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Capability Approach to Developing Global Health Initiatives for Equitable Access to Vaccines

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Structural injustices in national and global health architectures have become conspicuous from the initial stages of the outbreak and global spread of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2) virus,[1] aggravating health inequalities particularly among already vulnerable individuals and communities. Inequalities have widened across social position indicators, all closely tracking gross inequities that arise from the distribution of vaccines, ventilators, and healthcare services on the wider canvas of global health, especially during the initial stages of the pandemic from early 2020 to the third quarter of 2021. To be sure, such inequalities are not unique to this pandemic, even if the global death toll and societal disruptions attributed to COVID-19 will quite easily distinguish it as one of the most devastating.[2] Yet what is arguably different about the COVID-19 pandemic is the speed at which effective vaccines have been developed, essentially by countries that are relatively well resourced and technologically proficient, and the role that private and nongovernmental organizations (NGOs) assumed on the global health stage through the Access to COVID-19 Tools – Accelerator (ACT-A), quite possibly the largest public–private partnership to have ever been established as a pandemic countermeasure.

As ACT-A is essentially a pandemic response initiative, it did not engage with the structural causes and catalysts of COVID-19 and the devastation that its outbreak caused on many fronts. Instead, it focused on countering the pandemic based on three sets of technologies, namely diagnostics, treatments, and vaccines. This chapter focuses on vaccines, which fall under the purview of the COVID-19 Vaccines Global Access (COVAX), the vaccine pillar of ACT-A. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi (formerly known as

[1] Arush Lal et al., *Fragmented Health Systems in COVID-19: Rectifying the Misalignment between Global Health Security and Universal Health Coverage*, 397 Lancet 61 (2021).

[2] Grace E. Patterson et al., *Societal Impacts of Pandemics: Comparing COVID-19 with History to Focus our Response*, 9 Front Pub. Health 630449 (2021). *See also* Kelsey Piper, *Here's How COVID-19 Ranks among the Worst Plagues in History*, Vox (Jan. 11, 2021), www.vox.com/future-perfect/21539483/covid-19-black-death-plagues-in-history (last visited Dec. 9, 2023).

the Global Alliance for Vaccination and Immunization) and the World Health Organization (WHO), alongside key delivery partner United Nations International Children's Emergency Fund (UNICEF). Although a noble project that was conceived out of a concern for global solidarity, COVAX failed to live up to expectations owing to various conditions, some of which were beyond its control. As part of a global program to develop and distribute vaccines through pooled purchases, its choice of vaccine type was ultimately constrained by its inability to raise adequate funds,[3] as well as to procure sufficient vaccines,[4] and its failure to adapt to changed circumstances, notably when well-resourced governments procured vaccines directly from vaccine manufacturers through bilateral deals. To meet vaccine shortfalls, COVAX ultimately had to accept surplus vaccines from high-income countries. These vaccines were in turn rejected by some of the intended donee countries for reasons that included national pride and vaccines being nearly expired.[5] COVAX has also been criticized for limiting access to vaccines by under-resourced governments and blocked sharing of vaccine technology, which, had it occurred, could have enabled less well-resourced countries to build their vaccine manufacturing capacity earlier.[6]

As I shall discuss further later on in this chapter, COVAX did not provide financial support for the development of mRNA vaccines as these were considered to be too risky and cost ineffective. From June 2020, vaccines developed through more conventional technology platforms were already approved for emergency use by vulnerable groups, and the hope was to scale up their production and distribution if they were proven to be safe and effective for wider use. At that time, a number of research initiatives were underway to develop vaccines through novel technological means, including mRNA technology. Initial success was publicized by the Pfizer–BioNTech partnership and Moderna, with the latter announcing a pledge in October 2020 that it would not enforce patents related to its mRNA COVID-19

[3] Adam Taylor, *Why Covax, the Best Hope for Vaccinating the World, Was Doomed to Fall Short*, Wash. Post (Mar. 22, 2022), www.washingtonpost.com/world/2022/03/22/covax-problems-coronavirus-vaccines-next-pandemic (last visited Dec. 9, 2023). A report indicates that COVAX did not invest in mRNA vaccines as they cost as much as ten times more per dose than traditional vaccines, This turned out to be a mistake as mRNA vaccines turned out to be generally more effective and were quick to receive regulatory approval.

[4] For instance, when India halted the export of vaccines in order to meet its own domestic needs during the second wave of its COVID-19 outbreak, and when Johnson & Johnson failed to deliver 200 million vaccine doses in May 2021.

[5] Francesco Guarascio, *Poorer Nations Reject over 100 Mln COVID-19 Vaccine Doses as Many Near Expiry*, Reuters (Jan. 14, 2022), www.reuters.com/business/healthcare-pharmaceuticals/more-than-100-million-covid-19-vaccines-rejected-by-poorer-nations-dec-unicef-2022-01-13 (last visited Dec. 9, 2023).

[6] Jamie Ducharme, *COVAX Was a Great Idea, but Is Now 500 Million Doses Short of Its Vaccine Distribution Goals. What Exactly Went Wrong?* TIME (Sep. 9, 2021), https://time.com/6096172/covax-vaccines-what-went-wrong (last visited Dec. 9, 2023).

vaccine while the pandemic continued.[7] Moderna's announcement was made at a time when a proposal was put forward to the World Trade Organization (WTO) by India and South Africa for a waiver from certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sets out the rights, obligations, and standards of the international intellectual property (IP) regime.[8] The mRNA vaccine developed by Pfizer–BioNTech was first to receive regulatory approval for use, on December 2, 2020,[9] and this mRNA vaccine technology has proven to be most effective against COVID-19 in clinical trials.

In spite of the availability of different types of vaccines and the intermediation of COVAX in facilitating vaccine development and access, a large proportion of the world's population remained unvaccinated throughout 2021. By the end of that year, over 90 percent of Africa had not received a single dose of any vaccine.[10] Independently of COVAX, various countries began to discuss the possibility of establishing local production of mRNA vaccines.[11] In June 2021, the WHO announced that it was in discussion with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities, and Africa Centres for Disease Control and Prevention to establish the first COVID-19 mRNA vaccine technology transfer hub in Africa.[12] By early 2022, the WHO-backed mRNA technology transfer consortium in South Africa announced that it was close

[7] *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic*, Moderna (Oct. 8, 2020), https://investors.modernatx.com/Statements–Perspectives/Statements–Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx (last visited Dec. 9, 2023). In 2022, Moderna clarified that its pledge not to enforce its patents for mRNA COVID-19 vaccines only applied to companies manufacturing in or for the ninety-two low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC). *See Moderna's Updated Patent Pledge*, Moderna (Mar. 7, 2022), https://investors.modernatx.com/Statements–Perspectives/Statements–Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx (last visited Dec. 9, 2023).

[8] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[9] Press Release, Medicines and Healthcare Products Regulatory Agency, UK Medicine's Regulator Gives Approval for First UK COVID-19 Vaccine (Dec. 2, 2020), www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine#full-publication-update-history (last visited Dec. 9, 2023).

[10] Michelle Nichols, *U.N. Chief Grades World on Vaccine Rollout: "F in Ethics,"* Reuters (Sep. 22, 2021), www.reuters.com/business/healthcare-pharmaceuticals/un-chief-grades-world-vaccine-rollout-f-ethics-2021-09-21 (last visited Dec. 9, 2023).

[11] Miyoung Kim & Reuters Team, *Vietnam in Talks with U.S. for Local Production of COVID-19 mRNA Vaccine*, Reuters (Jul. 22, 2021), www.reuters.com/business/healthcare-pharmaceuticals/vietnam-says-receive-3-mln-moderna-covid-19-vaccines-via-covax-2021-07-22 (last visited Dec. 9, 2023).

