

Global Value Chains, Intellectual Property, and Knowledge Diffusion in Pharmaceuticals: Rethinking the TRIPS Waiver Debate

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I. Introduction

The COVID-19 pandemic prompted one of the most serious challenges to the international intellectual property (IP) system since the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement entered into force. Early in the pandemic, advocacy groups, policy officials, and commentators were concerned that IP rights would hinder the timely provision of affordable medicines in sufficient quantities to meet global demand. Consequently, there were calls and proposals to suspend IP protection for the duration of the pandemic.

This chapter evaluates the TRIPS waiver proposal through the lens of global value chains (GVCs), the international networks through which biopharmaceutical firms organize production. Pharmaceutical research and production are dispersed across firms and borders, much of which is contracted to specialized contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs). A lead firm therefore decides task by task whether to make or to buy, and IP protection is one of the considerations that govern the choice.

The chapter shows that IP rights shape not only how much pharmaceutical innovation occurs but how the value chain that delivers it is organized. It argues that neither the adopted waiver, nor a broader one, would have overcome supply-chain bottlenecks or improved access. The binding constraints lay in manufacturing capacity, upstream inputs, delivery infrastructure, and the coordination of production and distribution. Lower-income countries faced further obstacles with cold chain storage, timely delivery, and the specialized facilities required to work with messenger RNA (mRNA) technology. Two-thirds of the world was nonetheless fully vaccinated by mid-2024, though coverage lagged sharply by income group. None of these constraints was the IP system. The systemic failure lay further back, in advance contract design, which did not build global distribution requirements into ex-ante funding agreements.

A waiver only removes legal exclusivity; it does not transfer know-how. Where capacity did expand, it expanded through voluntary licensing accompanied by the transfer of know-how. A

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waiver weakens the incentive of lead firms to share that know-how with independent partners, and to form the partnerships through which such sharing occurs. Moreover, the anticipation of suspension discourages investment in the outbreak pathogens on which the next response depends.

II. Intellectual Property and the Organization of Pharmaceutical Value Chains

A. Two Views of IP and Firm Boundaries

The pharmaceutical industry is strongly knowledge-intensive. Few industries depend on patent protection as heavily as this one.¹ Yet much of what it sells it does not make itself, contracting instead with outside suppliers. The framework for understanding that choice is the theory of the firm under incomplete contracts, applied to global value chains.

A lead firm that needs a customized input faces a make-or-buy choice: produce the input within firm boundaries or purchase it from an independent supplier. When contracts are incomplete, so that not every contingency can be specified and enforced, this choice affects both how the surplus is split and how hard each party invests. Two literatures address this choice and disagree on whether stronger IP favors integration or outsourcing.

The first is the property-rights theory of the firm. Ownership gives control over assets in contingencies the contract does not specify, which strengthens the owner's hand when the relationship is renegotiated, and hence its share of the surplus.² Integration allows the lead firm to extract more rent, but it dulls the supplier's incentive to make relationship-specific investments because the supplier anticipates being held up. Outsourcing does the reverse: the supplier keeps more of what its own effort produces and so invests more, while the lead firm takes a smaller share of the surplus. On this account stronger IP raises the value of what ownership confers, so it strengthens the case for integrating: the firm brings a stage in-house to capture the rents that protection creates.

The second is the appropriability literature, where the binding constraint is not bargaining but leakage: a partner may take the know-how it receives and use it independently. Stronger

¹ Kristina Acri-Lybecker, "Health and Biopharmaceutical Innovation," in Walter Park (ed.) *Handbook of Innovation and Intellectual Property Rights*, Edward Elgar (2024).

² Sanford Grossman and Oliver Hart, "The Costs and Benefits of Ownership: A Theory of Vertical and Lateral Integration," *Journal of Political Economy* 94, no. 4 (1986): 691-719.

protection lowers that risk, so the firm can contract at arm's length for work it would otherwise have kept in-house.³

The two views are less opposed than they appear, since they concern different hazards: holdup in renegotiation on the one hand, imitation by a partner on the other. Which dominates depends on what must be transferred. Codified knowledge is well protected by law, so arm's-length dealing is relatively safe, but tacit know-how is harder to protect with any legal instrument, since, once transmitted, it cannot be recovered. In pharmaceuticals the lead firm's most valuable assets are knowledge assets, research capability, clinical data, and regulatory approvals, rather than factories.⁴ That raises the stakes on both sides: more rent to capture by integrating, more know-how at risk in contracting out.

Antràs and Chor extend the make-or-buy problem from a single supplier relationship to a value chain with a continuum of sequential stages.⁵ A final-good producer (the lead firm) contracts with a sequence of suppliers, each of which makes a stage-specific, customized input. Whether a stage is integrated or outsourced depends on where it sits in the chain and on whether the stages are complements or substitutes. The stages are complements when more investment upstream makes downstream contributions more valuable, and substitutes when it makes them less valuable. Which case applies depends on two *elasticities*: the price elasticity of demand, which captures how sensitive buyers are to the final good's price, and the elasticity of input substitution, which captures how easily one input can be swapped for another. The intuition is that the demand elasticity governs how quickly buyers' willingness to pay tapers off as the product gets more plentiful. If demand is relatively price-insensitive – say, buyers desire a fixed quantity – doubling output mostly lowers the price rather than doubling revenue. If earlier stages have already raised output, little extra revenue is left for later stages to capture. This makes stages sequential substitutes. On the production side, when one input cannot easily substitute for another, a better upstream input makes every later contribution more valuable. This makes stages sequential complements. The

³ David J. Teece, "Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy," *Research Policy* 15, no. 6 (1986): 285-305; Ashish Arora and Marco Ceccagnoli, "Patent Protection, Complementary Assets, and Firms' Incentives for Technology Licensing," *Management Science* 52, no. 2 (2006): 293-308.

