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# Part IV

# COVID-19 and Access to Medicines

# Lessons from COVID-19 for Medicines Access

*Amaka Vanni*

## Introduction

Cases of COVID-19 first emerged in late 2019, when a mysterious illness was first reported in the city of Wuhan in China's Hubei Province. The cause of the disease was soon confirmed as a new kind of coronavirus. Later named severe acute respiratory syndrome (SARS)-CoV-2, this form of coronavirus can cause mild flu-like symptoms (or even be asymptomatic) that can progress to acute pneumonia-like respiratory illness called novel coronavirus-infected pneumonia (NCIP). On March 11, 2020, the World Health Organization (WHO) officially announced that COVID-19[1] is a global pandemic.[2] The magnitude and impact of COVID-19 is staggering. It has crashed economies, caused thousands of deaths, crippled national health systems, separated families and coworkers, emptied public spaces, and disrupted our world as we know it. At the time of writing, the number of infections worldwide has crossed over 3.5 million while more than 245,000 people have died. (Un)surprisingly, Europe and the United States (US) are the hardest hit and projections estimate the number will swell to hundreds of thousands in the coming months.

This concluding chapter undertakes two tasks. First, the magnitude and urgency of COVID-19 has forced us to revisit the present system of patents, and intellectual property (IP) more generally, and to see more clearly the ways that it is not the model for delivering the products now needed to respond to global health emergencies. The second task addresses the issue of research and development (R&D) of new treatments for infectious diseases without the whims of the market such that we can be best prepared for future pandemics.

1 This is not the formal name for the virus. The International Committee on Taxonomy of Viruses (ICTV) calls it the "severe acute respiratory syndrome coronavirus 2," or SARS-CoV-2. *See* A.E. Gorbalenya et al., *The Species Severe Acute Respiratory Syndrome-Related Coronavirus: Classifying 2019-nCoV and Naming it SARS-CoV-2*, 5 Nat. Microbiol. 536–44 (2020), https://doi.org/10.1038/s41564-020-0695-z.

2 Peng Zhou et al., *A Pneumonia Outbreak Associated with a New Coronavirus of Probable Bat Origin*, 579 Nature 270–73 (2020).

## Global Patent Regime and Structural Violence

The public health impact of the COVID-19 pandemic has resurfaced the importance of pharmaceuticals on everyday lives and the need to de-link the costs of R&D from the prices of products.[3] It has also highlighted another issue that was always actively present within the global IP regime – the structural violence[4] embedded within our world order, which manifests in our treatified global economic structure, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and other free trade agreements (FTAs).

### *Understanding Structural Violence*

Our concept of structural violence builds on the work of Johan Galtung, who defines it as "forms of harm or violence built in the systems (social, economic, biological) and shows up as unequal power and consequently as unequal life chances."[5] According to Galtung, it is the avoidable "impairment of fundamental human needs or human life, which lowers the actual degree to which someone is able to meet their needs below that which would otherwise be possible."[6] These structures – tying in with the theoretical framework explicated in our introduction to mean the modern global capitalist framework – by their very nature (and history) churn out harm, generate or perpetuate poverty and inequality, and cause basic human needs deficits.[7] This form of violence is indirect because there may not be any person who directly harms another in the structure, and yet harm is done because this form of violence is embedded and enabled in our social and economic systems. For example, Galtung explains, if a "person died from tuberculosis in the 18th century, it would be hard to conceive this as violence since it might have been quite unavoidable, but if he dies from it today, despite all the medical resources in the world, then violence is present according to our definition."[8] In a similar vein, he continues, "life expectancy of thirty years during the Neolithic period was not an expression of violence but the same life-expectancy today (whether due to wars, or social injustice, or both) would be seen as violence according to our definition."[9] Thus for Galtung, if people are dying or starving when such death or starvation is objectively

