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Intellectual Property as a Determinant of Health

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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 socio-economic 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 paper conceptualizes post-TRIPs IP as a contributing element to the literature on the socio-economic 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

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international IP regimes. This paper 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 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 paper 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.

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I. IP AND THE DETERMINANTS OF HEALTH: CURRENT PERSPECTIVES

A. THE FRAMEWORK FOR THE SOCIO-ECONOMIC DETERMINANTS OF HEALTH

Public health-oriented scholars, policymakers and institutions have long recognized the existence of a series of non-clinical factors that affect the health of populations across the globe. Known as the determinants of health, these factors consist in a set of socio-economic 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 non-clinical factors that ultimately have an impact on the quality of life and health outcomes associated with certain populations.² These factors include race, ethnicity,

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

² See e.g Allan S. Noonan et al., *Improving the Health of African Americans in the USA: An Overdue Opportunity for Social Justice*, 37 PUB. HEALTH REV. 12 (2016); U.S. NAT’L CTR. HEALTH STATS., HEALTH, UNITED STATES, 2015: WITH SPECIAL FEATURE ON RACIAL AND ETHNIC HEALTH DISPARITIES (2015), <https://www.cdc.gov/nchs/data/hus/hus15.pdf>; U.S. CTRS. DISEASE CONTROL & PREVENTION, RACIAL AND ETHNIC DISPARITIES CONTINUE IN PREGNANCY-RELATED DEATHS (Sept. 5, 2019); (collectively documenting race- and ethnicity-based disparities). See also DovileVilda et al., *Income Inequality and Racial Disparities in Pregnancy-Related Mortality in the US*, 9 SSM POP. HEALTH 1 (2019) (focusing on income inequality); Keith P. Gennuso et al., *Deaths of Despair(ity) in Early 21st Century America: The Rise of Mortality and Racial/Ethnic Disparities* 57 AM. J. PREVENTIVE MED. 585 (Sept. 24, 2019) (focusing on diseases of despair).; David Hartley, *Rural Health Disparities, Population Health, and Rural Culture*, 94 AM. J. PUB. HEALTH 1675 (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, PENGUIN (2017).

gender, state of residency (or even zip code within a city),³ education, class⁴ and income.⁵ Similar studies have arrived at comparable conclusions within other countries in the Global North,⁶ as well as within countries across the 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 heterogenous in origin and kind, these inequalities have been found to share

³ See Jay Bhatt, *Your Zip Code, Your Health*, AM. HOSP. ASS'N (May 16, 2018). See also ROBERT WOOD JOHNSON FOUND., COULD WHERE YOU LIVE INFLUENCE HOW LONG YOU LIVE?, <https://www.rwjf.org/en/library/interactives/whereliveaffectshowlongyoulive.html>.

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

⁵ Dhruv Khullar & Dave A. Chokshi, *Health, Income, & Poverty: Where We Are & What Could Help*, HEALTH AFF. BRIEF (Oct. 4, 2018) [Hereinafter *Health, Income, & Poverty*].

⁶ See e.g. Johan P. Mackenbach et al., *Trends in Health Inequalities in 27 European Countries*, 115 PROCEEDINGS NAT'L ACAD. SCI. 6440 (Jun. 19, 2018); Churnrurtai Kanchanachitra & Viroj Tangcharoensathien, *Health Inequality Across Prefectures in Japan*, 390 LANCET 1471 (Sept. 23, 2017); AUST. INST. HEALTH & WELFARE, Gavin Turrell et al., *Health Inequalities in Australia: Morbidity, Health Behaviours, Risk Factors and Health Service Use* (Apr. 6, 2007).

⁷ See e.g. Alba Llop-Gironés et al., *Inequalities in the Access to and Quality of Healthcare in Mozambique: Evidence from the Household Budget Survey*, 31 INT'L J FOR QUAL. HEALTH CARE 577 (2019); Nandini Oomman, *Uzbekistan Inequalities in Health, Nutrition and Population*, World Bank Report (2003), <https://elibrary.worldbank.org/doi/abs/10.1596/29578>; Celia Landmann-Szwarcwall & James Macinko, *A Panorama of Health Inequalities in Brazil*, 15 INT'L J. EQUITY HEALTH 174 (2016). See generally Christopher Garimoi Orach, *Health Equity: Challenges in Low Income Countries*, 2 AFR. HEALTH SCI. 49 (2009); Davidson R Gwatkin, *Trends in Health Inequalities in Developing Countries*, 5 LANCET 371 (Apr. 1, 2017).

⁸ Marmot, *supra* note 1, at 1099. See e.g. WORLD HEALTH ORG., FACT FILE ON HEALTH INEQUITIES, <https://www.who.int/sdhconference/background/news/facts/en/> (noting, inter alia, a “36-year gap in life expectancy” between Malawi and Japan).

⁹ See e.g. Ichiro Kawachi, *Socioeconomic Determinants of Health: Health And Social Cohesion: Why Care About Income Inequality?*, 314 BRITISH MED. J. 1037 (Apr. 5, 1997).

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 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 including 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 others, as well as

¹⁰ Marmot, *Social Determinants of Health Inequalities*, *supra* note 1, at 1101.

¹¹ *Id.*, *ib.*

¹² WORLD HEALTH ORG., SOCIAL DETERMINANTS OF HEALTH, https://www.who.int/social_determinants/en/

¹³ *Id.*, *ib.*

¹⁴ See e.g. NEW ZEALAND NAT’L ADVISORY COMM. HEALTH & DISABILITY, *The Social, Cultural and Economic Determinants of Health in New Zealand: Action to Improve Health* (1999), at 23,

<https://www.health.govt.nz/system/files/documents/publications/det-health.pdf>. See also Yannish Naik et al., *The*

commentators and policymakers, take a hybrid approach, speaking of socio-economic 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 co-exist. 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 determinants include exposure to toxic substances, interaction with the built environment, as well as consequences of climate change.²¹

Macro-Economic Determinants of Health and Health Inequalities—Umbrella Review Protocol, 6 SYST REV. 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 2018), <http://files.kff.org/attachment/issue-brief-beyond-health-care>.

¹⁶ *Supra*, note 12.

¹⁷ Health Impact Assessment are 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.” EUR. CTR. HEALTH POL’Y., HEALTH IMPACT ASSESSMENT (Gothenburg, 1999), http://www.healthedpartners.org/ceu/hia/hia01/01_02_gothenburg_paper_on_hia_1999.pdf.

¹⁸ WORLD HEALTH ORG., HEALTH IMPACT ASSESSMENT (HIA), <https://www.who.int/hia/en/>.

