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The Intellectual Property of COVID-19

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The Intellectual Property of COVID-19

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THE INTELLECTUAL PROPERTY OF COVID-19

Ana Santos Rutschman*

This chapter describes and analyzes intellectual property issues arising during the race to develop new treatments, vaccines and other medical technologies needed to address the public health problems posed by COVID-19. The chapter highlights two contrasting dimensions of the pandemic: on the one hand, the persistence of siloed approaches to R&D, technology transfer and allocation of health goods; and on the other, the emergence of countervailing collaborative efforts seeking to offset the progressive commodification of public health goods, as well as overly proprietary traits of current innovation regimes.

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I. THE COVID-19 PANDEMIC FROM THE VIEWPOINT OF INTELLECTUAL PROPERTY

The response to COVID-19 is indissolubly tied to intellectual property. In an increasingly globalized world in which infectious disease pathogens travel faster and wider than before, the development of vaccines, treatments and other forms of medical technology has become an

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integral part of public health preparedness and response frameworks.¹ The development of these technologies, and to a certain extent the allocation and distribution of resulting outputs, is informed by intellectual property regimes. These regimes influence the commitment of R&D resources, shape scientific collaborations and, in some cases, may condition the widespread availability of emerging technologies. As seen throughout this chapter, COVID-19 has exposed the shortcomings of ingrained reliance on intellectual property as a channel for the production and dissemination of medical technologies needed to address the problems posed by pandemics and epidemics. At the same time, COVID-19 has brought new life to countervailing efforts to explore legal and policy mechanisms to potentially offset some of the problems posed by the pervasiveness of, and shortcomings associated with, intellectual property dynamics.

In tracing the dual ways in which intellectual property has affected preparedness for, and the response to, COVID-19, this chapter highlights three features of contemporary intellectual property regimes and examines their impact on innovation(s) needed to address public health crises. First, it explores the incentives function of patent law and policy, which places considerable emphasis on market-driven investment in R&D on medical technologies. In so doing, intellectual property becomes one of the driving forces of the commodification of goods—vaccines, drugs or ventilator parts, for example—which are best understood as public health goods.

Second, the chapter illustrates how intellectual property has reinforced an ethos of siloed R&D, as illustrated by the COVID-19 vaccine race, which at the time of writing includes hundreds of separate vaccine development projects.² These siloes further extend into the allocative domain: with the development of medical technologies now largely steeped in proprietary frameworks, several countries have resumed the practice of reserving significant amounts of emerging technologies for their domestic populations,³ thus curtailing the possibility of equitable transnational approaches to a global public health crisis. This approach is commonly known in the field of vaccines as “vaccine nationalism.”⁴ Nationalism skews the distribution of medical technologies developed during a pandemic, reducing opportunities for transnational coordination

¹ See e.g. MILKEN INST., *COVID-19 Treatment and Vaccine Tracker*, *infra* note XX, (listing over 200 COVID-19 vaccine projects and over 300 COVID-19 treatment projects as of Aug. 25, 2020) (last accessed Aug. 25, 2020).

² *Id.*, *ib.* See also *infra*, Part III.A.

³ *Infra*, Part III.C.

⁴ See e.g. Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT’L. AFF. ONLINE (Jul. 3, 2020).

and, as seen below, tendentially limiting access to these technologies by populations in economically disadvantaged parts of the world.

The chapter ends nonetheless on a positive note, as COVID-19 has also made it abundantly clear that the legal infrastructure needed to address many of these problems is already in place. Early in the pandemic, several countries signaled that they would rely on intellectual property mechanisms to ensure broad and equitable access to medical technologies developed during (and possibly after) the pandemic, such as vaccines and treatments for COVID-19. These mechanisms embody different types of commitments to share intellectual property, data and knowledge.⁵ At the allocative level, a significant number of countries joined an ad hoc vaccine distribution facility coordinated by Geneva-based international organizations. These efforts, albeit nascent and, in many cases, likely transient nature, constitute meaningful steps towards a better innovation ecosystem for medical technologies needed to prevent and respond to future pandemic.

II. INTELLECTUAL PROPERTY BEFORE A PANDEMIC

An often-cited purpose of intellectual property is its incentives function.⁶ Patent rights, in particular, are partly regarded as catalysts for investment in areas traditionally considered risky and time- or resource-intensive.⁷ Yet, literature and practice have long identified a growing number of areas in which this proposition does not fully account for current dynamics in innovation processes and the motivations of R&D players.⁸

Many of health goods needed for pandemic preparedness and response are among those that tend to fare poorly if their development and production is primarily dependent on intellectual

⁵ These commitments were undertaken both by countries (C-TAP) and institutions, including private-sector R&D players (Open COVID-19 Pledge). See *infra*, Parts IV.A and IV.B.

⁶ See generally Stephen M. Maurer, *Intellectual Property Incentives: Economics and Policy Implications*, in OXFORD HANDBOOK OF INTELLECTUAL PROPERTY LAW (ROCHELLE DREYFUSS & JUSTINE PILA, EDs.) (2018). See also Adrian Towse, *A Review of IP and Non-IP Incentives for R&D for Diseases of Poverty. What Type of Innovation is Required and How Can We Incentivise the Private Sector to Deliver It?*, Final Report for the WHO Commission on Intellectual Property Rights, Innovation and Public Health (2005).

⁷ See e.g. Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, HEALTH AFF. (2015).

⁸ See e.g. Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437 (2010); Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017).

property incentives or other forms of market-driven forces.⁹ Some of these goods might be scientifically complex and challenging to produce – for instance, a vaccine targeting HIV has yet to be developed, in spite of long-lasting R&D efforts – while others constitute relatively simple forms of technology – as is the case of ventilators, which were in short supply during the COVID-19 pandemic and for which there have been shortages in national stockpiles before pandemics occur.¹⁰

Because intellectual property incentives may strongly condition funding for R&D, some of these goods may remain undeveloped (or insufficiently developed) before a large-scale public crisis occurs.¹¹ This happens if the public health value of a particular good is hard to estimate, or if the anticipated return-on-investment is estimated as being insufficiently attractive from an economic perspective.¹² Preventatives like vaccines, which embody both of these problems, illustrate this dissociation between market incentives (including intellectual property) and public health goals. Vaccines are critical for the prevention of outbreaks of infectious diseases, yet their successful deployment translates into a non-event, or a limited public health crisis. Both outcomes are hard to quantify from the perspective of savings to health systems.¹³ At the same time, most vaccine manufacturers do not expect significant return-on-investment on vaccines targeting emerging pathogens.¹⁴ While there is a strong patenting culture in the field of vaccines as a whole,¹⁵ the prospect of being granted a patent appears to be of limited importance in terms of catalyzing investment in pre-outbreak vaccine R&D.¹⁶

Dissociations between R&D priorities and public health imperatives tend to be cured (or at least lessened) by the occurrence of a pandemic or epidemic.¹⁷ COVID-19 has illustrated this phenomenon in the form of concomitant R&D races to develop diagnostics, vaccines, treatments

⁹ See Ana Santos Rutschman, *IP Preparedness of Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018); Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. ONLINE 170 (2020); Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, __ J. L. & BIOSCI. __ (forthcoming 2020).