3 James Love, *Discussion Paper: An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines*, Knowledge Ecology International (2016), https://www.keionline.org/wp-content/uploads/Delinkage_economic-perspective_Feb2016.pdf.
4 Johan Galtung, *Violence, Peace, and Peace Research*, 6 J. Peace Res. 167–91 (1969).
5 *Id.* at 171; *see also* Johan Galtung & Dietrich Fischer, *Violence: Direct, Structural and Cultural*, *in* 5 SpringerBriefs on Pioneers in Science and Practice 35 (Hans Günter Brauch ed., 2013).
6 Johan Galtung, *Violence, Peace and Peace Research*, 6 J. Peace Res. 167–91 (1969).
7 Galtung & Fischer, *supra* note 5.
8 *Id.* at 168.
9 *Id.* at 168.

avoidable, then violence is being committed regardless "of whether there is a clear subject-action-object relation, as during a siege or no such clear relation, as in the way world economic relations are organized today."[10]

Paul Farmer expands this theory further and draws it into the field of public health and anthropology to show how structural violence is embodied in epidemic diseases, violation of human rights, and genocide.[11] For Farmer, while structural violence manifests in the ways violence is exerted systematically and indirectly by everyone who belongs to a certain social order, it is also about power – the power to decide over the distribution of and access to resources, including (but not limited to) health care, education, food, and water quality.

### *Global IP Regime and Structural Violence*

The current global property law regime exported by the developed countries, particularly the US and embodied in the TRIPS Agreement and other TRIPS-plus FTAs exemplifies a form of *structural violence*. As analyses in this book have shown, the avoidable deaths from HIV/AIDS as a result of lack of medicines access due to high prices caused by patent monopoly, and despite pharmaceutical developments and availability of required medications, illustrate this. The growing practice of patent thickets and exclusivities in domestic IP regimes, exported in trade agreement, and adds years of monopoly protection underscores how violence is built into IP structures. This allows pharmaceutical companies to increase prices at whim, subsequently deepening unequal access and unequal life chances. Thus, to the extent that there is an increasing presence of society divided only by the ability to access medication ("privileged-to-access medicine" or PTAM), it is possible to critique the international and domestic IP regimes in terms of *structural violence* because it facilitates the conditions for global health inequities and continues to inflict harm by systematically disadvantaging certain groups of people from access to lifesaving medicines. In this view, the structural violence of the patent regimes continues to play itself out in the daily injury and deaths it causes – the inequity and inequality in access as a result of high prices caused by patent monopoly. It goes without saying there are other factors that inhibit equitable medicines access such a poor, underfunded healthcare systems and corruption to state failure. While these are valid factors, it is also important to recognize the role of law in maximizing the profitability of particular forms of property, regardless of the human cost.

Of course, many could argue (and have already argued) that pharmaceutical companies are to be explicitly blamed for the deaths as a result of exorbitant costs

10 *Id*. at 171.

11 Paul Farmer, *An Anthropology of Structural Violence*, 45 Curr. Anthropol. 305–25 (2004). Paul Famer built on the work of Galtung to define structural violence as "violence exerted systematically—that is, indirectly—by everyone who belongs to a certain social order."

attached to essential lifesaving medicines, which are priced out of reach for the poor[12] and thus directly responsible for those pernicious avoidable deaths. While such analysis is valid, it ignores the complex factors that expanded the scope of protection and introduced novel patent-related rights such as market and data exclusivities, thereby allowing pharmaceutical companies to exploit global and national IP regimes. In fact, a historical examination of the contemporary patent regime shows how colonialism,[13] racism,[14] and inequality[15] became deeply sedimented into the international IP law, particularly patents, to enforce a particular type of property rights and to protect the economic interest of the transnational capitalist class.

Furthermore, the TRIPS Agreement – in harmonizing IP rules across regions – disregards wealth disparities, disease burdens, and asymmetrical levels of development within and across countries. It also created "exclusivity" that set the stage for a systematic model of harm in the production of inequitable access to medicines and health technologies. This exclusivity gives rise to scarcity as right owners decide who is allowed to use an innovative drug, at what cost, and who is excluded. The outcome and potency of this scarcity is not only in the lack of access but also in the normalization of the attendant morbidity and deaths. Monopoly, as a result of patents, has turned medicines and access to them into strategic assets that shape life so precariously. Thus, by its very nature, the contemporary patent regime primarily and irrevocably perpetuates violence, especially at a time when scientific research continues to yield miraculous outcomes.

