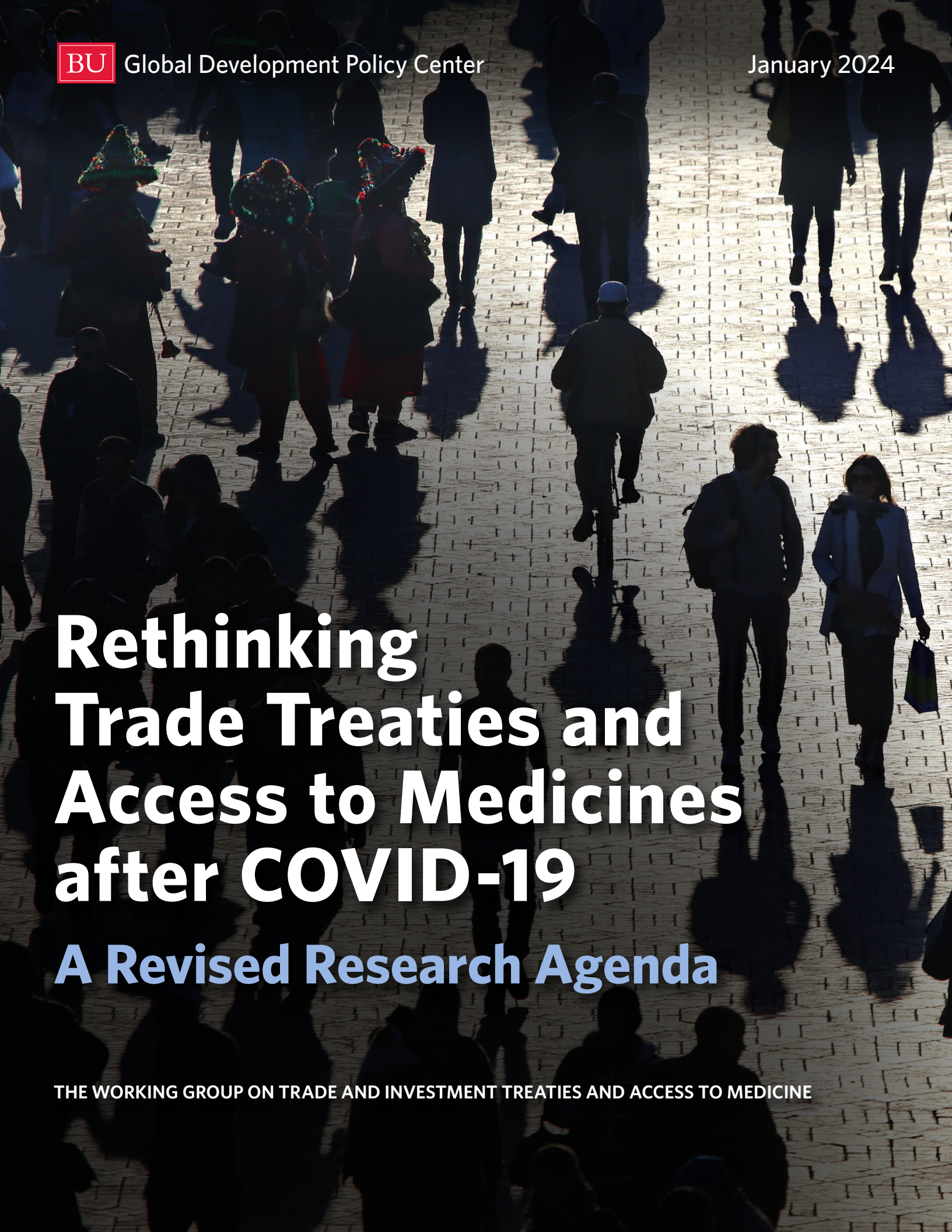

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Rethinking Trade Treaties and Access to Medicines after COVID-19

A Revised Research Agenda

THE WORKING GROUP ON TRADE AND INVESTMENT TREATIES AND ACCESS TO MEDICINE

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ABBREVIATIONS

ACT-A	Access to COVID-19 Tools Accelerator (WHO)
AfCFTA	African Continental Free Trade Agreement
BARDA	Biomedical Advanced Research Development Authority (US)
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
C-TAP	COVID-19 Technology Access Pool
CEPI	Coalition for Epidemic Preparedness Innovations
CL	Compulsory License
COVAX	Vaccine pillar of the WHO's Access to COVID-19 Tools Accelerator
CPTPP	Comprehensive and Progressive Trans-Pacific Partnership
EU-MERCOSUR	Trade agreement between the European Union and MERCOSUR states
FTA	Free Trade Agreement
HIC	High-Income Country
IHR	International Health Regulations
IP	Intellectual Property
IPRs	Intellectual property rights
LMIC	Low- and middle-income country
MPP	Medicines Patent Pool
NIH	National Institutes of Health (US)
NRA	national regulatory authority
RCEP	Regional Comprehensive Economic Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)
USMCA	United States-Mexico-Canada Agreement
USTR	United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

Since the establishment of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2001, there has been a concern that the now-global rules governing intellectual property (IP) protection would present obstacles to securing access to medicines for populations in low- and middle-income countries (LMICs). A few years later, the Doha Declaration on TRIPS and Public Health was born out of a hope that global cooperation could begin to deliver on its promise of creating a multilateral system "for the benefit and welfare of [all] peoples" (WTO 2001).

Nevertheless, 22 years and a global pandemic later, the world still wrestles with on-going large inequities in global public health. Four years ago, the Working Group on Trade and Investment Treaties and Access to Medicines hosted at the Boston University Global Development Policy Center conducted a literature review to develop an agenda for research on trade and investment regimes and their impacts on access to medicines. In our previous research agenda, we identified three broad research gaps:

1. More analysis of treaty provisions, including their adoption and implementation into domestic law and interpretation in domestic and international litigation, to understand better how such provisions constrain access to medicines;
2. More rigorous empirical studies to quantify the effects of IP rights (IPRs) and treaties on access to medicine for people residing in LMICs; and
3. More analysis of political economy factors which influence the process and effects of LMIC governments in signing and implementing treaties in their domestic health and IP policy.

In the wake of the COVID-19 pandemic, the Working Group was convened in June 2023 to assess the current political, legal and technological landscape in the four years since our first meeting. In consultations with one another and with outside experts, we largely find that the scope and level of policy engagement, as well as the relevance of domestic IP protection mechanisms have shifted substantially as a result of the COVID-19 pandemic. These changes have made it necessary to significantly rethink the legal, econometric and political economy agenda for interdisciplinary research on IP, trade and access to medicines.