¹⁹ U.S. OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION, SOCIAL DETERMINANTS OF HEALTH, <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health> (2020).

²⁰ *Id.*

²¹ *Id.*

The unifying thread in how existing definitions of determinants of health are populated resides in the fact 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 non-clinical in nature, even if they might create the need for clinical interventions. Recent studies looking at premature death rates have underlined the relevance of non-clinical factors in health outcomes: currently, only 10% of premature deaths in the United States are linked to issues arising in the context of clinical care; 30% of premature deaths are attributable to genetic factors; and 60% are attributable to social, environmental and behavioral factors that fall under the general umbrella of socio-economic determinants of health.²³

This article uses the expression “socio-economic determinants of health” in an expansive way, to include all types of non-clinical 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 section, the 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 non-legal fields alike. Since the Agreement on Trade-Related Aspects of

²² Jennifer Prah Ruger, *Ethics of the Social Determinants of Health*, 364 LANCET 1092, 1092 (Sept. 18, 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/doi/10.1377/hblog20171025.721263/full/>.

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 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

²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement].

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 LAW & TECH. J. 125 (2004); Bryan C. Mercurio, *TRIPs-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM, in LORAND BARTELS & FEDERICO ORTINO, EDs., (2006); Susan K. Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, AM. U. RESEARCH PAPER NO. 15 (2010).

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 (CARLOS M. CORREA ED., 2010), 52-109.

²⁷ See e.g. Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPs Agreement and Public Health*, 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 Rajec, *The Harmonization Myth in International Intellectual Property Law* (draft on file with author) (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. R. 21, 21-22 (2004).

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 biotechnologies, 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 and even when compelled to apply the patent floors mandated by the Agreement, it carved out a patentability regime for pharmaceutical innovations that is 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

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. Law 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. PITT. L. REV. 491 (2007).

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

were then structured.”³³ The foundational IP treaties,³⁴ whose ethos and many a provision were absorbed by TRIPs,³⁵ pre-date 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; but 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 universe of determinants of health, at least as currently adopted for operational purposes.

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 (as revised on July 14, 1967 in Stockholm).

³⁵ TRIPs Agreement, Articles 2 and 9.

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

³⁷ See *infra*, case study on HIV prevention drugs in the United States.

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

Socio-economic 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. In this area, and 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

³⁹ Jennifer Prah Ruger, *Ethics of the Social Determinants of Health*, 364 LANCET 1092, 1092 (Sept. 18, 2004).

⁴⁰ *Infra*, Part II.

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 instance, recent studies have shown that the manufacturers of the eight best-selling biologics 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 Administration⁴⁴ and product hopping,⁴⁵ sponsors of these drugs estimate that follow-on competitors are not able to enter the market for periods ranging from 31 to 48 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

⁴¹ See Inmaculada Hernandez et al., *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, 38 HEALTH AFF. (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).

⁴³ See IMAK, *OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES* (2018), at 2.

⁴⁴ See e.g. Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015); 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 Karshedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129 (2019).

⁴⁶ *Supra* note 43.

⁴⁷ *Supra* note 25.

recent years has not increased the prices of pharmaceuticals in developing countries.⁴⁸ Work by Kapczynski, Sampat and Shadlen, however, has 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 has 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 access of indicated patients 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% effective in prevention 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 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 socio-economic 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

⁴⁸ See Thomas J. Bollyky, *What Past Trade Deals Reveal About Drug Pricing*, FOREIGN AFF. (Oct. 28, 2016).

⁴⁹ Amy Kapczynski et al., *Trade Agreements, Patents, and Drug Prices: Continuing the Debate*, 572 YALE L. & ECON. RESEARCH PAPER (2017) (further documenting several flaws in the Bollyky study).

IP discourses, 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, the article in 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 socio-economic 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 section 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

⁵⁰ 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, JONATHAN D. PUTNAM, ED. (2001); Rebecca S. Eisenberg, *Intellectual Property Issues in Genomics*, 14 TRENDS IN BIOTECH. 302 (1996).

⁵² See generally RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND CLIMATE CHANGE, JOSHUA D. SARNOFF, ED. (2016).

of the enabling factors for this exclusion is IP, through choices that are made at the beginning of, or during, R&D processes. The case studies thus seek to illustrate the impact of these choices on populations who are priced out of some inventions and populations who would benefit from relatively inexpensive medical technologies that 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 21ST CENTURY

As shown by Jerome Reichman and Rochelle Dreyfuss, progressive rounds of harmonization of international IP have had detrimental effects not only to populations in the Global South, but to 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 focused 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

⁵³ 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).

⁵⁴ See e.g. William W. Fisher III & Cyril 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>.

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 turned R&D on drugs that could be used in the treatment and prevention of HIV into a public health priority.⁵⁵

In the early 2000s, research demonstrated that a two-drug combo—emtricitabine and tenofovir disoproxil fumarate, which block an enzyme the virus needs in order to replicate itself within a human body—was effective in the treatment of HIV-positive patients. 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 The sponsor of the drug was Gilead, a large pharmaceutical company headquartered in California.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 initially decided not to promote Truvada as a

⁵⁵ See Ronald Bayer, *The Medicalization of HIV Prevention: New Opportunities Beset by Old Challenges*, 92 *Milbank Quarterly*, 3, 434 (2014) (summarizing the overall response to the AIDS epidemic in the United States).

⁵⁶ U.S. FOOD & DRUG ADMIN., TRUVADA APPROVAL LETTER, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_Truvada_Approv.pdf.

⁵⁷ GILEAD, <https://www.gilead.com>.

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

⁵⁹ U.S. CTRS. DISEASE CONTROL & PREVENTION, CDC STATEMENT ON FDA APPROVAL OF DRUG FOR HIV PREVENTION (Jul. 16, 2012), <https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html>; U.S. CTR'S DISEASE CONTROL & PREVENTION, PRE-EXPOSURE PROPHYLAXIS (PREP), <https://www.cdc.gov/hiv/risk/prep/index.html>.

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, and it has since 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 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 and 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

⁶⁰ NBC NEWS, *Switching Course, Gilead Markets HIV Drug for Prevention* (Nov. 30, 2016), <https://www.nbcnews.com/feature/nbc-out/switching-course-gilead-markets-hiv-drug-prevention-n690271>.

⁶¹ U.S. CTRS. DISEASE CONTROL & PREVENTION, HIV PREP GUIDELINES (May 14, 2014), <https://www.cdc.gov/nchhstp/newsroom/2014/PrEP-Guidelines-Press-Release.html>.