Although there are exceptions and flexibilities within the global patent regime to remedy the harm caused, it still does not make it less so. If anything, it increases the scope for structural inequality by expanding a patentee's control of an unjust system. For instance, a government can issue a compulsory license (CL) but it also has to pay royalties to a patent holder, who usually benefits

12 David Barnard, *In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries*, 12 Kennedy Inst. Ethics J. 159–74 (2002).

13 Amaka Vanni, 1 Patent Games in the Global South: Pharmaceutical Patent Law-Making in Brazil, India and Nigeria 37–51 (2020). On the introduction of patent law through colonialism, *see* Edith Penrose, *International Patenting and the Less-Developed Countries*, 83 Econ. J. 768 (1973); Constantine Vaitsos, *Patents Revisited: Their Function in Developing Countries*, 9 J. Dev. Stud. 71–97 (1972).

14 Natsu T. Saito, *From Slavery and Seminoles to AIDS in South Africa: An Essay on Race and Property in International Law,* 45 Villanova Law Rev. (2000). In fact, it has been argued that an analytic omission and erasure of these histories in analysis of public health policies and interventions (I will also add IP laws in general and patent regimes in particular) is a form of structural violence. *See* Farmer, *supra* note 11, at 1690.

15 B.S. Chimni, *Political Economy of the Uruguay Round of Negotiations: A Perspective*, 29 Int. Stud. 135–58 (1992); Antony Anghie, *Time Present and Time Past: Globalization, International Financial Institutions, and the Third World*, 32 N.Y. Univ. J. Int. Law Polit. (2000); Antony Anghie, *Imperialism, Sovereignty, and the Making of International Law*, Cambridge Studies in International and Comparative Law (2005).

from government subsidies.[16] And even at that, CLs are insufficient measures to remedy the harm caused by patent policies because they require a capable manufacturing exporter who can successfully produce the emergency medicines. In fact, the chapters on Brazil and Thailand in this volume succinctly illustrate this. Other commentators also highlight voluntary license (VL)[17] practices as an acceptable solution to overcome the market effect of patents and to increase access to lower cost generic medicines, especially in low- and middle-income countries. While a VL does bring down the price of newer expensive drugs, its role as a remedy remains fragile as long as its success depends on the willingness and benevolence of pharmaceutical companies. This is because individualistic benevolence is not a substitute for systemic change. In fact, the VL deal Gilead issued for *remdesivir* underscores this.[18] Though this agreement allows generic manufacturers to produce the medicine for 127 countries, it excludes key lower middle–income countries with high COVID-19 infections such as Brazil, China, and Mexico. In this regard, the Gilead monopoly still holds and it gets to decide who lives and who dies.

## *COVID-19, Patents, and the Revolving Door of Structural Violence*

The COVID-19 pandemic has underscored the continued harm caused by patents and the politico-economic systems that maintain them. The global high demand, limited supply, and the risk that pharmaceutical companies will exploit the patent regime for financial benefits bring attention to this structural violence – the life and death significance, and the way in which health and medical resources will be allocated and experienced, especially at a time when the world could ill-afford such.[19]

16 According to the National Institute of Health (NIH), it invests about $41.7 billion annually in medical research for the American people. *See also* Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing from Coronavirus*, N.Y. Times (Mar. 18, 2020), https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html. According to Mariana Mazzucato and Azzi Momenghalibaf, the NIH funding contributed to every one of the 210 new drugs approved by the Federal Drug Administration from 2010 to 2016.

17 Voluntary license refers to a practice where IP owners voluntarily grant licenses to their patents to generic manufactures against the payment of royalties. *See* Jorge Bermudez & Ellen 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 Open AIDS J. 37–40 (2010); Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLoS Med. 4–6 (2012).

