

# Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic

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## ABSTRACT

The COVID-19 pandemic has brought into stark relief the gaps in global preparedness to address widespread outbreaks of deadly viral infections. This article proposes legal mechanisms for addressing critical issues facing the international community in terms of providing equitable access to vaccines, treatments, diagnostics, and medical equipment. On the supply side, the authors propose the establishment of mandatory patent pools ('Licensing Facilities') on a global or regional, or even national basis, depending upon the degree of cooperation that may be achieved. The authors also discuss the importance of creating shared production facilities. On the demand side, the authors propose the establishment of Regional Pharmaceutical Supply Centers (RPSCs) for the collective procurement of products, and the need to coordinate the issuance of necessary compulsory licenses for production and/or importation, depending on relevant circumstances. The authors envisage that centralized coordination by RPSCs should assist in overcoming difficulties individual countries may encounter in addressing administrative and technical issues in procuring supplies, as well as creating improved bargaining leverage with potential suppliers. The authors finally address the problem created by the decision of various high-income countries to 'opt out' as eligible importing countries under the World Trade Organization TRIPS Agreement Article 31*bis* amendment that addresses the predominant export of pharmaceutical products under compulsory licenses.

## I. INTRODUCTION AND BACKGROUND: THE URGENT NEXT PHASE

The COVID-19 pandemic has brought into stark relief the gaps in global preparedness to address widespread outbreaks of deadly viral infections. These gaps reflect a general problem with preparing for low-probability, high-risk events.<sup>1</sup> Government budgets are

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1 See Olga B. Jonas, 'Pandemic Risk', World Bank Development Report Background Paper, October 2013, e.g. at 7.

constrained, and establishing priority for ‘unlikely’ events inevitably elicits resistance from more immediate demands. As for private sector enterprises, the prospect that a new vaccine, treatment, or diagnostic to address a ‘contingent’ outbreak ultimately may not be needed, or needed in sufficient quantity, makes investment in research and development (R&D) potentially problematic for shareholders.<sup>2</sup> In consequence, private sector R&D on pharmaceutical products to address new pathogens, including a pandemic virus, often must be subsidized through one of several mechanisms.

The gaps in preparedness for COVID-19 (or its pathogen equivalent) had been repeatedly identified by the scientific community for years. Those gaps might have been filled by substantially increased investment in the platform technologies needed to accelerate development and introduction of needed vaccines and treatments.<sup>3</sup> The lack of adequate investment in manufacturing facilities needed to respond on demand was well known, as was the general withdrawal of the major pharmaceutical companies from the vaccine sector.<sup>4</sup> As a result, the response has been an historically unprecedented ramp-up in the amount of government subsidization flowing to the pharmaceutical industry.<sup>5</sup>

### A. Scrambling to catch up

As of June 2020, there were no vaccines available that appear capable of preventing the spread of COVID-19, although promising research results have been announced.<sup>6</sup>

- 2 See, e.g. Dominic Foray and Gaétan de Rassenfosse, ‘COVID-19—Insights from Innovation Economists’, UNCTAD, (visited 30 June 2020), <https://unctad.org/en/pages/newsdetails.aspx?OriginalVersionID=2338>.
- 3 See, e.g. Shmona Simpson, Michael C. Kaufmann, Vitaly Gluzman, and Ajoy Chakrabarti, ‘Disease X: Accelerating the Development of Medical Countermeasures for the Next Pandemic’, 20 *The Lancet Infectious Diseases* (2020), at e108–e115, published online 17 March 2020, [https://doi.org/10.1016/S1473-3099\(20\)30123-7](https://doi.org/10.1016/S1473-3099(20)30123-7) (visited 8 May 2020); Amesh A. Adalja, Matthew Watson, Anita Cicero, and Tom Inglesby, ‘Vaccine Platforms: State of the Field and Looming Challenges’, Johns Hopkins Center for Health Security, 2019, available at [https://www.centerforhealthsecurity.org/our-work/pubs\\_archive/pubs-pdfs/2019/190423-OPP-platform-report.pdf](https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2019/190423-OPP-platform-report.pdf) (visited 8 May 2020).
- 4 See, e.g. ‘Vaccine Supply’, in Committee on the Evaluation of Vaccine Purchase Financing in the United States, Institute of Medicine, National Academies Press (US)(2003), at 107–144, [https://www.ncbi.nlm.nih.gov/books/NBK221813/pdf/Bookshelf\\_NBK221813.pdf](https://www.ncbi.nlm.nih.gov/books/NBK221813/pdf/Bookshelf_NBK221813.pdf) (visited 20 June 2020); Paul A. Offit, ‘Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?’, 24 (3) *Health Affairs* (May/June 2005), <https://doi.org/10.1377/hlthaff.24.3.622> (visited 8 May 2020); Roxanne Khamsi, ‘If a Coronavirus Vaccine Arrives, Can the World Make Enough?’, *Nature*, 9 April 2020, <https://www.nature.com/articles/d41586-020-01063-8> (visited 14 May 2020); David Willman, ‘Federal Vaccine Development Sites Ill-Suited to Counter Covid-19 Epidemic’, *The Washington Post*, 15 March 2020; Knvul Sheikh, ‘Find a Vaccine. Next: Produce 300 Million Vials of It’, *New York Times*, 1 May 2020.
- 5 Noah Weiland and David E. Sanger, ‘Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists’, *New York Times*, 15 June 2020 (updated); Lev Facher, ‘NIH Partners with 16 Drug Companies in Hopes of Accelerating Covid-19 Treatments and Vaccines’, *STAT*, 19 April 2020; Nick Paul Taylor, ‘J&J, BARDA Commit \$1B to COVID-19 Vaccine R&D’, *FierceBiotech*, 30 March 2020; David Kirk, ‘EU Pitches Into €7.4B Fund Supporting Covid-19 Treatments & Vaccines’, *Labiotech.eu*, 7 May 2020. The industry did not enter the pandemic ‘undercapitalized’. See, e.g. Ed Silverman, ‘FTC Approves AbbVie’s \$63 Billion Deal for Allergan Amid Scornful Dissent’, *STAT Pharmalot*, 6 May 2020. A substantial portion of the research and clinical trials on remdesivir were jointly conducted and financed by the US government, which kept Gilead’s Ebola-vaccine project alive. Kathryn Ardizzone, ‘Role of the U.S. Federal Government in the Development of GS-5734/Remdesivir’, KEI Briefing Note 2020:1, updated 25 March 2020.
- 6 Amirah Al Idrus, ‘Moderna Posts “Positive” early Data for COVID-19 Vaccine’, *FierceBiotech*, 18 May 2020.

Some treatments may effect modest improvement, but nothing approaching a ‘cure’ has so far been developed.<sup>7</sup> Nevertheless, ongoing studies suggest that COVID-19 may be addressable by known pharmaceutical technologies and that the development of efficacious vaccines and treatments appears likely within the next 12 to 18 months, although the ultimate degree of effectiveness remains uncertain. Whenever these new vaccines or drugs are ready to be used by a reasonably wide public, their manufacture and distribution will take priority.

In the short run, however, constraints due to manufacturing capacity shortfalls are likely, particularly for vaccines.<sup>8</sup> These constraints may be exacerbated if the technologies needed to address the pandemic are closely held by individual private enterprises with decision-making authority over how, where, and when to produce and distribute vaccines and treatments that will typically have been developed with large-scale government subsidization. These private sector controls will be grounded in intellectual property rights (IPRs), including patents and regulatory-based market exclusivity regimes.

### B. A bit of history

In the past 25 years, public-health specialists, pharmaceutical companies, nongovernmental organizations, and intellectual property experts have struggled over the terms and conditions under which access to medicines (including vaccines) could be facilitated.<sup>9</sup> The human immunodeficiency virus–acquired immunodeficiency syndrome (HIV-AIDS) pandemic precipitated a wide-ranging debate about the role played by patents and other forms of market exclusivity for drugs needed to treat significant parts of the global population, especially in poorer countries where personal incomes are low. The United Nations (UN) Secretary-General convened a High-Level Panel on Access to Medicines that conducted an in-depth study, with inputs from a wide range of interested groups, and issued a Report that encapsulates the different sides of this debate without proposing major new solutions.<sup>10</sup>

- 7 Remdesivir appears to be helpful in at least early stage treatment for some patients. U.S. Food & Drug Administration (“FDA”) News Release, Coronavirus (COVID-19) Update: U.S. Food & Drug Administration (“FDA”) Issues Emergency Use Authorization for Potential COVID-19 Treatment, 1 May 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment> (visited 20 May 2020); Arlene Weintraub, ‘Is Dexamethasone Really a COVID-19 Breakthrough? Not so Fast, Doctors Say,’ *Fierce Pharma*, 17 June 2020, <https://www.fiercepharma.com/pharma/dexamethasone-really-a-covid-19-breakthrough-not-so-fast-doctors-say> (visited 20 June 2020).
- 8 See ‘Vaccine Supply’, above n 4, and; Julie Steenhuisen and Kate Kelland, ‘Vaccine Makers Face Biggest Medical Manufacturing Challenge in History’, *Reuters*, 25 June 2020; Sydney Lupkin, ‘What Would It Take to Bring More Pharmaceutical Manufacturing Back to The U.S.?’ *NPR Shots*, 24 April 2020, <https://www.npr.org/sections/health-shots/2020/04/24/843379899/pandemic-underscores-u-s-dependence-on-overseas-factories-for-medicines> (visited 9 May 2020).
- 9 See Frederick M. Abbott and Jerome H. Reichman, ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions’, 10 *Journal of International Economic Law* 921 (2007) [hereinafter ‘Abbott and Reichman 2007’].
- 10 See, e.g. Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines, September 2016 (hereinafter ‘UN High-Level Panel’), <http://www.unsgaccessmeds.org/final-report> (visited 9 May 2020); Ellen ‘t Hoen ‘The Global Politics of Pharmaceutical Monopoly Power’, *Open Society* (2009), <https://www.opensocietyfoundations.org/publications/global-politics-pharmaceutical-monopoly-power> (visited 9 May 2020).

