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Lessons from Covid-19 for Global Health Security

Innovation, Access, and the Systems Between

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Acronyms and Abbreviations

API	Active pharmaceutical ingredient
BLAs	Bilateral agreements
CAMR	Canada's Access to Medicines Regime
CL	Compulsory licensing
FDA	Food and Drug Administration
IP	Intellectual property
JPA	Joint Procurement Agreement
LMIC	Low- and middle-income countries
MPP	Medicines Patent Pool
MSD	Merck, Sharp & Dohme
R&D	Research and development
TRIPS	Trade-Related Aspects of Intellectual Property
VL	Voluntary licensing
WHO	World Health Organization
WHOPQ	World Health Organization Prequalification Program
WTO	World Trade Organization

Executive Summary

The Covid-19 pandemic reignited global debates over intellectual property (IP) and access to medicines. Some policymakers, advocacy groups, and international organizations focused significant attention on compulsory licensing (CL)—which allows a government to authorize the use of patented technology without the patent holder's consent under specified conditions—and proposals to waive certain obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), arguing that patents represented a primary barrier to equitable access. Yet the experience of the pandemic revealed a more complex reality: While IP became the focal point of international policy discussions regarding how to accelerate access to Covid-19 vaccines and treatments, the most significant barriers to access often stemmed from resource constraints, supply chain disruptions, export restrictions, regulatory bottlenecks, and lack of local health infrastructure.

This report argues that access to medicines is fundamentally a systems challenge rather than an IP challenge. The ability to translate scientific discovery into widespread patient access depends on the interaction between two interconnected systems: (1) the innovation system, which generates new technologies through research, investment, and IP protections that enable lengthy and costly investments, and (2) the delivery system, which manufactures, distributes, and administers medicines. This broader health framework also encompasses financing and procurement mechanisms, regulatory institutions, quality assurance, healthcare infrastructure, and the community engagement, information, and trust needed to ensure the uptake of new vaccines and therapeutics. Sustainable access depends on the strength of the connections between these systems and the institutions that support their effective coordination.

Just as transportation networks move goods and digital networks move information, IP systems facilitate the movement of knowledge, technology, capital, and expertise across organizations.

Within this framework, IP rights should be understood as a form of strategic infrastructure. Just as transportation networks move goods and digital networks move information, IP systems facilitate the movement of knowledge, technology, capital, and expertise across organizations and borders. By fostering predictable rules governing ownership, collaboration, and technology transfer, IP provides the institutional foundation upon which firms can invest, partner, and scale. Voluntary licensing (VL)—an arrangement in which an IP holder voluntarily authorizes another party to use its IP under agreed terms and conditions—transforms this infrastructure into an operational mechanism for expanding access by enabling innovators to share IP, technical know-how, regulatory data, and manufacturing expertise with qualified partners.

The Covid-19 pandemic provides the most significant real-world test of competing approaches to access. Although CL and the proposed TRIPS waiver dominated much of the public debate, neither played a significant role in expanding the availability of Covid-19 vaccines or therapeutics. Instead, access expanded primarily through VL agreements, technology transfer partnerships, manufacturing collaborations, and coordinated supply chain investments. During the first year following the introduction of Covid-19 vaccines, companies entered into hundreds of manufacturing and production agreements worldwide, including 93 VL agreements, most of which involved developing countries. Roughly three-quarters of these partnerships included licensing arrangements and technology transfer, with at least 20 specifically focused on mRNA vaccine production. These arrangements enabled the deployment of treatments and vaccines across more than 100 low- and middle-income countries (LMICs).[1]

This report finds that VL arrangements were successful because they provided benefits beyond the legal structure authorizing the use of patented technologies. The most effective licensing arrangements bundled IP rights agreements with technology transfer, manufacturing partnerships, regulatory data access and expertise, quality assurance support, and supply chain coordination. Case studies involving the multinational pharmaceutical firms Gilead, Eli Lilly, Pfizer, and Merck—as well as the Medicines Patent Pool (MPP) and licensees and manufacturers in emerging markets—demonstrate how VL can accelerate production, expand manufacturing capacity, and facilitate the transfer of the technical capabilities necessary to produce complex medicines safely and at scale in a pandemic setting. In doing so, VL functions as a mechanism for capability building and ecosystem development rather than merely a legal arrangement.

By contrast, CL had limited practical impact during the pandemic. While several countries explored or implemented CL measures, these efforts frequently encountered procedural, regulatory, and manufacturing obstacles. More fundamentally, the pandemic demonstrated that legal authority

alone cannot create the capabilities necessary to manufacture and distribute complex health technologies, as most significant barriers to access were unrelated to IP. Export restrictions disrupted the movement of critical inputs and finished products. Regulatory approval processes often delayed the availability of therapeutics and vaccines even where manufacturing capacity existed, as many countries failed to prioritize review and approval. Trade-related barriers complicated the movement of materials, personnel, and equipment across borders. And in many countries, limited cold-chain capacity, inadequate healthcare infrastructure, and workforce shortages constrained the deployment of available products. These challenges proved more consequential than patent protections in shaping access outcomes.

A major lesson of the Covid-19 pandemic is that access to medicines is best understood as a systems-level governance challenge. Future efforts to improve global health security should focus on strengthening the manufacturing, regulatory, trade, and delivery systems that allow that innovation to scale. Policies that support VL, technology transfer, geographically distributed manufacturing capacity, regulatory cooperation, resilient supply chains, and stronger local health infrastructure are likely to produce greater gains in access than efforts focused solely on weakening IP protections.

Strengthening global health security will therefore require a more integrated approach—one that recognizes IP not as a barrier to access, but as a critical component of the innovation infrastructure that, when paired with effective delivery systems, enables life-saving technologies to reach patients around the world.

Introduction

IP as Infrastructure for Innovation

The Covid-19 pandemic sparked a global debate over IP and access to medicines. As countries struggled to secure vaccines, therapeutics, and medical supplies, policymakers and advocates increasingly focused on patents, CL, and proposals to waive certain IP obligations under TRIPS.[2] These debates often rested the assumption that IP protections were a primary obstacle to equitable access, particularly in LMICs.

The pandemic revealed a more complicated reality. While IP became the focal point of international policy discussions, the barriers to access frequently emerged elsewhere. resource constraints, export restrictions, supply chain disruptions, regulatory bottlenecks, shortages of skilled labor and production inputs, and weaknesses in local health and supply chain infrastructure proved to be the greatest constraints on access.[3] In many cases, the major challenge was acquiring the technical expertise, production capacity, regulatory and quality assurance expertise, timely regulatory approval, and distribution networks necessary to manufacture and deliver vaccines and therapeutics at scale, rather than one of legal access to patents.[4]

This distinction matters because access to medicines is not solely a legal question—it is a systems challenge. The ability to translate scientific breakthroughs into widely available products depends on the interaction between two interconnected systems. The first is the innovation system: research institutions, firms, and investors, along with the public policy framework (including IP protections and technology transfer policies) supporting the research and development of new technologies. The second is the delivery system: manufacturing networks, supply chains, regulatory institutions, trade relationships, financing and procurement mechanisms, and health infrastructure, combined

with the community engagement, information, and trust needed to ensure the uptake of new medicines and vaccines. Failures in either system can limit access. Sustainable access therefore depends on the strength of the connections between innovation and delivery, as well as on the broader health system enabling products to be financed, authorized, distributed, and ultimately used by patients.

