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The Intellectual Property and Public Health Regime Complex:
Considerations on Vaccine Access and Equity

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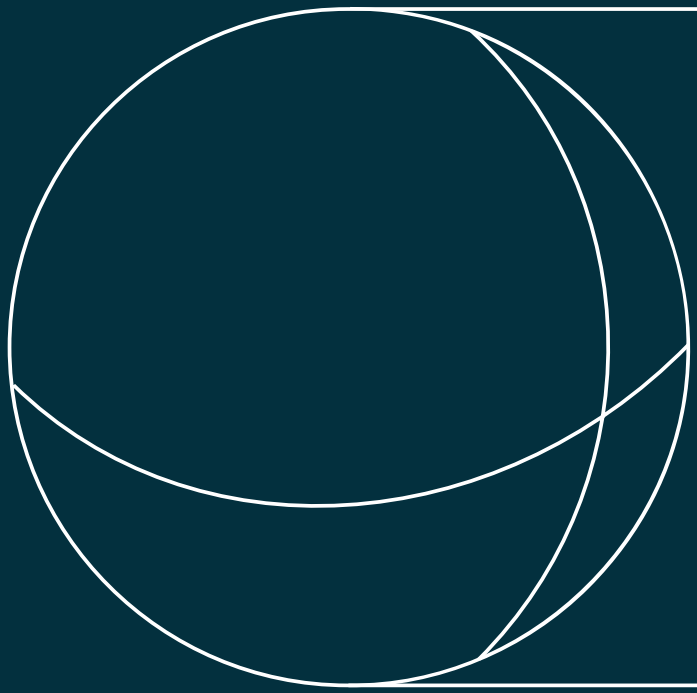

Abstract

The COVID-19 pandemic underscored long-standing tensions within the global regime complex for intellectual property (IP) and public health, particularly regarding the balance between strong IP protections and equitable vaccine access. This report examines how the institutional fragmentation of IP–public health governance – structured around the World Trade Organization, the World Intellectual Property Organization, and the World Health Organization – has shaped policy responses and created opportunities for forum shopping. We analyse key stakeholder positions, historical policy shifts, and institutional interactions to assess how forum shopping has influenced rule-setting, enforcement, and reform efforts concerning the IP–public health nexus. We find that, despite significant contestation, the global regime complex governing the intersection of IP and public health is likely to remain broadly stable. With regime complexity set to continue shaping the robustness, effectiveness, and democracy of global governance in this issue area, we explore potential pathways to mitigate existing challenges.

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Introduction

The COVID-19 pandemic underscored the urgent need for equitable access to vaccines. As the world scrambled to develop, manufacture, and distribute vaccines, stark disparities emerged. Many low- and middle-income countries faced prolonged shortages while wealthier nations secured abundant supplies. These inequities sparked intense debate over the role of intellectual property (IP) rights in global health governance, particularly whether they serve as a necessary incentive for medical innovation or an unjust barrier to access.

For some observers and stakeholders, IP protections – such as patents on vaccines and other medical products – are a cornerstone of pharmaceutical innovation. They argue that these rights incentivise research and development (R&D) by ensuring that innovators can recoup their investments, creating life-saving products that will become more widely available over time. From this perspective, IP rights and vaccine access are not inherently in conflict: IP is seen as a mechanism enabling long-term global health improvements. High-income countries, particularly the United States (US) and the European Union (EU) – home to the pharmaceutical giants that first developed COVID-19 vaccines – supported these views on IP protections.

However, many critics challenge this view – particularly in the context of medical countermeasures deployed during public health emergencies. These critics contend that IP protections are not always a fundamental driver of innovation and often impede equitable access, especially when vaccines and treatments have been developed with substantial public funding (see Christou and Della Porta 2024). From this perspective, patents and other IP mechanisms create artificial scarcity, driving up costs and allowing private actors to extract excessive financial gains. Low- and middle-income countries tend to be the ones to raise these concerns and push for greater flexibility in IP rules. In 2020, India and South Africa co-sponsored a proposal at the World Trade Organization (WTO) calling for a temporary waiver of certain IP protections on COVID-19-related medical countermeasures (World Trade Organization 2020).

After prolonged and contentious negotiations, WTO members reached a compromise enabling a waiver of some IP obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (World Trade Organization 2022b).[1] This compromise reflected a growing recognition that standard IP rules could be too rigid during a pandemic such as COVID-19. Even high-income countries resorted to mechanisms such as compulsory licences – government-issued licences that authorise making, using, selling, or importing a product without the patent owner's consent – to facilitate domestic vaccine supply during the pandemic (South Centre 2021).

1 While we use the common term 'TRIPS waiver' for the sake of simplicity, the relevant WTO Ministerial Decision did not automatically waive any TRIPS requirements, but rather offered developing member states limited opportunities to do so (World Trade Organization 2022b; Interview 6).

This agreement left many unsatisfied. Staunch advocates of IP rights credited the existing system for the rapid development of COVID-19 vaccines and viewed the TRIPS waiver as a dangerous precedent that could weaken the WTO (International Federation of Pharmaceutical Manufacturers and Associations 2022). Both supporters and sceptics criticised the waiver for offering little beyond the flexibilities already built into the TRIPS framework (Patnaik 2024). Some also warned that narrowly focusing on debates over patents risked overshadowing other critical barriers to vaccine access in low- and middle-income countries, such as limited manufacturing capacity, insufficient knowledge transfers (which are subject to a different type of IP protection), weak healthcare infrastructure, and vaccine hesitancy.

Thus, the pandemic sparked renewed interest in the intersections of IP and public health. While the WTO's TRIPS Agreement has attracted the most scrutiny, this issue area also involves the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO). Following Kal Raustiala and David G. Victor (2004), we posit that these three institutions form a 'regime complex' – defined as "an array of partially overlapping and nonhierarchical institutions governing a particular issue-area" (p. 279). While collaboration has become more institutionalised over time, philosophical differences and competing legitimacy claims persist. Drawing from the shared terminology of the ENSURED project (Choi et al. 2024), this report asks the following research question: How has regime complexity shaped the *robustness*, *effectiveness*, and *democracy* of global governance in the IP–public health nexus? Our findings suggest that regime complexity has often been detrimental across the board. The most common pattern has been that high-income countries have redirected discussions about public health concerns – prevalent within the WHO – towards narrower debates about IP protection, as spearheaded by WIPO and the WTO.

How has regime complexity shaped global governance in the intellectual property-public health nexus?

Our report proceeds as follows. In the next section, we describe how the regime complex connecting IP and public health came into being and present the primary debates that have swirled around it for more than three decades. In the third section, we introduce some of the major stakeholders in this regime complex, sketching their broad narratives of support or contestation by relying on official documents, public statements, and original interview data. The fourth section presents the main windows for policy adaptations and innovations that have opened since 2020, while the fifth section turns to the EU's role vis-à-vis these and past initiatives. The final section offers some concluding remarks, including our views on future scenarios for the global governance of IP and public health.

The Global Regime Complex at the IP-Public Health Nexus

The global regime complex governing the intersection of IP and public health is structured mainly around the WTO, WIPO, and the WHO. Over time, these organisations have agreed to jointly foster "a better understanding of the linkage between public health, trade and intellectual property policies" and to enhance "a mutually supportive implementation of those policies" (World Trade Organization, n.d.-b). However, the regime complex has consistently fallen short of delivering equitable access to vaccines and other medical products, especially during public health crises. A significant challenge lies in the involvement of organisations with very different mandates. Authority is not evenly distributed among them, but is instead primarily concentrated in the organisations that are not oriented towards public health: the WTO and, to a lesser extent, WIPO. This authority distribution, combined with a proliferation of bilateral and plurilateral trade agreements, has allowed high-income countries to increase their leverage in negotiations, undermine democratic decision-making, and tilt the scale away from access to medical products and towards stringent IP protection.

The codification and institutionalisation of global intellectual property rules have not been linear.

The codification and institutionalisation of global IP rules have not been linear. In 1970, a specialised United Nations (UN) agency entered the picture: WIPO. Currently, it administers 28 IP treaties and comprises 193 member states. This organisation is unique among UN agencies, as it is almost entirely self-funded. Approximately 95 percent of its budget derives from fees paid by users of its IP services, rather than member-state contributions (World Intellectual Property Organization n.d.). As for non-state actor participation, WIPO "has long had liberal rules" (Woodward 2012, 52), but it has traditionally attracted industry-related stakeholders. Since the turn of the century, civil society has engaged more intensively with WIPO, reflecting efforts to integrate development concerns into IP policy (Taubman 2020).

The WTO was founded in 1995. Its creation altered the ways in which IP policy was formulated and enforced, shifting the emphasis towards a trade-centric approach that has complicated public health efforts (Raustiala and Victor 2004, 299). Historically, international IP governance granted countries broad discretion in defining patent laws, with health products often exempted from patentability even in high-income countries ('t Hoen 2009, 9). However, the WTO's TRIPS Agreement represented a major step towards harmonising IP rights internationally. The new agreement established a minimum of 20 years for patent terms "in all fields of technology," including pharmaceutical products.

TRIPS was the result of fractious negotiations. Low- and middle-income countries initially tried to resist horizontal 'forum shifting' (Sell 2003; 2009; 2010) or 'regime shifting' (Helfer 2004; 2009) away from the UN system (see also Drahos 1995; 't Hoen 2009). Eventually, high-income countries – led by the US – overcame these objections by framing TRIPS as a side

payment in exchange for enhanced market access. The single-undertaking principle that formed the basis of the Uruguay Round – "nothing is agreed until everything is agreed" – facilitated this outcome. This principle and the WTO's consensus-based decision-making distinguish the WTO from WIPO, which is characterised by à la carte negotiations in which high-income countries can be outvoted (Gagliani 2020, 58–59), although consensual decisions are preferred. Other key differences between the two organisations are the WTO's relative insulation from non-state actor input and the fact that it has a dispute settlement mechanism – despite the challenges this mechanism currently faces (see Parizek and Weinhardt 2025). While low- and middle-income countries support this mechanism, as do virtually all 166 WTO members, it is also "a formidably resource-demanding system [that] resource-constrained developing countries have often stumbled over" (Bahri 2018, 13).

