note 73.

76. Luthra & Gorman, *supra* note 67. Additional factors include lack of knowledge about the drug, poor patient-physician relationships, and fear of stigma. *See id.*

77. *See What is 'Ending the HIV Epidemic: A Plan for America'?*, HIV.GOV <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (last visited Jan. 21, 2021) [<https://perma.cc/K7GJ-GBUG>] (archived Jan. 21, 2021).

78. *See Pre-Exposure Prophylaxis (PrEP)*, *supra* note 59.

79. *See AIDSVu Map (HIV Infection)*, AIDSVu, <https://map.aidsvu.org/map> [<https://perma.cc/QHWA4-3LA5>] (archived Jan. 21, 2021) (providing an interactive account of the number of cases of HIV infection by county).

80. *See HIV in the United States by Region*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (2018), <https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html> [<https://perma.cc/57AR-TXF8>] (archived Jan. 21, 2021) (further reporting new HIV diagnoses in U.S. dependent areas to account for 1%).

81. *See Lenny Bernstein, This HIV Pill Saves Lives. So Why Is It So Hard to Get in the Deep South?*, WASH. POST (Mar. 11, 2019), https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a_story.html [<https://perma.cc/S9DW-MWX3>] (archived Jan. 21, 2021).

82. *See Robert Goldstein, PrEP Prevents HIV — So Why Aren't More People Taking It?*, HARV. HEALTH PUBL'G: HARV. HEALTH BLOG (Oct. 4, 2019),

slightly over 15 percent of total new infections—three quarters of reported new infections occur among women of color.⁸³ These populations are also among the most likely to be underinsured or to have no insurance at all.⁸⁴

According to CDC estimates, the overall number of people in the United States indicated for PrEP therapy is around 1.2 million.⁸⁵ Gilead has indicated that only a fraction of this population, roughly 167 thousand people, is taking Truvada.⁸⁶ This corresponds to 18.1 percent of persons with indications.⁸⁷ Among patients taking PrEP, three-quarters of prescriptions are dispensed to white gay patients in coastal states.⁸⁸

To be sure, this gap between geographical areas and populations indicated for PrEP and actual PrEP intake cannot be attributed exclusively to the high price tag of the drug. Factors like lack of awareness and concerns with stigma still play a role in limiting the intake of the drug.⁸⁹ Nevertheless, it is generally accepted that the price of Truvada for PrEP remains one of the major barriers to widespread adoption of PrEP.⁹⁰ The excessive price tag is particularly concerning at a time when the levels of HIV infection in the United States continue at epidemic proportions. As commentators and AIDS activists have often pointed out: “[w]e have the most effective tool for ending the HIV epidemic, and one reason we’re unable to scale up is because it costs so [much] unnecessarily.”⁹¹

The main driver of price inflation in the case of Truvada for PrEP is the monopoly-esque market position conferred by patents on the drug. Even though the relevant patents are approaching their terms, only recently has their validity—and their instrumentalization in

<https://www.health.harvard.edu/blog/prep-prevents-hiv-so-why-arent-more-people-taking-it-2019100417942> [<https://perma.cc/GA9G-2YPU>] (archived Jan. 21, 2021).

83. See *id.*

84. See Robert H. Goldstein, Carl G. Streed & Sean R. Cahill, *Being PrEPared — Preexposure Prophylaxis and HIV Disparities*, 379 NEW ENG. J. MED 1293, 1294 (2018).

85. See U.S. Ctrs. Disease Control & Prevention, *Vital Signs: Status of Human Immunodeficiency Virus Testing, Viral Suppression, and HIV Preexposure Prophylaxis — United States, 2013–2018*, MORBIDITY AND MORTALITY WEEKLY REPORT (Dec. 6, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm> [<https://perma.cc/8WRK-AW23>] (archived Jan. 21, 2021).

86. Luthra & Gorman, *supra* note 67.

87. See U.S. Ctrs. for Disease Control & Prevention, *supra* note 85.

88. See Goldstein, Streed & Cahill, *supra* note 84, at 1293.

89. See *id.*

90. See Bernstein, *supra* note 81; Complaint, *supra* note 69, at 34.

91. See Anna Gorman, *Cost of PrEP Is Out of Most People’s Reach*, PLUS (July 9, 2018), <https://www.hivplusmag.com/prevention/2018/7/09/cost-prep-out-most-peoples-reach> [<https://perma.cc/DT6Q-ZLBT>] (archived Feb. 14, 2021) (alteration in original); see also James Krellaenstein, Aaron Lord & Peter Stately, *Why Don’t More Americans Use PrEP?*, N.Y. TIMES (July 16, 2018), <https://www.nytimes.com/2018/07/16/opinion/prep-hiv-aids-drug.html> [<https://perma.cc/4GYG-YCUX>] (archived Jan. 22, 2021).

gouging the price of Truvada for PrEP—attracted public attention and scrutiny.

An important part of the basic research on the drug combo that ultimately became the PrEP regimen was done by scientists at the Centers for Disease Control and Prevention (CDC).⁹² While Gilead obtained four patents on an emtricitabine and tenofovir combo that would become Truvada in its nonprophylactic version,⁹³ the CDC obtained four patents for its research on PrEP.⁹⁴ After Gilead obtained FDA approval to market Truvada in 2004 for the treatment of HIV infection, work done through a partnership between the CDC and Emory University, and primarily supported by \$50 million in federal grants,⁹⁵ showed that the drug combo could also be used prophylactically. It was at this point that Gilead sponsored Truvada for PrEP and gained market approval for this new indication from the FDA. The patents supporting Truvada for PrEP are thus the same that supported nonprophylactic versions of Truvada. One expires in late 2020 and the others remain throughout 2021.⁹⁶

Commentators and patent experts have made the case that the prophylactic emtricitabine-tenofovir combo is quite distinct from the nonprophylactic one.⁹⁷ For instance, it was the CDC that discovered and confirmed the prophylactic properties of the drug combo, as well as the appropriate dosing.⁹⁸ As such, there is a distinct possibility that Gilead's Truvada for PrEP may be infringing on the CDC's patent portfolio.⁹⁹

While Gilead now holds rights in some of the active pharmaceutical ingredients used in PrEP, one of those ingredients (emtricitabine) was, in fact, discovered and patented by researchers at Emory University, who used federal funding for their research. In Gilead's hands PrEP was used as treatment and not prevention. It was the CDC that discovered that once-a-day oral PrEP can prevent HIV, and it was the National Institutes of Health and the Gates

92. See Complaint, *supra* note 69, at 1–2.

93. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (Truvada), FDA, <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm> (last visited Jan. 22, 2021) [<https://perma.cc/82WS-2N6Q>] (archived Jan. 22, 2021).

94. See *id.*

95. See Christopher Rowland, *An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But a Pharma Giant is Making Billions*, WASH. POST (Mar. 26, 2019), https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5af-b4-40fc-11e9-9361-301ffb5bd5e6_story.html [<https://perma.cc/A3L8-72EU>] (archived Jan. 22, 2021).

96. See *Orange Book*, *supra* note 93.

97. See Christopher J. Morten & Amy Kapczynski, *United States v. Gilead: Can a Lawsuit Yield Better Access To PrEP?*, HEALTH AFF. BLOG (Nov. 18, 2019), <https://www.healthaffairs.org/do/10.1377/hblog20191118.218552/full/> (noting that “the U.S. government very rarely goes to court to enforce its patents”).

98. Complaint, *supra* note 69, at 25.

99. See Morten & Kapczynski, *supra* note 97.

Foundation that funded the first clinical trials to prove that PrEP is safe and effective in people.¹⁰⁰

In line with this view, the CDC notified Gilead of its patent applications and attempted to negotiate a licensing agreement with Gilead in 2017 and 2018, a proposition that the company declined.¹⁰¹ In November 2019, the US government, through the Department of Health and Human Services (HHS), sued Gilead for patent infringement.¹⁰²

At the time of the lawsuit, the HHS secretary “recognize[d] Gilead’s role in selling Truvada” but argued that “Gilead must respect the US patent system, the groundbreaking work by CDC researchers, and the substantial taxpayer contributions to the development of these drugs.”¹⁰³ In the complaint, the government characterizes Gilead’s behavior in repeatedly refusing to obtain a license as “malicious, wanton, deliberate, consciously wrongful, flagrant, and in bad faith.”¹⁰⁴

Gilead has made the case that the company has heavily supported the clinical trials that resulted in FDA approval of Truvada for PrEP. In response, the government has said “that claim is disingenuous. Its support of early clinical trials was typically limited to only the donation of study drugs.”¹⁰⁵ Gilead has also suggested that the patents held by the CDC are themselves invalid “because the use of Truvada as prophylaxis was widely known at the time the CDC sought these patents.”¹⁰⁶ Nonetheless, the company initially announced that it would not challenge the CDC’s patents “because we value our collaborative relationship with the agency.”¹⁰⁷ Three months later, however, it brought an *inter partes* review. In February 2020, the Patent Trial and Appeals Board at the Patent and Trademark Office ruled that Gilead had “failed to demonstrate it was likely to win its argument for overturning the patents held by the CDC.”¹⁰⁸

100. *See id.*

101. Complaint, *supra* note 69, at 57–58.

102. Press Release, U.S. Dep’t Health & Human Servs., United States Files Patent Infringement Lawsuit Against Gilead Related to Truvada® and Descovy® for Pre-exposure Prophylaxis of HIV (Nov. 6, 2019), <https://www.hhs.gov/about/news/2019/11/06/us-files-patent-infringement-lawsuit-against-gilead-pre-exposure-prophylaxis-hiv.html> [https://perma.cc/XEB8-XHMH] (archived Jan. 22, 2021).

103. *See id.*

104. Complaint, *supra* note 69, at 69.

105. *See id.* at 37.

106. Statement of Daniel O’Day, Chairman and Chief Exec. Officer Gilead Scis., Inc. Before the Comm. on Oversight & Reform U.S. H. of Reps. (May 16, 2019), <https://docs.house.gov/meetings/GO/GO00/20190516/109486/HHRG-116-GO00-Wstate-ODayD-20190516.pdf> [https://perma.cc/25QH-NTWV] (archived Jan. 22, 2021).