18 *Voluntary Licensing Agreements for Remdesivir*, Gilead, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir (last visited July 3, 2020).

19 Not there is ever a time violence of any sort is warranted. However, with such an invisible enemy such as coronavirus and its history-shattering impact, any sort of avoidable violence is needed.

Around $8 billion of public, philanthropic, and private funding has already been poured into R&D efforts to detect, treat, and prevent COVID-19.[20] Yet, because of patent monopoly ensuing as a result of possibly developing the innovative drug for its treatment, pharmaceutical companies will most likely determine its market price. A report has emerged that investment banks are urging pharmaceutical companies to raise their prices and to create a business out of products currently under development.[21] Meanwhile, some companies are already employing age-old patent barrier practices in the production and provision of vital coronavirus drugs. In March 2020, Gilead applied to the US Food and Drug Administration (FDA) for orphan drug status for the drug *remdesivir* when it was reported that the drug could be used in COVID-19 treatment.[22] Orphan drug status is designated for the treatment of rare diseases affecting less than 200,000 to allow the drug maker to recoup development costs because the drug serves a relatively small patient population. It also gives the manufacturer tax breaks and a seven-year marketing exclusivity period, which would allow Gilead to charge high monopoly prices and block the market entry of lower cost generic versions. In fact, what was most glaring about Gilead's attempt was that, at the time of its application and approval by the FDA, there were already more than 40,000 confirmed COVID-19 cases in the US, and an estimation that the number will grow exponentially in the coming weeks.[23] After much criticism from the press and public, Gilead rescinded its application.

20 Matina Stevis-Gridneff & Lara Jakes, *World Leaders Join to Pledge $8 Billion for Vaccine as U.S. Goes it Alone*, N.Y. Times, https://www.nytimes.com/2020/05/04/world/europe/eu-coronavirus-vaccine.html (last visited May 18, 2020).

21 Lee Fang, *Banks Pressure Health Care Firms to Raise Prices on Critical Drugs, Medical Supplies for Coronavirus*, Intercept, https://theintercept.com/2020/03/19/coronavirus-vaccine-medical-supplies-price-gouging/ (last visited May 7, 2020).

22 Lee Fang & Sharon Lerner, *Coronavirus Treatment Developed by Gilead Sciences Granted "Rare Disease" Status, Potentially Limiting Affordability*, Intercept, https://theintercept.com/2020/03/23/gilead-sciences-coronavirus-treatment-orphan-drug-status/ (last visited May 8, 2020).

23 *Id. See also* Manas Mishra & Michael Erman, *Gilead Asks FDA to Take Back Lucrative Orphan Drug Status on Possible Coronavirus Treatment U.S.*, Reuters, https://www.reuters.com/article/us-health-coronavirus-gilead-sciences/gilead-asks-fda-to-take-back-lucrative-orphan-drug-status-on-possible-coronavirus-treatment-idUSKBN21C3MG (last visited May 8, 2020). A study by the pharmaceutical advocacy groups, Knowledge Ecology International (KEI) and Public Citizen, shows that *remdesivir* benefited at every stage of development from public funding through federal grants and clinical trials. From KEI, *see* Kathryn Ardizzone, *KEI Briefing Note 2020: 1 Role of the Federal Government in the Development of GS-5734/Remdesivir*, Knowledge Ecology International, https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf (last visited May 8, 2020). From Public Citizen, *see* Public Citizen, *The Public Already Has Paid for Remdesivir*, Public Citizen, https://www.citizen.org/news/the-public-already-has-paid-for-remdesivir/ (last visited May 8, 2020).

