

11-2023

## Technology Specificity and Equitable Access to Pharmaceuticals

Ana Santos Rutschman

Follow this and additional works at: <https://scholarlycommons.law.northwestern.edu/njtip>

---

### Recommended Citation

Ana Santos Rutschman, *Technology Specificity and Equitable Access to Pharmaceuticals*, 21 NW. J. TECH. & INTELL. PROP. (2023).

<https://scholarlycommons.law.northwestern.edu/njtip/vol21/iss1/2>

This Article is brought to you for free and open access by Northwestern Pritzker School of Law Scholarly Commons. It has been accepted for inclusion in Northwestern Journal of Technology and Intellectual Property by an authorized editor of Northwestern Pritzker School of Law Scholarly Commons.

N O R T H W E S T E R N  
JOURNAL OF TECHNOLOGY  
AND  
INTELLECTUAL PROPERTY

**TECHNOLOGY SPECIFICITY AND  
EQUITABLE ACCESS TO  
PHARMACEUTICALS**

*Ana Santos Rutschman*



## TECHNOLOGY SPECIFICITY AND EQUITABLE ACCESS TO PHARMACEUTICALS

*Ana Santos Rutschman*\*

**ABSTRACT**—Current models of production of pharmaceuticals, particularly those dependent on intellectual property (and adjacent) protections, often contribute to the highly asymmetrical and inequitable distribution of resulting outputs. These problems are especially acute when emerging pathogens cause transnational public health crises in which there is concurrent demand for the same medicines in both lower- and higher-income countries, with populations in the Global South getting very limited timely access, if any, to preventatives and life-saving medicines—even when an outbreak disproportionately affects populations in these very countries.

This essay examines an under-theorized and under-explored way to help correct this historical and persisting deficit in distributive justice: it introduces and develops the concept of “technology specificity,” situating it in the context of the transfer of patented pharmaceutical products. As used here, technology specificity refers to a component-by-component evaluation of the pharmaceutical landscape surrounding products needed for pandemic and epidemic preparedness, with an emphasis on proprietary rights and logistical barriers to tech transfer. The essay further advocates for a more deliberate use of technology-specific strategies on part of policymakers before the onset of a pandemic or epidemic. This contrasts with the current practice of negotiating contractual terms when a public health crisis is already underway.

The *ex ante* approach proposed here can help lessening many of the political economy hurdles that arise when policymakers in lower-income countries are forced to compete on unlevel playing fields with those in

---

\* Professor of Law, Villanova University Charles Widger School of Law. Draft versions of this work were presented at the 2023 *Northwestern Journal of Technology and Intellectual Property's Symposium*, the workshop on *A Human-Centered Approach to Health Innovations: Reconciling Intellectual Property with Human Rights*, held at Yale University on October 29-30, 2022, the 2023 *CeBIL Symposium: Sustainable Health Innovation, Grand Challenges & the Laws* at the Centre for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen, and the 2022-23 TECHNIS web seminar series. The essay has benefited greatly from comments provided by participants at these events. I am especially grateful to Brook Baker, Jorge Contreras, Rochelle Dreyfuss, Mark Eccleston-Turner, Aidan Hollis, Andreas Panagopoulos, Laura Pedraza-Fariña, Michelle Rourke, Josh Sarnoff, Katerina Sideri and Peter Yu.

wealthier countries at the height of a pandemic or epidemic. In turn, this affords policymakers greater flexibility to negotiate equitable access provisions—thus ensuring that, when demand for a pharmaceutical or a particular component does arise, populations in lower-income regions are not left out.

- I. ASYMMETRIES AND INEQUITIES IN THE TRANSNATIONAL ALLOCATION OF PHARMACEUTICALS .....58
- II. PROPRIETARY FRAMEWORKS AND INEQUITABLE ACCESS TO PHARMACEUTICALS AT THE TRANSNATIONAL LEVEL .....60
  - A. *Intellectual Property Frameworks*..... 60
  - B. *Other Proprietary Frameworks: The Role of Contractual Bilateralism* .....62
- III. TOWARDS MORE EQUITABLE APPROACHES: THE ROLE OF “TECHNOLOGY SPECIFICITY” .....64
  - A. *Defining “Technology Specificity”*..... 64
  - B. *Explaining “Technology Specificity”* ..... 65
  - C. *Contrast With Non-Technology Specific Approaches*..... 67
  - D. *Policy and Legal Implications of Technology Specificity* ..... 69
  - E. *An Incremental Approach: Technology Specificity in the Context of Access to Pharmaceuticals* ..... 73

I. ASYMMETRIES AND INEQUITIES IN THE TRANSNATIONAL ALLOCATION OF PHARMACEUTICALS

Emerging pathogens,<sup>1</sup> such as the one that triggered the COVID-19 pandemic, are expected to cause pandemics and large-scale epidemics at an increasing pace,<sup>2</sup> with potentially devastating effects to the health of populations around the globe. A wide range of pharmaceuticals—some already in development, others that by nature can only be developed once a novel pathogen or strain becomes known—will play a key role in the prevention, diagnosis, and treatment of these emerging diseases.<sup>3</sup>

Foundational principles from a variety of disciplines dictate that, once developed, these pharmaceuticals should be distributed predominantly according to public health criteria, which traditionally operate on a medical

---

<sup>1</sup> Virologist Stephen Morse first defined these pathogens as those causing “infections that have newly appeared in the population or are rapidly increasing their incidence or geographic range.” Stephen S. Morse, *Factors in the Emergence of Infectious Diseases*, 1 EMERGING INFECTIOUS DISEASES 7, 7 (1995).

<sup>2</sup> See, e.g., Katherine F. Smith et al., *Global Rise in Human Infectious Disease Outbreaks*, 11 J. ROYAL SOC’Y INTERFACE (2014).