107. Complaint, *supra* note 69, at 59.

108. Gilead v. United States., No. IPR2019–01455 (P.T.A.B. Feb. 5, 2020), <http://freepdfhosting.com/0a58c071ad.pdf> [https://perma.cc/UQN7-R5MT] (archived Jan. 22, 2020); Gilead v. United Statees., No. IPR2019–01456, (P.T.A.B. Feb. 5, 2020),

In October 2019, Gilead gained FDA approval for a newer generation PrEP drug, Descovy.¹⁰⁹ Descovy is also a combination of tenofovir and emtricitabine, but it uses tenofovir alafenamide as opposed to the version of tenofovir found in Truvada.¹¹⁰

While the patent dispute between HHS and Gilead is still unfolding, it is worth noting that a direct relationship can be discerned between the IP-enabled pricing practices adopted by the manufacturer of Truvada for PrEP¹¹¹ and the difficulties in controlling the burden of HIV infection in the United States. The complaint explains:

Another critical barrier to increasing access to PrEP in the United States has been the cost of Truvada®, which presently is only sold by Gilead, by virtue of U.S. patents that purportedly cover the product. This is a major reason that many at risk of HIV infection in the United States are not currently taking Truvada for PrEP®. Many AIDS activists and many in the medical community have criticized Truvada®’s price in the United States, particularly in light of HHS’s patents, the Government’s funding of clinical research on PrEP, and the relatively low cost at which Gilead apparently makes the product.¹¹²

And while this case study explored only one embodiment of price gouging, the problem is systemic, affecting health outcomes and risks among diversified populations. For instance, with regard to drugs¹¹³ used in the treatment of some of the most serious conditions—from autoimmune diseases to oncology—price gouging of on-patent drugs remains a constant.¹¹⁴

<http://freepdfhosting.com/e4e6827eea.pdf> [<https://perma.cc/NG3Y-KGK3>] (archived Jan. 22, 2021).

109. Press Release, U.S. Food & Drug Admin., FDA Approves Second Drug to Prevent HIV Infection as Part of Ongoing Efforts to End the HIV Epidemic (Oct. 3, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-second-drug-prevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic> [<https://perma.cc/5S9X-SKPR>] (archived Jan. 22, 2021).

110. See Silverman, *supra* note 64.

111. Gilead was the sole manufacturer in the HIV PrEP space until 2017, at which point the FDA approved the first PrEP generic. See Mezher, *supra* note 66.

112. See Complaint, *supra* note 69, at 48–49.

113. These drugs, known as biologics, are structurally different from the category to which Truvada for PrEP belongs. They are subject to separate R&D and regulatory approval processes and tend to be exponentially more expensive than conventional drugs. See *Vaccines, Blood & Biologics*, FDA, <https://www.fda.gov/vaccines-blood-biologics> (last visited Apr. 17, 2021) [<https://perma.cc/5UDT-JWFM>] (archived Apr. 17, 2021).

114. See generally Ana Santos Rutschman, *Regulatory Malfunctions in the Drug Patent Ecosystem*, 70 EMORY L.J. 347 (2020).

B. A Case Study on Epidemic and Pandemic Preparedness: From Ebola to COVID-19 Vaccines and Treatments

The existence of one or several patents is not the only IP feature that influences access to pharmaceuticals or biotechnologies by populations in need. In the case of off-patent drugs, there are several instances of products not covered by IP that fail to attract interest from manufacturers in the private sector. The FDA keeps a list of drugs with expired patents and market exclusivities for which there is no commercial interest, even though there is demand from indicated populations.¹¹⁵ This type of problem relates to a different dimension of IP, which determines what kinds of products enter the market; this one conceptually and temporally distinguishable from pricing issues arising in connection with the commercialization of pharmaceuticals and biologic drugs.

Utilitarian discourses depicting patents as incentive mechanisms for socially desirable innovation often emphasize the role of IP as a *sine qua non* of R&D in traditionally underfunded areas. These discourses tend to pay particular attention to biopharmaceutical innovation, which is known for high R&D costs, combined with significant risk of failure.¹¹⁶ Absent some form of exclusivity-conferring lead time on the market, investors and R&D players are likely to underinvest or to allocate their resources elsewhere.

While the prospective function of patents appears to be one of the drivers of biopharmaceutical R&D for mainstream or blockbuster drugs,¹¹⁷ scholars and commentators have found scant evidence that the patent system truly functions as a catalyst for R&D in the case of drugs with smaller markets—both in the case of markets of limited size, as exemplified by R&D on orphan diseases,¹¹⁸ and in the case of temporary markets, as exemplified by R&D on drugs, vaccines, and other pharmaceutical products needed to respond to outbreaks of

115. *List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic*, FDA, <https://www.fda.gov/media/105829/download> (last visited Jan. 22, 2021) [<https://perma.cc/RE5M-AFQ4>] (archived Jan. 22, 2021); see also Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Policy to Improve Access and Foster Price Competition for Drugs That Face Inadequate Generic Competition (Feb. 15, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-pr> [archived Jan. 22, 2021].

116. See, e.g., WILLIAM W. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (Harvard Univ. Press 2003).

117. See, e.g., Why Patents Are Necessary for The Pharmaceutical Industry, SERVIER (Sept. 10, 2014), <https://servier.com/en/news/why-patents-are-necessary-for-the-pharmaceutical-industry/> [<https://perma.cc/8X2H-SECU>] (archived Jan. 22, 2021).

118. See *infra* note 174 and accompanying text.

infectious diseases.¹¹⁹ Moreover, with regard to the latter, patent-driven models are often fundamentally at odds with public health imperatives of preparedness—the ability of health systems to anticipate and operate proactively to develop response mechanisms to be deployed when an outbreak (or other public health crisis) occurs.¹²⁰ Preparedness frameworks emphasize the need to develop and stockpile drugs and other pharmaceutical products needed to respond to an outbreak. Yet, current preparedness approaches are detached—both conceptually and in practice—from the legal ecosystem that is supposed to function as a catalyst for biopharmaceutical R&D.¹²¹

As noted in prior work, while large-scale public health crises such as the COVID-19 pandemic paradoxically cure market failures for the development of vaccines and other pharmaceutical products needed to respond to an outbreak,¹²² they do not address this fundamental dissociation between IP as a system of incentives and current levels of R&D on pandemic drugs during the pre- or inter-outbreak period—which is exactly the period during which public health policy prescribes robust preparedness efforts.

Consider the case of the vaccine R&D landscape prior to the 2014–16 Ebola outbreak. The diseases caused by Ebola and other pathogens in the same viral family (filoviridae) have been studied by scientists across the world for decades.¹²³ The Ebola virus, in particular, was first identified in 1976.¹²⁴ By the early 2000s, a promising vaccine candidate had been developed in North America, first through work largely performed and funded by the United States public sector as part of the country’s post-9/11 bioterrorism preparedness strategy,¹²⁵ and then

119. See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170, 176–77 (2020) [hereinafter Rutschman, *The Intellectual Property of Vaccines*] (addressing the problem of lacking R&D in the vaccine space); Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J.L. & BIOSCIENCES 1, 3–4 (2020).

120. See, e.g., Lawrence O. Gostin, *Public Health Emergency Preparedness: Globalizing Risk, Localizing Threats*, 320 J. AM. MED. ASS’N 1743, 1743 (2018), <https://jamanetwork.com/journals/jama/fullarticle/2712530> [<https://perma.cc/96GU-J7WY>] (noting that “[e]mergency preparedness requires proactive planning and funding”).

121. See Ana Santos Rutschman, *Vaccines and IP Preparedness in the Coronavirus Outbreak*, NW. U. L. REV. NOTE (May 18, 2020), <https://blog.northwesternlaw.review/?p=1414> [<https://perma.cc/PUA4-VQEQQ>] (noting the role of intellectual property in pandemic preparedness frameworks).

122. Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1203–04 (2018) [hereinafter Rutschman, *IP Preparedness*].

123. *Id.* at 1218–19.

124. See *What Is Ebola Virus Disease?*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 1, 2020), <https://www.cdc.gov/vhf/ebola/about.html> [<https://perma.cc/36LR-UR35>] (archived Jan. 22, 2021).

125. See *Ebola Vaccines*, U.S. NAT’L INST. OF ALLERGY AND INFECTIOUS DISEASES (Jan. 9, 2020), <https://www.niaid.nih.gov/diseases-conditions/ebola-vaccines> [<https://perma.cc/U7HV-CDQL>] (archived Jan. 22, 2021).

through work performed and funded by the Canadian public sector.¹²⁶ The Canadian government applied for a patent covering a recombinant vaccine candidate targeting Ebola in 2003.¹²⁷ It then continued R&D, estimating that clinical trials would start around 2008, with the vaccine being fully licensed and ready for distribution two to three years later.¹²⁸ In order to move a vaccine candidate through the later stages of R&D (including clinical trials, regulatory review, and manufacturing), the public sector normally collaborates with, or licenses the relevant technology to, one or more partners in the private sector, which has the resources and infrastructure to bring a vaccine to market. In the case of the Ebola vaccine candidate, however, the Canadian public sector struggled to attract potential licensees.¹²⁹ An article published in the Canadian Medical Association Journal in 2005 aptly described the ongoing situation through its title: “Wanted: Manufacturer for Ebola and Marburg Vaccines.”¹³⁰ Eventually, the vaccine was licensed to a small American pharmaceutical company, NewLink, which received an exclusive license to “make, use, improve, develop and [c]ommercialize” the vaccine.¹³¹ Until the beginning of the 2014–16 Ebola outbreak, however, NewLink did not invest any resources on testing and manufacturing the vaccine.¹³² As journalist Denise Grady put it: “[The] Ebola vaccine, ready for test, sat on the shelf.”¹³³

Elsewhere, this author has discussed the case of this Ebola vaccine candidate as a transactional problem with a salient IP dimension.¹³⁴ Having originally obtained control over the IP associated with the vaccine for \$205,000, NewLink did not perform any additional R&D before a large-scale outbreak occurred. At that point, it

126. Francis A. Plummer & Steven M. Jones, *The Story of Canada’s Ebola Vaccine*, 189 CAN. MED. ASS’N J. E1326, E1326 (2017); Matthew Herder, Janice E. Graham & Richard Gold, *From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*, J.L. & BIOSCIENCES 1, 4 (Jan. 16, 2020).

127. Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers, Can. Patent No. WO 2004/011488 A2 (filed July 28, 2003).

128. 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/QR27-JGA9] (archived Feb. 15, 2021).