The role of IP as infrastructure within this network is evident across advanced industries. In semiconductors, Arm Holdings' licensing model allows firms such as Apple, Qualcomm, and Samsung to build customized products on shared processor architectures, enabling specialization and innovation across a globally distributed ecosystem.[5] In clean energy, licensing arrangements have enabled emerging manufacturers to acquire advanced wind turbine technologies and build domestic production capabilities without replicating decades of research and development. For example, companies such as India's Suzlon Energy and South Korea's Hyundai entered the wind turbine industry by licensing designs and technologies from established firms, enabling them to develop domestic manufacturing capabilities while avoiding the costs and delays associated with developing technologies independently.[6] More broadly, international initiatives such as the Indo-Pacific Economic Framework's Clean Economy Agreement recognize that technology diffusion depends on access to IP, but also on knowledge exchange, workforce development, capacity building, and industrial partnerships. In these cases, VL functions as one component of a broader ecosystem that enables countries to absorb, adapt, and scale advanced technologies.[7] In agricultural biotechnology, licensing agreements have facilitated the transfer of improved crop varieties, breeding technologies, and biotechnology traits through partnerships among research institutions, multinational firms, and local producers.[8] In each case, IP enabled innovation to diffuse, scale, and generate wider economic and societal benefits.[9]

The same dynamics apply to global health challenges. Developing a new medicine is only the first step. Ensuring that medicine reaches patients requires significant regulatory, quality assurance, manufacturing, and distribution expertise, sufficient manufacturing capacity, a robust supply chain, regulatory review and approvals across markets, financing mechanisms, and delivery infrastructure. The Covid-19 pandemic was an illustrative example of this. As WTO Director-General Ngozi Okonjo-Iweala observed at the 2026 CSIS Futures Summit, achieving true vaccine equity requires moving beyond geographically concentrated production systems and building a more distributed global manufacturing base.[10] Creating a system that is robust will require the deconcentration of supply chains, production capacity, and technological capabilities across regions. Achieving that goal will require expanding manufacturing infrastructure and strengthening the institutional mechanisms that enable technology transfer and industrial collaboration. In practice, these capabilities cannot simply be mandated. Effective technology transfer and industrial partnerships often emerge through voluntary collaboration, supported by incentives that encourage firms, research institutions, and innovators to share expertise, invest in joint ventures, and build trusted networks. Creating conditions that attract and connect partners with complementary capabilities may therefore be as important as expanding physical manufacturing capacity itself.

Effective technology transfer and industrial partnerships often emerge through voluntary collaboration, supported by incentives that encourage firms, research institutions, and innovators to share expertise, invest in joint ventures, and build trusted networks.

This report finds that sustainable access to medicines is a challenge that cannot be addressed through access to IP alone. It examines how IP, VL, manufacturing networks, trade policies, regulatory systems, and local infrastructure interact to shape access outcomes, taking the Covid-19 pandemic as a global case study. It concludes that strengthening global health security will therefore require policies that support both innovation and the systems that enable innovation to scale.

International Rules Governing Access to Pharmaceutical Products

The international framework for IP protection is rooted in TRIPS, which established minimum standards for the protection and enforcement of IP rights across WTO member states, including requirements for pharmaceutical patent protection.[11]

TRIPS requires WTO members to provide patent protection for at least 20 years for inventions "in all fields of technology," including medicines, and to establish domestic enforcement mechanisms for these rights, with the exception for Least Developed Countries (Article 66.1). The agreement also defines the conditions under which governments may limit patent exclusivity. Article 31, "Other Use Without Authorization of the Right Holder," permits CL as a narrow exception when certain criteria are met:[12]

- The prospective licensee must first attempt to obtain authorization from the patent holder on reasonable commercial terms.
- Compulsory use must be justified by a public-interest rationale, such as a national emergency, extreme urgency, or public noncommercial use.
- The patent owner must receive adequate remuneration reflecting the economic value of the authorization.
- The license must be predominantly for domestic supply and limited in scope and duration to the stated purpose.[13]

These provisions balance the need to protect inventors with the recognition that, in rare circumstances, governments might need to override patent rights for national emergencies.

Concerns that TRIPS could restrict access to life-saving medicines in LMICs culminated in the 2001 Doha Declaration on TRIPS and Public Health (championed by Brazil, India, and South Africa), which reaffirmed that TRIPS "does not and should not prevent members from taking measures to protect public health."[14] The subsequent 2003 waiver and 2017 Article 31bis amendment allowed countries lacking manufacturing capacity to import medicines made elsewhere under compulsory license.[15]

Covid-19 as a Test Case: What Determined Access During the Pandemic?

The Covid-19 pandemic provided the most significant real-world test of these competing approaches to access. As governments, international organizations, and civil society groups sought to expand the availability of vaccines and therapeutics, debates over patents, CL, and the proposed TRIPS waiver moved from legal and academic discussions to the center of global health policy. The key question was straightforward: If IP protections were relaxed or overridden, would they enable LMICs to access medicines at the same time as high-income countries?

The pandemic ultimately offered an opportunity to evaluate this assumption against observed outcomes.

THE RESURGENCE OF IP-CENTERED ACCESS DEBATES

Before the Covid-19 pandemic, CL remained a relatively limited policy tool, used primarily in a small number of cases involving HIV/AIDS, tuberculosis, and other infectious diseases in LMICs.[16] Although governments periodically considered compulsory licenses to address affordability and access concerns, their use remained episodic and typically focused on specific products rather than large-scale manufacturing or distribution efforts.[17] Historically, calls for CL have tended to intensify during major public health emergencies—including the HIV/AIDS crisis, the H1N1 influenza outbreak, and Covid-19.[18] Still, the pattern has been remarkably consistent: Governments invoke the possibility of CL as leverage in broader policy debates, yet relatively few licenses are ultimately issued, and fewer still result in meaningful expansion of access.[19] Studies examining CL activity between 1995 and 2020 suggest that most proposals never progress to implementation and that successful deployment often depends on factors beyond patent rights alone, including manufacturing capacity, regulatory approvals, and supply chain capabilities.[20] This historical pattern provides important context for understanding the resurgence of IP-centered access debates during the Covid-19 pandemic.[21]

The Covid-19 pandemic generated unprecedented public policy debates over CL for vaccines and therapeutics. In addition, the pandemic's global demand for vaccines, therapeutics, and diagnoses created both political and logistical pressure for broader use of IP flexibilities, culminating in debates around the other form of coercion for bypassing IP: the TRIPS waiver, which authorizes the overriding of patent rights by consensus of WTO members. Several countries amended domestic laws or activated emergency authorities that would permit CL if needed, while others publicly

considered invoking existing TRIPS flexibilities. Incongruously, despite all the public debate, neither CL nor the TRIPS waiver had any discernible effect on the course of the pandemic.[22]

For example, Bolivia attempted to use Article 31bis of the TRIPS Agreement, which provides a legal authority for exporting products manufactured under CL. Yet the effort to import Johnson & Johnson vaccines from a Canadian manufacturer ultimately stalled amid regulatory and procedural hurdles, not directly related to IP, highlighting the limitations of implementation rather than the absence of legal authority.[23] Similarly, Hungary issued a compulsory license for Gilead's remdesivir in 2020, but production under CL remained limited and the license expired within months. [24] At the same time, in India, policymakers publicly acknowledged that manufacturing constraints, shortages of raw materials, technology transfer capacity and timelines, and workforce limitations posed more immediate barriers to scaling production than patent rights.[25] These assessments suggested that a compulsory license, while addressing patent-related barriers, would have been insufficient to overcome the broader production constraints facing manufacturers. For a more detailed discussion of CL initiatives and proposals during the Covid-19 pandemic, see Appendix A.

THE TRIPS WAIVER DEBATE

The debate and eventual implementation of the TRIPS waiver highlighted the extent to which access to Covid-19 health technologies was shaped by a broader set of manufacturing, regulatory, trade, and distribution challenges rather than IP rights.

- On October 2, 2020, India and South Africa jointly petitioned the TRIPS Council of the WTO for a temporary patent waiver for Covid-19 drugs, vaccines, and associated technology and equipment.[26]
- On June 17, 2022, nearly two years after the India/South Africa petition was submitted, the WTO adopted the Ministerial Decision on the TRIPS Agreement providing that member states could use the subject matter and any ingredients or parts thereof of a patent without the consent of the patent holder with respect to Covid-19 vaccines only to the extent necessary to address the Covid-19 pandemic. The Ministerial Decision provided that such measures could be taken whether or not a member had a CL regime in place. The waiver is to remain in force for a period of five years, subject to annual review. [27]
- The waiver provided a legal basis and clarification for members to authorize domestic manufacturers to produce Covid-19 vaccines without the consent of the patent holders, as well as to export those vaccines to other countries. Several countries unsuccessfully advocated for an extension of the waiver to Covid-19 treatments and diagnostics.[28]

The TRIPS waiver had no impact on global vaccine access during the pandemic. Although seen as an emergency measure, implementation required approval of all 164 WTO members, a process that took nearly two years. Furthermore, at the end of 2022—seven months after the issuance of the waiver—not a single country had declared an intention to make use of it.[29] Following the WTO decision, some proponents of the waiver acknowledged that the circumstances surrounding the pandemic had changed significantly. For example, Indian Minister of Commerce and Industry Piyush Goyal observed that "vaccines have already lost relevance," reflecting the extent to which

vaccine availability and demand had evolved.[30] On May 5, 2023, the World Health Organization (WHO) declared that the Covid-19 pandemic had ended.[31] Over the intervening years, the TRIPS waiver had failed to solve the issues of access.