⁶² NBC NEWS, *Switching Course*, *supra* note 60.

⁶³ See Jason Rhode, *PrEP Drug Priced Out of Most People's Reach*, GEORGIA VOICE (Jul. 13, 2018), <https://thegavoice.com/news/national/prep-drug-priced-out-of-most-peoples-reach/>.

⁶⁴ <https://www.statnews.com/pharmalot/2020/02/05/gilead-hiv-patents-truvada-cdc/>.

⁶⁵ <https://www.statnews.com/pharmalot/2020/02/05/gilead-hiv-patents-truvada-cdc/>.

⁶⁶ <https://www.raps.org/regulatory-focus™/news-articles/2017/6/fda-approves-first-generic-version-of-gilead-s-hiv-drug-truvada>.

⁶⁷ Shefali Luthra & Anna Gorman, *Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many*, NPR (Jun. 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> (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/>.

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 it 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 higher than elsewhere in the Global North: in Australia, 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

⁶⁹ United States v. Gilead Sciences, Complaint [hereinafter Complaint] at 46.

⁷⁰ 2016 was the year prior to FDA approval of the first generic competitor to Truvada in the United States market.

⁷¹ GILEAD, *Press Release: 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>.

⁷² <https://www.statnews.com/pharmalot/2020/02/05/gilead-hiv-patents-truvada-cdc/>.

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>.

⁷⁴ *EU Door Opens for Generic Version of AIDS Medicine Truvada*, MEDICAL XPRESS (Jul. 26, 2018), <https://medicalxpress.com/news/2018-07-eu-door-version-aids-medicine.html>.

⁷⁵ Rowland, *Americans Pay \$US2000 for Drug Costing Aussies Less Than \$6*, *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.

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% in populations who do not use controlled substances, and at least 74% 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% of new HIV diagnoses, with Western states a distant second at 19%, followed by 16% in the Northeast and 13% 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% of all new reported infections occur among black and Latino gay and transgender populations.⁸² Among women—who account for slightly over 15% of

⁷⁷ HIV.GOV, WHAT IS ‘ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA’?, <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

⁷⁸ U.S. CTRS. DISEASE CONTROL & PREVENTION, PRE-EXPOSURE PROPHYLAXIS (PREP), <https://www.cdc.gov/hiv/risk/prep/index.html>.

⁷⁹ AIDSVU, Map (HIV Infection), <https://map.aidsvu.org/map> (providing an interactive account of the number of cases of HIV infection by county).

⁸⁰ U.S. CTRS. DISEASE CONTROL & PREVENTION, HIV IN THE UNITED STATES BY REGION (2018), <https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html> (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.

⁸² Robert Goldstein, *PrEP Prevents HIV — So Why Aren't More People Taking It?*, Harv. Health Blog (Oct. 4, 2019), <https://www.health.harvard.edu/blog/prep-prevents-hiv-so-why-arent-more-people-taking-it-2019100417942>.

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 167,000 people, is taking Truvada.⁸⁶ This corresponds to 18.1% 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 the major barriers for 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

⁸³ *Id., ib.*

⁸⁴ Robert H. Goldstein et al., *Being PrEPared — Preexposure Prophylaxis and HIV Disparities*, 379 N. ENG. J. MED. 1293 (Oct 4., 2018).

⁸⁵ U.S. CTRS. DISEASE CONTROL & PREVENTION, VITAL SIGNS: STATUS OF HUMAN IMMUNODEFICIENCY VIRUS TESTING, VIRAL SUPPRESSION, AND HIV PREEXPOSURE PROPHYLAXIS — UNITED STATES, 2013–2018 (Dec. 6, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm>.

⁸⁶ Shefali Luthra & Anna Gorman, *Rising Cost of PrEP to Prevent HIV Infection Pushes It Out of Reach for Many*, NPR (Jun. 30, 2018), *supra* note 67.

⁸⁷ U.S. CTRS. DISEASE CONTROL & PREVENTION, VITAL SIGNS: STATUS OF HUMAN IMMUNODEFICIENCY VIRUS TESTING, VIRAL SUPPRESSION, AND HIV PREEXPOSURE PROPHYLAXIS — UNITED STATES, 2013–2018 (Dec. 6, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm>.

⁸⁸ Goldstein et al., *Being PrEPared*.

⁸⁹ *Id., ib.*

⁹⁰ See Bernstein, *This HIV Pill Saves Lives*, *supra* note 81; United States v. Gilead Sciences, Complaint at 34.

commentators and AIDS activists have often pointed out: “We 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 term, only recently has their validity—and their instrumentalization in 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 non-prophylactic version,⁹³ the CDC was granted 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

⁹¹ See Anna Gorman, *Cost of PrEP Is Out of Most People's Reach*, HIV PLUS MAG. (July 9, 2018), <https://www.hivplusmag.com/prevention/2018/7/09/cost-prep-out-most-peoples-reach>. See also James Krellenstein et al., *Why Don't More Americans Use PrEP?*, N.Y. TIMES (July 2016, 2018), <https://www.nytimes.com/2018/07/16/opinion/prep-hiv-aids-drug.html>.

⁹² United States v. Gilead Sciences, Complaint at 1-2.

⁹³ U.S. FOOD & DRUG ADMIN., ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (TRUVADA), https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm.

⁹⁴ *Id.*, *ib.*

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/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html.

new indication from the FDA. The patents supporting Truvada for PrEP are thus the same that supported non-prophylactic versions of Truvada. One expires in late 2020, and the remaining throughout 2021.⁹⁶

Commentators and patent experts have made the case that the prophylactic emtricitabine-tenofovir combo is quite distinct from the non-prophylactic one.⁹⁷ For instance, it was 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 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 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

⁹⁶ U.S. FOOD & DRUG ADMIN., ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (TRUVADA), https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm.

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) (noting that “the U.S. government very rarely goes to court to enforce its patents”).

⁹⁸ Complaint at 25.

⁹⁹ See Christopher J. Morten & Amy Kapczynski, *United States v. Gilead: Can a Lawsuit Yield Better Access To PrEP?*, HEALTH AFF. BLOG (Nov. 18, 2019) (noting that “the U.S. government very rarely goes to court to enforce its patents”).

¹⁰⁰ *Id.*, *ib.*

declined.¹⁰¹ In November 2019, the United States 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 “recognized Gilead’s role in selling Truvada” but argued that “Gilead must respect the U.S. 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 “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 CDC’s patents “because we value our collaborative relationship with the agency.”¹⁰⁷ Three months later,

¹⁰¹ Complaint at 58.