129. See Dan Lett, *Wanted: Manufacturer for Ebola and Marburg Vaccines*, 173 CAN. MED. ASS’N J. 472, 472 (2005).

130. See *id.*

131. *Sole License Agreement for Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers*, GOV’T OF CAN., <https://www.canada.ca/en/public-health/services/infectious-diseases/viral-haemorrhagic-fevers/sole-license-agreement-recombinant-vesicular-stomatitis-virus-vaccines-viral-hemorrhagic-fevers.html> (last visited Jan. 22, 2021) [https://perma.cc/J72V-A96M] (archived Jan. 22, 2021).

132. See Plummer & Jones, *supra* note 126.

133. Grady, *supra* note 128.

134. Rutschman, *IP Preparedness*, *supra* note 122, at 1244–48.

negotiated with a large pharmaceutical company (Merck), to which it transferred IP rights for \$30 million, with an additional milestone payment of \$20 million due at the beginning of clinical trials.¹³⁵ In this transactional sense, IP rights enable rent-seeking behaviors that are at odds with public health goals of having vaccines—or other health goods—come to market as soon as technically and scientifically possible.¹³⁶

There is nonetheless an additional dimension to this story, which illustrates the shortcomings of overreliance on IP incentives as a way to catalyze R&D and bring certain types of health goods to market. Even when a patent has already been granted, there are cases in which the status quo—be it in the form of patent-related or nonpatent incentives—is simply inadequate to further preparedness and public health goals. Against a backdrop of little to no economic return anticipated in connection with the development of an Ebola vaccine—compounded by the prevalence of the associated disease among populations outside the geopolitical lines of the developed world—a vaccine that could have been developed and potentially approved before a large outbreak struggled to attract private-sector attention, only to remain untouched for years once the Canadian government succeeded in licensing it. From an incentives perspective, the primary trigger for late-stage R&D was thus the onset of a public health crisis in the form of the 2014–16 outbreak—the first Ebola outbreak that resulted in the death of a patient on US soil.¹³⁷

The current misalignment between IP-centric incentives and preparedness frameworks affects some health goods more markedly than others. The development of vaccines targeting emerging infectious diseases¹³⁸—from Ebola to coronaviruses and other

135. See *id.* at 1247; see also Stacy Lawrence, *Merck, NewLink Nab Up to \$76M BARDA Contract to Back Ebola Vaccine*, FIERCE BIOTECH (Oct. 5, 2016), <https://www.fiercebiotech.com/biotech/merck-newlink-nab-up-to-76m-barda-contract-to-back-ebola-vaccine> [https://perma.cc/Z956-EEWC] (archived Feb. 15, 2021).

136. The point here is not that transactability of IP rights is problematic. In fact, as a structural feature of IP regimes, transactability can promote a more efficient allocation of rights, as well as serve as a catalyst for collaborative R&D. In the case at hand, however, the transfer of IP from the public sector to NewLink results in a situation in which the new rightsholder instrumentalizes IP to magnify economic returns without having contributed to the R&D process. See Rutschman, *IP Preparedness*, *supra* note 122, at 1221–22.

137. See Clarence Spigner, *Patient Zero: Thomas Eric Duncan and the Ebola Crisis in West Africa and the United States*, BLACK PAST (Oct. 29, 2014), <https://www.blackpast.org/global-african-history/perspectives-global-african-history/patient-zero-thomas-eric-duncan-and-ebola-crisis-west-africa-and-united-states/> [https://perma.cc/GG3H-648G] (archived Jan. 20, 2021) (chronicling the story of Thomas Eric Duncan).

138. These diseases are characterized as “[o]utbreaks of previously unknown diseases[:] [k]nown diseases that are rapidly increasing in incidence or geographic range in the last 2 decades[:] or persistence of infectious diseases that cannot be controlled.”

pathogens resulting in respiratory illness—is among the areas most affected by this misalignment. If regarded as commodifiable goods, vaccines are generally unattractive in terms of return on investment.¹³⁹ They are preventatives, leading either to the production of nonevents (the inexistence of an outbreak) or the mitigation of the effects of the disease (the occurrence of a smaller outbreak, or the production of less severe consequences to public and individual health);¹⁴⁰ they offer scarce possibilities of repeated consumption;¹⁴¹ as biological products, they require costly and specialized manufacturing and distribution chains;¹⁴² and, in the case of vaccines targeting emerging infectious diseases, indicated populations have traditionally been largely confined to economically disadvantaged areas of the world, further dimming revenue prospects.¹⁴³

This dissociation between public health value and market-driven incentives to biopharmaceutical R&D is not restricted to vaccines. As the COVID-19 pandemic started to unfold, scientists began exploring hundreds of different potential treatments.¹⁴⁴ A significant number of treatment candidates consisted of repurposed drugs—drugs already in

See *Emerging Infectious Diseases*, JOHNS HOPKINS MED., <https://www.hopkinsmedicine.org/health/conditions-and-diseases/emerging-infectious-diseases> [https://perma.cc/4U79-TMVX] (archived Jan. 20, 2021).

139. See generally Rutschman, *The Intellectual Property of Vaccines*, *supra* note 119.

140. But see Rino Rappuoli, Henry I. Miller & Stanley Falkow, *The Intangible Value of Vaccination*, 297 SCI. MAG. 937, 937 (2002) (expressing uncertainty about the viability of vaccines as a preventative strategy); Meghan L. Stack, Sachiko Ozawa, David M. Bishai, Andrew Mirelman, Yvonne Tam, Louis Niessen, Damain G. Walker & Orin S. Levine, *Estimated Economic Benefits During The Decade of Vaccines' Include Treatment Savings, Gains in Labor Productivity*, 30 HEALTH AFFS. 1021, 1026–27 (2011) (collectively noting economic gains attributable to widespread vaccination of indicated populations).

141. See, e.g., *Recommendations for Routine Immunizations*, WHO https://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua [https://perma.cc/W82H-4MLL] (last updated Sept. 2020) (listing recommended doses for the most commonly administered vaccines across the world); see also Patricia M. Danzon, Nuno Sousa Pereira & Sapna S. Tejwani, *Vaccine Supply: A Cross-National Perspective*, 24 HEALTH AFFS. 706, 712–14 (2005) (citing the shortages and demand uncertainty regarding manufacturers' production of vaccines).

142. See, e.g., WORLD HEALTH ORG., TRAINING FOR MID-LEVEL MANAGERS (MLM), MODULE 1: COLD CHAIN, VACCINES AND SAFE-INJECTION EQUIPMENT MANAGEMENT 32–38 (2008), https://www.who.int/immunization/documents/MLM_module1.pdf [https://perma.cc/WE8V-RAVX] (archived Jan. 20, 2021).

143. See Rutschman, *IP Preparedness*, *supra* note 122, at 1211 (noting that “[t]he economic footprint of the regions where outbreaks occurred in the past have been too small to trigger strong private-sector R&D investment, while interest from other players has been overshadowed by more visible neglected diseases like malaria or HIV/AIDS.”).

144. As of September 18, 2020, there were 339 treatment candidates for COVID-19 being tested across the world. *COVID-19 Treatment and Vaccine Tracker*, MILKEN INST., https://covid-19tracker.milkeninstitute.org/#treatment_antibodies (last updated Jan. 19, 2021, 10:15 PM) [https://perma.cc/PY98-EBB5] (archived Jan. 20, 2021).

use (or being studied) for a different indication.¹⁴⁵ Among these, the antiviral remdesivir¹⁴⁶ emerged early on as one of the leading candidates;¹⁴⁷ in May 2020, it became the first COVID-19 treatment temporarily authorized by the FDA for the treatment of hospitalized patients.¹⁴⁸ In August, Gilead—the pharmaceutical company sponsoring remdesivir—submitted a new drug application to the FDA seeking full approval of the drug.¹⁴⁹

While the quick timeline under which remdesivir was developed and tested as a treatment for COVID-19 is remarkable, it also points to a misalignment between preparedness standards and current R&D models leaning heavily on IP and market forces.¹⁵⁰ Remdesivir was originally developed through contributions from both the US public sector (through research performed at government institutions, such as the U.S. Army Medical Research Institute of Infectious Diseases, as well as grants to academic research institutions) and scientists at Gilead.¹⁵¹ During the 2014–16 Ebola outbreak, remdesivir was tested on animals and, after showing promise, progressed to phase one clinical trials.¹⁵² Nevertheless, as the outbreak began to unwind, so did

145. See generally Sudeep Pushpakom Francesco Iorio, Patrick A. Eyers, K. Jane Escott, Shirley Hopper, Andrew Wells, Andrew Doig, Tim Guiliams, Joanna Latimer, Christine McNamee, Alan Norris, Philippe Sanseau, David Cavalla & Munir Pirmohamed, *Drug Repurposing: Progress, Challenges and Recommendations*, 18 NATURE REV. DRUG DISCOVERY 41 (2019).

146. See Katherine Seley-Radtke, *Remdesivir Explained — What Makes This Drug Work Against Viruses?*, CONVERSATION (May 6, 2020, 8:20 AM), <https://theconversation.com/remdesivir-explained-what-makes-this-drug-work-against-viruses-137751> [https://perma.cc/VDJ6-FFJH] (archived Jan. 20, 2021) (outlining basic information about remdesivir).

147. John H. Beigel et al., *Remdesivir for the Treatment of Covid-19 – Final Report*, 383 NEW ENG. J. MED. 1813, 1814 (Nov. 5, 2020).

148. *Gilead's Investigational Antiviral Remdesivir Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of COVID-19*, GILEAD (May 1, 2020), <https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19> [https://perma.cc/39B7-VS5U] (archived Jan. 20, 2021).

149. See *Gilead Submits New Drug Application to U.S. Food and Drug Administration for Veklury® (Remdesivir) for the Treatment of COVID-19*, GILEAD (Aug. 10, 2020), <https://www.gilead.com/news-and-press/press-room/press-releases/2020/8/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-veklury-remdesivir-for-the-treatment-of-covid19> [https://perma.cc/CR7N-MSGX] (archived Jan. 20, 2021).