⁴ James Markusen, "The Boundaries of Multinational Enterprises and the Theory of International Trade," *Journal of Economic Perspectives* 9, no. 2 (1995): 169-189.

⁵ Pol Antràs and Davin Chor, "Organizing the Global Value Chain," *Econometrica* 81, no. 6 (2013): 2127-2204.

chain is one of sequential complements when the demand elasticity exceeds the elasticity of input substitution, and of sequential substitutes otherwise.

The model predicts where integration occurs along the chain. Under sequential complements, the lead firm outsources upstream stages and integrates downstream ones. Outsourcing early elicits greater investment from upstream suppliers, which raises marginal revenue downstream, and it avoids the fixed costs of integration; integrating late lets the firm extract rents at the stages where the most value has accumulated. Under sequential substitutes, the pattern reverses: the firm integrates upstream and outsources downstream. Integrating early curbs overinvestment by upstream suppliers that would erode the marginal value of later inputs, while outsourcing late incentivizes suppliers to raise the quality of downstream output. Firms facing similar technology can still land in different places. In the COVID vaccine chains, Pfizer handled drug substance and fill and finish largely in-house, while Moderna contracted drug substance to Lonza and fill and finish to Catalent.⁶

Bolatto et al. add IP to this framework using the appropriability channel.⁷ In their model, stronger IP protection lowers the cost of transmitting knowledge to an arm's-length partner, because the lead firm is less exposed to expropriation when it shares know-how with an outside supplier. Under sequential complements, stronger protection raises outsourcing relative to vertical integration, and the shift is largest at the downstream stages, where inputs embody more accumulated knowledge and are therefore the most IP-sensitive. Because the baseline model has the firm integrating those same stages, IP works at the margin against that pattern. Conversely, weak protection induces the lead firm to internalize production earlier to safeguard its knowledge. Under sequential substitutes, IP has at most a weak effect on the organizational margin, because the firm can reallocate tasks across stages and reduce its dependence on any single IP-sensitive input.

The sequential-production models are static: they abstract from the lags involved in switching modes, such as the time to establish or absorb an affiliate or to find or divest a vendor. Those lags are the reason an organizational structure, once set, cannot be rearranged on the timescale of an emergency.

⁶ Chad P. Bown and Thomas J. Bollyky, "How COVID-19 Vaccine Supply Chains Emerged in the Midst of a Pandemic," *The World Economy* 45, no. 2 (2022): 468-522.

⁷ Stefano Bolatto, Alireza Naghavi, Gianmarco I. P. Ottaviano, and Katja Zajc Kejžar, "Intellectual Property and the Organization of the Global Value Chain," *Economica* 90, no. 359 (2023): 707-745.

B. Empirical Evidence

The evidence broadly supports the sequential-production framework and confirms that IP shapes the organization of cross-border production, though the direction of the effect varies with whether rent capture or leakage dominates. Antràs and Chor provide the original evidence for the sequential-production framework, using the share of U.S. intra-firm trade as a measure of integration.⁸ Classifying a chain requires both elasticities, but input substitutability is difficult to estimate directly, so they classify industries by buyers' demand elasticity alone, assuming that substitutability does not vary systematically with demand elasticity. Among industries whose buyers face elastic demand, the intra-firm share rises as inputs become more downstream; where buyer demand is inelastic, it falls. The test is at the industry level, however, so it places whole industries within the economy's input-output structure rather than stages within a single product's chain.

Bolatto et al. take the IP extension to data, using Slovenian firm-level data, in which an imported input counts as integrated when it falls under the core activity of a foreign affiliate and as outsourced otherwise.⁹ Their baseline classification splits industries at the median demand elasticity. They also construct proxies for input substitutability, chiefly a Herfindahl index of how concentrated a firm's imported inputs are across product categories, on the reasoning that inputs from the same category substitute more easily for one another. For complementary inputs, stronger IP lowers the probability of integration, and the effect is strongest for the more downstream, IP-sensitive inputs. For substitutable inputs the estimated effects are statistically insignificant.

Other studies reach mixed conclusions, and they divide along the two literatures. Biancini and Bombarda find that stronger IP raises vertical integration rather than lowering it, which is what the property-rights account predicts.¹⁰ In their model imitation threatens both modes, since even an affiliate's own workers may leave and operate the technology independently. But the more productive firms, which integrate, transfer more technology, so stronger protection raises the profitability of integration disproportionately. Their setting is single-stage production rather than

⁸ Antràs and Chor, *supra* note 5.

⁹ Bolatto et al., *supra* note 7.