Low- and middle-income countries secured some flexibilities in the TRIPS Agreement. These sought to minimise potentially adverse effects of the agreement, including on access to medical products. The most critical flexibility is that WTO members can issue compulsory licences under certain conditions. Moreover, low- and middle-income countries were granted a transition period in TRIPS implementation, which lasted 10 years in the case of pharmaceuticals. Least-developed countries (LDCs) – a special category of low- and middle-income countries – are still benefitting from a longer phase-in period, recently extended until 2034 (World Trade Organization 2021c). However, from the perspectives of low- and middle-income countries, practical obstacles to using these flexibilities have reinforced the need for reform of the regime complex.

Shortly after TRIPS was adopted, concerns about its impact on access to medical products spilled over to the WHO.

Shortly after TRIPS was adopted, concerns about its impact on access to medical products – such as vaccines – spilled over to the WHO. Founded in 1948 and currently comprising 194 members, the WHO is the UN's dedicated agency in the field of public health. Compared to WIPO and the WTO (Gagliani 2020, 61), the WHO is less member-state driven: it has a stronger secretariat and is more open to input from civil society (Helfer 2009, 41). In 1996, the WHO's decision-making body – the World Health Assembly (WHA) – adopted a resolution that mandated the organisation to report on the health-related effects of WTO rules (World Health Assembly 1996). This resolution paved the way for the WHO's involvement in the trade–public health nexus (which by then also included IP) – a development that faced resistance from the US and several European countries, where the pharmaceutical industry expressed serious reservations (Helfer 2004, 43; 't Hoen 2016, 24–25; Velásquez and Boulet 2015, xii). In subsequent years, the WHA kept underpinning the WHO's role in IP and influencing the debate over TRIPS, even as the organisation's IP programme struggled with staffing and remained reluctant to issue concrete recommendations on the use of TRIPS flexibilities ('t Hoen 2009, 26–27).

The pressure exerted by low- and middle-income countries and activists at both the WHO and the WTO, combined with the increased salience of the HIV/AIDS crisis and the West's interest in stabilising the WTO, led to

the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001 (Drezner 2008, 176–203; Helfer 2009, 42). This declaration clarified that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (World Trade Organization 2001). It also reaffirmed countries' "right to grant compulsory licenses and their freedom to determine the grounds on which such licenses are issued" (World Trade Organization 2001). However, it did not fundamentally change the international IP framework (Abbott 2024, 423), nor did it prevent large pharmaceutical companies and their home governments from challenging the use of TRIPS flexibilities. Some WTO accession agreements include "TRIPS-plus" provisions establishing even stricter IP protections. The US and the EU have also promoted such provisions through preferential trade agreements, a strategy referred to as 'vertical forum shifting' (Sell 2010; see also Helfer 2009, 41–43; 't Hoen 2009, 69–78). Notably, TRIPS upholds the Most-Favoured-Nation principle without exceptions for free trade agreements, meaning that any member who consents to additional IP protections through such instruments must extend those protections to all WTO members.

The Doha Declaration deferred discussions on the contentious TRIPS Article 31(f), which stipulates that compulsory licences must be granted "predominantly for the supply of the domestic market." In low- and middle-income countries, this provision undermined the economic viability of local pharmaceutical production and restricted opportunities for pharmaceutical imports. In 2003, a compromise was reached in the form of the 'August 30 Decision,' which temporarily waived Article 31(f) and allowed countries to export pharmaceuticals produced under compulsory licences to "eligible importing members," with LDCs automatically qualifying as such (Abbott 2005, 335). In 2005, this waiver was formally adopted as the first-ever amendment to the TRIPS Agreement (Article 31bis), which came into effect in 2017, once enough states had ratified it. However, the conditions for utilising the waiver and subsequent amendment have been criticised as "cumbersome" and "suboptimal" (Sell 2009, 10) – an outcome that "was in rough accord with great power preferences" (Drezner 2008, 198). To date, Article 31bis provisions have been invoked only once. Nevertheless, the amendment is believed to have given low- and middle-income countries some leverage in pharmaceutical procurement negotiations (Vidigal and Parwani 2024, 33 and 51–53).

High-income countries set regime complexity in motion.

Meanwhile, high-income countries set regime complexity in motion once again. As a response to the WTO's Doha Declaration and in parallel with the negotiations on TRIPS Article 31(f), high-income countries pursued another horizontal forum shift back to WIPO in an attempt to achieve higher IP protection standards by means of the Substantive Patent Law Treaty (Reichman and Dreyfuss 2007; Sell 2010, 450). This effort was met with a counter-move, as Argentina and Brazil co-sponsored WIPO's Development Agenda in 2004, seeking to integrate development considerations into the organisation's work (World Intellectual Property Organization 2004). Whereas negotiations on the Substantive Patent Law Treaty were put on hold in 2006, WIPO's Development Agenda was adopted in 2007. Under this umbrella, WIPO has explored available options for the flexible implementation of the TRIPS Agreement (Gagliani 2020, 67).

By the late 2000s, a period of relative stability had emerged, though forum shopping and regime shifting continued to present challenges for the robustness, effectiveness, and democracy of the regime complex. The WTO's Doha Declaration, WIPO's Development Agenda, and the WHO's 2008 Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (World Health Assembly 2008) paved the way for intensified coordination among the three organisations. Thus, the WHO–WIPO–WTO Trilateral Cooperation was born, featuring a series of joint technical symposiums and a landmark collaborative publication – the 2013 Trilateral Study – examining the intersections of public health, IP, and trade (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2013). At the core of the Trilateral Cooperation was an implicit bargain: the WIPO and WTO secretariats fully recognised the WHO as a legitimate interlocutor on IP, while the WHO Secretariat agreed to further consider WTO and WIPO interpretations of IP-related issues. This new dynamic enhanced legal certainty and contributed to a more stable regulatory landscape, fostering greater awareness and acceptance of TRIPS flexibilities (Abbott 2013; Haugen 2021). Access to medicines became a more prominent international norm, as exemplified by the global HIV/AIDS response. In this context, voluntary licencing – the practice of IP-holders choosing to allow another party to use their protected intellectual property – expanded significantly, partly due to the establishment of the Medicines Patent Pool (MPP) in 2010 (Kavanagh 2024).

The COVID-19 pandemic reignited global debates over intellectual property and access to vaccines and other pharmaceuticals.

Yet increased coordination between the WHO, WIPO and the WTO was no panacea, as the three organisations did not wholly overcome their past frictions. While the 2013 Trilateral Study highlighted a "more progressive approach to public health and IP" (Abbott 2013, 502), the process was characterised by "tensions among the Secretariats and their staffs" (p. 494). While they do not always align, WIPO and the WTO have an extended history of collaboration (World Trade Organization 1995; see also Gagliani 2020, 52), whereas the WHO has struggled to consolidate itself as an equal partner. Meanwhile, national governments have persisted in their forum-shifting attempts. High-income countries have continued to pursue their TRIPS-plus agenda in relatively non-transparent negotiations on trade and investment agreements, with varying levels of success (Vidigal and Parwani 2024, 24–27). Moreover, the disabilities of the WTO (see Parizek and Weinhardt 2025) have led to "a shift in the center of gravity back toward WIPO in terms of multilateral discussions of new IP rules" (Abbott 2024, 418). This shift was spurred by the failure of the Anti-Counterfeiting Trade Agreement in the early 2010s, through which high-income countries attempted to create an entirely new regime beyond the authority of any international organisation.

The COVID-19 pandemic further disrupted the status quo, reigniting global debates over IP and access to vaccines and other pharmaceuticals. In multilateral discussions, low- and middle-income countries frequently

framed IP as an actual or potential barrier to vaccine access, making it a central point of contention. Some commentators argue that these concerns were misplaced. According to Bryan Mercurio and Pratyush Nath Upreti (2022), "far from preventing access to vaccines and treatments, the IP system encouraged spending on R&D and not only identified the cause of the deadly pandemic but also produced multiple vaccines within the space of a year" (p. 643). Others took a different stance, asserting that IP is not merely a scapegoat but can hinder vaccine access and equity (Park et al. 2023, 1). Coordinated efforts led the WHO, WIPO, and the WTO to adopt a nuanced position. The updated Trilateral Study, released in 2020, highlighted the benefits of IP while also noting that it can "pose barriers to competition in vaccine manufacture" (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020, 227).

Despite diverging views on the extent to which IP is a catalyst or a barrier, there is consensus among the main actors in the regime complex that vaccine development – particularly for mRNA vaccines – is more complex than the production of non-biological medicines (Interview 11). Vaccine "biosimilars" can be produced but are subject to stringent regulatory requirements (Nguyen and Schwalbe 2019, 2911). As Sung-Pil Park et al. (2023) explain, "vaccine production requires not only patents, but undisclosed know-how and specific manufacturing technologies that may take months or years to transfer and implement properly. Without such know-how and confidential information, vaccine development would become dangerous or even impossible" (p. 3; see also Mercurio and Upreti 2022, 349). This argument reflects the widely shared notion that vaccine access challenges cannot be addressed by revising patent rules alone (Abbott 2024, 425).

The existing landscape has tilted policies to favour intellectual property protection over equitable access to pharmaceuticals.

In sum, the governance of IP and medical products remains a highly complex and contested issue. While efforts such as the WTO's Doha Declaration, WIPO's Development Agenda, and various WHO resolutions and action plans have attempted to balance IP protections with global health needs, structural challenges persist. The fragmented institutional and regulatory landscape – characterised by the WHO, WIPO, and the WTO operating alongside a series of bilateral and plurilateral agreements – has enabled forum shopping and regime shifting. Most often, the existing landscape has tilted policies to favour IP protection over equitable access to pharmaceuticals. Nevertheless, at times, complexity has also worked to the benefit of low- and middle-income countries. In the following section, we discuss the positions of key stakeholders towards the regime complex, with a focus on the post-COVID period.

Key Stakeholders and Broad Narratives

The preferences of key actors in the global debate on IP and vaccine access have been deeply entrenched for decades. Views expressed in multilateral fora over the last five years, since the outbreak of COVID-19, tend to reproduce a long-standing fracture between IP proponents and IP sceptics (Kohler, Wong, and Tailor 2022). These two positions can be briefly explained as follows.

