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BRIDGING THE GAPS: VACCINE INEQUITY IN THE COVID-19 PANDEMIC AND BEYOND

This panel was convened at 2:00 p.m. on Wednesday, March 29, 2023, by its moderator, Roojin Habibi of the University of Ottawa, who introduced the speakers: Padideh Ala'i of AUWCL; Jelena Madir of Gavi, the Vaccine Alliance; Luke McDonagh of the London School of Economics; and Steven Solomon of the World Health Organization.

Introductory Remarks by Roojin Habibi*

It is stunning that we can finally convene in person again after the ordeal the world has been through the last three years. We are not yet out of woods with the COVID-19 pandemic, but we now have a critical mass of information and experience that allow us to reflect back on what went wrong and what went right over the course of the pandemic. Central to that reflection are the issues surrounding global access to vaccines and other medical countermeasures we need to fend off not just the pandemics and epidemics we know of today, but those that emerge in the future.

Within less than a year, the world managed to produce not one but several safe and effective vaccines against the virus that causes COVID-19. This unprecedented feat was in no small part thanks to the broad spirit of international cooperation, scientific research, and knowledge sharing that emerged in the earliest stages of the pandemic.

Despite this the world failed to scale up the global distribution of vaccines enough for it to meaningfully stem the tide of a global pandemic. At the height of the pandemic, in 2021, only ten economies around the world accounted for more than 75 percent of the vaccine doses administered. Even today, more than three years since COVID-19 was described as a pandemic by the World Health Organization director-general, only one in three people in low-income countries are estimated to have received at least one dose of a vaccine.[1]

Pandemic threats are a fact of life in our modern globalized era. But the tools that we needed to fight them—the medical countermeasures—are governed by a complex and sometimes conflicting ecosystem of international organizations, laws, norms, and interests.

I am delighted to welcome our panelists to help us unpack this ecosystem.

We will first turn to Steven Solomon, who is the Principal Legal Officer at the World Health Organization in Geneva. He heads the Legal Office's unit on international, constitutional, and global health law, where, in addition to providing legal support for the Organization's response to COVID-19, he focuses on normative global health matters, including the International Health Regulations, the Framework Convention on Tobacco Control, and the Pandemic Influenza Preparedness Framework (or the PIP Framework).

Next, we will hear from Jelena Madir, joining us online from Geneva. She is the General Counsel of Gavi, the Vaccine Alliance. Prior to joining Gavi in 2019, she spent nearly eleven years at the

* University of Ottawa.

[1] UNDP, *Global Dashboard for Vaccine Equity*, Data Futures Platform, *at* https://data.undp.org/vaccine-equity.

European Bank for Reconstruction and Development in London. She has previously worked as a finance lawyer for several U.S. law firms in Washington D.C., Frankfurt, and Zagreb. She has won several awards for her legal leadership and is the author and editor of several books on fintech, health tech, and multilateral development bank sanctions.

We will then turn to Professor Padideh Ala'i who is a Professor of Law at the American University Washington College of Law. She specializes in international economic law, law of the World Trade Organization (WTO), and comparative legal traditions. Her scholarship has concentrated on the history of universalizing the administrative state through the multilateral trading system, as well as good governance and evolution of international anti-corruption norms.

Finally, we will turn online to Professor Luke McDonagh, of the London School of Economics' (LSE) Law School, where he undertakes research in the area of intellectual property law. Prior to taking up his position at LSE, Professor McDonagh was a Senior Lecturer at City, University of London, a Lecturer at Cardiff University, and an LSE Fellow. He has published widely in respected journals, and is the author of several monographs, as well as a textbook on Intellectual Property Law published by Oxford University Press in 2019.

World Health Organization, Learning Lessons from COVID-19 Vaccine Inequity and the Intergovernmental Negotiating Body for a Pandemic Accord

*By Steven A. Solomon**

The costs of the shortcomings of the world's response to the COVID-19 pandemic can be expressed in terms of lives lost, well-being compromised, and setbacks in other metrics of public health. Such costs can be both measured and modeled, offering guidance for governments and their delegations in Geneva as they look for ways to limit or avoid these costs in future public health emergencies.

Among such modeling efforts is a project described in an October 2022 article in the journal *Nature Medicine*, which modeled the effect of increased global vaccine *sharing* on the COVID-19 pandemic.[1]

The modeling suggested, among other things, that distributing COVID-19 vaccines more fairly with lower-income countries might have saved more than a million lives.

Additionally, fairer, public-health based vaccine allocation might have also blunted the spread of SARS-CoV-2 variants, potentially reducing the pandemic's impact on all countries, both rich and poor.

The authors of the article concluded that "[t]he message for any emerging outbreak is clear: distributing vaccines across the globe proportional to need, rather than to wealth, will have beneficial effects for all."