150. See Heled, Rutschman & Vertinsky, *supra* note 119, at 17–22.

151. See Silverman, *supra* note 64.

152. GILEAD, DEVELOPMENT OF REMDESIVIR 1 (2020), https://www.gilead.com/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf [https://perma.cc/WEV4-D3WK] (archived Jan. 20, 2021); see also Ned Pagliarulo, *A Closer Look at the Ebola Drug That's Become the Top Hope for a Coronavirus Treatment*, BIOPHARMA DIVE (Mar. 5, 2020), <https://www.biopharmadive.com/news/coronavirus-remdesivir-gilead-antiviral-drug-covid-19/573261/> [https://perma.cc/UNA3-T9YS] (archived Jan. 20, 2021).

R&D on remdesivir, even though its antiviral potential was already well understood.¹⁵³ Gilead made R&D on remdesivir a priority as soon as the magnitude of the COVID-19 pandemic became apparent.¹⁵⁴ As the company awaits approval from the FDA to broadly market remdesivir, it has announced that a full five-day course of treatment—which costs \$10 per dose to manufacture¹⁵⁵—will cost \$3,120 to Medicare, Medicaid, and private insurers in the United States.¹⁵⁶ Other developed countries will be able to buy the drug at a 25 percent discount.¹⁵⁷ The company also announced that developing countries would pay “significantly less” for remdesivir, without providing further details on specific numbers.¹⁵⁸

Thus, while preexisting R&D turned remdesivir into a leading candidate for the treatment of emerging diseases, it was a severe public health crisis that effectively nudged R&D actors to see its development through the R&D pipeline. Once again, this is at odds with public health principles of epidemic and pandemic preparedness, which prioritize investment in, and the development of, health goods before a public health crisis occurs.

This misalignment is not solely attributable to IP frameworks. Yet, it illustrates how contemporary constructions of IP as systems of incentives to innovate fit poorly with goals of epidemic and pandemic preparedness. In the case of remdesivir, Gilead first applied for a patent in the United States in 2015.¹⁵⁹ The patent was issued in 2019.¹⁶⁰ The prospect of imminent patent-induced market exclusivity was not enough to prioritize pre-pandemic R&D on remdesivir, though.

The repercussions of this dissociation are not insignificant. Once studied in connection with Ebola, remdesivir was repurposed to treat a respiratory disease. While this repurposing appears to constitute a positive development from a scientific perspective, it is matched by a lack of continued R&D in connection with viruses in the Ebola family, as well as corresponding opportunity costs. Since the 2014–16

153. See Soley-Radtke, *supra* note 146 (noting that remdesivir belongs to “oldest and most important classes of drugs”).

154. GILEAD, *supra* note 152, at 2.

155. Rohan Chalasani & Walid Gellad, *The US Is Paying Way Too Much for Remdesivir*, WIRED (July 17, 2020), <https://www.wired.com/story/the-us-is-paying-way-too-much-for-remdesivir/> [https://perma.cc/Y5ZN-FBNK] (archived Jan. 20, 2021).

156. See, e.g., Sarah Hansen, *Gilead Finally Reveals Remdesivir Pricing After Weeks of Speculation*, FORBES (June 29, 2020, 9:28 AM), <https://www.forbes.com/sites/sarahhansen/2020/06/29/gilead-finally-reveals-remdesivir-pricing-after-weeks-of-speculation/#6e14859a405b> [https://perma.cc/5UEV-7ZD2] (Jan. 20, 2021). A five-day course of remdesivir will cost \$2,340 to the Department of Veterans Affairs and the Indian Health Service. *See id.*

157. *See id.*

158. *See id.*

159. See Silverman, *supra* note 64.

160. Methods for Treating Arenaviridae and Coronaviridae Virus Infections, U.S. Patent No. 10,251,904B2 (issued Apr. 9, 2019).

outbreak, there have been several Ebola outbreaks in Africa.¹⁶¹ An outbreak in 2018, affecting the Democratic Republic of the Congo and (to a lesser extent) Uganda, registered 3,470 reported cases and a fatality rate of 66 percent.¹⁶² A 2020 outbreak in the same country resulted in 130 reported cases and a fatality rate of 42.3 percent. The latest Ebola outbreak, also affecting Democratic Republic of the Congo, started in February 2021 and is ongoing at the time of writing.¹⁶³

Merck's Ebola vaccine, known as Ervebo, was finally approved in December 2019, three years after the 2014–16 outbreak, seventeen years since a patent application was initially filed, and around fifteen years since the Canadian government started looking for a manufacturer.¹⁶⁴ As Ebola continues to affect primarily populations in economically depressed areas of the globe, the misalignment between incentives systems and public health needs is most taxing on some of the most vulnerable populations. The World Health Organization's Regional Office for Africa has surveyed different types of socioeconomic determinants of health and their impact on health outcomes across the African continent.¹⁶⁵ IP—be it its pricing facet or its incentive function—is not part of this analysis, or of standard literature on the determinants of health. Yet, as the case of pandemic and epidemic vaccines and drugs illustrates, IP and IP-adjacent decisions and priorities routinely inform levels of public health preparedness across the developing world—by directly influencing the types of health technologies available to prevent and respond to outbreaks of infectious diseases, and ultimately bearing an imprint in individual and systemic public health outcomes.

At a different level, the case of remdesivir marries incentive problems with pricing issues somewhat similar to the ones described in Part II.A. From the early stages of the coronavirus outbreak onwards, studies have repeatedly shown that COVID-19 has placed a disproportionately heightened health, social, and economic burden on racial minorities and economically disadvantaged populations in the

161. *40 Years of Ebola Virus Disease Around the World*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vhf/ebola/history/chronology.html> [https://perma.cc/3J8B-W9JW] (archived Jan. 20, 2021).

162. *See id.*

163. *See id.*

164. *See First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2020), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health> [https://perma.cc/C7HX-BXML] (archived Jan. 20, 2021).

165. *See Social and Economic Determinants of Health*, WORLD HEALTH ORG. REGIONAL OFFICE FOR AFRICA, <https://www.afro.who.int/health-topics/social-and-economic-determinants-health> [https://perma.cc/3AHV-AW4Q] (Jan. 20, 2021).

United States.¹⁶⁶ The current price point for remdesivir is likely to further underscore these disparities, which are precisely the type of problem(s) that interventions based on determinants of health frameworks seek to correct. For these reasons—as well as the ones developed in connection with the next case study—Part III will further make the case for considering IP, and in particular the patent system, as a determinant of health.

C. A Case Study on AgTech: Genetically Modified Crops

The final case study focuses on an example outside the field of pharmaceuticals and vaccines. This case concerns genetically modified rice, which was developed in response to nutritional deficiencies among populations in certain areas of the developing world. Vitamin A deficiency, in particular, is one of the leading causes of malnutrition-related morbidity and mortality across the Global South.¹⁶⁷ Every year, an estimated 1 million children die from causes related to vitamin A deficiency, while an additional 350 thousand lose their sight.¹⁶⁸ In line with other efforts to address this pressing public health problem, in the 1990s, scientists at European research institutions took the first steps towards the genetic modification of a species of rice (*Oryza sativa*), adding beta-carotene, which the human body transforms into vitamin A.¹⁶⁹ This type of enriched rice became known as “Golden Rice” due to its yellowish color, and was hailed as an invention that could potentially benefit countless people, and in particular children, in low-income economies, where rice has long been the most-consumed crop.¹⁷⁰

In order to modify *Oryza sativa*, scientists incorporated two genes from daffodils and one bacterium into the rice species.¹⁷¹ Because scientists involved in the project had relied on preexisting technology, they were concerned about the IP landscape surrounding Golden Rice,

166. See, e.g., *Health Equity Considerations and Racial and Ethnic Groups*, CDC (July 24, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html#fn2> [https://perma.cc/R9L2-YT4H] (archived May 12, 2021).

167. Robert E. Black, Lindsay H. Allen, Zulfiqar A. Bhutta, Laura E. Caulfield, Mercedes de Onis, Majid Ezzati, Colin Mathers & Juan Rivera, *Maternal and Child Undernutrition: Global and Regional Exposures and Health Consequences*, 371 LANCET 243, 243 (2008).

168. J. Madeleine Nash, *This Rice Could Save a Million Kids a Year*, TIME (July 31, 2000), <http://content.time.com/time/magazine/article/0,9171,997586,00.html> [https://perma.cc/57GY-A336] (archived Jan. 21, 2021).

169. See Xudong Ye, Salim Al-Babili, Andreas Klöti, Jing Zhang, Paola Lucca, Peter Beyer & Ingo Potrykus, *Engineering the Provitamin A (β-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCI. MAG. 303, 303 (2000).

170. Nash, *supra* note 168.

171. *The Golden Rice Technology*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, https://www.isaaa.org/kc/inforesources/biotechcrops/The-Golden_Rice_Technology.htm [https://perma.cc/6QLT-XPP7] (Jan. 21, 2021).

as well as with the prospect of having to negotiate multiple licensing agreements with different rightsholders.¹⁷² A study conducted in 2000 by the International Service for the Acquisition of Agribiotech Applications (ISAAA), an American nonprofit tech transfer company, identified a minimum of seventy patents “that could have implications for the commercialization” of Golden Rice.¹⁷³ At that point, Golden Rice research had been funded by the Rockefeller Foundation, the Swiss Government, and the EU.¹⁷⁴ Funding from the EU required the participation of a private sector company.¹⁷⁵ A large British agrochemical and biotech company, Zeneca—later AstraZeneca and today, Syngenta—thus joined the project as a research partner. Importantly, the company had an exclusive license over one of the genes that scientists had used to develop Golden Rice.¹⁷⁶

Against the backdrop of potentially costly and protracted IP negotiations, the scientists who had invented Golden Rice—and who were interested in making it available to the world’s poorest populations—turned to a German startup company, Greenovations, to broker the IP negotiations.¹⁷⁷ The result of the negotiations was two-fold: AstraZeneca obtained an exclusive license to commercialize Golden Rice in the Global North, as well as to “medium and large-scale farmers” in the Global South.¹⁷⁸ The company then granted back to the scientists the right to sublicense Golden Rice in the South at no cost.¹⁷⁹ Additionally, the company pledged “to give regulatory, advisory, and research assistance” to bring Golden Rice to developing economies.¹⁸⁰

On its face, the creation of two separate streams to diffuse the innovation, one commercial and the other “humanitarian” (as it became known),¹⁸¹ appears to further the interest of populations in need while balancing incentives frameworks as currently entrenched in global IP-centric industries.

172. *Golden Rice and Trojan Trade Reps: A Case Study in the Public Sector’s Mismanagement of Intellectual Property*, RAFI COMUNIQUE, Sept./Oct. 2010, at 1, 2–3 [hereinafter *Golden Rice and Trojan Trade Reps*].

