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THE POST-PANDEMIC ORDER: A BLUEPRINT FOR BALANCING HEALTH AND IP INTERESTS IN THE AGE OF COVID VARIANTS

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In December 2021, the World Health Assembly ("WHA") convened to develop a pandemic response treaty for future pandemics. Unfortunately, as presently envisioned, the resulting pandemic response framework will suffer from many of the same inadequacies that prevented existing frameworks from responding effectively to COVID-19. The threat of new pandemics emerging in the future—and new variants developing in the present—call for a more integrated, robust, comprehensive solution.

This Article lays a blueprint for that solution: a global multilateral Council empowered to (1) investigate developing pandemics; (2) incentivize pharmaceutical companies to rapidly produce vaccines and share them through voluntary licenses or TRIPS compulsory licensing provisions; (3) facilitate the rapid creation of raw material pipelines to vaccine and treatment developers; and (4) resolve related legal disputes to ensure a rapid and coordinated response to emerging diseases and variants.

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I. INTRODUCTION

"[Y]ou can't go home again," wrote American novelist Thomas Wolfe. "You can't go . . . home to the old forms and systems of things which once seemed everlasting, but which are changing all the time—back home to the escapes of Time and Memory."[1] Wolfe was writing in the 1930s, but his thesis is applicable today. Some events are so significant that, once they have passed, there is no going back to the way things were.

In the first months of the coronavirus ("COVID-19") pandemic, the chief motivation for following public health advice was to promote an end to lockdown and a swift return to "normal."[2] Later, as the pandemic dragged on, pundits began cautiously discussing a "new normal": the world was never going to go quite back to the way it was before.[3] Subsequent events have shown these pundits to be prophetic. Despite the remarkable speed and success of the vaccine,[4] COVID-19 and its consequences remain a fact of everyday life. The pandemic is an ongoing watershed that will leave no industry or community unchanged. Rather than trying to claw back the way things were, business leaders, lawmakers, and academics must turn their attention to what the future should be. The next great human project will be constructing the new normal.

Like so many others in the pandemic's early days, health organizations and pharmaceutical companies have been guilty of overreliance on pre-pandemic frameworks. These frameworks were imperfect under ideal scenarios and totally inadequate to the pressures and demands of the present hour. After decades of zero-sum thinking

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[1] THOMAS WOLFE, YOU CAN'T GO HOME AGAIN 602 (1941).

[2] Early pandemic measured were explained in terms of weathering an initial wave of infection, with the promise of more relaxed measures and lower risks on the other side. *See* Siobhan Roberts, *Flattening the Coronavirus Curve*, N.Y. TIMES (Mar. 27, 2020), https://www.nytimes.com/article/flatten-curve-coronavirus.html.

[3] Lisa Maragakis, *The New Normal and Coronavirus*, JOHNS HOPKINS MED., 2 (Jun. 14, 2020), https://www.johnshopkinssolutions.com/wp-content/uploads/2020/06/Johns-Hopkins_COVID_NewNormal_V061620.pdf.

[4] Smriti Mallapaty, Ewen Callaway, et al., *How COVID Vaccines Shaped 2021—in Eight Powerful Charts*, 600 NATURE 580–81 (2021).

and unhappy compromises, the present watershed is a rare opportunity for intellectual property ("IP") holders and public health organizations to come to the table and broker a more equitable, sustainable mediation of rights.[5]

This Article briefly surveys the history of conflict between pharmaceutical patent holders and public health organizations before evaluating previous efforts to balance their competing interests. Existing vaccine sharing frameworks like the COVID-19 Vaccines Access ("COVAX"), the International Drug Purchase Facility, and the various COVID IP pledges that have been announced all suffer from the same problems: they are expensive, underfunded, and inflexible. When they do not compel rights-holders to license their IP, they fail to provide adequate incentives to coax voluntary licensing. Further-reaching collaborative projects are presently underway with greater potential to provide lasting solutions. These projects include the Trilateral Cooperation Agreement for the Current Pandemic, the Trilateral Flu Preparedness Framework, and the Multilateral Leader's Task Force on COVID-19. While promising, these collaborative projects suffer from many of the same problems as the existing frameworks. They are not ambitious enough to provide meaningful change.

Building on the successes and failures of these previous efforts, this Article proposes a more durable solution: a blueprint for a Multilateral Council on Pandemic Response jointly chaired by the World Health Organization ("WHO"), World Intellectual Property Organization ("WIPO"), World Trade Organization ("WTO"), International Monetary Fund ("IMF"), and World Bank. This Council would be empowered to investigate the origins and movements of dangerous diseases, equitably broker both voluntary and compulsory IP licenses, rapidly distribute raw materials around the globe to facilitate vaccine production, and resolve disputes that might hinder a unified response. By tapping five respected international organizations, empowering them to respond meaningfully to health crises, and ensuring representation for the interests of each key stakeholder, this

[5] For a general discussion of rights mediation, *see* JAMAL GREENE, HOW RIGHTS WENT WRONG xvii–xxi, (Houghton Mifflin Harcourt 2021).

blueprint offers what previous attempts have failed to achieve: an ambitious, equitable, sustainable international framework for responding to disease outbreaks. If adopted, the blueprint could ensure that vaccines and raw materials are as readily available in the global south as they are in the north. It could provide a useful check against vaccine nationalism. It could find synergies between public health needs and corporate economic necessities, allowing nations to protect their citizens without stifling pharmaceutical companies' profit incentives. Most importantly, it could provide a comprehensive solution that solves more than just the narrow IP licensing dilemma. It would address future viruses and variants at every stage, preventing and tracking outbreaks while also facilitating vaccine development, licensing, manufacturing, and distribution.

In the wake of COVID-19, bobbing with the flotsam and jetsam of the old order, governments and patent holders cannot go home again. The rapid development and spread of new viral variants mean that stop-gap measures or narrow efforts that try to preserve the spirit of the old status quo will likewise be inadequate. Fortunately, the construction of a new order is already underway. The post-pandemic order promises to be more equitable, more effective, and more sustainable than what came before.

II. BACKGROUND

A. Conflicts of Interest

The old order is the product of decades of negotiated solutions between parties with conflicting interests. These conflicts exist at multiple levels and run in different directions. They pit pharmaceutical companies against public health organizations, northern nations against southern ones, wealthy nations against poor ones, and even wealthy nations against each other. To understand the foundation upon which the new order must be built, one must appreciate the complex conflicts of interest around which previous solutions have been negotiated.

1. Public Health Organizations vs. Pharmaceutical Companies

Public health agencies and pharmaceutical companies have been at odds over IP licensing for decades. Drugs are risky and expensive to develop.[6] Virtually all require a large initial outlay, but relatively few succeed in securing the necessary approvals to reach the market.[7] Of those that secure approval, only some become commercial successes.[8] Because research and development ("R&D") expenses are so high, pharmaceutical companies operate on a "race to patent" model.[9] When the market calls for a pharmaceutical solution, drug companies start gambling, investing vast amounts of time and money into R&D in hopes of solving the problem first, patenting their solution, and then resting secure in the knowledge that their patent will be a source of income for years, restoring their R&D investment and eventually returning a hefty profit.[10] The steep cost of R&D is how

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[6] *See* Olivier J. Woulters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844 (2020); *but see* Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, THE ATL. (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/ [hereinafter *Emanuel*].

[7] Conor Hale, *New MIT Study Puts Clinical Research Success Rate at 14 Percent*, CENTERWATCH (Feb. 5, 2018), https://www.centerwatch.com/articles/12702-new-mit-study-puts-clinical-research-success-rate-at-14-percent#:~:text=Nearly%2014%20percent%20of%20all,MIT%20Sloan%20School%20of%20Management.

[8] *See* Derek Lowe, *Only Two Out of Ten Drugs? Really?*, SCIENCE.ORG (Mar. 30, 2016), https://www.science.org/content/blog-post/only-two-out-ten-drugs-really (evaluating the common claim that "only two of every ten drugs on the market ever earn back enough money to match the costs of R&D and the FDA approval process before the patent expires." BIOTECH. INNOVATION ORG., UNLEASHING THE NEXT GENERATION OF BIOTECHNOLOGY INNOVATION 3 (2015), https://www.bio.org/sites/default/files/legacy/bioorg/docs/Whitepaper-Final.pdf).

[9] Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. UNIV. J. L POLICY 167, 173 (2021), https://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=2187&context=law_journal_law_policy.

[10] *See generally* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Companies*, JAMA (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720075

drug companies justify the high prices of their products and the vigor with which they protect their intellectual property.[11] According to drug manufacturers, patents—and the steep prices their monopolies command—are required to fund the research and development of new vaccines and remedies.[12] No patents, the reasoning goes, no lifesaving drugs.[13]

This focus on profits may be an economic necessity, but it creates problems for public health. Pharmaceutical companies' incentive to research a disease is proportional to the amount people can pay for a vaccine or cure. This profit incentive creates a disconnect between the diseases that affect the most people globally and the diseases that enjoy the greatest R&D investment.[14] The effects of this disconnect are felt both geographically and temporally.

a. Geographic and Temporal Inequities

Geographically, the afflictions of wealthy nations receive the bulk of R&D spending, while diseases common in poorer countries receive little investment.[15] This is true both of therapeutic drugs for treating diseases and vaccines for preventing them.[16] Temporally, research often lags far behind the spread of emerging diseases, particularly when those diseases emerge in the global south.[17] Ebola, Zika, and previous coronaviruses like MERS and SARS were not the subjects of sustained research attention until they had already reached a boiling point in their countries of origin and spilled over into Europe

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(finding that most cancer drugs that secure FDA approval generate significant profits over time).

11 Emanuel, *supra* note 6.

12 *Id.*

13 *See* Rutschman, *supra* note 9 ("[T]he possibility of obtaining a patent serves, at least nominally, as an incentive to investment in R&D projects deemed especially risky, costly and time-consuming. According to this often-cited strand of intellectual property discourse, one of the primary roles of the patent system is thus to provide incentives to overall risky R&D, of which pharmaceutical and biopharmaceutical are often listed as classical examples." *Id.*).

14 *See* Rutschman, *supra* note 9, at 170–71.

15 *Id.*

16 *Id.*

17 *Id.* at 169.

or the United States.[18] Because pharmaceutical companies are loath to invest their resources into developing diseases that may or may not become serious enough to generate a lucrative market, they tend to wait until a definite market exists before committing to R&D.[19] As a consequence, a disease may have run halfway around the world before pharmaceutical R&D ever crosses the starting line. By the time a disease has affected enough people to create a promising market for a pharmaceutical solution, it has often already spread extensively and affected many thousands of people.[20] The profit-driven race-to-patent model is fundamentally reactive. Rather than patrolling the neighborhood and looking for suspicious activity, it responds only once the alarm has been pulled—and then only when enough damage has already occurred to make it worth an expensive trip.

The real race begins once a clear market has developed and multiple pharmaceutical companies begin R&D at once.[21] It may take months or even years, but eventually a "winner" will emerge with a viable pharmaceutical solution—either a drug to treat the disease or a vaccine to prevent its spread—and immediately patent it. The patent will ensure that nobody else is able to profit from the solution or use it without permission. It also means that the patent-holder can charge a premium for the medicine or vaccine, in many cases placing it beyond the reach of the poorer countries where the disease emerged in the first place. This has the unhappy effect of leaving poorer countries unprotected both before and after emerging diseases receive R&D attention: no preventative solution exists to slow the disease in its early stages, and by the time a solution has arrived it costs too much to be readily available to its first victims. In some cases, the governments of

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[18] *Id.*

[19] *See* Helen Branswell, *Big Pharmaceutical Companies Reluctant to Produce Zika Vaccine*, PBS (Aug. 9, 2016, 12:33 PM), https://www.pbs.org/newshour/health/big-pharmaceutical-companies-reluctant-produce-zika-vaccine ("For now, vaccine development seems like a risky venture for manufacturers that have recently taken part in a string of emerging diseases rodeos, from SARS and Ebola to the West Nile virus and the 2009 H1N1 pandemic. Those efforts have required significant investments on the part of major pharmaceutical companies, and have yielded either modest or no financial return.").

[20] *See* Rutschman, *supra* note 9, at 170–71 (describing the problem in terms of the Ebola outbreak).

[21] *Id.* at 173 (discussing the features of the "race to patent" business model).

wealthy countries partner with pharmaceutical companies to fund research and development, but once a product emerges, the subsequent patent keeps it in the hands of the funding state, inaccessible to other countries who need it.[22] The system effectively leapfrogs the countries where emerging diseases are most common.

b. Deadlocked Incentives

It is no wonder that pharmaceutical companies struggle to find common ground with public health organizations. One is driven by profit, even if it means falling out of alignment with public health needs. The other is driven by the public interest, even if it comes at the expense of private-sector profits. Yet both groups need each other. Public health organizations, despite usually being branches of state governments, often lack the resources to perform major R&D work on their own.[23] They rely on the research and products of pharmaceutical companies, but that research does not necessarily track public health needs, and those products are locked away behind patents. On the other hand, pharmaceutical companies cannot protect their IP on their own. They rely on governments to grant and maintain the patents that allow them to profit on their research.