¹⁰ Sara Biancini and Pamela Bombarda, "Intellectual Property Rights, Multinational Firms and Technology Transfers," *Journal of Economic Behavior & Organization* 185 (2021): 191-210.

a multi-stage GVC, which may account for the opposite sign. Pisani and Ricart¹¹ examine 128 offshoring implementations by 78 MNEs from developed countries and find that stronger IP promotes offshoring, but the effect fades with experience, since repeat offshorers substitute internal safeguards for host-country protection. Kukharsky shows that knowledge-intensive parent firms integrate to protect their IP assets, with stronger IP relaxing this dependence on integration, as appropriability predicts, whereas firms intensive in physical capital outsource to local manufacturers to elicit relationship-specific investment.¹²

As Ivus, Park, and Saggi note, each of these studies measures one organizational mode at a time, either the make-or-buy choice or the volume of FDI, so none can detect a firm shifting from one to the other.¹³ They examine affiliated and unaffiliated licensing jointly and find that stronger IP both raises the overall scale of an MNE's technology transfers and shifts their composition toward unaffiliated, arm's-length licensing. The mechanism is the same appropriability logic as in Bolatto et al., applied to licensing rather than sourcing: an independent licensee could imitate the know-how it receives, so weak protection pushes transfers inside firm boundaries. Because protection also determines whether the firm is willing to transfer at all, it moves the scale of transfers and not only their composition. The composition matters for economic development. Outsourcing and arm's-length licensing are the channels through which frontier knowledge most readily reaches independent firms in developing countries and so help determine where those countries sit in the value chain.

C. Spiders, Snakes, and Pharmaceutical Chains

Where do pharmaceuticals fall: are their stages complements or substitutes? The answer is not straightforward. Demand for many medicines is price-inelastic, which taken alone points toward sequential substitutes, but the industry's inputs are close to non-substitutable: an active ingredient cannot be exchanged for another in a given formulation, and regulatory approval ties a product to specified inputs and manufacturing sites, so substitution requires refiling rather than

¹¹ Niccolò Pisani and Joan Enric Ricart, "Offshoring Innovation to Emerging Countries: The Effects of IP Protection and Cultural Differences on Firms' Decision to Augment versus Exploit Home-Base-Knowledge," *Management International Review* 58 (2018): 871-909.

¹² Bohdan Kukharsky, "A Tale of Two Property Rights: Knowledge, Physical Assets, and Multinational Firm Boundaries," *Journal of International Economics* 122 (2020) 103262.

¹³ Olena Ivus, Walter Park, and Kamal Saggi, "Patent Protection and the Composition of Multinational Activity: Evidence from U.S. Multinational Firms," *Journal of International Business Studies* 48 (2017): 808-836.

reordering.¹⁴ Inputs are least substitutable for biologics (drugs produced in living cells) and most for small molecules, whose IP lies largely in the compound itself. If input substitutability is the binding consideration, pharmaceuticals fall, at the industry level, in the complements case.

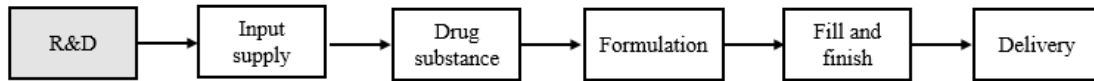
Yet the way firms organize production does not match that classification. Research and development (R&D) is typically performed in-house upstream, while manufacture of the active pharmaceutical ingredient and fill and finish (the filling and packaging of finished doses) are frequently outsourced or offshored to firms in emerging markets such as India, Brazil, and South Africa. Integration upstream and outsourcing downstream is the pattern the Antràs-Chor model predicts under sequential substitutes, not complements. The literature's own classification points the same way, since Antràs and Chor and Bolatto et al. both sort industries by demand elasticity, which would place a low-elasticity industry such as pharmaceuticals among the substitutes. The classification matters: if pharmaceuticals really were a substitutes chain, IP should barely affect how the chain is organized, which is difficult to reconcile with the industry's exceptional dependence on patents.

The difficulty lies in the shape assumed for the chain. The Antràs-Chor benchmark is a snake, a single line of stages.¹⁵ Pharmaceutical production is closer to a spider, in which a lead firm mixes organizational forms across modules that feed assembly in parallel. Figure 1 contrasts the two. Antràs and Chor sketch such a variant, but every module there is internally a snake with a common input substitutability, so a single comparison between the two elasticities still classifies the whole chain. Pharmaceutical modules are not alike in that respect: substitutability is near zero in biologics drug substance, where the process is the product, and considerably higher in small-molecule manufacture and fill and finish once a site is qualified. As panel B shows, a firm may integrate core R&D and the manufacture of biologics while contracting out early-stage discovery, clinical trials, and fill and finish. The make-or-buy decision is thus made task by task rather than once along a single chain, and the aggregate pattern need not match the prediction for any single classification.

¹⁴ Bown and Bollyky (2022), *supra* note 6.

¹⁵ Richard Baldwin and Anthony Venables, "Spiders and Snakes: Offshoring and Agglomeration in the Global Economy," *Journal of International Economics* 90, no. 2 (2013): 245-254.