[12] Press Release, World Health Organization, WHO Supporting South African Consortium to Establish First COVID mRNA Vaccine Technology Transfer Hub (Jun. 21, 2021), www.who.int/news/item/21-06-2021-WHO-supporting-South-African-consortium-to-establish-first-COVID-mRNA-vaccine-technology-transfer-hub (last visited Dec. 9, 2023).

to completing its own version of Moderna's mRNA COVID-19 vaccine;[13] a development that was seen as a capacity for not just South Africa but the whole African continent to be self-reliant, and as a step toward greater preparedness for the next pandemic.[14] While the WHO's other partners in the COVAX program (together with Medicine Patent Pool, or MPP) appear to be involved in the mRNA vaccine technology transfer hub,[15] their exact roles and responsibilities are unclear. As a key driver of the technology transfer hub initiative, the WHO voiced unequivocal support for a broad patent waiver, which (as I shall also discuss further) has more recently been endorsed by the WTO. These developments are instructive for the implicit acknowledgment of the grave inequities that limit the means of low-resource health systems to respond to a pandemic, even with the aid of international partnerships such as COVAX. It also provides the opportunity to reimagine what a fairer global health system could look like, and when it may be necessary to work outside of the international IP regime.

This chapter adopts the capability approach in arguing for deeper relationality in the global health governance of vaccine development, production, and distribution, and from within a human development paradigm, which is designed to actualize this approach. The capability approach seeks to expand people's freedoms and capabilities that are comparatively assessed against a wider set of principles (rather than only or primarily efficiency) with a focus on people as agents who are to be valued as ends in themselves and on the realization of outcomes that are just. Under TRIPS, IP rights holders are legally empowered to prevent others from using protected technology or proprietary information unless with their permission, usually through means such as licensing agreements or other kinds of contractual arrangements. This is a very limited form of relationality (if relational at all), and is essentially one-sided since rights holders are free to disengage unless compelled otherwise under extremely limited conditions.

The capability approach enables deeper relationality by adopting a more dynamic interpretation of the information function of IP rights, not only as a means of incentivizing investment in, as well as the disclosure of, novel technological know-how, but also as a means of building and sustaining trust through the sharing of technological capability. By this approach, the IP protection system and its goal of advancing science and technology are treated firmly as means, and not ends in themselves. There should be no controversy on the point that IP rights are, like all other property rights, instrumental in nature. There is general consensus in theories on property law that property rights are never absolute. The strength of possessory

[13] *mRNA Made in Africa*, 40 Nature Biotech. 284 (2022).

[14] WHO, *South Africa's mRNA Hub Progress Is Foundation for Self-Reliance*, Africa Renewal (Feb. 11, 2022), www.who.int/news/item/11-02-2022-south-africa-s-mrna-hub-progress-is-foundation-for-self-reliance (last visited Dec. 9, 2023).

[15] WHO, *The mRNA Vaccine Technology Transfer Hub*, www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub (last visited Dec. 9, 2023).

rights in an asset (whether tangible or intangible) should depend on a number of factors, including the prioritization of use by an agent (or group of agents) that is capable of maximizing the asset's value for that agent's benefit. Arguably, IP should be more amenable to wider relationality beyond a single agent since it is open to multiple uses at the same time, and is hence nonexclusive by its nature.

Intellectual property (similar to tangible property) encapsulates different rights and interests, and their relative importance depends on the context within which they are nestled. There is unresolved debate as to whether, or to what extent, global health should fall within a market-based IP context, where only limited exceptions apply within narrowly construed TRIPS flexibilities.[16] After all, a health product (unlike a regular consumer good) may be life-sustaining and thereby a necessity, and can also affect the health and well-being of others, notably where vaccines are concerned. While this point may seem obvious, the extension of IP protection through "TRIPS-plus" measures involving the use of supplementary protection certificates and other forms of market exclusivity across all technological fields seem to prioritize technological progress over the freedoms and well-being of people. A similar and essentially market-based mindset is evident in ACT-A. To be sure, market-based approaches can and have been useful to building capacity, but excessive reliance on market-driven forces to determine and shape progress in science and technology (in our case, vaccine development and production) leads to economically suboptimal outcomes, while exacerbating inequities and producing results that contradict the goals of public and global health.[17]

The limitations of ACT-A as a market-based pandemic countermeasure has not escaped notice by the global health community. In May 2020, the Solidarity Call to Action was launched as a complement to ACT-A by the WHO and Costa Rica.[18] The Solidarity Call sought the assistance of WHO member states to ensure that all publicly and donor-funded research outputs remain accessible on a global scale through a variety of arrangements that include legal measures to lower barriers such as IP rights. This initiative did not garner much support from high-income countries. The recent measures adopted by the WHO and the WTO to facilitate technology transfer represent alternative approaches to pandemic response that are

[16] The public health-related TRIPS flexibilities are associated with the provisions in the agreement on parallel imports (art. 6), preventing or redressing anticompetitive practices (arts. 8, 31 (k) and 40), patentability criteria (art. 27), limited exceptions that do not unreasonably conflict with a normal exploitation of the intellectual property or prejudice the legitimate interests of the rights holder (art. 30), and compulsory licensing and government use (art. 31).

[17] *See* William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law (2003); Richard A. Posner, *Do We Have Too Many Intellectual Property Rights?*, 9 Marq. Intell. Prop. L. Rev. 173 (2006). More recently, *see* Ana Santos Rutschman, Vaccines as Technology: Innovation, Barriers, and the Public Health (2022); Haochen Sun, Technology and the Public Interest (2022).

[18] WHO, *Solidarity Call to Action* (May 29, 2020), www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action (last visited Dec. 9, 2023).

not market-based and better reflect building deeper relationality in the capability approach. A health system should have, whether on its own or through geopolitical association, the (technological) capability to access sufficiently safe and effective vaccines as a pandemic countermeasure when such vaccines are available. Such a capability includes the means of contributing to the development, production, and distribution of vaccines. In the section that follows, I first examine the rise of ACT-A and consider why the global pandemic response should not be defined by this private–public partnership alone. I then consider how measures like the WHO-led mRNA technology transfer initiative and the TRIPS waiver are important as means of operating outside of a market-based paradigm, while still retaining the relevance of property-based tools.[19] In the third section, the capability approach is applied to explain why these complementary or supplementary measures to ACT-A are likely to be more impactful over a longer time horizon, particularly in advancing pandemic preparedness and the human development agenda through forging deeper relationality. Here, relationality refers to the technological capability of health systems and sovereign states to contribute to or participate in technological (specifically, vaccine) development, production, and distribution. In the final section, the need for a global framework to ensure that these developments are sustained beyond the current COVID-19 pandemic and in ways that are fair and equitable is highlighted.

1 ACT-A AND THE PROBLEM WITH THE STATUS QUO

About three months after the declaration of the outbreak of SARS-CoV-2 as a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR),[20] ACT-A was launched on April 24, 2020. Its structure is of a voluntary partnership that draws on the existing global health infrastructure, but without the intent of becoming a new entity. Conceived at a virtual event co-hosted by the WHO, the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation (BMGF), ACT-A was intended to serve as an informal and agile coordination mechanism for three

[19] Ana Santos Rutschman discusses at length existing mechanisms available under current domestic and international law to address some of the challenges that have emerged, including the commodification of vaccines and "vaccine nationalism." Collaborative solutions discussed include patent pools, patent pledges and public–private partnerships. However, these solutions are essentially market-based and continue to operate within the strict confines of IP law. RUTSCHMAN, *supra* note 17, 114–155.