¹⁰ See e.g. Hsin-Chan Huang et al., *Stockpiling Ventilators for Influenza Pandemics*, 23 EMERGING INFECTIOUS DISEASES 914 (2017).

¹¹ See Rutschman, *IP Preparedness*, *supra* note 9.

¹² See Rutschman, *The Intellectual Property of Vaccines*, *supra* note 9.

¹³ *Id.*, *ib.* See also Q. Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, __ J. L. & BIOSCI. __ (forthcoming 2020).

¹⁴ *Id.*, *ib.* But see Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, __ TEXAS A&M PROP. J. __ (forthcoming 2020) (describing examples of commercially successful vaccines).

¹⁵ See Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729 (2019).

¹⁶ See Rutschman, *IP Preparedness*, *supra* note 9.

¹⁷ *Id.*, *ib.*

and other medical technologies. As these races unfold, the imprints of intellectual property are visible across different domains. The following section explores this shift in R&D approaches in the context of COVID-19, and highlight the persistence of proprietary approaches to the development, production and distribution of health goods needed during a pandemic.

III. INTELLECTUAL PROPERTY AND THE SILO CULTURE DURING A PANDEMIC

The COVID-19 pandemic ushered in a seemingly global race to develop treatments, vaccines and several other types of medical technologies. Yet, in spite of extraordinary goodwill and resource commitment towards expedited R&D, many of the efforts to produce these technologies still took place in siloed environments. While a pandemic or other form of large-scale public health crisis may temporarily solve some of the incentives and funding shortcomings registered in pre-outbreak periods, it does not fundamentally change traditional R&D dynamics. In particular, it does not do away with the siloed nature of R&D processes leading to the production of goods needed to respond to a borderless public health problem. This, in turn, breeds instances of duplication, secrecy and lack of collaboration, active non-cooperation and inequitable allocation of R&D outputs.

A. DUPLICATION, PROPRIETARY R&D AND AFFORDABILITY ISSUES

As an illustration of the siloed nature of pandemic R&D, consider the case of vaccines. COVID-19 unleashed the most densely populated vaccine race in history: by late summer 2020, there were over 200 discrete vaccine development projects across the world.¹⁸ These projects varied in developmental stage, ranging from pre-clinical studies to phase II and III clinical trials.¹⁹

As a general rule, a plethora of scientific approaches – combined with the influx of numerous players – to a traditionally underpopulated and underfunded field of R&D constitutes a welcome development. However, COVID-19 triggered what is arguably an overpopulation of the R&D field. Governments quickly decided to prioritize a small number of vaccine candidates,

¹⁸ MILKEN INST., *COVID-19 Treatment and Vaccine Tracker*, <https://covid-19tracker.milkeninstitute.org> (listing 203 vaccine projects as of Aug. 21, 2020) (last accessed Aug. 25, 2020).

¹⁹ *Id.*, *ib.*

funneling public funding largely to a small number of selected candidates. For instance, in the United States, Operation Warp Speed had narrowed down the field to 5 vaccine candidates by early June 2020.²⁰

That such a narrowing down of priority vaccine candidates should occur is inevitable given both the nature of pharmaceutical R&D and funding constraints. Nonetheless, the enormous dispersion of resources and R&D attention during the COVID-19 vaccine race – with the inevitable lack of coordination and duplication of efforts it entails – also speaks to systemic shortcomings in the development and production of health goods in periods of crisis.²¹ R&D performed in response to pandemics or epidemics largely magnifies the structure and dynamics of standard drug development, which is largely firm or consortia-specific, as well as based on patent-driven innovation processes.²² As such, while a pandemic temporarily triggers a spike in R&D funding and a compression of R&D timelines, these are likely to result in overpopulated vaccine or drug races that lead to wasteful duplication.

Concerns with duplication are not exclusive to vaccines. For instance, the race to develop treatments for COVID-19 was also unusually populated, in terms of the number of R&D players and products, as well as temporally. In late summer 2020, there were over 300 discrete treatment development projects, from antivirals to monoclonal antibodies and plasma products.²³

The duplication problem is further compounded by a general lack of collaboration among players participating in different R&D projects. Data, know-how and other forms of knowledge are not shared universally or made available in meaningful ways, and in some cases – including the manufacture of goods critical for pandemic response and preparedness like certain vaccines – can easily be kept secret.²⁴ In sum, R&D in a pandemic continues to follow proprietary models of innovation instead of tendentially collaborative approaches.

²⁰ U.S. DEP'T HEALTH & HUM. SERVICES, *Fact Sheet: Explaining Operation Warp Speed* (Jun. 26, 2020); Stephanie Soucheray, *Operation Warp Speed Names 5 COVID-19 Vaccine Candidates*, CTR. FOR INFECTIOUS DISEASE RESEARCH & POL'Y (Jun. 4, 2020).

²¹ WHO Blueprint.

²² See Heled et al., *supra* note 9.

²³ MILKEN INST., *COVID-19 Treatment and Vaccine Tracker*, <https://covid-19tracker.milkeninstitute.org> (listing 316 treatment projects as of Aug. 21, 2020) (last accessed Aug. 25, 2020).

²⁴ See W. Nicholson Price II et al., *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, SCI. (Aug. 21, 2020).

While problems of duplication and lack of collaboration are not solely attributable to the prevalence of an intellectual property-based R&D culture,²⁵ they denote a certain generalized complacency with the commodification of vaccines, treatments and other public health goods. This commodification extends beyond the domain of R&D. Once developed and authorized or approved by regulatory agencies like the U.S. Food and Drug Administration or the European Medicines Agency, these goods may be made available in ways that effectively exclude some indicated populations from accessing them.²⁶ Early on in the COVID-19 pandemic there were concerns with that excessive pricing of emerging vaccines and treatments, especially in the United States.