<sup>3</sup> See, e.g., Felicity Nelson, *Billion-Dollar Project Aims to Prep Drugs Before the Next Pandemic*, NATURE (Aug. 31, 2022), <https://www.nature.com/articles/d41586-022-02776-8> [<https://perma.cc/D7H6-CRQ4>] (describing ongoing efforts to fund the development of some types of pharmaceuticals for future pandemics).

need-basis.<sup>4</sup> As a rule, in situations of product scarcity, a substantial amount of existing pharmaceuticals should be allocated to the populations either experiencing or likely to experience the greatest burden of disease.<sup>5</sup>

Yet, practice seldom conforms to these principles in the case of large transnational outbreaks. This problem is especially acute when demand for newly developed pharmaceuticals arises simultaneously in both higher- and lower-income countries.<sup>6</sup> As illustrated by the two most recent pandemics (swine flu in 2009<sup>7</sup> and COVID-19<sup>8</sup>), countries in the Global North tend to purchase most of the available doses of pharmaceuticals, leaving populations in the Global South to wait months or years for access to these products.<sup>9</sup> As recent history also attests, this asymmetrical allocation of scarce pharmaceuticals during pandemics and epidemics occurs even when populations in the Global South experience a higher disease burden than those in the countries acquiring disproportionately large amounts of potentially life-saving products.

This disconnect between public health need and allocative choices is profoundly inequitable. Yet, it is anchored on practices that are compatible with, and in some cases enabled by, existing legal frameworks.

---

<sup>4</sup> See generally TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *Principles of Biomedical Ethics*, 267-326 (8th ed. 2019) (providing an ethical standard for a global health policy).

<sup>5</sup> See, e.g., Ezekiel J. Emanuel et al., *Fair Allocation of Scarce Medical Resources in the Time of COVID-19*, 382 NEW ENG. J. MED. 2049 (2020).

<sup>6</sup> See *infra* note 32 and accompanying text.

<sup>7</sup> See generally *2009 H1N1 Pandemic (H1N1pdm09 virus)* U.S. CTRS. DISEASE CONTROL & PREVENTION (2019), <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html> [<https://perma.cc/A2NJ-LWY5>]; Harvey V. Fineberg, *Pandemic Preparedness and Response--Lessons From the H1N1 Influenza of 2009*, 370 NEW ENG. J. MED. 1335 (2014) (collectively describing the pandemic that preceded COVID-19).

<sup>8</sup> See generally *COVID-19* U.S. CTRS. DISEASE CONTROL & PREVENTION (2022), <https://www.cdc.gov/coronavirus/2019-nCoV/index.html> [<https://perma.cc/7TET-LSLM>]; Marco Ciotti et al., *The COVID-19 Pandemic*, 57 CRITICAL REVS. CLINICAL LAB. SCIS. 365 (2020) (collectively describing the COVID-19 pandemic).

<sup>9</sup> See generally Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT'L AFFS. (Jul. 3, 2020), <https://gja.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism> [<https://perma.cc/WQN2-JUTE>]; Sam F. Halabi & Ana S. Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, 36 EMORY INT'L L. REV. 1, 9-17 (2022) [hereinafter *Viral Sovereignty*]; Mark Turner, *Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons From 2009-H1N1*, 11 GLOB. PUB. HEALTH 322 (2016) (collectively describing examples in which unequal pharmaceutical purchasing power between the Global North and Global South manifested).

## II. PROPRIETARY FRAMEWORKS AND INEQUITABLE ACCESS TO PHARMACEUTICALS AT THE TRANSNATIONAL LEVEL

### A. *Intellectual Property Frameworks*

One of the most relevant legal frameworks in this area is intellectual property. To be clear, this essay does not take the view that intellectual property is the sole (or even main) source of the asymmetrical allocation of scarce pharmaceuticals during large transnational public health crises. But it does underscore the role of proprietary frameworks—and, among them, intellectual property rights—in enabling allocative practices that result in the exclusion of populations in the Global South.

Exclusionary dynamics are baked into intellectual property systems. The heart of intellectual property rights is formed by the ability to prevent others from using one's creations or inventions, for reasons now commonly associated with incentives-based innovation policy.<sup>10</sup> These exclusionary powers are nonetheless (somewhat) limited. At first blush, the exclusionary nature of the global intellectual property system can be calibrated to accommodate public health priorities. To begin with, in setting forth the international laws governing the design of intellectual property systems, the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)<sup>11</sup> imposes an obligation in article 7 to balance “rights and obligations.”<sup>12</sup> Moreover, article 8 specifically allows countries to “adopt measures necessary to protect public health.”<sup>13</sup> Article 31 further allows countries to issue compulsory licenses.<sup>14</sup> These licenses can be issued for patents covering eligible products or process without the consent of the patent holders, subject to the payment of adequate compensation.<sup>15</sup> In the case of public health emergencies, including epidemics and pandemics, article 31(b) provides a departure from the general regime, which typically requires governments seeking to issue a compulsory license to attempt to

---

<sup>10</sup> See, e.g., Eric E. Johnson, *Intellectual Property and the Incentive Fallacy*, 39 FLA. ST. U. L. REV. 623 (2012). For a broader discussion of justifications for IP regimes, see Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988); William Fisher, *Theories of Intellectual Property*, in NEW ESSAYS IN THE LEGAL & POL. THEORY OF PROP. 168 (Stephen R. Munzer, ed., 2001).

<sup>11</sup> The TRIPS Agreement sets minimum standards for the protection and enforcement of intellectual property rights. See Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979, 980 (2009).

<sup>12</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS]. See generally Yu, *supra* note 11 at 1018-46 (analyzing the normative content of articles 7 and 8).

<sup>13</sup> TRIPS, *supra* note 12, art. 8.

<sup>14</sup> See *id.* art. 31.

<sup>15</sup> *Id.*

negotiate with patent holders.<sup>16</sup> Article 31(b) allows them to waive the pre-compulsory licensing negotiating phase in order to respond more expeditiously to ongoing public health crises.<sup>17</sup> Additionally, article 31*bis* allows countries seeking access to a given pharmaceutical product to import it from countries with manufacturing capacity under a compulsory license.<sup>18</sup> This ability was reaffirmed by the 2001 Doha Declaration on the TRIPS Agreement and Public Health,<sup>19</sup> which expressly articulated the notion that TRIPS “does not and should not prevent [m]embers from taking measures to protect public health.”<sup>20</sup>

In spite of the theoretical balance between patent protection and access to medicines as articulated in the TRIPS Agreement and the Doha Declaration, the current global intellectual property system remains an overly exclusionary one, leaving populations in lower-income countries struggling for equitable access to pharmaceuticals.<sup>21</sup> To give but one example, consider the case of the inequitable divide between the Global South and the Global North in access to HIV/AIDS drugs at the turn of the century. For several months, the American and European pharmaceutical companies that produced some of the patented antiretroviral drugs needed to respond to the HIV/AIDS crisis would only agree to sell them at prices that were unaffordable to governments in the Global South.<sup>22</sup> Only when some of the countries with the largest economies in the Global South began taking

---

<sup>16</sup> See *id.* art. 31(b).