[20] Under the IHR, the Director-General of the WHO has the power to declare an outbreak to be a PHEIC upon the recommendation of the Emergency Committee. This was the 6th PHEIC declaration since the IHR was revised in 2005. At the time of the declaration, 7,818 confirmed cases of COVID-19 were reported worldwide. *See* WHO, *Listings of WHO's Response to COVID-19* (updated Jan. 29, 2021), www.who.int/news/item/29-06-2020-covidtimeline (last visited Dec. 9, 2023).

products deemed crucial in the mobilization of a rapid global response to the pandemic, namely vaccines, therapeutics, and diagnostics (subsequently referred to as the "three product pillars"). ACT-A is also possibly the largest public–private partnership of its kind to have been constituted, and its partners were co-opted based on their ability to contribute collectively toward the development, production, and equitable distribution of the three product pillars.[21] The partnership initially comprised the BMGF, CEPI, Gavi, the Global Fund, Unitaid, Wellcome, the WHO, and three industry groups (the Developing Country Vaccine Manufacturers' Network, the International Federation of Pharmaceutical Manufacturers & Associations, and the International Generic and Biosimilar Medicines Association). A facilitation group, comprising nine high-income countries (or donor governments), the WHO, two charitable foundations, and one international NGO, was responsible for coordinating among the different partners, with the WHO also assuming various roles in this mechanism.[22] By late June 2020, a system-level concern was added as the fourth pillar of ACT-A along with a description of the roles of the partners:[23] (i) Vaccines, headed by CEPI and Gavi; (ii) Therapeutics, headed by UNITAID and Wellcome; (iii) Diagnostics, co-led by a new collaborator,[24] the Foundation for Innovative New Diagnostics (FIND), and the Global Fund; and (iv) the Health Systems Connector, headed by the World Bank and the Global Fund, and subsequently involving the WHO as a co-convenor. That year, the WHO highlighted in its report for the World Health Assembly a number of antipandemic initiatives, including increased support for the evaluation of vaccines and maintaining communication among funders for implementation of critical research, and the sharing of viral materials, clinical samples, and data for public health purposes.[25]

A "Facilitation Council" was launched on September 10, 2020 to provide high-level advice, guidance, and leadership to facilitate the work of ACT-A.[26] The terms of reference of the Facilitation Council do not give it decision-making or oversight authority, although its composition was intended to ensure appropriate and diverse

[21] For ACT-A vision, mission and commitment statements, *see* WHO, *Access to COVID-19 Tools (ACT) Accelerator: A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 Diagnostics, Therapeutics and Vaccines* (Apr. 20, 2020), www.who.int/docs/default-source/coronaviruse/access-to-covid-19-tools-(act)-accelerator-call-to-action-24april2020.pdf?sfvrsn=5f721eaf_6 (last visited Dec. 9, 2023).

[22] The WHO was represented in between the Facilitation group and the (then) three pillars to support and coordinate, and as playing specific roles within each pillar.

[23] Press Release, WHO, ACT-Accelerator Update (Jun. 26, 2020), www.who.int/news/item/26-06-2020-act-accelerator-update (last visited Dec. 9, 2023).

[24] Guarascio, *supra* note 5.

[25] WHO, *Public Health Preparedness and Response*, WHO Doc. A73/11 (Jun. 12, 2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_11-en.pdf (last visited Dec. 9, 2023).

[26] WHO, *ACT-Accelerator Facilitation Council – Terms of Reference* (Feb. 21, 2022), www.who.int/docs/default-source/coronaviruse/acta_fc-tor_2022-01-english.pdf?sfvrsn=60d5fef7_20 (last visited Dec. 9, 2023).

representation of global leaders and partners. Donations were made directly to co-convenors, not to the ACT-A itself since it was not a legal entity, and donors retain "full oversight of the allocation of their pledges," and "grant management and financial reporting to donors will be managed by the receiving entity."[27] ACT-A has consistently emphasized that its loose governance structure ensured that it remained "nimble"[28] and "time-bound"[29] in the realization of its vision of "rapid development, scale-up and equitable distribution of COVID-19 vaccines, therapeutics and diagnostics, underpinned by the strengthening of health systems."[30] By April 2021, ACT-A governance roles were assumed by the Facilitation Council, a new Principals Group, and ACT-A Hub, which would collectively provide advice, guidance, fundraising, advocacy, and coordination of the three operational pillars (Vaccines, Diagnostics, and Therapeutics) and two cross-cutting functional areas (Health Systems Connector and Access and Allocation).[31] ACT-A did not include the three industry groups as part of the Principals Group, but "industry" has been noted to have "standing invitations," along with civil society and communities, to the Facilitation Council.[32] For the purposes of this chapter, my discussion from this point onwards will focus on the vaccine operational pillar of ACT-A, better known as COVAX. As I noted earlier, COVAX is headed by CEPI, which has expertise in investing in vaccines research and development, and by Gavi, with expertise in procurement and allocation through financing mechanisms such as advance market commitment. The WHO has also contributed its expertise in effective regulation and optimal allocation, as well as vaccine injury indemnification in certain health systems.

Unlike vaccine development in the past, ACT-A recognized that scaling up manufacture and completion of human trials for vaccine candidates must be done in parallel. The COVAX pillar of ACT-A was intended to be a collaborative risk-pooling mechanism to facilitate vaccine development and access through portfolio diversification, pooling of financial and scientific resources, and economies of scale.[33] It uses both the "push" and "pull" mechanisms to support vaccine

[27] WHO, *What Is the Access to COVID-19 Tools (ACT) Accelerator, How Is It Structured and How Does It Work?* (Apr. 29, 2021), www.who.int/docs/default-source/coronaviruse/act-accelerator/act-a-how-it-works-at-6april2021.pdf?sfvrsn=ad5f829f_24 (last visited Dec. 9, 2023).

[28] *See* WHO, *ACT-A Status Report and Plan* (Sep. 24, 2020), www.who.int/docs/default-source/coronaviruse/act-accelerator/status-report-plan-final-v2.pdf?sfvrsn=ee8f682b_4 (last visited Dec. 9, 2023).

[29] *See* WHO, *supra* note 27.

[30] WHO, *Facilitation Council for the Access to COVID-19 Tools (ACT) Accelerator: About Us*, www.who.int/groups/act-accelerator-facilitation-council/about (last visited Dec. 9, 2023).

[31] WHO, *supra* note 27.

[32] WHO, *ACT-Accelerator: Status Report and Plan, September 2020–December 2021* (Sep. 24, 2020), www.who.int/docs/default-source/coronaviruse/act-accelerator/status-report-plan-final-v2.pdf?sfvrsn=ee8f682b_4 (last visited Dec. 9, 2023).

[33] WHO, *COVAX, the Act-Accelerator Vaccines Pillar: Insuring Accelerated Vaccine Development and Manufacture* (Aug. 6, 2020), www.who.int/docs/default-source/coronaviruse/act-acceler

development and production. These mechanisms push development by providing funding up-front (for example, grants and innovation funds) and pull in innovators by offering a financial reward once a product has been developed (for example, through advance market commitments). This market-based approach to financing vaccine development is mainly directed at offsetting development costs. The first investment cases were published in mid-2020, with total funding cost for R&D and manufacturing, volume guarantees, or procurement and delivery costs determined to be $18.1 billion for 2020/2021.[34] By these projections, high- and upper-middle-income countries would commit funds to procure approximately 950 million doses through the COVAX facility and to underwrite the costs of manufacturing at risk in order to ensure that vaccines can be delivered at the greatest possible speed, in particular to low- and middle-income countries. This "portfolio approach" allows participating countries to buy a share of many vaccine candidates as a hedge against the failure of some of these candidates. Vaccine candidates that turn out to be successful would be procured and distributed in a cost-effective and targeted manner. This arrangement would enable governments with limited or no financial resources to pursue bilateral procurement with vaccine manufacturers to have access to the vaccines. Pooling risks was also expected to lower prices as competition for a limited supply of vaccines would otherwise lead to a disorderly market as individual buyers seek to outbid each other.