173. See *id.* at 3.

174. See Nash, *supra* note 168.

175. Peter Beyer, Salim Al-Babili, Xudong Ye, Paola Lucca, Patrick Schaub, Ralf Welsch & Ingo Potrykus, *Golden Rice: Introducing the β-Carotene Biosynthesis Pathway into Rice Endosperm by Genetic Engineering to Defeat Vitamin A Deficiency*, 132 J. NUTRITION 506S, 509S (2002).

176. Nash, *supra* note 168.

177. Beyer, Al-Babili, Ye, Lucca, Schaub, Welsch & Potrykus, *supra* note 175, at 509S.

178. See *Golden Rice and Trojan Trade Reps*, *supra* note 172, at 3 (“medium and large-scale farmers” were defined as those who sold more than \$10,000 of Golden Rice).

179. See Beyer, Al-Babili, Ye, Lucca, Schaub, Welsch & Potrykus, *supra* note 175, at 509S–10S.

180. *Golden Rice and Trojan Trade Reps*, *supra* note 172, at 1.

181. Beyer, Al-Babili, Ye, Lucca, Schaub, Welsch & Potrykus, *supra* note 175, at 509S.

Nevertheless, a closer look at the information supporting the finding of a patent thicket in ISAAA's survey reveals a different IP landscape. The decision to grant an exclusive license to a large agtech company rested, according to one of the inventors of Golden Rice,¹⁸² on the understanding shared by scientists and funders alike that diffusion of the invention—even through the humanitarian stream—faced a “severe intellectual property rights problem.”¹⁸³ The problem was characterized by the inventor as insurmountable but for the collaboration with AstraZeneca, which held one of the blocking patents.¹⁸⁴ In late 2000, however, a study by the Rural Advancement Foundation International (RAFI) showed that ISAAA's pre-licensure survey vastly overstated the number of patents at stake.¹⁸⁵ Instead of a minimum of seventy and up to 105 patents, as identified by ISAAA, RAFI's study showed that there were only eleven relevant patents at a maximum.¹⁸⁶ Part of the reason for the overcalculation had to do with the fact that several of the patents in ISAAA's calculations had actually been accounted for twice based on (or under the guise of) different numbers issued by the US and the European patent offices.¹⁸⁷ When corrected for duplicate entries, the number came down to forty-four.¹⁸⁸

Moreover, the ISAAA survey expressly made the point that IP rights would likely prevent distribution of Golden Rice across most of the South, even if the inventors made them available for free. It provided that “widespread release of the current version of *GoldenRice™* will require significant licensing activity if it is to legitimately become available to the world, either commercially or for humanitarian purposes.”¹⁸⁹

The post-licensure study again showed that not to be the case.¹⁹⁰ In over 50 percent of the countries with serious levels of vitamin A deficiency (thirty-five out of sixty), there were no patents covering any of the technology involved in Golden Rice.¹⁹¹ In the remaining countries, only twelve patents were found to be potentially relevant.¹⁹² At the same time, among the dozen countries with populations with

182. See *id.*

183. See *id.*

184. See *id.*

185. See *Golden Rice and Trojan Trade Reps*, *supra* note 172, at 3.

186. See *id.*

187. See *id.* at 4.

188. See *id.*

189. David R. Kryder, Stanley P. Kowalski & Anatole F. Krattiger, *The Intellectual and Technical Property Components of Pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-to-Operate Review*, 20 ISAAA BRIEFS i, vii (2000).

190. See *Golden Rice and Trojan Trade Reps*, *supra* note 172, at 4.

191. *Id.*

192. *Id.*

vitamin A deficiency who “consume rice in sufficient quantity to make them potential targets,” half had no relevant patents.¹⁹³

It should be pointed out that, as a genetically modified food product, Golden Rice has been met with concern and criticism by several commentators, activists, and organizations. Some of the issues that have been raised are health focused and relate to the larger question of the impact of genetically modified crops on human health.¹⁹⁴ Others are ecological and relate to the effects and sustainability of the shift in farming practices introduced by Golden Rice and similar genetically engineered products.¹⁹⁵ Others still speak to ongoing debates on the stringency—or lack thereof—of current regulatory regimes for biotechnology.¹⁹⁶

While Golden Rice has not been approved for commercialization in affluent countries, regulatory agencies in the Global North (Australia, New Zealand, Canada, and the United States) have evaluated Golden Rice at the request of the International Rice Research Institute,¹⁹⁷ a large intergovernmental research institute based in the Philippines.¹⁹⁸ All four regulatory agencies declared to have “no further questions” about the safety of Golden Rice.¹⁹⁹ In December 2019, the Department of Agriculture in the Philippines approved Golden Rice for use as food, feed, and for processing,²⁰⁰ and a similar regulatory approval process is currently underway in Bangladesh.²⁰¹

This is not to opine on the merits of Golden Rice in itself, a topic completely outside the scope of this Article. A large portion of the story of this product of modern agtech is steeped in complex scientific, social, and policy queries. Likewise, from a legal perspective, the history of Golden Rice also threads into a more complex universe of domestic and

193. *Id.*

194. See, e.g., Dan Charles, *In A Grain of Golden Rice, A World Of Controversy Over GMO Foods*, NPR (Mar. 7, 2013), <https://www.npr.org/sections/thesalt/2013/03/07/173611461/in-a-grain-of-golden-rice-a-world-of-controversy-over-gmo-foods> [https://perma.cc/58PX-MWJE] (archived Jan. 13, 2021).

195. See, e.g., Nash, *supra* note 168.

196. See, e.g., *id.*

197. See e.g., Brian Owens, *Golden Rice is Safe to Eat, Says FDA*, 36 NATURE BIOTECHNOLOGY 559, 559 (2018).

198. INT'L RICE RSCH. INST., <https://www.irri.org> (last visited Jan. 13, 2021) [https://perma.cc/B8TP-4UWH] (archived Jan. 13, 2021).

199. Owens, *supra* note 197, at 559.

200. Katherine J. Wu, *Golden Rice Approved as Safe for Consumption in the Philippines*, SMITHSONIAN MAG. (Jan. 3, 2020), <https://www.smithsonianmag.com/smart-news/golden-rice-approved-safe-consumption-philippines-180973897/> [https://perma.cc/T6US-82R2] (archived Jan. 13, 2021).

201. *Philippines Approves Golden Rice for Direct Use as Food and Feed, or for Processing*, INT'L RICE RSCH. INST. (Dec. 18, 2019), <https://www.irri.org/news-and-events/news/philippines-approves-golden-rice-direct-use-food-and-feed-or-processing> [https://perma.cc/MT7R-834G] (archived Jan. 13, 2021).

transnational regulatory choices affecting food regimes. But there is a core component of the Golden Rice case that illuminates ongoing challenges at the intersection of IP and public health: a product of biotechnology, and more specifically of agtech, which may have an impact on nutrition levels across several of the most impoverished areas of the Global South, is covered by a plurality of patents that exacerbate informational asymmetries between inventors and holders of patent rights covering ancillary technologies.²⁰²

It is also worth noting that Golden Rice—as was the case with the technologies surveyed in the previous Parts—does not constitute an isolated case in the field of biotechnology. Other examples of genetically modified foods developed in patent-dense environments include ferritin-enriched lettuce in Japan,²⁰³ disease-resistant papayas in Hawaii,²⁰⁴ and disease-resistant dwarf wheat in India.²⁰⁵

III. TOWARDS A FRAMEWORK FOR THE IP DETERMINANTS OF HEALTH

A. *The Existing IP Framework*

As seen in Part I, the fields of the determinants of health and of IP have largely operated as separate doctrinal categories, even though there are multiple ways in which patent laws and norms directly affect health outcomes and risk in countries in the Global South and North alike.

Arguably, a balanced implementation of the TRIPs Agreement could have helped curb some of the rights-maximizing behaviors that have repeatedly resulted in price gouging and the exclusion of populations in need of critical inventions protected by patents. Article 7 subjects both the protection and the enforcement of IP rights to “the mutual advantage of producers and users” of protected goods, a “balance of rights and obligations,” and the larger principle of the promotion of “social and economic welfare.”²⁰⁶ This balancing approach is further complemented by Article 8, which establishes that countries

202. See *infra* Part III.A.

203. See generally IMPACTS OF AGRICULTURE ON HUMAN HEALTH AND NUTRITION 138–54 (Ismail Cakmak & Ross M. Welch eds., 2009).

204. See generally Michael Goldman, *The IP Management of the PRSV-Resistant Papayas Developed by Cornell University and the University of Hawaii and Commercialized in Hawaii*, in IP HANDBOOK OF BEST PRACTICES 1837 (2007), <http://www.iphandbook.org/handbook/ch17/p27/> [<https://perma.cc/DJC8-HYPE>] (archived Jan. 21, 2021).

205. See generally David Biello, *Norman Borlaug: Wheat Breeder Who Averted Famine with a “Green Revolution,”* SCI. AM. (Sept. 14, 2009), <https://blogs.scientificamerican.com/news-blog/norman-borlaug-wheat-breeder-who-av-2009-09-14/> [<https://perma.cc/452S-QS68>] (archived Jan. 21, 2021).

206. TRIPs Agreement, *supra* note 24, art. 7.

may adopt additional measures “to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology,” as long as these measures are consistent with the letter and the spirit of the TRIPs Agreement.²⁰⁷

Even though TRIPs provides the theoretical foundation to address some of the current imbalances in the diffusion of health-related innovations,²⁰⁸ many scholars have observed that implementation processes have often veered away from balancing tenets.²⁰⁹ This trend is underscored by the adoption of maximalist approaches in bilateral and plurilateral trade agreements.²¹⁰

Exploring the ways in which there may be meaningful links between IP laws and frameworks for determinants of health entails making the case that TRIPs Article 7 should become central to current and future applications of international and domestic IP laws, both at the legislative and interpretive levels. The connection between (purportedly) innovation-promoting regimes and the dissemination of health-related goods is given enhanced attention in TRIPs. In fact, Article 8 expressly forecasts the need to give the areas of “public health” and “nutrition” a particularized treatment at the national level: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Agreement.”²¹¹ The provision further extends the possibility of the adoption of additional measures to cases in which countries may need “to promote the public interest in sectors of vital importance to their socioeconomic and technological development.”²¹² While vastly underused, Article 8 does provide enabling language that could support the establishment of national regimes that leave much less room for behaviors like price gouging by explicitly incorporating a

207. *Id.* art. 8.2.