The first red flag happened in February 2020, when Secretary of Health and Human Services Alex Azar publicly stated that the government would not guarantee that COVID-19 vaccines would be priced affordably in the United States.²⁷ Secretary Azar explained the position of the government by alluding to a version of the incentives narrative alluded to in the previous section: “We can’t control that price [of COVID-19 vaccines] because we need the private sector to invest.”²⁸

It should be noted that there are multiple legal mechanisms that would allow the government to guarantee the affordability of COVID-19 vaccines and drugs. Inventions that receive federal funding, as was the case of remdesivir, are subject to march-in rights, which allow funding agencies to grant a license to other drug manufacturers in order “to alleviate health or safety needs” not reasonably satisfied by the patent holder.²⁹ Recently, scholars have made the case that provisions regulating government use of patented technologies – namely 28 U.S.C. § 1498 – can and should be used by the government to make or otherwise obtain a generic version of an excessively priced patented drug.³⁰ As Hannah Brennan and colleagues have noted:

The government may negotiate a license in the shadow of its § 1498 power. Alternatively, the government may simply make or purchase

²⁵ See e.g. Ana Santos Rutschman, *The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation*, COLUM. J. INT’L AFF. (Mar. 21, 2020) (noting the existence of “governance deficits in biopharmaceutical innovation systems”).

²⁶ The ability

²⁷ See Nicole Wetsman, *Health Secretary Alex Azar Won’t Promise that a Coronavirus Vaccine Would be Affordable*, VERGE (Feb. 27, 2020).

²⁸ *Id.*, *ib.*

²⁹ 35 U.S.C. § 203. See also Ryan Whalen, *The Bayh–Dole Act & Public Rights in Federally Funded Inventions: Will The Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015).

³⁰ 28 U.S.C. § 1498; Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH 275, 301-302 (2017). See also Charles Duan & Christopher J. Morten, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises* (on file with author).

the patented invention, leaving the patent holder to sue for damages if it is dissatisfied with the compensation offered. The present statute, like the 1910 Act, provides the only remedy available to a patent holder is reasonable and entire compensation; the patent holder may not seek injunctive relief.³¹

There are also legal mechanisms unrelated to intellectual property that would enable the government to promote the affordability of drugs, vaccines and other emerging products needed to respond to the COVID-19 pandemic. In March 2020, the United States government used the Defense Production Act (DPA) to compel General Motors to start producing ventilators.³² Many commentators argued that the government should use this pathway more extensively to obtain a broad range of products, from tests to N95 masks, and potentially beyond.³³ So far, however, the government has not done so.

The second red flag in this area occurred when prices were publicized for the first drug indicated for the treatment of COVID-19, an antiviral called remdesivir.³⁴ In June 2020, Gilead – the pharmaceutical company holding patent rights over remdesivir – announced that a full course of treatment (which takes place over five days) would cost \$3,120 to Medicare, Medicaid and private insurers in the United States.³⁵ This price is 33% higher than the one charged to governments in other developed countries – which will pay \$2,340, the same price tag supported in the United States by the Department of Veterans Affairs and the Indian Health Service, a division of the Department of Health and Human Services.³⁶ For developing countries, the company announced it would sell remdesivir at a “substantially lower” yet unspecified price.³⁷

Both instances – the general lack of a guarantee of affordability of COVID-19 vaccines and the specific price tag for a COVID-19 treatment, considered steep by many commentators – illustrate one of the most significant problems associated with the ongoing commodification of public health goods. As R&D processes and distribution of these goods have been largely

³¹ Brennan et al., *ib.*

³² See Aishvarya Kavi, *Virus Surge Brings Calls for Trump to Invoke Defense Production Act*, N.Y. TIMES (Jul. 22, 2020).

³³ *Id.*, *ib.*

³⁴ See Gina Kolata, *Remdesivir, the First Coronavirus Drug, Gets a Price Tag*, N.Y. TIMES (Jun. 29, 2020).

³⁵ See Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (Jun. 29, 2020),

³⁶ *Id.*, *ib.*

³⁷ See Hannah Denham et al., *Gilead Sets Price of Coronavirus Drug Remdesivir at \$3,120 as Trump Administration Secures Supply for 500,000 Patients*, WASH. POST (Jun. 29, 2020).

subsumed into overly proprietary rights frameworks, public interest considerations have been eroded – namely the public interest in broad, affordable access to vaccines, drugs and other goods needed to address the pandemic.

B. PROPRIETARY RIGHTS AND NON-COOPERATIVE BEHAVIORS

Intellectual property may leave a different type of imprint on the response to a pandemic. COVID-19 provided an illustration of the possible chilling effects of a culture that places too much emphasis on the dynamics of intellectual property rights in the face of a situation of dire public health crisis.

Consider the following case. A hospital in Brescia, one of the Italian cities the most affected by the COVID-19 outbreak, was rapidly going through its stock of valves needed to connect patients to ventilators.³⁸ After being unable to acquire replacement valves from the original manufacturer, the hospital turned to local engineers who were able to reverse engineer the valves and create a 3D-printable prototype, even though the original manufacturing company refused to share the digital files containing the instructions to print the valves.³⁹ Through a partnership with local owners of 3D printers, the engineers were able to print 100 valves in a single day.⁴⁰ Moreover, while a valve from the original manufacturer had a price tag of over \$10,000, the locally 3D-printed valves were produced at the cost of just over one dollar.⁴¹ The partnership, however, refused to share the files containing instructions to print the valves with other companies, citing concerns about intellectual property liability for such distribution.⁴²

This example illustrates how a web of intellectual property rights in an unsettled area of the law can detrimentally affect the use of life-saving medical devices during a pandemic. It is possible – in fact, likely – that several intellectual property violations occurred throughout the process that delivered valves to an overburdened hospital. These violations include the creation

³⁸ Dinusha Mendis et al., *3D Printing: How an Emerging Technology May Help Fight a Pandemic*, IPR INFO (Feb. 25, 2020).

³⁹ *Id.*, *ib.* See also Anas Essop, *Hospital in Italy Turns to 3D Printing to Save Lives of Coronavirus Patients*, 3D PRINTING INDUSTRY (Mar. 18, 2020), <https://3dprintingindustry.com/news/hospital-in-italy-turns-to-3d-printing-to-save-lives-of-coronavirus-patients-169136/>

⁴⁰ Mendis et al., *supra* note 38.