The COVID-19 pandemic acted as a stress-test for the global health regime that once more revealed for many the presence of unacceptable inequities in access to health products. Individual countries entered the COVID-19 pandemic with their own scientific, public health, political and financial trajectories. These histories, in turn, arguably contribute to the complexity of an often dysfunctional global biomedical and public health "eco-system" which, in principle, must take these various histories into account when creating policies to improve global health indicators.

Given the new realities and priorities, the revised research agenda will be structured according to topic, rather than discipline. Key topics that emerged from the discussion with experts were: (1) TRIPS flexibilities; (2) transparency, trade secrets and technology transfer; and (3) regional production. In each theme, knowledge gaps and the proposed research agenda stretch across legal, economic, political and sociological disciplines.

Following our analysis, three new research gaps emerged:

- **Impacts of TRIPS flexibilities.** After 30 years of advocating for the need for and the use of TRIPS flexibilities, there is still an active debate about their use and usefulness. Research highlighting best practices, legal approaches and real-world impacts of implementing TRIPS flexibilities could support the narrative that these flexibilities are both useful and needed.

- **Transparency, trade secrets and technology transfer.** Manufacturers in the Global South need access to confidential information needed for production, which is currently protected as trade secrets. Researchers and policymakers need greater transparency on biopharmaceutical research and development, costs, pricing, supply and licensing agreements, clinical trial data, and IP and regulatory rules. For that reason, research will be needed to improve understanding of how best to increase transparency, as well as encourage technology transfer and the sharing of trade secret information, when necessary, especially in cases where time is of the essence.
- **Importance of regional or national regulations.** Since governments assess risk differently, and each country has its own regulatory capacity and other constraints, researchers must understand more about the national regulatory environments that contribute to and engage in regional supply chains.

In light of the changing landscape and newly identified research gaps, we present a revised research agenda as a jumping-off point to fill in knowledge gaps and better empower LMICs to introduce policies that increase their access to medicines.

BACKGROUND

The COVID-19 pandemic has been a stress-test for the global health regime, and for many, it unveiled the presence of unacceptable inequities in access to health products. Individual countries entered the COVID-19 pandemic with their own scientific, public health, political and financial trajectories. These histories, in turn, arguably contribute to the complexity of an often dysfunctional global biomedical and public health "eco-system" which, in principle, must take these various histories into account when creating policies to improve global health indicators. Lack of adequate technology transfer mechanisms and weak domestic regulations and national infrastructure disparities alongside global intellectual property (IP) standards are some of the root causes of these disparities (Amin and Kesselheim 2022; Baker 2021b; 2021a; Gleeson et al. 2023; Gold 2022; Perehudoff et al. 2022).

Here, we explore the political, legal and technological landscape in the four years since the Working Group on Trade and Investment Treaties and Access to Medicines published its first report "Rethinking Trade Treaties and Access to Medicines: Toward a Policy-Oriented Research Agenda." That landscape will shape further research priorities in the areas of IP, trade and investment agreements, and access to medicines. We largely find that the scope and level of policy engagement, as well as the relevance of domestic IP protection mechanisms have shifted substantially as a result of the COVID-19 pandemic. These changes have informed a new legal, econometric and political economy agenda for interdisciplinary research in IP, trade and access to medicines.

Although getting rapid access to treatments and vaccines (as well as protective equipment and diagnostics) is critical to addressing health threats, research and development (R&D), innovation, and in the most technologically complex products, even manufacturing capacity remains in the hands of a few high-income countries (HICs) (USITC 2023; Dunleavy 2023). As such, the diffusion of those products to LMICs must overcome a myriad of obstacles, from domestic regulatory hurdles and lack of infrastructure for transportation and distribution, to the network of patent thickets and closely held trade secrets set up in HICs to incentivize that innovation (Figueroa et al. 2021; Hassan and Aliyu 2022).

To overcome the obstacles to diffusion, many governments took unprecedented action to promote national and global access to health products, including extensive subsidies in R&D and production and investment measures to incentivize domestic production (Thrasher et al. 2023). However,

several countries, especially HICs, made many of these policy decisions in a near-sighted manner. By hoarding COVID-19 vaccine doses and imposing export restrictions, they demonstrated their willingness to benefit their own populations at the expense of people elsewhere (Espitia, Rocha and Ruta 2020; Scheibner, Nielsen and Nicol 2022; Thrasher et al. 2023).

We conducted a literature four years ago to develop an agenda for research on trade and investment regimes and their impacts on access to medicines (Working Group on Trade, Investment Treaties and Access to Medicines 2019). Even in HICs, the literature showed that mechanisms for providing effective, equitable access to medicines and vaccines were found wanting (Donadio et al. 2021). The pandemic, however, has given a new urgency to prevent the harmful effects of IP, trade and investment regimes on health and access to medicines.

On the one hand, the pandemic has generated renewed attention to a set of long-studied issues in global public health: (1) the relationship between higher levels of IP protection and prices, availability, and allocation of health products (Tenni et al. 2022); (2) the constraints that treaties create for governments attempting to adopt lower levels of IP protection (Rahman et al. 2021; Islam et al. 2020; Baker and Thrasher 2023); and (3) the importance of national-level implementation of treaty provisions in IP and health policy, and the political environment in which they are implemented, in determining health and medicines outcomes (Townsend et al. 2020; Tenni et al. 2022). At a closer look, however, there are certain new political and geopolitical realities, a rapidly shifting legal landscape and a fast-developing field of medical technologies that require a new set of research questions informed by the global experience of the COVID-19 pandemic.

In our previous research agenda, we identified three broad research gaps (Working Group on Trade, Investment Treaties and Access to Medicines 2019). We identified the need for:

1. More analysis of treaty provisions, including their adoption and implementation into domestic law and interpretation in domestic and international litigation, to understand better how such provisions constrain access to medicines;
2. More rigorous empirical studies to quantify the effects of IP rights (IPRs) and treaties on access to medicine for people residing in LMICs; and
3. More analysis of political economy factors which influence the process and effects of LMIC governments in signing and implementing treaties in their domestic health and IP policy.

Those categories largely persist in the present agenda, but take on a distinctive, post-pandemic shape that will differ from the earlier iteration. The next section details the shift in the political, legal and technological landscape that gives shape to the research agenda that follows.