In addition, protective equipment and diagnostic test tools have become the other focal points in the coronavirus pandemic. Makers of the 3M respiratory masks filed multiple patents between March 3 and April 7,[24] preventing generic competitors from manufacturing the respiratory masks. Meanwhile, countries such as the Netherlands were unable to scale up testing for COVID-19 because of shortage of chemical apparatus needed for testing, particularly the lysis buffer solution, which breaks down cells in the molecular analysis of the coronavirus. This is because the Swiss manufacturer Roche, the original maker of the lysis buffer, "refused to reveal the formula and technical specifications needed to ensure compatibility with Roche's hardware."[25] Hiding access to lifesaving knowledge behind thickets of patents (or over-patenting) not only slows progress but is also at variance with the objective of the TRIPS Agreement.[26] Over-patenting, many scholars acknowledge, is now a growing business strategy to "avoid competition in order to earn outsized profits on medicines for many years beyond what was intended."[27] According to I-Mak, patent thickets increase the price of branded drugs by an average of 68 percent in six years, and stall generic competition by an average of 38 years.[28] Doris Long in her chapter illustrates this scenario with the case of 12 top-selling patented drugs in the US, which have at least 71 granted patents per drug.[29] This shows how the present patent regime is ill-suited to respond to global public health needs as private profits continue to take precedence over human life. Again, we see how the current neoliberal capitalist structure, made legitimate through shifts in patent rules that promote exclusivity, monopoly, and predatory value extraction over human life, continues to wreak violence on the lives and bodies of the "have-nots" by denying access to lifesaving medicines. These events reveal just how structural violence, at the root of the patent regime, takes up new forms in every era.[30]

24 Alexander Zaitchik, *No Vaccine in Sight*, New Republic, https://newrepublic.com/amp/article/157594/no-coronavirus-vaccine-big-pharma-drug-patent-system (last visited May 14, 2020).

25 Ed Silverman, *Roche Backpedals on Providing Liquid for Covid-19 Tests in the Netherlands,* Stat, https://www.statnews.com/pharmalot/2020/03/27/roche-covid19-coronavirus-netherlands/ (last visited May 14, 2020). *See also* Ellen 't Hoen, *Protect Against Market Exclusivity in the Fight Against COVID-19*, Nat. Med. 813 (2020).

26 Article 7, TRIPS Agreement states that the objective of the agreement is to contribute to the promotion of technological innovation, the transfer and dissemination of technology in a mutually advantageous way to producers and users of technological knowledge.

27 I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf (last visited Apr. 3, 2020).

28 *Id*. at 11.

29 *See* Doris Long, Part III, chapter 6.

30 Farmer, *supra* note 11, at 315.

## Post-COVID-19 and Addressing Infectious Diseases

While many nations are rightly focused on the COVID-19 pandemic, the issues of lack of access to medicines and treatment for other infectious diseases still remain. Commentators, for example, estimate that in a typical year, the influenza virus causes as many as five million cases of severe illness in humans and 500,000 deaths.[31] Meanwhile, infectious disease incidents in the early 2000s such as the SARS in 2003, the H5N1 avian influenza in 2005, the H1N1 influenza in 2009, and the Ebola outbreak in 2013 underscored the global inability to address the problem of preparedness for serious disease events. For example, in reviewing the global response to the 2009 H1N1 influenza that killed over 100,000 people,[32] Harvey V. Fineberg notes that the inability to distribute enough influenza vaccines in a timely way was the most serious operational shortcoming in the global response to the outbreak. Furthermore, though "78 million doses of vaccine were sent to 77 countries, it was mainly long after they would have done the most good."[33] Other commentators noted how high-income governments stockpiled most of the world's vaccine supply through early purchase commitments, leaving many poor and lower income countries out in the cold.[34] The same failure was seen during the Ebola outbreak.[35] These failures highlight the critical importance of global vigilance for infectious diseases. Yet, the severity of and the damages caused by COVID-19 shows how the world is nowhere close to being prepared to handle a pandemic. Importantly, the difficulties experienced with the coronavirus response demonstrate the multifaceted failure of the drug development system and the market framework that props it up, and how we cannot abandon the treatment of infectious diseases to the whims of the market such that we can be best prepared for future pandemics.