On the one hand, the informal Friends of IP and Innovation group at the WTO represents the views of those who are roughly satisfied with the status quo in global IP governance. This group has varied in its composition (World Trade Organization 2022a) but currently comprises Western members (Australia, Canada, the EU, New Zealand, Switzerland, the UK, and the US) and Asian members (Hong Kong, Japan, Singapore, South Korea, and Taiwan) (World Trade Organization 2024c, 1). All of these countries are wary of other states exploiting the flexibilities inscribed in the TRIPS Agreement[2] and oppose any weakening of current IP protections in this or other relevant treaties. The EU and the US are by far the largest markets and most influential voices in the pro-IP camp. Both are also among the largest vaccine developers, considering both R&D investment and the number of biopharmaceutical companies involved in vaccine innovation. Such interests inform their preference for WIPO and WTO governance of this issue area, as these organisations prioritise IP protection.

The leadership and secretariats of WIPO and the WTO tend to refrain from making overtly political statements. This reflects their relatively technical and restricted mandates, as well as their satisfaction with the current division of labour in the regime complex (Interview 3). Regarding non-state actors, the innovative pharmaceutical industry is the most important and influential stakeholder in the pro-IP camp, coalescing around lobbying organisations such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

On the other hand, countries in the Global South are generally keen on leveraging TRIPS flexibilities and frequently denounce pressure exerted by countries in the Global North to prevent them from doing so. Many low- and middle-income countries lack domestic vaccine production capabilities. They therefore depend on imports or technology transfers, which can be hindered by strict IP rules. Yet Global South positions are not uniform and are dependent on both economic capacities and the ideological leanings of national governments.

2 Nevertheless, TRIPS flexibilities are not the exclusive remit of low- and middle-income countries. Researchers have identified 24 instances of high-income countries executing or threatening to execute a TRIPS flexibility (Medicines Law & Policy n.d.; Vidigal and Parwani 2024, 35).

India and South Africa, the initial proponents of the COVID-19 TRIPS waiver, have often embraced a leadership role to defend equity and affordability. However, the Indian government restricted exports of the Oxford-AstraZeneca vaccine, licenced to the Serum Institute of India (the world's largest vaccine manufacturer by volume), and has generally adopted a friendlier stance towards IP rights (Shah and Katz 2024). Meanwhile in South Africa, the African National Congress entered a governing coalition with pro-market and conservative forces in 2024 – the first power-sharing government since the end of apartheid. To be sure, these two countries have continued to emphasise the health priorities of low- and middle-income countries: at the G20, for example, and through South Africa's role as co-chair of the WHO's Intergovernmental Negotiating Body (INB), tasked with pursuing an agreement to strengthen pandemic prevention, preparedness, and response. That said, some countries in the Global South express dissatisfaction with India's and South Africa's roles in the TRIPS waiver discussions as members of the informal "Quad" negotiating group, which also included the EU and the US (Patnaik 2022). According to one interviewee, India and South Africa "have become a lot more silent than expected after the [TRIPS] waiver" (Interview 7).

All of these factors have resulted in Colombia and Brazil emerging as standard bearers of vaccine equity under the helm of their current progressive governments. Colombia has been especially active on the matter at the WTO by spearheading a TRIPS implementation review under Article 71.1, the timeline and scope of which are currently being debated (World Trade Organization 2024e). Brazil is always a sought-after partner for Colombia and numerous other low- and middle-income countries (Interview 7). It played an essential role in the 2001 Doha Declaration on TRIPS and public health, and in 2004, it co-sponsored WIPO's Development Agenda (World Intellectual Property Organization 2004). Recently, Brazil was also instrumental in the adoption of the latest WIPO Treaty on IP, Genetic Resources and Associated Traditional Knowledge, which was the culmination of more than 20 years of negotiations based on an original Colombian proposal (Wendland 2024).

Global South countries tend to advocate for a more prominent role for the WHO in intellectual property matters.

Global South countries tend to advocate for a more prominent role for the WHO in IP matters because they see this organisation as more amenable to their interests. Tellingly, the Director-General of the WHO explicitly supported India and South Africa's initial TRIPS waiver proposal. Another case in point is the recently concluded talks on a pandemic agreement, which gave Brazil and Colombia the opportunity to promote strong language on the right to use TRIPS flexibilities (Balasubramaniam 2024b). These reformist positions have found considerable support in the work of the South Centre, an international organisation encompassing 55 low- and middle-income countries. The South Centre has amassed significant technical expertise in IP matters and consolidated itself as a widely recognised voice in the debate. This organisation has observer status at the WHO and WIPO, although not on the WTO's TRIPS Council, where its attempts to gain that status – explicitly supported by China and Indonesia at a recent meeting – have been blocked by the US (World Trade Organization 2024b, 62). In addition,

non-state actors that favour a more flexible IP regime include NGOs such as Knowledge Ecology International, *Médicins Sans Frontières*, and the Third World Network, as well as the generic pharmaceutical industry, whose pro-competition stance is articulated via the International Generic and Biosimilar Medicines Association (IGBA).

Despite frictions between the two camps, some modest progress has been made in bridging the divide over the last five years. The WHO–WIPO–WTO Trilateral Cooperation is one example. Reportedly, this cooperation is "not smooth sailing" and involves "a lot of tension in the work between the three" (Interview 3), with COVID-19 further complicating matters (Interviews 3 and 5). However, it boasts a series of recent milestones, including the 2020 update of the Trilateral Study (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020). This publication included a COVID-19-specific insert that was refined on two subsequent occasions (for the latest version, see World Health Organization et al. 2023). The WHO–WIPO–WTO cooperation has also led to greater recognition of public health priorities within WIPO and the WTO (Interviews 3 and 5). For instance, the WIPO Secretariat recently updated a document on the constraints faced by low- and middle-income countries and LDCs in making full use of patent flexibilities (World Intellectual Property Organization 2024) – a document which met with strong opposition from IFPMA (International Federation of Pharmaceutical Manufacturers and Associations 2024). Moreover, the three organisations established a Trilateral Technical Assistance Platform during the COVID-19 pandemic, the scope of which subsequently expanded. Although one interviewee still notes a general "push to sideline WHO from the side of WIPO and the WTO" (Interview 3), stakeholders tend to interpret joint technical efforts as a step in the right direction, even if this assistance platform is yet to be used by any member state (Interview 6). Across the pharmaceutical sector, more limited progress has been made in unifying the various positions. IFPMA and IGBA released a joint statement in late 2020 in which they expressed their commitment "to the principles of global equitable access to COVID-19 medicines and vaccines" (International Federation of Pharmaceutical Manufacturers and Associations 2020). However, the statement left those principles largely undefined, and the scarce language on IP is equally blurry.

In Table 1 below, we illustrate the positions of six key stakeholders on the regime complex for IP and public health – with a special focus on vaccine access – by drawing on ENSURED's key indicators: *robustness*, *effectiveness*, and *democracy*. The selected stakeholders are Brazil, Colombia, the EU, the US, the South Centre (on behalf of low- and middle-income countries), and IFPMA (on behalf of the innovative pharmaceutical industry). This limited selection is not intended to downplay the contributions of other important actors over the last five years. For example, China plays a very significant role in global access to vaccines, but it often opts for bilateral engagement – as evidenced during the COVID-19 pandemic – rather than active participation in multilateral IP negotiations (Interview 7). Instead, our selection emphasises three criteria: a diverse range of stakeholder types (states, international organisations, non-state actors), a representative sample of global viewpoints, and the stakeholder's current visibility in the relevant multilateral settings. This selection is based on

our own assessment, which was progressively refined in view of the input we obtained from interviewees. The actors' positions are derived from interview insights, meeting minutes of the relevant international organisations, and official statements and publications. We will examine some of these positions in detail in subsequent sections.

The COVID-19 pandemic once again exposed considerable tensions between the positions of high-income countries and low- and middle-income countries on securing IP rights and promoting access to vaccines and other medical products. Central to these discussions were questions about the *effectiveness* of the regime complex in ensuring rapid and equitable vaccine access, its *robustness* in maintaining stability under pressure from dissatisfied stakeholders, and its *democracy* in representing diverse voices and upholding accountability. The international organisations central to this regime complex – the WHO, WIPO, and the WTO – have all served as key venues in this regard, albeit to different degrees. Some context-specific adjustments have been implemented, but none of the potentially transformative avenues have resulted in genuine reforms, and the central tensions in the regime complex have remained unresolved.

Table 1a: Key States and Regional Actors' Positions on the IP–Public Health Regime Complex (2020–2024)

Indicators	Positions (2020–2024)
Brazil	
Robustness	Build on the WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge at the WTO. Empower the WHO to fulfil its mandate on access to medical products.
Effectiveness	Increase response speed and contemplate a more frequent and ambitious use of flexibilities (including compulsory licencing). Frame the TRIPS implementation review as an effectiveness assessment.
Democracy	Encourage transparency and the involvement of non-state actors, including technical experts.
Overall position	**Reformist player.** Comfortable with a leadership role on behalf of Global South countries under da Silva's presidency.
Colombia	
Robustness	Review the status quo, particularly TRIPS Article 31. Empower the WHO to fulfil its mandate on access to medical products.
Effectiveness	Increase response speed and contemplate a more frequent and ambitious use of flexibilities (including compulsory licencing). Frame the TRIPS implementation review as an effectiveness assessment.
Democracy	Encourage the involvement of non-state actors and prevent governance complexity from handcuffing reform-oriented actors.
Overall position	**Reformist player**, especially under Petro's presidency. Reluctant to be singled out as such.
European Union	
Robustness	Prevent IP discussions from shifting to the WHO (and, if possible, WIPO). Foster TRIPS-plus provisions whenever possible or appropriate.
Effectiveness	Defend IP even in times of emergency. Increase effectiveness by focusing on voluntary licencing and productive capacity. Prevent the TRIPS implementation review from becoming an effectiveness assessment.
Democracy	Encourage the involvement of non-state actors, although less so at the WTO.
Overall position	**Largely status-quo player**, highly favourable towards the WTO. Frequently advocates increased stringency but is open to playing a mediating role in line with historical precedent and normative leanings (e.g., Universal Health Coverage).
United States	
Robustness	Prevent IP discussions from shifting to the WHO. Defend TRIPS even while working to hollow out the WTO. Foster TRIPS-plus provisions whenever possible or appropriate.
Effectiveness	Defend IP even in times of emergency. Increase effectiveness by focusing on voluntary licencing and productive capacity. Prevent the TRIPS implementation review from becoming an effectiveness assessment.
Democracy	Satisfied with the status quo (e.g., opposes granting the South Centre observer status on the TRIPS Council).
Overall position	**Largely status-quo player.** Frequently advocates increased stringency but was more open to Global South perspectives under Biden's presidency (e.g., COVID-19 vaccine waiver, TRIPS implementation review).