The vaccine research and development for COVID-19 occurred at an impressive pace following the publication of the genetic sequence of SARS-CoV-2 on January 11, 2020 through the Global Initiative on Sharing All Influenza Data (GISAID). By April 8, 2020, around 115 vaccine candidates were being investigated, with the first vaccine clinical trial being tested on humans on March 16, 2020.[35] In a relatively short time span, there were 356 vaccine candidates, of which 138 were in clinical testing.[36] Regulatory approval for emergency use of vaccines similarly followed in rapid succession, beginning with the CanSino vaccine in China on June 25, 2020,[37]

ator/covax/covax-pillar-background.pdf?sfvrsn=b6d9a2a8_2 (last visited Dec. 9, 2023). From a financing angle, COVAX supports vaccine development and production by advance market commitments (pull financing) and through at-risk investments for R&D, as well as manufacturing capacity reservation and inventory (push financing). The plan was to scale up on the availability of vaccines to a cumulative 2 billion doses by the end of 2021, this figure being determined based on epidemiological need.

[34] *Id.*, at 6.

[35] Tung Thanh Le et al., *The COVID-19 Vaccine Development Landscape*, 19 NAT. REV. DRUG DISCOV. 305 (2020).

[36] *Landscape*, COVID-19 Vaccine Tracker, https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape (last visited Dec. 9, 2023).

[37] *CanSino's COVID-19 Vaccine Candidate Approved for Military Use in China*, REUTERS (Jun. 29, 2020), www.reuters.com/article/us-health-coronavirus-china-vaccine-idUSKBN2400DZ (last visited Dec. 9, 2023).

the Sputnik V vaccine in Russia on August 11, 2020,[38] the Pfizer–BioNTech vaccine on December 2, 2020 in the United Kingdom and on December 11, 2020 in the United States of America.[39] Approximately a year from first reports of the outbreak of COVID-19, at least four of the six technology platforms were used to create a vaccine that is effective against COVID-19; these being:[40]

(1) Nucleic acid or genetic platform, whereby self-replicating RNA or (in some cases, nucleoside modified) mRNA is used to produce B-cell and T-cell immune responses by inducing target cells to produce S protein. Lipid nanoparticles are used in the delivery of mRNA, and may be the cause of anaphylaxis (or severe adverse reactions) in a small handful of individuals. COVID-19 vaccines that apply this platform include the Pfizer–BioNTech and Moderna vaccines;
(2) Adenovirus vector platform, which is used to produce viral vector-based vaccines. These vaccines, such as the Oxford–AstraZeneca COVID-19 vaccine and the Sputnik V COVID-19 vaccine, relies on a nonreplicating adenovirus shell to elicit an immune response. Although the shell contains DNA which encodes a SARS-CoV-2 protein, it is nonreplicating;
(3) Inactivated virus platform, which uses viral particles that are grown in culture and then killed to stimulate an immune response. This technological approach has been used to develop Sinovac's CoronaVac and Sinopharm's BIBP (Beijing Institute of Biological Products) and WIBP-CorV vaccines; and
(4) Protein subunits platform, which uses one or more antigen (or some fragments of the pathogen) to stimulate immune response rather than introducing the entire pathogen. The Novavax COVID-19 vaccine and the Sanofi-GSK vaccine have been developed using this platform.

Of these various platforms, the mRNA vaccines have been found in clinical trials to be most effective in adults and also among young persons between the ages of five

[38] Peter Beaumont & Luke Harding, *Russia Approves Sputnik V COVID Vaccine despite Testing Safety Concerns*, The Guardian (Aug. 11, 2020), www.theguardian.com/world/2020/aug/11/russia-approves-coronavirus-vaccine-despite-testing-safety-concerns-vladimir-putin (last visited Dec. 9, 2023).

[39] Elisabeth Mahase, *Covid-19: UK Approves Pfizer and BioNTech Vaccine with Rollout Due to Start Next Week*, 371 Brit. Med. J. m4714 (2020); Press Release, US Food & Drug Administration, FDA Takes Key Action in Fight against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited Dec. 9, 2023).

[40] Dmitry Kudlay & Andrey Svistunov, *COVID-19 Vaccines: An Overview of Different Platforms*, 9 Bioengineering 72 (2022). *See also* WHO, *The Different Types of COVID-19 Vaccines* (Jan. 12, 2021), www.who.int/news-room/feature-stories/detail/the-race-for-a-covid-19-vaccine-explained (last visited Dec. 9, 2023).

and eighteen years.[41] However, COVAX did not invest in this vaccine technology platform, or so it was reported by the *Washington Post* after it gained access to an internal document that was circulated by COVAX.[42] As Larry Gostin observes, financing mechanisms that COVAX deployed might have helped to drive down costs, but leaving IP protections intact still pose a hurdle to wide access if some vaccines are developed outside of COVAX.[43]

The nucleic acid or genetic technology platform was at that time novel and hence riskier, and the cost per dose of mRNA vaccine was said to be ten times more than traditional vaccines. For essentially budgetary reasons, COVAX entered into advance purchase contracts with AstraZeneca and Novavax for vaccines developed using more conventional technological platforms, and reached agreement with the Serum Institute of India (SII) for 1.1 billion doses. As the *Washington Post* reports, COVAX failed to deliver on the vaccines when AstraZeneca faced production issues while SII was prevented from exporting vaccines produced by it when India experienced its most intense wave of COVID-19 outbreaks between April and June 2021. Even if we leave aside the issue of choice of vaccine technology platforms, COVAX's pooled purchasing approach could itself have been too conservative in concentrating the development and production of vaccines to a handful of vaccine developers, which were themselves hampered by production issues.[44] In contrast, the establishment of technology transfer hubs represents a different philosophy, as the sharing of technical knowledge (whether through IP waivers or through more open licensing arrangements) was intended to enable developing countries to acquire vaccine manufacturing capacity, and to become self-reliant. Pooled purchasing might have been an attempt to side-step entanglement with IP rights, but with early signs that mRNA vaccines could be a safe and effective pandemic countermeasure, IP waiver became front-page news.

2 OUTSIDE OF A MARKET-BASED PARADIGM

In October 2020, India and South Africa put forward a proposal to the WTO for the waiver of patents, industrial designs, copyright, and trade secrets covering products

[41] *COVID-19 Vaccine Effectiveness Monthly Update*, Centers for Disease Control & Prevention (Nov. 10, 2022), https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness (last visited Dec. 9, 2023).

[42] Adam Taylor, *Why Covax, the Best Hope for Vaccinating the World, Was Doomed to Fall Short*, Wash. Post (Mar. 22, 2022), www.washingtonpost.com/world/2022/03/22/covax-problems-coronavirus-vaccines-next-pandemic (last visited Dec. 9, 2023).

[43] Lawrence O. Gostin, Global Health Security: A Blueprint for the Future 203–204 (2021).