Patents, while powerful, are not absolute. Virtually all national governments have legal provisions that force IP holders to license their work to others if certain conditions are met.[24] These non-voluntary, or compulsory, licenses are a powerful tool in the arsenal of health organizations, constituting a trump card that allows governments to distribute patented pharmaceuticals however they choose, regardless of the IP rights-holder's wishes, if the situation becomes sufficiently dire.[25] On the one hand, if pharmaceutical companies price lifesaving

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22 Harris Meyer, *After a COVID-19 Vaccine: Collaboration or Competition?*, 39 HEALTH AFF. 1856, 1857 (2020) ("The COVAX initiative grew out of the world's experience in dealing with the H1N1 influenza pandemic in 2009, when the US delayed for months in sharing with less wealthy nations the vaccine it had developed to combat that virus.").

23 *See* Branswell, *supra* note 19.

24 For an overview of voluntary and compulsory licensing schemes, *see* Arjun Padmanabhan, *Coronavirus, Compulsory Licensing, and Collaboration: Analyzing the 2020 Global Vaccine Response with 20/20 Hindsight*, 30 TEX. INTELL. PROP. L. J. 75, 87–88.

25 *Id.*

products unreasonably and reap profits too gratuitously during a health crisis, the national government may intervene and force them to issue licenses. If, on the other hand, government health agencies rely on compulsory licenses too often, they risk killing the golden goose: with profit incentives impaired, pharmaceutical companies might stop producing the drugs and research that fuel public health efforts. Accordingly, governments rarely exercise their compulsory licensing schemes, choosing to try to coax pharmaceutical companies into issuing voluntary licenses instead.[26]

Unlike compulsory licenses, which are a product of legislation, voluntary licenses are essentially a contract between the pharmaceutical company and the licensee.[27] Because pharmaceutical companies are free to determine the terms of voluntary licenses, these licenses are often limited in scope and require the payment of hefty royalties.[28] With the leverage balanced so evenly between them, pharmaceutical companies and health organizations have spent decades walking a razor's edge, locked in a tense codependent relationship despite their apparently irreconcilable interests.[29]

2. Nation vs. Nation

a. Vaccine Nationalism

While COVID-19 is a pandemic in the truest sense—its effects are felt worldwide—national governments have struggled to address it as a global issue or shed state-centric attitudes. In the same way that pharmaceutical companies think first about the interests of their shareholders, national governments tend to think first about the interests of their citizens. History has shown them to be hesitant to invest national funds into international enterprises, even when they might yield significant benefits for citizens. Accordingly, when a nation

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[26] *Id.* at 91–93 (discussing U.S. attempts to use march-in rights against pharmaceutical patent holders during pandemics).

[27] *Id.*

[28] *See id.* at 87.

[29] *Id.* at 91–93 (discussing U.S. attempts to use march-in rights against pharmaceutical patent holders during pandemics).

invests in a vaccine, it tends not to share it across borders.[30] Despite initial good intentions—the presidents of both France and China made speeches arguing that COVID-19 vaccines should be treated as "global public goods" and made universally available regardless of their origin[31]—the COVID-19 vaccines have been no exception to this rule.[32]

At the outset of the pandemic, wary of the aforementioned temporal problem, wealthy governments created a lucrative market for COVID-19 R&D by setting aside billions of dollars to fund and buy vaccines.[33] Spurred into action by the promise of tremendous profits, pharmaceutical companies raced potential vaccines through clinical trials while simultaneously engaging would-be buyers in bidding wars over potential doses. In these bidding wars, the same wealthy countries that put up the initial R&D money unsurprisingly came away victorious, locking up most doses before they were even on the market.[34] The U.S. COVID-19 initiative, ambitiously called "Operation Warp Speed," involved brokering deals with dozens of pharmaceutical companies, offering to contribute money toward research on the condition that the resulting vaccines be made available first to U.S. citizens.[35] Other countries followed suit. By November 2020, as the race for a vaccine built toward a climax, the United States, UK, EU, and Japan had agreed to buy more than 300 billion doses between them, and there was little hope that China and India would share the results of their research programs with other nations.[36] For

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30 Thomas J. Bollyky & Chad P. Bown, *The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic*, 99 FOREIGN AFFS. 96, 96–97 (2020).

31 Anna Marie Merlo, *Macron to WHO: 'The Vaccine is a Global Public Good'*, IL MANIFESTO (May 20, 2020), https://global.ilmanifesto.it/macron-to-who-the-vaccine-is-a-global-public-good/; Corinne Gretler, *Xi Vows China Will Share Vaccine and Gives WHO Full Backing*, BLOOMBERG (May 18, 2020), https://www.bloomberg.com/news/articles/2020-05-18/china-s-virus-vaccine-will-be-global-public-good-xi-says.

32 *See generally* Meyer, *supra* note 22.

33 *Id.* at 1857.

34 *Id.*

35 *Id.*

36 *Id.*

poorer countries, vaccines were effectively sold out before they ever even hit the shelves.[37]

As the vaccines neared completion, inter-state competition became even more apparent. In May 2020, Sanofi, a major French pharmaceutical company, announced that it was going to give most of its initial doses to the United States.[38] The United States, it reasoned, had contributed the largest amount of funding and so it deserved the lion's share of the early doses.[39] France, outraged that a domestic company would send vital products overseas in a time of crisis, condemned the decision in the strongest terms.[40] President Macron, mindful of the tax exemptions his government granted Sanofi, summoned its leadership to a meeting at the Élysée Palace to remind them of the fact.[41] Sanofi reversed course shortly thereafter and promised to share its vaccines more generously with its domestic benefactor.[42] France had been previously criticized by its European neighbors for not sharing its supply of protective medical equipment when they needed it.[43]

It makes sense that nations would look after their own in a time of crisis. Government leaders' duty to their own people is clear and stark; their duty to the world, or to the citizens of foreign nations, is

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37 *Id.*

38 James Patton et al., *U.S. Likely to Get Sanofi Vaccine First if It Succeeds*, BLOOMBERG (May 13, 2020), https://www.bloomberg.com/news/articles/2020-05-13/u-s-to-get-sanofi-covid-vaccine-first-if-it-succeeds-ceo-says.

39 *See id.*

40 James McAuley, *France Angered by Suggestion U.S. Would Get First Access to Coronavirus Vaccine by French Pharma Company Sanofi,* WASH. POST (May 14, 2020), https://www.washingtonpost.com/world/europe/coronavirus-vaccine-sanofi/2020/05/14/821c7c12-95e2-11ea-87a3-22d324235636_story.html.

41 *See* Eleanor Beardsley, *French Drug Giant Sanofi Takes Heat After Suggesting U.S. May Get 1st Vaccine Access*, NPR (May 15, 2020), https://www.npr.org/2020/05/15/856293764/french-drug-giant-sanofi-takes-heat-after-suggesting-u-s-may-get-1st-vaccine-acc.

42 Noemie Bisserbe, *Sanofi Bows to France's Demand for Coronavirus Vaccine Supplies*, WALL STREET J. (Jun. 16, 2020), https://www.wsj.com/articles/sanofi-bows-to-frances-demand-for-coronavirus-vaccine-supplies-11592322940.

43 *See* Beardsley, *supra* note 41.

much murkier.[44] Self-preservation is an inward-facing instinct, leading people to put their own interests ahead of others when the stakes are high. However, a pandemic is a perfect example of a situation where nations' instinct for self-preservation works against them. In a closely-connected world where national economies rely on foreign markets, there can be no isolated escape from the consequences of COVID-19—no victory at another nation's expense.[45] Countries will either defeat the virus together, or not at all.[46]

b. Resource Sharing

Even in a universe where pharmaceutical companies were willing to share their patents for drugs and vaccines freely, there would still be a hurdle in the way for poorer countries. A patent is simply a blueprint and turning a blueprint into a real-life product requires material resources. Countries that are unable to afford licenses for patents are unlikely to have the resources or expertise required to turn blueprints into safe and effective vaccines or therapeutic drugs. This issue has been particularly prevalent in countries like India that have manufacturing capacity but lack easy access to the arcane and expensive materials required to manufacture vaccines.[47] This problem is made more acute by embargoes: when large, wealthy nations levy embargoes against poorer ones, it becomes very difficult for those countries to get access to the materials they need to vaccinate their populations.[48]

In some dramatic circumstances, states that otherwise enjoy good diplomatic relations have made it illegal to share vaccines or materials between themselves.[49] Italy blocked a shipment of AstraZeneca vaccine to Australia in March 2021, throwing the

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[44] Sarah Joseph & Gregory Dore, *Vaccine Apartheid? A Human Rights Analysis of COVID-19 Vaccine Inequity*, SSRN, 1, 11 (Jun. 30, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3876848.

[45] *See* Meyer, *supra* note 22, at 1857.

[46] *See id.* (quoting GAVI CEO Seth Berkley, "With infectious disease, no one is safe until everyone is safe.")

[47] *See* Joseph & Dore, *supra* note 44, at 12.

[48] *Id.*

[49] *Id.*

Australian pandemic response into disarray.[50] When India needed certain resources to produce vaccines later that year, it asked the United States for help, only to have its request flatly denied.[51] Both Italy and the United States justified their decisions to obstruct the flow of vaccine ingredients to other countries by arguing that their own need was objectively greater than that of the other state.[52]

The problem of resource-sourcing is one that has been largely overlooked in the current vaccine licensing discourse, perhaps because it is not a *prima facie* IP issue. However, just like funding, R&D, and distribution, it is a critical part of the vaccine life-cycle,[53] and one that cannot be overlooked without consequence. Granting a vaccine license to a country that lacks access to the materials necessary to produce it is like giving a key without a car or a password without a computer—a largely empty gesture.

III. THE CURRENT LANDSCAPE: EXISTING FRAMEWORKS

There are many ongoing initiatives to combat virulent pandemics, including COVID-19. These initiatives include vaccine sharing frameworks and collaborative projects, all aimed at increasing access to medicine or treatment related IP for notable pathogens ranging from the common influenza to HIV/AIDS.[54] The key players in designing and implementing these frameworks are usually intergovernmental organizations ("IGOs"), particularly the World Health Organization ("WHO"), World Intellectual Property Organization ("WIPO"), World Trade Organization ("WTO"), International Monetary Fund ("IMF"), and World Bank. Although these projects are robust, their hosting organizations have so far been

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50 *Id.*

51 *Id.*

52 *Id.*

53 Georgina Drury et al., *Process Mapping of Vaccines: Understanding the Limitations in Current Response to Emerging Epidemic Threats*, 37 VACCINE 2415, 2418 (2019) (describing the process of sourcing and purifying raw materials, testing them for viability, adding stabilizers and preservatives, and packaging the final product for distribution).

54 *See supra* Parts II.A & II.B.

unable to efficiently leverage their infrastructure and procedures to combat COVID-19.

As early as 2016, the WHO recognized that the status quo left nations vulnerable to rapidly-spreading emerging diseases and published a comprehensive action plan in an effort to right the ship.[55] Styled as an "R&D Blueprint," the action plan's goal was to create a framework that would bring interests into better alignment and ensure the whole world—both north and south—was better prepared to deal with future outbreaks of emerging diseases.[56]

In May 2020, the World Health Assembly ("WHA"), recognizing the existential threat COVID-19 posed to global health interests, charged the Director-General of the WHO to form what became the Independent Panel for Pandemic Preparedness & Response (the "Independent Panel").[57] The purpose of the Independent Panel was to "initiate an impartial, independent, and comprehensive review of the international health response to COVID-19 and of experiences gained and lessons learned from it, and to make recommendations to improve capacities for the future."[58] In a report, the Independent Panel recognized several key issues which contributed to the breakdown in the healthcare response including that: (1) countries and healthcare initiatives were reluctant to implement healthcare experts' recommendations in a timely manner; (2) national pandemic preparedness initiatives were underfunded; (3) national governments lacked comprehensive preparedness plans with multi-sectoral coordination and contingencies; and (4) international collaboration projects failed to gain traction or broad support in time to be effective.[59]

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[55] WORLD HEALTH ORG., COVID-19 RESEARCH AND INNOVATION ACHIEVEMENTS 18 (2021), https://www.who.int/publications/m/item/covid-19-research-and-innovation-achievements [hereinafter *R&D Blueprint*].

[56] *See* Rutschman, *supra* note 9, at 170.

[57] INDEP. PANEL FOR PANDEMIC PREPAREDNESS & RESPONSE, COVID-19: MAKE IT THE LAST PANDEMIC 8 (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

[58] *Id.*

[59] *Id.* at 15–19, 28, 38, 41.

Bearing in mind these findings, this Part will discuss existing vaccine sharing frameworks and international collaborative projects before analyzing their effectiveness and drawbacks. Of the issues that the Independent Panel identified, this Part will focus on the lack of funding and collaboration to share resources, medicines, and IP.