Table 1b: Other Key Actors' Positions on the IP–Public Health Regime Complex (2020–2024)

Indicators	Positions (2020–2024)
South Centre	
Robustness	Shift the regime complex to WIPO and the WHO, where it has observer status. Empower the WHO to fulfil its mandate on access to medical products.
Effectiveness	Increase effectiveness by using existing flexibilities to their fullest extent, including compulsory licencing. No need to frame the TRIPS waiver as indispensable for this purpose.
Democracy	Emphasise that country capacity undermines state participation. Encourage external stakeholder involvement (i.e., international and civil society organisations). Attempt to obtain observer status at the WTO.
Overall position	**Cautious reformist.** Emphasises supporting lower-income countries to make the best of the status quo while selectively pursuing opportunities for favourable reforms.
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)	
Robustness	Emphasise the need for rule stability. Prevent IP discussions from shifting to the WHO. Advocate TRIPS-plus provisions whenever possible.
Effectiveness	Defend IP even in times of emergency. Increase effectiveness by focusing on voluntary licencing and productive capacity. Depict TRIPS vaccine waiver as an 'empty shell'; oppose the waiver in all of its formats.
Democracy	Encourage external stakeholder involvement. Moderately satisfied with WHO progress in this regard. Less satisfied with certain WIPO developments, despite more substantive alignment.
Overall position	**Largely status-quo player.** Perennially advocates increased stringency, but exhibited a more defensive mindset during the COVID-19 pandemic.

A Chronicle of Post-COVID-19 Developments

Effectiveness: Efforts to Improve Access to Vaccines

The vast majority of the transformation efforts made since the start of the pandemic have sought to increase the regime complex's effectiveness, mainly in terms of response speed and goal attainment (Choi et al. 2024, 10–13). The WTO became the focal point for low- and middle-income countries' criticism of vaccine equity during the pandemic, due to the importance of the TRIPS Agreement in governing IP rights (Mercurio and Upreti 2022; Zaman 2022). The TRIPS waiver proposal – introduced by India and South Africa in 2020 and later co-sponsored by 63 additional countries – aimed to suspend IP protections for COVID-19-related medical countermeasures (World Trade Organization 2021b; Kohler, Wong, and Tailor 2022, 163). However, high-income economies – led by the EU – opposed this broad waiver, arguing that IP was not the main barrier to vaccine access (World Trade Organization 2021a, 109–11). Instead, they pointed to insufficient manufacturing capacity, trade restrictions, and supply-chain bottlenecks. Several institutional innovations were undertaken within the WHO to address these problems. Two such initiatives stand out: COVAX and the mRNA Vaccine Technology Transfer Hub. Both allowed high-income countries to maintain their position on IP protections while pursuing alternative means to improve vaccine access.

The vast majority of the transformation efforts made since the start of the pandemic have sought to increase the regime complex's effectiveness.

COVAX, the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A), was established in 2020 as a cornerstone of global efforts to ensure equitable vaccine distribution. By pooling resources and negotiating purchases on behalf of participating countries, COVAX aimed to prevent vaccine nationalism. However, its performance was hindered by several well-documented challenges (de Bengy Puyvallée and Storeng 2022; Pushkaran, Chattu, and Narayanan 2023; Usher 2021; Yoo et al. 2022). These included high-income countries' bilateral agreements with pharmaceutical companies, through which they outcompeted COVAX for early vaccine supplies. By mid-2022, COVAX had delivered over 1.5 billion doses, but it missed its initial target of distributing 2 billion doses by the end of 2021 by a wide margin. Despite its contributions, COVAX thus fell well short of eliminating the disparities in global vaccine access. It ceased operations in December 2023.

The mRNA Vaccine Technology Transfer Hub was designed to address a different set of barriers: insufficient manufacturing capacity and technical know-how in low- and middle-income countries. This hub – launched by the WHO, the MPP, and ACT-A in 2021 and based in South Africa –

sought to empower low- and middle-income countries to produce mRNA vaccines independently (Tundang 2023). However, the major mRNA vaccine companies, including Moderna and Pfizer-BioNTech, declined to voluntarily licence their technology (Panagopoulos and Sideri 2023). Without cooperation from these companies, the hub relied on publicly available data and reverse-engineering efforts (Roelf 2023), which are time consuming and resource intensive. Thus, the hub failed to deliver COVID-19 vaccines at scale (Palmer 2022) and continues to face significant hurdles (Herder and Benavides 2024).

At the WTO, the eventual compromise on the TRIPS waiver in 2022 – which was limited to patents for COVID-19 vaccines – reflected the dominance of high-income countries in shaping the trajectory of the IP–public health regime complex (Fischer et al. 2024). This agreement only applied to developing WTO members, as China opted out under pressure from the US and other countries (Yu 2024, 357), and it did not cover diagnostics or therapeutics. Efforts made between 2022 and 2024 to extend the waiver beyond vaccines were unsuccessful.

In parallel, the WHO has sought to strengthen the effectiveness of global governance in ensuring vaccine access. The review of the International Health Regulations (IHR), finalised in 2024, led to the inclusion of some vague language on equitable access to health products, which was supposed to be more specific in the proposed pandemic agreement (Barber 2024; Berman and Sharma 2024). The negotiations on the latter addressed key issues such as R&D, technology transfer, and access and benefit-sharing. High-income countries pushed for open access to pathogen gene-sequence data, which is essential for pandemic preparedness, while resisting binding commitments to transfer IP or technology derived from such data. Instead, they continue to favour voluntary licencing on mutually agreed terms. In contrast, low- and middle-income countries advocated for stronger guarantees on technology transfer and diversified production to ensure equitable access to pandemic-related products. In the course of these negotiations, high-income countries made diluted commitments on technology transfer, offering low- and middle-income countries a new – though yet to be fully defined – pathogen-access and benefit-sharing framework instead (Beer and Koker 2024). Due to this and other contentious matters, delegates failed to meet the May 2024 deadline for reaching an agreement (Searchinger 2024), and extended discussions were complicated by the outcome of the November 2024 US presidential election. On April 16, 2025, negotiators finally agreed on a draft pandemic agreement, now pending formal adoption in the May 2025 World Health Assembly.

Robustness: Stable IP Rules, For Better or For Worse

Throughout the pandemic, the IP–public health regime complex demonstrated relatively high levels of robustness, understood here in terms of rule stability (Choi et al. 2024, 15–16). This enabled legal certainty but compromised adaptability (Choi et al. 2024, 19). Although contested,

the centrality of the WTO and the TRIPS Agreement to the regime complex has not waned. The TRIPS waiver provided little more than a clarification of existing flexibilities, which proved difficult to utilise during the pandemic. A review of the TRIPS Agreement's implementation under Article 71.1, most actively advocated for by Colombia (World Trade Organization 2024d), holds out the potential to change the status quo, but it has not been framed as a reform attempt (World Trade Organization 2024b, 24). Another element of continuity is the substantive insulation of TRIPS from President Trump's assaults on the WTO – an insulation that was also visible during his first term. IP protection is expected to remain a cornerstone of US trade and health policy, likely framed in more "hawkish" terms than during the Biden Administration (Interview 3). That said, TRIPS could be affected indirectly if the Trump Administration's protectionist and unilateral trade policy continues to undermine the WTO, the overall robustness of which has long been questioned – as most clearly exemplified by the fact that its dispute settlement mechanism has been paralysed since 2019 (see Parizek and Weinhardt 2025).

One of the most significant threats to the robustness of the regime complex lies in the possibility that countries will bypass IP rules by invoking national security exceptions under Article 73 of the TRIPS Agreement (Abbott 2020; Oke 2022). This article allows countries to override TRIPS provisions during an "emergency in international relations," which made it a plausible alternative during the COVID-19 pandemic. However, no government chose this path. Low- and middle-income countries recognised the benefits of full TRIPS compliance, including access to global trade networks and the ability to negotiate reforms from within. Exiting the regime de facto by invoking Article 73 might have entailed significant diplomatic and economic costs, including potential retaliatory trade measures by the affected parties and reduced access to essential markets. Despite these strong incentives to adhere to the rules, restraint is not a given. If low- and middle-income countries perceive the system as disproportionately favouring wealthier nations while failing to meet their needs during a crisis, then the cost-benefit calculation of remaining within the regime could shift.

Throughout the pandemic, the intellectual property–public health regime complex demonstrated relatively high levels of robustness.

Looking beyond the WTO, the most significant reform avenue was a potential WHO pandemic agreement with progressive language on IP, which could have raised "the possibility of conflict between WHO rules and decisions, and WTO rules and decisions" (Abbott 2024, 418). If such an ambitious instrument had been adopted, bringing about a genuine regime shift – as Matthew M. Kavanagh (2024) had proposed – then the resulting legal uncertainties would have been exacerbated by the likely refusal of the US, and perhaps even of other countries, to join the new agreement (Abbott 2024, 419). Such legal uncertainties have been largely averted. The recently finalised draft pandemic agreement recognises the Doha Declaration and the right to use TRIPS flexibilities to the fullest extent, but contains no transformative language on IP. Moreover, the Trump Administration's announced withdrawal from the WHO will challenge the organisation's financial capacity to foster future compliance with the agreement and lead other global health initiatives.

Meanwhile, WIPO stands out as the most robust of the three key organisations in the regime complex, primarily due to its self-financing model, which provides financial stability and shields it from some of the political and economic pressures faced by the WTO and the WHO. However, WIPO's specialised focus on IP rights means that it has historically played a limited role in addressing broader public health issues, including vaccine equity. While WIPO has collaborated with the WHO and the WTO under the Trilateral Cooperation Framework, its contributions have been largely confined to technical assistance. Nevertheless, there is no legal impediment to WIPO regaining its role as the primary forum on IP governance – which is a more plausible scenario now that the WTO's most distinctive feature (its dispute settlement mechanism) has been handicapped. While not centred primarily on public health, the new WIPO Treaty on IP, Genetic Resources and Associated Traditional Knowledge has demonstrated that momentum can shift back to this organisation if the political will exists. As Brazil recently observed: "TRIPS should perhaps evolve to take into consideration this new WIPO Treaty, as well as other new developments at WIPO in terms of norm setting" (World Trade Organization 2024a, 18) – a proposal the US promptly rebuffed (World Trade Organization 2024a, 18).