SHIFTS IN THE POLICY, LEGAL AND TECHNOLOGICAL LANDSCAPE: INTERNATIONAL AND NATIONAL

Shifts in the International Policy and Legal Landscape

During the pandemic, multilateral institutions focused primarily on IP-related initiatives to address access barriers while remaining within the existing system of patent-driven incentives for innovation. Public statements acknowledged the need for an "integrated health, trade and IP approach" to respond to COVID-19 and future pandemics (WTO, WHO and WIPO 2023). As individual organizations, the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) and the World Trade Organization (WTO) has each overseen initiatives that have often relied on the centrality of patents for innovation incentives and knowledge diffusion.

WIPO, for example, established a COVID-19 Index within their Patentscope database, aiming to increase access to knowledge related to COVID-19 diagnosis, treatment and prevention, identifying patent documents as being "rich sources of technological know-how" for researchers and policymakers alike (WIPO 2023). The WHO developed the Access to COVID-19 Tools Accelerator (ACT-A) Partnership, with its separate vaccine pillar (COVAX) to pool the purchasing and demand of COVID-19 products and distribute them according to need all around the world. On the supply side, the WHO established the COVID-19 Technology Access Pool (C-TAP), a platform modeled on the Medicines Patent Pool (founded by Unitaid), wherein pharmaceutical originators could share IP related to COVID-19 within the Pool (Abbas 2020; Perehudoff and Sellin 2020). WTO leadership made many statements and reports on the impact of COVID-19 on trade, and the importance of increasing access to COVID-19 products, as well as making information available about vaccine rollout and calling on private firms to urgently ramp up vaccine production (WTO 2023). Its most widely publicized effort, however, came in the form of negotiations over a proposed waiver of certain provisions of the TRIPS Agreement for COVID-19 products (TRIPS Council 2021).

All these efforts met with little success in substantially increasing access to COVID-19 products. WIPO's COVID-19 Index may have made patent information available to generic manufacturers and other researchers, but in the absence of efforts to license that technology and the capacity to make use of it, the technological know-how in the Patentscope database was far from sufficient to ramp up access to medicines in the short-term. ACT-A and COVAX were severely under-funded from the start, in part because all the potential donor countries had funds tied up in purchasing vaccines for their own populations (de Bengy Puyvallée and Storeng 2022). C-TAP received so little interest from pharmaceutical originators that vaccine technology wasn't shared until May 2022 (US Department of Health and Human Services 2022). The WTO's TRIPS Waiver negotiations stretched over 20 months and, despite widespread support by the majority of WTO members for a comprehensive waiver addressing all types of countermeasures and all types of IP barriers, the Ministerial Decision of June 2022 resulted only in minor adjustments to a small set of TRIPS provisions, has so far been restricted to vaccines, and does not address the issue of trade secrets, an important barrier to more widespread vaccine manufacturing.

Why did these efforts fail to have a significant impact on access to COVID-19 products? On the one hand, this failure may have been rooted in their inability to address the root causes of inequity by making substantial changes to the balance of interests and power (Sell and Williams 2020). On a more pragmatic level, another reason may have been that the national policymaking was insufficient for addressing the access challenges that individual countries faced.

In the wake of the pandemic, those same institutions have continued to take action to build capacity for pandemic prevention, preparedness and response in the future, though the focus seems to have shifted. At the multilateral level, the WHO is undertaking an update to the International Health Regulations 2005 (IHR), "an overarching legal framework that defines countries' rights and obligations in handling public health events" ("International Health Regulations" n.d.). The update, which will incorporate lessons learned during the pandemic, is expected to conclude with draft amendments by May 2024 (WHO 2023). Simultaneously, the WHO is negotiating a new legal instrument, the Pandemic Prevention, Preparedness and Response Accord (often referred to as the "pandemic treaty"), which includes various proposals to address equitable access to pandemic-related products. Meanwhile, the WHO has demonstrated an interest in developing equitable and resilient *regional* supply (e.g., Fisher, Okediji and Sampath 2022) by establishing the mRNA Technology Transfer Program, located in Cape Town, South Africa with 14 partner countries. These negotiations, however, are fraught with the same political barriers as many other pandemic-era multilateral initiatives. The European Union (EU) and the United States, while willing to discuss and promote voluntary initiatives, are extremely

reluctant to engage in conversations about decreasing or changing IP protection for health technology innovation, even temporarily during global health emergencies (Working Group on Trade, Investment Treaties and Access to Medicines 2023).

Like multilateral initiatives, shifts are occurring in regional and bilateral free trade agreements (FTAs). Literature prior to the pandemic has shown that FTAs often contain TRIPS-plus commitments – agreements between countries that exceed the IP commitments required under TRIPS (Gleeson et al. 2019; Sell and Williams 2020). Nevertheless, some developments in recent years suggest that the IP commitments in FTAs may be changing. A comparison between IP chapters of the United States-Mexico-Canada Agreement (USMCA), the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), Regional Comprehensive Economic Partnership (RCEP) and the EU-MERCOSUR Association Agreement demonstrate that the Global South may still have a say in what commitments they make about their own IP policies (See e.g., Nolff 2022; Blasetti and Correa 2021; Boru 2020). Moreover, new types and structures of treaties are in the works, like the Indo-Pacific Economic Framework (IPEF) and the African Continental Free Trade Agreement (AfCFTA) (Nolff 2021; Adebola 2020). In their current form, neither of these treaties incorporates IP commitments. Rather, they represent new models of FTAs that may take on new characteristics.

Shifts in National Policies and Legal Landscapes

Given that it is national governments who determine the implementation of IP and other policies relevant to pharmaceuticals into their laws and regulations, national legislation continues to play a major role in facilitating access to medicines. Governments have long funded basic science and early translational research for pharmaceuticals. During the pandemic, however, public subsidies and de-risking of biopharmaceutical R&D expanded exponentially. Massive subsidization, as well as procurement contracts, ensured that countries with the means would be able to make vaccines available to their populations as soon as they were available (Sampat and Shadlen 2021). In LMICs, the pandemic encouraged national regulatory authorities to coordinate their pharmaceutical registration processes in completely novel ways (*Nature* 2020). COVID-19 vaccines and medicines needed to be authorized for use in each country where the industry intended to commercialize its product, resulting in a patchwork of regulations that influenced the speed at which these products were launched and the standards that governed them.