<sup>17</sup> *Id.*

<sup>18</sup> See *id.* art. 31*bis* (included as part of the TRIPS agreement, as amended on 23 January 2017).

<sup>19</sup> World Trade Organization, *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2001) [hereinafter Doha Declaration]. For a collective assessment of the impact of the Doha Declaration, see both Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT’L ECON. L. 469 (2002); and James T. Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties*, 15 HARV. J. L. TECH. 291 (2002).

<sup>20</sup> Doha Declaration, *supra* note 19, para. 4.

<sup>21</sup> See Peter K. Yu, *TRIPs and its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 379-386 (2006) (articulating a larger critique of the TRIPS Agreement as one of the legal instruments that has helped perpetuate or exacerbate the divide between lower- and higher-income countries, both with regard to public health and in other domains). See generally Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006) (discussing the growing “asymmetries in intellectual property norm-setting and interpretation occurring in multilateral and bilateral activities across the world.”).

<sup>22</sup> See generally Eduardo Urias, *The Potential Synergies Between Industrial and Health Policies for Access to Medicines: Insights from the Brazilian Policy of Universal Access to HIV/AIDS Treatment*, 9 INNOVATION & DEV. 245 (2019) (surveying the role of compulsory licensing in pricing negotiations).

steps to issue compulsory licenses on these drugs did the patent holders agree to meaningfully lower the price of the drugs.<sup>23</sup>

In this particular case, the legal tool that helped lower the price of these patented products—and thus expand access to critically needed medicines—was available within the intellectual property system itself, in the form of a compulsory license. Compulsory licenses, however, may not always be available,<sup>24</sup> or they may not be the appropriate tool for increasing production of certain medicines, as was the case of vaccines during the COVID-19 pandemic.<sup>25</sup>

### *B. Other Proprietary Frameworks: The Role of Contractual Bilateralism*

While intellectual property is often regarded as the main legal regime devised to implement innovation policy agendas, it is not the only legal tool informing allocative outcomes during pandemics and epidemics. Intellectual property places constraints on the use or replication of protected goods, but nothing in the global patent system dictates that the allocation of those goods should follow primarily market-based and nationalistic demand, as is the current practice.<sup>26</sup> It is possible to imagine, for example, a global procurement system that would centralize the purchase of patent-protected pharmaceuticals, which would then be distributed primarily according to epidemiological and public health criteria.<sup>27</sup>

---

<sup>23</sup> *Id.* See also Jennifer L. Rich & Melody Petersen, *Brazil Will Defy Patent on AIDS Drug Made by Roche*, N.Y. TIMES (Aug. 23, 2001), <https://www.nytimes.com/2001/08/23/business/brazil-will-defy-patent-on-aids-drug-made-by-roche.html>.

<sup>24</sup> See TRIPS, art. 31 (listing the requirements that have to be met before a compulsory license is issued).

<sup>25</sup> For a discussion of the limitations surrounding the use of compulsory licenses in connection with structurally complex drug, such as vaccines and other biologics, see Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, HARV. BILL HEALTH (May 5, 2021), <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver> [https://perma.cc/W9KT-V8Y7] (noting that, unlike the antiretrovirals used in the treatment of HIV/AIDS, more complex drugs are much harder to replicate without some degree of knowledge transfer or technical assistance from the original manufacturer). For discussions of legal and practical limitations to the compulsory licensing system, see also generally Gabriele Spina Ali, *The Sound of Silence: International Treaties and Data Exclusivity as a Limit to Compulsory Licensing*, 38 EUR. INTELL. PROP. REV. 744 (2016); Cameron Hutchison, *Over 5 Billion Not Served: The TRIPS Compulsory Licensing Export Restriction*, 5 U. OTTAWA L. & TECH. J. 43, (2008); Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 514. (2022); and Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. L. MED. & ETHICS 247 (2009).

<sup>26</sup> See *infra* note 32 and accompanying text.

<sup>27</sup> This is what entities like COVAX (during the COVID-19 pandemic) and Gavi, the Vaccine Alliance (with regard to childhood vaccines) do on a smaller scale. See Vincenza Gianfredi et al., *Vaccine Procurement: A Conceptual Framework Based on Literature Review*, 9 VACCINES 1434 (2021).



Under current allocative modes, however, the primary method for allocating scarce medicines—particularly in the context of pandemics and large transnational epidemics—is through contract bilateralism.<sup>28</sup> When concurrent demand for medicines arises, higher-income countries have historically moved to capture a significant majority of the bulk of initially produced doses.<sup>29</sup> They do this by entering into “advance purchase agreements”<sup>30</sup> with pharmaceutical manufacturers.<sup>31</sup> This type of contractual mechanism allows parties to place orders for pharmaceutical products even before they have been fully developed, or gained market authorization from the relevant regulators.<sup>32</sup> Relying on their economic power and established relationships with pharmaceutical manufacturers, higher-income countries are thus able to secure priority access to drugs and vaccines for their own populations, even in cases in which the public health need for those same drugs and vaccines might be higher in lower-income countries.<sup>33</sup>

The most recent embodiment of this phenomenon happened during the early stages of the COVID-19 pandemic, during which most of the existing supply of newly developed vaccines was captured by a very restricted number of countries in the Global North,<sup>34</sup> with countries in the Global South left to wait anywhere from several months to years for doses of vaccine.<sup>35</sup> Contract bilateralism has thus become another relevant exclusionary force in the global landscape of access to medicines, particularly in the context of pandemics and large-scale transnational epidemics.