A. Existing Vaccine Sharing Frameworks

1. COVAX (Gavi)

An attempt to balance the interests of wealthy producer countries with poorer ones, COVAX is a mechanism for getting COVID-19 vaccines into the hands of countries in the global south where they were desperately needed, but in short supply.[60] Its premise is that, when many countries have access to an effective vaccine collectively, each benefits individually.[61] As Health Affairs reported, the project's selling point is that, "Wealthier countries get the promise of guaranteed access to a broader pool of potentially effective vaccines, and the entire world's population gets vaccinated, enabling the global economy to reopen."[62]

A collaboration between the WHO, the Coalition for Epidemic Preparedness ("CEPI"), the United Nations Children's Fund ("UNICEF"), and Gavi, the Global Vaccine Alliance, COVAX enlists wealthier countries to fund research and pre-purchase vaccine doses that are then distributed to countries according to need, rather than ability to pay.[63] The goal is to produce and distribute enough vaccine doses that at least 20% of the population of participating states can be vaccinated by the end of 2021.[64] Twenty percent of the population is significant—enough to potentially provide for the vaccination of the elderly and otherwise vulnerable, but not enough to affect the spread of the disease.[65]

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60 Meyer, *supra* note 22, at 1857.
61 *Id.*
62 *Id.*
63 Joseph & Dore, *supra* note 44.
64 *Id.* at 4.
65 *Id.*

While it has played an important role in developing the Moderna, AstraZeneca, Inovio, and Novavax Vaccines, to date COVAX cannot be characterized as an international success.[66] In order to attract wealthier countries to participate, COVAX organizers redesigned the program to be less strict, allowing funding countries to retain more control over the vaccines they paid for.[67] Nevertheless, key players like the United States still declined to participate.[68] By the time the deadline for commitments had passed, seventy-eight wealthier countries and ninety-two poorer countries had agreed to participate.[69] Participating states contributed more than $1.4 billion to the program but the WHO reported that it needed half that sum to effectively capitalize on research and development opportunities.[70] Wary of placing all their eggs in the COVAX basket, participating states have continued to broker independent deals with pharmaceutical companies on terms less conducive to global vaccine sharing.[71] Finally and most recently, COVAX has suffered from supply issues.[72] Its distribution plans relied on large shipments of the AstraZeneca vaccine pledged by the Serum Institute of India, but when COVID-19 fatalities began to surge in India, those shipments were delayed indefinitely.[73]

2. International COVID-IP Pledge

During ordinary times, patents and copyrights spur innovation and motivate inventors and artists to create work they can monetize. In times of crisis, however, they can prevent critical information from spreading, thus impeding the development of vaccines and treatments.[74] To facilitate information sharing, a multitude of businesses have pledged to license some or all of their IP for the

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66 Meyer, *supra* note 22, at 1857.

67 *See id.*

68 A White House Spokesperson explained that COVAX is "influenced by the corrupt World Health Organization and China." *Id.* at 1857.

69 *Id.*

70 *Id.* at 1857 ("[A]n additional $1 billion is needed to move the research and development portfolio forward, according to the WHO.").

71 *Id.*

72 Joseph & Dore, *supra* note 44, at 4.

73 *Id.*

74 Jorge L. Contreras et al., *Pledging Intellectual Property for COVID-19*, 38 NATURE BIOTECH. 1146, 1146 (2020).

duration of the pandemic.[75] These companies include Microsoft, Amazon, IBM, Intel, Hewlett Packard, and Facebook.[76] Relevant products produced by these companies can be readily licensed by anyone who intends to use them for "ending and mitigating the COVID-19 pandemic."[77]

These pledges are organic, voluntary, and spontaneous; no body enforces or oversees them, and each company sets its own terms.[78] Some pledges are more formal than others, however. The Welcome Trust Publisher's Pledge, Open COVID Pledge, and Open COVID-19 Declaration, for instance, serve as charters to which willing companies can accede.[79] To prevent scalpers, many of these voluntary licenses contain "share alike" provisions requiring that those who use the licensed IP to create new products or works make those products or works available under the same terms as the license.[80]

Considering the success of open-source software; it comes as no surprise that most of the companies willing to grant these pandemic licenses have tech pedigrees. With few exceptions, the pledges have not caught on with pharmaceutical companies.[81] Oxford University made waves when it announced its intention to donate the rights to its COVID-19 vaccine to a drugmaker for free.[82] Despite multiple announcements and public commitments to provide a vaccine at low cost or for free, Oxford quietly changed course in 2020 and sold its vaccine to AstraZeneca.[83] The deal contained no provisions guaranteeing broad access or low prices.[84] Many considered the sale to be a frustrating relapse into a flawed status quo. "If there was ever an

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75 WORLD TRADE ORG, THE TRIPS AGREEMENT AND COVID-19 at 1 (2020), https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

76 *Id.* at 4.

77 *Id.*

78 Contreras et al., *supra* note 74.

79 *Id.* at 1147.

80 *Id.* at 1147–48.

81 *Id.*

82 Jay Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, then Sold them to Pharma*, KHN (Aug. 25, 2020), https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/.

83 *Id.*

84 *Id.*

opportunity," wrote Ameet Sarpatwari of Harvard Medical School, "this would have been it."[85] Instead of providing the vaccine in a way guaranteed to allow affordable access, "it is business as usual, where the manufacturers are getting exclusive rights and we are hoping on the basis of public sentiment that they will price their products responsibly."[86]

3. International Drug Purchase Facility

Designed to "build new international approaches towards ensuring universal access to, and efficient national systems of procurement and distribution for anti-Tuberculosis drugs,"[87] the Global Drug Facility is an arm of the WHO.[88] It has a mandate to ensure that countries have ready access to tuberculosis drugs, stimulate political support for anti-tuberculosis measures, and ultimately secure the control and elimination of the disease entirely.[89] Primarily, the Global Drug Facility sets international quality standards for tuberculosis drugs.[90] By encouraging new suppliers, consolidating orders, and implementing "a competitive and transparent tendering process among the manufacturers," the Global Drug Facility has been able to significantly reduce the prices of tuberculosis drugs over time.[91]

UNITAID is an International Drug Purchase Facility funded by a creative scheme of international taxation.[92] Frustrated by the toll that diseases like malaria, HIV, and tuberculosis were taking on the world, and the inadequate resources available to address these diseases in a global way, five national governments joined together in 2006 to

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85 *Id.*

86 *Id.*

87 Robert Matiru and Timothy Ryan, *The Global Drug Facility: A Unique, Holistic and Pioneering Approach to Drug Procurement and Management*, 85 WORLD HEALTH ORG. BULL. 348, 348 (2007) (quoting the Global Drug Facility's prospectus).

88 *Id.*

89 *Id.* at 352.

90 Kaspars Lunte, Thierry Cordier-Lassalle, and Joel Keravec, *Reducing the Price of Treatment for Multidrug-Resistant Tuberculosis through the Global Drug Facility*, 93 WORLD HEALTH ORG. BULL. 279, 282 (2015) [hereinafter Lunte].

91 *Id.* at 280.

92 CATHERINE A. WITHROW, POLITICAL WILL AND THE GLOBAL IMPLEMENTATION OF UNITAID AND THE AIRLINE TICKET TAX 17 (2007).

create a new drug purchase facility.[93] UNITAID's goal is to increase access to treatment and diagnostics for malaria, HIV, and tuberculosis in the poorest areas of the world.[94] Unlike other international health initiatives, which are often financially neglected, UNITAID had the good fortune of being conceived with a built-in financing mechanism: an international tax on airline ticket sales.[95] Certain states that have adopted UNITAID—chiefly France and Chile—charge a solidarity fee on commercial flights to and from their countries.[96] They then use the money to place massive orders with pharmaceutical companies, relying on volume-buying to secure steep discounts.[97] Between 2006 and 2011, eight countries agreed to participate in the airline tax.[98] In those five years, the tax generated $2 billion, which comprised 80% of UNITAID's funding.[99]

This built-in funding mechanism is UNITAID's differentiating quality and greatest strength. However, the drug purchase facility has been criticized on other grounds. A persistent criticism is that medical infrastructure, not drug availability, is the chief problem facing poor countries in their battles against HIV and tuberculosis.[100] Drugs are useless, the criticism argues, if there are no trained doctors to administer them and no safe facilities to administer them in.[101] The other frequent criticism of UNITAID is that its efforts are duplicative of existing programs and that its administration expenses on the back-

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93 *Id.* at 17–18.

94 *Id.* at 17.

95 *Id.* at 19.

96 *Id.* at 21–22.

97 *Id.*

98 Denis Broun, *UNITAID Innovative Financing Mechanism*, WORLD HEALTH ORG., at *2 (Oct. 2011), https://www.who.int/hiv/amds/unitaid_oct2011.pdf?ua=1 [https://perma.cc/B4Y6-MSHQ].

99 *Id.*

100 JEREMIAH NORRIS AND S. JEAN WEICHER, UNITAID/IDPF: AN ANALYSIS OF THE INTERNATIONAL DRUG PURCHASE FACILITY 10 (Center for Science in Public Policy 2006).

101 *Id.*

end of distributing drugs result in higher prices for the countries it serves.[102]

B. Collaborative Projects

1. Trilateral Cooperation Agreement for the COVID-19 Pandemic

An exciting step toward a more collaborative future, the Trilateral Cooperation Agreement for the COVID-19 Pandemic established the foundation for a partnership between the WHO, WTO, and WIPO.[103] This agreement unites the foremost IGOs representing the interests of public health organizations, (WHO), pharmaceutical companies, (WIPO), and the financial world, (WTO). The partnership is informal, without a charter or contract to hold it together or set its boundaries. The WIPO explains the relationship as a loose but robust and results-oriented one:

> The three organizations meet regularly, exchange information on their respective work programs and discuss and plan, within the possibilities of their respective mandates and budgets, common activities. The trilateral cooperation is intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing public health in relation to IP and trade. The WHO Global Strategy and Plan of Action on Public Health, Innovation and IP, the WIPO Development Agenda and the WTO Declaration on the TRIPS agreement and public health, provide the broader context for an

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[102] *Id.* at 20. It should be noted that this analysis has aged poorly in some ways. "Issues of price, demand and drug supply were yesterday's problems," its authors wrote in 2006, with optimism that the passing years have demonstrated to have been misplaced.

[103] *WHO, WIPO, WTO launch updated study on access to medical technologies and innovation*, WORLD HEALTH ORG. (Jul. 29, 2020), https://www.who.int/news/item/29-07-2020-who-wipo-wto-launch-updated-study-on-access-to-medical-technologies-and-innovation [hereinafter *WHO Launch*].

> informal and practical trilateral cooperation at the working level.[104]

In announcing the collaboration, WTO Director General Roberto Azevedo emphasized the need for all three organizations to form collaborative and coherent policies, taking account of each other's interests.[105] "Close collaboration between our three specialized agencies has yielded important practical benefits," he said.[106] "It is only through joint efforts at the global level that we can achieve our shared public health goals."[107]

The tangible product of the collaboration is a sprawling research study: the Trilateral Study on Promoting Access to Medical Technologies and Innovation.[108] This study "highlights the interplay between the distinct policy domains of health, trade, and intellectual property, and how they affect innovation and access to medical technologies, such as medicines, vaccines, and medical devices."[109] It is designed to aid policy makers in navigating the political, economic, health, and intellectual property challenges inherent in addressing the pandemic.[110]

The cooperation has been so successful that in May 2021, the World Health Assembly held a special session to discuss the possibility of enshrining the partnership in more formal terms.[111] It proposed that a convention, agreement, or other international instrument on

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104 *WHO, WIPO, WTO Trilateral Cooperation on Public Health, IP and Trade*, WORLD INT'L PROP. ORG. (2020), https://www.wipo.int/policy/en/global_health/trilateral_cooperation.html.

105 WHO Launch, *supra* note 103.

106 *Id.*

107 *Id.*

108 WORLD HEALTH ORG. et al., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION (2d. Ed. 2020), https://www.wto.org/english/res_e/booksp_e/who-wipo-wto-2020_e.pdf.

109 WHO Launch, *supra* note 103.

110 *Id.*

111 *Special session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instrument on Pandemic Preparedness and Response*, WORLD HEALTH ORG. Doc. WHA74(16) (May 31, 2021), https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74(16)-en.pdf.

pandemic preparedness and response be signed by member states, bringing together the same key players.[112] The World Health Assembly convened in December 2021 to discuss the proposal further and potentially prepare a draft convention.[113]

The great strength of this Trilateral Cooperation Agreement is its inclusivity: it brings together several of the key stakeholders involved in brokering solutions to the conflicts of interest discussed above. By ensuring that these sometimes-disparate voices are in frequent touch with each other, it increases the likelihood of democratic solutions working themselves out organically between the parties. It facilitates communication and understanding. It allows institutional knowledge to be shared across disciplines. Perhaps most importantly, it allows the IGOs involved to compare notes, ensuring that their goals are uniform.

However, the weakness of the collaboration is its informality. There is nothing obligating the IGOs to coordinate, and they are treated the same collectively as they are separately. Their cooperation does not constitute a new super-IGO or international organization. Accordingly, some synergies between their institutional expertise must necessarily be missed as they tackle projects separately. While the report they produce is very useful, a single document is far short of what these IGOs could accomplish if they came together more formally.

2. Pandemic Flu Preparedness Framework

Another project of the WHO, the Pandemic Flu Preparedness Framework is an attempt to create a global surveillance and response system for influenza.[114] Its primary purpose is to provide ready and equitable access to vaccines and information about viruses with the

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112 *Id.*

113 *Id.*

114 WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS (2d ed. 2021), https://apps.who.int/iris/rest/bitstreams/1351857/retrieve.

potential to cause human pandemics.[115] As the name suggests, however, its scope is limited to H5N1 avian flu, with all other diseases—and even other strains of influenza—specifically excepted.[116]

The World Health Assembly adopted the framework in 2011, urging member states to accept it and allocate enough resources for its local implementation.[117] Signatories agree to share H5N1 vaccines amongst themselves in proportion to public health risk and need.[118] They agree to collect biological material from suspected H5N1 cases and rapidly share it with WHO laboratories, allowing member states to catch outbreaks in a timely manner.[119] Further, they agree to certain tracing and reporting mechanisms, the genetic sequencing of collected data, the provision of diagnostic test kits, etc.[120] The Flu Preparedness Framework creates a general vaccine stockpile with contributions from member states, but also provides that a portion of vaccines manufactured be set aside for special distribution to developing countries.[121] The framework acknowledges the problem of IP licensing, but stops short of proposing any concrete solutions.[122]

The Pandemic Flu Preparedness Framework is a step in the right direction for global pandemic response and prevention. Of special interest are its provisions for monitoring and responding to the spread of H5N1. Rather than focusing narrowly on treating cases, the framework takes a broader approach and attempts to limit, or at least

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115 *Id.* at 1.