⁴¹ *Id.*, *ib.*

⁴² *Id.*, *ib.*

and use of the digital file, the printing of the valves and the printed valves. Had the engineers shared the files containing instructions for the 3D printing of the valves, further violations would in all likelihood have occurred.⁴³

Currently, there is no legal mechanism to expeditiously compel transfers of intellectual property during public health crises.⁴⁴ Similarly, defenses available in other areas of the law, such as the necessity defense or self-defense, are not recognized in intellectual property theory and law.⁴⁵ While these problems remain unaddressed for the time being, the COVID-19 pandemic has prompted the development and implementation of several initiatives that seek to minimize some of the siloed effects of our patent-centric R&D culture – the chapter turns to these efforts in Part IV, describing the patent pool created by the World Health Organization and the Open COVID-19 Pledge.

C. INEQUITABLE ALLOCATION OF RESULTING GOODS

Pandemics pose global public health problems. Treatments, vaccines and other medical technologies emerging from pandemic-induced R&D races may nonetheless be allocated in ways that are geographically and economically skewed.

No other area embodies this phenomenon more saliently than the development of COVID-19 vaccines – to the point that the expression “vaccine nationalism” is now firmly embedded into the popular discourse.⁴⁶ Vaccine nationalism can be defined as “efforts to influence the allocation of newly developed vaccines, or first batches thereof, to the detriment – often the exclusion – of other, generally poorer countries.”⁴⁷

During the early stages of the COVID-19 pandemic, several developed countries moved to reserve large numbers of vaccine doses for their domestic populations.⁴⁸ They have done so by entering into contractual agreements – often called pre-production orders – with pharmaceutical

⁴³ *Id.*, *ib.*

⁴⁴ Rutschman, *Vaccine Race*, *supra* note 9.

⁴⁵ But see Heled et al., *The Need for the Tort Law Privileges of Self-Defense and Necessity in Intellectual Property Law*, CHI. U. LEGAL F. (forthcoming 2021).

⁴⁶ See e.g. Adam Taylor, *Why Vaccine Nationalism is Winning*, WASH. POST (Sept. 2, 2020), <https://www.washingtonpost.com/world/2020/09/03/why-coronavirus-vaccine-nationalism-is-winning/>

⁴⁷ Sam F. Halabi & Ana Santos Rutschman, *Viral Sovereignty and Vaccine Nationalism: Constructing the Post COVID-19 Vaccine International Order* __ (forthcoming) (draft on file with author).

⁴⁸ See Rutschman, *The Reemergence of Vaccine Nationalism*, *supra* note 4.

companies working on vaccine candidates in the more advanced stages of the R&D pipeline.⁴⁹ By mid-August 2020, the United Kingdom had placed orders for 340 million doses of vaccine, becoming the largest per-capita buyer in the world of COVID-19 vaccines.⁵⁰ The United States had placed orders with at least six vaccine manufacturers for 800 million doses of vaccine.⁵¹ Overall, by late summer 2020, developed countries had placed pre-purchase order for over two billion doses of COVID-19 vaccines.⁵²

At first blush this might appear consistent with contemporary notions of sovereignty and domestic public health agendas. In practice, unfettered allocation of vaccines through bilateral channels – such as pre-purchases contracts between governments and pharmaceutical companies – is bound to result in inequitable allocation of vaccines.

A recent study conducted by the Coalition for Epidemic Preparedness Innovations (CEPI) calculated that global manufacturing capacity for COVID-19 vaccines is between two and four million doses 2-4 billion doses by the end of 2021.⁵³ Given this estimate, contract bilateralism is likely to result in a disproportionate allocation of the first batches of emerging vaccines to countries that have the economic ability to negotiate pre-purchase orders. Conversely, indicated populations in developing countries – which have been deeply affected by COVID-19 – are likely to only be able to access a disproportionately smaller number of vaccines doses. Given the global nature of the pandemic, this split is inequitable towards populations in economically disadvantaged countries. Moreover, this form of nationalism runs counter to public health and epidemiological principles, which take a global (or at least transnational) approach to problems like COVID-19 rather than sovereignty-based responses to pandemics and epidemics.

Allocative problems like vaccine nationalism are not strictly intellectual property problems. Nevertheless, they derive from the same siloed and proprietary approaches to pharmaceutical innovation that intellectual property so often intensifies. As seen in Part IV.C, there are ongoing efforts to curb vaccine nationalism, including the formation of a large-scale procurement mechanism (COVAX) aimed at the global and equitable distribution of COVID-19

⁴⁹ *Id., ib.*

⁵⁰ Ewen Callaway, *The Unequal Scramble for Coronavirus Vaccines — By the Numbers*, NATURE (Aug. 24, 2020).

⁵¹ *Id., ib.*

⁵² *Id., ib.*

⁵³ CEPI, *CEPI Survey Assesses Potential Covid-19 Vaccine Manufacturing Capacity* (Aug. 5, 2020).

vaccines.⁵⁴ Several countries, however, have declined to join COVAX.⁵⁵ Pursuant to its current policy of international isolationism, the United States is one of these countries.

IV. INTELLECTUAL PROPERTY COLLABORATIONS

While the previous section documented different instances in which a silo mentality has prevailed over collaborative endeavors in the response to COVID-19, the ongoing pandemic has also originated a number of countervailing efforts aimed at fostering collaborations at the R&D and distributive levels. Some of these collaborations resort to well-known mechanisms in intellectual property history and practice (patent pools and pledges) to mitigate intellectual property-induced inefficiencies.⁵⁶ Others eschew purely nationalist approaches to the distribution of medical technologies emerging from R&D performed during the pandemic through the creation of tendentially global models to finance and allocate health goods (procurement facilities, particularly in the field of vaccines).

A. PATENT POOLS

In March 2020, the government of Costa Rica submitted a proposal to the World Health Organization for the creation of a patent pool designed to cover a broad range of medical technologies:

This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country.⁵⁷

The World Intellectual Property Organization defines patent pool as “an agreement between two or more patent owners to license one or more of their patents to one another or to

⁵⁴ *Infra*, Part IV.C.