The policies and outcomes were inconsistent, however. Countries such as China, Russia and Argentina deployed COVID-19 vaccines before the conclusion of clinical phase 3 trials (Smith et al. 2020), while other LMICs stressed that no vaccines would be approved unless they met certain regulatory standards (Avorn and Kesselheim 2020). Moreover, despite billions spent by HICs to accelerate product development, fund clinical trials and expand manufacturing capacity, governments neglected to impose IP licensing, technology transfer, fair pricing or equitable global distribution requirements on the subsidized industry (Baker and Thrasher 2023). This resulted in huge transfers of wealth to a narrow subset of pharmaceutical companies at the hands of wealthy countries.

As the pandemic has subsided in HICs, national approaches seem to also be shifting to prepare for future crises. The United States' Inflation Reduction Act, though better known for promoting domestic climate action, has several key provisions aimed at decreasing out-of-pocket medicines expenditures for patients covered by Medicare (Stewart, Zhou and Leber 2022). Similarly, the European Commission has proposed a new compulsory licensing legislation to the European Parliament and the Council to facilitate such licenses and harmonize legal approaches across the EU (European Commission 2023). Meanwhile, California is considering a proposition to incentivize local production of insulin manufacturing (Bowman 2023) and India is considering a new Clinical Trial

Act (*Reuters* 2023). These efforts indicate a new interest in policies aimed at increasing affordable access to medicines, even in HICs, and in building resilient domestic supply chains where possible.

Technological Complexity and Secrecy of Vaccine and Biological Production

A third shift has taken place over the course of the past four years – in the technological landscape and growing recognition of the importance of trade secrets in blocking competition. The biggest changes were the emergence of the mRNA platform for vaccine development and an increasing reliance on biologics more generally in treatment (Price and Rai 2016; Shadlen 2020). What this means from a technological point of view is that health technology development is even more costly and technically demanding. Moreover, important technological information and materials are not just protected by patent rights but by trade secret/confidential information rules. As an example, BioNTech and Pfizer's mRNA vaccine was "made from 280 different ingredients and sourced from 19 different countries" (Cueni 2021), though the know-how for commercial scale production was a closely guarded secret that neither company – nor Moderna – was willing to share broadly with LMIC manufacturers. Some other treatments and vaccines developed for COVID-19 were similarly complex (Shores, Haversack and Storaska 2021; Gaviria and Kilic 2021). Due to this technical complexity, trade secret protections, and the ambiguities in the so-called 'best mode' patent disclosure requirement, disclosed information in patent applications may no longer be sufficient for generic firms to be able to begin production of a generic product once the patent has expired or been involuntarily licensed by governments (Shadlen 2020; Belleflamme 2020). Indeed, even firms with compulsory licenses from their governments were unable to easily reverse engineer the medicines. This was due in part to the fact that the know-how required to do so is not easily codifiable and thus not included in the patent documents. It is also due to the fact that the urgency of the pandemic did not allow the time scale needed to reverse engineer without the active participation of the originators (Gurgula and Hull 2021).

In addition to the reliance on trade secrets and confidential information to exclude competitors, biopharmaceutical companies have intensified their effort to impose non-disclosure agreements and trade secret/confidential information protection on governments and other buyers, over and above the financial benefits they already received in the form of R&D funding, indemnification terms and many other factors. This differs from the historical HIV context, in which firms, governments and others routinely published price information, as well as purchase agreements and, in some cases, access licenses – a move led and supported by the Medicines Patent Pool. During the pandemic, however, that same information was shrouded behind a curtain of trade secret and non-disclosure agreements. This prevented confirmation of safety and efficacy of products, as well as price comparisons and fair pricing agreements, enabled supply inequities and eliminated public oversight and accountability for tens of billions of dollars spent on COVID-19 health products (Arguedas-Ramírez 2022). Controversy over this secrecy has resulted in court action in South Africa and political controversy in the EU (Auranen 2023; Malan 2023).

The Need for a Revised Research Agenda

These shifts have created an urgency to craft a revised research agenda that is informed by the concerns and realities that decisionmakers face, as well as new priorities in global health. As noted, each country comes with its own history and trajectory within the biomedical and public health "eco-system". These differences result in disparities that are only partially understood, and which research will help to unveil.

In addition to global shifts and a growing recognition of national diversity, there are also opportunities created by this new landscape of players, powers and interests. Due to the consensus in international and national institutions around the need to be prepared for the next pandemic, there may be new data available on contractual terms and licensing agreements between countries and firms, from organizations and national institutions like the National Institutes of Health (NIH), Biomedical Advanced Research Development Authority (BARDA) and Coalition for Epidemic Preparedness Innovations (CEPI), as well as the WHO COVID-19 Technology Access Pool (Cambridge Economic Policy Associates 2022). There may also be a new appetite for more concretely criticizing the role of the US Trade Representative (USTR) for its Special 301 process as it applies to access to medicines.

To speak to the international and national decisionmakers in a way that allows their decisions to be informed by the best research and best practices, a research agenda must reflect the new policy priorities and opportunities, as well as the gaps in expert knowledge. The following section reflects the conversations among members of the Working Group on Trade and Investment Treaties and Access to Medicines during a June 2023 workshop, in consultation with outside policy experts, in pursuit of deciding upon the most critical research questions for the post-pandemic era.

A REVISED RESEARCH AGENDA BASED ON NEW REALITIES

Given the new realities and priorities outlined, the revised research agenda will be structured according to topic rather than discipline. Key topics that emerged from the discussion with experts were: (1) TRIPS flexibilities; (2) transparency, trade secrets and technology transfer; and (3) regional production. In each theme, knowledge gaps and the proposed research agenda stretch across legal, economic, political and sociological disciplines (See Table 1).

Need for Optimizing the Use of TRIPS Flexibilities

The first theme orbits around the concept of TRIPS "flexibilities." After 30 years of advocating for the need for and the use of TRIPS flexibilities, there is an active debate about their use and usefulness. Research has shown that at least some of the flexibilities have been widely implemented in national laws (McGivern 2023; 't Hoen et al. 2018). Concomitantly, others have argued that they are not being used to their full potential (Tenni et al. 2022). Obstacles to their use include significant procedural difficulties and external political pressure (particularly from the US and EU). Moreover, in some cases, countries may not have adopted the TRIPS flexibilities most essential to their national markets and public health needs (Tenni et al. 2022). Nevertheless, when countries do not effectively use these flexibilities, it reinforces the narrative from pharmaceutical firms that neither the current flexibilities nor any additional flexibilities are needed. As such, research highlighting best practices, legal approaches and real-world impacts of implementing flexibilities could help to support this effort.