It is worth noting that, although it is not a mechanism rooted in intellectual property, contract bilateralism should not be understood as entirely separate from the intellectual property ecosystem. When these contracts are negotiated and executed, the players on the supply side of the

---

<sup>28</sup> See generally Ana Santos Rutschman, *Vaccine Contracts in the Context of Pandemics and Epidemics*, 64 N.Y.U. J. INT'L. L. & POL. 167 (2022); Halabi, *Viral Sovereignty*, *supra* note 9 at 9-17 (collectively describing contract bilateralism in the two most recent pandemics, COVID-19 and swine flu).

<sup>29</sup> See Rutschman, *supra* note 9; Halabi & Rutschman, *supra* note 9, at 5.

<sup>30</sup> See Ernst R. Berndt & John A. Hurvitz, *Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues*, 24 HEALTH AFFS. 653 (2005).

<sup>31</sup> Halabi & Rutschman, *supra* note 9, at 5.

<sup>32</sup> *Id.*

<sup>33</sup> See Ana Santos Rutschman, *Increasing Equity in the Transnational Allocation of Vaccines Against Emerging Pathogens: A Multi-Modal Approach*, 51 J. L. MED. ETHICS 247, 248-249 (2023) (describing this divorce between allocative methods and public health need).

<sup>34</sup> See Rutschman, *supra* note 9; Halabi, *supra* note 9.

<sup>35</sup> See *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*, DUKE GLOB. HEALTH INST. (Nov. 9, 2020), <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive> [<https://perma.cc/FT9L-VNF8>] (projecting that, due to contract bilateralism, many lower-income countries would have to wait several years to be able to vaccinate their populations against COVID-19).

bargain are normally the companies holding the intellectual property rights covering the then-scarce pharmaceutical products needed by populations located in different socioeconomic regions of the globe.<sup>36</sup> And the players making successful bids on the purchasing side are many of the same higher-income countries that have pushed maximalist agendas in the development and maintenance of the current global intellectual property dynamics.<sup>37</sup>

Having briefly sketched these allocative imbalances, the essay now turns to potential interventions aimed at lessening—albeit incrementally—some of the inequitable features surveyed above.

### III. TOWARDS MORE EQUITABLE APPROACHES: THE ROLE OF “TECHNOLOGY SPECIFICITY”

This Part explores an under-theorized approach to increase equity in the allocation of scarce pharmaceutical products, particularly in the context of pandemics and large-scale transnational epidemics. It is worth noting that the approach proposed here—one that relies on “technology specificity” as defined below<sup>38</sup>—cannot, on its own, cure the allocative problems described in the previous sections. Rather, it is presented here as a set of first steps aimed at policymakers, governments, funders and any other players interested in having more doses of pharmaceuticals committed to equitable forms of allocation of medicines when a pandemic or epidemic arises. In this sense, it is an approach designed to co-exist with other allocative schemes. Its main contribution is to use existing legal frameworks (e.g., funding agreements or other types of contracts) to incrementally commit doses of pharmaceuticals to equitable distribution at the global level—and to do so ahead of outbreaks of emerging diseases, when a spike in market demand and several other geopolitical constraints make equity-centered frameworks much harder to implement.

#### A. Defining “Technology Specificity”

This essay defines “technology-specific” approaches as those that take into account the heterogenous nature of pharmaceutical products within the same group or class, and seek to identify the components of a given product (e.g., the active ingredient or an adjuvant in a vaccine, as opposed to the entire set of technologies that make up a vaccine) that are critical for product

---

<sup>36</sup> See MARIO GAVIRIA & BURCU KILIC, A NETWORK ANALYSIS OF COVID-19 MRNA VACCINE PATENTS, 39 NAT. BIOTECH. 546 (2021); see also E. RICHARD GOLD, WHAT THE COVID-19 PANDEMIC REVEALED ABOUT INTELLECTUAL PROPERTY, 40 NAT. BIOTECH. 1428 (2022) (collectively describing the main holders of patents related to COVID-19 vaccine technology).

<sup>37</sup> Gaviria, *supra* note 36. See also Rutschman, *supra* note 9; Halabi & Rutschman, *supra* note 9.

<sup>38</sup> See Part III.A.

replication and relatively easy to transfer (either on a voluntary or compelled basis) from both a rights-clearance and a logistical perspective.

As further detailed below, by identifying products, or components thereof, that match these two categories, policymakers may then consider the adoption of more targeted interventions to facilitate technology transfer and scale up the production of critically needed medicines during transnational public health crises.

### B. Explaining “Technology Specificity”

Pharmaceutical products are often regarded as a whole. For instance, for both regulatory and extra-regulatory purposes, it is common to distinguish between conventional drugs<sup>39</sup> (the vast majority of medicines, often commercialized in tablet form) and biologics<sup>40</sup> (structurally larger drugs made inside living cells,<sup>41</sup> such as vaccines, gene therapies and therapeutic proteins). Another distinction commonly made contrasts complex medical products (such as ventilators and other life-supporting devices) with less complex ones (such as hand-held surgical instruments).<sup>42</sup>

---

<sup>39</sup> See U.S. Food & Drug Admin., *What Are “Biologics” Questions and Answers* (2018), <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers> [<https://perma.cc/TMV8-WWQU>] (defining these drugs as pharmaceuticals “that are chemically synthesized, and their structure is known”). See Ian Haydon, *Biologics: The Pricey Drugs Transforming Medicine*, CONVERSATION (July 26, 2017), <https://theconversation.com/biologics-the-pricey-drugs-transforming-medicine-80258> [<https://perma.cc/22BT-LA72>] (“Conventional medicines are stitched together by chemists in large factories using other chemicals as building blocks. Their molecular structures are well defined and relatively simple.”). Examples of conventional drugs include aspirin, antacids and statins, a type of cholesterol-lowering drugs in widespread use. *Id.* See 21 U.S.C. § 321(g) (The U.S. Food, Drug and Cosmetic Act describing these pharmaceuticals as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals”).

<sup>40</sup> See U.S. Food & Drug Admin., *supra* note 39. See also U.S. Food & Drug Admin., *Vaccines, Blood & Biologics* (2022), <https://www.fda.gov/vaccines-blood-biologics> [<https://perma.cc/52PJ-CGGM>]. See generally Favour Danladi Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, 9 MED. IN DRUG DISC. 100075, 2021, at 1. See 42 U.S.C. § 262(i)(1) (describing biologics as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine ( . . . ) applicable to the prevention, treatment, or cure of a disease or condition of human beings”).