116 *Id.* at 7 ("This Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework").

117 *Id.*

118 *Id.* at 3.

119 *Id.* at 12.

120 *Id.* at 12–17.

121 *Id.* at 18–19.

122 *Id.* at 4 ("[I]ntellectual property rights do not and should not prevent Member States from taking measures to protect public health." "[I]ntellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.").

monitor, the spread of H5N1 on a global scale.[123] This broader approach is laudable. Taking into account the full lifecycle of a pandemic, from its origins and spread through to its treatment and eradication, allows the WHO to take more informed and effective action.

While the framework adopts a broad approach in the way it considers H5N1, its failure to consider anything else limits its utility in the COVID-19 context. Like so many other collaborative projects, the Flu Preparedness Framework is a narrowly tailored solution devised in response to a particular threat. Despite being a largely successful and promising initiative, the framework is an example of the fundamentally reactive nature of most international public health solutions. Public health organizations create frameworks in the immediate aftermath of a disease crisis, narrowly tailored to prevent the reemergence of that particular threat or strain—in this case H5N1. Even when created with the best intentions and most deliberate attention, these frameworks are unhelpful when it comes to catching or preventing new strains or threats. Accordingly, when a new threat emerges—and one always does—it catches the world unprepared.

3. Multilateral COVID-19 Task Force

The final and most relevant project currently underway is the Multilateral COVID-19 Task Force ("Task Force"). A joint initiative of the IMF, World Bank, WHO, and WTO, its goal is to accelerate the distribution of COVID-19 vaccines to developing countries by harnessing the power of the financial markets.[124] Because vaccines, like any commodity, must navigate governments' regulatory landscapes to be bought or sold, there are often financial or trade roadblocks in the way of fast and efficient distribution.[125] The Task Force seeks to remove these obstacles, harnessing the institutional knowledge and

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123 *WHO Launches New Global Influenza Strategy*, WORLD HEALTH. ORG. (Mar. 11, 2019), https://www.who.int/news/item/11-03-2019-who-launches-new-global-influenza-strategy [https://perma.cc/C7DX-H6JN].

124 *About*, COVID19TASKFORCE.COM, https://www.covid19taskforce.com/en/programs/task-force-on-covid-19-vaccines/about (last visited Dec. 30, 2021) [https://perma.cc/7JQ5-89WK].

125 *Id.*

authority of the IMF, World Bank, and WTO to do so.[126] The Task Force is an exciting marriage of public health and trade expertise. By putting the IMF, World Bank, and WTO at the same table as the WHO, it opens doors that would not otherwise be available.

One IGO is notable by its absence from the Task Force. Despite the conflict between public health and IP interests being at the very heart of pandemic containment, the WIPO does not play a role in the Task Force. Without the WIPO or other similarly purposed organization, IP rights holders have no true voice for their interests on the task force. This stunts the capability of what might otherwise be a robust and durable solution.

C. Drawbacks of the Current Frameworks and Projects

These frameworks and collaborative projects all suffer from the same defects. Those that are robust enough to make a difference are too narrow to be broadly useful, and those with enough scope to cover emerging diseases are not empowered to make a difference. The narrow scope of international vaccine and information sharing frameworks is a product of underfunding, which is itself a symptom of a lack of political will behind them. Further, most solutions are the products of only one IGO—the WHO.[127] Of course, the WHO ought to drive the discourse, but for solutions to be enduring, there must be more seats at the table. Groups like the WIPO and World Bank should be included from a project's earliest stages to ensure that the interests of vaccine manufacturers and developing nations are represented. Finally, solutions to date have failed to adequately incentivize vaccine manufacturers to issue voluntary licenses for their IP.

1. Lack of Funding

Although it has been instrumental in overcoming or curbing the effects of pathogenic threats like HIV/AIDS, SARS, Zika and Ebola over the past seventy years, the WHO is still woefully

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126 *Id.*

127 *See supra* Part III.A, III.B.

underfunded.[128] Its two-year budget for the 2020-2021 term is only $4.84 billion,[129] which is a $420 million increase from its $4.42 billion budget for 2018-2019.[130] The WHO's financial plight may be illustrated by pointing to the $6.99 billion operating budget of a single leading American hospital system in 2015.[131] The public health organization responsible for tracking and treating diseases across the whole world has less funding than a regional hospital system.

The WHO's funding structure relies on two forms of revenue: assessed contributions and voluntary contributions.[132] Assessed contributions are the "dues" that each Member state pays annually based on their GDP.[133] Voluntary contributions are donations or gifts which can come from a variety of sources including Member States, IGOs, philanthropic initiatives and the private sector.[134] In recent years, the WHO has relied on voluntary contributions to form the bulk of the budget.[135] These voluntary contributions are often pre-allocated

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[128] Lawrence Gostin & Sarah Wetter, *Two Legal Experts Explain Why the U.S. Should Not Pull Funding from the WHO Amid COVID-19 Pandemic*, FORBES (Apr. 13, 2020, 9:55 AM), https://www.forbes.com/sites/coronavirusfrontlines/2020/04/13/two-legal-experts-explain-why-the-us-should-not-pull-funding-from-the-world-health-organization-amid-covid-19/?sh=242e67531df7.

[129] *Programme Budget 2020–2021*, WORLD HEALTH ORG. Doc. WHO/PRP/19.1 at 7 (May 30, 2019).

[130] *Overview of Financial Situation: Programme Budget 2018–2019*, WHO Doc. A72/34 at 2 (May 13, 2019), https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_34-en.pdf [https://perma.cc/HF2Y-ZQVY].

[131] *A Look at Our Books: Fiscal Year 2015 Capital Budget and Annual Operating Plan*, JOHNS HOPKINS MED. 1, 1 (2015), https://www.hopkinsmedicine.org/news/publications/_docs/operating_capital_budget_infographic.pdf [https://perma.cc/VRN6-G2FB].

[132] *How WHO is Funded*, WORLD HEALTH ORG., https://www.who.int/about/funding (last visited Sep. 27, 2021), [https://perma.cc/U3VR-HQ8R].

[133] *Id.*

[134] *Id.*

[135] Charles Clift, *What's the World Health Organization For?*, THE ROYAL INSTITUTE OF INT'L AFFS., CHATHAM HOUSE 1, 28 (May 2014), http://ghiadvisors.org/Docs/WHOHealthGovernanceClift.pdf [https://perma.cc/PU6U-9CBF].

toward certain initiatives by the donors.[136] Not only does this decrease transparency as to where and why money is being spent, it forces the WHO to support certain initiatives over others, regardless of their priority at the time.[137] Many donors only support the WHO through voluntary contributions if they can decide where their money is spent.[138] Previous initiatives like the Contingency Fund for Emergencies ("CFE") were pitifully unsuccessful because they relied solely on voluntary donations that could not be earmarked for specific activities.[139] From 2018–19, the CFE barely raised enough money to support a response to a minor Ebola outbreak in a single country.[140] The WHO must therefore rely on state contributions to cover its operating costs which is why it and many other IGOs[141] are chronically underfunded. This limits their ability to participate in projects outside their wheelhouse. It results in narrow, reactive solutions like the Pandemic Preparedness Framework and limits the possibility of broader, preventative solutions.

The UNITAID International Drug Purchase Facility offers a useful model for funding public health projects between nations. While unable to levy domestic taxes, IGOs can be the beneficiaries of international taxes. UNITAID is evidence that international pandemic response programs work best when they are conceived with a built-in funding mechanism independent of their parent organizations.

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136 *See* Gostin & Wetter, *supra* note 128.

137 Clift, *supra* note 135, at 30.

138 *See* Gostin & Wetter, *supra* note 128.

139 *Id.*

140 *Id.; see also Contingency Fund for Emergencies (CFE)*, WORLD HEALTH ORG., https://www.who.int/emergencies/funding/contingency-fund-for-emergencies (last visited Dec. 18, 2021), [https://perma.cc/B3DD-RUHT] (detailing the 2021 financial contributions to the CFE that only amounted to $45 million); *cf. Pakistan*, KPMG, https://home.kpmg/xx/en/home/insights/2020/04/pakistan-government-and-institution-measures-in-response-to-covid.html (last updated June 24, 2020), [https://perma.cc/H82A-JGQ5] (stating that Pakistan, the 46th largest economy by GDP, spent over $6.7 billion in COVID-19 relief packages in 2020. This is more than 148 times what the CFE received in donations in 2021).

141 Which IGOs?

2. Lack of Incentive for Rights-Holders to License IP

As previously noted, it is expensive to develop new vaccines.[142] Pharmaceutical companies are willing to undertake expensive R&D in part because patents make it possible for them to control the distribution and price of the resulting products. Having spent the money to develop a new vaccine, relying on a monopoly to recover the initial outlay and turn a profit, pharmaceutical companies are understandably unwilling to give away their formulas or sell them at a discount.[143] Nevertheless, because national governments are wary of the consequences of enforcing compulsory licenses, pandemic response to date has depended on the issuance of voluntary licenses.[144] Without some added incentive, however, these voluntary licenses are elusive.[145] Why would a pharmaceutical company voluntarily trade away its profits, or perform labor-intensive R&D for free? With the whole weight of economics on one side of the scale and mere altruism on the other, most corporations have not found it to be a close question. To be sustainable, a lasting pandemic response framework must rebalance the scales by adding economic incentives that weigh in favor of granting licenses.

IV. PROPOSED BLUEPRINT FOR A MULTILATERAL PANDEMIC RESPONSE COUNCIL

Given the circumstances of the 2020–21 pandemic era, the initiatives mentioned in the previous Part arguably fulfilled their basic purpose: to combat the COVID-19 virus, in its original form, through technology sharing and collaborative development. That said,

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142 *See* Olivier J. Woulters, Martin McKee, and Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 323 JAMA 844 (Mar. 3, 2020).

143 *See* Rutschman, *supra* note 9, at 174.

144 *Supra* Part II.A.1.b; *see* Jay Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, then Sold them to Pharma*, KHN (Aug. 25, 2020), https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/.

145 Jay Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, then Sold them to Pharma*, KHN (Aug. 25, 2020), https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/.

COVID-19 variants[146] continue to spread across the world at alarming speed. As of the writing of this Article, thousands of variants have been identified.[147] Although only five are considered variants of concern,[148] it is indisputable that the longer the pandemic draws on, the more variants will develop that either decrease the effectiveness of existing antiviral technologies or render them ineffective altogether.

The COVID-19 pandemic has also revealed glaring flaws in the global healthcare network that future viruses could potentially exploit to bring about even more devastating pandemics. By far, the largest deficiency in the global response to COVID-19 is that it was not a *unified* global response. Although pharmaceutical companies were able to develop a vaccine for the original virus in record time, politics, supply issues, and vaccine nationalism prevented rapid production and equitable distribution efforts from being realized before significant variants of concern (such as the Delta and Omicron variants) began impacting their effectiveness.

This Part will present a detailed plan for a new organization, a Multilateral Council on Pandemic Response (hereinafter the Council). It will have the ability to strengthen international IP collaboration and sharing through a broad range of powers. Chief among those powers would be the ability to investigate global pathogenic events and institute a variety of IP licensing regimes to increase antiviral technology development and distribution in a timely manner. This Part will also propose a regulatory structure that would allow the Council

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[146] *Tracking SARS-CoV-2 Variants*, WORLD HEALTH ORG., https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (last visited Oct. 19, 2021), [https://perma.cc/X87Z-XSGC] (explaining that variants are mutations of an original virus that occur over time. Although most have no impact on the the virus's properties, some variants "affect the virus's properties, such as how easily it spreads, the associated disease severity, or the performance of vaccines, therapeutic medicines, diagnostic tools, or other public health and social measures.").

[147] Meryl Davids Landau, *Is a Variant Worse than Delta on the Way? Viral Evolution Offers Clues*, NAT'L GEOGRAPHIC (Sep. 17, 2021), https://www.nationalgeographic.com/science/article/is-a-variant-worse-than-delta-on-the-way-viral-evolution-offers-clues [https://perma.cc/N27C-MEY2].

[148] *Tracking SARS-CoV-2 Variants*, WORLD HEALTH ORG., https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (last visited Oct. 19, 2021), [https://perma.cc/X87Z-XSGC].

to establish pipelines for raw materials essential to antiviral treatments. Additionally, it will advance an argument for an internal dispute resolution system to expeditiously resolve legal claims that might hinder the Council's mission. Finally, this Part proposes a funding structure similar to tried and tested systems already in effect to combat other diseases, as well as a novel approach.

A. Participating Entities

The Council must have the ability to influence different sectors of the global network so that it can effectively manage the various facets of healthcare IP and end product distribution. The Trilateral Cooperation Agreement discussed above demonstrates the need for IGO cooperation to address all aspects of a global vaccination initiative.[149] Relevant sectors include intellectual property, healthcare, and international trade, touching the expertise of the WIPO, WHO, and WTO. The Council would build on that spirit of cooperation by further incorporating the perspectives and cooperation of the IMF and the World Bank.