¹⁰² U.S. DEP’T HEALTH HUM. SERV., PRESS RELEASE: 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>.

¹⁰³ U.S. DEP’T HEALTH HUM. SERV., PRESS RELEASE (NOV. 6, 2019), <https://www.hhs.gov/about/news/2019/11/06/us-files-patent-infringement-lawsuit-against-gilead-pre-exposure-prophylaxis-hiv.html>.

¹⁰⁴ Complaint, at 69.

¹⁰⁵ Complaint, at 37.

¹⁰⁶ Statement of Daniel O’Day, Chairman and Chief Executive Officer Gilead Sciences, Inc. before the Committee on Oversight and Reform U.S. House of Representatives (May 16, 2019), <https://docs.house.gov/meetings/GO/GO00/20190516/109486/HHRG-116-GO00-Wstate-ODayD-20190516.pdf>.

¹⁰⁷ Complaint, at 37.

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

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 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:

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

¹⁰⁸ Gilead v. U.S., IPR 2019-01455 (<http://freepdfhosting.com/0a58c071ad.pdf>); Gilead v. U.S., IPR 2019-01456 (<http://freepdfhosting.com/e4e6827eea.pdf>).

¹⁰⁹ 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>.

¹¹⁰ Ed Silverman, *Gilead Loses its Challenge to a Pair of U.S. Patents for an HIV Prevention Pill*, STAT (Feb. 5, 2020).

¹¹¹ Gilead was the sole manufacturer in the HIV PrEP space until 2017, at which point the FDA approved the first PrEP generic. See Michael Mezher, *FDA Approves First Generic Version of Gilead's HIV Drug Truvada*, RAPS (Jun. 9, 2017), <https://www.raps.org/regulatory-focus™/news-articles/2017/6/fda-approves-first-generic-version-of-gilead-s-hiv-drug-truvada>.

¹¹² Complaint, at 48-49.

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

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 which kinds of products enter the market, and that is conceptually and temporally distinguishable from pricing issues arising in connection with the commercialization of pharmaceuticals and biologic drugs.

¹¹³ These drugs, known as biologics, are structurally different from the category to which Truvada for PrEP belongs. They are subject to a separate R&D and regulatory approval processes and tend to be exponentially more expensive than conventional drugs.

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

¹¹⁵ U.S. FOOD & DRUG ADMIN., *List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, <https://www.fda.gov/media/105829/download>. See also 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*, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-price-competition>.

Utilitarian discourses depicting patents as incentives 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 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

¹¹⁶ See e.g. WILLIAM W. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW*, HARVARD UNIVERSITY PRESS (2003), at 316.

¹¹⁷ See e.g. SERVIER, *WHY PATENTS ARE NECESSARY FOR THE PHARMACEUTICAL INDUSTRY*, (Sept. 10, 2014), <https://servier.com/en/news/why-patents-are-necessary-for-the-pharmaceutical-industry/>.

¹¹⁸ See *infra* note 222 and accompanying text.

¹¹⁹ See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170 (2020) (addressing the problem of lacking R&D in the vaccine space); Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J. L. & BIOSCI. __ (2020).

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 the country’s post-9/11 bioterrorism preparedness strategy,¹²⁵ and then through work

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> (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. OF NOTE (2020) (noting the role of intellectual property in pandemic preparedness frameworks).

¹²² Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. Rev. 1200 (2018).

¹²³ *Id.*, at 1218-19.

¹²⁴ U.S. CTRS. DISEASE CONTROL & PREVENTION, WHAT IS EBOLA VIRUS DISEASE? (2019), <https://www.cdc.gov/vhf/ebola/about.html>

¹²⁵ U.S. NAT’L. INST. HEALTH, EBOLA VACCINES, <https://www.niaid.nih.gov/diseases-conditions/ebola-vaccines>

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 “make, use, improve, develop and commercialize” the vaccine.¹³¹ Until the beginning of the 2014-16 Ebola outbreak, however,

¹²⁶ Francis A. Plummer & Steven M. Jones, *The Story of Canada’s Ebola Vaccine*, 189 CAN. MED. ASS’N J. e1326 (2017); Matthew Herper et al., *From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*, __ J. L. & BIOSCI. __ (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>

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

¹³⁰ *Id.*, *ib.*

¹³¹ GOV’T OF CAN., *Sole License Agreement for Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers*, at G1, <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>

NewLink did not invest any resources on testing and manufacturing the vaccine.¹³² As journalist Denise Grady, put it: “Ebola vaccine, ready for test, sat on the shelf.”¹³³

Elsewhere, I have 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 which point it 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 non-patent incentives—is simply inadequate to further preparedness and public health goals. Against a backdrop of little to no economic return

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

¹³³ Grady, *supra* note 128.

¹³⁴ Rutschman, *supra* note 122, at 1244-48.

¹³⁵ *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>

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.

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 United States 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 pathogens resulting in respiratory illness—is among the areas the 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 non-events (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

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/> (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 p]ersistence of infectious diseases that cannot be controlled.” See JOHNS HOPKINS, WHAT ARE EMERGING INFECTIOUS DISEASES?, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/emerging-infectious-diseases>

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

¹⁴⁰ But see see Rino Rappuoli et al., *The Intangible Value of Vaccination*, 297 SCI. 937(2002); Meghan L. Stack et al., *Estimated Economic Benefits During The ‘Decade of Vaccines’ Include Treatment Savings, Gains in Labor*

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 use (or being studied) for a different indication.¹⁴⁵ Among these, the anti-viral remdesivir¹⁴⁶ emerged early on

Productivity, 30 HEALTH AFF. (2011) (collectively noting economic gains attributable to widespread vaccination of indicated populations).

¹⁴¹ See e.g. WORLD HEALTH ORG., RECOMMENDATIONS FOR ROUTINE IMMUNIZATIONS, https://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua (listing recommended doses for the most commonly administered vaccines across the world). See also Patricia M. Danzon et al., *Vaccine Supply: A Cross-National Perspective*, 24 HEALTH AFF. 706 (2005).