[44] For instance, Johnson & Johnson itself failed to make timely delivery of its single-shot vaccines to COVAX. *See* Benjamin Mueller & Rebecca Robbins, *Where a Vast Global Vaccination Program Went Wrong*, N.Y. Times (Aug. 2, 2021), www.nytimes.com/2021/08/02/world/europe/covax-covid-vaccine-problems-africa.html (last visited Dec. 9, 2023).

and technologies that were needed to prevent, contain, or treat COVID-19.[45] After months of negotiation, a watered down proposal was presented in May 2021 to call for a temporary waiver of legal obligations under the TRIPS Agreement for a duration of at least three years, and in relation to the types of health products and technologies needed in response to COVID-19 (diagnostics, therapeutics, vaccines, medical devices, and personal protective equipment), rather than by broad classes of IP rights.[46] Under this revised formulation of the proposal, WTO member states may issue a single authorization for access to patented products and technologies, as well as their components and processes. Weighing in on the side of IP waiver, the Human Rights Council of the United Nations General Assembly (UNGA) highlighted the need to ensure equitable, affordable, timely, and universal access to COVID-19 vaccines.[47] This resolution was subsequently adopted by the UNGA,[48] and its message on equitable access to vaccines was reiterated in a more general call for global solidarity to ensure wider access to pandemic countermeasures.[49]

Vaccines and other medical products (as well as their components) that are required to prevent, diagnose, and treat COVID-19 are protected under the TRIPS Agreement when patented. As temporary suspension of IP rights is not permitted under the TRIPS Agreement, the proposed waiver ensures that WTO member states that issue compulsory licenses to use such patented products or technologies will not violate their international law commitments. Unlike the existing TRIPS flexibilities, the patent waiver will release the WTO member state from its obligation of having to issue a compulsory license individually in order for a patented technology to be used without the patent holder's permission, and thereby help to free up public resources in a time of public health emergency. The proposed waiver will also lend clarity to the inclusion of trade secrets, which may not fall within the scope of a compulsory licensing regime. By the middle of 2022, a

[45] Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (last visited Dec. 9, 2023).

[46] Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela, and Zimbabwe, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True (last visited Dec. 9, 2023).

[47] Human Rights Council, *Ensuring Equitable, Affordable, Timely and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic*, U.N. Doc. A/HRC/46/L.25/Rev.1 (Mar. 17, 2021), https://documents-dds-ny.un.org/doc/UNDOC/LTD/G21/066/56/PDF/G2106656.pdf?OpenElement (last visited Dec. 9, 2023).

[48] UNGA, Ensuring Equitable, Affordable, Timely and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic: Resolution / Adopted by the General Assembly, U.N. Doc. A/RES/76/175 (Dec. 16, 2021).

[49] G.A. Rev. 74/270 (Apr. 2, 2020).

ministerial decision was made during the 12th session of the WTO Ministerial Conference on the TRIPS Agreement to allow WTO member states to diversify production of COVID-19 vaccines and to dislodge patent exclusivity through a targeted waiver for a period of five years from June 17, 2022,[50] while recognizing the need for WTO member states to explore means of fully utilizing all the TRIPS flexibilities.[51] In this vein, a proposal was put forward by essentially high-income WTO members to promote different licensing models for a range of IP rights including patents, copyright, trademarks, and know-how to be applied, and for a collaborative ecosystem to be developed by enabling WTO members through the provision of training, online guidelines, contract templates, legal services, and dispute settlement mechanisms.[52] When the WHO announced in May 2023 that the COVID-19 pandemic no longer constitutes a public health emergency of international concern, the possible inclusion of an IP waiver for COVID-19 diagnostics and therapeutics was still being discussed.

The European Union was initially hesitant to support the proposal for a TRIPS waiver owing to concerns that innovation (presumably in mRNA technology spearheaded by German biotechnology company BioNTech) could be stifled, and instead emphasized other measures that include limiting expert restrictions, resolving production bottlenecks, and increasing contributions to COVAX.[53] Others, notably the International Federation of Pharmaceutical Manufacturers & Associations,[54] considered the TRIPS waiver to be a wrong solution to inadequate

[50] WTO, Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30, WT/L/1141 (Jun. 22, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True (last visited Dec. 9, 2023).

[51] WTO, Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, WTO Doc. WT/MIN(22)/31, WT/L/1142 (Jun. 22, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True (last visited Dec. 9, 2023).

[52] Communication from Australia; Canada; the European Union; Japan; Singapore; Switzerland; Hong Kong, China; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; the United Kingdom and the United States of America, *Intellectual Property and Innovation: IP Licensing Opportunities*, WTO Doc. IP/C/W/691 (Jun. 23, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W691.pdf&Open=True (last visited Dec. 9, 2023).

[53] Press Release, European Parliament, MEPs Split over Waiver for COVID-19 Vaccine Patents (May 19, 2021), www.europarl.europa.eu/news/en/press-room/20210517IPR04116/meps-split-over-waiver-for-covid-19-vaccine-patents (last visited Dec. 9, 2023). The conventional measures proposed by the European Union are not new and have not been taken up in any meaningful way to alleviate challenges to vaccine supply and distribution, as a number of observers have noted. *See* Andrew Green, *Europe Still Can't Get on Board with the Trips Waiver*, DEVEX (May 31, 2021), www.devex.com/news/europe-still-can-t-get-on-board-with-the-trips-waiver-100027 (last visited Dec. 9, 2023).

[54] Press Release, International Federation of Pharmaceutical Manufacturers & Associations, Pharmaceutical Industry Expresses Deep Disappointment with Decision on Waiving Intellectual Property Rights Adopted at the World Trade Organization Ministerial Conference (Jun. 17, 2022), www.ifpma.org/resource-centre/pharmaceutical-industry-expresses-deep-disappointment-with-decision-on-waiving-intellectual-property-rights-adopted-at-the-world-trade-organization-ministerial-conference (last visited Dec. 9, 2023).

supply and unequitable distribution of vaccines. From an academic standpoint, Ana Santos Rutschman and Julia Barnes-Weise challenge the claim (based on the information function of patents) that if the exclusionary right for a certain period of time is dispensed with, manufacturers will be able to replicate existing vaccines and produce them at scale so that populations in low-resource settings will be able to access them.[55] They raise two objections to this claim. First, they argue that information disclosed would not increase availability of vaccines for populations in low-resource settings since dislodging exclusivity problems through means such as compulsory licensing was unlikely to enable other manufacturers to produce the vaccines and bring prices down. Second, they observe that patent waiver would not address other constraints on vaccine production by other manufacturers, notably lack of know-how (or tacit knowledge) in producing a complex biologic product, and the absence of human capital, raw materials, and infrastructure to produce and distribute COVID-19 vaccines. Additionally, patent waiver may disincentivize investment in vaccine research and development for COVID-19, and may lead to fewer vaccines and vaccine producers, and ultimately limit technology transfer. In essence, Rutschman and Barnes-Weise consider the limited availability of COVID-19 vaccine to populations in low-resource settings to be contractual and infrastructural problems rather than an IP problem.

In a follow-up paper that speaks more broadly to proprietary rights that apply to COVID-19 vaccine technology,[56] the same stance is reiterated, along with a proposal to support – both financially and structurally – collaborative relationships between innovators and potential trusted regional partners, as well as to cultivate trust-building partnerships. Importantly, Rutschman and her colleagues recognize that formation of collaborative relationships and partnerships can be challenging as the parties concerned have different priorities, interests, and bargaining power. In their opinion, greater effort is required on the part of the global community to build "relationships, infrastructure, best contractual practices and capacity, as well as funding earlier purchases of vaccines by countries in need and procurement mechanisms such as COVAX."[57] While Rutschman and her colleagues hold fast to the status quo of the international IP regime, key international organizations appear to be more open to change. This is implicit in a key question raised in a report jointly published by the WTO, the World Intellectual Property Organization (WIPO), and the WHO:

[55] Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, Bill of Health (May 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver (last visited Dec. 9, 2023).