⁵⁵ See Donato Paolo Mancini & Michael Peel, ‘Vaccine Nationalism’ Delays WHO’s Struggling Covax Scheme, *Fin. Times* (Sept. 1, 2020), <https://www.ft.com/content/502df709-25ac-48f6-ae1-ae7ac03c759>

⁵⁶ See Parts IV.A and IV.B.

⁵⁷ Letter from Costa Rica to the World Health Organization, Knowledge Ecology Int’l (Mar. 23, 2020), <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf>

third parties.”⁵⁸ Daniel Crane has aptly described patent pools as “a form of intra-industry social contract permitting the emergence from this Hobbesian war of each against all.”⁵⁹ Patent pools focused on health technologies, or segments thereof, are not a new figure in the international landscape.⁶⁰ One of the largest and most well-known examples is the Medicines Patent Pool (MPP),⁶¹ an organization created by Unitaid in 2010 to negotiate voluntary licenses for medicines needed in lower-resource countries (HIV, hepatitis C and tuberculosis).⁶²

In addition to constituting an early response to time- and demand-driven pressures on COVID-19 R&D pipelines, Costa Rica’s proposal was partly fueled by concerns that health technologies emerging during the pandemic might be priced unaffordably for economically disadvantaged populations.⁶³ As implementation of the proposed patent pool began in the following months, the World Health Organization further recognized that overreliance on intellectual property-based modes of innovation was unlikely to result in equitable access to health goods, even in periods of transnational public health crises:

⁵⁸ WORLD. INTEL. PROP. ORG., PATENT POOLS AND ANTITRUST – A COMPARATIVE ANALYSIS (2014), https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf. See also generally Ryan Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry*, 70 J. ECON. HIST. 898 (2010); Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY, INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY, ROCHELLE COOPER DREYFUSS ET AL. (EDS.) (2010); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in INNOVATION POLICY AND THE ECONOMY, VOLUME I (ADAM JAFFE ET AL., EDs.) (2001); Michael J. Madison et al., *Constructing Commons in the Cultural Environment*, 95 Cornell L. Rev. 657, 660-661, 681-687, 700-706 (2010); Jean Tirole & Josh Lerner, *Efficient Patent Pools*, NBER Working Paper No. w9175 (2002); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J. L. REFORM, 141, 216-220 (2004).

⁵⁹ Daniel A. Crane, *Patent Pools, RAND Commitments, and the Problematics of Price Discrimination*, in WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY (ROCHELLE C. DREYFUSS ET AL., EDs.) (2010).

⁶⁰ See Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L. J. 1563, 1599-1604 (2013) (describing the SARS patent pool); Brook K. Baker, *A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines*, 10 NORTHEASTERN U. L. REV. 226 (2018); Esther van Zimmeren et al., *Patent Pools and Clearinghouses in the Life Sciences*, 29 TRENDS BIOTECH. 569 (2011).

⁶¹ Medicines Patent Pool, About Us, <https://medicinespatentpool.org>. See also Esteban Burrone, *Patent Pooling in Public Health*, in THE CAMBRIDGE HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT, MARGARET CHON ET AL., EDs. (2018); Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L. J. 293 (2012); Sandeep Juneja et al., *Projected Savings Through Public Health Voluntary Licences of HIV Drugs Negotiated by the Medicines Patent Pool (MPP)*, 12(5) PLOS ONE (2017).

⁶² UNITAID, *The Medicines Patent Pool*, <https://unitaid.org/project/medicines-patent-pool/#en> (last accessed Aug. 28, 2020).

⁶³ See Ed Silverman, *WHO is Asked to Create a Voluntary Intellectual Property Pool to Develop Covid-19 Products*, STAT (Mar. 24, 2020), <https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/>

The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies. This initiative sets out an alternative, in line with WHO's efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.⁶⁴

The COVID-19 Technology Access Pool (C-TAP) was rolled out in late May 2020.⁶⁵ The goals of C-TAP are manifold. It aims to promote and accelerate the public disclosure of information critical to COVID-19 R&D through the sharing of gene sequencing research and clinical trial results.⁶⁶ It also advocates for the insertion of provisions into agreements mandating equitable distribution of COVID-19 treatments, vaccines and other emerging products, as well as the disclosure of clinical trial data.⁶⁷ It seeks to promote the licensure of these products to both large and small manufacturers and distributors. And, finally, it advocates for "open innovation models and technology transfer that increase local manufacturing and supply capacity."⁶⁸

Patent pools like C-TAP are designed to reduce the risk and transaction costs associated with negotiating processes.⁶⁹ Moreover, they can potentially help speeding up R&D timelines through their signaling function: R&D players (from scientists to institutional representatives to funders) know early on that a patent committed to the pool indicates that the underlying technology or method can be licensed as opposed to substitutes or worked around.⁷⁰

Yet, patent pools are not without drawbacks. Participation in a pool is voluntary, often leading to limitations in terms of participants, their heterogeneity and the number and scope of pooled patents.⁷¹ Additionally, patent pooling does not necessarily mean that distribution of, and access to, emerging innovations will automatically occur on an equitable basis. Agreements

⁶⁴ WORLD HEALTH ORG., *Solidarity Call to Action: Making the Response to COVID-19 a Public Common Good*, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action/>, (last accessed Aug. 29, 2020).

⁶⁵ WORLD HEALTH ORG., *COVID-19 Technology Access Pool*, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> (last accessed Aug. 29, 2020).

⁶⁶ WORLD HEALTH ORG., *WHO Director-General's opening remarks at the media briefing on COVID-19 - 29 May 2020* (May 29, 2020), <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---29-may-2020>

⁶⁷ *Id.*, *ib.*

⁶⁸ *Id.*, *ib.*

⁶⁹ See Muhammad Zaheer Abbas, *Treatment of the Novel COVID-19: Why Costa Rica's Proposal for the Creation of a Global Pooling Mechanism Deserves Serious Consideration?*, 7 J. L. & BIOSCI. 1 (2020). See Crane, *supra* note 59.