<sup>41</sup> See Haydon, *supra* note 39.

<sup>42</sup> See U.S. Food & Drug Admin., *Overview of Medical Device Classification and Reclassification* (2017), <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification> [<https://perma.cc/7C8H-3EQR>] (using a risk-based approach to classify medical devices on a scale of I (lowest risk) to III (highest risk), regulating Class II and III devices more stringently than class I devices). See 21 C.F.R. § 860.10 and § 878.4800 (classifying life-supporting and life-sustaining devices as class III devices, while typically classifying hand-held surgical instruments as class I devices).

Nevertheless, even when belonging to the same group or class,<sup>43</sup> pharmaceutical products are highly heterogenous.<sup>44</sup> Pharmaceutical regulators recognize this by creating product-specific rules. For example, even within the category of biologics—which broadly subjects all products to the same requirements to gain market approval<sup>45</sup>—there are rules that apply specifically to vaccines and not to other biological products.<sup>46</sup> And even within vaccines, the regulatory regime and agency guidance further differentiate between the varying types of technological components (e.g., the use of mRNA<sup>47</sup> as the technology platform used to make a vaccine versus the use of a killed or weakened pathogen to accomplish the same purpose).<sup>48</sup> This type of distinction may even occur at a more atomic level, where distinctions are based on individual components of a product (e.g., vaccines made with adjuvants<sup>49</sup> containing aluminum versus vaccines made with non-alum-based adjuvants).<sup>50</sup>

This essay argues that a comparable degree of atomization in the treatment of pharmaceutical technology might be useful in calibrating interventions designed to improve the transnational allocation of scarce pharmaceuticals needed to respond to pandemics and epidemics—which has long been marked by profound inequities, with populations in higher-income

---

<sup>43</sup> Such as the drug/biologic distinction or FDA’s medical device classification. *See supra* notes 1-4 and accompanying text.

<sup>44</sup> *See, e.g.*, U.S. Food & Drug Admin., *General Drug Categories* (2015), <https://www.fda.gov/drugs/investigational-new-drug-ind-application/general-drug-categories> [<https://perma.cc/8BVQ-EXLR>] (listing forty different types of pharmaceutical drugs, such as antibiotics, anti-inflammatories, muscle relaxants and sleeping drugs).

<sup>45</sup> *See generally* Adrian Towse & Patricia M. Danzon, *The Regulation of the Pharmaceutical Industry*, in *THE OXFORD HANDBOOK OF REGULATION* 548 (Robert Baldwin et al. eds., 2010).

<sup>46</sup> *See generally* PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW* 1441-61 (5<sup>th</sup> ed. 2022).

<sup>47</sup> *Understanding How COVID-19 Vaccines Work*, U.S. CTRS. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html> [<https://perma.cc/G58D-CM8G>] (last updated Sept. 12, 2023) (describing mRNA vaccines).

<sup>48</sup> *See generally Explaining How Vaccines Work*, U.S. CTRS. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html> [<https://perma.cc/63LG-WXP4>] (last reviewed May 24, 2023) (describing the different types of vaccines currently on the market).

<sup>49</sup> For a definition of adjuvant, *see Adjuvants and Vaccines*, U.S. CTRS. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html> [<https://perma.cc/3MJJ-S4M5>] (last reviewed Sept. 27, 2022) (“An adjuvant is an ingredient used in some vaccines that helps create a stronger immune response in people receiving the vaccine. In other words, adjuvants help vaccines work better.”).

<sup>50</sup> *See generally* Bali Pulendran, Prabhu S. Arunachalam & Derek T. O’Hagan, *Emerging Concepts in the Science of Vaccine Adjuvants*, 20 *NATURE REV. DRUG DISCOVERY* 454, 454-76 (2021).

countries typically having access to critically needed vaccines and other pharmaceutical well ahead of those in lower-income countries.<sup>51</sup>

### C. Contrast With Non-Technology Specific Approaches

Many of the interventions proposed during the COVID-19 pandemic rely on intellectual property or intellectual property-adjacent proposals applicable to pharmaceuticals in general, or to entire classes thereof.<sup>52</sup>

Consider the case of compulsory licensing of medicines established in the TRIPS Agreement,<sup>53</sup> which illustrates the case of a broad “generalist” approach from a technological perspective. Article 31 of the Agreement enables countries to issue licenses for a patented product or process that are issued without the consent of the patent holder(s).<sup>54</sup> Both the legal regime codified in TRIPS and proposals for its stronger use at the national level apply to any type of qualifying pharmaceutical, irrespective of its technological characteristics (e.g., whether the products happens to be a conventional drug or a biologic).

The waiver of intellectual property rights proposed (and eventually adopted) during the COVID-19 pandemic was also initially devised as a generalist instrument. In October 2020, India and South Africa asked the TRIPS Council to recommend the temporary suspension of the implementation, application and enforcement of several provisions of the TRIPS Agreement.<sup>55</sup> As proposed, the waiver would apply to products or processes needed for the “prevention, containment or treatment of COVID-19.”<sup>56</sup> In the case of patent-protected products and processes, this would

<sup>51</sup> See Rutschman, *supra* note 9; Halabi & Rutschman, *supra* note 9, at 9-17. See also Turner, *supra* note 9 (discussing the problem of inequitable access to pandemic vaccines in the context of the 2009 swine flu pandemic).

<sup>52</sup> The same is true about legal and policy interventions proposed before the pandemic by scholars and policymakers worried about persisting systemic inequities in the global allocation of pharmaceuticals. For a discussion of these legal and policy options, see, e.g., Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Loyola University Chicago School of Law, Research Paper No.2011-011, 2011) [hereinafter *Access to Medicine in the Global Economy*] (2011).

<sup>53</sup> See *supra* notes 11-20 and accompanying text.

<sup>54</sup> *Id.*

<sup>55</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa* [hereinafter *Waiver Proposal*], WTO Doc. IP/C/W/669 (Oct. 2, 2020). See also generally Peter K. Yu, *The COVID-19 TRIPS Waiver and the WTO Ministerial Decision*, in *INTELLECTUAL PROPERTY RIGHTS IN TIMES OF CRISIS: LESSONS LEARNED FROM THE COVID-19 PANDEMIC* (Jens Schovsbo, ed., forthcoming Feb. 2024).