¹⁴² See e.g. WORLD HEALTH ORG., COLD CHAIN, VACCINES AND SAFE-INJECTION EQUIPMENT MANAGEMENT (2008), https://www.who.int/immunization/documents/MLM_module1.pdf

¹⁴³ 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. MILKEN INST., COVID-19 TREATMENT AND VACCINE TRACKER, https://covid-19tracker.milkeninstitute.org/#treatment_antibodies

¹⁴⁵ See generally Sudeep Pushpakom et al., *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?*, THE CONVERSATION (May 6, 2020), <https://theconversation.com/remdesivir-explained-what-makes-this-drug-work-against-viruses-137751> (outlining basic information about remdesivir).

as one of the leading candidates,¹⁴⁷ and in May 2020 it became the first COVID-19 treatment temporarily authorized by the FDA for the treatment of hospitalized patients.¹⁴⁸ In August, the pharmaceutical company sponsoring remdesivir, Gilead, 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 the United States 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, a large private-sector pharmaceutical company.¹⁵¹ During the 2014-16 Ebola outbreak, remdesivir was

¹⁴⁷ John H. Beigel et al., *Remdesivir for the Treatment of Covid-19 - Preliminary Report*, N. ENGL. J. MED. (May 22, 2020).

¹⁴⁸ GILEAD, *Gilead's Investigational Antiviral Remdesivir Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of COVID-19* (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>.

¹⁴⁹ See GILEAD, *Gilead Submits New Drug Application to U.S. Food and Drug Administration for Veklury® (Remdesivir) for the Treatment of COVID-19* (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>

¹⁵⁰ See Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, *supra* note 119.

¹⁵¹ See Ed Silverman, *The U.S. Government Contributed Research to a Gilead Remdesivir Patent — But Didn't Get Credit*, STAT (May 8, 2020), <https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/>

tested on animals and, after showing promise, progressed to phase 1 clinical trials.¹⁵² Nevertheless, as the outbreak began to unwind, so did 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 while other developed countries will be able to buy the drug at a 25% 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 pre-existing 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

¹⁵² GILEAD, DEVELOPMENT OF REMDESIVIR, https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf. 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/>

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

¹⁵⁴ GILEAD, DEVELOPMENT OF REMDESIVIR, *supra* note 152.

¹⁵⁵ Rohan Chalasani & Walid Gellad, *The US Is Paying Way Too Much for Remdesivir*, WIRED (Jul. 17, 2020), <https://www.wired.com/story/the-us-is-paying-way-too-much-for-remdesivir/>

¹⁵⁶ See e.g. Sarah Hansen, *Gilead Finally Reveals Remdesivir Pricing After Weeks of Speculation*, FORBES (Jun. 29, 2020), <https://www.forbes.com/sites/sarahhansen/2020/06/29/gilead-finally-reveals-remdesivir-pricing-after-weeks-of-speculation/#6e14859a405b>. A five-day course of remdesivir will cost \$2,340 to the Department of Veterans Affairs and the Indian Health Service. *Id.*, *ib.*

¹⁵⁷ *Id.*, *ib.*

¹⁵⁸ *Id.*, *ib.*

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 innovation 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 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 outbreak, there have been four 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%.¹⁶² The latest Ebola outbreak, also affecting Democratic Republic of the Congo, started on June 1, 2020 and is ongoing at the time of writing.¹⁶³

¹⁵⁹ Silverman, *supra* note 151.

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

¹⁶¹ CTRS. DISEASE CONTROL & PREVENTION, CASES AND OUTBREAKS OF EVD BY YEAR (2020), <https://www.cdc.gov/vhf/ebola/history/chronology.html>

¹⁶² *Id.*, *ib.*

¹⁶³ *Id.*, *ib.*

Merck's Ebola vaccine, known as Erverbo, was finally approved in December 2019, three years after the 2014-16 outbreak, 17 years since a patent application was initially filed, and around 15 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 socio-economic determinants of health and their impact on health outcomes across the African continent.¹⁶⁵ IP—be it its pricing facet or its incentives 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 incentives 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 United States.¹⁶⁶ The current price point for remdesivir is likely

¹⁶⁴ See U.S. Food & Drug Admin., *First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response* (Dec. 19, 2020), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>

¹⁶⁵ WORLD HEALTH ORG. REGIONAL OFFICE FOR AFRICA, SOCIAL AND ECONOMIC DETERMINANTS OF HEALTH, <https://www.afro.who.int/health-topics/social-and-economic-determinants-health>

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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: the case of 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 350,000 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

¹⁶⁷ Robert E. Black et al., *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 (Jul. 31, 2000), <http://content.time.com/time/magazine/article/0,9171,997586,00.html>.

¹⁶⁹ See Xudong Ye et al., *Engineering the Provitamin A (β - Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCIENCE 303 (Jan. 14, 2000).

¹⁷⁰ Nash, *supra* note 168.

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 pre-existing technology, they were concerned about the IP landscape surrounding Golden Rice, 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 non-profit tech transfer company, identified a minimum of 70 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 European Union.¹⁷⁴ Funding from the European Union 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

¹⁷¹ INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, THE GOLDEN RICE TECHNOLOGY, https://www.isaaa.org/kc/inforesources/biotechcrops/The_Golden_Rice_Technology.htm.

¹⁷² RURAL ADVANCEMENT FOUND. INT’L, *Golden Rice and Trojan Trade Reps: A Case Study in the Public Sector’s Mismanagement of Intellectual Property* [hereinafter *Golden Rice and Trojan Trade Reps*], Comunique 66 (Sept./Oct. 2010), at 2-3.

¹⁷³ *Golden Rice and Trojan Trade Reps*, at 3.

¹⁷⁴ Nash, *supra* note 168.

¹⁷⁵ Peter Beyer et al., *Golden Rice: Introducing the β -Carotene Biosynthesis Pathway into Rice Endosperm by Genetic Engineering to Defeat Vitamin A Deficiency*, 132 J. NUTRITION 506S (Mar. 1, 2002).

¹⁷⁶ Nash, *supra* note 168.

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.

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

¹⁷⁷ Beyer, *supra* note 175.

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

¹⁷⁹ Beyer, *supra* note 175.

¹⁸⁰ *Golden Rice and Trojan Trade Repts*, *supra* note 172.

¹⁸¹ Beyer, *supra* note 175.

¹⁸² *Id.*, *ib.*

¹⁸³ *Id.*, *ib.*

¹⁸⁴ *Id.*, *ib.*

overstated the number of patents at stake.¹⁸⁵ Instead of a minimum of 70 and up to 105 patents, as identified by ISAAA, RAFI's study showed that there were only 11 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 U.S. and the European patent offices.¹⁸⁷ When corrected for duplicate entries, the number came down to 44.¹⁸⁸

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: "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. In over 50% of the countries with serious levels of vitamin A deficiency (35 out of 60), there were no patents covering any of the technology involved in Golden Rice.¹⁹⁰ In the remaining countries, only 12 patents were found to be potentially relevant.¹⁹¹ At the same time, among the dozen countries with populations with vitamin A deficiency who "consume rice in sufficient quantity to make them potential targets," half had no relevant patents.¹⁹²

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

¹⁸⁶ *Id.*, *ib.*

¹⁸⁷ *Id.*, at 4.