⁷⁰ *Id.*, *ib.*

⁷¹ See generally, Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543 (2015).

between licensors and licensees might be silent on pricing and distribution issues, which in turn might lead to the exclusion of indicated populations, especially in economically disadvantaged areas of the globe.⁷²

To date, thirty countries and several international organizations have joined C-TAP.⁷³ While the numbers are somewhat encouraging, they showcase some of the inherent limitations of patent pools. In particular, some of the most salient players in pharmaceutical R&D have been reluctant to contribute patents to the pool.⁷⁴ After having commented favorably on other initiatives created to speed up COVID-19 R&D, the Director General of the International Federation of Pharmaceutical Manufacturers & Associations, expressed his views on C-TAP: “I don't quite see what the new initiative adds.”⁷⁵

Even against this backdrop, an important advantage of C-TAP is that it is part of a larger effort by the World Health Organization and other institutional players in the international public health space to break down R&D silos and expedite both the development and the distribution of health goods needed to address the COVID-19 pandemic. In parallel with the formation of the pool, the World Health Organization coordinated the creation and development of the Access to COVID-19 Tools (ACT) Accelerator, described as a “global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.”⁷⁶ As described in Part IV.C, this collaboration is overseen by a network of international organizations and public health-oriented private organizations, including the World Health Organization, the Wellcome Trust, the Bill and Melinda Gates Foundation, the World Bank group and the Global Fund.⁷⁷ The ACT Accelerator is divided into four pillars: diagnostics, treatments, vaccines and the strengthening of health systems.⁷⁸

⁷² See e.g. Ana Santos Rutschman, *How ‘Vaccine Nationalism’ Could Block Vulnerable Populations’ Access to COVID-19 Vaccines*, THE CONVERSATION (Jun. 17, 2020), <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689>

⁷³ UNITED NATIONS, *COVID-19: Countries Support ‘One-Stop Shop’ to Share Science and Research*, <https://news.un.org/en/story/2020/05/1065132> (last accessed Aug. 29, 2020).

⁷⁴ Chris Dall, *Pharma Execs Say Several COVID Vaccine Options Needed*, CIDRAP NEWS (May 29, 2020). See also Ed Silverman, *The WHO Launched a Voluntary Covid-19 Product Pool. What Happens Next?*, STAT (May 20, 2020) (noting that “the pharmaceutical industry has dismissed the notion [of the patent pool], which underlies concerns that such a project is unlikely to succeed without widespread involvement”).

⁷⁵ *Id.*, *ib.*

⁷⁶ WORLD HEALTH ORG., *The Access to COVID-19 Tools (ACT) Accelerator* (Apr. 24, 2020), [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator)

⁷⁷ WORLD HEALTH ORG., *The Access to COVID-19 Tools (ACT) Accelerator*, <https://www.who.int/initiatives/act-accelerator>

⁷⁸ WORLD HEALTH ORG., *The Access to COVID-19 Tools (ACT) Accelerator*,

As seen above, the United States has by and large chosen not to embrace collaborative international frameworks in its response to the COVID-19 pandemic. The U.S. Patent and Trademark Office has nonetheless created a voluntary program – Patents 4 Partnerships – to facilitate the licensure of patented technologies.⁷⁹ In its current iteration, the initiative focuses on technologies relevant to the response to COVID-19.⁸⁰ These technologies encompass patented products or processes “related to the prevention, diagnosis, and treatment of COVID-19, including, for example, personal protective equipment, disinfectants, ventilators, testing equipment and components thereof.”⁸¹ USPTO has made available a searchable platform – the IP Marketplace Platform⁸² – that provides access to a centralized list of patents and patents applications.⁸³ As with patent pools, this mechanism seeks to reduce transaction costs and speed up R&D efforts during the pandemic. At the time of writing, there were over 300 patents listed as available for licensing.⁸⁴

Neither the transnational patent pool model promoted by the WHO nor the more modest experiment led by the USPTO have fully displaced instances of nationalism and silo problems inherent to contemporary R&D processes. But these efforts – especially C-TAP in its tendentially global approach – illustrate the long-felt need for transactional intellectual property frameworks that do not adhere to strictly proprietary worldviews. In particular, they underscore and seek to address the tension between the nature of public health crises and scientific collaborations on the one hand, and overly siloed R&D processes based on patent-protected health goods on the other.

B. PATENT PLEDGES

Another pathway to promote the use of patented inventions consists in the adoption of yet another type of voluntary mechanism – the patent pledge.⁸⁵ Unlike patent pools, which signal a

<https://www.who.int/initiatives/act-accelerator>

⁷⁹ U.S. PAT. & TRADEMARK OFFICE, *Patents 4 Partnerships*,

<https://developer.uspto.gov/ipmarketplace/search/patents>

⁸⁰ U.S. PAT. & TRADEMARK OFFICE, *About the Platform*, <https://developer.uspto.gov/ipmarketplace/search/platform>

⁸¹ *Id.*, *ib.*

⁸² U.S. PAT. & TRADEMARK OFF., *IP Marketplace Platform*,

<https://developer.uspto.gov/ipmarketplace/search/patents>

⁸³ U.S. PAT. & TRADEMARK OFF., *About the Platform*, <https://developer.uspto.gov/ipmarketplace/search/platform>

⁸⁴ *Id.*, *ib.*

⁸⁵ Contreras, *supra* note 71.

willingness to license proprietary technologies, patent pledges are structured around the non-assertion, or limited assertion or use, of patent rights.⁸⁶ As Jorge Contreras explains

[patent pledges] are commitments made voluntarily by patent holders to limit the enforcement or other exploitation of their patents. They are made not to direct contractual counterparties, but to the public at large, or at least to large segments of certain markets. And they are made without any direct compensation or other consideration.⁸⁷

In recent years, patent pledges have become more common across several industries, from the automotive industry to computer software.⁸⁸ During the early stages of the COVID-19 pandemic, a group of legal scholars and scientists developed the framework for a COVID-specific pledge.⁸⁹ The Open COVID-19 Pledge (hereinafter the Pledge) was launched in March 2020 as “a commitment by holders of intellectual property to share their intellectual property for the purposes of ending and mitigating the COVID-19 Pandemic.”⁹⁰

Founding adopters of the Pledge included Facebook, Amazon, Intel, IBM, Microsoft, Hewlett Packard and the Sandia National Laboratories.⁹¹ The Pledge quickly amassed a wide-ranging portfolio of patents. For instance, NASA has pledged a patent covering 3D-printed respirators.⁹² Fujitsu has pledged a patent covering disease diagnosis through automated

⁸⁶ *Id.*, at 546.