WHAT HAPPENED IN PRACTICE?

While much of the international debate during the Covid-19 pandemic focused on patents, CL, and the TRIPS waiver, access was primarily expanded through VL agreements and broader technology transfer partnerships. These arrangements were built upon licensing models that had previously been used to expand access to HIV/AIDS and hepatitis C treatments, among other things.

The scale of these arrangements reflects an important reality often overlooked in debates centered on IP. VL did not simply provide legal permission to produce patented medicines. Rather, it enabled the transfer of know-how, clinical data, manufacturing expertise, quality control procedures, and regulatory information necessary to produce complex pharmaceutical products at scale. Bilateral licensing agreements between innovators and generic manufacturers frequently included the sharing of technical knowledge and regulatory support, reducing barriers to production and accelerating approval processes in recipient countries.[32] Similarly, the MPP acted as an intermediary that identified qualified manufacturers, negotiated sublicenses, and coordinated implementation across LMICs, reducing transaction costs and helping to ensure quality and reliability throughout the supply chain.[33]

The experience of remdesivir illustrates how access depended on far more than patent rights alone. By the time Covid-19 emerged, Gilead had invested more than $1 billion in the development of remdesivir and had accumulated years of research, safety data, and manufacturing expertise. Producing the drug required more than 70 raw materials and over 20 sequential manufacturing steps, creating significant production challenges even before global demand surged. Gilead expanded its manufacturing capacity by a factor of 100, partnered with 40 manufacturers across 13 countries, reduced production timelines from 12 months to 6 months, and ultimately increased supply by a factor of 400 by the end of 2020.[34] Through royalty-free VL agreements and long-standing partnerships with generic manufacturers in India, Egypt, and Pakistan, remdesivir was supplied to 127 LMICs and reached an estimated 7.5–8 million patients in developing economies.[35]

Similar approaches were adopted across the industry. Eli Lilly combined VL, humanitarian partnerships, and manufacturing agreements to expand access to baricitinib without waiving IP rights. AstraZeneca licensed production of its Covid-19 vaccine through partners such as the Serum Institute of India, while Merck entered agreements with multiple generic manufacturers for molnupiravir.[36] Through the MPP, Merck licensed molnupiravir to 31 generic manufacturers for distribution across 106 countries, Pfizer licensed nirmatrelvir/ritonavir to 36 manufacturers serving 95 countries, and Shionogi licensed ensitrelvir to 7 manufacturers covering 117 countries.[37] In total, 119 LMICs were covered by at least one MPP-brokered Covid-19 therapeutic license, all of which were royalty-free during the pandemic. For a more detailed overview of VL agreements during the Covid-19 pandemic, see Appendix B.

DEBATE VERSUS REALITY

The Covid-19 pandemic exposed a growing disconnect between the focus of international access debates and the factors that ultimately shaped access outcomes. Public discussions frequently centered on patents, CL, and the proposed TRIPS waiver, reflecting a widespread assumption that IP protections represented the principal barrier to equitable access. These debates emerged within a broader architecture of global pharmaceutical governance that includes VL, CL, non-assert declarations (in which patent holders proactively commit not to enforce their rights in low-income or developing countries), donation programs, and multilateral initiatives such as Gavi, the Global Fund, and COVAX. At the center of the discussion was a fundamental question: Would expanding access to IP rights significantly increase the availability of vaccines and therapeutics in LMICs?

In practice, access was expanded primarily through mechanisms that operated within, rather than outside, the existing IP framework, such as bilateral and MPP licensing agreements, the majority of which explicitly partnered international innovators with generic producers in developing economies.[38] Rather than relying on the suspension of IP rights, governments, innovators, manufacturers, and international organizations largely pursued collaborative approaches that linked IP to production capabilities and distribution networks.

Voluntary Licensing as a Mechanism for Scaling Innovation and Access

Innovative solutions are indispensable to the rapid and widespread resolution of global health threats. Patents and IP rights contribute to innovation-driven economies by enabling firms and research institutions to undertake the extraordinary financial, technical, and temporal risks inherent in research and development (R&D). IP also supports the collaborations needed to translate promising science into commercial products and enables the infrastructure for global manufacturing and distribution of medicines and vaccines.

Patent rights prohibit others from making, using, or selling a new medicine or vaccine for a set period. They provide the economic foundation for private investment in breakthrough science while also creating the legal architecture for technology transfer, manufacturing partnerships, and commercialization pathways that enable the broad deployment of new medical technologies. Across sectors, this system has mobilized billions in R&D investment and driven technological progress—nowhere more visibly than in the biopharmaceutical industry's development of novel vaccines and therapeutics. The Covid-19 pandemic demonstrated both the extraordinary capacity of modern innovation systems to deliver life-saving technologies at unprecedented speed and the persistent structural barriers that constrain equitable access across LMICs, particularly last-mile distribution challenges (see Appendix A for examples).[39]

While maintaining patent rights, VL has enabled patent holders to authorize qualified generic manufacturers—often in countries with lower cost of production—to produce and supply affordable versions of patented medicines for designated low- and middle-income markets, making it economically feasible in certain circumstances to expand availability without requiring generics

to bear the original R&D costs. As one review notes, the core purpose of VL is to reduce global health inequity by increasing access to pharmaceuticals in LMICs.[40] A 2022 *Lancet* review of pre-pandemic licensing agreements similarly concluded that voluntary (including MPP) licenses have expanded access to quality-assured, affordable formulations and have generated meaningful health and economic benefits in LMICs. [41] By contrast, despite the prominence of debates over CL and the TRIPS waiver during Covid-19, these measures had limited operational impact. These realities highlight that sustainable preparedness depends less on suspending IP rights than on strengthening partnerships and production networks that can scale in future emergencies.[42]

Intellectual Property: The Enabler for Voluntary Licensing

The global IP system, based on the TRIPS Agreement, establishes minimum standards for the protection of IP, providing innovating firms with the certainty that they can make large, extremely long-term investments in R&D, thus putting them in a position to respond rapidly to global health emergencies. Practical experience during the pandemic demonstrated that IP helped increase, rather than decrease, access to medicines for low-income countries.[43] An Eli Lilly executive testified in 2023 that weakening IP protections would not address the broader regulatory, manufacturing, distribution, and health-system barriers limiting access to Covid-19 products.[44] Similarly, testimony before the House Judiciary Committee in 2023 cited Gilead Sciences' argument that IP is a prerequisite to expanding access rather than a barrier to it, and that a TRIPS waiver would therefore not address access challenges.[45] However, the debate over extending the WTO TRIPS decision to Covid-19 therapeutics and diagnostics highlighted broader disagreements regarding the principal barriers to access.

Developing a new medicine typically requires 10–5 years of research and testing, with no guarantee of success. According to studies, only about 12 percent of drug candidates that enter clinical trials are ever approved for use in patients.[46] Estimates suggest that only about 0.01–0.02 percent of compounds synthesized in laboratories ultimately reach the market, and only around 1 in 10 candidates that enter clinical development receive regulatory approval and are commercialized.[47] Each failure represents a sunk cost in both time and capital in terms of risky R&D investments, and innovators bear the entire burden of these losses—unlike generic manufacturers, who produce only proven compounds once they have demonstrated safety and efficacy. Revenues from successful products must therefore recover not only the cost of those individual drugs but also the accumulated expense of failed candidates across the pipeline.[48] These returns are what enable continued investment in high-risk or low-return areas—including rare and neglected diseases—as well as in donation programs, public-private partnerships, and VL initiatives that expand access in low-income markets. Sustaining this innovation-access cycle requires a predictable IP framework that balances incentives for discovery with mechanisms that ensure equitable global health outcomes.