¹⁸⁸ *Id.*, *ib.*

¹⁸⁹ David R. Kryder et al., *The Intellectual and Technical Property Components of pro-Vitamin A rice (GoldenRice™): A Preliminary Freedom-to-Operate Review* (2000) ISAAA BRIEF 20 (2000).

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

¹⁹¹ *Id.*, *ib.*

¹⁹² *Id.*, *ib.*

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.¹⁹³ 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.¹⁹⁴ Others still speak to ongoing debates on the stringency—or lack thereof—of current regulatory regimes for biotechnology.¹⁹⁵

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,¹⁹⁶ a large intergovernmental research institute based in the Philippines.¹⁹⁷ All four regulatory agencies declared to have “no further questions” about the safety of Golden Rice.¹⁹⁸ In December 2019, the Department of Agriculture in the Philippines approved Golden Rice for use as food, feed and for processing,¹⁹⁹ and a similar regulatory approval process is currently underway in Bangladesh.²⁰⁰

¹⁹³ 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>

¹⁹⁴ Nash, *supra* note 168.

¹⁹⁵ *Id.*, *ib.*

¹⁹⁶ See e.g. Brian Owens, *Golden Rice is Safe to Eat, Says FDA*, 36 NATURE BIOTECH. 559 (2018).

¹⁹⁷ INTERNATIONAL RICE RESEARCH INSTITUTE, <https://www.irri.org>.

¹⁹⁸ Owens, *Golden Rice is Safe to Eat*, *supra* note 196.

¹⁹⁹ 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/>.

²⁰⁰ INTERNATIONAL RICE RESEARCH INSTITUTE, *Philippines Approves Golden Rice for Direct Use as Food and Feed, or for Processing*, (Dec. 18, 2019), <https://www.irri.org/news-and-events/news/philippines-approves-golden-rice-direct-use-food-and-feed-or-processing>.

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 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.²⁰¹

It is also worth noting that Golden Rice—as was the case with the technologies surveyed in the previous sections—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,²⁰² disease-resistant papayas in Hawaii²⁰³ and disease-resistant dwarf wheat in India.²⁰⁴

III. TOWARDS A FRAMEWORK FOR THE IP DETERMINANTS OF HEALTH

A. THE EXISTING IP FRAMEWORK

²⁰¹ See *infra*, Part III.A.

²⁰² Ismail Cakmak & Ross M. Welch, IMPACTS OF AGRICULTURE ON HUMAN HEALTH AND NUTRITION 2, at 138-154.

²⁰³ Michael Goldman, *The IP Management of the PRSV-Resistant Papayas Developed by Cornell University and the University of Hawaii and Commercialized in Hawaii*, <http://www.iphandbook.org/handbook/ch17/p27/>.

²⁰⁴ David Biello, *Norman Borlaug: Wheat Breeder Who Averted Famine with a "Green Revolution,"* SCI. AM. BLOG (Sept. 14, 2009), <https://blogs.scientificamerican.com/news-blog/norman-borlaug-wheat-breeder-who-av-2009-09-14/>.

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 right 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.”²⁰⁵ This balancing approach is further complemented by article 8, which establishes that countries 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.²⁰⁶

Even though TRIPs provides the theoretical foundation to address some of the current imbalances in the diffusion of health-related innovations,²⁰⁷ implementation processes have often

²⁰⁵ TRIPs Agreement, art. 7.

²⁰⁶ TRIPs Agreement, art. 8.2.

²⁰⁷ See e.g. Peter K. Yu, *The Objectives and Principles of the TRIPs Agreement*, 46 Hous. L. Rev. 797 (2009).

veered away from balancing tenets, as many scholars have observed,²⁰⁸ a trend underscored by the adoption of maximalist approaches in bilateral and plurilateral trade agreements.²⁰⁹

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, as 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.”²¹⁰ 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 socio-economic and technological development.”²¹¹ While vastly underused, article 8 does provide enabling language

²⁰⁸ See e.g. SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003); GRAEME B. DINWOODIE & ROCHELLE COOPER DREYFUSS, EDs. *A NEOFEDERALIST VISION OF TRIPs: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME* (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 (2000); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004); Reichman & Dreyfuss, *Harmonization Without Consensus*, *supra* note 33.

²⁰⁹ See e.g. Ruth Okediji, *Back to Bilateralism?*, *supra* note 25; Bryan Mercurio, *TRIPs-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM, LORAND BARTELS & FEDERICO ORTINO EDs. (2006); Henning Grosse Ruse-Khan & Annette Kur, *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).

²¹⁰ TRIPs Agreement, art. 8.1.

²¹¹ *Id.*, *ib.*

that could support the establishment of national regimes that leave much less room for behaviors like price gouging by explicitly incorporating a 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,²¹² which states that

(...) the 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.²¹³

A particular type of TRIPs-compatible intervention that some countries in the Global South have taken advantage of in the field of pharmaceuticals has been compulsory licensing.²¹⁴ Under TRIPs 31, 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.”²¹⁵ The Doha Declaration both clarified and expanded the cases in which national governments may issue compulsory licenses.²¹⁶ 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

²¹² 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., Vol. 921 (2007); Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health*, *supra* note 30.

²¹³ Declaration on the TRIPs Agreement and Public Health [hereinafter Doha Declaration], Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001), para. 4.

²¹⁴ TRIPs Agreement, art. 31 (laying out the procedural and substantive frameworks for compulsory licensing).

²¹⁵ Y. Tayler, *Battling HIV/AIDS: A Decision-Maker's Guide to the Procurement of Medicines and Related Supplies*, cited in FREDERICK ABBOTT ET AL., *INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY* (2007), at 271.

²¹⁶ Doha Declaration, para. 5.b-c.

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.²¹⁷ A first wave of countries that resorted to compulsory licensing in the context of infectious disease outbreaks included Thailand²¹⁸ and Brazil,²¹⁹ both in connection with HIV/AIDS drug Efavirenz.

TRIPs, as informed by Doha, thus expresses a particular concern with abuses or insufficiencies of IP regimes that may have a direct impact on health-related issues, and 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.²²⁰

Furthermore, even though TRIPs contributes the legal framework for individual countries to address the over-maximization of patent rights resulting in price gouging and exclusion of

²¹⁷ Doha Declaration, para. 5.c.