[56] Julia Barnes-Weise et al., *Assessment of the Proposed Intellectual Property Waiver as a Mechanism to Address the COVID-19 Vaccine Scarcity Problem*, 76 J. Epidemiol. Community Health 317 (2022).

[57] *Id.*, at 318.

> Whether a solution to access problems in developing countries can be found by operating within the IP system, including by making full use of the flexibilities in the TRIPS Agreement, or whether such a solution would require waiving certain obligations under the TRIPS Agreement during the pandemic in order to allow for a rapid scaling up of manufacturing capacities.[58]

While it may be useful to collect evidence on whether IP did constitute a barrier to accessing COVID-19 vaccines, it is unlikely that any analysis of this kind will produce a definite and conclusive answer to the question. Meanwhile, the Director-Generals of the WHO, WIPO, and WTO have in a joint statement committed to intensifying cooperation in support of access to health products and technologies to address challenges arising from the COVID-19 pandemic.[59] Initiatives introduced include: (1) Compile and share online all COVID-related IP measures by the Secretariat of the TRIPS Council of WTO;[60] (2) Establish and manage an online platform on COVID-19 Policy Tracker by WIPO;[61] and (3) Launch a trilateral COVID-19 technical assistance platform to help WTO members and WTO accession candidates address their capacity-building needs to respond to the COVID-19 pandemic.[62] While these initiatives remain market-based, the focus appears to have shifted back to concerns over capacity building and human development.

3 CAPABILITY APPROACH AND THE CASE FOR VACCINE INTERDEPENDENCE

Few will dispute that vaccines are informationally and legally complex as they are usually constituted by proprietary and nonproprietary information or data. Additionally, the distribution of information or data, whether proprietary or not, tends to be across multiple layers and may reside with individuals or within organizations. The proprietary aspect is usually defined by patents and trade secrets, which give rise to ownership rights in, for instance, test data from the development of vaccine candidates, or information relating to vaccine production. Nonproprietary data on vaccine development or production may be tacit or experiential knowledge,

[58] World Trade Organization et al., Promoting Access to Medical Technologies and Innovation 15 (2021), https://apps.who.int/iris/bitstream/handle/10665/78069/9789241504874_eng.pdf?sequence=1&isAllowed=y (last visited Dec. 9, 2023).

[59] WTO, *WHO, WIPO, WTO Map Out Further Collaboration to Tackle COVID-19 Pandemic: Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic* (Jun. 24, 2021), www.wto.org/english/news_e/news21_e/igo_23jun21_e.htm (last visited Dec. 9, 2023).

[60] WTO, *COVID-19: Measures Regarding Trade-Related Intellectual Property Rights* (Apr. 20, 2022), www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm (last visited Dec. 9, 2023).

[61] WIPO, *COVID-19 IP Policy Tracker*, www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations (last visited Dec. 9, 2023).

[62] WTO, *WHO, WIPO, WTO Launch Trilateral COVID-19 Technical Assistance Platform* (Apr. 1, 2022), www.wto.org/english/news_e/news22_e/igo_11apr22_e.htm (last visited Dec. 9, 2023).

but is nonetheless exclusive since such know-how may be difficult to replicate by a third party without the benefit of past knowledge or experience, or to otherwise reverse engineer.

As discussed above, it is in the light of these complexities that some have argued the TRIPS waiver will not increase the supply of vaccines and could stifle research and innovation. By this view, there is an implicit assumption that only existing vaccine developers could produce certain types of vaccines based on a relatively well-defined combination of proprietary and nonproprietary information or data. It follows that there may be insufficient recognition that other developers could use information or data that becomes available from the TRIPS waiver to produce different vaccines in combination with the knowledge or data that they possess. This more open-ended approach to vaccine research, development, and production is perhaps best represented by the WHO-backed mRNA vaccine technology transfer hub that was established in South Africa in July 2021 to produce mRNA vaccine at laboratory scale and to transfer its technology to six African countries. As the WHO explains, mRNA technology is a good focus for the technology transfer hub as mRNA vaccines have proved highly efficacious against COVID-19 and new variants that have emerged. From a development viewpoint, this technology can more crucially be adapted for other diseases and treatments, and is easy to share, develop, and adapt to new COVID-19 variants.[63] At the time of writing, the number of mRNA technology recipients has increased to fifteen, inclusive of Biovac in South Africa.[64] It may be helpful to recapitulate at this juncture that, quite aside from the TRIPS waiver, Moderna indicated in October 2020 that it was prepared to share its knowledge of the mRNA vaccine technological platform with vaccine producers in developing countries to meet local needs, and has since invested in building a manufacturing plant in Kenya. BioNTech has also announced plans to establish mRNA vaccine production in different jurisdictions, starting with the establishment of a manufacturing facility in Rwanda.[65]

Unlike ACT-A, the goals of mRNA technology transfer hubs are not limited to countering the COVID-19 pandemic. As training facilities that seek to establish a relatively new technology at industrial scale, these hubs are intended to build technological and production capacity in low- and middle-income countries over a longer-term horizon. As the WHO has indicated, its hope is to enable manufacturers in these jurisdictions to deploy mRNA technology to develop vaccines and treatments for other diseases, particularly those that are underserved by the global pharmaceutical market. Labeled by some as a "plug and play" technology, this

[63] WHO, *FAQ – The mRNA Vaccine Technology Transfer Hub*, www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq (last visited Dec. 9, 2023).
[64] WHO, *Recipients of mRNA Technology from the WHO mRNA Technology Transfer Hub*, www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/recipients-of-mrna-technology-from-the-who-mrna-technology-transfer-hub (last visited Dec. 9, 2023).
[65] *mRNA Made in Africa*, *supra* note 13.

vaccine platform could in theory be easily adapted to other diseases.[66] There are additionally at least two positive spillover effects. First, capability in managing intellectual property and in issuing licenses may be acquired, as the technology transfer hub provides a platform for local or regional manufacturers to access the expertise of the Medicines Patent Pool.[67] Second, manufacturers in these jurisdictions could acquire the capability to procure and/or produce essential raw materials that are required for vaccine production. The WHO recognizes that supply chains are a critical barrier to national and regional responses, and is working with its partners to introduce production know-how, quality control, and licenses to overcome these barriers.

Evaluating these developments through a normative lens, both the ACT-A initiative and that of the mRNA technology transfer hub are directed at justice-related concerns, particularly in its distributive sense. ACT-A raises questions over the possibility of reconciling egalitarian commitments with the endorsement of robust rights of private ownership, alongside a strong presumption against paternalism, even if international law tends not to be paternalistic in the way that private law could be. Confronted with the limited success of COVAX, we are again confronted with the question of how our social and economic institutions should be arranged in order to fairly distribute the benefits and burdens of social cooperation on a global scale, while simultaneously problematizing the nature of social cooperation itself. Aside from the urgency of mounting a pandemic response, COVAX reflects a tendency of distributive justice initiatives to focus on distributable goods. As we have seen, COVAX as a procurement and allocation mechanism made little progress in achieving distributive justice, although for reasons that are not entirely attributable to it.[68] This failing does underscore a crucial precondition to Rawlsian-style distributive justice, which includes the existence of institutions that constitute the basic structure of society, along with social primary goods that correspond to needs and capacities within a normal range. Without a clear constitutional order and effective means of enforcement, international institutions, international norms, and state actions do not fit neatly with the Rawlsian paradigm. Even then, international institutions and state actions could be assessed to be unjust if they disrupt fair distribution.

In contrast, the capability approach may be more appropriate to consider and apply for its focus on human development. The capability approach is essentially

[66] David Pilling, *Pandemic Sets Continent's Sight on Vaccine Independence*, Financial Times (Aug. 28, 2022), at 3.