Companies that invest in R&D on new treatments and vaccines argued that high prices enabled by patents and regulatory market exclusivity were necessary to provide capital for the investigation of new treatments.<sup>11</sup> Public-health specialists and advocacy groups concerned with access countered that innovative treatments are not useful unless they are reasonably affordable.<sup>12</sup> Legislators and other government officials lined up on different sides of the issues.

In retrospect there is considerable evidence that the current system underlying the development and distribution of medicines is ‘suboptimal’. A range of proposals for retooling that system already exists. For example, several highly articulated ‘delinkage’ proposals to separate R&D activities from manufacturing and distribution have sought to ensure that companies would be well compensated for successfully developing new treatments—through subsidies or prizes (i.e. push and pull mechanisms)<sup>13</sup>—without selling medicines at high prices.<sup>14</sup> Thus, manufacturing and distribution would become ‘generic’, while the R&D elements would be separately compensated.<sup>15</sup> Given a worldwide emergency, it seems a good time for reflecting on such proposals to reorganize the basic system.

### C. Exclusive private rights

We cannot accurately predict when a pharmaceutical company, academic researchers, a teaching hospital, or biotech startup will develop a successful treatment for COVID-19, or an efficacious vaccine. Almost certainly there will be more than one of each since this is being worked on by so many. Nevertheless, it is fairly certain that various new treatments and vaccines will be patented. Absent government intervention, the patent owners will enjoy the exclusive rights to make, use, and sell the covered treatments and vaccines for a minimum term of 20 years.<sup>16</sup> Innovators could thus prevent any third parties from making and selling the same drugs or vaccines. In ordinary practice, innovators would possess monopoly pricing power enabling them to charge what the market

- 11 See, e.g. Elaine Ruth Fletcher, ‘Pharma Under the Microscope in the COVID-19 Crisis’, *Health Policy Watch*, 19 May 2020, <https://healthpolicy-watch.org/pharma-under-the-microscope-in-the-covid-19-crisis/> (visited 20 May 2020); earlier, see, e.g. Harvey E. Bale, Jr, ‘Patent Protection for Pharmaceuticals: A Platform for Investment, Markets and Improved Health in the Americas’, paper presented to Workshop ID, Cartagena, March 1996, [http://www.sice.oas.org/ip/Phrma\\_e.asp](http://www.sice.oas.org/ip/Phrma_e.asp) (visited 19 May 2020).
- 12 See recently, e.g. Svet Lustig Vijay and Elaine Ruth Fletcher, ‘World Health Assembly Resolution On COVID-19 Response: The Stark Choices Faced in a Polarized World of Global Health’, *Health Policy Watch*, 5 May 2020, <https://healthpolicy-watch.org/wha-resolution-on-covid-19-political-football-polarized-global-health/> (visited 10 May 2020). It is no secret that lobbying campaigns by the pharmaceutical industry play a significant role in the way policy is ultimately developed.
- 13 See, e.g. Michael Kremer and Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton: Princeton University Press, 2004).
- 14 See Knowledge Ecology International, et al., ‘The Need for Global Negotiations on Agreements to Fund R&D within the Context of a Progressive De-linking of R&D Costs from Product Prices’, Submission to UN High Level Panel, 28 February 2016, <http://www.unsgaccessmeds.org/inbox/2016/2/29/james-love> (visited 20 May 2020).
- 15 See, e.g. UN High-Level Panel, above n 10, at 29–30.
- 16 Arts. 28 & 33, WTO Agreement on Trade-Related Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, in World Trade Organization, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* 321 (1999), as amended on 23 January 2017 [hereinafter ‘TRIPS Agreement’], [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_01\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm) (visited 9 May 2020).

will bear, especially in a country like the USA where the government largely abstains from pricing decisions.<sup>17</sup> The private sector innovator industry has not hesitated to fully exercise this pricing power.<sup>18</sup>

At the time of writing, a number of pharmaceutical companies that are receiving substantial government subsidies to develop vaccines and treatments to address COVID-19 have declared that they intend to provide them on a 'not-for-profit' basis, although nothing in their grant arrangements appears to require specific pricing commitments,<sup>19</sup> and there is limited public transparency on this account. Several factors may underlie a commitment to not-for-profit supply. First, because government subsidies involve paying companies for their R&D expenses, they may already be profiting from the amounts paid by the government for such work without further need to profit from the sales. That posits an 'accounting question.'<sup>20</sup> Second, the recipients of federal subsidies are already under scrutiny by legislators and the public, and they lack a 'reservoir of goodwill'. A not-for-profit approach to the pandemic may thus be a way to improve the image of the industry and forestall future price regulation. Third, once any specific medicine becomes the standard treatment, it may enhance the prospects of a company in competing for future opportunities, including additional subsidies and/or product sales. Fourth, one cannot entirely discount charitable tendencies within the pharmaceutical industry even though it may appear to be more the exception than the rule.

Moreover, price—however important—is not the only factor to be considered. Because innovators file patent applications in countries around the world, and especially in countries where pharmaceutical products may be manufactured, monopoly control effectively becomes worldwide. Left to their own devices, a few major originator pharmaceutical companies will end up controlling the global supply of treatments and vaccines for COVID-19 and thereby set the conditions for public access to them.

Given a predictably large-scale demand for vaccines and treatments, their production and distribution should be maximized, a task best accomplished by allowing effectively open-access to the technologies needed to attain this objective.<sup>21</sup> Clearly, innovators should be paid well for their efforts. Nevertheless, steps should be taken now to ensure reasonable pricing and wide distribution of COVID-19 treatments, vaccines,

17 Jim Hahn, 'Federal Drug Price Negotiation: Implications for Medicare Part D', CRS RL33782, 5 January 2007.

18 Frederick M. Abbott, 'Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health', 6 *UC Irvine Law Review* 281 (2016) [hereinafter 'Abbott, Excessive Prices'].

19 Press release, 'Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use', 30 March 2020, <https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use> (visited 9 May 2020).

20 For a more skeptical perspective, see, e.g. 'A Not-For-Profit Vaccine from Johnson & Johnson? Not So Fast, Press Release', *Patients for Affordable Drugs*, 28 April 2020, <https://www.patientsforaffordabledrugs.org/2020/04/28/covid-blog-3/> (visited 9 May 2020).

21 See, e.g. Bernard Pecoul, 'New Health Tools for COVID-19', *Euractiv*, 4 May 2020, <https://www.euractiv.com/section/coronavirus/opinion/new-health-tools-for-covid-19/> (visited 9 May 2020).

diagnostics, and medical equipment (including personal protective equipment (PPE)) so that appropriate measures are ready when the need arises.

Vaccines, treatments, and diagnostics may also be developed by entities that are not profit oriented. While these entities are also likely to secure patents (at least for defensive purposes),<sup>22</sup> they may elect to pursue manufacturing and distribution on a nonprofit basis as a matter of institutional preference. Their participation in wider efforts to make technologies available on an equitable basis should not raise concerns.

The treaties administered by the World Intellectual Property Organization (WIPO)<sup>23</sup> and the World Trade Organization (WTO)<sup>24</sup> clearly allow for the grant by governments of compulsory patent licenses, that is, licenses granted without consent of patent owners. Such licenses can be issued to private enterprises or directly to governments under ‘government-use’ licenses.<sup>25</sup> The legitimacy of all such licenses, although never seriously in doubt, was expressly reconfirmed by the Doha Declaration on the TRIPS Agreement and Public Health in 2001.<sup>26</sup> Their availability to address national public health needs was then further amplified by an amendment to the TRIPS Agreement, in the form of Article 31*bis*, which was initially adopted by a waiver in 2003 and finally ratified in 2017.<sup>27</sup>

Nevertheless, the pharmaceutical innovator or ‘originator’ companies have stridently contended—for many years—that the use of compulsory licensing should be strictly limited (if allowed at all) because overriding patents would destabilize investor expectations and reduce future investment in the development of new drugs.<sup>28</sup> The

- 22 Nonprofit entities typically elect to secure patents on their pharmaceutical innovations to preclude third parties from claiming rights to the same innovations (i.e. defensive patenting), and to facilitate licensing.
- 23 See Article 5.A of the Paris Convention for the Protection of Industrial Property of 20 March 1883 (as amended on 28 September 1979), [https://www.wipo.int/edocs/lexdocs/treaties/en/paris/tt\\_paris\\_001en.pdf](https://www.wipo.int/edocs/lexdocs/treaties/en/paris/tt_paris_001en.pdf) [hereinafter ‘Paris Convention’] (visited 9 May 2020).
- 24 See TRIPS Agreement, Articles 31 & 31*bis*.
- 25 This authority was decisively confirmed by the Members of the WTO in 2001 after witnessing the obstacles patents had created in addressing the HIV-AIDS pandemic, and after US Health Secretary Tommy Thompson—to address a release of Anthrax following 9/11—threatened to issue a compulsory license on Bayer’s Cipro antibiotic (following which Bayer dramatically lowered the price). See, e.g. Frederick M. Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’, 5 *Journal of International Economic Law* 409 (2002), at 469–505 [hereinafter ‘Abbott, Lighting a Dark Corner’].
- 26 Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/MIN(O1)/DEC/2 (20 November 2001) [hereinafter ‘Doha Declaration’]. See further, Abbott, *Lighting a Dark Corner*, *ibid*.
- 27 WTO General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 2 September 2003. See further WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement WT/L/641, 8 December 2005, with attached Protocol Amending the TRIPS Agreement (with Annex setting out terms of Article 31*bis*); WTO Amendment of the TRIPS Agreement (2017), [https://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm) (visited 2 August 2020). Frederick M. Abbott, ‘The WTO Medicines Decision: The Political Economy of World Pharmaceutical Trade and the Protection of Public Health’, 99 *American Journal of International Law* 317–358 (2005).
- 28 See, e.g. Harvey E. Bale, Jr, ‘Patent Protection for Pharmaceuticals: A Platform for Investment, Markets and Improved Health in the America’s’, Paper Presented to Workshop ID, Cartagena, March 1996, [http://www.sice.oas.org/ip/Phrma\\_e.asp](http://www.sice.oas.org/ip/Phrma_e.asp) (visited 19 May 2020); perspective of industry reaffirmed in

industry has also argued that countries issuing compulsory licenses will fail to attract foreign direct investment, even though they have not provided evidence to support that implicit threat.<sup>29</sup>

When the arguments concerning the alleged threats from invoking compulsory licensing are viewed from the perspective of equitable access to medicines, they have some substantial flaws. First, a very small portion of global R&D is contributed from drug purchases in countries and by populations with limited incomes.<sup>30</sup> Very little would accordingly be lost by overriding patents in their favor.