²¹⁸ INT’L CTR. FOR TRADE & SUSTAINABLE DEV., *Thailand Issues Compulsory Licence [sic] For Patented AIDS Drug* (Dec. 13, 2006), <https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug>. See also generally HOLGER HESTERMEYER, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES* (2008) (describing other instances of compulsory licensing of pharmaceuticals—or threat thereof—in the Global South).

²¹⁹ INT’L CTR. FOR TRADE & SUSTAINABLE DEV., *Brazil Issues Compulsory Licence [sic] For Aids Drug* (May 8, 2007), <http://www.ictsd.org/brazil-issues-compulsory-licence-for-aids-drug>.

²²⁰ A recent development that bolstered the compulsory licensing framework for pharmaceutical—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. TRIPs Agreement, art. 31*bis*. See also William New, *It’s Official: TRIPS Health Amendment in Effect, First Ever to A WTO Agreement*, IP WATCH (Jan. 23, 2017), <https://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/>.

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 diseases²²¹ or orphan diseases²²² 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.

The following section 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 disfunctions 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 above. An intervention affecting one or more determinants—e.g. income or education levels—might mitigate the problem for individual patients, and thus produce effects on ad hoc basis, but it is unlikely to provide any mechanisms that can be used in the short-term to prevent systemic

²²¹ WORLD HEALTH ORG., NEGLECTED TROPICAL DISEASES, https://www.who.int/neglected_diseases/diseases/en/.

²²² U.S. FOOD & DRUG ADMIN., ORPHAN PRODUCTS: HOPE FOR PEOPLE WITH RARE DISEASES, <https://www.fda.gov/drugs/drug-information-consumers/orphan-products-hope-people-rare-diseases>.

infection. Moreover, they cannot eliminate the root of excessive pricing practices, which in itself represents a malfunction of a legal regime.

In this section, 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 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 non-clinical 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 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 towards 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, a behavior that increases transaction costs, obscures informational signals and accentuates bargaining imbalances between rightsholders 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.²²³ 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, the Bayh-Dole Act,²²⁴ gives the government the ability to “march-in” on patents held by entities in the private-sector covering publicly funded inventions.²²⁵ 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

²²³ 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>; David Gross et al., *International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom*, 15 HEALTH CARE FIN. REV. 127 (1994).

²²⁴ Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980).

²²⁵ 35 U.S.C. § 203.

reasonably satisfied” by the way the rightsholder is practicing the invention.²²⁶ 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.²²⁷

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, they have so far proved underused, with the exception of a few countries in the South.²²⁸

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, I have explored the possibility of liability regimes in connection with patentable vaccine technology.²²⁹ 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

²²⁶ 35 U.S.C. § 203(a)(2). See also, *A Rare Deterrent to Limitless Drug Price Increases May Die Under Trump*, WASH. POST (Apr. 18, 2019) (quoting the academic view that “[t]he idea that the price is too high fits pretty comfortably in the wording of the statute.”), https://www.washingtonpost.com/business/economy/a-rare-deterrent-to-limitless-drug-price-increases-may-die-under-trump/2019/04/17/7578e5e0-5bcd-11e9-a00e-050dc7b82693_story.html.

²²⁷ See e.g. NAT’L INST. OF HEALTH, OFFICE OF THE DIR., DETERMINATION IN THE CASE OF PETITION OF CELLPRO, INC., <https://www.otn.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf> (denying a march-in petition of a stem cell separation device based on § 203(a)(2) public health grounds).

²²⁸ See e.g. Ryan Whalen, *Will the Agencies Ever Go Marching In? Public Rights in Federally-Funded Inventions*, 109 NW. U. L. REV. (2015) (providing an overview of the landscape in the United States).

²²⁹ Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 5 Tex. A&M J. Prop. L. ___ (2020); *The Vaccine Race*, *supra* note **Error! Bookmark not defined.**

entitlement without consent and against the payment of an “objectively determined value.”²³⁰ 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.²³¹

Consider how these two regimes would operate differently in cases in which second comers have the ability to manufacture follow-on 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.²³²

²³⁰ 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). See also William W. Fisher III, *Property Rules v. Liability Rules*, in THE CANON OF AMERICAN LEGAL THOUGHT (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 (1997); 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. (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).

²³¹ Calabresi & Melamed, *ib.*

²³² Jack M. Balkin & Ian Ayres, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L. J. 703, 704 (1996).

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,²³³ my argument here is 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. I have 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 policy- and lawmakers,²³⁴ especially as patent holders generally do not expect a meaningful return-on-investment in this area.²³⁵ Conversely, a liability regime covering next-generation vaccine technology—such as the seemingly imminent case of mRNA vaccines which might be coming to market in the wake of the COVID-19 pandemic²³⁶—would be ill-advised, as the R&D landscape in this area is much more populated, well-funded and programmatically different from the lacking R&D pipeline that unites the case studies presented in Part II.

²³³ See Ana Santos Rutschman, *The Vaccine Race in the Twenty-First Century*, 61 ARIZ. L. REV. 729, 762-770 (2019); *id.*, *Property and Intellectual Property in Vaccine Markets*, *supra* note 229.

²³⁴ *The Vaccine Race in the Twenty-First Century*, at 767. But see *id.* at 768-769 (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 (KEITH E. MASKUS & JEROME H. REICHMAN, EDs) (2005), at 354-365.

²³⁵ See e.g. COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI), PRELIMINARY BUSINESS PLAN, 2017-2021 (Nov. 2016) (noting that “it is anticipated that vaccines developed with CEPI support will not be profitable”).

²³⁶ See e.g. Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, N. ENGL. J. MED. (Jul. 14, 2020).

Beyond these particular illustrations, the broader point here is that there are legal solutions that would be less taxing of 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.²³⁷

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.²³⁸ A liability approach, especially if implemented surgically, does not do away with the metaphoric bundle of rights conferred by the grant of a patent, but rather 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.²³⁹

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 infection (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,

²³⁷ *Supra*, Part III.A. See also Sapna Kumar, *Patents, Pharma, and the Pandemic*, __ (forthcoming, __) (on file with author).

²³⁸ TRIPs Agreement, Article 27.1 (establishing patent protection for meritorious inventions in “in all fields of technology”).

²³⁹ See *supra*, note 235.

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 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,²⁴⁰ they also promote distributive justice²⁴¹—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.²⁴²

²⁴⁰ See e.g. Calabresi & Melamed, *One View of the Cathedral*, *supra* note 230, at 1093; Kaplow & Shavell, *Property Rules versus Liability Rules: An Economic Analysis*, *supra* note 230.

²⁴¹ Calabresi & Melamed, *One View of the Cathedral*, at 1106.