IP is also the key enabler of VL arrangements by protecting the investments of both innovators and licensees, while ensuring the quality and efficacy of licensed products in ways that are not possible under CL conditions. VL allows for:

- **Security for Generics Licensees:** Licensing agreements provide the legal framework for the creation and use of IP. They typically address the right to use patented processes, as well as make (or have made) and sell the patented product. However, licensing agreements may also provide for the sharing of trade secrets, expertise, data, or other technical information needed to produce the product and obtain regulatory approval. The financial security and know-how shared through these agreements often provide generic manufacturers with the confidence to invest in production capacity, staffing, and distribution infrastructure without the risk of unlicensed competitors undermining the market with inferior or duplicative products. Licensing agreements also result in trusted manufacturing partners, increasing the potential for licensees to receive future licensing deals.[49]
- **Sharing of Know-How and Technology:** IP enables the structured sharing of the know-how, trade secrets, and technical information essential for producing complex medicines—capabilities that patents alone do not convey. While CL permits the legal override of patent rights, it does not provide the technical know-how specific to the product or assurances for specifications and quality.[50] VL facilitates this transfer through coordinated partnerships that support quality assurance and can accelerate regulatory review, including through data-sharing arrangements that allow licensees to rely on existing clinical trial data for the branded version when seeking marketing approval rather than having to duplicate long, costly clinical trials.[51]
- **Velocity to Market:** VL could potentially accelerate time to market and scale-up by facilitating early technical collaboration and coordinated manufacturing through preexisting partnerships with trusted generic manufacturers, enabling faster delivery of medicines in LMICs during health emergencies.[52] In some cases, licenses can be issued during clinical development, further allowing generic production planning to proceed before final approval.[53] The operational dynamics can differ, however, between direct bilateral agreements—often tailored and rapidly negotiated—and indirect licensing through the MPP, which may prioritize standardized contracts (and, sometimes, broad geographic coverage).
- **Quality Assurance:** Voluntary license agreements encompass a wide array of partnership structures, such as patent pools (e.g., MPP) and direct bilateral contracts. Within these structures, most bilateral voluntary license agreements include terms committing licensees to minimum quality standards, as well as an agreement by the patent holder to maintain pharmacovigilance (i.e., monitoring, risk assessment, and data collection and analysis) for licensed drugs. MPP licensors typically ask licensees to demonstrate that their manufacturing facilities meet good manufacturing practice standards. Subcontracts mandate robust pharmacovigilance and pre-commercialization adverse event reporting mechanisms, verified market supply capacity, and adherence to anti-bribery and anti-corruption assessments.[54]

Moreover, VL arrangements facilitate the provision of key inputs such as reference listed drug designations for studies to establish the bioequivalence of the generic product under development with the approved patented version.[55] While VL agreements are generally private contractual arrangements and do not typically require government approval as licensing instruments, the

introduction of a licensed product into a national market remains subject to domestic regulatory authorization. As a result, although voluntary licenses do not depend on the formal CL or TRIPS waiver procedures initiated by governments, their practical implementation ultimately depends on regulatory review and approval. In cases where governments oppose a particular product or arrangement, delays or denials in authorization could entail substantial bottlenecks. [56]

Voluntary Licensing and the Potential Expansion of Local Innovation Ecosystems

Evidence from industry further illustrates how VL operates as a mechanism for scaling access while building geographically diverse manufacturing capacity that matches global demand. Partnerships between originator firms and licensed manufacturers in emerging markets demonstrate how IP-enabled collaboration can translate into rapid deployment, affordability, and long-term ecosystem development.

For example, Pakistan-based Ferozsons Laboratories, a licensee of several U.S. innovative medicines, has played a central role in expanding access to antiviral treatments across LMICs. Through VL agreements, the company was able to rapidly scale production of therapies such as sofosbuvir for hepatitis C—contributing to the treatment of tens of thousands of patients at some of the lowest global costs.[57] During the Covid-19 pandemic, Ferozsons leveraged similar licensing arrangements to produce remdesivir at scale within weeks, supplying treatments to multiple countries across Asia, Latin America, and beyond. These partnerships also enabled the firm to build domestic capabilities in formulation, fill-finish operations, and active pharmaceutical ingredient (API) manufacturing, reinforcing longer-term industrial capacity.[58]

Similarly, Dr. Reddy's Laboratories in India illustrates how VL can accelerate both access and innovation. Through licensing agreements with companies such as Gilead; Merck, Sharp & Dohme (MSD); and Pfizer, the firm expanded production of treatments for HIV and Covid-19, while working with global health organizations to reach underserved populations. VL arrangements enabled faster regulatory pathways, reduced time to market, and facilitated technology transfer, allowing products to be deployed in as little as one to two years, or even within a matter of months in some cases.[59] These partnerships have also supported market expansion into regions such as Africa and enabled incremental innovation, including the adaptation of existing therapies for new delivery formats and patient populations.[60]

Another example is EVA Pharma. Under EVA Pharma's collaboration with Eli Lilly in December 2022, Lilly supplies insulin API at a reduced cost and provides technology transfer support, while EVA Pharma conducts formulation, fill-finish, quality control, regulatory approval, and local manufacturing.[61] In December 2024, Lilly reported that EVA Pharma had established a new biologics facility, secured regulatory approval for locally manufactured insulin glargine in Egypt, and began production for regional markets. This example illustrates how stepwise partnerships—combining technology transfer, manufacturing know-how, and local investment—can help firms

move up the pharmaceutical value chain from conventional medicines to advanced biologics manufacturing.[62]

These cases highlight several consistent features of VL in practice: the ability to rapidly scale production through an optimal number of qualified manufacturers, the transfer of technical know-how necessary to ensure quality and regulatory compliance, and the creation of sustainable commercial incentives for both licensees and licensors that support access and continued innovation. Beyond immediate access gains, these partnerships contribute to broader economic development by strengthening local pharmaceutical ecosystems, building manufacturing capabilities, and supporting workforce and supply chain development in participating countries.

They also underscore the limitations of alternative approaches. While CL may generate political visibility, it often lacks the coordination, technical transfer, and market incentives required to achieve comparable outcomes in access, quality, long-term capacity building, and ecosystem development.[63] Evidence from a systematic analysis of 30 CL cases, benchmarked against 673 comparable international procurements, suggests that CL does not consistently deliver the most cost-effective access outcomes. In 19 of the 30 cases, prices obtained through CL were higher than median international procurement prices, often by more than 25 percent. These findings indicate that legal authorization to produce a medicine does not by itself replicate the efficiencies generated through coordinated procurement, established supply chains, and functioning manufacturing markets. The results were particularly unfavorable where lower-income countries relied on local production, underscoring how limited manufacturing capacity and market conditions can constrain the effectiveness of CL.[64]

The long-term validity of these collaborative models is reflected in post-pandemic data, which demonstrates how secure IP unlocks vital capital to drive sector growth. This legal predictability supported a surge of 4,787 global therapeutic patent filings between 2020 and 2022.[65] This structural stability became crucial when biotech venture capital fell 41 percent in 2023, forcing smaller, innovative firms to utilize their patent portfolios for "nondilutive" financing.[66] By licensing specific assets to larger corporations for upfront cash, the volume of these partnerships grew to double or triple pre-pandemic levels. This strategic funding mechanism is highlighted by major corporate announcements, such as Ipsen's $900 million global deal with Sutro Biopharma and Gilead's exclusive cancer treatment partnership with Xilio Therapeutics.[67] Protecting these IP rights has ultimately sustained high-risk investments, fueling an advanced research pipeline of 1,762 active therapeutic clinical trials worldwide by mid-2023.[68]

The Limited Impact of Compulsory Licensing

During the Covid-19 pandemic, debates around the TRIPS waiver proposal effectively reopened the door to calls for extensive and expanded use of CL (despite waivers being functionally distinct from compulsory licenses). The TRIPS Agreement already enables compulsory licenses for the supply of the domestic market and also enables export to countries lacking manufacturing capacity, subject to additional requirements.[69] The waiver—initially conceived as a broad suspension of certain IP obligations for vaccines and treatments—was, in practice, an additionally expansive interpretation of the CL principle. While intended to accelerate access, it underscored both the legal complexity and limited practical benefits of compulsory mechanisms compared to collaborative approaches such as VL, donation programs (e.g., Gavi), public-private partnerships, and non-assert declarations.