<sup>56</sup> See *supra* note 55.

encompass a large array of technologies, including diagnostics, vaccines, and treatments for COVID-19.<sup>57</sup>

As negotiations between countries supporting the proposal and those opposing it unfolded, the scope of the waiver was considerably reduced. By 2022, it covered only one type of intellectual property (patents) and one type of health good (COVID-19 vaccines, with diagnostics and treatments left out).<sup>58</sup> This represents a shift from the broadest possible form of generalist approach (the one encompassing all types of health products needed to respond to the COVID-19 pandemic) to a somewhat more contained form of generality—one that encompasses all COVID-19 vaccines.

Still, in both the case of compulsory licensing and that of the waiver, policymakers were painting with a relatively broad brush from a technological perspective—one that might work well for some, albeit not all, situations. To continue with the example of compulsory licensing, this broad “technological” brush was an appropriate mechanism to correct some of the most egregious imbalances in the context of the HIV/AIDS crisis, when countries like Brazil and Thailand effectively using it as a way to expand access to HIV/AIDS medicines for their domestic populations.<sup>59</sup>

In other contexts, however, this broad “technological brush” approach might not be effective. As elucidated by COVID-19, scaling up production of vaccines without the collaboration of the patent owners is much more difficult than doing the same with smaller and structurally simpler conventional drugs, such as the ones needed for the treatment of HIV/AIDS.<sup>60</sup>

For this reason, this essay argues that policymakers should consider adopting strategies—and, in particular, intellectual property ones—that more closely reflect the differences between types of pharmaceuticals. As further detailed in the following section, in some cases it might even make sense to distinguish between the different technological components within a single pharmaceutical product (e.g., the different ingredients within a given vaccine).

<sup>57</sup> *Id.*

<sup>58</sup> *Draft Ministerial Decision on the TRIPS Agreement*, WT/MIN(22)/W/15/REV.2 (June 17, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True> [<https://perma.cc/E2FW-CGXG>].

<sup>59</sup> See *supra* notes 1-58 and accompanying text. See generally Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. L. MED. & ETHICS 247 (2009) [hereinafter *Compulsory Licensing*]; Cynthia M. Ho, *Access to Medicine in the Global Economy*, 125-156, n.13 (2011).

<sup>60</sup> See generally 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/> [<https://perma.cc/HT8C-2K3H>].

#### D. Policy and Legal Implications of Technology Specificity

##### 1. Increased Granularity

The first implication of technology specificity is increased granularity. By focusing their attention on a more targeted set of products or components thereof, policymakers can direct more resources towards discrete technologies. In turn, this should facilitate to some extent the scaling up of production to meet demand in regions traditionally neglected during worldwide spikes in demand for a given medical product.

##### 2. Political Economy Implications

The second implication relates to the political economy. Technology-specific approaches translate into smaller asks: it is easier to bargain with one or more players over one or more discrete components of a product (e.g., provide pre-pandemic funding for research and development (R&D) on a chosen vaccine delivery method) than to bargain over an entire, potentially newly developed product. By identifying products or components thereof for which demand is in the future and uncertain, policymakers face fewer pressures and greater flexibility in negotiating technology transfer agreements and bringing together synergistic collaborators.

##### 3. A Shift Towards Ex Ante Approaches

Relatedly, the third implication is the possibility of a shift towards a model of greater emphasis on R&D for pandemic and epidemic preparedness (i.e., R&D performed ahead of public health crisis) as opposed to the current model, which focuses on the development of finished whole products (e.g., a treatment for coronavirus disease) once an outbreak is underway. Epidemiologists have identified most of the emerging pathogens projected to trigger large-scale outbreaks of infectious diseases over the coming decades.<sup>61</sup> While some R&D can only occur in response to the emergence of a specific new strain, a substantial amount of the technology needed to diagnose, prevent and treat diseases caused by novel pathogens is actually developed prior to the outbreak. For instance, the vaccine developed by Moderna during the COVID-19 pandemic was largely based on pre-pandemic R&D on a vaccine targeting a different coronavirus (the one causing Middle East Respiratory Syndrome, or MERS).<sup>62</sup> Because it is

---

<sup>61</sup> See World Health Org., *An R&D Blueprint for Action to Prevent Epidemics* (2016), <https://www.who.int/publications/m/item/an-r-d-blueprint-for-action-to-prevent-epidemics> [<https://perma.cc/JKL9-G42K>].

<sup>62</sup> See Michele Costanzo et al., *Anti-Coronavirus Vaccines: Past Investigations on SARS-CoV-1 and MERS-CoV, the Approved Vaccines from BioNTech/Pfizer, Moderna, Oxford/AstraZeneca and others under Development Against SARS-CoV-2 Infection*, 29 CURRENT MED. CHEMISTRY 4 (2022); Philip Ball,

possible to anticipate some of the future technological needs posed by emerging pathogens, but impossible to fully develop the final products needed for future pandemics and epidemics, policymakers and funders in the public health space should therefore direct their attention and resources to bolstering pre-pandemic/epidemic development of technological components that can be used synergistically when the need for a particular product does arise in connection with the onset of a pandemic or epidemic.

#### 4. *A Focus on Smaller and Middle-Sized R&D Players*

The fourth implication is that, when funding R&D and/or setting preparedness policy goals, policymakers, and funders may want to consider targeting smaller- and middle-sized R&D players. Larger firms operate according to entrenched business models that favor in-house development of a large number of products, combined with the purchase of targeted components (or of the actual smaller firms that produce these components) on an as-needed basis. Additionally, these large firms tend to enter the R&D arena when there is a projectably stable market for their R&D outputs. If they engage in pandemic- or epidemic-related R&D, they often do so reactively, and not proactively. During the early stages of the COVID-19 pandemic, Dr. Anthony Fauci noted that large pharmaceutical companies in the United States were initially reluctant to start development projects for vaccine candidates due to uncertainty about the magnitude of the outbreak and future demand for such vaccines.<sup>63</sup> Against this backdrop, support for R&D for preparedness—especially if focusing on one or a limited number of technological components as opposed to the whole product—is likely better directed at smaller, up-and-coming companies.<sup>64</sup> These players are more likely to be willing to perform R&D on niche fields and on products (or components therefor) with uncertain future markets—an R&D posture that

---

*The Lightning-Fast Quest for COVID Vaccines — And What It Means For Other Diseases*, NATURE (Dec. 18, 2020), <https://www.nature.com/articles/d41586-020-03626-1> [<https://perma.cc/5U9U-XR2R>].