1. Responsibilities of Each IGO

With so many moving parts and organizations at play, the Council must define clear areas of influence for each IGO so as to minimize confusion as to what each organization's role is. Each IGO has the ability to control their own area of influence while still contributing knowledge and manpower to develop solutions that touch on multiple areas of influence.

Like in several of the newer cooperation agreements including the Trilateral Cooperation Agreement, [150] the WHO, WIPO, and WTO will form the backbone of the Council. The WHO is a specialized United Nations agency that "connects nations, partners and people to promote health, keep the world safe, and serve the vulnerable" through "expand[ing] universal health coverage."[151] It also coordinates global

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149 *See supra* III.B.

150 *See supra* Part III.B.1.

151 *About WHO*, WORLD HEALTH ORG., https://www.who.int/about (last visited Nov. 24, 2021).

responses to health emergencies by gathering data on potential healthcare emergencies[152] and grading those emergencies to determine whether to trigger WHO protocols.[153] Those protocols include activating initiatives like the R&D Blueprint, which is a "global strategy and preparedness plan that allows the rapid activation of research and development activities during epidemics."[154] The R&D Blueprint for COVID-19 is comprehensive and details the WHO's efforts towards developing disease identification and vaccine development initiatives into global collaboration projects.[155] These responsibilities, namely threat detection and response coordination, would carry over to the WHO's responsibilities in the Council. Where its efforts would benefit from the Council is in enhanced threat detection, treatment research and development, and therapeutic production.

Treatment research and development largely hinges on intellectual property issues. Because of the exorbitant costs of researching and developing medical treatments, pharmaceutical companies often protect their research and products with a myriad of process and utility patents.[156] Although patents disclose the best method to make the invention, pharmaceutical companies also use trade secrets to protect critical components of a pharmaceutical's design to further discourage replication.[157] These patents and trade

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[152] *Surveillance*, WORLD HEALTH ORG., https://www.who.int/emergencies/surveillance (last visited Nov. 24, 2021) (describing the WHO's ability to collect health-related data and disease surveillance data to identify potential outbreaks); *see also Risk Assessments*, WORLD HEALTH ORG., https://www.who.int/emergencies/risk-assessments (last visited Nov. 24, 2021) (describing the public health related risk assessments the WHO presents to the UN Secretary-General's Office); *WHO Grading of Public Health Events and Emergencies*, WORLD HEALTH ORG., https://www.who.int/emergencies/grading (last visited Nov. 24, 2021).

[153] *WHO Grading of Public Health Events and Emergencies*, *supra* note 152.

[154] *R&D Blueprint and COVID-19*, WORLD HEALTH ORG., https://www.who.int/teams/blueprint/covid-19 (last visited Nov. 24, 2021).

[155] *COVID-19 Research and Innovation Achievements*, WORLD HEALTH ORG., at 6–15, 18 (Apr. 2021), https://www.who.int/publications/m/item/covid-19-research-and-innovation-achievements.

[156] Stanley Plotkin et al., *The Complexity and Cost of Vaccine Manufacturing – An Overview*, 35 VACCINE 4064, 4065 (2017).

[157] Allison Durkin et al., *Addressing the Risks that Trade Secret Protections Pose for Health and Rights*, 23 HEALTH & HUMAN RIGHTS J., 129, 132–34 (2021).

secrets impact collaboration and the licensing initiatives that will be proposed later in this Part. As the leading IP-focused IGO, the WIPO is well suited to deal with these issues in the context of global healthcare.[158] WIPO's mission includes "shap[ing] international IP rules" and providing "global services to protect IP across borders and to resolve disputes."[159] Additionally, it provides "technical infrastructure to connect IP systems and share knowledge," and supports "cooperation and capacity-building programs to enable all countries to use IP for economic, social and cultural development."[160] In the existing Trilateral Cooperation Agreement, the WIPO attempted to fulfil that mandate by developing IP training institutions and hosting technology transfer and licensing workshops.[161] Its role in the new Council would expand its responsibilities into regulating licensing frameworks and incentivizing voluntary technology sharing while still preserving IP-holders' rights.[162]

Favorable trading conditions are also key to a rapid response to an emergency. Access to a consistent supply of raw materials, or lack thereof, is a frequent impediment that hinders pharmaceutical companies' response to global health events. Vaccine manufacturers often have to source components from all over the world.[163] Trading those components in a cost effective and timely manner will allow for faster research, scaled up production, and more efficient

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158 *Inside WIPO*, WORLD INT'L PROP. ORG., https://www.wipo.int/about-wipo/en/ (last visited Nov. 24, 2021).

159 *Id.*

160 *Id.*

161 *WIPO's COVID-19 Related Services and Support*, WORLD INT'L PROP. ORG., https://www.wipo.int/covid-19/en/ (last visited Nov. 24, 2021).

162 *See supra* Part III.B.2.

163 Shyam Rele, *COVID-19 Vaccine Development During Pandemic: Gap Analysis, Opportunities, and Impact on Future Emerging Infectious Disease Development Strategies*, HUM. VACCINES & IMMUNOTHERAPEUTICS 1, 1–2 (2020), https://www.tandfonline.com/doi/full/10.1080/21645515.2020.1822136 [https://perma.cc/LE2L-MNCH].

distribution.[164] The WTO facilitates trading between nations.[165] Its goal is to "ensure that trade flows as smoothly, predictably and freely as possible."[166] It accomplishes this by removing red tape and expediting transit for trade goods.[167] The WTO is currently working on an expedited vaccine delivery method that includes measures such as (1) expediting vaccine approval, (2) expediting border clearances, (3) encouraging member states to lower tariffs on therapeutics, and (4) relaxing regulatory standards.[168] The WTO's role while on the Council during future pandemics would mirror these responsibilities as well as facilitating raw material procurement. International trade collaboration through incentivization or tariffs, if necessary, will streamline the end-to-end process of vaccine development and distribution.

The last two members of the Council are the IMF and the World Bank. The IMF is an IGO with over 190 member states that is tasked with "foster[ing] global monetary cooperation, secur[ing] financial stability, facilitat[ing] international trade, promot[ing] high employment and sustainable economic growth, and reduc[ing] poverty around the world."[169] As discussed earlier, insufficient funding has restricted many of the WHO's initiatives.[170] The IMF has experience developing innovative financing structures to support WHO-led healthcare initiatives.[171] Liaising with it to manage the organization's financial support structure would bring logistical and experiential support from seasoned financial experts.

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164 *See* Chad P. Brown & Thomas J. Bollyky, *The World Needs a COVID-19 Vaccine Investment and Trade Agreement*, *in* PIIE BRIEFING 21-3: MAKING THE MOST OF THE 2021 WTO MINISTERIAL, PETERSON INST. FOR INT'L ECON. 6, 6, 8–9 (Oct. 2021), https://www.piie.com/sites/default/files/documents/piieb21-3.pdf.

165 *The WTO*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/thewto_e.htm (last visited Nov. 24, 2021).

166 *Id.*

167 *Id.*

168 *The Global Race to Vaccinate COVID-19*, WORLD TRADE ORG. (Aug. 10, 2021), https://www.wto.org/english/tratop_e/covid19_e/global_race_infographic_e.pdf.

169 *About the IMF*, INT'L MONETARY FUND, https://www.imf.org/en/About (last visited Oct. 19, 2021).

170 *See supra* Part II.C.1.

171 *See supra* Part III.C.1.

The World Bank would support the IMF with financing structures and dispute resolution in lower-to-middle income countries ("LMICs"). While the IMF primarily works to stabilize international financial and monetary systems, the World Bank "works with developing countries to reduce poverty and increase shared prosperity."[172] Since the start of the pandemic, the World Bank has focused on mitigating the economic effects of the lockdowns, facilitating investments in LMICs, and funding vaccine initiatives that deliver treatments and personal protective equipment to those countries.[173]

The World Bank also has a dispute resolution arm, the International Centre for Settlement of Investment Disputes ("ICSID"), that deals with international investment dispute settlement.[174] ICSID arbitrates disputes between international actors arising out of matters including financing, technology, and investment.[175] The World Bank's existing experience in dealing with global disasters and its dispute resolution platform would bring versatility and feasibility to the Council.

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[172] *The World Bank Group and The International Monetary Fund (IMF)*, WORLD BANK, https://www.worldbank.org/en/about/history/the-world-bank-group-and-the-imf (last visited Nov. 24, 2021).

[173] *How the World Bank Group is Helping Countries Address COVID-19 (Coronavirus)*, WORLD BANK, https://www.worldbank.org/en/news/factsheet/2020/02/11/how-the-world-bank-group-is-helping-countries-with-covid-19-coronavirus (last updated Oct. 1, 2021). *See also World Bank Financing for COVID-19 Vaccine Rollout Reaches $2 Billion*, WORLD BANK (Apr. 20, 2021), https://www.worldbank.org/en/news/press-release/2021/04/20/world-bank-financing-for-covid-19-vaccine-rollout-reaches-2-billion (detailing the World Bank's $6 billion in donations to funding vaccine and personal protective equipment initiatives in LMICs as well as its overall plan to finance $12 billion into the project over 24 months).

[174] *About ICSID*, INT'L CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES, https://icsid.worldbank.org/About/ICSID (last visited Nov. 28, 2021).

[175] *See generally*, *Introducing ICSID*, INT'L CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES, at 1 (last visited Nov. 24, 2021), https://icsid.worldbank.org/sites/default/files/ICSID_Primer_1.16.19.pdf (describing the capabilities and purpose of ICSID).

Together the WHO, WIPO, WTO, IMF, and World Bank would form the core of the new Council. Similar to how countries are represented in the UN, each IGO would have delegates that would represent their interests on the Council and liaise with state actors and non-governmental organizations ("NGOs") in their area of expertise.[176] Delegates from each relevant IGO would be in subcommittees based on the responsibilities outlined in the Council's Scope of Charter below.

B. Scope of Charter

As a preliminary matter, and because of the wealth of talent that the previous Section involves, the Council would have broad reach over the end-to-end process of identifying a virus, developing a treatment, and distributing that treatment in a timely and equitable fashion. It would also facilitate economic recovery and arbitrate disputes arising out of the Council's actions. This reach is necessary to ensure a comprehensive response to global health events like pandemics. The international community responded quickly to COVID-19 in some ways, but in others, such as IP collaboration, it lagged due to understandable bureaucratic roadblocks.[177] The Council must have the authority to engage parties like pharmaceutical companies and national governments in meaningful dialogue with the power to influence those discussions with incentives and guarantees. These incentives would serve to establish licensing structures for relevant intellectual property and later pave the way for raw resource procurement at favorable rates so as to assist in expediting the production of affordable treatments.

This Section will break down the Council's powers over virus identification, treatment, and dispute resolution. It will also cover

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[176] Other IGOs, like the International Medical Device Regulators Forum, which supports the international regulation and distribution of critical devices like ventilators and test kits, have situational relevance based on the crisis at hand. *See About IMDRF*, INT'L MEDICAL DEVICE REGULATORS FORUM (last visited Apr. 20, 2022), https://www.imdrf.org/about [https://perma.cc/58U9-XTMD]. Therefore, while these IGOs are not full members of the Council, liaising with them when their field of expertise is relevant will allow the Council to efficiently leverage expertise while remaining cost effective.

[177] *See supra* II.A.2.b.

funding models to support this initiative and address any risks or concerns associated with the council's structure and ability to carry out its proposed responsibilities. As noted previously, many of the Council's members already carry out responsibilities similar to those assigned forthwith.[178] The purpose of the Council is to engage in a concerted global response when a pandemic is identified. To that end, where the Council's responsibilities overlap with those of the individual IGOs, the IGOs would work independently per their mandate until a pandemic is identified. When that pandemic is identified, the IGOs' overlapping responsibilities would be subsumed into the overarching imperatives of the Council.

1. Investigative Capabilities

First and foremost, among the Council's powers would be the ability to investigate emerging diseases and their origins. Tracking the origin of a viral outbreak is critical to understanding it. By studying where a virus came from, researchers are able to learn how it interacts with other organisms and the environment around it, how it spreads, and potentially even how it may be stopped or countered.[179] In particular, studying other host organisms to determine at what point the virus becomes zoonotic (transmissible to humans) has provided researchers a host of information, including potential avenues to explore to develop antiviral treatments.[180]

Epidemiologists have also been able to use investigations of existing pandemics to predict future ones, including COVID-19. COVID-19 is the third zoonotic coronavirus to emerge in the 21st century, following the SARS-CoV virus in 2003,[181] and the MERS-CoV virus in 2012.[182] Scientists were able to predict the emergence of

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178 *See supra* Part IV.A.1.

179 Qihui Wang et al., *Tracing the Origins of SARS-CoV-2: Lessons Learned from the Past*, 21 CELL RES. 1139, 1139–40 (2021).

180 *Id.* at 1139–40.

181 *CDC SARS Response Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/history/sars/timeline.htm (last visited Nov 22. 2021).

182 *Middle East Respiratory Syndrome Coronavirus (MERS-CoV)*, WORLD HEALTH ORG. (Mar. 11, 2019), https://www.who.int/news-room/fact-sheets/detail/middle-east-respiratory-syndrome-coronavirus-(mers-cov).