Second, a rather substantial portion of the funding for R&D in the current crisis has been provided by governments and private foundations. In this context, questions about the stability of investor expectations are secondary at best. The private sector pharmaceutical companies have not significantly invested in vaccines and treatments for addressing unknown viruses and pathogens because the returns on such investments were inherently speculative. Making new pharmaceuticals available under compulsory licensing should do little to affect investor expectations, since investors had modest expectations to begin with.

Third, even crediting the originator industry perspective that government-use or compulsory licensing of patents may have a long-run adverse effect on capital aggregation, there are cases where we must be more concerned with immediate public health needs than with the long-term financial prospects. This was starkly illustrated during the emergence of the HIV-AIDS pandemic in the 1990s.<sup>31</sup> It took a surprising amount of struggle to force accommodations that eventually allowed the HIV-AIDS pandemic to be addressed in low- and middle-income countries (LMICs) by means of generic versions of antiretroviral treatments, not to mention the role of the USA (President's Emergency Plan for AIDS Relief [PEPFAR])<sup>32</sup> and international financing for such solutions. These struggles continue in many countries, including the USA, where prices of antiretroviral treatment remain high.

Whether patents and other forms of market exclusivity are necessary or useful in the context of addressing the COVID-19 pandemic remains an open question. Much depends, *inter alia*, on how the development of individual products is financed. It seems clear, however, that such exclusive rights in technologies should not be allowed to stand as obstacles to production and distribution of vaccines, treatments, diagnostics, and medical equipment to address global public health needs.

Health Policy Watch, above n 11. See also Allen O. Sykes, 'TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"', 3 *Chicago Journal of International Law* 47 (2002).

29 Supporting absence of evidence, see James Thuo Gathi, 'Strength in Intellectual Property Protection and Foreign Direct Investment Flows in Least Developed Countries', 44 *The Georgia Journal of International and Comparative Law* 499 (2016).

30 See Frederick M. Abbott, 'WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries', Study Paper 2a, United Kingdom Commission on Intellectual Property Rights, 2002, available at SSRN: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1924420](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420) (visited 9 May 2020).

31 The originator industry insisted on protecting patent monopolies that enabled them to charge more than \$10,000 per year for treatment while literally millions of individuals faced death in sub-Saharan Africa—and while treatments otherwise could have been manufactured for several hundred dollars per year (and today much lower). See 't Hoen, above n 10.

32 U.S. President's Emergency Plan for AIDS Relief (PEPFAR), <https://www.hiv.gov/federal-response/pepfar-global-aids/pepfar> (visited 30 June 2020).

The next two sections of this article set out proposals addressing both the supply and demand sides of the problems regarding access to essential health technologies. The potential interconnection between these proposals is discussed later in this article.<sup>33</sup>

## II. THE SUPPLY SIDE

There was recognition early on that government intervention would be necessary to address the gaps in R&D, production and distribution of vaccines, treatments, diagnostics, and medical equipment pertaining to the COVID-19 pandemic. That IPRs in emerging technologies might constrain equitable access to them was also foreseen.

### A. Early proposals

In March 2020, the government of Costa Rica submitted a proposal to the World Health Organization (WHO) Director General for the creation of a voluntary technology sharing pool.<sup>34</sup> That proposal resulted in the launch by the WHO of a voluntary pooling arrangement,<sup>35</sup> as well as a decision by UNITAID to expand the operational scope of the voluntary Medicines Patent Pool (MPP).<sup>36</sup>

G-20 leaders also issued a statement supporting what appeared to be progressive access policies, although without regard to how patents and other forms of exclusive rights were to be addressed, and without specifying how the objectives would be attained.<sup>37</sup> Other governments have made proposals for funding R&D, procurement, and the distribution of vaccines and treatments with respect to COVID-19, including a European-led initiative—the Access to Covid-19 Tools (ACT) Accelerator—that promises to make vaccines and treatments ‘accessible and affordable to all’.<sup>38</sup> The ACT proposal expressly refers to several institutions with substantial experience creating ‘push’ and ‘pull’ mechanisms designed to promote wide access to needed medical supplies.<sup>39</sup> In early days, it was unclear how the WHO, G-20, European Union, or other governments and institutions were preparing to organize vaccine and treatment

33 Below, Section V.

34 See World Health Assembly (WHA) Resolution, COVID-19 response, A73/CONF./1 Rev. 1, 18 May 2020, at OP8.2. See also, e.g. Ed Silverman, ‘WHO Director-General Endorses a Voluntary Intellectual Property Pool to Develop Covid-19 Products’, STAT Pharnalot, 6 April 2020, <https://www.statnews.com/pharnalot/2020/04/06/covid19-coronavirus-patents-voluntary-pool-world-health> (visited 26 April 2020).

35 WHO COVID-19 technology access pool, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> (visited 9 May 2020).

36 ‘The Medicines Patent Pool and UNITAID respond to access efforts for COVID-19 treatments and technologies’, Joint Statement of March 31, 2020.

37 Extraordinary G20 Leaders’ Summit Statement on COVID-19, 26 March 2020, available at [https://g20.org/en/media/Documents/G20\\_Extraordinary%20G20%20Leaders%E2%80%99%20Summit\\_Statement\\_EN%20\(3\).pdf](https://g20.org/en/media/Documents/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_Statement_EN%20(3).pdf) (visited 3 May 2020).

38 Robin Emmott, ‘World Leaders Pledge \$8 Billion to Fight COVID-19 but U.S. Steers Clear’, *Reuters World News*, 4 May 2020, <https://www.reuters.com/article/us-health-coronavirus-eu-virus/world-leaders-pledge-8-billion-to-fight-covid-19-but-us-steers-clear-idUSKBN22G0RM> (visited 9 May 2020).

39 Supported in the World Health Assembly (WHA) Resolution on COVID-19 response, above n 34, at OP9.8. There are few specific details about how it will deal with claims of exclusive rights to existing technologies, though EU officials have said that while companies will not be asked to forgo intellectual property (IP) rights,

production, or to address distribution and access issues from a practical standpoint. National governments, at least, have announced plans for various arrangements with private sector companies.<sup>40</sup>

Nevertheless, there are reasonable grounds for concern that, in the midst of a pandemic, national governments will hoard medical supplies in defense of the local population, and there is reason to believe this will prove to be the case in the current pandemic.<sup>41</sup> Already there are controversial plans for special ‘national priorities’ being granted to governments that have financed R&D and production facilities.<sup>42</sup> More generally, there is evidence of a stunning deterioration in international relations that might be characterized as a ‘psycho-pathology.’<sup>43</sup> Although a more general trend toward nationalism was clearly in evidence before the pandemic outbreak, political relations between the USA and China subsequently have become reminiscent of the Cold War, and it is difficult to foresee where the ‘off switch’ for this deterioration might lie.

## **B. Establishing global, regional, or national licensing facilities for essential medicines**

Maximizing the supply of vaccines, treatments, diagnostics, and medical equipment can best be accomplished by allowing open access to the underlying technologies. This does not equate to eliminating patents. As previously noted, patents remain useful in various contexts, representing identifiable public interests in specific technologies that innovators have been spurred to develop. Innovators should accordingly be compensated by measures that recognize contributions to the public interest, but not necessarily through elevated sales prices.

With specific regard to treatment and prevention of COVID-19 infection, governments should agree that owners of patents must place their patents into a ‘pool’ from which licenses may be freely taken and used by manufacturing companies in return for specified compensation. To the extent that regulatory marketing exclusivity grants might otherwise interfere with use of the patents, these restrictions should also be

they should commit to making vaccines and treatments available worldwide at affordable prices. See Emmott, above n 38.

40 See, e.g. Reuters, ‘AstraZeneca Agrees to Supply Europe with 400 Million Doses of COVID-19 Vaccine’, 13 June 2020, <https://www.reuters.com/article/us-health-coronavirus-vaccines/astrazeneca-agrees-to-supply-europe-with-400-million-doses-of-covid-19-vaccine-idUSKBN23K0HW> (visited 14 June 2020).

41 See, e.g. Helen Branswell, ‘As Coronavirus Pandemic Worsens, Health Officials Fear Nationalization of Drugs and Supplies’, *STAT Health*, 15 March 2020, <https://www.statnews.com/2020/03/15/as-coronavirus-pandemic-worsens-health-officials-fear-nationalization-of-drugs-and-supplies/> (visited 16 March 2020). We note that there have been several instances already in which governments have restricted exports of pharmaceutical products and/or PPE that they have deemed essential to the local population. General Agreement on Tariffs and Trade (GATT) Article XI(2)(a) may countenance such restrictions on a temporary basis. GATT 1994: General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994).

42 See, e.g. Leila Abboud, Michael Peel and Hannah Kuchler, ‘Macron Summons Sanofi Chief for Claim US has “Right to” First Covid-19 Jab’, *Financial Times*, 14 May 2020, <https://www.ft.com/content/60434224-a70d-4a8d-821f-6ac239b4a349> (visited 15 May 2020).