(A) Snake: Stages in a single sequence



(B) Spider: Modules feeding assembly in parallel

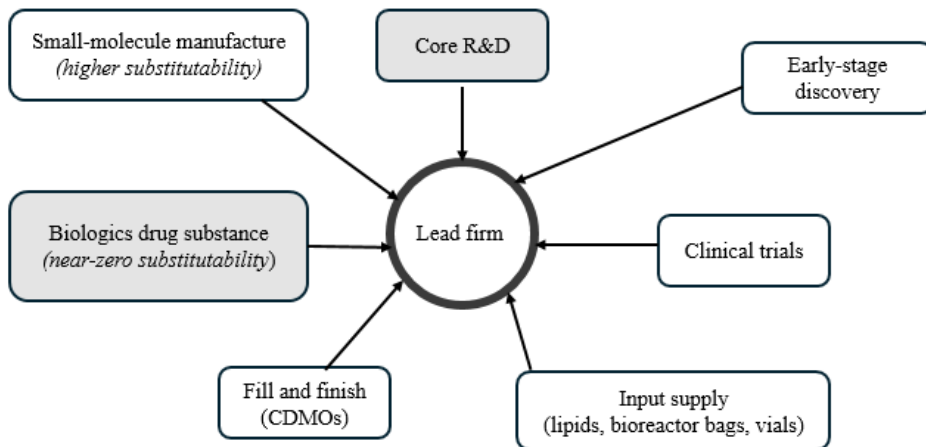


Figure 1. Snake and Spider Structures of a Pharmaceutical Value Chain

Notes: Shaded boxes are integrated, unshaded outsourced. Panel A follows Table 3; panel B disaggregates its stages, one configuration among several. *Source: Authors' illustration.*

The industry-level nature of the Antràs-Chor test generates the apparent puzzle here: the integrated and outsourced modules sit at different points in the economy's input-output structure, so the industry pattern can look like the substitutes case even when the modules are not. IP sensitivity also varies across modules, so a change in protection reaches only the tasks where rights matter, which is one reason why a waiver's reach is narrower than its advocates supposed.

The spider structure cuts both ways. Parallel suppliers offer redundancy that a single sequential line lacks, but they also multiply the relationships a lead firm must coordinate, and it was coordination rather than redundancy that proved scarce during the pandemic.

III. The TRIPS Waiver: Background

The World Health Organization (WHO) characterized COVID-19 as a pandemic on March 11, 2020. In October 2020, India and South Africa asked the TRIPS Council to waive core

provisions of the Agreement for products related to the prevention, containment, and treatment of COVID-19. The proposal was initially very broad, covering patents, trade secrets, industrial designs, and copyrights. On June 17, 2022, the Twelfth Ministerial Conference adopted a decision confined to patents, and to vaccines rather than diagnostics and therapeutics.¹⁶ The decision clarified the flexibilities already available under Article 31 and waived the requirement of Article 31(f) that production under a compulsory license be predominantly for the domestic market, thereby permitting export to eligible members. An eligible member need not require the proposed user to have sought authorization from the right holder first, a condition that Article 31(b) already allows members to waive in a national emergency. Remuneration under Article 31(h) remained due, though the determination of adequate remuneration could take account of the humanitarian and non-profit character of the distribution. Developing country members with capacity to manufacture COVID-19 vaccines were encouraged not to avail themselves of the waiver.

No member invoked the decision. By the time it was adopted, demand for vaccines had fallen and disease incidence had declined.

A. Arguments for the Waiver

Advocates of a patent or IP waiver present the following arguments.

1. This was a global emergency. The need for speed and scale meant that countries could not wait for generic/biosimilar entry.
2. IP is a barrier because of fees and other transaction costs, data exclusivity, and litigation risks.
3. Monopoly restricts output. On the standard account, a patent holder charges more and supplies less than a competitive market would.
4. Existing IP flexibilities, such as compulsory licensing and parallel importation, were inadequate.
5. A waiver confined to patents would not have sufficed, which is why the petitioners sought a comprehensive one. They anticipated that manufacturing know-how and trade secrecy protection would be a key barrier. On this view, only a comprehensive waiver would have allowed follow-on manufacturers to establish their own value chains.

¹⁶Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30, WT/L/1141.

6. The R&D was publicly funded, as was the academic work that contributed to it.
7. Public support and advance purchase agreements (APAs) had already borne firms' risk. The argument concerns not the level of return but its risk profile: when the state funds R&D at risk and commits to purchase before regulatory approval, it has absorbed the downside and has already paid the risk premium. Allowing the firm to price above average cost ex post compensates it a second time for a risk it did not bear.

Based on the last two points, advocates held that other, more powerful incentives for innovation existed.¹⁷

B. Arguments against the Waiver

First, while vaccines were based on decades of prior research and pre-existing IP, innovation was still ongoing. Important patents were issued before and during the pandemic. These could not be suspended or waived without chilling early-stage innovation, and a waiver could have disrupted ongoing projects, incentives, and investments. Public and academic research did contribute to vaccine development, but those results still had to be adapted for the market and scaled.

Second, a waiver would not have exempted entrants from regulatory oversight. Because vaccines are complex biologics, regulatory approval attaches to a specific manufacturer's process at a specific facility. Approval was not guaranteed.