The Three Ts: Transparency, Trade Secrets and Technology Transfer

The second theme is oriented around three related ideas – transparency, trade secrets and technology transfer (the three Ts). A consensus has emerged that, given the new technological landscape and the ways that pharmaceutical firms are operating with confidentiality and non-disclosure agreements, access to medicines will require more knowledge than is published in a patent application. Manufacturers in the Global South need access to confidential information needed for production which is currently protected as a trade secret, and researchers and policymakers need greater transparency on biopharmaceutical R&D, costs, pricing, supply and licensing agreements, clinical trial data, and IP and regulatory landscapes (see, e.g., Shadlen 2020; Gallogly-Swan and Thrasher 2021).

For that reason, research will be needed to improve understanding of how best to increase transparency, as well as encourage technology transfer and the sharing of trade secret information when necessary, especially in cases where time is of the essence.

Renewed Interest in Regionalism and National Regulation as an Important Part of an Industrial Policy

The third theme is related to the scope and structure of the new landscape of pharmaceutical production: regionalism and national regulation. Working Group experts agree that the global production patterns and supply chains, as they exist, left many countries vulnerable to lacking access to essential products during the pandemic (Thrasher et al. 2023). The countries that could produce tests, treatments and vaccines tended to turn inward and focus on supplying their own market (Hafner et al. 2022). Not all countries have that kind of manufacturing capacity, however, and economic theory would suggest that eschewing economic specialization completely would simply drive-up prices for all. Instead, a middle-ground seems attractive – to establish certain regional hubs for supplying essential health products and technologies (Fisher, Okediji and Sampath 2022; Maybarduk 2021; Gallogly-Swan and Thrasher 2021). Even at a regional level, however, national regulatory regimes will govern the local commercialization, transportation and distribution mechanisms. Since governments assess risk differently, and each country has its own regulatory capacity and other constraints, researchers must understand more about the national regulatory environments that contribute to and engage in regional supply chains (Vogel 2012; da Fonseca et al. 2021).

The following section describes the three themes in more detail.

Table 1. Research Questions: Comprehensive List (by Theme and Discipline)

Theme	Research Questions by Discipline
Leveraging TRIPS "Flexibilities"	Legal questions • What examples exist of a "mandatory" or "presumptive" compulsory licensing (CL) regime? What can we learn from analyzing those examples from a legal framework? • What are various (legal) mechanisms for achieving economies of scale in a CL regime – such as a "facility" for CLs or automatic CLs for Medicines Patent Pool licensed medicines? • Based on the EU model of the "Regional Emergency CL board," what lessons can be learned for other regions? What needs to be modified for it to work for African Union or Latin America and the Caribbean? • How have countries used TRIPS Article 73 (emergency clause)? How could it be used better in the future? • What are the different legal models for patent examination or patent opposition which facilitate keeping low-quality or secondary innovations from being patented? • Have firms pushed back on the use of TRIPS flexibilities? Has there been any additional investor-state dispute settlement cases related to access to medicines? Econometric questions • To what extent have mandatory or presumptive CLs had an impact on price or availability of any technology (drawing from other sectors to learn the potential in medicines)? • What is the case and utility for a country to "really" take advantage of CLs – what is the economic impact of such an approach? • Given that secondary patents are being rejected in higher numbers (in Argentina), can we find out the price/availability of those medicines upon rejection of secondary patents? • To what extent do strict patent examination requirements and accessible mechanisms for patent opposition impact access to medicines? • When and by how much have prices declined when countries have used TRIPS flexibilities?

Theme	Research Questions by Discipline
Leveraging TRIPS "Flexibilities" *(continued)*	Political-economy questions • What case studies are the most illustrative that show how countries have benefitted from TRIPS flexibilities as implemented domestically? • What key countries have strong and growing pharmaceutical industries such that they may be major players in the next few years? • What are the political-economy levers to push on so countries can effectively take advantage of CLs and other TRIPS flexibilities? • Identify selected factors which impact countries' decisions for CL and the approaches of the observed countries/cases to CL. Consider issues such as national legislation and pandemic effects. • If domestic legal language needs to change – what are the barriers to making those changes? • What can we learn from how Argentina examines patent applications given the findings from the literature that suggest that secondary patents are more likely rejected? • What is the political economy of pharmaceutical regulation? How can we explain the variation in pharmaceutical regulations across countries? • To what extent can we use documentation of the positive impacts of HIC policy on global public health – such that our material is more "carrot" and less "stick"?
Three "Ts": Tech transfer, trade secrets and transparency	Legal questions • What constitutes trade secrets and confidential information, and how are they covered in national and international laws? • What are the strengths and weaknesses of voluntary licenses with respect to trade secrets and know-how (in terms of contract provisions)? • Have there been successful examples of contracts for R&D and procurement that could drive or have driven more equitable access? • How can increased transparency (in domestic legal language or contract terms) be encouraged or influenced? • What can effectively encourage technology transfer for vaccines, therapeutics and diagnostic production (in domestic legal language or contract terms)? • Is it possible for countries to come up with novel trade secret law with public interest and public health exceptions and even involuntary access to confidential information and materials from right holders and regulatory authorities? • What domestic regulatory issues are relevant (as an obstacle or opportunity) in access to medicines? • How can national R&D funding processes be reformed to increase transparency and improve access to the resulting products? • What is the impact of trade secrets and lack of transparency on the effective utilization of the TRIPS Agreement flexibilities at the national level? Econometric questions • To what extent does greater protection of trade secrets impact access to medicines? What measures would we use to explore this? Political-economy questions • What can be learned from Working Group member Deborah Gleeson's schematic of the political economy of access to COVID-19 health products? • What are the strengths and weaknesses of voluntary licenses (in terms of power balances), achieving the goal? • What countries have the actual power to develop public health friendly contracts with pharmaceutical companies? What lessons can be learned from these? • How can we effectively encourage technology transfer for vaccine production (by building political will)? • How can increased transparency (in terms of political will and coalition-building) be encouraged or influenced?