43 See generally, Harold D. Lasswell, *World Politics and Personal Insecurity* (McGraw Hill 1935) on the economic and social insecurity that affected individual psychology and facilitated the rise of the National Socialist Party in Germany in the 1930s, culminating in the Second World War.

waived and compensated by means of the relevant public interest license.<sup>44</sup> In other words, a system of compulsory patent pooling and licensing should include express suspension of any regulatory marketing exclusivity while ensuring that actual production remains dependent on demonstrating compliance with good manufacturing practice.<sup>45</sup>

Conceptually, it might be ideal to anchor the Licensing Facility within the WHO global architecture. However, there are significant political obstacles to negotiations within the ambit of the WHO. These problems are further exacerbated by the current targeting of the WHO as a scapegoat for the failures of national leaders to react to COVID-19. Moreover, because the proposed Licensing Facility implies concrete action to address potential obstacles to access inherent in intellectual property rights (IPRs), it would likely be resisted by some WHO members on behalf of perceived industry interests. Hence, one should consider alternatives to global arrangements that might more realistically be possible.

One such alternative is for Licensing Facilities to be established by countries party to existing regional agreements, or simply by groups of like-minded countries. One should not assume that like-minded countries would be limited to LMICs, given that there are a number of Organisation for Economic Co-operation and Development (OECD) countries that have either issued compulsory patent licenses with respect to COVID-19 technologies or that have proposals to do so on the table.<sup>46</sup> There are various reasons why governments may consider it in their best interest to override exclusive rights in favor of wider access to medicines. Moreover, a country would not need to become a party to the Licensing Facility in order to take advantage of imports from countries that are parties to it, although they may nonetheless need to take certain legal steps to comply with international treaties. The technical and legal details of such arrangements should not constitute a significant obstacle, and it is reasonable to foresee that other countries might gradually join existing arrangements once they became operational.

Patent pools are a relatively common mechanism used in the private sector to accomplish different objectives, and competition authorities have accordingly prescribed guidelines for these types of arrangements.<sup>47</sup> While various institutional frameworks are feasible, the Licensing Facility(ies) should be constituted by government

44 National or regional regulatory approvals as required for marketing of generic products would remain but should be facilitated by mutual recognition of approval of bioequivalence. For example, once a product under license has demonstrated bioequivalence to a recognized stringent regulatory authority, it should be made available for wider distribution as part of the pool mechanism.

45 Companies with existing manufacturing approvals from national drug regulatory authorities, such as the US FDA, EU European Medicines Agency (EMA), and China National Medical Products Administration (NMPA) should be deemed to meet the criteria. The WHO Prequalification program may be a useful adjunct to the Licensing Facility arrangement.

46 See, e.g. Sebastian Fuchs, 'COVID-19: New German Legislation to Fight Pandemic may Affect Granted German Patents', *Bird & Bird*, May 2020, <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents> (visited 20 June 2020); Steven Cattoor and Ine Letten, 'Legislative initiatives on compulsory licensing in light of Covid-19', *LexGobe* 8 May 2020, <https://www.lexgo.be/en/papers/ip-it-telecom/intellectual-property-law/legislative-initiatives-on-compulsory-licensing-in-light-of-covid-19,136382.html> (visited 20 June 2020).

47 See, e.g. Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03), sec 4.4 (Technology pools).

parties through some form of international agreement. If that agreement was part of an existing multilateral or regional arrangement, the institutional structure could generally be incorporated within that multilateral or regional arrangement. Otherwise, a *sui generis* agreement would confer standing on the Licensing Facility as an international legal institution. That agreement would prescribe the customary governance features, such as an Executive Director and decision-making mechanisms, along with specified functions and obligations of the parties, including dispute settlement and other specific duties as appropriate. The principal obligation of all the parties would be to contribute rights to patents granted within their territories to the Licensing Facility and to ensure that licensees from the Facility would be authorized to distribute pooled products within their territorial jurisdictions.

### C. Compensation

The innovator patent owners should be compensated for use of their technology through the payment of royalties and by other means of remuneration. Various options for determining, collecting and distributing remuneration exist, and any specific mechanism may depend on the country parties involved and on their choice of institutional structure. For example, royalties could be paid by producer/user licensees—through the pool—to the government entities involved in the Facility, which entities might then allocate royalty payments (or other forms of compensation) to patent owners within their jurisdictions. The royalty entitlements of each such entity might be based on the expenditures within that country for R&D on the products used to address COVID-19. Countries that had more heavily subsidized R&D would also be entitled to higher aggregate distributions reflecting that subsidization, and private sector investments would be taken into account.<sup>48</sup> Moreover, countries participating in the pool could establish an allocation formula that varied over time based on changing developments.<sup>49</sup> Governments that granted the compulsory licenses would be responsible for distributing the remuneration to patent owners within their jurisdictions.<sup>50</sup> The level of royalties payable by producer/user licensees would vary depending on the country where the licensee supplies specific products (e.g. taking account of such factors as population and per capita gross domestic product (GDP)).<sup>51</sup> Least Developed Countries

48 Regarding methodology for determining the cost of a new pharmaceutical product, and a reasonable profit increment, see Abbott, *Excessive Prices*, above n 18.

49 This is not so different from any number of cooperative international endeavors in which there are multiple contributions from different governments, for example, with respect to development and sale of military equipment.

50 Potential claims by patent owners with respect to royalty compensation would lie within the jurisdiction or jurisdictions where their investments were made. Such compensation might be based on the cost to the patent owners of developing the new drugs or vaccines, plus a fair profit under the circumstances.

51 Although innovators may be reluctant to disclose their R&D costs, it would be reasonable for them to make an exception in this case, particularly if compensation becomes dependent on disclosure. To provide an additional incentive for investment in R&D, there might be a supplementary fund established to add a social benefit premium that reflects a specific contribution a pharmaceutical product makes to addressing the pandemic. Guidelines or milestones could be established for allocating such premium payments, and it is foreseeable that there may be disputes regarding what costs might be allocated or attributable to a particular drug or vaccine.

(LDCs) should remain exempt from financially contributing to the global R&D effort, recognizing their budgets continue to be constrained.<sup>52</sup>

The proposed Licensing Facility also envisages a patent royalty board to assist member governments in establishing entitlements to royalties. In principle, the burden of financing subsidization should be shared reasonably among governments and populations that stand to benefit from the resulting technologies. One must also recognize that longer-term benefits accrue from investing in R&D. This may disproportionately benefit countries where R&D is undertaken in terms of developing their own knowledge base and infrastructure.<sup>53</sup>

Given that diverse contribution and royalty payment options are available and that different Licensing Facilities might elect to approach this task in different ways, a specific formula is not prescribed in this article. The point is to emphasize that there are viable mechanisms for recognizing financial and scientific contributions in keeping with overall incentivizing objectives.

#### **D. Compatibility with intellectual property norms**

The WTO TRIPS Agreement does not pose an obstacle to establishment of the proposed Licensing Facility. As earlier noted, the TRIPS Agreement in Article 31 makes provision for the grant and exercise of compulsory licenses, both in the private commercial and government-use contexts. The inherent authority of governments to grant compulsory licenses was confirmed by the Doha Declaration on the TRIPS Agreement and Public Health in 2001. In cases of emergency or government-use (i.e. public noncommercial use), licensing is further facilitated by Article 31(b), which allows grant of licenses without prior negotiation with or even prior notification to the patent owner.<sup>54</sup> The requirement that authorization be based on the individual merits of the licenses can be addressed by identifying categories of products meeting urgent public health needs.<sup>55</sup> The establishment of a royalty mechanism under the Licensing Facility satisfies the requirement for payment of adequate remuneration as the circumstances require.<sup>56</sup> The authors will in Section IV address a related issue regarding the opt-out by certain high-income countries (HICs) as eligible importing countries under the Article 31*bis* mechanism and explain why this does not pose an obstacle to any given pooling and regional supply arrangements. Moreover, WTO rules provide a mechanism

52 This is consistent with the approach that WTO Members have taken in authorizing exemption for LDCs from obligations to grant and enforce patents that are otherwise the mechanism used to return profits to the patent owners that may be reinvested in R&D. LDCs are not required to grant pharmaceutical patent protection or to enforce existing patents at least until 1 January 2033. Decision of the Council for TRIPS of 6 November 2015, Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products, IP/C/73, 6 November 2015.

53 There may be questions regarding government oversight of expenditure and how much 'waste' has occurred.

54 TRIPS Agreement, Article 31(b).

55 See, e.g. Canada's legislation implementing Article 31*bis* of the TRIPS Agreement that formally identifies the range of products that have been determined to be available for compulsory licensing for export. Section 21.01 (definition of 'pharmaceutical product') and Schedule 1, Statutes of Canada 2004, Bill C-9, assented to 14 May 2004, Chapter 23 ([https://www.parl.ca/Content/Bills/373/Government/C-9/c-9\\_4/C-9\\_4.pdf](https://www.parl.ca/Content/Bills/373/Government/C-9/c-9_4/C-9_4.pdf)) (visited 30 May 2020).

56 TRIPS Agreement, Article 31(h).

for the waiver of otherwise applicable rules when needed, and one would expect that the necessary three-fourths of WTO Members would accommodate a TRIPS Agreement waiver to address a pandemic.<sup>57</sup> WTO Members also have the right to invoke Article 73 of the TRIPS Agreement, which establishes a national security exception to address emergencies in international relations, and Members are understood to have substantial discretion in making use of that provision.<sup>58</sup>

In general, national and/or regional patent legislation should provide adequate flexibility for the grant of compulsory and/or government-use licenses.<sup>59</sup> Typically, use by the government is expressly facilitated.<sup>60</sup> For purposes of establishing and implementing Licensing Facilities intended to meet urgent global public health needs, such facilitated government-use licensing may suffice to accomplish most objectives, although some commercial use licensing may also be needed. Implementation of an internationally agreed compulsory pooling arrangement (whether global, regional, or like-minded) could nonetheless require implementing legislation at the national (or regional) level with some modifications to existing domestic rules. So long as participating governments have agreed to such arrangements, legislative modifications should be achievable.