Democracy: Modest Progress in Non-State Actor Participation

The three organisations comprising the IP–public health regime complex are state-based and have broad memberships. Their inclusivity often hampers their effectiveness in terms of rapid decision-making (Choi et al. 2024, 17), as evidenced by recent developments in all three organisations. Nearly all the same actors are members of the WHO and WIPO. While the WTO lags behind by nearly 30 members, this discrepancy does not significantly limit the organisation's representativeness in the eyes of regime members, nor does it hinder Trilateral Cooperation activities (Interview 6). We should also note that the vast majority of WTO non-members have observer status at the organisation. Additionally, seven non-members are UN-recognised LDCs, meaning they would be exempted from applying most TRIPS provisions even if they acceded to the WTO (World Trade Organization n.d.-a).

TRIPS Council engagement with non-state actors is still minimal, and high-income countries continue to favour the WTO's state-centric governance model.

Efforts to enhance democracy by increasing non-state actors' participation and the regime complex's accountability (Choi et al. 2024, 6–9) have seen limited progress over the last five years. Some state representatives and civil society organisations at the WHO have called for the pandemic agreement negotiations to be more open and accessible. Some improvements have gradually been made (Interview 8), but less so in the areas of transparency and access to information. For example, open sessions are webcast, but verbatim records are not made available – contrary to standard practices at WIPO (which provides automatic transcripts) and the WTO (which publishes detailed minutes, although these are restricted for 45

days after their circulation). One notable development at the WTO was the Informal Thematic Session for External Stakeholder Input held by the TRIPS Council on September 28, 2023. This session, the first of its kind, allowed non-state actors such as civil society organisations, public health advocates, pharmaceutical companies, and academic experts to share their perspectives (World Trade Organization 2023). While this initiative provided a platform for stakeholder consultation, it remained a one-off informal mechanism. TRIPS Council engagement with non-state actors is still minimal, and high-income countries continue to favour the WTO's state-centric governance model.

Having discussed the main post-COVID-19 developments in the IP–public health nexus from the perspective of the regime complex's effectiveness, robustness, and democracy, we proceed to summarise these developments in Table 2 below. The table includes adopted proposals, ongoing initiatives, and abandoned efforts. We focus on the three international organisations under consideration here while also listing the primary outcomes of the WHO–WIPO–WTO Trilateral Cooperation, as mentioned in the previous section.

Table 2: IP and Public Health Governance – Key Milestones in the Post-COVID-19 Era (2020–2024)

	Proposed/actual milestone	Relevant developments/ substance	Date(s)
WHO	COVAX	Did not address IP rules; limited effectiveness	2020–2023
	mRNA Vaccine Technology Transfer Hub	Did not address IP rules; limited effectiveness	2021–present
	Amendment of the 2005 International Health Regulations	Article 13 on public health response and equitable access to health products	2022 (negotiations began) -2024 (adopted)
	Proposed agreement on pandemic prevention, preparedness, and response	Preamble; Article 11 on pandemic-related health products	2022 (negotiations began) –present
WIPO	New Treaty on IP, Genetic Resources and Associated Traditional Knowledge	Disclosure of the source of the genetic resources or traditional knowledge used in an innovation (e.g., a drug)	2001 (negotiations began) –2024 (adopted)
WTO	COVID-19: waiver of TRIPS provisions	India and South Africa's communication (initial proposal)	10/02/2020
		EU's communication (counter-proposal)	06/04/2021
		WTO Ministerial Decision on a vaccine waiver	06/17/2022
		Waiver extended to diagnostics and therapeutics	2022 (negotiations began) –2024 (abandoned)
		External stakeholder session at TRIPS Council	09/28/2023
	TRIPS implementation review (Article 71.1)	Communication from Colombia	04/15/2024
WHO–WIPO–WTO Trilateral Cooperation	Second edition of the Trilateral Study	Update of the 2013 Trilateral Study	07/29/2020
	COVID-19 'insert' in the Trilateral Study	Regular updates of information notes on COVID-19	07/29/2020 08/30/2021 05/17/2023
	Trilateral Technical Assistance Platform	Initial focus on COVID-19; subsequently broadened	2022–present

The Role of the European Union

The EU is a key actor at the intersection of IP and public health, often seeking to play a mediating role between high-income and low- and middle-income countries (Interviews 4 and 11). In the early 1980s, European countries were not enthusiastic about embracing a trade-based understanding of IP (Sell 2003, 104–8). When negotiations on TRIPS kicked off in earnest within the framework of the Uruguay Round, Europe was reluctant to accept a wide-ranging agreement. The 1973 European Patent Convention recognised pharmaceuticals as patentable inventions, but a few European countries – such as Greece, Portugal, and Spain – were still applying an exemption in the early 1990s (Boscheck 2015). Ultimately, this did not prevent an eventual compromise on TRIPS, and the EU secured several concessions, including "more forgiving" provisions on compulsory licencing than those advocated for by the US (Sell 2003, 116).

The EU is a key actor at the intersection of intellectual property and public health.

Since TRIPS came into force, the EU's relatively progressive role in pharmaceutical access has become more ambivalent. The bloc's evolving thinking on the matter was captured in a 1998 European Commission note, which asserted that "no priority should be given to health over intellectual property considerations in particuar [sic] in light of the absence of any evidence of conflict between the two" (European Commission 1998). While analysts have often singled out the US as a proponent of stringent IP protection through bilateral or plurilateral agreements, the EU has engaged in this practice as well ('t Hoen 2009, 74). In 2008, the EU was a major proponent of the Anti-Counterfeiting Trade Agreement (Sell 2010, 433) – an attempt to bring about a vertical forum shift away from WIPO and the WTO. This treaty faced strong public opposition in Europe, with widespread criticism of its opaque negotiations, which led to the European Parliament's first-ever rejection of an international agreement (European Parliament n.d.). Despite its failure, the proposed treaty ushered in an era of even stricter "TRIPS-plus-plus" clauses in EU bilateral and regional deals – a development largely driven by the 2008 Lisbon Treaty and the EU's expanded competencies in IP (Sunner 2020, 245–46). Compared to the late 1990s, however, the EU's IP agenda in the twenty-first century has been more permeable to the concerns of low- and middle-income countries. For example, the EU's bilateral and regional agreements have frequently invoked the 2001 Doha Declaration, reflecting a broader trend identifiable in preferential trade agreements worldwide (Vidigal and Parwani 2024, 26). The EU's willingness to temper TRIPS-plus (or TRIPS-plus-plus) clauses with human rights provisions has been most visible in trade deals with South and Central American nations (Sunner 2020, 325).

While the EU has typically sought to push the TRIPS Agreement towards greater stringency, it has primarily behaved as a status-quo player vis-à-vis the trilateral WHO–WIPO–WTO relationship. The EU is content with the WTO's central role in the regime complex, since that forum most clearly plays to the EU's strengths (Interview 4). At the WTO, the EU can leverage its large single market, which constitutes its greatest asset internationally (Bradford 2020; Damro 2012). From the European

Commission's perspective, the EU's single representation at the WTO offers distinct advantages – even more so when one considers that the WHO and WIPO only accept states as members, which relegates the EU to an observer role. Nevertheless, the EU can exercise influence even from that position (Gehring, Oberthür, and Mühleck 2013). For instance, the EU decisively shaped and eventually became a party to the 2003 Framework Convention on Tobacco Control, the only treaty adopted under WHO auspices (Chamorro 2016; Guigner 2009; Ruiz Cairó 2021), with the pandemic agreement now likely to become the second. Meanwhile, the EU has also been an important presence at WIPO, even though it is a party to some conventions and not others (Gagliani 2020, 55–56). These caveats aside, the WTO remains the most attractive forum for the EU, largely because it presents an opportunity to circumvent the often-painstaking internal coordination efforts that are unavoidable in other organisations (Interview 4).

The WTO remains the most attractive forum for the EU.

The EU's conflicted stance on equitable access became evident after COVID-19 struck and medical countermeasures began to enter the market. On the one hand, the EU co-sponsored and contributed to ACT-A and its vaccine pillar, COVAX. The EU and its member states – "Team Europe" – collectively emerged as the leading donors of COVID-19 vaccines worldwide (World Health Organization-EMRO 2022). The EU's 2022 Global Health Strategy highlighted some additional EU achievements in the COVID-19 context while acknowledging that "combatting current and future health threats [...] calls for enhanced equity in the access to vaccines and medical countermeasures" (European Commission 2022, 6). Multiple analysts argued that the EU's response to the pandemic fell short in that department, chiefly because the European Commission reached advance purchase agreements with pharmaceutical companies that undermined COVAX (de Bengy Puyvallée and Storeng 2022; Deters and Zardo 2023). The EU's 2022 Global Health Strategy remained largely silent on the IP–public health nexus,[3] and the EU's preferences were largely unaltered by the COVID-19 pandemic. For example, once the pandemic began to subside, the EU and India resumed their negotiations on a bilateral free trade agreement, which Médicins Sans Frontières denounced: "the EU had brought back some of the harmful provisions that were removed in earlier negotiations due to strong pushback" (Médicins Sans Frontières Access Campaign 2024a).

Throughout the pandemic, much of the scrutiny directed at the EU concerned its role at the WTO, where it "voiced the strongest opposition to the TRIPS waiver" ('t Hoen 2021). The EU defended the robustness and effectiveness of the TRIPS Agreement, claiming that its flexibilities were more than adequate and that IP should be credited for the rapid development of COVID-19 vaccines. When the US shifted its initial position and embraced a limited TRIPS waiver, the EU was forced to adjust. However, the eventual WTO Ministerial Decision closely resembled the EU's proposal (Furlong, Aarup, and Horti 2022), which was widely dismissed as lacking

3 The only exception is a rather vague paragraph on "ensur[ing] that international trade policy works for global health," which includes a reference to the TRIPS waiver (European Commission 2022, 16).

real impact (Médicins Sans Frontières Access Campaign 2021; 't Hoen 2021). Between 2022 and 2024, the EU opposed extending the waiver to diagnostics and therapeutics, and more recently it expressed scepticism about the proposed TRIPS implementation review. The EU believes that "the objective, scope, substance, modalities, and working arrangements of this review should be thoroughly assessed and agreed by the Members before the review process can be launched" (World Trade Organization 2024a, 25) and does not see "much room for the engagement of external stakeholders" (World Trade Organization 2024a, 26). As one interviewee suggested (Interview 3), a critical point of contention is whether the review would primarily address the *impact* of TRIPS implementation or the *degree* of implementation, including potential cases of non-compliance. The EU's preference is the latter, but this guarded stance does not reflect the views of all its member states, some of which – especially smaller ones – would be more willing to contemplate a less protectionist approach to IP (Interviews 4 and 7). Yet the sharp division of labour between the EU's mission to the WTO and its delegation to the UN in Geneva tends to reinforce the EU's commitment to rule stability, obstructing the engagement of health-focused delegates at WTO negotiations.