Theme	Research Questions by Discipline
Regionalism and National Regulation	Legal questions • How might the AfCFTA IP protocol, as an example, make room to incorporate regional priorities in its negotiated text? • What guidance did governments provide to industry regarding the streamlined formulation of vaccines, and how does this relate to guidance from the WHO? • What is the approval process for pandemic-related vaccines and medicines, and how and why does the process differ by country? • What models might there be to regulate pandemic-related vaccines and medicines under incomplete information about clinical trials? Econometric questions • What impact might political aggregation at the regional level have on the price or availability of medicines? Are there any other sectors that provide illustrative examples? • How might different regulatory models interact with national and regional access to medicines? Political-economy questions • How might the AfCFTA IP protocol, as an example, make room to incorporate regional priorities through its institutional and political structure? • To what extent have multilateral institutions been successful in increasing access to medicines through convening decisionmakers, and what changes, if any, have resulted? How do we measure "success" in these cases? • What are the political economy characteristics needed to achieve political aggregation at a regional level? • What are some political or policy steps to be taken at a national level to get countries to engage regionally? • What political support or economic success will be needed to make the mRNA hub successful? • How can patent pools work (better)? • What political economy characteristics will help regional initiatives to pass the "stress test" of devolving into competing national policies during an emergency? • How can we analyze the tension between local and regional production efforts? What obstacles are there to each and how do they interact? • What factors determine countries' regulatory capacity? • To what extent did governments prevent potentially harmful, non-approved "vaccines" from entering the market and addressing misinformation? • When do countries decide to rely on international guidelines or create their own rules? Why? • How are regulatory reliance pathways implemented and translated to local rules? How do countries choose reference agencies, and why do they choose them?

Source: Working Group on Trade, Investment Treaties and Access to Medicines 2023.

INCREASING IMPLEMENTATION OF TRIPS FLEXIBILITIES

The challenge of increasing the domestic implementation of TRIPS "flexibilities" is really a challenge of domestic legal reform (see Annex Table 1). The existence of TRIPS "flexibilities" is owed to persistent advocacy by countries to preserve some policy space for creating their own IP laws and standards (Abbott 1996; Yu 2009). Evidence has shown that certain flexibilities, like compulsory licensing, are correlated with lower medicine prices (Urias and Ramani 2020). Nevertheless, despite widespread implementation of compulsory licensing laws, three decades of state practice have resulted in relatively few compulsory licenses, and comparatively few national laws implementing other TRIPS flexibilities (McGivern 2023; 't Hoen et al. 2018; Tenni et al. 2022). This could be due to policymakers not considering those flexibilities necessary or sufficient to increase access to medicines for their populations. It may also result from political pressure from the US and other wealthy economies not to utilize those flexibilities, as well as other implementation challenges.

Ample research has shown the difficulty LMICs face in gaining access to essential medicines and health technologies (Tenni et al. 2022; Trachtenberg et al. 2019). The COVID-19 pandemic revealed the extent of this and the result for the most vulnerable populations (Gallogly-Swan, Thrasher and Omer 2021; Tenni et al. 2022; Urias and Ramani 2020). Countries struggle to implement their flexibilities through new IP policies due to a lack of institutional capacity and the complexity and costs of such change given the constraints of the TRIPS Agreement (See, e.g., Deere 2008). They may also face legal obstacles to introducing TRIPS flexibilities when they sign FTAs that include TRIPS-plus provisions (see Annex Table 2), such that the flexibilities in the TRIPS Agreement are foreclosed due to a later-in-time treaty (Baker 2019). Finally, and perhaps most importantly, researchers have extensively documented the political pressure exerted by large pharmaceutical firms directly, as well as through the USTR Special 301 report process, to discourage countries from taking advantage of these flexibilities (Medecins Sans Frontieres Access Campaign 2015; Palmedo 2021; Baker and Thrasher 2023).

Given the low levels of implementation, however, supporters of stronger IP rights worldwide are able to argue that there is no consistent evidence of the need for these flexibilities (e.g., WTO 2022). The evidence of success in using TRIPS flexibilities is still limited (Urias and Ramani 2020). This is where trade and medicines researchers can fill the gap. By undertaking and disseminating research to understand the real potential of relying on TRIPS flexibilities, researchers can assist countries in terms of policymaking and regulation for access to medicines. The following illustrative inter-disciplinary research questions would provide national decisionmakers with new information. In addition, changes to the legal and policy landscape will allow researchers to assess in the future the effect of these changes for future generations. Some example research questions under this theme include:

- What are the legal characteristics of a "useable" compulsory licensing provision in domestic law, and what example or models are available in comparative law?
- To what extent are the use of TRIPS flexibilities (other than compulsory licenses) correlated with lower prices for medicines or increased quantities of those medicines, and what are the contextual factors that enable or hinder increased technology access?
- What are various (legal) mechanisms for achieving economies of scale in a compulsory licenses regime – such as a coordination "facility" for compulsory licenses or automatic compulsory licenses for Medicines Patent Pool licensed medicines?

- In light of the EU's proposed regional compulsory licensing legislation, what aspects can be applied to alternative contexts, and which will need to be "translated" for different political and legal contexts?
- Given that secondary patents are being rejected in higher numbers in Argentina, can the price/availability of those medicines upon rejection of secondary patents be examined?

THEMATIC AREA 2

LEVERAGING TRANSPARENCY, TECHNOLOGY TRANSFER AND TRADE SECRETS FOR ACCESS TO MEDICINES

Historically, in the trade and access to medicines space, researchers and advocates alike have focused on the role of patents and licensing ('t Hoen 2002; Smith, Correa, and Oh 2009; Shadlen, Sampat and Kapczynski 2020). On the heels of the pandemic, the world saw the shortcomings of compulsory licensing in the new technological landscape, and some began to believe that voluntary licenses and other measures by large firms were the best way forward given the need for speed combined with the complexity of biologics and especially the mRNA platform for vaccines (Shadlen 2020). Still, other research has frequently shown, and the pandemic revealed, that voluntary licenses and patent pools are often insufficient for increasing global access to medicines (Baker and Thrasher 2023; Shadlen 2022).

Most pharmaceutical patents do not, alone, contain enough information about how to re-create new technological advancements in these fields, at least not on short time-scales (Shadlen 2020). The pandemic demonstrated the importance of a mechanism for facilitating rapid increases in manufacturing and distribution. As a result, even pooling patent information may not provide the adequate technology transfer and know-how needed for generic firms to put this patent information to use quickly enough to respond to pandemic needs. Moreover, firms sometimes rely on the protection of privately held "trade secret" information to further control the knowledge needed to make their products (Williamson 2023).