### E. Single country option

If the ambitious Licensing Facility was to demand too much international cooperation in a short span of time, the establishment of needed pools could be left to individual governments with their own licensing policies. For example, the USA could form its own COVID-19 licensing pool to be administered by the Department of Health and Human Services or another suitable agency.<sup>61</sup> While such a pool would only cover patents granted in the USA, R&D enterprises across the world normally apply for patents in this country. Already the Federal Court of Claims determines the appropriate amount of royalties when the US government, pursuant to existing statutory authority

57 See WTO Agreement, Article IX (3) & (4).

58 In a dispute between the Ukraine and Russia involving transit barriers imposed by Russia under GATT Article XXI, the USA as a third party argued that the scope of the Security Exceptions was self-determined by each WTO Member, and effectively nonjusticiable. *Russia—Measures Concerning Traffic in Transit*, WTO Report of the Panel, WT/DS512/R, 5 April 2019, at, e.g. paras 7.51–7.52. The Panel that decided the Ukraine-Russia dispute did not go so far as the US position, but it did signal substantial deference to the determination made by the invoking Member. *Ibid.*, paras 7.102–7.103 & 7.131–7.139.

59 See, e.g. WIPO Secretariat, Draft Reference Document on the Exception regarding Compulsory Licensing, SCP/30/3, 21 May 2019, prepared for WIPO Standing Committee on the Law of Patents, Thirtieth Session, Geneva, 24–27 June 2019, [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_30/scp\\_30\\_3-main1.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf) (visited 30 May 2020); for further discussion of compulsory licensing of patents as a policy instrument, see World Health Organization, World Intellectual Property Organization & World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 2nd ed., 2020, [https://www.wto.org/english/res\\_e/booksp\\_e/who-wipo-wto\\_2020\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf) (visited 29 July 2020).

60 See discussion of US government-use legislation, below, text at n 61.

61 Pursuant to the Bayh-Dole Act and implementing regulations, the federal government maintains ‘march-in’ rights with respect to patents arising out of federally funded research (e.g. pharmaceutical R&D funded by NIH) that could be used to create a pooling arrangement for treatments that become available. Bayh-Dole Regulations, 37 CFR 401.6 Exercise of march-in rights.

(28 USC §1498), makes use of patents without the consent of patent owners.<sup>62</sup> Private companies may also want to take advantage of licenses not covered by specific government programs, and a federal pool would accommodate a private option.<sup>63</sup> There will likely be many relevant patents covering drug and vaccine candidates, and it would seem advisable to organize a comprehensive response from the outset.

### F. Distinguishing voluntary arrangements

One model for a kind of licensing arrangement similar to that discussed above is the Medicines Patent Pool to which originator companies contributed patent licenses on HIV-AIDS, tuberculosis, and hepatitis C treatments that are sublicensed to generic drug manufacturers for distribution of pharmaceutical products in LMICs.<sup>64</sup> As noted earlier, the MPP has already expanded its scope to cover COVID-19 related treatments.<sup>65</sup> The Licensing Facility proposed in this article would differ from the MPP model in that companies (and other patent owners) would be required to contribute their patents under mandatory participation rules.

Voluntary patent licensing arrangements, such as the MPP, do not generate the same political or legal pushback associated with compulsory licensing. Under ordinary circumstances, a patent owning pharmaceutical company faced with the prospect of a compulsory license (e.g. an application by a generic producer) will challenge the potential grant in administrative proceedings and/or a court, which may delay the grant for a substantial period of time, or block it altogether. Such delay is less likely to occur under a 'government-use' license because national statutes typically restrict options for patent owners to block the issuance of such licenses, even if subsequent challenges concerning remuneration remain available. The mere possibility that a government intends to grant a compulsory (including government-use) license almost invariably triggers a political reaction from the home-base government of the patent owner, combined with threats of financial retaliation in one form or another.

For these reasons, it may seem 'easier' to rely more on voluntary licensing than compulsory licensing, especially since voluntary licensing arrangements, such as the MPP, have successfully facilitated the supply of low-price medicines. Thus, it may seem imprudent to forgo this faster and easier path and instead to pursue compulsory licensing. On closer inspection, however, the MPP and other voluntary pools have significant limitations.

62 See, e.g. *Zoltek v. United States*, 672 F. 3d 1369 (Fed. Cir. 2012). See further Jerome H. Reichman with Catherine Hasenzahl, 'Nonvoluntary Licensing of Patented Inventions', ICTSD/UNCTAD Issue Paper No. 5 (2003), available at [https://unctad.org/en/PublicationsLibrary/ictsd2003ipd5\\_en.pdf](https://unctad.org/en/PublicationsLibrary/ictsd2003ipd5_en.pdf) (visited 30 June 2020).

63 The USA has perhaps the easiest to use 'government-use' statute in the world. Simply put, US patent owners may not block the US government or its designated contractors from making use of their patents. The only remedy for the patent owner is a claim at the Federal Court of Claims for an appropriate royalty (or a negotiated deal with the government). This authority is used on a regular basis by the US federal government and its contractors in connection with US defense R&D and production. If the US government wants to request a pharmaceutical company to produce drugs for distribution to the public, regardless of who owns the patents, it can do that. In the government-use sense, there is no need for a patent pool.

64 Medicines Patent Pool website at <https://medicinespatentpool.org/> (visited 30 May 2020).

65 Above, text at n 36.

First, private sector companies determine what patents and related products are made available to such entities. There is accordingly no assurance whatsoever that the most successful and/or most needed treatments would be made available under voluntary pooling arrangements.

Second, private sector companies establish limits on the countries allowed to receive their licensed products. With respect to COVID-19, this option may exclude countries for which access is vitally important. Brazil, for example, has previously been excluded from receiving products under MPP licenses, and Brazil is among those most seriously affected by COVID-19. Moreover, all HICs are typically excluded from benefits under the MPP, while the proposal envisioned here is definitely intended to also address the needs of HICs.

Third, the MPP relies on individual companies to grant licenses for specific products on a case-by-case basis. With respect to COVID-19, patents on relevant technologies will likely be held by a wide variety of entities, including foundations, teaching hospitals, and government laboratories, and case-by-case licensing could both be difficult and problematic.

Fourth, governments should not refrain from pursuing arrangements that rely on compulsory licensing because this would antagonize pharmaceutical companies that may protest to their home governments. To do so would imply that the refraining governments have surrendered their sovereign authority.

This article, in contrast to voluntary mechanisms, is proposing potentially large-scale compulsory licensing programs involving multiple countries, preferably operating under a global regime. In the past, compulsory licensing has been controversial in the sense of provoking adverse political reaction and civil litigation. From a broader perspective, however, the world community has not witnessed a crisis on the scale precipitated by the COVID-19 pandemic since the Second World War. Armed conflict has the perhaps surprising characteristic of promoting innovation. Necessity is the mother of invention. If only because of that, we do not think that national governments faced with the prospect of a public health emergency that threatens significant parts of local populations should or would refuse to undertake reasonable measures because pharmaceutical industry executives, or their home governments, consider such action inconvenient. Even if governments might yet be dissuaded from taking appropriate measures to address COVID-19, the proposals in this article may provide useful—and workable—suggestions to address future public health exigencies.

### **G. Joint manufacturing arrangements**

Current manufacturing capacity for supply of COVID-19 vaccines is almost certainly not adequate to address global demand.<sup>66</sup> A substantial ramp-up in the construction of vaccine manufacturing facilities is thus required. In the case of pharmaceutical treatments (i.e. drugs), there is more substantial worldwide manufacturing capacity, although existing facilities (including for active pharmaceutical ingredients) may need

66 See notes 4 & 8, above.

to be repurposed. Nonetheless, there is not likely to be the same scale of manufacturing shortfall for pharmaceutical treatments as for vaccines.

Just as governments should pool patents and other technology resources, they should also be planning investments in manufacturing facilities that could efficiently serve substantially larger populations than in the past. Particularly for countries with smaller populations, it may be useful to plan and invest in jointly owned and operated vaccine production facilities. Agreement on the geographic location of such facilities may well prove difficult, given that the distribution of economic opportunities has traditionally challenged countries engaging in regional cooperation efforts. Because the availability of vaccines may determine life or death outcomes, the immediate stakes are raised during a pandemic when supplies prove inadequate.

Which among a group of countries will be the better location to house manufacturing facilities depends on a variety of factors, including the state of infrastructure in any given location (e.g. transport, electric grid, etc.) and the availability of technically trained staff.<sup>67</sup> Because funding is an equally important factor in some cases, an external funding source, like the World Bank, could play an important role in facilitating agreement on location, priority of access to output, and other issues.

The authors of this article witnessed or participated in projects under the auspices of international and regional organizations directed toward enhancing national and regional production and distribution of pharmaceutical products and are well aware of the possible obstacles. There is no easy solution to the problems of regional coordination that have impeded diverse economic integration efforts for generations. But it is important that governments quickly begin to work on solving manufacturing gaps and distribution issues, and obstacles they have confronted in the past are not a good reason for failing to pursue new efforts. The urgency of addressing the COVID-19 pandemic should provide the stimulus to action.

### III. THE DEMAND SIDE

Sufficiently robust solutions to the problems of manufacturing and distributing vaccines, treatments, diagnostics, and medical equipment might overcome potential obstacles that governments and the public are likely to face when attempting to access them. There is, however, substantial risk that supply-side initiatives will not be sufficiently comprehensive to address aggregate global demand. Therefore demand-side initiatives are also proposed.