COVID-19 as far back as 2016, when they collated data from the previous two coronavirus outbreaks.[183] Additionally, the data gathered from the previous outbreaks provided a strong starting point when researchers began studying COVID-19.[184] The similarities between the COVID-19, SARS-CoV, and MERS-CoV enabled those researchers to access and leverage a wealth of data and epidemiological research that jumpstarted therapeutic development and treatment.[185] This experience underscores the importance of allowing researchers timely on-site access at emerging outbreak epicenters and logistical support to conduct expansive field tests.

The COVID-19 pandemic drove this lesson home. When the disease first appeared in Wuhan, WHO investigators flew to China but were received coldly and granted only limited access.[186] Although the WHO publicly praised China's cooperation with its investigators, China withheld COVID-19's genetic sequence for more than a week after it had decoded it.[187] China also delayed providing the WHO access to critical disease transmission data within international

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[183] Shuo Su et al., *Epidemiology, Genetic Recombination, and Pathogenesis of Coronaviruses*, 24 TRENDS IN MICROBIOLOGY 490, 490, 496, 499 (2016). *See also* Qihui Wang et al., *Tracing the Origins of SARS-CoV-2: Lessons Learned from the Past*, 21 CELL RSCH.1139, 1139 (2021) ("After the outbreaks of two zoonotic coronaviruses (CoVs), severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV), researchers worldwide have reached a consensus that the occurrence of the next CoV spillover event is only a matter of time, as supported by research data and the natural laws of pathogen emergence.").

[184] Yen-Der Li et al., *Coronavirus Vaccine Development: From SARS and MERS to COVID-19*, 27 J. BIOMED. SCI. 1, 1, 2 (2020), https://jbiomedsci.biomedcentral.com/track/pdf/10.1186/s12929-020-00695-2.pdf.

[185] *Id.*

[186] Jon Cohen, *'The House was on Fire.' Top Chinese Virologist on How China and U.S. Have Met the Pandemic*, SCIENCE INSIDER (May 22, 2020), https://www.science.org/content/article/house-was-fire-top-chinese-virologist-how-china-and-us-have-met-pandemic [https://perma.cc/YW8B-JBMK]; *see also China has Rejected A WHO Plan for Further Investigation into the Origins of COVID-19*, NPR, (Jul. 22, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/07/22/1019244601/china-who-coronavirus-lab-leak-theory.

[187] *China Delayed Releasing Coronavirus Info, Frustrating WHO*, A.P. NEWS (Jun. 2, 2020, 2:04 PM), https://apnews.com/article/united-nations-health-ap-top-news-virus-outbreak-public-health-3c061794970661042b18d5aeaaed9fae.

statutory regulations and refused researchers access to Wuhan—ground zero for the initial outbreak.[188] Furthermore, the Chinese government also censored doctors who attempted to share relevant information and instead had officials declare over and over that the COVID-19's risk of transmission was low.[189] In fact, the struggle to properly investigate the origins of the virus continues even now. China rejected multiple plans to study the origins of COVID-19 throughout 2020 and 2021,[190] and in the instances where it allowed independent researchers in, actively screened their access to data or withheld relevant information altogether.[191] These obstructionist behaviors significantly hindered the WHO, and by extension the world's ability to understand and respond to the virus.[192]

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188 *Id. See also* Donald G. McNeil Jr. & Zolan Kanno-Youngs, *C.D.C. and WHO Offers to Help China Have Been Ignored for Weeks*, N.Y. TIMES (Feb. 7, 2020), https://www.nytimes.com/2020/02/07/health/cdc-coronavirus-china.html (stating that although Chinese doctors stated a need for external assistance in early 2020, the Chinese government refused CDC and WHO assistance).

189 *China Exonerates Doctor Reprimanded for Warning of Virus*, A.P. NEWS (Mar. 19, 2020), https://apnews.com/article/virus-outbreak-accidents-ap-top-news-international-news-arrests-6f2e666485e9abae4bb112251eca77be. *See also* Nectar Gan et al., *Beijing Tightens Grip over Coronavirus Research, Amid US-China Row on Virus Origin*, CNN (last updated Apr. 16, 2020, 4:10 AM), https://www.cnn.com/2020/04/12/asia/china-coronavirus-research-restrictions-intl-hnk/index.html (noting that China imposed restrictions on the publication of any academic research pertaining to the origin of COVID-19, actively censored publications from leading research universities, including Fudan University and the China University of Geoscience, and suppressing researchers who presented research that contradicted the government's narrative).

190 *Coronavirus: China Rejects Call for Probe into Origins of Disease*, BBC (Apr. 24, 2020), https://www.bbc.com/news/world-asia-china-52420536; Associated Press, *China Has Rejected a WHO Plan for Further Investigation into the Origins of COVID-19*, NPR (Jul. 22, 2021, 9:44 AM), https://www.npr.org/sections/coronavirus-live-updates/2021/07/22/1019244601/china-who-coronavirus-lab-leak-theory.

191 Javier C. Hernández & James Gorman, *On W.H.O. Trip, China Refused to Hand Over Important Data*, N.Y. TIMES (last updated Jun. 16, 2021), https://www.nytimes.com/2021/02/12/world/asia/china-world-health-organization-coronavirus.html; *Covid: WHO Team Investigating Virus Origins Denied Entry to China*, BBC (Jan. 6, 2021), https://www.bbc.com/news/world-asia-china-55555466.

192 Stephanie Nebehay & John Miller, *Data Withheld from WHO Team Probing COVID-19 Origins in China: Tedros*, REUTERS (Mar. 30, 2021, 10:56 AM),

As easy as it is to solely blame China for the communication breakdown that set the WHO and other research divisions behind, many other countries were slow to provide relevant data that would have helped researchers combat COVID-19. The inability to identify COVID-19 outbreaks and collect data on its transmissibility in developing countries such as Iran and Brazil hindered epidemiologists' attempts to grasp the scope of the pandemic.[193] Even more recently, insufficient testing and reporting in India during the summer of 2021 prevented scientists from seeing the full scope of the Delta variant's virulence.[194]

To resolve this issue, the Council would support existing WHO pandemic investigation teams with gathering information at emerging hotspots in two major ways. First, it would work directly with hospitals and private healthcare partners to cut through the red tape and allow researchers access to all existing and relevant data. To do this it would be responsible for developing a standardized virus origin study plan that is pre-approved by all UN member states. This plan would be adaptable to different situations as the situation requires. However, it would retain basic procedures and practices as well as a predetermined set of data types that investigators would need, such as accurate infection rates by geographic area. Pre-approval of access to the most critical data would allow researchers to immediately begin collating and analyzing information while local governments hash out

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https://www.reuters.com/article/us-health-coronavirus-who-china-report/data-withheld-from-who-team-probing-covid-19-origins-in-china-tedros-idUSKBN2BM26S.

193 Maggie Michael, *Doctors and Nurses Suffered as Iran Ignored Virus Concerns*, ASSOCIATED PRESS NEWS (May 12, 2020), https://apnews.com/article/virus-outbreak-health-ap-top-news-international-news-iran-6c7715f300797502329f6117e1141503; David Biller, *In Bolsonaro's Brazil, Everyone Else is to Blame for the Virus*, ASSOCIATED PRESS NEWS (May 25, 2020), https://apnews.com/article/virus-outbreak-health-caribbean-ap-top-news-brazil-7a7e8a0d3c524986412245ec9a23fad0.

194 Denise Chow, *Where's the Data on Delta? Lack of Testing, Info Makes it Hard to See Virus's Full Scope*, NBC NEWS (Aug. 19, 2021, 7:44 AM), https://www.nbcnews.com/science/science-news/delta-variant-response-hindered-covid-test-limitations-lack-data-rcna1692.

a more detailed and virus specific action plan for the immediate situation.

Second, if countries refuse to provide necessary information or grant investigators access, the Council must have the ability to exert economic and social pressures on them to compel cooperation. As COVID-19 has proven, non-cooperation that leads to a delay in the response to a virus can have drastic and lasting effects on the world as a whole, regardless of where the virus originated. The Council would have the power to put forward a sanctioning regime against uncooperative countries. Ultimately the UN would have the final decision on whether to apply the sanctioning regime, but by ensuring that it receives expedited review, the Council can exert pressures that hold countries accountable to the rest of the world for obstructionist behavior.

Once the Council has sufficient data to properly analyze emerging viral threats, it would then determine the severity of the threat. The Center for Disease Control and Prevention identifies an epidemic as "an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area."[195] A pandemic emerges when multiple epidemics "occur over a wide area and cross international boundaries to usually affect a large number of people."[196] Because the proposed Council addresses global threats, its role in addressing localized epidemics would be minimal apart from continued monitoring and investigation. If or when an epidemic becomes a pandemic, the Council's additional responsibilities of developing response plans would kick in.

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[195] U.S. Dep't of Health and Human Servs., Epidemic Disease Occurrence, Section of Lesson One: Introduction to Epidemiology, of Principles of Epidemiology in Public Health Practice 3d ed., CTRS. FOR DISEASE CONTROL AND PREVENTION 1-1, 1-72 (May 2012), https://www.cdc.gov/csels/dsepd/ss1978/SS1978.pdf [https://perma.cc/9HSP-P68U].

[196] *Padmanabhan*, *supra* note 24, at 111 (citing *Pandemic*, A DICTIONARY OF EPIDEMIOLOGY 209 (Miguel Port et al. eds, 6th ed. 2014)).

2. Voluntary and Non-Voluntary Licensing Capabilities

Assuming that the viral outbreak grows to pandemic proportions, the Council's next role would be to facilitate technology transfer. As previously mentioned, slow or nonexistent technology sharing hinders a rapid response to viral threats. Time and effort are wasted because each pharmaceutical manufacturer must reinvent the wheel and find their own way to make the cure. Much of that time and money could be saved if manufacturers shared information and IP early on to guide others away from formulas or methods that were already proven unsuccessful. To be clear, however, this is not an endorsement of free technology sharing. Free and unrestricted sharing would provide little incentive for pharmaceutical companies to innovate because the R&D costs alone would be prohibitive if there were no guarantee of a return on investment.

The Council that this blueprint proposes would have the power to facilitate voluntary and non-voluntary licenses. Voluntary licenses are far more collaborative by nature and will be prioritized as a way of sharing IP. Non-voluntary licenses would be a last resort and would be treated as such.

a. Voluntary Licensing

Voluntary licensing should be the first approach to bring pharmaceutical companies to the table to share their IP. It is collaborative and far less adversarial than non-voluntary licensing. As previously mentioned, voluntary licenses are a contract between the pharmaceutical company and a licensee wherein the licensee compensates the pharmaceutical company in return for access to the IP.[197] The Council can facilitate this process by working with state or private licensees to provide sufficient incentives to encourage a pharmaceutical company to license. Easing up on international loan interest rates or international tariffs might provide tantalizing incentives for manufacturers to enter a deal with the pharmaceuticals. In exchange for helping the manufacturers enter a beneficial deal, the manufacturers would have to assist the Council in deploying a

197 *See supra* Part II.A.b.

percentage of the treatments to where the Council would deem fit. This would likely end up being in a country in the global south that lacks the infrastructure or capabilities to produce their own treatments.

On the other side, the Council would also negotiate with the pharmaceutical companies and other IP rights-holders to encourage them to enter contracts with the licensees. There too the Council has a wide variety of levers to pull that might make the arrangement palatable to licensors. By working with the global community to guarantee favorable trading terms for vaccine components or facilitating expedited (yet still thorough) clinical reviews of the finished products, the Council can provide pharmaceutical companies a wealth of support to increase their profits and decrease their costs. In exchange for that support the pharmaceutical companies would also commit to subsidizing and distributing a portion of their inventory to developing nations. The WHO contingent of the Council can work with existing vaccine delivery initiatives like the COVID-IP Pledge and International Drug Purchase Facility to equitably deliver pharmaceuticals to the global south.

b. Non-Voluntary Licensing

Although the Council should use voluntary licensing as the primary method of facilitating IP sharing, it must also have the ability to issue non-voluntary licenses if needed. Non-voluntary licenses are licenses of an IP rights-holder's IP without their consent.[198] They have little to no control over the terms of the lease, including who the licensees are and how long the licenses are in effect.[199] This lack of control makes them highly unpalatable to rights holders and developed IP regimes alike.

Despite that unpopularity, however, international treaties such as the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement, provide statutory support for the use of non-

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[198] Mark W. Lauroesch, *General Compulsory Patent Licensing in the United States: Good in Theory, But Not Necessary in Practice*, 6 SANTA CLARA HIGH TECH. L.J. 41, 41, 47 (1990).

[199] Gianna Julian-Arnold, International Compulsory Licensing: The Rationales and the Reality, 33 IDEA 349, 350–54 (1993).

voluntary licenses in certain circumstances.[200] Articles 8, 30, and 31 work in tandem to support a sovereign nation's ability to issue non-voluntary licenses and abridge patent rights to "adopt measures necessary to protect public health and nutrition"[201] provided they pay adequate remuneration.[202] Additionally, Article 31*bis* allows TRIPS-compliant importing powers to countries without the infrastructure to manufacture their own vaccines.[203]

Although there is a wealth of TRIPS provisions at the international level, and at national level in individual nations' intellectual property licensing regimes, non-voluntary licensing is underused because of the countervailing interests at stake. Although pharmaceutical companies often pay billions of dollars for research and development, rigorous patent and trade secret protections on their therapeutics allow them to reap the rewards when they charge higher prices for their products.[204] These companies are often loath to part with their rights or allow others to develop alternative manufacturing methods that might result in cheaper generic versions of their pharmaceuticals. Developing nations favor compulsory licensing regimes that give them access to generic drugs[205] because they cannot afford to license the patented intellectual property and their citizens cannot afford the patented drug.