Finally, a waiver did not address the challenges facing global vaccine supply chains. How far and how fast vaccines diffused had more to do with manufacturing capacity and input sourcing than with any hindrance from IP. Consider Figure 1 again. In a snake, a blockage at R&D halts everything downstream, so removing it unclogs the entire flow. In a spider, IP covers only some modules, and a waiver does nothing for the modules that constrained output: input supply and manufacturing capacity. Moreover, IP shapes how a GVC is organized: stronger protection makes lead firms willing to transmit know-how to arm's-length partners rather than internalize production, as discussed in Section II. Section V takes up those challenges.

¹⁷ See Joseph Stiglitz and Lori Wallach, "Preserving Intellectual Property Barriers to COVID-19 Vaccines is Morally Wrong and Foolish," *Washington Post*, April 26, 2021, Opinion; Richard Gold "What the COVID-19 Pandemic Revealed about Intellectual Property," *Nature Biotechnology*, Vol. 40, 2022, 1428-1430.

C. Innovation and Patenting during COVID-19

1. *The Patent Landscape before and during the Pandemic*

According to the Chemical Abstracts Service, over thirty years of research on mRNA preceded the pandemic. A slow upward trend of journal articles on mRNA, 571 in total, ran from 1965 to 2019, followed by significant growth in 2020 to 2024, with 7,933 publications related to mRNA vaccines. Patent publications went from 151 during 1971 to 2019 to 908 during 2020 to 2024.¹⁸

Montobbio et al. find that the patent landscape was dense in the field of COVID-related vaccines.¹⁹ Examining core patents and their backward citations for patent families on mRNA vaccine technologies published between January 2010 and April 2020, they collect 152 distinct families and find that innovation on the core technology was thriving three years before COVID-19. Among the assignees, universities accounted for 17.8 percent and government and public research organizations for 3.85 percent, while biotechnology companies accounted for 36.9 percent and pharmaceutical companies for 19.9 percent.

Data from the World Intellectual Property Organization for January 2020 to September 2022 are roughly consistent.²⁰ Over that period, 7,758 patents were filed on coronavirus-related matters in general, with 1,298 filings related to vaccine development and 4,787 on therapeutics. Vaccine-related filings peaked in April 2020 and patent publications on COVID vaccines peaked in October 2021. The filings covered several platforms: protein subunits, viral vectors, nucleic acids, and antigen-presenting cells.

2. *Litigation*

Between forty and fifty patent litigation cases involved the core companies as plaintiffs or defendants, including a dispute between BioNTech and CureVac in 2020.²¹ Most involved opposition and validity actions and were concentrated in the United States, Germany, and the

¹⁸Preeti Jain, “The future of mRNA vaccines beyond COVID-19,” *Chemical Abstracts Service*. (March 14, 2025) <https://www.cas.org/resources/cas-insights/future-mrna-vaccines>.

¹⁹Fabio Montobbio, Gabriele Pellegrino, and Valerio Sterzi, “Patent Landscape Analysis of mRNA COVID-19 Vaccine Technology,” in Walter Park (ed.) *Handbook of Innovation and Intellectual Property Rights*, (2024) op cit.

²⁰World Intellectual Property Organization, *COVID-19 Vaccines and Therapeutics* (Geneva: WIPO, 2023). <https://www.wipo.int/publications/en/details.jsp?id=4658>.

²¹Montobbio et al. (2024), *supra* note 19.

United Kingdom. They did not involve lower-middle-income or low-income countries in any way that interfered with technology transfer to them.

The infringement cases came only after the rollout. Moderna filed suit in the United States and Germany against Pfizer and BioNTech on August 26, 2022, over the chemical modification used in Spikevax,²² and sought damages rather than an injunction, which would have affected production, sales, and distribution. Moderna had earlier pledged not to enforce its mRNA patents until after the pandemic.

3. Implications for the Waiver

Waivers would have altered this trajectory, particularly for ongoing research projects and collaborations. These innovations came after Operation Warp Speed (OWS) and the Defense Production Act (DPA) and were not ready for commercialization. They were in the research stage; there was no way to speed this up. IP waivers could have had the unintended consequence of disrupting research through uncertain ownership rights and control. Large pharmaceutical firms collaborated with small biotechnology companies, which in turn worked with academic institutions and different manufacturers. Almost a quarter of patent applications had at least two assignees.

IV. Global Vaccine Distribution

A. Disease Burden by Income Group

Figure 2 shows monthly average daily excess deaths per 100,000 people by income group during 2020. Income groups follow World Bank classifications as of the start of the pandemic. Excess deaths are the difference between how many people died from all causes and how many would be expected to die based on historical trends; negative values indicate fewer deaths than normal.

The figure shows the timing of each group's epidemiological need, which we compare with the vaccination rollout. High-income excess mortality was negative through February, rose sharply to lead all groups in March and April, and fell back by May. This pattern is consistent with the virus initially spreading along international trade and travel networks, which disproportionately affected richer economies. From June the upper-middle-income group had the highest excess

²² Id.

mortality, peaking in July and again in November and December, when high-income mortality rose to a second peak. The lower-middle-income group also peaked in July, while the low-income series stayed comparatively flat throughout. Measurement error is a concern in lower-income countries; the elevated low-income readings in January and February, before the virus had established itself, illustrate the problem. Gill and Schellekens also note that the developing world is more populous, and so even low death rates translate into large absolute counts.²³