#### A. The critical role of pooled procurement strategies

In an earlier work, the authors of this article have already proposed that developing countries seeking access to patented medicines should establish Regional

67 For discussion of elements important to local production of pharmaceuticals, including suggestions pertaining to regional manufacturing zones, see 'Indian Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health', World Health Organization (Geneva), 2017, and; 'China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health', World Health Organization (Geneva), 2017.

Pharmaceutical Supply Centers in order to strengthen their respective bargaining positions.<sup>68</sup> Such Centers would enable participating governments to pool their procurements of patented medicines, which in and of itself would give them greater bargaining power with respect to both originator pharmaceutical companies and generic suppliers than if each country operated on its own.<sup>69</sup> A pooled procurement strategy could also stimulate more local production of pharmaceuticals in developing countries, in part by affording potential investors more advantageous revenue prospects than those offered to purveyors of imports alone.<sup>70</sup> For present purposes, we emphasize that a pooled procurement strategy along these lines would also greatly strengthen the inherent power of governments in developing countries to threaten and, when needed, to issue compulsory licenses for patented pharmaceuticals under Articles 31 and 31*bis* of the TRIPS Agreement.<sup>71</sup>

As explained below, Article 31*bis* already addresses the lack of pharmaceutical production capacity in most developing countries. At the same time, it should be noted that very few countries, including HICs, maintain the capacity to produce all of the important pharmaceutical products that are required to meet the needs of their national populations. These inherent limitations may require governments considering the use of compulsory licenses to seek assistance from other provider countries that do possess the requisite manufacturing capacity as well as access to the key active ingredients. However, even when the latter governments were inclined to consider helping by issuing a second compulsory license for exports of needed drugs, they were potentially stymied by Article 31(f) of the TRIPS Agreement. This provision requires that medicines produced under a compulsory license must be ‘predominantly for the supply of the domestic market of the Member authorizing such use’ and thus not produced principally for export to other countries.<sup>72</sup>

To alleviate this obstacle, the amended Article 31*bis* now expressly allows a country willing to assist other countries needing pharmaceuticals at affordable prices to produce them entirely for export, typically under back-to-back compulsory licenses.<sup>73</sup> In other words, Article 31*bis* authorizes countries inclined to issue compulsory licenses for patented pharmaceuticals to seek assistance from other countries willing and able to provide the drugs in question and to export them in special packaging formats under supplementary compulsory licenses issued for that purpose.<sup>74</sup> Under Article 31*bis*, none of the goods in question need be sold in the markets of the exporting countries,

68 See Abbott and Reichman 2007, above n 9.

69 Ibid, at 974–977.

70 Ibid, at 977–979. Cf. James Love, ‘Proposal for Patent Pool for Essential Medicines’, *Addis Ababa*, 3 March 2005, available at <http://www.cptech.org/cm/addisababa03032005.html> (visited 20 May 2020). See also Kevin Outterson, ‘Patent Buy-Outs for Global Disease Innovations for Low and Middle Income Countries’, 32 *The American Journal of Law & Medicine* 159, 171–173 (2006).

71 TRIPS Agreement, Article 31 and 31*bis*.

72 See TRIPS Agreement, Article 31(f).

73 TRIPS Agreement Article 31*bis*.

74 TRIPS Agreement, Annex, 2(b)(ii). The change of packaging reinforces the obligation to not re-export the drugs in question beyond the market specified in the initial compulsory licenses.

notwithstanding the language of the TRIPS Article 31(f) as originally drafted.<sup>75</sup> Adequate compensation of the patentee in question need only be paid in the country of exportation, taking into account the economic circumstances of the importing country where they will be sold and distributed at more affordable prices.<sup>76</sup>

Despite the carefully elaborated terms of Article 31*bis*, or perhaps because of them, there remains a widely held belief that its provisions fail in practice to make compulsory licensing of pharmaceuticals a viable option for most developing countries. The prevailing view, in other words, is that the various requirements set out in Article 31*bis* remain too complicated or too onerous to be of practical value to the countries that would most need to invoke them for access to medicines.<sup>77</sup>

### B. The real problem of coordination

The authors of this article have elsewhere explained why this belief in excessive complexity of the Article 31*bis* system is not well founded, and do not repeat the analysis here.<sup>78</sup> It is true that, to effectuate these provisions, WTO Members willing to supply other countries without manufacturing capacity must have some form of enabling mechanism in their domestic legal system. These mechanisms may, in turn, be more or less complicated depending on the specific national legal system in question.<sup>79</sup> Moreover, a compulsory license for export (or import) may well be granted under a WTO Member's general compulsory licensing or government-use provisions, so that specific legislation implementing this new provision of the TRIPS Agreement is not required. Alternatively, the procedural rules of Article 31*bis* can be followed without the necessity of express domestic legislation that establishes the national roadmap, though such enabling legislation may be useful.

75 All LDCs are automatically eligible to invoke Article 31*bis*. See generally Abbott and Reichman 2007, above n 9, at 939–947.

76 Para 2, TRIPS Agreement, Article 31*bis*, above n 27. See further Abbott and Reichman 2007, above n 9, at 929–949 (covering all aspects of Article 31*bis* and citing authorities). Pursuant to Article 31*bis*(3), there is a specific accommodation in favor of developing and LDC parties to regional trade agreements. The subject agreements must be comprised of at least half LDCs. It permits re-exports of pharmaceutical products produced or imported under compulsory license by one member to other members of the regional trade agreement without restriction regarding whether the re-exports are a predominant or non-predominant part of the compulsory license production.

77 See, e.g. Medicines Sans Frontieres (MSF), 'Access to Medicines Campaign, Doha Derailed, A Progress Report on TRIPS and Access to Medicines', 27 August 2003; MSF, 'Neither Expeditious or a Solution. The WTO August 10th Decision is Unworkable', International AIDS Conference, Toronto, Canada, August 2006. See also Oxfam International, 'Patents versus Patients: Five Years After the Doha Declaration', Oxfam Briefing Paper 95, December 2006.

78 See generally Abbott and Reichman 2007, above n 9, at 927–929.

79 See List of Members' laws implementing the 'Paragraph 6' system, at WTO TRIPS and Health, showing 20 legislative enactments, including that covering the European Union, as well as additional information from Japan regarding existing statutory basis for licensing for export [https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm) (visited 12 May 2020). Counting the EU as its 27 member states, this means that nearly 50 WTO Members have adopted or acknowledge specific legislation to implement Article 31*bis*.

The government of Canada has adopted enabling legislation that some have considered unnecessarily complicated,<sup>80</sup> and it was invoked in the criticized case of Rwanda's seeking AIDS drugs from that country. However, Canada's legislation also includes some positive elements, such as short fixed timelines for seeking voluntary licenses, well-considered royalty rates, and express recognition of the right to supply non-WTO Members.<sup>81</sup> Many other governments, including the European Union, have now enacted implementing statutes and have also expressed their willingness to collaborate in supplying needed medicines under Article 31*bis*.<sup>82</sup> That said, the very act of issuing compulsory licenses against patented inventions remains controversial, especially in the USA<sup>83</sup> where, however, they are nonetheless widely used for other purposes.<sup>84</sup> These political costs cannot be dismissed as readily as the alleged administrative complexities.<sup>85</sup>

Disregarding political costs, if the persistent view that using compulsory licenses under Article 31*bis* is technically 'complicated' will not withstand legal analysis, there are nevertheless problems of coordination that deserve more careful analysis. This problem begins with the internal domestic difficulties of aligning all the government agencies and departments whose inputs and approvals of such action are prerequisites. Once these hurdles are overcome, moreover, there remain the difficulties of negotiating and coordinating affirmative action by two or more governments involved in any pooled procurement strategy, as well as the further need to negotiate licenses for actual production and distribution of the pharmaceuticals in the manner prescribed by Articles 31 and 31*bis* of the TRIPS Agreement.<sup>86</sup> These problems would be present in almost any situation in which a number of countries were pursuing the procurement of medicines under some form of international arrangement.

To address these coordination problems more efficiently, the authors proposed establishing RPSCs, which would be tasked with implementing the pooled procurement strategies of different participating governments over time. To the extent that compulsory licenses—actual or threatened—were needed for this purpose, the Regional Centers, acting as trusted intermediaries, would possess the expertise to assist government agencies in organizing and completing the relevant administrative actions

80 See, e.g. *Medecins Sans Frontieres*, 'Neither Expeditious, nor a Solution: the WTO August 30 Decision is Unworkable: An Illustration through Canada's Jean Chretien Pledge to Africa', August 2006. [https://doctorswithoutborders.org/sites/default/files/2018-08/WTO\\_chretien.pdf](https://doctorswithoutborders.org/sites/default/files/2018-08/WTO_chretien.pdf) (visited 20 May 2020).

81 See Communication from Canada, Canada's Implementation of the 30th August Decision on TRIPS and Public Health, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/464, 14 November 2005.

82 See above n 79.

83 See, e.g. Valerie Bauman and Susan Decker, 'Covid Seen as Tipping Point to Lower Drug Prices, Patent Sharing', *Bloomberg Health and Business News*, 22 April 2020; Susan Decker and Malathi Nayak, 'Trump Urged to Limit Patent Rights on Ventilators, Treatment', *Bloomberg IP News*, 9 April 2020.

84 See Jerome H. Reichman with Catherine Hasenzahl, 'Nonvoluntary Licensing of Patented Inventions', above n 62.

85 The political pushback against issuing compulsory licenses was identified as an obstacle to making use of TRIPS flexibilities in UN High Level Panel, above n 10.