As these events unfolded at the WTO, the EU inadvertently set the stage for a potential forum shift in the governance of IP and public health through its advocacy of a pandemic agreement under WHO auspices. The former president of the European Council, Charles Michel, was the first world leader to float this idea (European Council 2020), in line with a broader EU effort to shield the WHO and multilateralism from President Trump's onslaughts (Schuette and Dijkstra 2023). Contrary to the IHR, which are exclusively state-based, a pandemic treaty would allow the EU to become a party to the contract (Ruiz Cairó 2022, 6). From the outset, the pandemic agreement was conceived as more expansive than the IHR. It thus transcended the EU's limited competencies in public health, justifying coordinated action across the bloc (Interview 4) and between the EU's delegation to the UN and its mission to the WTO in Geneva. However, this also meant that IP inevitably became part of the conversation, forcing the EU to attempt to constrain the very instrument it had championed. Commenting on the "Zero Draft" of the pandemic agreement, the EU and its member states jointly objected to the language on IP, asserting that "the WTO and WIPO are the most appropriate fora for international rule-making on intellectual property rights" (European External Action Service 2022, 12). At the same time, the EU has played a pivotal role in enhancing the transparency and openness of the negotiations, even at the risk of exposing itself to the criticism of civil society organisations that have frequently challenged its views on IP (Interview 8; see also Cullinan 2024).

The EU inadvertently set the stage for a potential forum shift in the governance of intellectual property and public health.

One final example of the EU's ambivalent role regarding IP and access to medical products is its draft legislation on a "Union Compulsory Licence," which would complement national schemes. While civil society organisations have generally welcomed this proposal, they have raised concerns about the export restrictions under consideration (Médicins Sans Frontières Access Campaign 2024b) and pointed out contradictions

with the EU's more rigid approach in the pandemic agreement negotiations (Balasubramaniam 2024a). The European Parliament has often been an ally of civil society in advocating flexible IP rules that prioritise affordability as well as greater transparency in international negotiations (Drezner 2008, 181; Sell 2010, 457), but the rightward shift that resulted from the 2024 EU elections may well alter this dynamic. Moreover, the COVID-19 pandemic revealed that the EU's concrete interests – including how to balance the robustness, effectiveness, and democracy of global governance mechanisms when trade-offs arise – are highly dependent on the context and the institution. In any case, the EU's frequent openness to diverse stakeholder input and its constant need to craft complex internal equilibria often results in a conciliatory approach in multilateral fora (Interview 4). This openness, combined with the pull factor of its single market, positions the EU as "probably the most important player in IP" (Interview 7) – thus, it is bound to continue shaping important conversations on IP, trade, and public health for the foreseeable future.

The COVID-19 pandemic revealed that the EU's concrete interests are highly dependent on the context and the institution.

Conclusion: The Future of the Regime Complex

This study has explored the following research question: How has regime complexity shaped the *robustness*, *effectiveness*, and *democracy* of global governance in the IP–public health nexus? We found that regime complexity has historically compromised robustness due to persistent forum shopping, although rule stability has generally increased over time. Regarding effectiveness, stringent IP protection has been prioritised over rapid and equitable access to vaccines and other pharmaceuticals. As for democracy, we have shown that the WTO – the cornerstone of the regime complex – performs worse than WIPO and the WHO on certain democratic indicators. We also raised concerns about the shortcomings of preferential trade agreements in terms of transparency and power imbalances.

The regime complex will likely remain broadly stable, with the WTO and WIPO maintaining their central positions. While the system has faced severe criticism, with many voices calling for an enhanced WHO role, the strength of status-quo players suggests that continuity will be the norm – with some caveats. WIPO appears more robust than the WTO, given the former's technical focus and relative insulation from geopolitical tensions. By contrast, the WTO is highly vulnerable to any increase in trade disputes. While these can spill over into IP discussions, there is little chance they will fundamentally reshape or undermine the TRIPS regime.

Any efforts to reform TRIPS by means of an implementation review – if indeed consensus to undertake such a review exists – are also unlikely to result in significant shifts. Adjustments are conceivable but would probably be modest, addressing procedural concerns rather than fundamentally altering the balance between IP rights and access to medical products. One possible area in which progress could be made is loosening export restrictions under compulsory licencing – an issue that has drawn attention for years, and one on which high-income countries might be willing to consider further flexibility. However, it would be a mistake to assume that any prospective adjustments in the regime complex would be in the interests of lower- and middle-income countries. For example, the new US administration is expected to pursue a strong IP agenda in the context of an "America first" trade policy, and we have seen signs that the EU will also continue to champion TRIPS-plus provisions in preferential trade deals. Stricter IP protection could thus become 'the new normal.'

The strength of status-quo players suggests that continuity will be the norm.

Negotiations around a WHO pandemic agreement addressed the need for equitable access, but they did not lead to transformative IP provisions. A treaty is set to emerge, without US participation, but its IP language will be limited to reaffirming TRIPS flexibilities rather than creating a new and potentially conflicting set of rules. Despite the technology transfer gaps in the response to COVID-19, particularly concerning mRNA vaccines,

negotiators from high-income countries have continued to underscore the benefits of voluntary licencing on mutually agreed terms.

As for the inclusiveness and accountability of the regime complex, there is some potential for improvement, mainly through incremental advances at the WHO and the WTO. The 2023 TRIPS Council session with external stakeholders offered a glimpse of how participation at the WTO could be expanded, and opportunities may exist to contemplate similar engagement mechanisms with non-state actors, even if these do not become highly institutionalised. Another concrete proposal would be to ensure that all international organisations provide meeting minutes in a timely and accessible manner. In this area, the WHO and the WTO currently lag behind WIPO. Such modest steps towards openness and transparency could boost the democratic legitimacy of the regime complex.

The WHO, WIPO, and the WTO must continue strengthening their Trilateral Cooperation.

Institutional recalibrations and even changes in national governments aside, member-state preferences can be expected to remain relatively constant, with forum-shopping dynamics following well-established patterns. In light of this, the WHO, WIPO, and the WTO must continue strengthening their Trilateral Cooperation. Stakeholders tend to evaluate this initiative positively overall, which makes it a rare example of an innovation that has gained widespread acceptance and helped to bridge deep-seated divides. Consolidating this and other transversal, implementation-focused instruments is a necessary – albeit not sufficient – condition if the regime complex on IP and public health is to deliver on the promise of equitable access.

List of Interviews

Number	Date	Interviewee	Location
1	11/20/2024	WHO official	Online
2	11/22/2024	EU official	Online
3	11/25/2024	South Centre staff member	Geneva
4	11/26/2024	WHO consultant	Geneva
5	11/26/2024	Public health organisation staff member	Geneva
6	11/27/2024	WTO official	Geneva
7	11/27/2024	Colombian official	Geneva
8	11/28/2024	NGO staff member	Geneva
9	11/28/2024	Public health organisation staff member	Geneva
10	11/29/2024	WIPO official	Geneva
11	12/20/2024	Pharmaceutical association staff member	Online

References

Abbott, Frederick M. 2005. "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health." *The American Journal of International Law* 99 (2): 317–58. https://doi.org/10.2307/1562501.

—. 2013. "Review: The Trilateral Study on Health, Intellectual Property, and Trade: The Virtue in Paving a Cleared Roadway." *Journal of International Economic Law* 16 (2): 493–503. https://doi.org/10.1093/jiel/jgt017.

—. 2020. "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic." Research Paper 116. Geneva: South Centre. https://www.southcentre.int/wp-content/uploads/2020/08/RP-116-reduced_1.pdf.

—. 2024. "The State of Intellectual Property and International Law." In *New Trends in International Law: Festschrift in Honour of Judge Hisashi Owada*, edited by Chia-Jui Cheng, 415–28. Leiden: Brill. doi.org/10.1163/9789004684140.

Bahri, Amrita. 2018. "Developing Countries at WTO Dispute Settlement Understanding: Strengthening Participation." In *Public Private Partnership for WTO Dispute Settlement*, 13–34. Cheltenham: Edward Elgar Publishing. https://www.elgaronline.com/monochap/9781786437488/chapter01.xhtml.

Balasubramaniam, Thiru. 2024a. "NGOs QUESTION EU'S PATENT FLIP-FLOP." Bluesky post. https://bsky.app/profile/thirugeneva.bsky.social/post/3l6rj3t42um2x.

—. 2024b. "The WHO Pandemic Treaty: The Peace Clause and Its Discontents." Knowledge Ecology International (blog), April 4, 2024. https://www.keionline.org/39585.

Barber, Melissa. 2024. "Technology Transfer, Intellectual Property, and the Fight for the Soul of WHO." *PLOS Global Public Health 4* (12): e0003940. https://doi.org/10.1371/journal.pgph.0003940.

Beer, Jeremy de and Rosa De Koker. 2024. "Negotiation of New International Health Law on Intellectual Property, Technology Transfer, Open Science and Pathogen Access and Benefit Sharing: A Textual and Contextual Analysis." *BMJ Public Health* 2 (2). https://doi.org/10.1136/bmjph-2024-001467.

Bengy Puyvallée, Antoine de and Katerini Tagmatarchi Storeng. 2022. "COVAX, Vaccine Donations and the Politics of Global Vaccine Inequity." *Globalization and Health* 18 (1): 26. https://doi.org/10.1186/s12992-022-00801-z.