208. See, e.g., Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979 (2009).

209. See generally SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 121–62 (2003); GRAEME B. DINWOODIE & ROCHELLE COOPER DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 49–143 (Oxford U. Press 2012); Jerome H. Reichman, *The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 441–44 (2000); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 1–9 (2004); Reichman & Dreyfuss, *supra* note 33.

210. See generally Okediji, *supra* note 25; Mercurio, *supra* note 25; Annette Kur & Henning Grosse Ruse-Khan, *Enough Is Enough — The Notion of Binding Ceilings in International Intellectual Property Protection* (Max Planck Inst. for Intell. Prop., Competition & Tax L., Research Paper Series No. 09-01, 2009).

211. TRIPs Agreement, *supra* note 24, art. 8.1.

212. *See id.*

balancing mechanism—such as a fair-pricing requirement, which could cap the increase of the price of pharmaceuticals, for example.

The TRIPs carve out for public health and nutrition was developed by the Doha Declaration,²¹³ which states:

[T]he TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.²¹⁴

Compulsory licensing is a particular type of TRIPs-compatible intervention, which some countries in the Global South have taken advantage of in the field of pharmaceuticals.²¹⁵ Under TRIPs, thirty-one domestic patent laws can allow for the “authorization by the government to itself or to a third party to use the patent without the permission of the patent holder.”²¹⁶ The Doha Declaration (Declaration) both clarified and expanded the cases in which national governments may issue compulsory licenses.²¹⁷ Importantly, the Declaration specifically addressed the public health toll posed by epidemics, “including those relating to HIV/AIDS, tuberculosis [and] malaria,” and made it clear that countries have the freedom to determine “what constitutes a national emergency or other circumstances of extreme urgency” for the purposes of issuing a compulsory license on a drug needed to address an epidemic or other form of public health crisis.²¹⁸ A first wave of countries that resorted to compulsory licensing in the context of infectious disease outbreaks

213. See Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 921 (2007); Abbott, *supra* note 30.

214. See World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002), para. 4 [hereinafter Doha Declaration].

215. See TRIPs Agreement, *supra* note 24, art. 31 (laying out the procedural and substantive frameworks for compulsory licensing).

216. *Battling HIV/AIDS: A Decision-Maker's Guide to the Procurement of Medicines and Related Supplies* (2004), in INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 195, 195 (Y. Tayler ed., 2007).

217. See Doha Declaration, *supra* note 214, para. 5(b)–(c).

218. See *id.* para. 5(c).

included Thailand²¹⁹ and Brazil,²²⁰ both in connection with the HIV/AIDS drug Efavirenz.

TRIPs, as informed by Doha, thus expresses a particular concern with the abuses or insufficiencies of IP regimes that may have a direct impact on health-related issues. Further, it provides countries with the ability to incorporate tools to respond to these problems in their domestic laws. As documented in IP scholarship, and as illustrated by the case study on HIV-prevention drugs in the United States, these tools have only been used in limited circumstances. For instance, while holding great potential, compulsory licensing has been sparse across the Global South, and driven primarily by the larger economies of the South.²²¹

Furthermore, even though TRIPs contribute to the legal framework that individual countries can use to address the over-maximization of patent rights resulting in price gouging and exclusion of populations indicated for a drug, there is little enabling power in the Agreement to address issues related to other aspects of IP—namely problems surrounding incentives for drugs regarded as having limited markets. The case study in Part II addressed the case of vaccines for infectious diseases, but drugs targeting neglected tropical diseases²²² or orphan diseases²²³ face similar incentives problems. Similarly, TRIPs-based solutions can do little to address the types of informational asymmetries in bargaining that are common in practice, as seen in the case of Golden Rice.

219. *Thailand Issues Compulsory Licence For Patented AIDS Drug*, INT'L CTR. FOR TRADE & SUSTAINABLE DEV (Dec. 13, 2006), <https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug>. See generally Holger P. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, in 7 WORLD TRADE REVIEW 584 (2007) (describing other instances of compulsory licensing of pharmaceuticals—or threat thereof—in the Global South).

220. *Brazil Issues Compulsory Licence For Aids Drug*, INT'L CTR. FOR TRADE & SUSTAINABLE DEV. (May 8, 2007), <https://ictsd.iisd.org/brazil-issues-compulsory-licence-for-aids-drug> [https://perma.cc/2XTD-7UN4] (archived Feb. 15, 2021).

221. A recent development that bolstered the compulsory licensing framework for pharmaceuticals—and which gives countries in the Global South additional tools to address public health crises—was a 2017 amendment to TRIPs, which codified the possibility of compulsory licenses being issued for the export of pharmaceuticals, replacing a temporary waiver under paragraph 6 of the Doha Declaration. See TRIPs Agreement, *supra* note 24, art. 31; see also William New, *It's Official: TRIPS Health Amendment in Effect, First Ever to A WTO Agreement*, INTELL. PROP. WATCH (Jan. 23, 2017), <https://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/> [https://perma.cc/9CG9-4962] (archived Jan. 21, 2021).

222. *Control of Neglected Tropical Diseases*, WORLD HEALTH ORG., https://www.who.int/neglected_diseases/diseases/en/ (last visited Jan. 21, 2021) [https://perma.cc/8NYC-NYSV] (archived Jan. 21, 2021).

223. *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> (last visited Jan. 21, 2021) [https://perma.cc/FU42-S9N7] (archived Jan. 21, 2021).

The following subpart suggests that viewing IP as a determinant of health might be useful to locate additional fixes for ongoing problems rooted in patent regimes that detrimentally affect health outcomes and health risks.

B. Complementing the Toolkit of Determinants of Health Through IP

Interventions informed by determinants of health frameworks may indirectly address some dysfunctions originating in patent regimes. However, they are limited in scope and are unlikely to address, let alone remove, the cause of the IP-related phenomenon that aggravates negative health outcomes and increases health risks. Consider the case of HIV-prevention drugs discussed in Part II.A. An intervention affecting one or more determinants—namely, income or education levels—might mitigate the problem for individual patients and thus produce effects on an *ad hoc* basis, but it is unlikely to provide any mechanisms that can be used in the short term to prevent systemic infection. Moreover, these interventions cannot eliminate the root of excessive pricing practices, which in itself represents a malfunction of a legal regime.

In this subpart, the Article turns to possible pathways to mitigate the impact of IP-enabled behaviors that detrimentally affect health outcomes and health risks. The first one is aimed at problems that currently allow for either excessive pricing of health-related goods, such as price gouging of HIV prevention drugs, or uncertainties surrounding the IP status of ancillary technologies needed to develop products capable of lessening malnutrition or other ailments through nonclinical interventions (such as the case of cloudy information and bargaining asymmetries in the licensure of Golden Rice): it shows how existing legal mechanisms—liability rules—can be tailored to offset some of the problems surveyed in Part II. The second pathway focuses on an emerging solution to the incentives side of the problem: transnational partnerships that have emerged in the health space (such as the case of scarcely incentivized R&D on vaccines). These are not meant to be a complete treatment of the areas surveyed, but rather an indication of possible pathways that can be pursued under a view that certain components of IP regimes produce effects that can determine—and often do determine—the production of undesirable health outcomes, or the accentuation of health risks among vulnerable populations.

More broadly, the Article notes that recognizing the role of IP as a determinant of health also sheds light on the need for a greater cross-pollination between traditional, institutional IP, and non-IP actors, particularly at the international level.

Certain embodiments of IP—dysfunctional ones, but in any case, actual ones—have contributed to the creation of patent regimes in

which the grant of proprietary rights may be instrumentally used to restrict access to pharmaceutical or biotech products that can be used to improve health outcomes and reduce health risks. One of those instrumental uses of IP results in the excessive pricing of pharmaceuticals, as illustrated by the example of Truvada for PrEP in the context of an HIV epidemic. Another constitutes a byproduct of the creation of patent thickets around health-related technologies, as seen in the case of Golden Rice. These behaviors increase transaction costs, obscure informational signals, and accentuate bargaining imbalances between rights holders and follow-on innovators.

The most direct fix for these types of problems is located at the national level through legislative or governmental interventions, or both. In Europe, for instance, there are price controls in place that impede some of the extreme gouging that occurs with regard to pharmaceuticals in the United States.²²⁴ International IP law, through compulsory licensing regimes as outlined above, provides governments with an operational framework to address problems related to the scarcity of health-related goods on the supply side.

These types of interventions, however, are often fraught with practical and political economy constraints. In the United States, for instance, pre-TRIPs (and TRIPs-compatible) legislation, like the Bayh-Dole Act,²²⁵ gives the government the ability to “march-in” on patents held by entities in the private sector covering publicly funded inventions.²²⁶ Funding agencies retain the ability to force the licensure of inventions to third parties in certain situations, including instances in which forced licensure is needed to “alleviate health or safety needs which are not reasonably satisfied” by the way the rightsholder is practicing the invention.²²⁷ In practice, however, no “march-in” petitions have ever been granted in the United States, even though they have been brought in connection with pharmaceutical drugs.²²⁸

224. See, e.g., Austin Frakt, *To Reduce the Cost of Drugs, Look to Europe*, N.Y. TIMES (Oct. 19, 2015), <https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs-look-to-europe.html> [https://perma.cc/5B94-2KLC] (archived Jan. 21, 2021); David Gross, Jonathan Ratner, James Perez, Sarah L. Glavin, *International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom*, 15 HEALTH CARE FIN. REV. 127, 127 (1994).

225. Bayh-Dole Act, 35 U.S.C. §§ 200 *et seq.*, Pub. L. No. 96–517, 94 Stat. 3015 (1980).

226. See 35 U.S.C. § 203.

227. See 35 U.S.C. § 203(b); see also, Christopher Rowland, *A Rare Deterrent to Limitless Drug Price Increases May Die Under Trump*, WASH. POST (Apr. 18, 2019), <https://perma.cc/4XHY-GGX6> (quoting the academic view that “[t]he idea that the price is too high fits pretty comfortably in the wording of the statute”).