86 See Abbott and Reichman 2007, above n 9.

and practical arrangements. Procedures that might otherwise seem complicated to government agencies taking their first steps to trigger any given compulsory licenses would thus be routinely pursued by agents well versed in all the legal and technical requirements applicable under the TRIPS Agreement.<sup>87</sup> The Centers could also assist LDCs in profiting from provisions in Article 31 *bis* intended to reduce the quantity of licenses needed to be issued when operating within certain regional arrangements, including several in Africa.<sup>88</sup>

Reliance on RPSCs should thus amplify the bargaining power of any countries needing to invoke Articles 31 and 31 *bis* of TRIPS when seeking access to medicines. On the one hand, the legal powers emanating from Article 31 *bis* should give originator pharmaceutical companies a greater incentive to supply the products in question at lower prices, in order to maintain their patents and trademarks in a number of small countries that coordinate their access efforts to obtain substantial discounts on a regional basis. On the other hand, a systematically organized strategy for pooled procurements of needed drugs in a number of different countries could stimulate greater interest in generic producers wherever situated. It could serve their interests, in other words, to respond positively to offers from RPSCs empowered to implement a number of compulsory licenses, if and when needed.

### C. The Marrakesh model for cross-border relief of the visually impaired

Here we refer to the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled, of 2013, which entered into force on 30 September 2016.<sup>89</sup> Under this treaty, copyrighted literary and artistic works normally subject to the amended Berne Convention of 1886,<sup>90</sup> may be made available in ‘accessible format copies’ to ‘beneficiary persons’ by ‘authorized entities’ who serve the interests of the blind and visually impaired.<sup>91</sup>

The Marrakesh Treaty does not expressly trigger a compulsory license provision in the manner of the TRIPS Agreement. Instead, signatory governments agree to enact limitations and exceptions in their copyright laws that facilitate cross-border exchanges

87 Ibid, at 927–929.

88 See n 76 above.

89 Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired, or Otherwise Print Disabled, adopted 27 June 2013, entered into force 30 September 2016. See also Convention on the rights of Persons with Disabilities, 13 December 2006, entered into force 3 May 2008.

90 Berne Convention for the Protection of Literary and Artistic Works, 9 September 1886, 1161 U.N.T.S., 31, as last revised at Paris, 24 July 1971 [hereinafter ‘Berne Convention’], available at <https://wipolex.wipo.int/en/text/283693> (visited 20 May 2020).

91 Marrakesh Treaty, above n 89, Arts 2–3. The beneficiary persons are, of course, blind or visually impaired or otherwise subject to a ‘reading disability which cannot be improved to give visual function equivalent to that of a person who has no such impairment or disability’. Id. Art. 3. An ‘authorized entity’ is one that governments recognize and allow ‘to provide education, instructional training, adaptive reading or information access to beneficiary persons on a nonprofit basis’ (including government entities). Id. Art. 2(c). An ‘accessible format copy’ of a relevant work is one ‘in an alternative manner or form which gives a beneficiary person access to the work ... [a]s feasible and comfortably as a person without visual impairment or other print disability’. Ibid, Article 2(b).

of accessible format copies in order to meet the needs of the visibly impaired in different countries.<sup>92</sup> For this purpose, Article 5 imposes a duty on Contracting Parties to allow importation and exportation of accessible format copies through ‘cross-border exchanges’, without the consent of the copyright owners themselves.<sup>93</sup> In other words, authorized entities are entitled ‘to distribute [or “make available”] format copies to beneficiary persons in the territories of other contracting parties.’<sup>94</sup> Article 6 then expressly allows the authorized makers of accessible format copies in one country to import such copies as needed from other countries.<sup>95</sup>

From a policy perspective, the Marrakesh Treaty endows a trusted intermediary—namely the World Union of the Blind (WUB)—with the marketing power that representatives of a print-disabled community might not otherwise possess. This follows because there are few countries, apart perhaps from India, in which the visibly impaired constitute a substantial market for literary works on their own.<sup>96</sup> The fact that the WUB can thus, in principle, supply the global market for such artifacts endows them with much greater clout than would otherwise be the case under the territoriality principle of the Berne Convention, which normally would require them to negotiate licenses with publishers on a country by country basis.<sup>97</sup>

#### D. Adapting the Marrakesh model to coordinate cross-border access to medicines

What the Marrakesh model should teach us is that the cross-border supply of essential knowledge goods requires both a suspension of any conflicting requirement of territorial IPRs and the services of some coordinating supply agency operating under public international law. Providing such services is perhaps the single most important task of the RPSCs discussed earlier in connection with the compulsory licenses now available under the TRIPS Agreement.<sup>98</sup>

The primary goal of any RPSCs is to provide access to medicines at prices people in relatively poor countries can afford. Phrased differently, their goal should be to redress the inequities attendant upon current marketing practices that ration access to patented pharmaceuticals for most of the world’s population in order to exploit the buying power of more affluent customers.<sup>99</sup> In so doing, the Centers—like ‘authorized

92 See *ibid*, Article 9, Cooperation to Facilitate Cross-Border Exchanges of Accessible Format Copies. See also, *ibid*, Articles 10–11.

93 *Ibid*, Article 5(1) (‘without the authorization of the rightholders’).

94 See *ibid*, Article 5(2).

95 See *ibid*, Article 6. See further *ibid*, Articles 9 (Cooperation to Facilitate Cross-Border Exchanges) and 10 (‘General Principles of Implementation’). See generally Laurence R. Helfer, Molly K. Land, Ruth Okediji and Jerome H. Reichman, *The World Blind Union Guide to the Marrakesh Treaty: Facilitating Access to Books for Print-Disabled Individuals* (USA: Oxford University Press, 2017) [hereinafter ‘World Blind Union Guide’].

96 India is said to have nearly five million visibly impaired inhabitants. Neetu Chandra Sharma, ‘Estimates of Blindness Reduced by 47% in 12 Years: Govt Survey’, *Livemint*, 11 October 2019.

97 Berne Convention, above n 90, Article 5(1). See also TRIPS Agreement, Article 9 (incorporating basic provisions of the Berne Convention).

98 See Abbott and Reichman 2007, above n 9.

99 This is known as the 90-10 problem. See, e.g. The 90/10 divide, *Medecins Sans Frontieres*, 1 August 2002, <https://www.msf.org/9010-divide> (visited 20 May 2020).

entities' under the Marrakesh Treaty<sup>100</sup>—would be implementing the larger goals of public international law embedded in the human right to health.<sup>101</sup>

Once established by agreement of the participating governments, the Regional Supply Centers could become the most efficient organizers of any given pooled procurement strategies authorized by those same governments. To the extent that compulsory licenses—threatened or imposed under Articles 31 and 31*bis* of the TRIPS Agreement—became potentially important tools in carrying out this assignment,<sup>102</sup> the Centers would find themselves in the best position to effectuate any such licensing strategies needed to provide cross-border supplies of essential medicines.

With specific regard to compulsory licensing of pharmaceuticals in a cross-border context, the RPSCs should play a role analogous to that of the WUB under the treaty.<sup>103</sup> In both cases, the coordination problems arise in the first instance from the territorial nature of intellectual property laws, which vary the barriers to be overcome in the cross-border supply of the products in question. Under the Marrakesh Treaty, the WUB must coordinate the supply of specialized books and articles from different publishers to the visibly impaired in different countries.<sup>104</sup> Under the TRIPS Agreement, the RPSCs would have to coordinate the purchase or procurement of specified pharmaceuticals needed in diverse countries as authorized by the relevant participating governments. These governments, in turn, must be ready, willing, and able to threaten to issue compulsory licenses, when needed, to bolster the bargaining power of the Supply Centers.

Like 'authorized entities' under the Marrakesh Treaty discussed above,<sup>105</sup> the RPSCs should operate as agents of the participating governments. In this capacity, they would—when necessary—obtain an exemption from the territorial intellectual property regimes otherwise applicable to the pharmaceutical products in question. They would thereby also help fulfill the objectives underlying the human right to health and related human rights treaties.<sup>106</sup> Governments needing essential medicines at affordable prices would delegate the Centers, as 'authorized entities', to provide them in a manner consistent with the TRIPS flexibilities.<sup>107</sup>

However, it is well to ask how often compulsory licenses would actually be needed if such a scheme were to be set in place and rendered operational. Once empowered to bargain on behalf of all the participating governments, the RPSCs could probably

100 See above n 96 and accompanying text.

101 See references to Human Right to Health and Rights of the Disabled in World Blind Union Guide, above n 95, at 1–5.

102 See above n 73–76 and accompanying text.

103 See World Blind Union Guide, above n 95, at 8–11.

104 *Ibid.*, at 21–38.

105 *Ibid.*, at 24–30.

106 See text at n 101, above.

107 See TRIPS Agreement, Annex, para 2(b)(ii), regarding special packaging, and Annex para 3 regarding anti-diversion measures. In effect, the Centers would thus become 'procurement agents' for specified medicines at 'reasonably affordable prices in the countries in question'. Governments would also commit to endowing these authorized entities with the legal tools allowed by TRIPS flexibilities for this purpose, including the power to implement requisite compulsory licenses when issued and pool them when needed for bulk purchasing. The Centers would also have to coordinate the special packaging and notification procedures required whenever back-to-back compulsory licenses were required under Article 31*bis*.

obtain the needed price concessions through centralized bargaining power without actually having to issue back-to-back compulsory licenses. This conclusion follows because the originator suppliers have long-term interests in dealing with the developing countries with whom they are already accustomed to applying differing tiered pricing mechanisms. The ability to preserve their patents and trademarks and their influence by directly supplying their products in greater quantities under pooled procurement arrangements could itself be an incentive to cooperate with the Supply Centers and to avoid the conflicts inherent in the triggering of compulsory licenses. As the Brazilian experience suggests, it is not always necessary to issue compulsory licenses when bargaining for the supply of products to a potentially large and growing market, once potential suppliers understand that the procuring government is ready, willing, and able to do so.<sup>108</sup>

In any event, the Regional Centers—like ‘authorized entities’ under the Marrakesh Treaty—would then distribute the exported medicines to ‘beneficiaries’ in participating countries that had initially requested them and whose governments had agreed to issue compulsory licenses for that purpose, if needed. Special packaging would be required as well as restrictions on re-exports from the importing countries.<sup>109</sup>

The fact that a relatively large-scale demand for such pharmaceutical products could be generated via a pooled procurement strategy should in and of itself encourage both originator and generic manufacturers to participate whenever feasible (i.e. when technical capacity exists and safety requirements are met). Authorized entities operating with the threat of Article 31*bis* should be able to provide large quantities of patented drugs at affordable prices to most countries. Moreover, this scheme—once implemented—could further encourage originator companies to adopt more realistic tiered pricing strategies in order to avoid conflicts with the authorized entities.<sup>110</sup> By the same token, these authorized entities could eventually find themselves in a position to encourage, and even help to fund, the production of bioequivalents and biosimilars at affordable prices for developing countries and LDCs.