[67] MPP co-leads the hub initiative with WHO, and assists WHO to negotiate with technical partners and supporting in the governance of the hubs. *See Governance & Team*, Medicines Patent Pool, https://medicinespatentpool.org/who-we-are/governance-teams (last visited Dec. 9, 2023).

[68] WHO, *ACT-Accelerator Strategic Review: An Independent Report Prepared by Dalberg* (Oct. 8, 2021), www.who.int/docs/default-source/coronaviruse/act-accelerator/act-a_strategic_review_report_8oct2021_final.pdf?sfvrsn=152da120_1 (last visited Dec. 9, 2023).

concerned with the effective freedoms of a person or people to achieve valuable states of being and doing (for example, escaping morbidity). There are clearly links between these two approaches since distributive justice speaks to capabilities rather than serving only as a humanitarian principle. Distributive justice usually includes both productive processes and distributive mechanisms, and is, in this sense, concerned with the distribution of advantages, and not only recognition and happiness. As Michael Walzer explains, the idea of distributive justice has as much to do with being and doing as with land, capital, or personal possessions.[69] However, the capability approach is wider in the sense that it is concerned with well-being and freedom, rather than institutional justice. Capability relates to combinations of functions (or achievements in being and doing) that reflect the freedom of people to lead the kind of life that they value. From a human development standpoint, freedom comprises the opportunities that are available for individuals to achieve valued outcomes, as well as the processes and conditions that allow them to exercise agency.[70] Development is therefore concerned with social, economic, and political institutions that impact on capabilities that people value or have reason to value. Amartya Sen has been critical of economic planning and policies that value people essentially as means of advancing market expansion and real income, arguing instead that the goal of economic growth should be the expansion of people's capabilities and freedoms. Freedoms not only create a means for development, but should also shape its ends. Martha Nussbaum explains that by focusing on capabilities rather than functioning, we are better able to consider a range of possible ways of life from which people can choose.[71]

While a goal of TRIPS was to facilitate technology transfer, especially from the Global North to the Global South, there is still a large and widening gap in the capability of people and sovereign states to draw on scientific and technological knowledge and tools to achieve health and general well-being. Where the COVID-19 pandemic is concerned, vaccine technological platforms are limited to a handful of mostly high-income jurisdictions. Of these platforms, the novel mRNA technology is confined to corporations that operate in the United States and European Union. With the capability approach, TRIPS has not adequately ensured that scientific advancement and innovation expand the real freedoms of people so that they have the opportunity to achieve a state of being that they value. In theory, the TRIPS flexibilities should have helped to address these concerns, but none of them were invoked during the pandemic. Moving forward, it will be instructive to understand why this has been the case, but the basic problem remains: how do we ensure that the international IP rights and global health regimes ensure that sovereign states and their peoples have the technological capability to mount a basic

[69] Michael Walzer, Spheres of Justice: A Defence of Pluralism and Equality (1983).
[70] Amartya Sen, Development as Freedom 17, 87 (1999).
[71] Martha Nussbaum, Creating Capabilities: The Human Development Approach (2011).

response to an epidemic or pandemic at the point of its emergence. The TRIPS waiver suggest some degree of recognition that there should be a sufficient level of technological capability across all health systems.[72]

For Sen, market expansion, raising real incomes, and economic growth should be placed squarely in the category of means that must be applied to advance the freedom of people.[73] By a similar reasoning, scientific advancement and technological innovation should be means to advance the freedom of people, rather than as ends in themselves. While not necessarily the best and most effective response to the shortage of mRNA vaccines, mRNA technology transfer hubs seek to address capability concerns and would, as an initiative, better represent (or be represented by) the capability approach. These hubs enhance freedoms not only in terms of meeting the more immediate health needs of the COVID-19 pandemic, but seek to enable their host states to address existing and future health challenges by means of this new technological platform. As many of the states that host these technology recipients are low- and middle-income countries (and some with limited technological means at their disposal), these hubs further help to reduce the capability gap between technologically advanced states and those that are less so.

The capability approach encourages a more relational approach because it firmly places IP rights and even science and technology as means to expand human freedoms. It goes without saying that the availability of safe and effective vaccines, diagnostics, and therapeutics is crucial during a pandemic, but working within the status quo (as ACT-A arguably sought to do) has not proven to be an effective strategy, at least in terms of the equitable distribution of vaccines. In a world of multiple crises (of pandemics and climate change occurring all at once), a stronger focus on human agency could be achieved by adopting a "people-centered" approach, where participation and collaboration are emphasized in making policy choices and advancing development goals. People's capabilities can be enhanced by public policy, just as participation by people can improve policy.[74] ACT-A sought to mount a rapid and efficient response to the pandemic by putting science, technology, and market-based mechanisms at center stage. Developments that followed show that efficiency is not the only value that should be prioritized; other values like human rights, solidarity, and justice are just as important, particularly since power (including IP rights) tends to be held by corporations or institutions. After all, the principles of human rights and justice are action-guiding, seeking to enable and sustain social cooperation. Relations of reciprocity must in turn be present for one party to assert claims to fair sharing of the goods that social cooperation makes available. Over the years, TRIPS has been the subject of much controversy,

[72] Lasse Nielsen & David V. Axelsen, *Capabilitarian Sufficiency: Capabilities and Social Justice*, 18 J. Human Dev. & Capabilities 46 (2017).

[73] Sen, *supra* note 70, at 41–44.

[74] Jean Drèze & Amartya Sen, India: Development and Participation 6 (2002).

particularly when applied in ways that limit access to health products such as vaccines. Even if the closer engagement among the WIPO, the WTO, and the WHO in responding to the COVID-19 pandemic is a promising development, the binary of exclusivity or free-for-all through the TRIPS flexibilities or the TRIPS waiver is unlikely to be helpful in meeting future pandemic challenges. Crucially, the TRIPS provisions might have been applied too broadly to prioritize reward for inventors or innovators, whereas initiatives like the mRNA technology transfer hubs suggest that the international IP regime could better enable technology transfer to empower health systems and global health.[75]

By design, the ACT-A is not an organization with its own legal status or central governing body, but has a complex, continuously evolving set of arrangements for governance, decision-making, and accountability.[76] While its structure and key actors are clearly set out, there is a lack of transparency over how decisions are made and why.[77] It has been unclear if a consultative process has been put in place to solicit inputs from its stakeholders and the wider global publics on its activities, policies, decisions, achievements, and struggles, or how it should and could be held accountable to governments, which are ultimately responsible for protecting public health within their jurisdictions.[78] As a public–private partnership, the involvement and role of industry (vaccine developers and producers where COVAX is concerned) have not been clear, since they tend to be set out in contractual agreements that are not publicly available. At a basic level, the issue of a TRIPS waiver arose in the absence of a transparent and accountable governance framework for innovation and access. More fundamentally, the failings of COVAX emphasize that all health systems, whether on their own or through collaborative engagement, should have the capability to be self-reliant. It does not auger well for global health justice if the majority of health systems have to rely on the goodwill of a few health systems, or worse, a few corporations and private organizations that are accountable only to their shareholders or sponsors. The COVID-19 pandemic has invigorated cooperation among key international organizations (particularly the WHO, the WTO, and the WIPO) along with their partners, and this momentum will need to be sustained if gains in the technological capability of underresourced health systems are to be

[75] Calvin Ho, *Utilitarianism and Patents: Justification and Change*, 2 Asian Bioethics Rev. 202 (2010).

[76] Surie Moon et al., *Governing the Access to COVID-19 Tools Accelerator: Towards Greater Participation, Transparency, and Accountability*, 399 Lancet 487 (2022).