I. A Key Challenge

Although the speed with which COVID-19 vaccines were developed, approved, and deployed was unprecedented, the distribution and allocation of those vaccines at the global level was based more on market dynamics than public health considerations.

* World Health Organization.

[1] Sam Moore et al., *Retrospectively Modeling the Effects of Increased Global Vaccine Sharing on the COVID-19 Pandemic*, Nature Medicine (2022), *at* https://www.nature.com/articles/s41591-022-02064-y.

This in part was due to the fact that when, on January 30, 2020, the World Health Organization (WHO) declared the outbreak a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR 2005), there was no globally agreed international framework for equitable pandemic vaccine access and distribution.

In an effort to fill this gap quickly, the COVAX facility was launched in March 2020.

Through COVAX, three organizations—WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi—worked together to support equitable access to COVID-19 vaccines worldwide, especially for low- and middle-income countries. While COVAX achieved significant successes, it is neither permanent, nor a globally agreed framework, established by countries.

Moreover, it is not an "access and benefit sharing system" (ABS system) in an international law sense, a distinction that matters for the 139 countries that are parties to the Nagoya Protocol to the Convention on Biological Diversity and which therefore have domestic and international obligations for the sharing of genetic resources, including pathogens, and access to benefits—notably vaccines—resulting from their use.

As of today, the international community still lacks a formal ABS system for pathogens in general. There is, however, a pathogen-specific, global framework for the specific topic of influenza—the flu—that addresses both access and benefit sharing for influenza viruses with pandemic potential—or IVPPs—and could be a model for a future, broader system covering all pathogens. It is called the Pandemic Influenza Preparedness—or PIP—Framework. This framework is one option that may be used as a reference, or blueprint, for a broader pathogen ABS system during the negotiations that are under way in Geneva.

II. Search for Solutions: The Intergovernmental Negotiating Body (INB) and Treaty Making Through WHO

In December 2021, at its second-ever special session, the World Health Assembly (the supreme governing body of the WHO, comprised of all of the WHO's 194 member states, with equal representation), established the INB to draft and negotiate a pandemic accord, or international instrument, under the WHO Constitution to strengthen pandemic prevention, preparedness, and response.

The INB's work, based on the principles of inclusiveness, transparency, member state leadership, and consensus, is focused on achieving a more effective and more equitable approach to countering future pandemic threats.

If established, the pandemic accord would represent only the second global health treaty adopted under the auspices of WHO, following the WHO Framework Convention on Tobacco Control, which celebrated its twentieth anniversary in 2023.

When speaking of WHO "treaties," it may be worth highlighting how misguided concerns are that developments in this area could impact on state sovereignty.

If a global ABS system for pathogens is established through a legally binding mechanism, and if countries decide that it should be part of a WHO instrument, it will be countries that decide the functions and structure of such a system. And it will still be countries that determine their domestic public health policies, including their pandemic prevention, preparedness, and response policies.

This is the case because WHO, where the negotiations are taking place, is an intergovernmental organization where countries develop and decide upon global public health policies and norms that serve their collective interests, as well as their national interests.

WHO has staff, of course, known as the Secretariat. It is composed of about 8,000 people worldwide, and led by an elected officer, the director-general, who serves for a maximum of two five-

year terms. But WHO staff do not decide on WHO regulations and international agreements. Only WHO's 194 member states have this power. And in the seventy-five-year history of WHO, member states have never decided to give the Secretariat the power to dictate any actions to any country—and there is no proposal for the pandemic accord, or any other instrument under consideration, that would change this.

III. The PIP Framework as a Possible Model for an "All Pathogen" ABS

Negotiators in Geneva are looking at the PIP Framework and other possibilities for a fairer, more efficient, and more equitable way of sharing, on the one hand, pathogens, and on the other hand, vaccines, as well as other medical countermeasures.

The PIP Framework was developed for influenza pandemics, but there is a view among both observers and a number of countries that its principles and strategies can serve as a valuable model for addressing equitable vaccine distribution in a broader context. In principle, by adopting similar approaches, policymakers could work toward ensuring fair and equitable access to vaccines for any pandemic pathogen, better safeguarding all populations, regardless of their socioeconomic status or geographic location, and focusing specifically on public health needs and risks.

In particular, the PIP Framework provides a comprehensive system to guide policymakers, WHO, and other international organizations, as well as public and private stakeholders in promoting speedy access to IVPPs, on the one hand, and equitable access and distribution of vaccines during public health emergencies, on the other.

Furthermore, the PIP Framework emphasizes global cooperation and collaboration, recognizing that effective pandemic response requires collective efforts.