<sup>63</sup> Nicholas Florko, *Major Drug Makers Haven't Stepped Up to Manufacture NIH Coronavirus Vaccine, Top U.S. Health Official Says*, STAT (Feb. 11, 2020), <https://www.statnews.com/2020/02/11/major-drug-makers-havent-stepped-up-to-manufacture-coronavirus-vaccine-top-u-s-health-official-says/> [<https://perma.cc/JKJ5-STWG>].

<sup>64</sup> Consider for instance that Moderna, which became a behemoth in the pharmaceutical arena during COVID-19, evolved from being a relatively modest player in the field, with no products in the market prior to the commercialization of its COVID-19 vaccine. Its work on lipid nanoparticles for mRNA delivery prior to the emergence of the virus causing COVID-19 positioned the company well to become a significant player during the pandemic. See Damian Garde & Jonathan Saltzman, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race*, STAT (Nov. 10, 2020), <https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/> [<https://perma.cc/5NT4-M9VJ>].



does not however exclude the possibility of generating platform technology<sup>65</sup> or other types of highly monetizable technology. Likewise, given the known limitations of existing funding for scientific research, particularly in the public sector,<sup>66</sup> smaller players are likely more amenable to financial incentives for R&D in this area than their larger, wealthier counterparts.

##### 5. *Inclusion of Equitable Access Provisions in Funding Contracts*

Lastly, and relatedly, the fifth implication of technology-specific approaches in this area is greater opportunity for the negotiation of meaningful equitable access provisions in the contracts governing R&D for preparedness. Because many of the temporal and geopolitical constraints of bargaining during pandemics or epidemics are removed, and because the target players for this approach are likely smaller firms, policymakers and funders could and *should* condition financial support for R&D on the acceptance of contractual provisions aimed at facilitating equitable access to the resulting products. Recall that many of the technological components developed ahead of a pandemic or epidemic face uncertain, at best future, demand. A smaller firm operating in the ultra-competitive ecosystem of players seeking R&D funding is more likely to agree to equitable access provisions than a firm for whom this type of funding is represents only a drop in their ocean of resources.

In the context above, the implementation of equitable access provisions may occur in multiple ways, depending on the particular goals of policymakers and funders. At a minimum, the funding contracts should include provisions imposing affordable pricing obligations—a requirement that is already in place in many contracts governing the development of pharmaceuticals during pandemics and epidemics.<sup>67</sup> But because the policies and contracts envisioned here are developed prior to the onset of a transnational public health crisis, they can also be designed more ambitiously than those generated during pandemics and epidemics. Funding can be tied

---

<sup>65</sup> See J.J. Prescott, *Improving Access to Justice in State Courts with Platform Technology*, 70 VANDERBILT L. REV. 1993 (2017) (describing the development of the concept of “platform technology” to describe “technology that provides the base on which other processes can be built and applied”) See generally Lea Skak Filtenborg Frederiksen et al., *The Long Road Toward COVID-19 Herd Immunity: Vaccine Platform Technologies and Mass Immunization Strategies*, 11 FRONTIERS IN IMMUNOLOGY 1817 (2020) (discussing platform technologies in the context of vaccine R&D).

<sup>65</sup> See, e.g., Shuting Shi et al., *Vaccine Adjuvants: Understanding the Structure and Mechanism of Adjuvanticity*, 37 VACCINE 3167 (2019).

<sup>66</sup> See, e.g., Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCI. (Mar. 9, 2017), <https://www.science.org/content/article/data-check-us-government-share-basic-research-funding-falls-below-50> [<https://perma.cc/Y8YX-CCFR>].

<sup>67</sup> See, e.g., *Master Alliance Provisions Guide (MAPGuide)*, Global Healthcare Innovation Alliances Accelerator, <https://ghiaa.org/mapguide-home/search-results/?qs=pricing> [<https://perma.cc/TD5T-XJ7J>] (listing funding contracts addressing pricing issues).

to the requirement to automatically<sup>68</sup> license the technology in case of a declared (or otherwise formally recognized) pandemic.<sup>69</sup> This licensure can be open-ended (to anyone wishing to use the covered technology) or narrowly defined (to one or more pre-defined entities or structures: for instance, a technology access pool akin to the one established by the World Health Organization during COVID-19).<sup>70</sup> Additionally, these contracts can also be used to stipulate that, should a pandemic be declared, transfer of the funded technology must be accompanied by the disclosure of the know-how (or other forms of non-explicit knowledge) needed to produce that product or utilize that particular process.<sup>71</sup>

#### 6. *Other Considerations*

Other potential implementations of technology-specific approaches may include provisions related to the allocation of end products—that is, the requirement that pharmaceuticals using components covered by these contracts be allocated equitably at the global level. This can be done by coupling technology-specific approaches with the formation of a structure (or network of structures) specifically aimed at governing the commitment of pharmaceutical technology in future pandemics or transnational epidemics. This commitment can be achieved through funding contracts negotiated during the pre-pandemic/epidemic period. Such a structure may even potentially set the criteria that will be used to coordinate product allocation once a transnational public health crisis begins.

Admittedly, the imposition of such a requirement is complicated by the fact that multiple technological components are needed to produce a pharmaceutical product, and some of them might originate from sources that are not bound to the same contractual requirements. This, in turn, has the

---

<sup>68</sup> I have proposed elsewhere the adoption of a “dormant licensing” scheme for selected technologies needed for pandemic preparedness and response. See Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200 (2018). See also Sapna Kumar & Ana Santos Rutschman, *Contractual Solutions to Overcome Drug Scarcity During Pandemics and Epidemics*, 40 NATURE BIOTECH. 301 (2022).

<sup>69</sup> See WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE (2009) [<https://perma.cc/K489-JPYU>].