As COVID-19 continues to spread, companies, institutes, and researchers race to find a cure or at least a vaccine. To shorten the timeline from development to market entry, pharmaceutical companies are "repurposing" medicines normally indicated for other diseases to treat COVID-19. For instance,

31 Harvey V. Fineberg, *Pandemic Preparedness and Response – Lessons from the H1N1 Influenza of 2009*, 370 New Eng. J. Med. 1335–42 (2014).

32 Estimates ranges of 123,000–203,000 deaths and 105,700–395,600 deaths. *See* Lone Simonsen et al., *Global Mortality Estimates for the 2009 Influenza Pandemic from the GLaMOR Project: A Modeling Study*, 10 PLoS Med. e1001558 (Nov. 2013); Fatimah S. Dawood et al., *Estimated Global Mortality Associated with the first 12 Months of 2009 Pandemic Influenza A H1N1 Virus Circulation: A Modelling Study*, 12 Lancet Infect. Dis. 687–95 (2012).

33 *Id.*

34 Gavin Yamey et al., *Ensuring Global Access to COVID-19 Vaccines*, 395 Lancet 1405–06 (May 2, 2020); Surie Moon, *The Vaccine Race: Will Public Health Prevail over Geopolitics?* (June 2020), https://globalchallenges.ch/issue/special_1/the-vaccine-race-will-public-health-prevail-over-geopolitics/.

35 Alexander Zaitchik narrates this failure in the case of Ebola vaccine development. *See* Alexander Zaitchik, *No Vaccine in Sight*, The New Republic (May 11, 2020), https://newrepublic.com/amp/article/157594/no-coronavirus-vaccine-big-pharma-drug-patent-system.

*remdesivir* – which is one of the leading candidates for COVID-19 treatment – was initially developed and approved for the treatment of Ebola. This practice of repurposing is particularly expedient in a pandemic in two ways. First, it helps reduce the cost of developing new drugs because approved methodologies and safety profiles have already been established, decreasing the need for costly clinical trials.[36] Second, it facilitates a rapid upscale of production of the most promising drugs within a shortened timeframe, thereby quickening market entry.[37] However, repurposing highlights a consequential failure of the current patent system to encourage the R&D of new drugs and vaccines for diseases which it sees as unprofitable – the so-called neglected diseases – because they primarily affect populations with little purchasing power, and therefore offer an insufficient market for attracting investment from the pharmaceutical industry.[38]

Meanwhile, many pharmaceutical companies have stopped investing in the development of new antibiotics or in general antibiotic research and innovation because there is no lucrative market for them.[39] Instead, these companies are focused on the development of blockbuster drugs with guaranteed high financial returns and on other shareholder obligations such as stock buybacks.[40] In 2018, 12 of the largest pharmaceutical companies in the US spent more money buying back their stock than on drug R&D.[41] The 2019 report by the Global Funding of Innovation for Neglected Diseases (G-Finder) also noted that while the global funding for neglected disease R&D rose to $4 billion in 2018, funding for neglected tropical diseases (NTDs) has gone backwards in the last decade, dropping by $34 million.[42] This highlights a broken patent system that encourages

36 Andrew Hill et al., *Minimum Costs to Manufacture New Treatments for COVID-19*, J. Virus Erad. 61–63 (Apr. 2020), http://viruseradication.com/journal-details/Minimum_costs_to_manufacture_new_treatments_for_COVID-19/.

37 *Id*.

38 Suerie Moon et al., *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?*, 9 PLoS Med. e1001218 (2012).

39 Sarah Boseley, *Big Pharma Failing to Invest in New Antibiotics, Says WHO*, The Guardian Jan. 17, 2020, https://www.theguardian.com/business/2020/jan/17/big-pharma-failing-to-invest-in-new-antibiotics-says-who.

40 Bob Herman, *Big Pharma is on a Stock Buyback Spree*, Axios Mar. 5, 2020, https://www.axios.com/big-pharma-stock-buybacks-research-123f10f1-79d0-44be-a515-a6603fbcfd9a.html.