By fostering partnerships with influenza vaccine manufacturers that will support the real time distribution of hundreds of millions of pandemic vaccine doses based on public health need, and by supporting year-round material and information-sharing through an established multilateral mechanism, as well as resource mobilization, the PIP Framework has worked since 2011 to facilitate the global response to future pandemic influenza threats by putting access and benefit sharing on an equal footing, and prioritizing the equitable distribution of vaccines across countries and regions.

This collaboration also works in "inter-pandemic" times to help developing countries strengthen their healthcare systems, monitor influenza threats and effectively prepare their pandemic response plans.

Additionally, the PIP Framework incorporates ethical considerations, emphasizing transparent decision-making processes, and review by independent experts. By integrating these elements, the Framework aims to prevent disparities and foster public trust in both virus collection and vaccination access, and distribution.

Finally, continuous evaluation is a fundamental component of the PIP Framework. Such monitoring enables implementers and WHO member states to identify issues and address them promptly. This iterative approach allows for ongoing improvements and adjustments, enhancing further the prospects for equitable distribution of vaccines in future influenza pandemics.

IV. Conclusion

In sum, the PIP Framework, as a formal, internationally agreed, and successfully implemented access and benefit sharing system that deals with one of the known pandemic threats, influenza,

offers governments and their delegations a possible model for an ABS system aimed at pathogens more broadly.

To be sure, creative thinking about expanding the pathogen-specific PIP Framework provisions to other pathogens will be needed. Among the concerns about PIP as a model is that "flu" is a "known" pandemic threat that also has "seasonal" public health aspects. Other potential pandemic threats do not share these features.

But the PIP Framework principles of fairness, equity, efficiency, predictability, and transparency provide a strong foundation for a broad approach to equitable sharing and vaccine access, making it a strong model for consideration by the INB as negotiators look for solutions to ensure more equitable and effective public health approaches to the costly problem of vaccine access and distribution inequities.

Learning Lessons from COVID-19 Vaccine Inequity and the TRIPS Waiver Debate

*By Luke McDonagh**

With the World Health Organization (WHO) having declared the emergency phase of the COVID-19 pandemic to be over, it is worth reflecting on what we can learn from the past three and a half years (Dec 2019–May 2023). In this presentation, I focus on the phenomenon of what the WHO refers to as global vaccine inequity. During 2021, vaccine supplies were hoarded by several rich countries—this meant that many developing countries were left in the lurch, unable to obtain sufficient supplies of vaccines, even via the voluntary scheme of COVAX. Thus, at the apex of the pandemic during 2021, lower- and middle- income (LMIC) countries were largely unable to obtain—to import—the supplies they needed to vaccinate their populations. Even when they arrived, donations of leftover vaccines from high-income countries often were too close to their expiration dates for developing countries to actually utilize. Meanwhile, vaccine manufacturers, such as Moderna and Pfizer-BioNTech, refused to share intellectual property (IP)-protected technology with initiatives like the WHO mRNA vaccine technology transfer hub in South Africa that were attempting to create a network of distributed vaccine production in the global south.[1]

In this presentation, I want to ask a series of linked questions: why were so many developing countries not in a position to produce vaccines in their own facilities for their own populations? Why were they so reliant on imports? What does the international protection of IP have to do with this? Why did India, South Africa, and more than sixty other Global South countries propose a temporary waiver of international IP rules?

One answer is that the international protection of intellectual property rights under the 1994 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has failed in a key promise to developing countries. Although encouraging technology transfer to the Global South was stated to be a key aim of TRIPS, in reality, TRIPS has done little to assist developing countries in building up local pharmaceutical manufacturing capacity. The strong protection of IP rights at the international level has been a positive for IP-exporting developed countries, but it has not led to local development of innovative

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[1] Siva Thambisetty et al., *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 Camb. L.J. 384 (2022).

pharmaceutical facilities in much of the Global South. Instead, over the past quarter of a century, many developing countries have become dependent on imports of medicines. This import-dependency led to developing countries being in a vulnerable position when the pandemic was declared in early 2020.

To understand how and why this local capacity problem exists in the Global South, we need to start with the history of patent protection in the Global North. This is the period when many of the countries that are now "developed" were then "developing" and building up their own local capacity. Importantly, this was a period when international IP rights were weak. A seminal paper by Fritz Machlup and Edith Penrose describes this battle as being between protectionists and free traders, dubbing it the "The Patent Controversy in the Nineteenth Century."[2] They point out that during the nineteenth century, patents were primarily national in character. In the trade context, patents were viewed as a form of (national) protectionism. Western countries, which are considered today to be "developed" or industrialized, typically went through an early-industrial phase where IP rights were only protected faintly, if at all, in order to allow their fledgling domestic industries to copy foreign-owned technologies and produce products for the national market. Indeed, several pro-free trade Western countries copied the technologies of their neighbors without recognizing the relevant patents or paying license fees. This allowed countries to build up their own manufacturing facilities within a national market economy. The paradigm case was the Netherlands, which abolished its patent system for a period of more than twenty years during the late nineteenth century, copying lots of technologies from neighboring countries, building up local industrial capacities. The development model that emerged from this period had a key element: once a country had built up its own industrial capacity, then—and only then—would it make economic sense to give strong protection to IP rights; because it is only at that stage that the country can begin to innovate and export its own IP products.