228. See, e.g., NAT'L INST. OF HEALTH, OFF. OF THE DIR., DETERMINATION IN THE CASE OF PETITION OF CELLPRO, INC., <https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf> [https://perma.cc/7WKJ-UEB8] (archived Jan. 15, 2021) (denying a march-in petition of a stem cell separation device based on § 203(a)(2) public health grounds).

While legal frameworks enabling the government-administered licensure of patents (under certain circumstances and subject to certain criteria) exist in domestic IP regimes in the North and South—namely in the form of compulsory licensing—they have proved underused thus far, with the exception of a few countries in the South.²²⁹

An alternative to the *ex post* intervention of governments through compulsory licensing is the *ex ante* establishment of liability regimes for certain types of patentable innovation—in the case at hand, in the form of a tailored liability regime focused on health-related areas that would allow for the forced licensure of technology needed when public health crises occur.

Elsewhere, this author has explored the possibility of liability regimes in connection with patentable vaccine technology.²³⁰ This framework may also be useful to mimic the effects of compulsory licensing in cases in which this mechanism, even though lawfully applicable, is not available for political economy or other reasons. Liability rules enable a second comer to use someone else's entitlement without consent and against the payment of an "objectively determined value."²³¹ This approach is in sharp contrast with proprietary modes of innovation, in which one or more patents shield the invention from unauthorized uses by second comers.²³²

Consider how these two regimes would operate differently in cases in which second comers have the ability to manufacture follow-on

229. See TRIPs Agreement, *supra* note 24, art. 31(b); see also Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. TECH. 1 (2020); Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015) (collectively exploring mechanisms beyond compulsory licensing). See generally Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. MED. ETHICS 247 (2009); Sapna Kumar, *Compulsory Licensing of Patents During Pandemics* (Jan. 6, 2021) (unpublished manuscript) (on file with author).

230. Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 5 TEX. A&M J. PROP. L. 1 (2020) [hereinafter Rutschman, *Property in Vaccine Markets*]; Ana Santos Rutschman, *The Vaccine Race in the Twenty-First Century*, 61 ARIZ. L. REV. 729 (2019) [hereinafter Rutschman, *The Vaccine Race*].

231. See, e.g., WILLIAM W. FISHER III, THE CANON OF AMERICAN LEGAL THOUGHT 401–13 (David Kennedy and William W. Fisher III eds., 2007); Louis Kaplow & Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 HARV. L. REV. 713 (1996); James E. Krier & Stewart J. Schwab, *Property Rules and Liability Rules: The Cathedral in Another Light*, 70 N.Y.U. L. REV. 440 (1995); Lucian A. Bebchuk, *Property Rights and Liability Rules: The Ex Ante View of the Cathedral*, 100 MICH. L. REV. 601 (2001); Carol M. Rose, *The Shadow of the Cathedral*, 106 YALE L.J. 2175 (1997); Andrew W. Torrance & Bill Tomlinson, *Property Rules, Liability Rules, and Patents: One Experimental View of the Cathedral*, 14 YALE J.L. & TECH. 138 (2011). See generally Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972).

232. See generally Calabresi & Melamed, *supra* note 231.

versions of prophylactic or preventative drugs and vaccines: under property rules, a follow-on innovator wishing to commercialize a cheaper version of such a drug or vaccine would need not only to obtain permission from the patentee(s), but also to support the transaction costs associated with the bargaining and licensure processes. If the patentee refused to negotiate, as it is currently allowed to, the follow-on innovator would not be able to make, use, or distribute the technology (or perform protected processes) for the duration of the relevant patent(s). By contrast, under a liability model, the same innovator would not have to wait for permission to commercialize a competing product. Rather, the second comer would “take and pay” for the technology irrespective of the will of the patentee, who would nonetheless be monetarily compensated by a third-party use of the technology.²³³

This example should not be understood as a suggestion that all types of socially valuable innovation—or even innovation in the pharmaceutical and agtech fields—should be subjected to liability frameworks. Rather, as in previous writings,²³⁴ this Article argues that it is possible to utilize existing legal constructs in narrowly tailored ways to address especially acute cases of transactional inefficiencies known to contribute to an increase in health risks or poor health outcomes for especially vulnerable populations. This author has argued in the past that a closed-list, narrowly-defined liability regime covering some components needed to develop vaccines against emerging pathogens would warrant consideration by policymakers and lawmakers,²³⁵ especially as patent holders generally do not expect a meaningful return on investment in this area.²³⁶ Conversely, a liability

233. See Jack M. Balkin & Ian Ayres, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L.J. 703, 704 (1996).

234. See Rutschman, *The Vaccine Race*, *supra* note 230, at 762–70. See generally Rutschman, *Property in Vaccine Markets*, *supra* note 230.

235. Rutschman, *The Vaccine Race*, *supra* note 230, at 767. But see *id.* at 768–69 (acknowledging the drawbacks of this proposal, including the likely need for legislative intervention to establish such a liability regime, however tailored). For an example of a different type of tailored liability regime proposed by legal scholars, consider, for instance, the work of Jerome Reichman and Tracey Lewis, who have proposed a liability regime focused on traditional knowledge and specifically designed to encourage small-scale innovation in developing countries. See Jerome H. Reichman & Tracey Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME* 337, 354–65 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

236. See, e.g., COAL FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI), PRELIMINARY BUSINESS PLAN 2017-2021 12 (2016), https://cepi.net/wp-content/uploads/2019/02/CEPI-Preliminary-Business-Plan-061216_0.pdf [https://perma.cc/UR E7-D88S] (archived Feb. 24, 2021) [hereinafter CEPI PRELIMINARY BUSINESS PLAN] (noting that “it is anticipated that vaccines developed with CEPI support will not be profitable”).

regime covering next-generation vaccine technology—such as the case of mRNA vaccines, which were made available for the first time during the COVID-19 pandemic²³⁷—would be ill-advised. This is an area in which the R&D landscape is much more populated, well-funded, and programmatically different from the lacking R&D pipeline that unites the case studies presented in Part II.

Beyond these particular illustrations, the broader point here is that there are legal solutions that would be less taxing on the political economy than some of the IP mechanisms considered (but seldom used) to address large public health crises, such as compulsory licensing to march-in rights.²³⁸

From an international IP perspective, narrowly tailored liability regimes targeting a specific and limited set of health goods or technologies would be compatible with the TRIPs precept that patents should be granted across fields of technology.²³⁹ A liability approach, especially if implemented surgically, does not do away with the metaphoric bundle of rights conferred by the grant of a patent. Rather, it limits the ability of the rights holder to refuse to license in exchange for a compensatory payment—which should offset some of the economic losses potentially endured by the rightsholder—in areas in which market-driven business models render return-on-investment difficult or, in some cases, virtually impossible.²⁴⁰

From a public health perspective, tailored liability regimes have the potential to make follow-on innovation less cumbersome (from a transactional perspective) and less costly in areas in which the development and production of critical health goods is traditionally underincentivized. As such, they constitute an example of an IP intervention that is closely aligned with the goals of corrective interventions informed by determinants of health frameworks. For instance, given the heightened importance of active ingredients in drugs needed to prevent HIV infections (or components of engineered crops or foods), a narrowly construed liability regime could be created for these critical components in cases of significant public health need. If created, a liability regime could be instrumental in attracting follow-on innovators (in the form of generic competitors) during epidemics of infectious diseases like HIV, or to boost competition for interventions targeting malnutrition in rural areas or the Global South. Similarly, a liability regime can instill competition in markets in which, through a

237. See, e.g., Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, NEW ENGL. J. MED. 1920, 1921 (Jul. 14, 2020), <https://www.nejm.org/doi/full/10.1056/nejmoa2022483> [https://perma.cc/2JCR-EQ49] (archived Feb. 15, 2021).

238. *Supra* Part III.A; see also Kumar, *supra* note 229.

239. See TRIPs Agreement, *supra* note 24, art. 27.1 (establishing patent protection for meritorious inventions in “in all fields of technology”).

240. See Rutschman, *The Vaccine Race*, *supra* note 230, at 752–54.

combination of IP and non-IP determinants of health, certain populations have limited or no access to life-changing or life-saving drugs.

In this sense, and although liability regimes are often discussed as mechanisms designed to further economic efficiency by reducing transaction costs,²⁴¹ they also promote distributive justice²⁴²—which is one of the main goals of interventions based on determinants of health frameworks—as they facilitate the development of, and access to, critical health technologies that are needed to improve health outcomes and reduce health risks.

The proposal sketched above focuses on an intervention aimed primarily at addressing transactional issues related to IP and enabling follow-on innovation, particularly in areas where lack of affordable goods or technologies is bound to result in detrimental effects to health risks and outcomes. Liability regimes, however, cannot guarantee that a certain drug or food technology will be produced in the first place. A different type of solution is needed to respond to problems arising in situations of insufficient incentives to R&D provided (at least partly) by IP regimes. In response to this need, the creation of large-scale public-private partnerships has recently emerged as a form of transnational self-organization designed to counter lacking incentives regimes in biopharmaceutical R&D.²⁴³

As seen in Part II, drugs and vaccines needed to both prevent and respond to public health crises—from infectious diseases now largely concentrated in economically disadvantaged areas like HIV to events felt at a global scale like COVID-19—are among the most routinely underfunded tools in public health preparedness. Until the early 2000s, there were very few multilateral responses to problems posed by the misalignment between IP incentives frameworks and R&D on underfunded diseases.²⁴⁴

One of the earliest attempts to address the lacking incentives framework for traditionally underfunded diseases resulted in the formation of the Drugs for Neglected Diseases Initiative (DNDi) in

241. See, e.g., Calabresi & Melamed, *supra* note 231, at 1093; Kaplow & Shavell, *supra* note 231, at 718.

242. See Calabresi & Melamed, *supra* note 231, at 1110.

243. See generally THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT (Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif eds., 2018); JON F. MERZ, INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS (2005); Roy Widdus, *Public-private Partnerships for Health: Their Main Targets, Their Diversity, and Their Future Directions*, 79 BULL. WORLD HEALTH ORG. 713 (2001), <https://apps.who.int/iris/bitstream/handle/10665/268389/PMC2566486.pdf?sequence=1&isAllowed=y> [https://perma.cc/4KLB-BQQL] (archived Jan. 16, 2021).