41 *Id*. According to the author, these companies repurchased $69.1 billion of their stock in 2018, while spending $65.9 billion on researching new medicines. Specifically, Amgen and Biogen spent more on stock buybacks for the entire period than they spent on R&D. Amgen's stock repurchases ($31.6 billion) were more than twice as much as research ($15.3 billion).

42 Nick Chapman et al., *Neglected Disease Research and Development: Uneven Progress*, Policy Cures Research (2019), https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/11150341/G-Finder2019.pdf. *See also* Médecins Sans Frontières, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, MSF Access to Essential Medicines Campaign (Sept. 2001), https://msfaccess.org/fatal-imbalance-crisis-research-and-development-drugs-neglected-diseases.

private monetary compensation over innovation at the expense of those who cannot purchase these expensive medicines or are afflicted by diseases of the poor.

The current system for the R&D of new medicines is inadequate to meet the needs of modern times, especially for medicines for new and more virulent pathogens and infections. This is crucial for preparedness and response to future crises,[43] which public health experts warn are likely to become more frequent due to zoonotic spillovers.[44] In fact, many of the problems that have emerged in response to COVID-19 are issues that have emphasized the inability of the market to deal with infectious diseases, particularly access to sufficient medical and health resources (such as drugs, vaccines, diagnostics, and other medical products), equitable delivery of health products, and emergency outbreak response and preparedness. Moreover, the scant efforts by the few pharmaceutical companies involved in drug development for infectious diseases remain ad hoc, fragmented, and lack a reliable sustainable mechanism to generate sufficient funding for research, while relying heavily on donor financing and priorities, and covering a limited set of diseases.[45] Thus, it has become a matter of existential urgency for the development of new technologies to extenuate the vast challenges posed by these infectious diseases, and to also mend the fragile global system for outbreak prevention and prepare for future pandemics.

### *Looking Ahead – When This is Over, What Next?*

Advances in medical science and public health practices have vastly improved our understanding of these illnesses. However, without equitable access, these medical breakthroughs and innovations are futile. The current coronavirus pandemic presents an opportunity for us to not only fundamentally rethink the present patent framework and drug development system, but also dismantle other forms of exclusivities that have been employed to prop up monopolies and have not necessarily led to the health-needed innovations they were meant to incentivize. The bluff of the pharmaceutical industry for the high patent regime and prices for R&D must be called out. Likewise, the era of numerous anticompetitive practices, relying on market forces to deliver on infectious diseases while extracting maximum value from the most expensive drugs for as long as possible, must end. We need to build a new paradigm on vaccine R&D and scale up new models if global efforts are going to tackle problems of new infectious outbreaks.

43 Bill Gates, *The Next Epidemic – Lessons from Ebola*, 372 New Eng. J. Med. 1381–4 (2015); Laurie Garrett, *The Next Pandemic?*, Foreign Affairs (2005), https://www.foreignaffairs.com/articles/2005-07-01/next-pandemic; Michael T. Osterholm, *Preparing for the Next Pandemic*, 84 Foreign Aff. 24–37 (2005).

44 Sonia Shah, *Think Exotic Animals Are to Blame for the Coronavirus? Think Again*, The Nation (Feb. 18, 2020), https://www.thenation.com/article/environment/coronavirus-habitat-loss/.

45 Moon et al., *supra* note 38.

While many alternatives have been offered by various commentators,[46] two key ideas stand out. First, open-source system, which – as the name denotes – is a structure of accessible and transparent development process and licenses. It involves scientists, creators, and inventors publicly sharing procedures and methods in the development of an invention to catalyze new research.[47] It also enables a culture of collaboration and inclusivity, thereby providing a genuinely new competing model for the discovery of new medicines. For instance, in the early days of the COVID-19 pandemic, researchers in countries, including China, Germany, the United Kingdom, and the US, shared information on the genome sequence for COVID-19.[48] This allowed researchers and laboratories around the world to collaboratively work to reveal the structures of key coronavirus proteins. As a result, a team of structural biologists at Shanghai Tech University in China was able to reveal the structure of a key enzyme, *Mpro*, that the virus needs to replicate.[49]