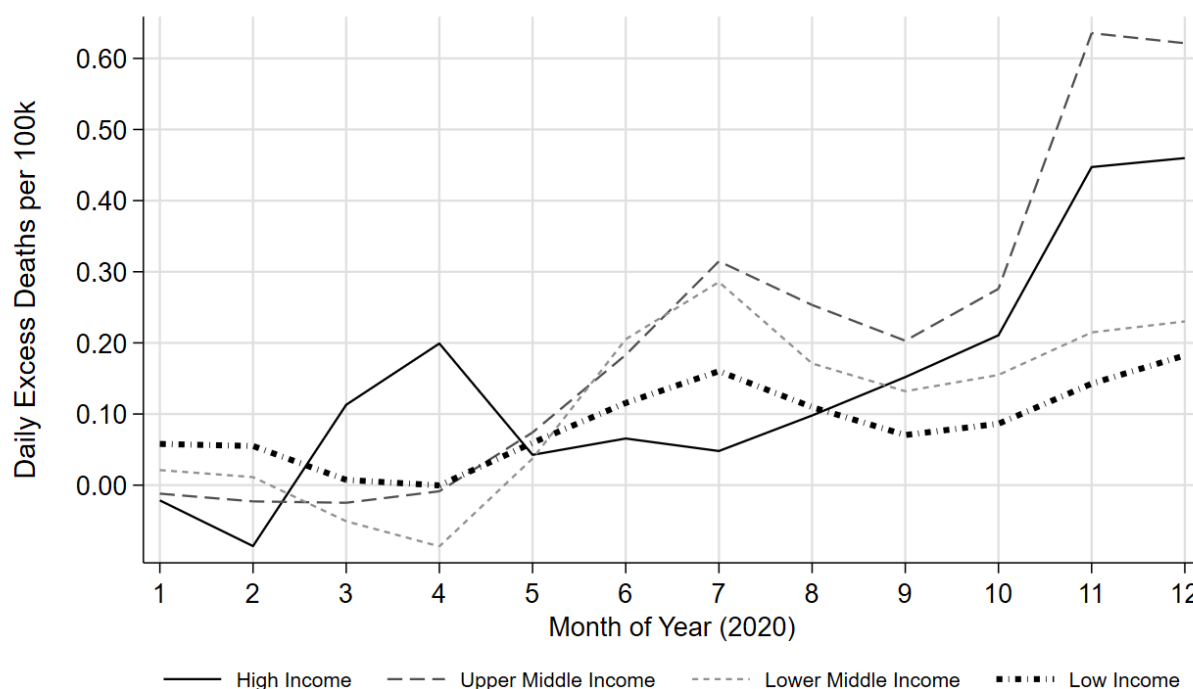


Figure 2. Average Daily Excess Deaths per 100,000 by Income Group, by Month, 2020

Source: Authors' calculations based on OWID (Our World in Data).²⁴

It made sense early on for vaccination to begin with the high-income and upper-middle-income groups. By mid-2021 the distribution of burden had inverted, and vaccination did not follow. Over 2021 the lower-middle-income share of daily mortality rose from 7 to 42 percent and the upper-middle-income share from 33 to 42 percent, while the high-income share fell from 59 to

²³Indermit Gill and Philip Schellekens, "COVID-19 is a Developing Country Pandemic," (2021)

<https://www.brookings.edu/articles/covid-19-is-a-developing-country-pandemic/>

²⁴Edouard Mathieu, Hannah Ritchie, Lucas Rod s-Guirao, Cameron Appel, Daniel Gavrilov, Charlie Giattino, Joe Hasell, Bobbie Macdonald, Saloni Dattani, Diana Beltekian, Esteban Ortiz-Ospina, and Max Roser, "Coronavirus Pandemic (COVID-19)," Our World in Data, 2020, accessed May 2026, <https://ourworldindata.org/coronavirus>.

15 percent.²⁵ For the pandemic’s first two years as a whole, middle-income countries accounted for 81 percent of an estimated 14.9 million excess deaths, against 15 percent for high-income countries.²⁶

The inversion is clear for the two middle-income groups, but not for the low-income group, whose measured share of mortality remained small throughout. The case for prioritizing this group is accordingly more ambiguous. Low-income populations are young, and COVID mortality rises with age, which would argue against prioritization. But vital registration is weak, and deaths may have gone uncounted, so the measured share is a lower bound. The argument for access here is one of caution under uncertainty.

B. Time to Vaccination Milestones

Table 1. Median Date of Reaching Vaccination Milestones, by Income Group				
Group	10%	25%	33%	50%
High Income	May 7, 2021 (73)	Jun 17, 2021 (73)	Jul 1, 2021 (73)	Aug 6, 2021 (69)
Upper Middle	Jul 15, 2021 (53)	Sept 4, 2021 (48)	Oct 1, 2021 (43)	Nov 25, 2021 (28)
Lower Middle	Sept 27, 2021 (47)	Nov 28, 2021 (41)	Jan 15, 2022 (37)	Jan 26, 2022 (23)
Low Income	Mar 6, 2022 (23)	Aug 28, 2022 (15)	Oct 30, 2022 (11)	Sept 4, 2022 (5)
Notes: Median dates within group, based on days since Jan 1, 2020. Number of countries is in parentheses. Source: Authors’ calculation based on OWID dataset.				