The RPSCs would logically pool their respective procurement requests for purposes of bargaining directly with the originator pharmaceutical companies and/or potential suppliers of generics. If these negotiations were successful, the Centers would also distribute the needed medicines directly to the participating governments or their agents at agreed prices.

If negotiations with originators proved unsuccessful, the Centers, as authorized entities, would seek to obtain production in countries with manufacturing capacity for purposes of exporting end products to requesting countries lacking such capacity under compulsory licenses when necessary. In effect, willing producers would thus supply the authorized entities with products for purposes of redistribution to participating governments. To this end, governments in producer countries must be

108 See, e.g. Abbott and Reichman 2007, above n 9, at 950–952.

109 *Ibid.*, at 942.

110 See Padmashree Gehl Sampath, ‘A Proposal for New Pricing Approaches to Enhance Access to Medicines’, working paper (in authors’ files), July 2020.

willing to issue compulsory licenses solely for the export of such pharmaceuticals to agents acting on behalf of requesting countries. Legal authority is grounded in Article 31*bis* of the TRIPS Agreement, as supplemented by human rights law and treaties.<sup>111</sup>

The RPSCs should thus be created with a view to finally achieving the goal proclaimed by the Doha Declaration of 2001, namely ‘access to medicines for all’.<sup>112</sup> In so doing, the Centers would not be limited in the time or circumstances needed only to address COVID-19. We propose these entities as durable institutions. In the long run, successful implementation of pooled procurement strategies might ultimately persuade the innovator pharmaceutical industry to market its life-saving products in a manner more consistent with the global public interest.

#### IV. THE ARTICLE 31*BIS* OPT-OUT PROBLEM

The creation of global supply and demand solutions for the production and distribution of vaccines and treatments, including Licensing Facilities and RPSCs, might encounter a ‘peculiar’ obstacle arising from a decision made by the USA, the European Union, and a number of other HICs at the tail end of the Paragraph 6 negotiations that resulted in the Article 31*bis* amendment to the TRIPS Agreement.<sup>113</sup> These HIC governments decided to forgo the right to import pharmaceutical products manufactured under compulsory license abroad (when such exports are a predominant part of production) by explicitly incorporating an ‘opt-out’ in the Annex to Article 31*bis*.<sup>114</sup>

##### A. An ill-considered decision

The HIC governments were not opting out because of a demand from LMICs. This was their own self-initiated action. Several other countries did not fully opt-out of the regime, but indicated their intention to use compulsory licensing for imports only in cases of emergency, circumstances of extreme urgency, and/or for public noncommercial use.<sup>115</sup> The HIC opt-out could become a problem for the people of the USA and other HICs that chose this option because the relevant pharmaceutical products would

111 See above text at n 71–76.

112 See above n 26.

113 See ‘Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31*bis* of TRIPS Agreement’, 7 April 2020, <https://www.keionline.org/32707> (visited 20 May 2020).

114 At the conclusion of the negotiations that took place with respect to implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the USA, European Union, and several other HICs (i.e. fn 3 ‘Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States’), stated that they would not make use of the agreed system as ‘eligible importing’ Members. This statement was initially made in connection with presentation of the Chairperson’s Statement when the 30 August 2003 waiver was adopted ([https://www.wto.org/english/tratop\\_e/trips\\_e/gc\\_stat\\_30aug03\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm), visited 30 June 2020) and was later codified in an Annex to Article 31*bis* constituting an amendment to the TRIPS Agreement. See Abbott, *The WTO Medicines Decision*, above n 27.

115 This group of Members indicated through the Chairperson’s Statement that they would not use the system other than in cases of emergency or extreme urgency. (‘As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These

not be available to them even in an emergency. But the potential problems are larger than this specific situation.

When the USA, European Union, Japan, Canada, Australia, Switzerland, among others, took themselves out of the equation as eligible importing countries under Article 31*bis*, they eliminated a large part of the potential global demand for pharmaceutical products originating from countries exporting under compulsory licenses. As a result, for example, if India were asked by countries in Africa and Latin America to manufacture drugs under compulsory license and export to them, the Indian producers might not be able to supply the HICs with the same products. The efficiencies in production that might otherwise be achieved by Indian manufacturing facilities when addressing a global market would be reduced. Giving effect to requested compulsory licenses would thus become less cost-efficient and might result in higher selling prices for purchasers everywhere.

It is difficult to foresee all the various scenarios in which the opt-out might have a material effect on prospective exporters and how it might influence the global supply situation. But it is at least worth bearing in mind that the creation of truly global pooling arrangements may ultimately run into some obstacles raised by the Article 31*bis* opt-outs.

## B. Opting back in

There are various legal approaches under which formerly opted-out countries may consider opting back in or otherwise making use of the Article 31*bis* system to import needed pharmaceutical products. These include: (1) relying on an interpretation of the text of paragraph 1(b) of the Annex which provides that ‘a Member may notify at any time that it will use the system in whole or in a limited way’ as qualifying the express opt-out in footnote 3;<sup>116</sup> (2) seeking a waiver pursuant to Article IX (3) and (4) of the WTO Agreement;<sup>117</sup> (3) collectively opting-in through a consensus decision incorporated as a TRIPS Council approved interpretation or amendment of the Annex text;<sup>118</sup> (4) acting without WTO preapproval and going before the Dispute Settlement Body, with the potential for withdrawal of trade concessions by a (hypothetically) successful complainant (including with arbitration on the justified amount of concession

- are the following: Hong Kong, China; Israel; Korea; Kuwait; Macao China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey and the United Arab Emirates.)
- 116 Whether a fully opted-out country can change course and opt-in can be addressed more facetly than through argument about textual interpretation of the Annex, thereby avoiding a lengthy struggle over the interpretative issue.
- 117 While the WTO attempts to achieve consensus among its Members in decision-making, the waiver mechanism expressly contemplates that a waiver decision can be taken by three-fourths of the Members.
- 118 The opt out was not a bargained-for concession in favor of the LMICs. This was an action by the HICs pursued for their own reasons. If the HIC Members collectively decided to opt back in, they would not have rebalancing of concessions claims against each other. In other words, there should be nothing to prevent all the formerly opting-out countries collectively to announce to WTO Members that they had decided to opt back in since they have no reciprocity commitment to other countries not to do so.

withdrawal)<sup>119</sup>; and (5) invoking Article 73 of the TRIPS Agreement (‘Security Exceptions’), which provides substantial deference to Members protecting essential security interests through measures taken in times of emergency in international relations.<sup>120</sup> There appears to be a widespread assumption among trade and intellectual property experts that whatever the WTO may say on the matter, HICs are not going to forgo importing pharmaceutical products under compulsory licenses regardless of the technical legal obligations. Nevertheless, from the standpoint of maintaining the integrity of a rule-based system, it would be preferable to identify an appropriate legal justification.

The 2003 opt-out by HICs was a misguided effort to protect the commercial interests of their pharmaceutical companies notwithstanding the most severe public health emergencies. WTO rules and practices should provide feasible options for reversing that short-sighted initial decision.

## V. THE INTERFACE OF SUPPLY AND DEMAND CONSIDERATIONS

This article has proposed several models for addressing access to essential medicines under the TRIPS Agreement of 1995 rather than one globally integrated proposal. Given a fractured global political environment in which the prospects for cooperation are constrained, one may expect that various solutions will be adopted to address the problem of developing and supplying vaccines, treatments, diagnostics, and medical devices to address the COVID-19 pandemic. These solutions should include patent and other technology pools on the supply side (including joint manufacturing facilities), as well as regional procurement systems on the demand side. Such proposals may well work in tandem, but they may also function independently if necessary.

Global implementation of a Licensing Facility, on the supply side, might obviate the need for full implementation of RPSCs, on the demand side, if it proves unnecessary for the latter to coordinate requests for compulsory licenses in exporting countries. Similarly, on the demand side, if RPSCs were made operational and able to coordinate compulsory licensing for imports from countries that agree to supply under compulsory licenses for export (under Article 31 and Article 31*bis* of the TRIPS Agreement), then the needs for a compulsory patent pool on the supply side would be limited (since the exporting countries would have agreed to issue compulsory licenses for this purpose).

A ‘middle ground’ combination of the two proposals might arise. To illustrate, using Article 31*bis* of the TRIPS Agreement, a RPSC could coordinate compulsory licenses for importation among a group of countries and seek exports to fulfill those licenses for importation. There may be a group of countries on the supply side that has established a patent licensing pool to satisfy the demand for pharmaceutical products within the group, and that also expects to have export capacity. RPSC compulsory licenses for importation could then be addressed to the group that has created the patent pool

119 Even if the WTO system was functioning, the case would take from beginning to end approximately 3 years, at which point the complainant might (assuming it was successful) be able to claim compensation in the form of rebalancing from the HIC importing and the exporting country. This would entail addressing the level of compensation (or rebalancing) due to the complainant.

120 See n 58, above.

with capacity for export. This would help to reduce coordination issues and facilitate production 'at scale'.

The current world political situation suggests that the possibilities for truly 'global' solutions may be limited. Nevertheless, there are likely to be a variety of solutions developed and implemented as time passes and as the needs for pharmaceuticals become more evident. Hence, this article has proposed potential solutions on both the supply and demand sides of the equitable access equation as models to aid policy planning in both developed and developing countries.