⁸⁷ *Id.*, *ib.*

⁸⁸ *Id.*, at 545-546. See also Jorge L. Contreras, *The Evolving Patent Pledge Landscape*, CTR. INT’L GOVERNANCE INNOVATION (Apr. 3, 2018), <https://www.cigionline.org/publications/evolving-patent-pledge-landscape>; Jonas Fabian Ehrnsperger & Frank Tietze, *Patent Pledges, Open IP, or Patent Pools? Developing Taxonomies in the Thicket of Terminologies*, PLOS ONE (Aug. 20, 2019); Elon Musk, *All Our Patent Are Belong to You* (sic), TESLA (Jun. 12, 2014), <https://www.tesla.com/blog/all-our-patent-are-belong-you>; Carey Gillam, *Monsanto Extends Pledge on Roundup Ready Soybeans*, REUTERS (Jul. 8, 2010), <https://www.reuters.com/article/monsanto-roundup/monsanto-extends-pledge-on-roundup-ready-soybeans-idUSN0824689420100709>

⁸⁹ See Matthew Bultman, *Scientists, Lawyers Create Coronavirus IP Pledge*, BLOOMBERG LAW (Mar. 27, 2020), <https://news.bloomberglaw.com/ip-law/scientists-lawyers-create-coronavirus-ip-pledge>

⁹⁰ See OPEN COVID-19 PLEDGE, *Frequently Asked Questions*, <https://opencovidpledge.org/faqs/> (last accessed Aug. 30, 2020).

⁹¹ *Id.*, *Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19*, <https://opencovidpledge.org> (last visited Aug. 30, 2020).

⁹² See *Id.*, *NASA-JPL-3D Printed Respirators* (May 20, 2020), <https://opencovidpledge.org/2020/05/20/nasa-jet-propulsion-laboratory/>

software.⁹³ And Facebook has pledged U.S. patent 20190163794, which covers systems and methods for the detection of contextual information indicative of misinformation.⁹⁴

In addition to collecting and centralizing commitments from pledgors, the Pledge operates by providing different types of licenses. Developers of the Pledge created a set of standard licenses that can be adopted on an as-is basis by pledgors.⁹⁵ Additionally, the Pledge recognizes sets of requirements that should be met by non-Pledge licenses deemed either “compatible licenses” or “alternative licenses” vis-à-vis the terms of the Pledge.⁹⁶

Standard licenses – for which there are two versions covering patents and copyrights and one covering patents only – address only essential contractual areas for technology licensure. They cover only five domains: grant and scope; time limitation; regulatory exclusivity; defensive suspension; and the inexistence of a warranty.⁹⁷

“Compatible” licenses consist of licensing frameworks that “provide a set of minimum use permissions.”⁹⁸ This group includes both pre-existing licensing frameworks that have been deemed to be consistent with the Pledge, such as the MIT license⁹⁹ and the Apache 2.0 license,¹⁰⁰ and licenses reviewed on a case-by-case basis and deemed to meet the overall requirements of the Pledge.

“Alternative” licenses consist of licensing frameworks that do not fit the previous categories, but which are nonetheless consistent with the Pledge.¹⁰¹ These include the Creative Commons Attribution-ShareAlike 4.0 International license¹⁰² and GNU’s GNU General Public License.¹⁰³ The Pledge has identified a set of terms that are not acceptable for a license to be

⁹³ See *Id.*, *Fujitsu – Faster Disease Diagnosis Using Computer Software* (Jun. 3, 2020), <https://opencovidpledge.org/2020/06/03/fujitsu-faster-disease-diagnosis-using-computer-software/>; U.S. PAT. 20200118682, *Medical Diagnostic Aid and Method*

⁹⁴ See *Id.*, *Facebook – Combating the Spread of COVID-19 Related Misinformation* (Aug. 11, 2020), <https://opencovidpledge.org/2020/08/11/facebook-combating-the-spread-of-covid-19-related-misinformation/>; U.S. PAT. 20190163794, *Contextual Information for Determining Credibility of Social-Networking*

⁹⁵ See e.g. *Id.*, *About the Licenses*, <https://opencovidpledge.org/licenses/> (last accessed Aug. 30, 2020).

⁹⁶ *Id.*, *ib.*

⁹⁷ See e.g. *Id.*, *Open COVID License 1.0 March 31, 2020*, <https://opencovidpledge.org/v1-0/> (last accessed Aug. 30, 2020).

⁹⁸ See e.g. OPEN COVID-19 PLEDGE, *About the Licenses*, <https://opencovidpledge.org/licenses/> (last accessed Aug. 30, 2020).

⁹⁹ See OPEN SOURCE INITIATIVE, *The MIT License*, <https://opensource.org/licenses/MIT>

¹⁰⁰ See APACHE, *Apache License, Version 2.0*, <https://www.apache.org/licenses/LICENSE-2.0>

¹⁰¹ See e.g. OPEN COVID-19 PLEDGE, *About the Licenses*, <https://opencovidpledge.org/licenses/> (last accessed Aug. 30, 2020).

¹⁰² CREATIVE COMMONS, *Attribution-ShareAlike 4.0 International (CC BY-SA 4.0)*, <https://creativecommons.org/licenses/by-sa/4.0/>

¹⁰³ GNU OPERATING SYSTEM, *GNU General Public License*, <https://www.gnu.org/licenses/gpl-3.0.en.html>

deemed consistent with the spirit of the Pledge.¹⁰⁴ For instance, licenses cannot be granted exclusively for non-commercial uses nor bear any kind of fees.¹⁰⁵

This broad array of licenses allows pledgors to choose the specific contractual frameworks that best fit their interests. For instance, standard license OCL-PC v1.0 (covering both patents and copyrights) lasts “until one year after WHO declares the COVID-19 Pandemic to have ended.”¹⁰⁶ Standards license OCL-PC v1.1 (covering both patents and copyrights) and OCL-P v1.1 (covering only patents) have the same default duration, but will not last “beyond January 1, 2023, unless otherwise extended by the Pledgor.”¹⁰⁷ Pledgors may thus choose between an open-ended or a specific term. Similarly, while standard licenses are silent on indemnification,¹⁰⁸ other versions may contemplate the possibility of requiring “the licensee to indemnify the licensor for liability directly attributable to the licensee’s actions.”¹⁰⁹

The breadth of health-related technologies encompassed by the Pledge, the multiplicity of flexible licensing frameworks it offers and the compressed timeline in which it was implemented set the Open COVID-19 Pledge apart from previous structured approaches to incentivize the licensure of patented goods – and especially of health technologies in a period of public health crisis. Perhaps more importantly, this effort shows how flexible licensing strategies can be used to promote technology transfer in furtherance of public interest goals *within* the dynamics of intellectual property. By maintaining their ownership interest while relaxing control of some of the sticks in their bundle of rights, pledgors adopt a different intellectual property strategy for a limited period of time that might result in the adoption of their technology – and potentially in valuable contributions to public health.