[77] Megan Donaldson & Benedict Kingsbury, *The Adoption of Transparency Policies in Global Governance Institutions: Justifications, Effects, and Implications*, 9 Ann. Rev. L. & Soc. Sci. 119 (2013).

[78] In February 2021, the ACT-A civil society group wrote in detail to ACT-A leaders requesting increased transparency with regard to decision-making and meaningful inclusion in ACT-A decisions. The letter to ACT-A Leadership and briefing from Civil Society and Community Representatives may be downloaded from this platform for ACT-A Civil Society and Community Representatives, www.globalfundadvocatesnetwork.org/tools-for-advocacy/covid-19-resources/act-accelerator-act-a/ (last visited Dec. 9, 2023).

consolidated at a higher level of pandemic preparedness and more equitable access to vaccines. The legal basis of initiatives like the one-off TRIPS waiver and the mRNA technology transfer hubs will benefit from clarification in terms of where they stand in relation to the TRIPS provisions and flexibilities. Crucially, the association between TRIPS and the global health regime will need careful calibration and management (perhaps dynamically) to ensure that IP rights (and the underlying technological innovations) and global health initiatives such as ACT-A continue to serve as means to secure human rights and freedoms, especially during an epidemic or pandemic.

4 CONCLUSION

As a species of property law institution, IP law comprises relatively stable and internally coherent categories of rights that are in turn governed by precise rules and clear standards. It is also subject to continuous evaluation and refinement through legislative, adjudicative, and administrative decisions and/or processes. In theory, there should be no inherent tension between IP law and the capability approach in their goals of securing agency and human flourishing through collective action. However, recent developments on the global health stage that we have considered in this chapter show the limitations of instituting market- or property-based mechanisms as the dominant paradigm in global health. In August 2022, Moderna filed lawsuits against Pfizer and BioNTech in the United States and in Germany for infringement of three patents on modifications to mRNA technology that allow for larger doses to be delivered and on the design of the spike protein.[79] Moderna developed its full-length spike protein technology when working on Middle East Respiratory Syndrome (MERS). Earlier on, in July 2022, BioNTech was sued by CureVac, another German biotech company, while Moderna was sued by Alnylam Pharmaceuticals, Arbutus Biopharma, and Genevant Sciences, which claim that their patent rights over the delivery mechanism used by Moderna were infringed. Possible outcomes from these disputes could result in Moderna's domination of the mRNA market if it succeeds in asserting its patent claims over the technology, or a more intricate web of cross-licenses will emerge. Either way, the cost and access implications are unlikely to be positive.

Meanwhile, ACT-A has reportedly been winding down its activities, although the COVAX facility could be moved to Gavi.[80] Whereas wealthy jurisdictions have

[79] Hannah Kuchler, *Moderna Battels for Covid Vaccine Rewards*, FINANCIAL TIMES, Nov. 11, 2022, at 10. *See also* Scott Berinato, *Moderna v. Pfizer: What the Patent Infringement Suit Means for Biotech*, HARV. BUS. REV. (Sep. 16, 2022), https://hbr.org/2022/09/moderna-v-pfizer-what-the-patent-infringement-suit-means-for-biotech (last visited Dec. 9, 2023).

[80] Erin Banco & Ashleigh Furlong, *World's COVID Vaccine, Drugs Equity Program Set to Wind Down This Fall*, POLITICO (Jul. 5, 2022), www.politico.com/news/2022/07/05/worlds-covid-equity-vaccine-drugs-program-set-to-wind-down-this-fall-00044008 (last visited Dec. 9, 2023).

achieved high rates of distribution and administration of vaccines, this has not been the case for underresourced countries. Only 20.9 percent of people in low-income countries have received at least one dose of COVID-19 vaccination,[81] compared to 67.7 percent of the world population. Hampered by a funding gap of $1.85 billion, according to the ACT-A Commitment Tracker, and waning global interest in the pandemic,[82] it is unlikely that access to COVID-19 vaccines will drastically improve via this route. The different WHO-based mRNA technology transfer hubs established around the world, facilities established by Moderna and the Pfizer–BioNTech partnership, and still other mRNA vaccines that are in the development pipeline are likely to take over the supply of mRNA vaccines.[83] The lack of coordination among these facilities, and – as I have noted – the contest over IP rights to the mRNA technology platform will need to be addressed at a global level, and ideally under a legally binding treaty on pandemic preparedness.[84] As Larry Gostin has observed more recently, COVID-19 highlighted the centrality of research and development, and to prepare for the next pandemic we cannot keep to the status quo but need to remake society to be more equitable, to have stronger safety nets, and to enable a new politics for global health security.[85] It is important for individual countries and industry stakeholders to overcome IP barriers, but as long as these efforts remain disjointed, equitable access to vaccines and other pandemic countermeasures among the world's poorest remains at stake.[86]

The capability approach provides a conceptual framework to reimagine global health governance and how IP rights should be situated in the shaping of technological development, production, and distribution, in terms of the product (for example, vaccine) and the technical means (for example, capability to contribute to the production of vaccine). In the short term, there will of course be challenges that are linked to raw materials, production facilities, human capital, as well as

[81] *Coronavirus (COVID-19) Vaccination*, Our World in Data, https://ourworldindata.org/covid-vaccinations (last visited Dec. 9, 2023). At the time of writing, vaccination coverage in Africa has been reported to be at 21.3 percent. *See COVID-19 Vaccination*, Africa Centres for Disease Control & Prevention, https://africacdc.org/covid-19-vaccination (last visited Dec. 9, 2023).

[82] WHO, *Access to COVID-19 Tools Funding Commitment Tracker* (Nov. 14, 2022), www.who.int/publications/m/item/access-to-covid-19-tools-tracker (last visited Dec. 9, 2023).

[83] Jon Cohen, *New Crop of mRNA Vaccines Aim for Accessibility*, 376 Science 120 (2022). If successful, new mRNA vaccines developed in China, Thailand, and Japan will not require storage at extremely low temperature.

[84] Prior to the COVID-19 pandemic, Lawrence Gostin has highlighted the need to improve health outcomes around the world and in a manner that is consistent with the requirements of justice, particularly the equitable sharing of health benefits and burdens. This means achieving good health for everyone in the aggregate and in fair distribution across all populations. This message is perhaps even more relevant now. *See* Lawrence O. Gostin, Global Health Law (2019).

[85] Lawrence O. Gostin, Global Health Security: A Blueprint for the Future 220, 226 (2021).

[86] *Id.*, at 205.

infrastructural and practical constraints.[87] However, deeper relationality in the capability approach requires that all health systems should be able to participate meaningfully in technological development, production, and distribution, unlike the current COVID-19 vaccines situation where a handful of (mainly high-income) countries provide vaccines to relatively "passive" (and mainly low-income) countries. The status quo reflects the technological divide between the "Global North" and the "Global South," which is in many ways sustained by the international IP regime as it is designed and implemented. The world will remain unprepared for the next pandemic unless we depart from the status quo by identifying, under the capability approach, for instance, stronger freedom-enhancing routes that are based on a wider set of principles and considerations.[88]

[87] *See also* Alice Park, *Moderna Is Sharing Its Vaccine Technology with Low-Income Countries. But That Doesn't Mean Locally Produced Shots Are Coming Soon*, TIME (Mar. 9, 2022), https://time.com/6155934/moderna-covid-19-vaccine-patent (last visited Dec. 9, 2023).

[88] Amartya Sen articulates this as global reasoning, which has characteristics that are not different from those that depict the rule of law, namely the capability of guiding its subjects' behavior, and to check on the arbitrary exercise of power. *See* AMARTYA SEN, THE IDEA OF JUSTICE 408–415 (2011).