While compulsory licenses can temporarily support access in moments of crisis, they often do so at the cost of predictability and trust in the broader IP system. CL can create concerns about long-term innovation incentives because it reduces the expected returns associated with patent exclusivity. Economic research has identified a potential trade-off between expanded access through CL and incentives for pharmaceutical R&D, although the empirical evidence on the magnitude of this effect remains mixed.[70] By contrast, VL arrangements preserve the integrity of patent protections while promoting access through collaborative partnerships and technology transfer. They provide a sustainable framework that aligns public health objectives with continued private-sector innovation—turning what might otherwise be a zero-sum trade-off between access and invention into a cooperative model for global health security. In general, they have the following limitations:

- **Compulsory licenses have limited impact on affordability and access.** Generic medicines produced under compulsory licenses are not always cheaper than the patented counterparts. The outcomes are mixed and often counterintuitive. A 2015 *Health Affairs* study found that antiretrovirals manufactured locally under CLs cost up to 25 percent more than those procured through international programs such as the Global Fund.[71] Similarly, in Thailand, a CL issued for clopidogrel was followed by a 50 percent price increase between 2009 and 2015—highlighting that CL does not ensure sustained price reductions.[72]
- **Persistent systemic barriers to access exist with compulsory licenses.** Neither CL nor VL can, on its own, overcome deeper structural constraints—such as weak healthcare delivery, inadequate public sector funding, and tariffs or taxes on medicines—that often contribute to limited access. A cross-country study of 36 developing and middle-income economies found that procurement and distribution inefficiencies were important contributors to high medicine prices and limited availability, underscoring that removing patent barriers alone is insufficient to ensure access.[73] The relevant distinction, therefore, is not that VL can resolve these broader health-system weaknesses, but that well-designed voluntary licenses can complement systemic reforms by facilitating coordinated supply, technology and know-how transfer, and partnerships with qualified manufacturers. CL primarily addresses the patent barrier and similarly must be accompanied by investments in procurement, distribution, financing, and health-system capacity to translate lower-cost production into sustainable patient access.
- **Compulsory licenses have minimal contribution to geographically diverse production or technology transfer.** A compulsory license transfers only a legal right—it does not include the underlying know-how, manufacturing expertise, or quality control systems required to ensure safe and effective production. When Brazil issued a compulsory license for an antiretroviral in 2007, domestic manufacturing took nearly two years to begin.[74] In Mozambique, Zambia, and Zimbabwe, local firms operating under compulsory licenses were soon outcompeted by Indian generic producers that could deliver the same drugs faster and at lower cost.[75] This advantage reflected India's preexisting strengths rather than the compulsory license itself: Indian firms already had large-scale generic manufacturing capacity, deep expertise in reverse engineering small-molecule drugs, established supply chains, and experience meeting international quality standards and serving global procurement programs, in large part also due to their partnerships with innovator companies through VL agreements across different therapeutic areas. In fact, nearly all compulsory licenses for imports have ultimately been filled by Indian companies rather than local manufacturers in Africa. This pattern underscores the limits of CL as a tool for building sustainable domestic capacity.[76]
- **There is limited application for complex technologies.** CL can provide legal authorization to use patented technologies, but for complex medicines, removing patent barriers may be insufficient to enable additional manufacturers to enter the market. For modern biologics and other advanced therapeutics, patents represent only part of

the knowledge required for manufacturing; critical expertise is frequently embedded in proprietary trade secrets, tacit know-how, manufacturing processes, and quality control systems that a compulsory license does not generally require the patent holder to transfer. VL arrangements may be better positioned to address these barriers when they include technology transfer, technical assistance, access to proprietary know-how, or other forms of cooperation from the originator, although voluntary licenses do not necessarily include such support. Other constraints—including regulatory approvals, pharmacovigilance requirements, supply chain coordination, and shortages of critical inputs—can impede production under either licensing framework. These broader production and regulatory challenges are not unique to compulsory licenses, but CL by itself generally provides no mechanism for securing the complementary knowledge and cooperation that may be necessary to overcome them.[77]

- **Economic and innovation disincentives occur under CL**. Frequent or politically motivated use of CL can undermine the stability and predictability of IP systems that drive biopharmaceutical innovation. Although CL does not eliminate patent protection, frequent or unpredictable use can reduce the expected value of patent exclusivity by increasing the risk that exclusive rights will be overridden before innovators have fully recouped their investments. This uncertainty may weaken incentives for firms to invest in costly and risky R&D, particularly in markets where the likelihood of CL is perceived to be high.[78] It may also discourage firms from voluntarily transferring proprietary technology and know-how or introducing advanced therapies in markets where IP protections are viewed as uncertain. Scholars Richard Epstein and F. Scott Kieff have warned that excessive reliance on compulsory licenses weakens investor confidence, deters technology transfer, and discourages the introduction of advanced therapies in affected markets.[79]

Beyond Intellectual Property

The Real Determinants of Access

There are significant political, regulatory, trade, and physical impediments to health access. During the pandemic, policy discussions over the need to expand access for LMICs to vaccines and therapeutics included prominent calls to override certain patent rights through CL and the TRIPS waiver. Whether IP protections themselves constituted a significant barrier to access, however, remained contested.[80] While some WTO members argued that additional IP flexibilities were necessary, others maintained that manufacturing capacity, regulatory approvals, supply chain disruptions, and trade restrictions represented more immediate constraints on the availability of Covid-19 health technologies. Ultimately, WTO members were unable to reach consensus on extending the TRIPS waiver beyond vaccines, reflecting continued differences over the relative importance of IP and non-IP barriers in shaping access outcomes.[81] The global health crisis highlighted the following barriers to access, none of which could be solved under CL.

Export Controls and Trade-Related Impediments

The WHO convened several countries to establish the COVAX task force to enable equitable access to vaccines and ingredients for LMICs, but the effort was impeded by shortages and "vaccine nationalism," pursuant to which countries capable of developing and producing vaccines, treatments, and ingredients imposed controls on their export.[82] Moreover, the development, manufacture, and supply of drugs is global in scope, with many inputs and finished medicines crossing international borders. Various trade-related procedures, measures, and requirements impeded this process and delay the delivery of drugs to consumers in LMICs:

- In April 2020, Belgium adopted an export ban on medicines and raw materials required for the treatment of Covid-19.[83] Several other EU member states banned the export of designated medicines used to treat Covid-19.[84]
- In January 2021, the European Union adopted Regulation 2021/111, which required an export authorization for Covid-19 vaccines and "active substances including master and working cell banks used for the manufacture of such vaccines."[85] Export authorizations would be issued only if they did not jeopardize the execution of purchasing agreements the European Union had concluded with drug makers to supply the bloc with vaccines.[86]
- In March 2021, India announced that it would curtail exports of Covid-19 vaccines, citing skyrocketing domestic infections.[87] India was one of the world's largest manufacturers of the AstraZeneca vaccine, and its action affected "mostly poor countries, and mainly those on the continent of Africa."[88]
- In April 2021, the United States invoked the Defense Production Act to restrict the export of key raw materials for the manufacture of Covid-19 vaccines, giving priority to domestic production.[89]

WTO analyses have identified more than 250 export restrictions, customs measures, and other trade-related barriers affecting vaccines, therapeutics, and critical manufacturing inputs during the Covid-19 pandemic. These measures disrupted global supply chains, delaying the movement of raw materials and components across borders.[90] In general, there is a lack of expedited procedures for exporting and importing vaccine and therapeutics ingredients, which are subject to strict documentation requirements and the repeated need to renew certificates and licenses. Moreover, many countries did not have a single point of contact to prioritize issues related to supply chain and access.[91] The administration of import and export restrictions is commonly unpredictable and subject to revision, complicating drug developers' and manufacturers' ability to plan the acquisition of essential inputs.[92] Furthermore, complex visa entry requirements impeded the ability of key personnel to move across borders, not only disrupting hands-on drug manufacturing but also stalling regulatory assessments, inspections, and trial coordination in other countries.[93] Finally, high tariffs on some inputs in manufacturing countries increased the cost of producing medicines, while trade measures obstructed the cross-border transport of noncommercial samples, such as experimental drug formulations and laboratory compounds, stalling critical clinical trials and safety testing in specialized laboratories in other countries.[94]

WTO analyses found that export restrictions and other trade measures disrupted global supply chains, limiting the availability of critical inputs needed for the production and distribution of vaccines, therapeutics, and personal protective equipment. The WTO concluded that such measures could exacerbate shortages, increase costs, delay deliveries, and undermine the resilience of international supply chains at a time when cross-border cooperation was most needed.[95]