The intrinsically limited duration of the Pledge means that it cannot be used to assist in the pursuit of broader R&D purposes targeting pathogens likely to cause future pandemic or epidemics. It does, however, provide a blueprint for the development of similarly structured efforts in upcoming the inter-outbreak period.

¹⁰⁴ See OPEN COVID-19 PLEDGE, *About the Licenses*, <https://opencovidpledge.org/licenses/> (last accessed Aug. 30, 2020).

¹⁰⁵ *Id.*, *ib.*

¹⁰⁶ See e.g. OPEN COVID-19 PLEDGE, *Open COVID License 1.0 March 31, 2020*, <https://opencovidpledge.org/v1-0/> (last accessed Aug. 30, 2020).

¹⁰⁷ See e.g. OPEN COVID-19 PLEDGE, *OCL-PC v1.1*, <https://opencovidpledge.org/v1-1-ocl-pc/> (last accessed Aug. 30, 2020).

¹⁰⁸ See, *Open COVID License 1.0 March 31, 2020*, *supra* note 106 (last accessed Aug. 30, 2020).

¹⁰⁹ *About the Licenses*, *supra* note 95.

C. POOLED PROCUREMENT

The COVID-19 pandemic has prompted the creation of the COVID-19 Vaccine Global Access Facility (COVAX) to both finance the development of new vaccines and guarantee their equitable distribution on a global level.¹¹⁰

COVAX is integrated into a larger scheme – the vaccines pillar of the ACT Accelerator.¹¹¹ This pillar is designed to coordinate the development and distribution of COVID-19 vaccines from end-to-end. Three organizations oversee different segments of this end-to-end process. The Coalition for Epidemic Preparedness Innovations (CEPI), a public-private partnership that funds vaccine R&D targeting emerging pathogens,¹¹² coordinates the stages of development and manufacturing of vaccine candidates.¹¹³ The World Health Organization is the main driver for vaccine policy and allocative decisions.¹¹⁴ And Gavi, a public-private partnership traditionally focused on the procurement of childhood vaccines for developing countries,¹¹⁵ operates at the procurement and delivery-at-scale level.¹¹⁶

Overseen by Gavi, COVAX is a risk-sharing mechanism built into this network's procurement strategy. Participation in COVAX is open to any country wishing to join, subject to an advance commitment to purchase a certain amount of vaccine and a monetary or material contribution (the latter taking the form of vaccine doses).¹¹⁷ In exchange, participating countries receive access to COVID-19 vaccines procured by COVAX once they become available, at a price negotiated between COVAX and individual pharmaceutical companies.¹¹⁸ In early June, COVAX entered into the first of these procurement agreements with AstraZeneca, securing access to 300 million doses of vaccine.¹¹⁹

¹¹⁰ See GAVI, COVAX, THE ACT-ACCELERATOR VACCINES PILLAR, https://www.gavi.org/sites/default/files/document/2020/COVAX-Pillar-background_3.pdf

¹¹¹ WORLD HEALTH ORG., *The Access to COVID-19 Tools (ACT) Accelerator*, <https://www.who.int/initiatives/act-accelerator>

¹¹² COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS [CEPI], *Our Mission*, <http://cepi.net/about/whyweexist/>

¹¹³ See GAVI, COVAX, THE ACT-ACCELERATOR VACCINES PILLAR, *supra* note 110.

¹¹⁴ *Id.*, *ib.*

¹¹⁵ GAVI, *About Our Alliance*, <https://www.gavi.org/our-alliance/about>

¹¹⁶ GAVI, COVAX, THE ACT-ACCELERATOR VACCINES PILLAR, *supra* note 110.

¹¹⁷ *Id.*, *ib.*

¹¹⁸ But see Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J. L. & POL'Y __ (forthcoming 2020) (draft on file with author) (criticizing the current allocative policy adopted by COVAX).

¹¹⁹ GAVI, *Gavi Launches Innovative Financing Mechanism for Access to COVID-19 Vaccines*, (Jun. 4, 2020), <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines>

In this way, COVAX uses the same type of legal instrument that enables nationalistic allocation of vaccines – pre-production contracts – to further global governance of vaccines, while diffusing risk through resource pooling and attempting to maintain relatively low vaccine prices.¹²⁰

The swift formation of COVAX, and more broadly of the vaccines pillar of the ACT Accelerator, also speaks to the limitations of intellectual property as a push mechanism in incentivizing vaccine R&D. Moreover, COVAX denotes the need for complementary pull mechanisms accompanying intellectual property incentives and curbing the excesses of overly proprietary or nationalist approaches to pharmaceutical innovation, particularly during pandemic and epidemic crises.

CONCLUSION: INTELLECTUAL PROPERTY FOR THE NEXT PANDEMIC

Many of the current approaches to pharmaceutical innovation during pandemics and epidemic rely on proprietary frameworks that are hard to reconcile with the public health demands posed by transnational outbreaks of infectious diseases. The COVID-19 pandemic illustrates these tensions through an accentuation of siloed modes of R&D, as well as the adoption of nationalistic approaches to the allocation of emerging medical technologies. While reinforcing the case for legal and policy changes ahead of the next pandemic, COVID-19 has provided a blueprint for interventions that may curb some of these siloed trends.

These efforts – from patent pools and pledges to procurement mechanisms – are nonetheless time-consuming and resource-intensive, in addition to being inevitably linked to geopolitical considerations. As such, when started during a pandemic, they constitute remedial modes of response, which are subject to accelerated timelines and practical constraints. Moving forward, the international community should direct attention during the next inter-outbreak period to the strengthening of some of these mechanisms – possibly turning some of the temporary initiatives described above, such as COVAX or pandemic patent pools, into more permanent structures.¹²¹ These developments are needed not only to save time when the next pandemic occurs, but also to increase notions of equity and to promote dialogue centered on equity issues ahead of (inevitable) future crises triggered by emerging pathogens.

¹²⁰ Rutschman, *The Reemergence of Vaccine Nationalism*, *supra* note 4.

¹²¹ See Halabi & Rutschman, *supra* note 47.