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[200] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex I.C., LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (as amended on Jan. 23, 2017), https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf [https://perma.cc/K2YE-DQC3] [hereinafter TRIPS Agreement].

[201] *Id.* art. 8.

[202] *Id.* arts. 30, 31.

[203] *Id.* art. 31*bis*.

[204] Stanley Plotkin, *Increasing Complexity of Vaccine Development*, 212 J. INFECTIOUS DISEASES S12, S12 (2015).

[205] *Generic Drug Facts*, FOOD & DRUG AGENCY (Feb. 22, 2021), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts [https://perma.cc/32MJ-33C9] (defining a generic pharmaceutical as "a medication created to be the same as an existing approved brand name-drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.").

The myriad of conflicting interests provides the perfect incentive to grant an independent organization the power to issue non-voluntary licenses during medical emergencies. The Council would have control over international compulsory licensing regimes and their implementation. The Council's charter will give it the power to implement compulsory licensing regimes on a case-by-case basis to help regions that were unable to previously secure a voluntary license. What would distinguish these regions from those that would normally benefit from equitable vaccine distribution initiatives is manufacturing capability. A nation could submit a request to the Council for an emergency license if it has the ability to manufacture safe and reliable treatments yet is unable to do so because (1) its native R&D initiatives are struggling, and (2) manufacturers refuse to grant it licenses to critical IP. The Council would review that request in context of the surrounding circumstances and determine whether or not to use TRIPS to compel IP sharing.

This approach to compulsory licensing leverages TRIPS provisions for their intended use while mitigating the effects of a significant hindrance to compulsory licensing: individual countries' reluctance to abrogate IP rights. As previously mentioned, many wealthy countries are reluctant to issue compulsory licensing provisions because they supposedly run counter to their ideals as capitalist economies.[206] These countries even go so far as to openly oppose other countries when they invoke compulsory licensing provisions to deal with domestic health emergencies.[207] This can result in lengthy legal battles that stymie IP sharing and stagnate innovative development.[208] By allowing an international body to issue licenses, much of the nation-specific agendas can be circumvented. The WHO

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206 *See supra* Part III.C.2.

207 Sara M. Ford, Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents, 15 AM. U. INT'L L. REV. 941, 955–56 (2000) (describing when the U.S. threatened trade sanctions against South Africa because it issued compulsory licenses for AIDS medication).

208 Bayer Corp. v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/compulsory_IPAB_Final_EN.pdf [https://perma.cc/T3K6-HDLC] (showing one example of a lengthy legal battle over compulsory licensing provisions in a developing country).

and WIPO are members of the Council, and can provide the countervailing perspectives necessary for the whole Council to review compulsory licensing requests holistically. If litigation were to still ensue after a license was issued, the dispute resolution arm of the Council would already have much of the material needed to resolve it expeditiously.[209]

1. The Last Resort License

The Council's charter should also include a contingency power to be used if a situation were to emerge that voluntary licensing and non-voluntary licensing could not address. In October 2020, India and South Africa proposed a radical IP waiver that would waive all IP rights until the end of the pandemic.[210] Although that version failed to gain traction, a revision in May that included a more definite sunset clause[211] received more support—including from the United States.[212] While it remains to be seen whether the revised waiver will be adopted, the fact remains that instituting blanket IP waivers for every future pandemic will likely be untenable given the importance of IP rights to progress and development.

That said, the Council should have a "break glass in case of emergency" power to issue non-voluntary licenses for entire geographical regions if they are still struggling to combat a pandemic

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209 *See infra* Part IV.B.4.

210 Request for Waiver by India & South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True [https://perma.cc/A6F3-Q57M] [hereinafter India/South Africa Waiver].

211 Communication from the African Group et al., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/669/Rev.1 (May 25, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True [https://perma.cc/BS9Y-DPSM] (setting the effective duration of the waiver to three years, subject to an extension if necessary at that point).

212 Andrea Shalal et al., *U.S. Reverses Stance, Backs Giving Poorer Countries access to COVID Vaccine Patents*, REUTERS (May 5, 2021, 2:10 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ [https://perma.cc/385X-NNKL].

even after voluntary and localized non-voluntary licenses have been instituted. In a previous paper, we proposed a licensing structure based on a North Atlantic Treaty Organization ("NATO") Article 5 Resolution.[213] If a country were to bring a demand for a united defense against a viral threat before the WHO, the WHO would, following a majority vote in favor of such action, issue widespread non-voluntary licenses to swiftly address the threat.[214] This blueprint expands on that proposal by giving the Council control over the beginning and end of that process. The Council would bring the proposal for widespread licensing provisions before the WHO. If the majority of the WHO's members vote in favor of compulsory licensing, the Council would take over and issue the licenses and manage any disputes that arise.

The overarching goal is to provide the Council a variety of options when it comes to licensing so that they can address different situations with responses of commensurate weight. This will allow the Council to respond efficiently in a manner that balances the rights of IP rights-holders and the general population as equitably as possible.

3. Ability to Establish Rapid-Response Raw Material Pipelines

In addition to licensing to promote IP sharing, the Council must also facilitate the next stage of pharmaceutical development: manufacturing and production. Raw material procurement is one of the most significant bottlenecks to both development and production.[215] Each vaccine requires raw materials that must be sourced from around the world and purified in expensive processes.[216] Supply chain breakdowns are significant hurdles that often severely bottleneck the production process and overall response to viral threats at inopportune times.[217] This was especially evident during the COVID-19 pandemic because the global supply chains for most

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213 *Padmanabhan*, *supra* note 24, at 111.

214 *Id.*

215 Plotkin et al., *supra* note 156.

216 *Id.*

217 Costa Paris, *Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target*, WALL. ST. J. (Dec. 3, 2020, 6:58 PM), https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787 [https://perma.cc/LHE8-ZDFN].

industries were impacted in some way by various lockdowns.[218] Further complicating this issue is the desire of countries to hoard materials for domestic production and use. Vaccine components and personal protective equipment hoarding are an extension of vaccine nationalism that has further strained the supply lines and available resources for a unified global response.[219]

The Council would alleviate these trade pressures by building the framework for flexible trade pipelines that go into effect when a pandemic is identified. Free trade agreements like the North American Free Trade Agreement reduce or eliminate barriers to trade and investment between signatories.[220] An analogous treaty between WHO members that specifically covers healthcare related trade items and only takes effect if a pandemic is identified would create a trade corridor for those goods as soon as they are needed. Pre-negotiated rates and trade systems will help healthcare product manufacturers avoid some of the struggles that existing manufacturers are facing during this pandemic: limited resources are only available at exorbitant costs. The downstream effects of this improvement would of course help pump more treatments out faster, thereby alleviating COVAX and other vaccine distribution initiatives' continuous struggle to compete with wealthier entities for treatments.

Global trade of critical supplies might also be well served if the trade agreement included a corollary that lays out a procedure for rapid cargo transportation when the world locks down. The WHO and UNICEF created a Supply and Logistics Guidance manual in February 2021 that lays out a procedure for shipment and delivery of both the

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[218] Holly Ellyatt, *Supply Chain Chaos is Already Hitting Global Growth. And It's About to Get Worse*, CNBC (Oct. 18, 2021, 6:28 AM), https://www.cnbc.com/2021/10/18/supply-chain-chaos-is-hitting-global-growth-and-could-get-worse.html [https://perma.cc/9E2R-EUD8].

[219] Bhuma Shrivastava & Chris Kay, *Vaccine Hoarding May Backfire on Rich Nations as India Reels*, BLOOMBERG (Apr. 27, 2021, 5:16 AM), https://www.bloomberg.com/news/articles/2021-04-27/vaccine-hoarding-set-to-backfire-on-rich-nations-as-india-reels [https://perma.cc/Y5KK-5V9N].

[220] *See North American Free Trade Agreement (NAFTA)*, INT'L TRADE ADMIN. (Jul. 1, 2020), https://www.trade.gov/north-american-free-trade-agreement-nafta [https://perma.cc/T2H7-W6BN].

vaccine components and finished product.[221] It lays out guidance for how to prepare for and execute a vaccination campaign as well as how to maintain logistic supply trains during tumultuous viral events.[222] Standardizing those recommendations and supporting the infrastructure ahead of a pandemic will help when countries begin restricting movement, trade, and transportation.

To further alleviate trade pressures and streamline distribution, the Council would use its trade initiatives to also streamline regulatory approval. As previously mentioned, regulatory approval bottlenecks pharmaceutical production and distribution.[223] Regulatory agencies, like the Food and Drug Administration ("FDA"), conduct redundant and wasteful trials all over the world instead of collaborating and sharing data.[224] Not only does this result in profligate waste of resources, but also of time.[225] However, as of late, regulatory agencies have been looking for ways to share data. Examples of data sharing using large scale real-world data ("RWD"), already exist in Japan, Europe, and the U.S.[226] And, as the FDA increasingly trusts RWD when making regulatory approval decisions,[227] RWD sharing has become increasingly important. By facilitating regulatory approval testing data sharing between different agencies, including the FDA and

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221 *See generally COVID-19 Vaccination: Supply and Logistics Guidance*, WHO & UNICEF (Feb. 12, 2021), https://apps.who.int/iris/bitstream/handle/10665/339561/WHO-2019-nCoV-vaccine_deployment-logistics-2021.1-eng.pdf [https://perma.cc/L5WL-BFVS].

222 *Id.* at 10–29.

223 *See supra* Part II.A.1.

224 Daria Kim & Joerg Hasford, *Redundant Trials Can be Prevented, If the EU Clinical Trial Regulation is Applied Duly*, 21 BMC MED. ETHICS 1, 2 (2020), https://bmcmedethics.biomedcentral.com/track/pdf/10.1186/s12910-020-00536-9.pdf (noting that up to 85% of clinical trials could be considered wasteful).

225 *Id.*

226 Hideki Maeda & Daniel Big Ng, *Regulatory Approval with Real-World Data from Regulatory Science Perspective in Japan*, 9 FRONTIERS. IN MED. 1, 2 (2022), https://doi.org/10.3389/fmed.2022.864960.

227 Ozlem Belen et al., *FDA Approval Demonstrates the Role of Real-World Evidence in Regulatory Decision-Making on Drug Effectiveness*, FOOD & DRUG ADMIN., https://www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness (last updated Aug. 04, 2021), [https://perma.cc/KZ6F-RNF8].

those in the European regulatory system,[228] the Council would be able to expedite review and approval for key drugs when they are needed. Fortunately, the infrastructure needed to share investigatory data[229] and intellectual property[230] can be used to effectuate this initiative.

4. Dispute Resolution

The Council's final responsibility would be dispute resolution. As previously mentioned, some of the Council's actions might spur legal claims. The issuance of a non-voluntary license, for example, might invite a claim of expropriation from a foreign pharmaceutical company whose patent is licensed and R&D investment is destroyed. The *Bayer v. Natco* case is an example of the sort of dispute that slows down the response to a pandemic.[231] Tedious court proceedings and injunctions thwart the imperative for a rapid response.

The Council will be empowered to adjudicate some of these claims and prevent others. A successful dispute resolution institution already exists that can serve as a model to emulate: ICSID.[232] Partially funded by the World Bank Group, ICSID specializes in addressing and resolving investment related disputes around the world.[233] Teams of trained international investment legal experts are assigned to each ICSID case to provide fact-finding and procedural assistance.[234] An

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228 *The European Regulatory System for Medicines: A Consistent Approach to Medicines Regulation Across the European Union*, EUR. MEDICINES AGENCY at 2 (2016), https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf ("The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 31 EEA countries (28 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA.").

229 *See supra* Part IV.B.1.

230 *See supra* Part IV.B.2.

231 Bayer Corp. v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/compulsory_IPAB_Final_EN.pdf [https://perma.cc/T3K6-HDLC].

232 *See supra* Part IV.A.1.

233 *About ICSID*, INT'L CTR. FOR SETTLEMENT OF INV. DISPS., https://icsid.worldbank.org/About/ICSID (last visited Nov. 30, 2021), [https://perma.cc/RR2X-2L6B].

234 *Id.*

independent Conciliation Commission or Arbitral Tribunal then hears evidence and legal arguments from both sides before rendering a binding award.[235] This impartial and thorough process has inspired confidence in financial entities worldwide and has allowed ICSID to manage and deliver awards in over 700 arbitrations.[236] In terms of prevention, the World Bank could work through ICSID to try to exclude Council efforts from the treaties that might give rise to expropriation or Fair and Equitable Treatment claims.

The Council could go one step further and create its own arbitral body, comparable to ICSID, capable of hearing claims and rendering awards in disputes related to the activities of the Council. The value of ICSID comes from its reputation for providing impartial and specialized support throughout the arbitration process.[237] Forum shopping is not a new concept. The practice of arbitral institutions tailoring their adjudicative expertise and administrative procedures to appeal to a niche of the legal community is tried and tested.[238] Federal judges in the Eastern and Western Districts of Texas in the United States famously tailored their courts to be patent litigation friendly by becoming experts on patent law, developing efficient and speedy administrative procedures for patent cases, and adopting beneficial local rules.[239] Although this led to the U.S. Supreme Court adopting a ruling in *TC Heartland LLC v. Kraft Food Group Brands LLC*,[240] that virtually prohibited forum shopping, the theory is still sound and can be applied to the current issue.