Regulatory Delays

The availability of generic Covid-19 treatments was also influenced by regulatory review processes, which are prerequisite for access to any vaccine or therapeutic. Although some countries implemented expedited pathways and prioritized pandemic-related products, many regulatory authorities faced capacity constraints or longer approval timelines, delaying patient access even after manufacturing had begun. For example, despite VL agreements covering all countries in Africa for several Covid-19 therapeutics, only a limited number of treatments ultimately received regulatory approval across the continent. Africa experienced a substantial delay in access to Covid-19 vaccines compared with high-income countries, contributing to first-dose vaccination coverage of only about 26 percent across the continent, well below the global average. While limited supply was a major factor, regulatory and procurement challenges—including delays in the rollout of the African Vaccine Acquisition Trust and national approval processes—further slowed vaccine deployment and compounded existing logistical constraints.[96]

Regulatory authorities in many low-income countries use WHO Prequalification Program (WHOPQ) assessments to facilitate their own approvals of imported medicines and vaccines.[97] Traditionally, it has taken three to four years to secure WHOPQ for a generic version of a new medicine from the time the IP holder secured its first approval.[98] However, to speed up access during the pandemic, regulatory bodies introduced extensive flexibility, including electronic dossiers, rolling submissions, fast-tracked reviews, and work-sharing initiatives. Frameworks including the WHO's emergency listings and the U.S. Food and Drug Administration (FDA) Emergency Use Authorization model successfully maximized administrative flexibility without compromising validity.[99]

Regulatory bottlenecks during the Covid-19 pandemic demonstrate the importance of more flexible and coordinated approval pathways during public health emergencies. Reliance on a relatively small number of stringent regulatory authorities and WHOPQ concentrated regulatory review among a limited set of institutions, contributing to bottlenecks and delays.[100] These challenges were compounded by independent national assessments, institutional inefficiencies, and differences in regulatory capacity. While countries with mature regulatory systems often served as primary scientific evaluators, many developing countries faced additional constraints related to regulatory capacity, logistics, and vaccine infrastructure.[101] Companies also had to obtain regulatory authorization in recipient countries where required. Where local authorities lacked well-developed emergency preparedness plans or did not effectively use regulatory reliance mechanisms, these additional reviews could further delay the delivery of countermeasures.[102] The FDA's emergency authorization model offers a useful reference for U.S. policymakers considering how regulatory systems can be designed to accelerate review and facilitate greater reliance on trusted regulatory decisions during future public health emergencies.[103]

Significant Local Infrastructure Gaps

Deploying Covid-19 vaccines and treatments in LMICs presented an array of unprecedented logistical challenges for which local infrastructure was frequently inadequate.

- As of 2018, 74 of 194 WHO countries had no adult vaccination programs for any disease, and no infrastructure was in place for deploying Covid-19 vaccines.[104] These countries may also lack adult immunization registries and the storage, distribution, and waste-management infrastructure needed to conduct vaccination programs at such a large scale.[105]
- Some Covid-19 vaccines have short shelf lives or require refrigeration and, in the case of the Pfizer/BioNTech vaccine, had to be administered within five days of leaving an ultra-cold environment. The necessary infrastructure often did not exist during the pandemic.[106]
- Even where doses were available, limited health-worker capacity and low public trust reduced uptake—and, in some cases, left doses unused or held in-country.[107]

Counterfeit Drugs

Though not as major an impediment as the previous obstacles, counterfeit drugs often amplify the uncertainty and fear that cloud decisionmaking ability during a health crisis. In several instances during the pandemic, counterfeit products proliferated when regulatory delays and supply constraints limited timely access to approved treatments, prompting desperate patients to seek alternative sources. Counterfeit versions of branded drugs endanger patient safety, frequently lack efficacy in treating disease, and can disrupt the distribution of legitimate proprietary medicines. The WHO estimates that approximately one million deaths annually are attributable to falsified products, which often contain no active pharmaceutical ingredients, incorrect dosages, contaminants, or deadly substances such as fentanyl, mercury, and lead.[108] They also undermine the value proposition for qualified generic manufacturers operating under voluntary licenses by eroding market trust and diverting demand away from quality-assured supply channels. This illicit market, totaling from $200 billion to $400 billion a year, drains critical revenues from legitimate producers, thereby reducing the available funds needs for biopharmaceutical R&D.[109]

Counterfeit medicines are increasingly associated with organized criminal networks that profit from copying and misappropriating the trademarks, branding, and reputations of legitimate manufacturers. The Organisation for Economic Co-operation and Development estimates that international trade in counterfeit pharmaceuticals reached $4.4 billion in 2016, while INTERPOL's Operation Pangea XVII led to the seizure of 50 million doses of illicit pharmaceuticals and the dismantling of 123 criminal groups operating across 90 countries.[110] In 2021, U.S. Customs and Border Protection agents reported seizing over 100 shipments of counterfeit remdesivir intended to be smuggled into Mexico. Each shipment included 10 to 30 vials of unapproved and unlicensed remdesivir produced in Bangladesh and India. By the end of 2021, the number of monthly seizures in the United States had increased to 300. Investigations of counterfeit branded remdesivir found that the tested samples contained no remdesivir API.[111] Meanwhile, in 2021, there were seven additional seizures of counterfeit remdesivir in Colombia, Ghana, Iran, Turkey, and Uzbekistan.[112] The pandemic further demonstrated that limited access to legitimate health products can create opportunities for counterfeit markets to emerge. Reports documented the circulation of fake Covid-19 vaccines and the dismantling of criminal networks distributing falsified doses, particularly in regions facing supply shortages and distribution challenges. These experiences reinforced that

equitable access depends not only on innovation but also on robust manufacturing, distribution, regulatory, and quality assurance systems capable of delivering trusted products at scale.[113]

IP holders—including owners of trademarks, patents, and copyrights—play an important role in efforts to combat counterfeit products. They regularly collaborate with regulatory authorities, customs officials, law enforcement agencies, and licensed manufacturers to identify, investigate, and disrupt illicit supply chains; remove falsified products from the market and protect patient safety.[114] IP rights provide both the legal framework and economic incentives for these ongoing resource-intensive enforcement efforts, helping preserve the integrity of legitimate pharmaceutical supply chains.

Conclusion and Policy Recommendations

In contrast to the history of compulsory licenses, the evidence of voluntary licenses and other industry efforts to form collaborative partnerships during the Covid-19 crisis reinforces the benefits of voluntary measures over coercive measures to expand access to vaccines and therapeutics, particularly during a pandemic situation. Voluntary efforts have the added benefits of expanding the technical and regulatory know-how of local manufacturers. Operationally, bilateral voluntary licenses tended to move fastest for urgent scale-up because they were bespoke and built on existing innovator-manufacturer relationships, reducing the time needed to assess capabilities and enabling faster tech transfer. MPP-brokered voluntary licenses, on the other hand, enable access to several potential licensors in one platform, particularly in the absence of preexisting networks. The availability of multiple approaches to licensing and access suggests that optionality remains an important policy consideration to solve for speed, scale, capability, and trust, particularly when it comes to facilitating a pandemic response.

The Covid-19 crisis reinforces the benefits of voluntary measures over coercive measures to expand access to vaccines and therapeutics, particularly during a pandemic situation.