In analyzing the open-source model for influenza, Amy Kapczynski notes how the Global Influenza Surveillance and Response Network produced data, analysis, and research that proved crucial in the discovery and development of new vaccines and diagnostics[50] – none of it could have happened in the closed proprietary black boxes of IP. Such information-sharing initiatives are required to prepare for and tackle future pandemics. Though a number of platforms have been designed to facilitate the free exchange of pharmaceutical technologies and epidemiological and research data on COVID-19 (such as the WHO COVID-19 Technology Access Pool or C-TAP),[51] there are no overarching legal frameworks or regimes in place today to ensure knowledge, data sharing, and scientific

46 James Love, *Discussion Paper: An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines*, UNITAID (2016), https://www.keionline.org/wp-content/uploads/Delinkage_economic-perspective_Feb2016.pdf; Jorge Bermudez & Ellen 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 THE OPEN AIDS J. 37–40 (2010); World Health Organization, World Intellectual Property Organization, World Trade Organization, *Promoting Access to Medical Technologies and Innovation – Intersections between Public Health, Intellectual Property and Trade* (2013), https://www.wipo.int/publications/en/details.jsp?id=305&plang=EN (last visited Jun 22, 2020).

47 Amy Kapczynski, *Order without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1544–46 (Sept. 2017), https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=4738&context=clr.

48 *Coronavirus: Everyone Wins When Patents are Pooled*, Editorials, 581 NATURE 240 (2020).

49 *Id.*

50 Kapczynski, *supra* note 47, at 1591–95.

51 Coronavirus Treatment Acceleration Program (C-TAP) was first proposed by was first proposed by Costa Rica and aims to accelerate the development of vaccines and medicines through the sharing of research and information and to increase manufacturing capacity for any products that are developed. *See* COVID-19 Technology Access Pool, *Live: Launch of the COVID-19 Technology Access Pool*, WORLD HEALTH ORG. (May 29, 2020), https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool.

cooperation. If we are to prepare for the next pandemic, rapid knowledge production and dissemination are essential. Limits to accelerating scientific research and understanding must be removed to ensure the production and sharing of data, knowledge, and technology.[52] This would not only avert long delays from laboratories to market, but would help expedite rapid scale-up and manufacture of new treatment for future epidemics.

Second, in addition to the open-source model, a move back to publicly funded research and innovation as well as the strengthening of health systems, including laboratories, are essential. The chaos and unraveling of public health facilities by the COVID-19 crisis, even in developed countries, has accentuated how severely unprepared many countries are in dealing with the emergence of deadly viruses. Years of defunding health systems and publicly funded research and surveillance structures have severely weakened coordinated national responses to manage new risks and dangers. As we have seen, without a functioning health system, it is very hard for a country to deal with epidemics. A robust investment in health facilities and sustainable financing of public research laboratories capable of developing and manufacturing drugs and vaccines on their own would ensure that the public interest and not market forces drive innovation.

## Conclusion: TRIPS Agreement and Medicines Access

The myriad issues explored in this book, as we have seen, address distinct shifts and *ruptures* within the medicines access debates and global pharmaceutical patent regime. In focusing on these issues, the chapters in this book have interrogated the substantive concerns and crises of the global pharmaceutical patent regime. The COVID-19 pandemic redoubles these crises, further generating unforeseen chaos globally, which has both short- and long-term implications. Auspiciously, the current crisis presents an opportunity for change and creates space for new beginnings. The world has a chance for an enduring systemic reform of IP rights, pharmaceutical industry practices, and the global system for responding to outbreaks and other infectious diseases. Let us not waste a "good" crisis so that the catastrophe of the coronavirus pandemic and the unnecessary deaths will never be repeated.

52 Katrina Perehudoff & Jennifer Sellin, *COVID-19 Technology Access Pool (C-TAP): A Promising Human Rights Approach*, Medicines Law & Policy (June 18, 2020), https://medicineslawandpolicy.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach/.