Berman, Ayelet and Kriti Sharma. 2024. "The New Amendments to the International Health Regulations (77th WHA, 2024)." NUS Centre for International Law. https://cil.nus.edu.sg/wp-content/uploads/2024/06/The-New-IHR-Amendments-2024_27.06.2024-FINAL.pdf.

Boscheck, Ralf. 2015. "Intellectual Property Rights and the Evergreening of Pharmaceuticals." *Intereconomics* 50 (4): 221–26.

Bradford, Anu. 2020. *The Brussels Effect: How the European Union Rules the World*. Oxford: Oxford University Press.

Chamorro, Lourdes. 2016. “Law and the EU Role in Global Health Strategies: The Case of the FCTC.” In *The European Union as a Global Health Actor*, edited by Thea Emmerling, Ilona Kickbusch, and Michaela Todd, 251–67. Singapore: World Scientific. https://www-worldscientific-com.are.uab.cat/worldscibooks/10.1142/9714#.

Choi, Ha Eun, Hylke Dijkstra, Andrea Liese, Thomas Sommerer, and Clara Weinhardt. 2024. “EU Support for Robust, Effective, and Democratic Global Governance: A Conceptual Framework.” *ENSURED Research Report*, no. 4 (July). https://www.ensuredeurope.eu/publications/conceptual-framework.

Christou, Stella and Donatella Della Porta. 2024. “Contesting Patents on COVID-19 Vaccines in the EU: The No Profit on Pandemic Campaign.” *Journal of European Public Policy*: 1–26. https://doi.org/10.1080/13501763.2024.2418330.

Cullinan, Kerry. 2024. “New Blood for Resumed Pandemic Agreement Negotiations.” Health Policy Watch, July 16, 2024. https://healthpolicy-watch.news/new-blood-for-resumed-pandemic-agreement-negotiations/.

Damro, Chad. 2012. “Market Power Europe.” *Journal of European Public Policy* 19 (5): 682–99. https://doi.org/10.1080/13501763.2011.646779.

Deters, Henning and Federica Zardo. 2023. “The European Commission in COVID-19 Vaccine Cooperation: Leadership vs Coronationalism?” *Journal of European Public Policy* 30 (6): 1051–71. https://doi.org/10.1080/13501763.2022.2064900.

Drahos, Peter. 1995. “Global Property Rights in Information: The Story of TRIPS at the GATT.” *Prometheus* 13 (June): 6–19. https://doi.org/10.1080/08109029508629187.

Drezner, Daniel W. 2008. *All Politics Is Global: Explaining International Regulatory Regimes*. Princeton: Princeton University Press.

European Commission. 1998. “European Commission (DG 1) Note on the WHO’s Revised Drug Stategy.” http://www.cptech.org/ip/health/who/eurds98.html.

—. 2022. “EU Global Health Strategy: Better Health for All in a Changing World.” Publications Office. https://data.europa.eu/doi/10.2875/22652.

European Council. 2020. “‘Towards a World Better Prepared for Shocks’ – Speech by President Charles Michel at the Paris Peace Forum.” November 12, 2020. https://www.consilium.europa.eu/en/press/press-releases/2020/11/12/intervention-du-president-charles-michel-au-forum-de-paris-sur-la-paix/.

European External Action Service. 2022. “Conceptual Zero Draft for the Consideration of the Intergovernmental Negotiating Body at Its Third Meeting: Specific Comments Prepared by the European Union and Its Member States.” https://www.eeas.europa.eu/sites/default/files/documents/INB%203%20-%20Conceptual%20Zero%20draft%20-%20Specific%20comments%20from%20the%20EU%20and%20EU%20MS.pdf.

European Parliament. n.d. “Everything You Need to Know about ACTA.” https://www.europarl.europa.eu/RegData/presse/pr_gran/2012/EN/03A-DV-PRESSE_FCS(2012)02-20(38611)_EN.pdf.

Fischer, Sara E., Lucia Vitale, Akinyi Lisa Agutu, and Matthew M. Kavanagh. 2024. “Intellectual Property and the Politics of Public Good during COVID-19: Framing Law, Institutions, and Ideas during TRIPS Waiver Negotiations at the WTO.” *Journal of Health Politics, Policy and Law* 49 (1): 9–42. https://doi.org/10.1215/03616878-10910269.

Furlong, Ashleigh, Sarah Anne Aarup, and Samuel Horti. 2022. "Who Killed the COVID Vaccine Waiver?" *POLITICO*, November 9, 2022. https://www.politico.eu/article/COVID-vaccine-poor-countries-waiver-killed/.

Gagliani, Gabriele. 2020. "The WIPO-WTO Relationship: Moving beyond the Forum-Shifting Theory?" *International Organizations Law Review* 18 (1): 46–71. https://doi.org/10.1163/15723747-2020017.

Gehring, Thomas, Sebastian Oberthür, and Marc Mühleck. 2013. "European Union Actorness in International Institutions: Why the EU Is Recognized as an Actor in Some International Institutions, but Not in Others." *JCMS: Journal of Common Market Studies* 51 (5): 849–65. https://doi.org/10.1111/jcms.12030.

Guigner, Sébastien. 2009. "The EU and the Health Dimension of Globalization: Playing the World Health Organization Card." In *The European Union and the Social Dimension of Globalization, edited by Jan Orbie and Lisa Tortell*, 131–47. New York: Routledge.

Haugen, Hans Morten. 2021. "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?" *The Journal of World Intellectual Property* 24 (3–4): 195–220. https://doi.org/doi.org/10.1111/jwip.12187.

Helfer, Laurence R. 2004. "Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking." *Yale Journal of International Law* 29 (1): 1–84.

—. 2009. "Regime Shifting in the International Intellectual Property System." *Perspectives on Politics* 7 (1): 39–44. https://doi.org/10.1017/S1537592709090069.

Herder, Matthew and Ximena Benavides. 2024. "'Our Project, Your Problem?' A Case Study of the WHO's mRNA Technology Transfer Programme in South Africa." *PLOS Global Public Health* 4 (9): e0003173. https://doi.org/10.1371/journal.pgph.0003173.

Hoen, Ellen 't. 2009. *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*. Amsterdam: AMB.

—. 2016. *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*. Health Action International.

—. 2021. "The EU Proposed COVID Waivers of Certain TRIPS Rules Are Mostly Meaningless." Medicines Law & Policy, October 14, 2021. https://medicineslawandpolicy.org/2021/10/the-eu-proposed-COVID-waivers-of-certain-trips-rules-are-mostly-meaningless/.

International Federation of Pharmaceutical Manufacturers and Associations. 2020. "IFPMA/IGBA 'Considerations on Equitable Access to COVID-19 Medicines and Vaccines.'" https://www.ifpma.org/news/ifpma-igba-considerations-on-equitable-access-to-COVID-19-medicines-and-vaccines/.

—. 2022. "COVID-19 Vaccines and Treatments Output Continues Apace; as Health Systems and Last Mile Hurdles Remain Collective Stumbling Blocks." April 13, 2022. https://www.ifpma.org/news/COVID-19-vaccines-and-treatments-output-continues-apace-as-health-systems-and-last-mile-hurdles-remain-collective-stumbling-blocks/.

—. 2024. “WIPO Standing Committee on Patents: Statement on Patents and Health.” October 16, 2024. https://www.ifpma.org/news/statement-at-the-36th-meeting-of-wipos-standing-committee-on-patents-patents-and-health/.

Kavanagh, Matthew M. 2024. “The WTO Failed the World in COVID.” *Foreign Policy*, February 28, 2024. https://foreignpolicy.com/2024/02/28/wto-COVID-pandemic-treaty-vaccines-patents-intellectual-property/.

Kohler, Jillian, Anna Wong, and Lauren Tailor. 2022. “Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders.” *Health and Human Rights* 24 (2): 159.

Medicines Law & Policy. n.d. “The TRIPS Flexibilities Database.” http://tripsflexibilities.medicineslawandpolicy.org.

Médicins Sans Frontières Access Campaign. 2021. “MSF Analysis of EU Communications to TRIPS Council on COVID-19 IP Waiver Proposal.” June 29, 2021. https://msfaccess.org/sites/default/files/2021-06/COVID19_TechnicalBrief_MSF_EU-counterproposal-analysis_WTO-TRIPS-Waiver_update_20210624_ENG.pdf.

—. 2024a. “EU Must Drop All Intellectual Property Provisions That Go beyond WTO Requirements in Trade Negotiations with India, as Recommended in Today’s SIA Report.” February 29, 2024. https://www.msfaccess.org/eu-must-drop-all-intellectual-property-provisions-go-beyond-wto-requirements-trade-negotiations.

—. 2024b. “Letter: Civil Society Calls on European Parliament to Support Global Access to Medical Tools by Removing Export Prohibition in Union Compulsory License.” March 5, 2024. https://msfaccess.org/letter-civil-society-calls-european-parliament-support-global-access-medical-tools-removing-export.

Mercurio, Bryan and Pratyush Nath Upreti. 2022. “From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for COVID-19 Vaccines and Treatments.” *World Trade Review* 21 (5): 633–49. https://doi.org/10.1017/S1474745622000283.

Nguyen, Aurelia and Nina Schwalbe. 2019. “Apples and Oranges? Can Second Generation Vaccines Become as Low Cost as Generic Medicines?” *Vaccine* 37 (22): 2910–14. https://doi.org/10.1016/j.vaccine.2019.04.016.

Oke, Emmanuel. 2022. “Access to COVID-19 Vaccines, Patent Rights, and the TRIPS Agreement.” *Maryland Journal of International Law* 36 (1): 7–13.

Palmer, Chris. 2022. “Access Issues Spur Local Vaccine Efforts in Developing World.” *Engineering (Beijing)* 15 (August): 3–5. https://doi.org/10.1016/j.eng.2022.06.001.

Panagopoulos, Andreas and Katerina Sideri. 2023. “From Lab to Mass Production: A Policy for Enabling the Licensing of mRNA Vaccines.” *Frontiers in Public Health* 11 (May): 1151713. https://doi.org/10.3389/fpubh.2023.1151713.

Parizek, Michal and Clara Weinhardt. 2025. “Revitalising and Reforming the World Trade Organization in an Age of Geopolitics.” *ENSURED Research Report,* no. 5 (May): 1-32. https://www.ensuredeurope.eu.