The greatest obstacles to the rapid dissemination of life-saving medicines to LMICs during the pandemic were the regulatory, trade, and logistical issues discussed at length in this paper. Looking ahead, policymakers should continue to explore policies expanding the role of public-private partnerships in responding to global health crises, reinforce strong IP rights by fostering VL arrangements and other partnerships, and focus on addressing the documented barriers to access. Member nations of global bodies such as the WTO and WHO can and should work together to ensure that these organizations can act on their respective missions while also safeguarding the economic security and innovative capacity to deliver life-saving drugs and therapeutics for future health crises. In that light, this report makes five key policy recommendations:

1. **Build out case studies on the long-term impacts of voluntary technology transfer agreements on local economies.** Additional research is needed to document the degree to which various forms of technology transfer through voluntary IP licensing accelerate the growth of particular sectors and their economic contributions over time. VL can generate benefits beyond access to a specific product. By working with qualified local partners, licensors can help strengthen local manufacturing capacity, attract investment, and transfer technical knowledge and know-how that may support the development and production of other innovative products. However, there has been little scholarship tracking these effects over time, particularly across countries that have relied on CL versus VL approaches. In trade agreements, decisionmakers should prioritize policies that enable and support strong IP rights in order to support future voluntary technology transfer and other collaborative cross-border partnerships.
2. **Strengthen medical supply chain resilience through open trade, IP, and logistics coordination.** Pandemic preparedness strategies should explicitly link innovation policy with supply chain resilience. Governments should refrain from import and export restrictions during crises, strengthen IP frameworks to incentivize scale-up, harmonize regulatory and logistical corridors, and support globally distributed manufacturing capacity. The Covid-19 experience underscores that resilient, multisource global supply chains—rather than single-source or purely "make local" approaches—are critical both for global access and national security.
3. **Identify key enabling factors for VL and technology transfer.** Governments, in partnership with industry and international organizations led by the WTO, should develop an evidence-based study of key enablers for VL arrangements, whether direct or through the MPP. It should reflect lessons learned from Covid-19, including (1) the importance of selecting the appropriate number of partners, (2) capabilities to manufacture at scale, speed, and quality, (3) determining when standardized contracts are useful versus when bespoke agreements are necessary, and (4) recognizing that VL may not be appropriate in all cases or for all markets to prevent the diversion of licensed products from high-need, resource-challenged markets. For certain complex products, direct collaboration with the innovator—including through their established supply chain networks and partners—may be more effective. The roadmap should pair licensing best practices with concrete regulatory capacity requirements, since without these systems in place, licensing alone will not deliver access.

4. **Elevate health infrastructure and capacity building as a global priority.** The international community should prioritize long-term investments in health infrastructure, including workforce development, regulatory capacity, and manufacturing readiness. Expanding local capabilities to produce, approve, distribute, and administer medicines is essential to ensuring that innovations can be translated into meaningful access during public health emergencies. Investments should support the development of skilled technical and regulatory personnel, strengthen national regulatory authorities, and improve healthcare delivery systems, particularly in LMICs. Building these capabilities before a crisis occurs can reduce dependence on emergency interventions, accelerate the deployment of life-saving technologies, and enhance overall resilience against future pandemics. Moreover, stronger health infrastructure enables countries to participate more effectively in global technology transfer partnerships and VL arrangements, creating a more distributed and robust global health ecosystem.
5. **Coordinate the core competencies of global institutions.** Strong multilateral governance of pandemic preparedness requires global institutions to remain focused on their core mandates while coordinating closely across systems. For instance, through their regular trilateral meetings, the WHO should lead on health surveillance, norms, and regulatory coordination; the WTO on trade disciplines, supply chains, and enforcement of TRIPS obligations; and the World Intellectual Property Organization on technical IP expertise, capacity building, and norm setting. Within this architecture, a rules-based predictable trade and IP environment and a robust health system could serve as core enablers of both pandemic preparedness and global health security. Multilateral coordination should therefore reinforce, rather than fragment, open trade flows and strong IP protection, recognizing that innovation incentives and global market integration are mutually reinforcing pillars of resilient supply chains and global health security.

Appendix A

Compulsory Licensing During the Covid-19 Pandemic

At the beginning of the Covid-19 pandemic in early 2020, governments took extraordinary measures in response, including closing borders, lockdowns, curfews, mask mandates, and mass quarantines. A large number of advocacy groups and academic observers called for CL of relevant drugs, and several governments established the legal basis for granting compulsory licenses for medicines to respond to the Covid-19 emergency.[115] However, the rapid scale-up in supply of Covid-19 vaccines—and ultimately therapies—obviated the need for such measures, instead underlining the more pressing need for logistical and regulatory reforms. Ultimately, the number of compulsory licenses granted during the pandemic was limited to a handful of cases which proved to be largely inconsequential in combating the pandemic.

Israel

On March 18, 2020, Israel issued a permit allowing the importation of a generic version of AbbVie's drug Kaletra from an Indian manufacturer, Hetero, for the treatment of Covid-19. The compulsory license was issued pursuant to Section 104 of the patent statute, which authorizes the government to override patents in a national emergency.[116]

- AbbVie's patent on Kaletra—a combination of the drugs lopinovir and ritonavir, previously used to treat HIV—was to expire in 2024, and in India and some other countries it had already expired.[117]
- The Israeli measure limited importation of Kaletra to the experimental treatment of Covid-19 patients.[118]

- Following Israel's issuance of the compulsory license, AbbVie stated that it would not enforce its patents worldwide for the use of Kaletra to treat Covid-19, given that the efficacy of the drug for that application was still undergoing clinical trials.[119]
- The outcome of this episode was anticlimactic. A 2020 Chinese government-funded assessment of Kaletra published in the *New England Journal of Medicine* found that the drug had no effect on the progression of Covid-19.[120] A 2021 survey published in the *Journal of Infections and Public Health* assessing seven medical studies of the efficacy of the drug concluded that "there is no benefit of the addition of lopinovir-ritonavir to the standard care in COVID-19 patients."[121]

Bolivia

In February 2021, Bolivia notified the WTO of its intent to invoke the TRIPS Article 31bis CL provisions to enable it to import 15 million doses of Johnson & Johnson's patented Covid-19 vaccine pursuant to an agreement with a Canadian generic manufacturer, Biolyse.

- While Biolyse could produce the 15 million doses, it first needed to secure a compulsory license for export pursuant to Canada's Access to Medicines Regime (CAMR). However, at the time, Covid-19 vaccines were not listed under Schedule 1 of the Canadian Patent Act, making them ineligible for the CL process.
- Adding a product to Schedule 1 involved a set process pursuant to which approval was required by the governor-in-council upon the recommendation of Canada's Ministry of Industry and Health.[122] The initiative faced immediate domestic requirements, as Canada had previously rejected the manufacturing license of Biolyse due to quality concerns. Bolivia was already pursuing vaccines through multiple procurement channels, including bilateral agreements and the COVAX facility, although these arrangements did not at the time provide access to the Johnson & Johnson vaccine sought through the Biolyse agreement.[123]
- Biolyse held nearly 30 meetings with Canadian officials from three agencies to get the vaccine added to Schedule 1, but "after nearly six months of effort, Biolyse was not able to even get the CAMR process started."[124] Biolyse reported that the "CAMR website gives a phone number to a line that is disconnected and that the link it provides to the list of Schedule One drugs is broken."[125]
- As the matter was ultimately not followed up by the participating parties, the vaccine was never added to Schedule 1, and the application lapsed by the time the WHO declared the Covid-19 pandemic at an end.[126]

Hungary

The government of Hungary granted a set of compulsory licenses for a generic version of Gilead Sciences' antiviral remdesivir in late 2020 with little notice. The action was taken pursuant to a government declaration of a "State of Danger" in June 2020, in response to the Covid-19 pandemic. The action faced criticism in the European Union and the United States because the Hungarian

government was simultaneously receiving remdesivir pursuant to an EU Joint Procurement Agreement (JPA) negotiated with Gilead. The Hungarian government did not indicate that the arrangements for delivery of the drug via the JPA were insufficient to meet national needs.[127]

The compulsory license lapsed without renewal in May 2021, six months after its issuance.[128] Some limited domestic production of remdesivir reportedly occurred in Hungary during this period. Gedeon Richter, a pharmaceutical company in which the Hungarian government held an ownership stake, announced in October 2020 that it had produced enough remdesivir to supply approximately 3,000 doses for Covid-19 patients as part of a clinical trial sponsored by the government.[129] However, publicly available information suggests that production remained small-scale, and it is unclear whether generic remdesivir manufactured under the compulsory license was administered to patients beyond the limited quantities referenced in Gedeon Richter's 2020 press release.[130]

On October 10, 2023, the Constitutional Court of Hungary annulled the compulsory licenses that were granted by the Hungarian Intellectual Property Office against Gilead's Veklury in December 2020.[131] Hungary's highest court found that in granting the compulsory licenses and then in the appeal proceedings, Gilead had been denied the opportunity to fully defend its legal rights and interests. The court's decision explained and underlined the necessity of ensuring that fair legal proceedings are upheld during and after the grant of a compulsory license, including during a global pandemic. The repeated proceedings are currently pending in the courts.