If the Council were to develop a dispute resolution forum like ICSID that supported international parties in pandemic healthcare and licensing claims, it would likely be able to create an appealing forum for those disputes. The Council's composition coalesces experts in

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235 *Id.*

236 *Id.*

237 Georges R. Delaume, *ICSID Arbitration and the Courts*, 77 AM. J. INT'L L. 784, 784 (1983).

238 J. Jonas Anderson, *Court Competition for Patent Cases*, U. PENN. L. REV. 631, 632 (2015).

239 *Id.* at 652.

240 TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514, 1521 (2017).

international healthcare, trade, intellectual property, and finance in one area. Problematic legal disputes that would hinder the Council's mission would have legal issues that touch on most, if not all of those specialties. Parties to those disputes who use the Council's dispute resolution system would not only benefit from experienced support on those matters, but also from a guaranteed fast-tracked resolution. The Council would expedite review of claims that affected their mission. Additionally, because the Council would lead the initiatives that are being challenged, its experts would already be well-versed in the rationale of those initiatives and have a deep understanding of the situation. Although they would not actively participate in the dispute resolution decision making, they could provide insight and data that would quickly bring the arbitrators or mediators up to speed.

The overarching goal is to develop a trusted dispute resolution system with expertise in the legal issues surrounding pandemic healthcare. By working to impartially assist aggrieved parties that are unhappy with the Council's actions, the dispute resolution system would rapidly target and address legal threats that could stymie a united global pandemic response.

C. Proposed Funding Model for Initiatives through Taxes

Finding funding to enable the Council and its initiatives will be one of the most challenging aspects to this proposal. As previously mentioned, IGOs like the WHO are woefully underfunded.[241] Voluntary contributions would likely be insufficient. The Council would therefore have to rely on other means of financial support. An obvious solution would be to fold it into another budget wherein countries would support it through their annual assessed contributions to the UN or WHO. That, however, would unlock a host of other issues and problems that are too numerous to be addressed here.

A potential solution lies in UNITAID's response to other global diseases. The airline ticket tax UNITAID uses to fund delivery of malaria, HIV, and tuberculosis relies on countries taxing a mode of transportation to fund an international healthcare initiative.[242] This

241 *See supra* Part III.A.3.

242 *Id.*

model can be adapted to fit a variety of other industries. Tourism and travel were two industries that were hit particularly hard by COVID-19.[243] The United Nations World Tourism Organization ("UNWTO") reported an estimated global loss of $1.3 trillion in export revenues stemming from the collapse of international travel.[244] Between 2019 and 2020, global international travel declined by 73%.[245] This loss was also felt in industries that intersect tourism and travel. The cruise industry in the United States contributed $55 billion to the American economy in 2019.[246] In 2020, it lost $32 billion.[247]

The survival of international tourism and travel is tied to the swift resolution of global viral events. Leveraging that need to institute national tourism taxes and cruise ticket taxes would be analogous to taxing international airline travel. And like the airline ticket tax, the tourism and cruise ticket taxes would go directly into funding Council initiatives that prevent prolonged pandemics that have the potential to hamstring the global economy.

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[243] *Secretary-General's Policy Brief on Tourism and COVID-19*, UN WORLD TOURISM ORG., https://www.unwto.org/tourism-and-covid-19-unprecedented-economic-impacts (last visited Nov. 30, 2021), [https://perma.cc/2KUN-H39L]; Matthew Graham et al., *Tourism and Related Industries Declined Sharply in Northeastern States in Spring 2020, Women and Young Workers More Affected Nationwide*, US CENSUS BUREAU (Jun. 23, 2021), https://www.census.gov/library/stories/2021/06/initial-impact-of-covid-19-on-travel-tourism-outdoor-recreation-varied-widely-across-states.html [https://perma.cc/D7LM-3CHT]; *2020: Worst Year in Tourism History with 1 Billion Fewer International Arrivals*, UN WORLD TOURISM ORG. (Jan. 28, 2021), https://webunwto.s3.eu-west-1.amazonaws.com/s3fs-public/2021-01/210128-barometer-en.pdf?GaI1QTYG.Ky9LDZ2tlDKc.iRZkinJeuH [https://perma.cc/C7XL-XPML] [hereinafter *UNWTO Tourism Report*].

[244] *UNWTO Tourism Report*, *supra* note 243.

[245] *Id.*

[246] Morgan Hines, *'Devastating Impact': Cruise Industry Says 254,000 American Jobs, $32 Billion in Economic Activity Lost*, USA TODAY (Nov. 19, 2020, 2:20 PM), https://www.usatoday.com/story/travel/cruises/2020/11/19/cruising-faces-254000-american-jobs-32-billion-lost-pandemic/3776982001/ [https://perma.cc/PLU7-CDPS].

[247] *Id.*

Starting first with the global cruise line tax, its structure would mimic the airline tax[248] in that it would be a domestic tax that would be determined by countries that choose to participate, with proceedings earmarked for use to fund the Council. From 2006 to 2011, the tax incomes from a handful of countries constituted 80% of UNITAID's funding.[249] With global support, the cruise industry would be able to offer the Council significant financial assistance if countries were to tax cruise tickets for cruises leaving their ports.

The tourism tax would be more complex. Tourism is an umbrella term for activities and services offered to individuals outside of the home environment.[250] Those services generally include local transportation, accommodation (such as hotels and inns), and ancillary services (such as shopping centers, facilities, entertainment, activities and attractions).[251] For taxing purposes, each nation's tax would be proportional to its tourism revenue. Nations would also independently set the tax rates for each service sector. The combined taxes from the service sectors would be rolled into the tourism tax revenue that the country would allocate to the Council.

Together, the tourism tax and the travel tax will help countries support the Council's initiatives and allow it to operate with funding commensurate with the scope of its responsibilities.

D. Risks and Concerns

Risks are inherent whenever suggesting sweeping changes like forming a new intergovernmental agency. Sovereign states enjoy their autonomy and would certainly hesitate to cede autonomy over

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248 *Brief 18: Innovative Financing – Airline Ticket Tax*, WORLD BANK GRP. & GAVI ALLIANCE, at *1 (Dec. 2010), https://www.who.int/immunization/programmes_systems/financing/analyses/Brief_18_Airline_Ticket_Tax.pdf?ua=1 [https://perma.cc/Y4UR-JZY4].

249 Broun, *supra* note 98.

250 Mark Anthony Camilleri, *The Tourism Industry: An Overview*, in *Travel Marketing, Tourism Economics and the Airline Product*, at *2 (2018), https://www.um.edu.mt/library/oar/bitstream/123456789/21436/5/The%20Tourism%20Industry%20-%20An%20Overview.pdf [https://perma.cc/NWF7-XUHV].

251 *Id.* at 7, 12, 16.

property rights to an external power. While this paper is unable to address all of the risks associated with forming a new IGO, it can discuss the largest one: a lack of national support for participation in the Council's initiatives. The concern is that the citizenry would not agree to grant power to the Council even if their countries' political leaders supported it. The economic insecurity caused by COVID-19 has led to widespread distrust of political institutions and political leaders.[252] The politicization of COVID-19 issues has further divided many countries' citizens and has affected their views on how their leaders are handling the pandemic.[253] This is problematic because even if healthcare officials see the need for the Council, political leaders who do not have their base's support and are seeking reelection would not support the initiative.

Unfortunately, there is no easy solution to this issue. It is very likely that no country would have supported forming the Council before 2020 because none would have seen the need. Since then, however, the world has had to endure lockdown after lockdown, and stifled economic growth for over two years. With new variants emerging regularly—like the Omicron variant that appeared in November 2021 and is more transmissible than any previous variant,[254]—there is no end in sight for COVID-19.[255] Although public trust in political institutions has decreased, increased education and

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[252] *The Politics of Economic Insecurity in the COVID-19 Era*, UNITED NATIONS DEPT. OF ECON. & SOC. AFFS. (Jan. 31, 2021), https://www.un.org/development/desa/dspd/2021/01/the-politics-of-economic-insecurity-in-the-covid-19-era/ [https://perma.cc/QH86-LVEX].

[253] Mara Mordecai & Aidan Connaughton, *Public Opinion About Coronavirus is More Politically Divided in the U.S. Than in Other Advanced Economies*, PEW RSCH. CTR. (Oct. 28, 2020), https://www.pewresearch.org/fact-tank/2020/10/28/public-opinion-about-coronavirus-is-more-politically-divided-in-u-s-than-in-other-advanced-economies/ [https://perma.cc/TUY6-7XVK].

[254] *Omicron Variant: What You Need to Know*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html (last visited Dec. 20, 2021) [https://perma.cc/UFW3-FQHQ].

[255] At the time of printing, an Omicron subvariant called BA.2 is the dominant strain in the United States, with virtually endless potential for continuing mutation and development. *See* Sumathi Reddy, *The BA.2 Variant is Spreading. Do You Need to Worry?*, WALL ST. J., (Apr. 10, 2022), https://www.wsj.com/articles/the-ba-2-variant-is-spreading-do-you-need-to-worry-11649556811.

pandemic exhaustion have pushed society towards cooperation in many areas that were previously not possible. Over the past year, more than seventy countries have united to call for a comprehensive pandemic treaty.[256] Despite numerous delays, including lockdowns in response to the Omicron variant, the WHA officially agreed to begin the treaty drafting process.[257] The first two meetings of the WHA's intergovernmental negotiating body ("INB") are set for March 1, 2022, and August 1, 2022.[258] The INB is expected to have a completed draft ready for consideration at the 77th World Health Assembly in 2024.[259]

The continued push for sweeping pandemic response reform allays many concerns that the erosion of trust in political institutions will result in national governments being unwilling to act. While it is far too early to celebrate, a renewed spirit of cooperation is prevalent that bodes well for support for IGOs like the Council that can facilitate and enable a unified global pandemic response.

V. CONCLUSION

The COVID-19 pandemic has changed everything. In its wake, any effort to restore an inadequate status quo is misguided. When it comes to pandemic prevention and response, the world cannot and should not go home again. The continuing threat of COVID-19 variants drives home the importance of creating a comprehensive global pandemic framework to address not just the emerging diseases of the future, but the continuing diseases of the present.

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256 Stephanie Nebehay, *WHO Nears Consensus on Future International Pact to Prevent Pandemics – Diplomat*, REUTERS (Nov. 26, 2021, 5:20 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/who-nears-consensus-future-international-pact-prevent-pandemics-diplomats-2021-11-26/ [https://perma.cc/84ZE-TBQH].

257 *World Health Assembly Agrees to Launch Process to Develop Historic Global Accord on Pandemic Prevention, Preparedness and Response*, WORLD HEALTH ORG. (Dec. 1, 2021), https://www.who.int/news/item/01-12-2021-world-health-assembly-agrees-to-launch-process-to-develop-historic-global-accord-on-pandemic-prevention-preparedness-and-response [https://perma.cc/RM8Y-NRVR].

258 *Id.*

259 *Id.*

Past frameworks and attempted solutions were the products of tensely-negotiated compromises between IP holders, public health organizations, and national governments, with assistance from trade and financial organizations. While many were inventive and narrowly effective, all suffered from defects such that the entire network of solutions in place in 2019 failed to predict or slow, let alone stop, the COVID-19 pandemic. Rather than slotting one more narrowly-tailored solution into the expected place, leaving room for the next pandemic to surprise the world, leaders ought to cast a wider net and create a more robust program. Now is not the time to stop leaks with a finger. It is time to reimagine the entire dike.

A multilateral pandemic council offers the chance to create a robust program to neutralize future viral threats. By controlling the end-to-end process of threat investigation, technology licensing, and treatment production, the Council would be able to synchronize different processes and systems to develop a unified response. Though it may seem cumbersome to include so many IGOs, wide representation ensures that the Council's actions will be thoughtful and durable. It promotes buy-in from key stakeholders whose voices went unheard in previous frameworks. Health interests can be balanced against IP interests and financial interests. This method ensures that all voices are heard before decisions are rendered. By building a spirit of cooperation, the blueprint builds on an understanding of trust and shared growth that will ensure its longevity. It promises a more equitable, effective, and sustainable solution than what has come before.

Admittedly, there are tremendous obstacles in the way of organizing the council as it is proposed here. Building international consensus around anything, even the imperative of stopping a pandemic, is almost impossible. The IGOs proposed as members of the Council face their own challenges and headwinds that could make cooperation and consolidation at the level proposed by this blueprint difficult. Conventional wisdom dictates that any ambitious project of international governance is doomed to irrelevance, if not stillbirth. But conventional wisdom also dictated that viral pandemics were a thing of the past, that science had triumphed over disease in the western world, and that the status quo was safe. We present this blueprint not

as an easy solution, or even a readily practical one, but as an extraordinary one called for by extraordinary circumstances. The proposal is as serious as the threat of the next global pandemic.

The COVID-19 pandemic has forced humanity to realize that "home" has never been an island of seclusion. Pandemics render insularism and nationalism impractical. Every time a new contagious disease emerges somewhere in the world, the entire global community is at risk. Only by working together can we thwart global pandemics and the isolation and desolation that they bring. COVID-19 is not the first viral threat to test the world, and it will not be the last. The implementation of a Multilateral Council on Pandemic Response as described above can ensure the world is ready for the next one.