In addition to the difficulties posed by technology transfer obstacles and trade secret information, there is an overall concern about the need for transparency – by both firms and countries in their dealings with each other. Transparency related to medicines prices gained prominence in 2019 when the Transparency Resolution was agreed at the World Health Assembly. The Resolution asks countries "to enhance public sharing of information on actual prices paid by governments and other buyers for health products, and greater transparency on pharmaceutical patents, clinical trial results and other determinants of pricing along the value chain from laboratory to patient." However, there is a gap in understanding how countries and multilateral organizations have used the resolution to affect change in their countries regarding medicines price transparency and transparency of other important market and product information. Price is a critical access barrier and thereby a sensitive marker to measure medicines access.

The "three Ts" represent the next horizon of IP "flexibilities." By better understanding how they can be drafted and implemented in national legislation and regulation to improve access to medicines, researchers can provide national decisionmakers with essential tools to reach public health goals. A selection of example research questions on this theme includes:

- What legal transparency language would improve the balance between increasing innovation and increasing access to medicines, treating both as a global public good? Are there any examples in national laws?
- What policies to enhance transparencies of the pharmaceutical market have potential to significantly increase access to medicines?
- To what extent do differing models of trade secret law have an impact on the price or availability of relevant medicines?
- What can be learned from countries that have leveraged the government's ability to develop contracts with pharmaceutical companies that encourage or even require open science and transfer of technology?
- Can technology transfer for vaccine and other biopharmaceutical production by building political will among private pharmaceutical firms be effectively encouraged?

THEMATIC AREA 3

REGIONAL PHARMACEUTICAL PRODUCTION: POSSIBILITIES AND PITFALLS

Traditional economic theory makes the case that liberalized trade, fewer barriers to moving products across borders according to the comparative advantage of each country, will result in the largest amount of goods and wealth in the world (e.g., Goodwin et al. 2018). Those goods and wealth are not automatically distributed evenly, but the overall "pie" is largest, and the "winners" are able to compensate those who lose out under this scheme, according to its logic.

As noted, the COVID-19 pandemic was a stress test that revealed, among other things, that governments in an emergency will put the well-being of their own populations first, often at the expense of others (Evenett 2020; Evenett et al. 2022; Thrasher et al. 2021). This reality gave rise to a new concern regarding resilient supply chains. In other words, countries began to shift priorities to ensure that enough of the most important products were made at home, or at least made within politically aligned nations, such that they did not need to worry about shortages in essential products (Gereffi 2020; Xu et al. 2020; Schatteman, Woodhouse and Terino 2020). However, traditional economic theory is still largely correct in asserting that it would be wildly inefficient and costly for each individual country to make everything. Indeed, most countries simply do not have the capacity in terms of arable land, infrastructure, human or financial capital to produce all that their populations need, even at grossly inflated prices. Shifting to reliance on domestic production would be disastrous for global welfare, especially in the context of medicines and health technologies.

The combined concern of the vulnerabilities of global supply chains and the infeasibility of national ones has given rise to a new interest in regional supply chains and production hubs (e.g., WHO 2022; Fisher, Okediji and Sampath 2022). Granted, regionalism itself is not new. The USMCA, the AfCFTA and the CPTPP are the youngest generation of FTAs among countries in a shared region with shared trade and political interests. What *is* new, however, is the focus on industrial policymaking at a regional level – that countries could pool resources to create economies of scale for both production and consumption, making supply chains more resilient for that regional arrangement. The WHO's mRNA Technology Transfer Programme, located in South Africa, is one example of this experimental model (WHO 2022).

Still, little is known about how to ensure that regional production hubs and regional supply chains are effective and efficient in improving the diffusion of innovative health technologies and more affordable and equitable access to medicines, as well as less susceptible to nationalist instincts in a crisis. Moreover, regional hubs will need to grapple with differences in national regulatory regimes governing pharmaceuticals. Pharmaceutical regulation in HICs has been well-studied (Vogel 1997; 2012; Abraham 2010; Permanand 2006), but much less is known about the remarkable variation in drug regulatory systems in LMICs – where there is most to gain from regional production hubs (Pezzola and Sweet 2016; da Fonseca et al. 2021). Another avenue, and yet a little explored element, is that national regulatory authorities (NRAs), particularly those in the Global South with intermediate to low regulatory capacities, may be able to rely on assessments conducted by another NRA within their region or trusted institution when registering vaccines and drugs. How these standards and procedures are translated into local rules is under-theorized.

Some analytical angles to explore the politics of pharmaceutical regulation and approval refer to how governments assess risk and how non-state actors influence the regulatory process. When analyzing the transatlantic differences in risk assessment in the face of scientific uncertainty, Vogel (2012) proposed that the variation can be explained according to the strength and scope of public pressure for more protective regulations, the preferences of government officials and the criteria by which governments assess and manage risk. Understanding how to design regional production hubs and national regulatory coordination programs, as well as what the obstacles and potential impacts will be is a major next frontier in access to medicines research. By answering the following illustrative research questions (and others, see Table 1), researchers will be able to inform these production, policy and regulatory experiments, as well as learn from them in the future.

- What legal language in the draft AfCFTA IP Protocol would incentivize or enforce regional collaboration and cooperation in the case of a crisis?
- What is the economic basis for political aggregation at the regional level?
- What political economy characteristics make regional political and economic integration more feasible and stable?
- What is the approval process for pandemic-related vaccines and medicines, and how and why does the process differ by country?
- What factors determine countries' regulatory capacity?

CONCLUSION: CHARTING A WAY FORWARD

The COVID-19 pandemic revealed existing weaknesses in both health systems and global governance structures. It also brought to the forefront new priorities for interdisciplinary research to understand how access to medicines is impacted by the globalized trading system and how nation states navigate this complex system. The workshop presentations and conversations coalesced around three key research themes: (1) understanding the importance of TRIPS "flexibilities" as implemented in national laws; (2) understanding how to promote transparency and technology transfer and best manage trade secret law; and (3) understanding how regional production efforts and national regulatory regimes can increase equitable and resilient supply chains in essential health technologies.

These research themes are especially important given the shifting political, legal and technological landscape. The difficulties of providing equitable access to diagnostics, vaccines and treatment that multilateral institutions faced has resulted in countries focusing more on their own domestic interests, with some renewed interest in regional trade and health priorities. As such, the research questions are focused on decision-making at the national, and to some extent, regional levels, rather than in multilateral organizations. Moreover, the high-tech nature of pharmaceutical innovation has

shifted research priorities away from patent-oriented research towards understanding the need for technology transfer, increased pharmaceutical market transparency and the problems presented by strong trade secret protection.