Russia

In January 2021, Russia issued a decree granting a one-year compulsory license to a domestic generic firm, Pharmasintez JSC, to use Gilead Sciences' patents on Veklury to manufacture generic remdesivir. On December 28, 2021, Russia extended this compulsory license for an additional year, expiring late 2022.[132]

The decree was based on the Article 1360 of the Russian Civil Code, which authorizes the government to issue compulsory licenses "in the interests of national security" without the patent holder's consent.[133] Gilead, which was prepared to supply the market, unsuccessfully challenged the measure in the Russian Supreme Court. While the court held that Gilead was entitled to due compensation, it did not contain any particular justification for the compulsory license grant nor any analysis of Gilead's arguments on the lack of unmet demand.[134]

On March 6, 2022, in the wake of the Russian invasion of Ukraine, the government issued Decree 299, which provided that in cases involving CL, if the IP holder is based in any of 48 "unfriendly countries" (including the United States and all 27 EU member states), the compensation payable to the IP holder is 0 percent.[135] The Russian government also issued another compulsory license in March 2021 permitting local company R-Pharm to produce generic remdesivir until 2022.

However, there is limited evidence that these measures materially expanded access to Covid-19 treatments or altered pandemic outcomes. By the time the licenses were in effect, Russia had already deployed its own Covid-19 vaccine, global demand for remdesivir was declining, and

debates over access had shifted toward broader manufacturing, regulatory, and distribution challenges rather than patent availability alone.[136]

India

At the outset, the Government of India publicly indicated that CL was unlikely to be an effective mechanism for rapidly increasing the supply of Covid-19 therapeutics such as remdesivir or other complex drugs.[137] In affidavits filed before Indian courts and in contemporaneous policy statements—including commentary attributed to NITI Aayog—the government emphasized that production constraints stemmed primarily from limitations in technology transfer, trained human resources, access to raw materials and essential inputs, and the availability of high-biosafety manufacturing facilities, rather than from patent exclusivity alone. The government further noted that "any additional permissions and licenses may not result in increased production immediately," although such measures could help build capacity for future crises.[138] In May 2021, Natco Pharma, an Indian generic manufacturer, filed an application for a compulsory license pursuant to Section 92 of the Indian Patent Act for baricitinib, a drug patented by Eli Lilly to treat rheumatoid arthritis but repurposed for the treatment of hospitalized Covid-19 patients. Section 92 requires the government to accept or reject an application based on a determination of the existence of a national emergency.[139]

Appendix B

Voluntary Licensing During the Covid-19 Pandemic

During the Covid-19 pandemic, at least 93 voluntary partnerships were concluded to enable the supply of vaccines and therapeutics to LMICs—a subset of at least 450 collaborative partnerships.[140] Rather than emerging as an entirely new concept during the crisis, these mechanisms built upon a proven structural framework deployed since the early 2000s to expand access to treatments for health challenges including HIV and hepatitis C. Two main kinds of established VL agreements were utilized: (1) bilateral agreements (BLAs), negotiated directly between drug developers and individual generic producers, and (2) indirect agreements concluded under the auspices of the MPP, which accounted for about two-thirds of the total.

Bilateral License Agreements

BLAs are a form of VL in which drug developers voluntarily license their IP rights directly to generic drug makers, authorizing them to develop, produce, or sell a licensed version of their drug at a lower price in lower-income countries. The licensees' costs are much lower because they are typically based in lower-cost countries and have not invested in the R&D to develop the drug or in the regulatory approval process. BLAs commonly provide for the sharing of know-how, data, and trade secrets to facilitate efforts by the licensees to develop the drug and to secure regulatory approval in recipient countries.[141]

Medicine Patent Pool

The MPP is a UN-backed international public health organization with a mission to enable development and to increase access to life-saving medicines for LMICs. It functions as an intermediary between drug developers and generic manufacturers, negotiating licensing agreements with drug IP holders who authorize MPP to sublicense the IP for their medicines to third parties. The MPP solicits bids for sublicense agreements, screens prospective generic producers, and oversees all aspects of implementing the sublicenses in developing countries. Coverage may be worldwide or limited to a smaller group of countries.[142] The MPP process eliminates the need for IP licensors who do not already have trusted generic partners to identify and vet reputable potential licensees.

Gilead and Remdesivir

Gilead began developing remdesivir in 2009, gathering data on its safety in humans and its potential to treat hepatitis C after it was used as a treatment for Ebola during the Congolese outbreak. Further research showed that remdesivir could be a potential treatment for SARS, Middle East Respiratory Syndrome, and Marburg, as well.[143] By the time the Covid-19 pandemic broke out, Gilead had invested over $1 billion in the development of remdesivir, demonstrating that remdesivir was safe in humans.[144]

Gilead drew on preexisting R&D related to remdesivir to rapidly initiate clinical trials in Covid-19 patients in February 2020. In light of emerging (though still preliminary) clinical evidence, the FDA issued an Emerging Use Authorization for remdesivir on May 1, 2020, with full approval subsequently, making it the first novel antiviral treatment approved for Covid-19.[145]

Gilead used its long-established relationships with its generics licensees to supply remdesivir on a royalty-free basis to 127 LMICs through an array of VL agreements with partners in India, Egypt and Pakistan.[146] In 2021, with Covid-19 cases surging in India, Gilead committed to donate at least 450,000 vials of remdesivir from its own limited supply and to support an increase in local manufacturing capacity by its Indian licensees.[147]

As of early 2023, with the pandemic ending, Veklury and licensed generic versions of remdesivir had been made available to more than approximately 12–13 million patients worldwide, including as estimated 7.5–8 million individuals in LMICs through VL arrangements.[148]

Eli Lilly and Baricitinib

Like Gilead, in the first days of the pandemic, Eli Lilly mobilized its resources, seeking ways to help combat Covid-19 through its global expertise in monoclonal antibody (mAb) therapies to develop new treatments as well as looking to its existing portfolio of patented drugs. Lilly and its partners rapidly generated therapeutic antibody treatments for Covid-19, executed tech transfer with rival manufacturers, and made them available on an equitable basis. It repurposed its JAK inhibitor baricitinib/olumiant, licensed for rheumatoid arthritis, contracting with generics partners to produce the drug.[149] Baricitinib was found to treat hospitalized Covid-19 patients requiring

supplemental oxygen, invasive or noninvasive mechanical ventilation, or extracorporeal membrane oxygenation, a support mechanism which takes over the function of the heart and lungs when the patient is gravely ill.[150] Lilly supported the clinical testing of baricitinib for Covid-19 applications, and based on successful results, the FDA granted an emergency use authorization in November 2020—first in combination with remdesivir and then, in July 2021, as a monotherapy. Baricitinib went on to be one of the medicines listed by WHO for Covid-19 treatment.[151]

Lilly also went on to develop its own portfolio of Covid-19 mAb therapies, expanding the range of available treatments during the pandemic.[152]

Additional Examples

Other pharmaceutical innovating firms also entered into bilateral licensing arrangements to supply Covid-19 vaccines and therapeutics to LMICs. British pharmaceutical firm AstraZeneca pursued a series of exclusive voluntary licenses with Serum Institute of India, among others, for its Covid-19 vaccine.[153]

Meanwhile, New Jersey–based Merck—which does business outside of the United States and Canada as MSD—concluded an agreement with eight generic makers of molnupiravir, the first oral antiviral to be included in the WHO treatment guidelines for Covid-19.[154] Merck identified 57 pending patent applications across 27 distinct jurisdictions within its VL framework. As a small-molecule antiviral that targets the underlying viral RNA-dependent RNA polymerase to stop replication, molnupiravir represents a highly sought-after platform for generic replication.[155]

Licensing by the Medicines Patent Pool

During the Covid-19 pandemic, 119 LMICs were covered by at least one MPP-brokered Covid-19 therapeutic license agreement, all of which were royalty-free during the period of the pandemic. MSD entered into agreements with 23 generic makers for production of molnupiravir for delivery to 106 countries.[156] New York–based Pfizer entered into agreements with 36 generic manufacturers for the nirmatrelvir co-packaged with ritonavir, both of which are antivirals, for delivery to 95 countries. Moreover, Japanese pharmaceutical firm Shionogi entered into agreements with seven generic makers for the antiviral ensitrelvir for delivery to 117 countries.[157]

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