Table 1 reports median dates of reaching successive vaccination milestones, where full vaccination is two doses or one full dose. Groups reach each milestone in descending order of income. The low-income group reached 10 percent nearly ten months after the high-income group, and 50 percent more than a year after. The high-income group moved from 10 to 50 percent coverage in about three months, the middle-income groups in about four months, and the low-income group in six.

The table also contains an anomaly: for the low-income group, the 33 percent date falls after the 50 percent date, a reversal no single country could show. The explanation is attrition. Countries that never clear a threshold drop out, so each successive milestone is computed over a

²⁵Gill and Schellekens (2021), *supra* note 23.

²⁶World Health Organization, “14.9 Million Excess Deaths Associated with the COVID-19 Pandemic in 2020 and 2021,” news release, May 5, 2022. <https://www.who.int/news/item/05-05-2022-14.9-million-excess-deaths-were-associated-with-the-covid-19-pandemic-in-2020-and-2021>.

progressively more successful subset. The survival analysis that follows handles this censoring directly.

C. Survival Analysis

Figure 3 plots a Kaplan-Meier survival curve by income group, showing the proportion of countries still below the 50 percent full-vaccination threshold. The starting date is each country's pre-Omicron mortality peak, which we take as a measure of the urgency to vaccinate; the Omicron date chosen was November 26, 2021. A country leaves the sample once it reaches the threshold, so the curve declines as countries drop out.

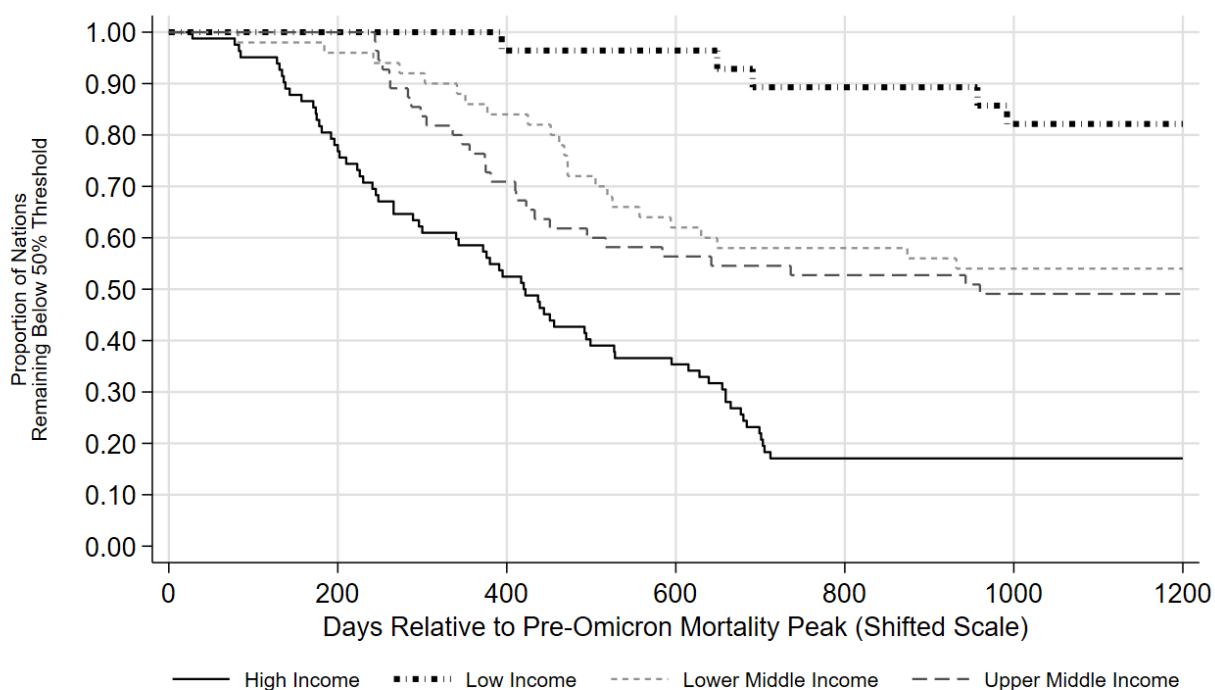


Figure 3. Kaplan-Meier Survival Curves to 50 Percent Full Vaccination, by Income Group.

Source: Authors' calculations.

The high-income curve declines fastest: about 700 days after the pre-Omicron peak, only 20 percent of countries remain below the 50 percent milestone. The gradient is monotonic from high income through upper-middle and lower-middle to low income. The low-income curve barely shifts down: even 1,000 days after the pre-Omicron peak, around 85 percent of countries in the group are still below this milestone.

D. Who Ever Reached the Milestones

Table 2 asks not when countries reached the milestones but whether they ever reached 33 percent and 50 percent full vaccination as of August 12, 2024, when the sample ends. The sample here is larger, since it includes countries that never met the 10 percent threshold.