Research in these areas can inform policy discussions and decisions at every level. The WHO, WTO and WIPO continue to play a role in convening country governments to coordinate national action. New regional integration approaches like the AfCFTA and others provide possibilities for new models of IP protection and IP incentives. Finally, national governments can learn from policy experiments, both in their own jurisdiction and externally. This revised research agenda not only informs national, regional and global decisions aimed at increasing access to medicines, it also creates a feedback loop, by which researchers may assess the impacts of changes for future generations of decision makers.

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Annex Table 1. Recognizing TRIPS "flexibilities" in specific TRIPS provisions

Flexibility	Definition
Exclusions from patentability (Art. 27.3)	Countries permitted to exclude "mere discoveries," surgical, diagnostic and therapeutic methods, genes or extractions from naturally occurring matter, new uses and methods of use of known substances, among others.
Standards of patentability (Art. 27)	High/strict standards of patentability, especially concerning combinations of prior art, novelty, inventive step and industrial applicability
Disclosure (Art. 29)	Applicant must disclose all known practical methods of carrying out the invention, and the best-known mode, as well as corresponding applications in other jurisdictions.
Patent revocation and opposition (Arts. 32 & 62.4)	Allows both pre- and post-grant opposition procedures with broad standing rights and easy-to-use administrative procedures. Also includes broad grounds for revoking patents, including inequitable conduct, fraud, non-payment of patent maintenance fees, failure to make required disclosures, and failure to satisfy requirements/standards of patentability.
Bolar/Early working exceptions (Art. 30)	Generic manufacturers allowed to use the patented invention for the purpose of seeking regulatory approval before the patent expires. Includes both commercial and non-commercial research rights, for domestic use and for export, and for pharmacy formulation and individual use.
Compulsory licensing and government use licensing (Arts. 31 & 44.1)	Broad grounds for issuing a government authorization for use of an invention without the consent of the patent holder, including excessive pricing, refusal to license, denial of access to an essential facility, and failure to supply sufficient quantities of a drug, among others. Licenses in the case of national security or public health crises allowed without prior negotiation. Public, non-commercial-use or government-use licenses without prior negotiation. Production for export licenses pursuant to Art. 31*bis* or, possibly, by an Art. 30 limited exception (although such an interpretation is not established in WTO jurisprudence). Judicial licenses also allowed with clear, efficient and easy-to-use administrative procedures and remuneration guidelines.
Parallel Imports (Art. 6)	Countries may choose whichever domestic rule of "patent exhaustion" they like. Under the adoption of an international exhaustion rule, for example, products sold ("first sale") by the patent owner or with the patent owner's permission in one country may be imported into another country without the approval of the patent owner. Furthermore, practices related to parallel importation cannot be challenged under the WTO dispute settlement system.
Data Protection (Art. 39)	Countries must protect undisclosed test data from unfair commercial use and other disclosure unless "necessary to protect the public or unless steps are taken to" protect against unfair commercial use.
LDC Waiver (Art. 66.1)	Least developed countries are not required to recognize patents on pharmaceuticals, as well as data rights, mailbox obligations and market exclusivity, currently extended by the TRIPS Council to the year 2033.
Competition policies (Arts. 8.2 & 40)	Prevents abuse of IPRs by right holders, practices that unreasonably restrain trade or adversely affect international transfer of technology. Also prevents licensing practices or other IPR conditions that restrain competition, adversely affect trade and impede transfer of technology
Enforcement flexibilities (various)	No border measures required for suspected patent infringement of goods in transit (Art. 51). No requirement of criminal penalties for patent violations (Art. 61). Although injunctions must be an available remedy, it is also permissible to limit remedies to adequate remuneration like that provided for compulsory and government use licenses (Art. 44). Although provisional measures must be possible, their use is not mandatory (Art. 50). Although compensatory damages must be an available remedy for infringement, alternative measures damages based on market value, selling price, or deterrence are not required (Art. 45).

Source: Baker 2020.

Annex Table 2. TRIPS-plus measures with implications for access to medicines

Measures	Mechanism of Impacting Access
Old provisions; New Standards	
Eased standards of patentability and secondary patents	Requires patents on: (1) new uses or methods of use of known medicines, and (2) new forms for known substances regardless of therapeutic efficacy. Lowers standards on novelty, inventive step (changed to "obviousness") and industrial applicability (changed to "usefulness"- both terms as used in the US). Secondary patents (additional, defensive patents) available on a broader range of inventions.
Limitations on patent revocation/ opposition	No or limited allowance of pre- or post-grant opposition procedures. Limited grounds for patent opposition/revocation by government.
Compulsory licensing limitations	Limiting a country's ability to authorize a party (other than the patent holder) to use, manufacture, sell, etc. that invention without the consent of the patent holder by allowing license language to restrict the grounds on which a license may be granted.
Limitations on Exhaustion	International exhaustion regime not permitted.
Lower requirement for disclosure in patent applications	Less stringent disclosure requirements or prevention of allowable disclosure requirements.
Weakened limited exceptions for patent use	Restriction on the use by non-patent holder of early working/Bolar provisions in obtaining third-market registration. No exception or weak exception for non-commercial and commercial research and educational use of patented technology. No exception permitted for prior use of patented technology.
New Provisions	
Patent term extension	Extensions for delays in processing patent applications, medicines registration and marketing and other regulatory delays.
Elimination of patent exceptions	Requires patents on diagnostic, therapeutic and surgical methods for treatment of humans.
Patent registration linkage	Restricts the medicine regulatory authority's ability to register a generic medicine whenever an originator merely claims that a patent would be infringed.
Data exclusivity	Gives exclusive rights to regulatory data to the patent holder and prohibits medicine regulator's reliance on, or reference to, innovator's submission data in reviewing registration applications of generics. Includes the possibility of extending data exclusivity upon submission of additional clinical data not available at the time of the original submission.
Enforcement measures	
Mandatory injunctions	Requires the availability of injunctions (and prohibits collecting royalties as a remedy for patent infringement).
Increased civil and border measures remedies	Deterrent civil remedies, such as damages based on average retail price. Requires seizure of goods in transit, mandatory destruction and allows third-party enforcement.
Broadened criminal remedies	Criminal sanctions for patent violations (beyond TRIPS requirement for criminal trademark counterfeiting and copyright piracy only).
Investor-state disputes settlement provisions	Inclusion of IPRs as covered investment, which permits ISDS claims based on patent decisions.

Source: Baker 2020; Gleeson et al. 2019.


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