244. See MERZ, *supra* note 243, at 17.

2003.²⁴⁵ DNDI is a nonprofit R&D organization focused on the development of “urgently needed treatments for neglected patients” at “affordable” prices.²⁴⁶ The diseases the organization targets are largely prevalent in, although not exclusive to, the Global South, including sleeping sickness, Chagas disease, cutaneous and visceral leishmaniasis, hepatitis C, river blindness, mycetoma, and pediatric HIV.²⁴⁷

From 2003 to 2023, DNDI operates with funding from the public (57 percent) and private (43 percent) sectors.²⁴⁸ Public donors include governments and public-sector institutions from countries in Europe (including the European Union), Asia, America, and Australia, as well as nonprofit organizations like Unitaid and The Global Fund to Fight AIDS, Tuberculosis and Malaria.²⁴⁹ Among the governmental funders, there are several emerging economies of the Global South, including Brazil, Colombia, and Thailand.²⁵⁰ And in contrast with recent trends in international cooperation, the United States remains a funder to DNDI through the United States Agency for International Development (USAID).²⁵¹

Private funding is provided through heterogeneous donor types. These include different branches of *Médecins Sans Frontières* (Doctors without Borders), several foundations (including the Bill & Melinda Gates, the Stavros Niarchos, and the Rockefeller Foundations in the United States, the Carlos Slim Foundation in Mexico and the Medicor Foundation in Liechtenstein), the Japanese pharmaceutical Takeda, the Wellcome Trust in the United States, private companies operating outside the health arena (including Goldman, Sachs & Co.), as well as named individuals and anonymous individual and foundation donors.²⁵²

DNDI likens its role to that of “a conductor of a ‘virtual orchestra’ of over 180 partners around the world to develop treatments for patients—not profits . . . [b]y bringing together the public, private,

245. See DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/> (last visited Jan. 16, 2021) [<https://perma.cc/E7CT-E3VR>] (archived Jan. 16, 2021).

246. *Id.*

247. See *Diseases*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/diseases/> (last visited Jan. 16, 2021) [<https://perma.cc/L22Y-E5MS>] (archived Jan. 16, 2021).

248. See *Our Donors*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/about/donors/> (last visited Jan. 16, 2021) [<https://perma.cc/TK9M-4QTK>] (archived Jan. 16, 2021).

249. See *Our Donors: Public Donors*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/about/public-donors/> (last visited Jan. 16, 2021) [<https://perma.cc/9XR5-9DYX>] (archived Jan. 16, 2021).

250. *See id.*

251. *See id.*

252. See *Our Donors: Private Donors*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/about/private-donors/> (last visited Jan. 16, 2021) [<https://perma.cc/28EH-F3SS>] (archived Jan. 16, 2021).

academic, non-profit, and philanthropic sectors.”²⁵³ By supporting and coordinating R&D specifically targeted to traditionally underfunded diseases and underserved populations, DNDI was one of the earliest public-private partnerships operating in the pharmaceutical R&D space.²⁵⁴ Between the early 2000s and the late 2010s, dozens of public-private partnerships dedicated to pharmaceutical or biopharmaceutical R&D were launched every year.²⁵⁵ Some took a more general-purpose approach to innovative R&D. For instance, the Innovative Medicines Initiative,²⁵⁶ to date the largest public-private partnership in the life sciences operates in twelve strategic areas, ranging from antimicrobial resistance to cardiovascular, neurodegenerative, psychiatric, and respiratory diseases.²⁵⁷ Others, by contrast, chose to focus in a single area, as is the case of the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), which funds “antibacterial research to tackle the global rising threat of drug-resistant bacteria.”²⁵⁸ Yet others are more oriented towards the development of a specific type or types of health technologies. A recent and already salient example is the case of the Coalition for Epidemic Preparedness Innovations (CEPI), a public-private partnership launched in the wake of the 2014–16 Ebola outbreak as a direct response to the longstanding and widely acknowledged underinvestment in R&D on vaccines, particularly in the field of emerging infectious diseases.²⁵⁹ Launched in 2017, CEPI was designed as a “gap” filler, funding and coordinating the development of new vaccines for diseases classified by the World Health Organization as emerging and in need of “priority” R&D.²⁶⁰ Less than three years later, as the COVID-19 pandemic began to

253. See *How We Work*, DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org/about/how-we-work/> (last visited Jan. 16, 2021) [<https://perma.cc/HV4B-ZLB3>] (archived Jan. 16, 2021).

254. See MERZ, *supra* note 243, at 17.

255. *See id.*; see also Mark D. Lim, Comment, *Consortium Sandbox: Building and Sharing Resources*, 6 SCI. TRANSLATIONAL MED. 1, 2 (2014).

256. See *About IMI*, INNOVATIVE MEDICINES INITIATIVE, <https://www.imi.europa.eu/about-imi> (last visited Jan. 16, 2021) [<https://perma.cc/ND2T-WDY5>] (archived Jan. 16, 2021).

257. See *Strategic Research Agenda*, INNOVATIVE MEDICINES INITIATIVE, <https://www.imi.europa.eu/about-imi/strategic-research-agenda> (last visited Jan. 16, 2021) [<https://perma.cc/7CED-MA9C>] (archived Jan. 16, 2021).

258. See *About*, CARB-X, <https://carb-x.org/about/overview/> (last visited Jan. 16, 2021) [<https://perma.cc/M2GY-FKTE>] (archived Jan. 16, 2021).

259. See *Why We Exist*, CEPI, <https://cepi.net/about/whyweexist/> (last visited Jan. 16, 2021) [<https://perma.cc/V9AT-RSAF>] (archived Jan. 16, 2021).

260. CEPI PRELIMINARY BUSINESS PLAN, *supra* note 236, at 10–11; see also Rutschman, *The Intellectual Property of Vaccines*, *supra* note 119, at 182.

unfold, CEPI was among the earliest and most significant funders of R&D on COVID-19 vaccines.²⁶¹

All of the organizations mentioned above operate predominantly as (co)funders and coordinators of R&D efforts among a plurality of transnational entities. They are known in the literature as “product development” public-private partnerships. These partnerships differ from “access partnerships,” which typically place large advance orders of goods (either fully developed or undergoing development, as is presently the case with COVID-19 vaccines²⁶²) as a way to nudge the development and manufacturing of products that can then be distributed at relatively affordable prices.²⁶³

One of the earliest examples of a health-oriented public-private partnership was Gavi, the Vaccine Alliance, which was established in Switzerland in 2000 and quickly became the coordinator of the largest procurement mechanism for childhood vaccines needed in the Global South.²⁶⁴ Gavi is now involved in the procurement of vaccines targeting COVID-19 through the COVID-19 Vaccine Global Access Facility (COVAX), a partnership created in summer 2020 to address the twin problems of manufacturing and allocation of vaccines at the global level.²⁶⁵ Through COVAX, Gavi has placed orders with different pharmaceutical companies before for vaccines that have yet to be approved by the competent regulatory authorities at the domestic level (such as the European Medicines Agency or the U.S. Food and Drug Administration).²⁶⁶ These advance commitments allow for at-risk manufacturing of vaccines, paving the way for the quickest distribution possible of the first batches of vaccine—provided that such distribution is cleared by regulatory authorities.²⁶⁷

Critically, the combination of product development and access partnerships illustrates the interdependence of incentives regimes,

261. *CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV-2019*, CEPI (Jan. 23, 2020), https://cepii.net/news_cepii/cepii-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/ [https://perma.cc/5526-2J7K] (archived Jan. 16, 2021).

262. See, e.g., Helen Branswell, *WHO, Partners Unveil Ambitious Plan to Deliver 2 Billion Doses of Covid-19 Vaccine to High-Risk Populations*, STAT (June 26, 2020), <https://www.statnews.com/2020/06/26/who-partners-unveil-ambitious-plan-to-deliver-2-billion-doses-of-covid-19-vaccine-to-high-risk-populations/> [https://perma.cc/U9YM-GJYU] (archived Jan. 15, 2021) (describing the formation of the public-private partnership COVAX).

263. See generally MERZ, *supra* note 243, at 2–4 (describing the differences between product development and access partnerships).

264. See *About Our Alliance*, GAVI, <https://www.gavi.org/our-alliance/about> (last visited Jan. 16, 2021) [https://perma.cc/34YE-5TBW] (archived Jan. 16, 2021).

265. See *COVAX Explained*, GAVI, <https://www.gavi.org/vaccineswork/covax-explained> (last visited Jan. 16, 2021) [https://perma.cc/L92S-9VML] (archived Jan. 16, 2021).

266. See *id.*

267. See *id.*

R&D processes, and the political economy. Addressing the problems posed by the ongoing underfunding of certain diseases (or types of health technologies) is bound to require a multiplicity of interventions, involving heterogenous players across geopolitical borders. Insofar as some of these problems are umbilically connected to IP dynamics, many non-IP players have played an integral role in transnational collaborations aimed at improving current R&D frameworks and enhancing access to health goods by populations in need. Conversely, IP players, norms, and policies have shaped the living conditions, health risks, and health outcomes of populations across the globe—especially in economically depressed or otherwise underserved areas of both the South and the North.

A holistic understanding of IP as a determinant of health will thus likely translate into the recognition that it is necessary to amplify IP debates in public health arenas and other non-IP venues, and to further recognize the role of transnational non-IP public health actors in interventions that have the potential to mitigate some of the imbalances introduced (or accentuated) by overly proprietary IP regimes. At the same time, actors moved by determinants of health frameworks would likely benefit from becoming more IP-literate and increasing their interaction with traditional IP players (such as the World Intellectual Property Organization or offices offering technical assistance in the field of IP at the domestic level), as well as with players in indirect IP fora—from the World Health Organization²⁶⁸ to public-private partnerships operating in pharmaceutical R&D or other fields related to public health.

IV. CONCLUSION

If IP is the default regime to incentivize innovation—including that in pharmaceutical, biopharmaceutical, and agricultural industries—then the ways in which these types of innovation are produced, distributed, or made available may have an impact on nonclinical factors that directly influence health risks and outcomes. This Article has provided an overview of how certain embodiments of post-TRIPs IP have come to have such an influence, primarily in ways that exclude or limit the access of certain populations to critical health goods. The Article has further posited that IP can and should be regarded as a determinant of health proper. This understanding would enable lawmakers and policymakers, as well as activists in non-IP domains, to consider additional solutions when seeking to remedy structural inequities affecting health risks and outcomes.

268. See Laura Pedraza-Fariña, *The Intellectual Property Turn in Global Health*, 36 OSIRIS (forthcoming 2021) (draft on file with author).