<sup>70</sup> See WORLD HEALTH ORG., WHO COVID-19 TECHNOLOGY ACCESS POOL (2023) [<https://perma.cc/8EWW-ZUUD>].

<sup>71</sup> Unlike what happens in the case of compulsory licensing, there is currently no mechanism in international intellectual property law that can be used by countries to compel the transfer of these types of knowledge. Article 39 of TRIPS requires members to protect “undisclosed information” that is kept secret and has commercial value. But TRIPS provides no compulsory licensing scheme, nor any other disclosure-enhancing mechanism, to compel the transfer of this type of knowledge. See Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 39(1)(2). See also Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 39(1)(2)(c) (further requiring that protectible undisclosed information be “subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret”).

potential to narrow the number of partners willing to work with a firm bound by equitable access terms. However, this problem should be at least partially lessened by the fact that a pandemic or epidemic ushers in relatively widespread demand for the pharmaceutical technologies relevant to a given emerging disease—a surge in demand that typically attracts a corresponding, if temporary, spike in funding for R&D and technology transfer.<sup>72</sup> As the market materializes and funding streams open up, more players come to the table.<sup>73</sup> In addition to the increased number of R&D players, the creation of a market brought about by the pandemic or epidemic also means that there is greater possibility for technology monetization. Furthermore, the ongoing pandemic treaty negotiations suggest that COVAX<sup>74</sup> (or a similar structure) will become a permanent procurement facility for pharmaceutical products needed for pandemic and epidemic preparedness.<sup>75</sup> The existence of such a structure may facilitate the creation and maintenance of a dedicated technology commitment pipeline—one that could serve the functions outlined above and attract a relatively large number of players, thus providing policymakers and funders with greater leverage in imposing equitable allocation requirements in technology-specific funding contracts.

When functioning at scale, this would help ensure that, when demand for a pharmaceutical product or a particular component does arise in the context of a transnational public health crisis, a more meaningful commitment of technological components would be available to R&D players and manufacturers serving populations in lower-income countries. In its most stringent formulation—requiring that any product incorporating one of these components be allocated equitably at the transnational level—the proposal outlined here could also help to increase the overall number of products commercialized through equitable frameworks rather than bilateral contracts between manufacturers and individual countries.

*E. An Incremental Approach: Technology Specificity in the Context of Access to Pharmaceuticals*

On its own, the approach outlined in the preceding section will not cure the root causes of the longstanding practices leading to the inequitable allocation of pharmaceuticals during pandemics and epidemics. Rather, it

---

<sup>72</sup> See generally Rutschman, *IP Preparedness for Outbreak Diseases*, *supra* note 68.

<sup>73</sup> *Id.*

<sup>74</sup> COVAX is an international vaccine procurement structure created during the COVID-19 pandemic to address disparities in access to COVID-19 vaccine doses. It is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization. See *COVAX*, GAVI, the Vaccine Alliance [<https://perma.cc/N2Y8-YQWB>]. See also generally Halabi & Rutschman, *Viral Sovereignty*, *supra* note 9.

<sup>75</sup> See Halabi & Rutschman, *Viral Sovereignty*, *supra* note 9.

seeks to play off of current R&D and technology transfer dynamics, which favor negotiating the transfer and sale of patented pharmaceutical technology when a public health crisis is already underway. At that point, the combined forces of intellectual property rights and contract bilateralism enable allocative choices that may be contrary to public health.<sup>76</sup> By contrast, technology specificity helps shift some of the contractual moment to the pre-pandemic or pre-epidemic period by recognizing that some technological components needed once an outbreak begins are actually available before a crisis begins, and likely easier to bargain over than after the onset of a pandemic or epidemic.

Technology specificity thus calls attention to the fact that some pharmaceutical products, or components thereof, can be the subject of renewed efforts by policymakers proactively seeking to foster a culture of commitments to pharmaceutical equity, particularly in the case of products developed or manufactured by relatively smaller players for whom pre-pandemic and epidemic funding may be valuable. The flipside of this proposition is a negative delimitation: not all technological components of pharmaceutical products will be likely candidates for the approach proposed in this essay. For instance, an R&D player who develops technology projected to be valuable beyond the context of a pandemic or epidemic (e.g., platform technology such as mRNA, which is expected to have multiple applications within—and especially outside—vaccinology)<sup>77</sup> might be unwilling to bind itself to equitable access provisions early on and will quite possibly have other funding avenues available throughout the R&D arc. Technology specificity is thus limited in scope.

It is also an incremental and partial approach. The goal is to enlarge the number and kind of technologies committed to pandemic and epidemic preparedness through contractual frameworks designed to counter exclusionary approaches to the allocation of pharmaceuticals. Its main limitation—that it does not preclude concomitant forms of exclusion based on intellectual property dynamics and bilateral contracts—may also be the reason why the approach proposed here might have a fighting chance in an intellectual property-dense world in which pharmaceuticals are treated as commodities. Since it targets smaller players and technologies that are typically not valued highly prior to a pandemic or epidemic, it can be adopted without facing the heightened pushback that “broader-brush” proposals—

---

<sup>76</sup> *Id.*

<sup>77</sup> See, e.g., Brian Buntz, *7 Potential Applications of mRNA-Based Therapies*, DRUG DISCOVERY & DEVELOPMENT (Jan. 7, 2022) <https://www.drugdiscoverytrends.com/7-potential-applications-of-mrna-based-therapeutics/> [<https://perma.cc/54D2-S9SU>].

especially those aiming to reduce or eliminate intellectual property protection for entire categories of pharmaceuticals—normally face.

Broader, systemic solutions are still sorely needed beyond the realm of the technology-specific approach articulated here—solutions that will start by recognizing the overdue need to regulate the production and allocation of pharmaceuticals in ways that reflect the needs of millions of human beings as opposed to predominantly economic and geopolitical considerations. As presented here, technology specificity departs from the opposite starting point: the idea that policymakers have room for intervention within the current, flawed global legal ecosystem. Embracing technology specificity for some of these interventions, shifting the contractual moment to an earlier point in time, and experimenting more robustly with binding equitable access provisions in funding contracts constitute a first step towards the adoption of progressively more human-centered approaches to the allocation of pharmaceuticals during pandemics and epidemics.