Park, Sung-Pil, Hye Jin Lee, Yang Yu, Eric Yong Joong Lee, and Young Soo Park. 2023. "Designing the Global Vaccine Supply Chain: Balancing Intellectual Property Rights with Post COVID-19 Vaccine Equity." *BMJ Global Health* 8 (11): e013669. https://doi.org/10.1136/bmjgh-2023-013669.

Patnaik, Priti. 2022. "Have India and South Africa, Lead Sponsors of the TRIPS Waiver Proposal, Reconciled to a Weak Text?" *The Wire* (blog), June 10, 2022. https://cms.thewire.in/world/diplomacy/have-india-and-south-africa-lead-sponsors-of-the-trips-waiver-proposal-reconciled-to-a-weak-text.

—. 2024. "Using TRIPS Flexibilities: Easier Said Than Done? [Update from WIPO SCP]." Substack newsletter. *Geneva Health Files* (blog), November 8, 2024. https://genevahealthfiles.substack.com/p/easier-said-than-done-using-trips-flexibiities-wipo-wto-who-patents-medicines-fta-ifpma.

Pushkaran, Anjali, Vijay Kumar Chattu, and Prakash Narayanan. 2023. "A Critical Analysis of COVAX Alliance and Corresponding Global Health Governance and Policy Issues: A Scoping Review." *BMJ Global Health* 8 (10): e012168. https://doi.org/10.1136/bmjgh-2023-012168.

Raustiala, Kal and David G. Victor. 2004. "The Regime Complex for Plant Genetic Resources." *International Organization* 58 (2): 277–309. https://doi.org/10.1017/S0020818304582036.

Reichman, Jerome H. and Rochelle Cooper Dreyfuss. 2007. "Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty." *Duke Law Journal* 57: 85–130.

Roelf, Wendell. 2023. "WHO Launches mRNA Vaccine Hub in Cape Town." *Reuters*, April 21, 2023. https://www.reuters.com/business/healthcare-pharmaceuticals/who-officially-launches-mrna-vaccine-hub-cape-town-2023-04-20/.

Ruiz Cairó, Elisabet. 2021. *The Promotion of Public Health in EU External Relations*. Zürich: Schulthess. https://www.schulthess.com/verlag/detail/ISBN-9783725588190/Ruiz-Cairo/The-promotion-of-public-health-in-EU-external-relations-PrintPlu%A7?bpmlang=fr.

—. 2022. "The European Union and the Negotiation of the International Pandemic Treaty: Interests at Stake and Potential Contribution." Policy Brief. Global Health Centre.

Schuette, Leonard and Hylke Dijkstra. 2023. "The Show Must Go on: The EU's Quest to Sustain Multilateral Institutions since 2016." *JCMS: Journal of Common Market Studies* 61 (5): 1318–36. https://doi.org/10.1111/jcms.13466.

Searchinger, Chloe. 2024. "Why Pandemic Agreement Negotiations Failed to Land." Think Global Health, May 24, 2024. https://www.thinkglobalhealth.org/article/why-pandemic-agreement-negotiations-failed-land.

Sell, Susan K. 2003. *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511491665.

—. 2009. "Cat and Mouse: Industries', States' and NGOs' Forum – Shifting in the Battle over Intellectual Property Enforcement." SSRN Scholarly Paper. Rochester, NY. https://doi.org/10.2139/ssrn.1466156.

—. 2010. “TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP.” *Journal of Intellectual Property Law* 18 (2): 447–78.

Shah, Kavia and Rebecca Katz. 2024. “Pharma’s Influence on India’s Global Health Engagement.” Think Global Health, November 12, 2024. https://www.thinkglobalhealth.org/article/pharmas-influence-indias-global-health-engagement.

South Centre. 2021. “Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic.” https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/.

Sunner, William Stephen. 2020. “Trips-plus Provisions in European Union Agreements: Enhanced Protection of Intellectual Property or Restriction of Human Rights?” Maynooth University. https://mural.maynoothuniversity.ie/id/eprint/13583/1/Liam%20Sunner%20Thesis%20%282%29.pdf.

Taubman, Antony. 2020. “Nothing for Us, without Us: Growth and Diversity in Observers Participation in WIPO.” In *Research Handbook on the World Intellectual Property Organization*, edited by Sam Ricketson, 376–401. Cheltenham: Edward Elgar Publishing. https://www.elgaronline.com/edcollchap/edcoll/9781788977661/9781788977661.00025.xml.

Tundang, Ronald Eberhard. 2023. “The Outlook for Transfer of Technology of mRNA Vaccines through the WHO Tech Transfer Hub.” *Journal of Intellectual Property Law & Practice* 18 (9): 673–81. https://doi.org/10.1093/jiplp/jpad067.

Usher, Ann Danaiya. 2021. “A Beautiful Idea: How COVAX Has Fallen Short.” *The Lancet* 397 (10292): 2322–25. https://doi.org/10.1016/S0140-6736(21)01367-2.

Velásquez, Germán and Pascale Boulet. 2015. *The WHO “Red Book” on Access to Medicines and Intellectual Property: 20 Years Later*. Geneva: South Centre.

Vidigal, Geraldo and Pramiti Parwani. 2024. “Beyond TRIPS and Waivers: The Interactional Law of Intellectual Property Protection and Public Health.” SSRN Scholarly Paper. Rochester, NY. https://papers.ssrn.com/abstract=4838041.

Wendland, Wend. 2024. “The New WIPO Treaty 25 Years in the Making: What Does It Mean and What Happens Next?” *WIPO Magazine*, October 3, 2024. https://www.wipo.int/web/wipo-magazine/articles/the-new-wipo-treaty-25-years-in-the-making-what-does-it-mean-and-what-happens-next-68223.

Woodward, Barbara K. 2012. “The Roles of Non-State Actors in Lawmaking within the Global Intellectual Property Regimes of WIPO and TRIPs.” *International Community Law Review* 14 (1): 33–61. https://doi.org/10.1163/187197312X617683.

World Health Assembly. 1996. “Revised Drug Strategy Resolution.” https://iris.who.int/handle/10665/172819.

—. 2008. “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.” https://doi.org/10.2471/B09072.

World Health Organization, World Intellectual Property Organization, and World Trade Organization. 2013. *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property, and Trade*. Geneva: World Health Organization; World Intellectual Property Organization; World Trade Organization.

—. 2020. *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*. 2nd ed. https://www.who.int/publications/i/item/9789240008267.

—. 2023. "An Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic." https://doi.org/10.30875/daff2007-en.

World Health Organization-EMRO. 2022. "Italy Joins Other European Union Member States to Increase Pledge of COVID-19 Vaccines to Syria." January 2, 2022. http://www.emro.who.int/syria/news/italy-joins-european-union-member-states-to-increase-pledge-of-COVID-19-vaccines-to-syria.html.

World Intellectual Property Organization. 2004. "Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO." https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_11.pdf.

—. 2024. "Constraints Faced by Developing Countries and Least Developed Countries (LDCS) in Making Full Use of Patent Flexibilities and Their Impacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in Those Countries (Update of Document SCP 26/5)." https://www.wipo.int/edocs/mdocs/scp/en/scp_36/scp_36_6.pdf.

—. n.d. "Results, Budget and Performance." https://www.wipo.int/about-wipo/en/budget/index.html.

World Trade Organization. 1995. "WTO-WIPO Agreement." December 22, 1995. https://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm.

—. 2001. "Declaration on the TRIPS Agreement and Public Health." https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

—. 2020. "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Communication from India and South Africa." https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

—. 2021a. "Council for Trade-Related Aspects of Intellectual Property Rights. Minutes of Meetings: 15–16 October 2020." https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M109A1.pdf&Open=True.

—. 2021b. "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Revised Decision Text. Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe." https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

—. 2021c. "WTO Members Agree to Extend TRIPS Transition Period for LDCs until 1 July 2034." June 21, 2021. https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm.

—. 2022a. "Members Updated on High-Level Talks Aimed at Finding Convergence on IP COVID-19 Response." March 10, 2022. https://www.wto.org/english/news_e/news22_e/trip_10mar22_e.htm.

—. 2022b. “Ministerial Decision on the TRIPS Agreement.” https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True.

—. 2023. “Council for Trade-Related Aspects of Intellectual Property Rights. Paragraph 8 of the Ministerial Decision on the TRIPS Agreement. Informal Thematic Session for External Stakeholder Input.” https://web.wtocenter.org.tw/.

—. 2024a. “Council for Trade-Related Aspects of Intellectual Property Rights. Minutes of Meeting: 10 July 2024.” https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M111A1.pdf&Open=True.

—. 2024b. “Council for Trade-Related Aspects of Intellectual Property Rights. Minutes of Meeting: 25–26 April 2024.” https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M110A1.pdf&Open=True.

—. 2024c. “Intellectual Property and Innovation: IP Awareness and Cooperation. Communication from Australia; Canada; the European Union; Hong Kong, China; Japan; Republic of Korea; New Zealand; Singapore; Switzerland; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; the United Kingdom; the United States of America.” https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W714.pdf&Open=True.

—. 2024d. “Review of the Implementation of the TRIPS Agreement: Article 71.1. Communication from Colombia.” https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W712.pdf&Open=True.

—. 2024e. “WTO Members Address TRIPS Implementation Review, Discuss Pandemic Preparedness.” November 8, 2024. https://www.wto.org/english/news_e/news24_e/trip_08nov24_e.htm.

—. n.d.-a. “Least-Developed Countries.” Accessed March 17, 2025. https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

—. n.d.-b. “Trilateral Cooperation on Intellectual Property, Trade and Public Health.” Accessed January 31, 2025. https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

Yoo, Katelyn J., Akriti Mehta, Joshua Mak, David Bishai, Collins Chansa, and Bryan Patenaude. 2022. “COVAX and Equitable Access to COVID-19 Vaccines.” Bulletin of the World Health Organization 100 (5): 315–28. https://doi.org/10.2471/BLT.21.287516.

Yu, Peter K. 2024. “China, the TRIPS Waiver, and the Global Pandemic Response.” In *Intellectual Property, COVID-19 and the Next Pandemic: Diagnosing Problems, Developing Cures*, edited by Haochen Sun and Madhavi Sunder, 343–63. Cambridge: Cambridge University Press. https://doi.org/10.1017/9781009282406.018.

Zaman, Khorsed. 2022. “The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence.” *European Journal of Risk Regulation* 13 (2): 295–310. https://doi.org/10.1017/err.2021.60.

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