²⁴² See generally CAMBRIDGE HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT, MARGARET CHON ET AL., EDS. (2018).; Jon F. Merz, *World Health Org., 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),

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.²⁴³

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 2003.²⁴⁴ DNDi is a non-profit R&D organization focused on the development of “urgently needed treatments for neglected patients” at “affordable” prices.²⁴⁵ The diseases targeted by the organization are largely prevalent in, although not exclusive to, the Global South: sleeping sickness, Chagas disease, cutaneous and visceral leishmaniasis, hepatitis C, river blindness, mycetoma and pediatric HIV.²⁴⁶

From 2003 to 2023, DNDi operates with funding from the public (57%) and private (43%) sectors.²⁴⁷ Public donors include governments and public-sector institutions from countries in Europe (including the European Union), Asia, America and Australia, as well non-profit organizations like Unitaid and The Global Fund to Fight AIDS, Tuberculosis and Malaria.²⁴⁸ Among the governmental funders, there are several emerging economies of the Global South,

²⁴³ See Merz, *supra* note 242.

²⁴⁴ DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://dndi.org>

²⁴⁵ *Id.*, *ib.*

²⁴⁶ DRUGS FOR NEGLECTED DISEASES INITIATIVE, DISEASES, <https://dndi.org/diseases/>

²⁴⁷ DRUGS FOR NEGLECTED DISEASES INITIATIVE, OUR DONORS, <https://dndi.org/about/donors/>

²⁴⁸ DRUGS FOR NEGLECTED DISEASES INITIATIVE, OUR DONORS: PUBLIC DONORS, <https://dndi.org/about/public-donors/>

including Brazil, Colombia and Thailand.²⁴⁹ 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).²⁵⁰

Private funding is provided through heterogenous donor types, including 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.²⁵¹

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, academic, non-profit, and philanthropic sectors...”²⁵² 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.²⁵³ Between the early 2000s and the late 2010s, dozens of public-private partnerships dedicated to pharmaceutical or biopharmaceutical R&D were launched every year.²⁵⁴ Some took a more general-purpose approach to innovative R&D: for instance, the

²⁴⁹ *Id., ib.*

²⁵⁰ *Id., ib.*

²⁵¹ DRUGS FOR NEGLECTED DISEASES INITIATIVE, OUR DONORS: PRIVATE DONORS, <https://dndi.org/about/private-donors/>

²⁵² DRUGS FOR NEGLECTED DISEASES INITIATIVE, HOW WE WORK, <https://dndi.org/about/how-we-work/>

²⁵³ See Merz, *supra* note 242, at 17.

²⁵⁴ *Id.* See also Mark D. Lim, *Commentary, Consortium Sandbox: Building and Sharing Resources*, SCI. TRANSLATIONAL MED. (Jun. 25, 2014).

Innovative Medicines Initiative,²⁵⁵ to date the largest public-private partnership in the life sciences, op to drug R&D in general, operates in 12 strategic areas, ranging from antimicrobial resistance to cardiovascular, neurodegenerative, psychiatric and respiratory diseases.²⁵⁶ 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.”²⁵⁷ 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 acknowledge underinvestment in R&D on vaccines, particularly in the field of emerging infectious diseases.²⁵⁸ 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.²⁵⁹ Less than three years later, as the COVID-19 pandemic began to unfold, CEPI was among the earliest and most significant funders of R&D on COVID-19 vaccines.²⁶⁰

All 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

²⁵⁵ INNOVATIVE MEDICINES INITIATIVE, ABOUT IMI, <https://www.imi.europa.eu/about-imi>.

²⁵⁶ INNOVATIVE MEDICINES INITIATIVE, STRATEGIC RESEARCH AGENDA, <https://www.imi.europa.eu/about-imi/strategic-research-agenda>

²⁵⁷ CARB-X, ABOUT CARB-X, <https://carb-x.org/about/overview/>

²⁵⁸ CEPI, WHY WE EXIST, <http://cepi.net/about/whyweexist/>

²⁵⁹ CEPI, PRELIMINARY BUSINESS PLAN 2017-2021 (2016), at 7, https://cepi.net/wp-content/uploads/2019/02/CEPI-Preliminary-Business-Plan-061216_0.pdf. See also Rutschman, *The Intellectual Property of Vaccines*, *supra* note 119, at 182.

²⁶⁰ CEPI, *CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV-2019* (Jan. 23, 2020), https://cepi.net/news_cepi/cepi-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/

literature as “product development” public-private partnerships, as opposed to “access partnerships,” which typically place large advance orders of goods (either fully developed or undergoing development, as is presently the case with COVID-19 vaccines²⁶¹) as a way to nudge the development and manufacturing of products that can then be distributed at relatively affordable prices.²⁶²

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.²⁶³ 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.²⁶⁴ Through COVAX, Gavi has placed orders with different pharmaceuticals 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).²⁶⁵ These advance commitments allow for at-risk manufacturing of vaccines, paving the way for as quick a distribution as possible of the first batches of vaccine—provided that such distribution is cleared by regulatory authorities.²⁶⁶

²⁶¹ See e.g. Helen Branswell, *WHO, Partners Unveil Ambitious Plan to Deliver 2 Billion Doses of Covid-19 Vaccine to High-Risk Populations*, STAT (Jun. 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/> (describing the formation of the public-private partnership COVAX).

²⁶² See generally Merz, *supra* note 242 (describing the differences between product development and access partnerships).

²⁶³ GAVI, ABOUT OUR ALLIANCE, <https://www.gavi.org/our-alliance/about>

²⁶⁴ GAVI, BRIEFING ON THE COVAX FACILITY (Jun. 11, 2020), https://apps.who.int/gb/COVID-19/pdf_files/11_06/GAVI.pdf

²⁶⁵ *Id.*, *ib.*

²⁶⁶ *Id.*, *ib.*

Critically, the combination of product development and access partnerships illustrates the interdependence of incentives regimes, 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 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 increase their interaction with traditional IP players (such as the World Intellectual Property Organization or offices offering technical assistant in the field of IP at the domestic level), as well as with players in indirect IP fora—from the World Health Organization²⁶⁷ to public-private partnerships operating in pharmaceutical R&D or other fields related to public health.

²⁶⁷ See Laura Pedraza-Fariña, *Essential Medicines and Culture Clash: How Competition between the WTO and WHO Shaped Global IP Regimes* (draft on file with author).

CONCLUSION

If IP is the default regime to incentivize innovation—including pharmaceutical, biopharmaceutical and agricultural innovation—then the ways in which these types of innovation are produced, distributed or made available may have an impact on non-clinical 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 population 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 law 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.