Prior to TRIPS, this model was used by many countries on the path to development. In the late 1960s and early 1970s, key developing countries, particularly India and Brazil, removed national patent protection from medicines in order to encourage the development of their own generic industries. Critically, pre-TRIPS, which was agreed in 1994, this was not a breach of international IP law. Crucially, the removal of patent protection on (largely Western-owned) medicines created a huge incentive for local manufacturers to invest in local capacity, and to export affordable generics to their neighbors in Latin America (in the case of Brazil) and Asia (in the case of India). From the late 1960s until the 1990s, due to a national legal system that did not protect patents on medicines, India and Brazil emerged as the pharmaceutical leaders in their regions, supplying huge volumes of generic medicines to LMICs. In other words, while it is true that where there is existing industrial capacity, patent rights may work as an incentive to develop production and innovation; however, in a country with little industrial capacity, the absence of patents can be a more effective incentive.

In 1994, TRIPS changed the game. Economists like Joseph Stiglitz pointed out at the time that forcing most developing countries to apply the same strong IP laws as rich countries would prove to be a disaster for development.[3] And so it has proven. We witnessed the first crisis of the post-TRIPS period was the HIV/AIDS crisis in the late 1990s and early 2000s, when patent-holding pharmaceutical companies sued South Africa for attempting to produce generic HIV/AIDS medicines. The United States imposed trade sanctions. Eventually, the cases were dropped—and through India-African collaboration, generic supplies were produced. The crisis began to abate.

During the COVID-19 crisis, developing countries anticipated (correctly) that they would be left in the lurch in the scramble for vaccines. As early as October 2020, before approved vaccines had

[2] Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1 (1950).

[3] JOSEPH E. STIGLITZ, GLOBALIZATION AND ITS DISCONTENTS (2002).

even been administered, India and South Africa put forward a proposal to waive certain obligations under the WTO TRIPS Agreement (the TRIPS waiver), with more than sixty LMICs voicing their support.[4] The original TRIPS waiver proposal was based on the need for affordable access to medical products for the prevention, containment, and treatment of COVID-19 during the pandemic. It sought to bring into force a waiver of WTO states' TRIPS obligations regarding patents, copyrights, industrial designs, and undisclosed information as they relate to COVID-19 health technologies.

Subsequent negotiations over the waiver were difficult and protracted. Only in May 2022 did an apparent "compromise" text emerge from the WTO director-general (DG), but without the explicit support of the waiver's main proponents, India and South Africa, leading to concern over the scope and effectiveness of the DG text. The final text agreed at WTO MC12 was a case of "too little too late," arriving after the worst of the pandemic was over and just as supply problems began to ease at the global level.

So what lessons can we learn? The first is that international IP law (exemplified by TRIPS) cannot be separated from the global political economy or broader concerns of public interest. The debate over COVID-19 vaccine inequity has revitalized the old discussion about the political nature of patents, and their use as a form of protectionism. The debate has changed the discourse on the overall political legitimacy of IP law and has shifted the way public health concerns are articulated with regard to IP.

The second is that we cannot expect the international protection of IP to stimulate capacity building in LMICs. The true meaning of vaccine equity would not equate to mere donations—it is not enough to transfer some vaccine doses to satisfy the short-term needs of some of the populations in LMICs. Equity requires technology transfer to enable regional production in the Global South, to facilitate a long-term sustainable supply of vaccines in LMICs for this and future pandemics, as well as for related health needs, linking the law explicitly to outcomes.

This positive momentum toward change in the political-economic structure around TRIPS must be maintained. Initiatives inspired, at least in part, by the TRIPS waiver—such as expanding the number of Medicines Patent Pool licenses, encouraging the nascent work of Afrigen and the mRNA hub in South Africa, and ensuring the negotiations over the WHO Pandemic Treaty include equity provisions—may outlive the waiver debate. In this respect, the legacy of the waiver debate may be to rebalance the global production of medicines toward regional hubs in the global south. This would go some way to fulfilling the broken technology-transfer promise of TRIPS.

[4] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19; Communication from India and South Africa, Oct. 2, 2020, IP/C/W/669 (TRIPS Waiver Proposal IP/C/W/669). See also revised text: Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 Revised Decision Text IP/C/W/669/Rev.1, May 25, 2021 (Waiver Revised Text IP/C/W/669/Rev.1).