Table 2. Share of Countries Reaching Vaccination Milestones, by Income Group			
<i>Group</i>	<i>Countries reaching 33% Vaccination</i>	<i>Countries reaching 50% Vaccination</i>	<i>Number of Countries (World population share)</i>
High Income	98.7%	93.2%	74 (16%)
Upper Middle	81.1%	52.8%	53 (37.3%)
Lower Middle	75.5%	46.9%	49 (38.6%)
Low Income	40.7%	18.5%	27 (8.1%)
Total			203
<i>Vaccine Chain</i>	<i>Countries reaching 33% Vaccination</i>	<i>Countries reaching 50% Vaccination</i>	<i>Number of Countries (World population share)</i>
Major Producers	100%	93.8%	16 (53%)
All Others	79.1%	58.8%	187 (47%)
Total			203
Notes: Vaccination achieved by August 12, 2024. World population (at that date) = 8.16 billion. Major producers are based on the WTO/IMF Covid-19 Vaccine Trade Tracker. Percentages are computed over countries reporting vaccination data. <i>Source:</i> Authors' calculations.			

The table adds information about a country's position in the value chain. All 16 major producers reached 33 percent and all but one reached 50 percent.²⁷ By contrast, about one in five low-income countries reached 50 percent during the sample period. Producing vaccines went with better coverage, though the advantage is hard to separate from income. South Africa, the only producer that never reached 50 percent, peaked at about 34 percent.

On a population-weighted basis, 5.3 billion people were fully vaccinated, roughly two-thirds of the world. Most of the unvaccinated people lived in upper- and lower-middle-income countries. Even if no one in the low-income group were fully vaccinated, this group would at most account for 23 percent of the world's unvaccinated population.²⁸

Together these data show that vaccine access tracked income and manufacturing status.

²⁷ Major producers are the EU nations (Belgium, France, Germany, Italy, Netherlands, Spain, Sweden), China, U.S., U.K., India, Korea, Japan, Russia, Brazil, and South Africa.

²⁸ The population of the low-income group is 0.66 billion; hence, $0.66/2.86$ is 23%, where $2.86=8.16-5.3$.

V. The Pharmaceutical GVC

A. Anatomy of the Chain

Table 3 presents the stages a biopharmaceutical supply chain typically contains. Chains vary in detail but not in structure.

Table 3. Stages of the COVID-19 Vaccine GVC		
Segment	Stage	Principal Activities
Upstream	1. R&D	Discovery, preclinical research, clinical trials.
Midstream	2. Input supply	Lipids, nucleotides, enzymes, plasmid DNA, materials for cell cultures, bioreactor bags, vials, stoppers, syringes.
	3. Drug substance	Production of bulk antigen or mRNA via cell culture or cell-free synthesis, followed by purification and capture.
	4. Formulation	Combining the active ingredient with inactive ones to create a final, usable form (e.g., lipid nanoparticle encapsulation for mRNA vaccines).
	5. Fill and finish	Filling into vials or syringes, labeling and final packaging.
Downstream	6. Delivery	Procurement and allocation (national contracts, COVAX), distribution and cold chain
Notes: Adapted from Bown and Bollyky (2022).		

Organizational mode can vary by task and by firm. In most GVCs there was a substantial mixture of outsourcing through CDMOs and CROs, arm's-length contracting, and in-house activity. Even integrated firms had affiliates and facilities in different cities within the United States and abroad, with different sites performing formulation, fill and finish, or distribution. The inputs, such as lipids, had their own supply chains.²⁹

Certain activities cut across the stages rather than occupying one of them. Regulatory review and approval, good manufacturing practice inspection, and batch lot release (under which a lot cannot be legally distributed until it passes quality control testing) can occur at any stage, and any of them can be rate limiting; that is, a drug cannot be scaled faster than the slowest node in its chain. A testing laboratory may be backlogged, or a firm establishing a facility may have to wait for a foreign regulatory authority to audit the site.

Similarly, some activities are planned ahead of downstream delivery, such as at-risk manufacturing or advance purchase commitments.³⁰ Input acquisition sits relatively upstream and

²⁹ Our terms upstream, midstream, and downstream refer to positions in the value chain. In the GVC literature, upstream refers to raw materials and downstream to final consumers. In pharmaceutical systems, R&D is upstream of bioprocessing. Within that bioprocessing, upstream refers to cell culture and fermentation, and downstream refers to purification and capture. Both bioprocessing steps fall within stage three.

³⁰ Government funding of vaccine projects before regulatory approval, with the loss borne if approval fails.

feeds several midstream stages: bioreactor bags are needed in stage three, lipids in stage four, and vials in stage five. Patents concentrate relatively early, in the R&D stage, while technology transfer cuts across stages. A patent waiver's reach is therefore narrow relative to where the binding constraints lay, namely at stages two and three, in input shortages and manufacturing capacity.

B. Lead Times to Build a Chain

Table 4 suggests the minimum time required to form a link in the supply chain for a COVID vaccine. These are lead times for experienced companies that already held the necessary rights; forming a chain from scratch would take longer. Lead times are anchored to the day of a major public announcement about a vaccine candidate, shown as Day 0.

Pfizer-BioNTech, for example, reached drug substance fifty days after its announcement, licensed lipid nanoparticle technology a couple of months later, and handled formulation and fill and finish in-house. For several other companies and link formations, it was not unusual for fill and finish to take up to a year, if not longer, from Day 0.

Table 4. Minimum Lead Times to Form Supply Chain Links, Selected Firms					
Producer	Day 0	Drug Substance	Input: License	Input: Production	Fill and Finish
Pfizer/BioNTech	Mar 16, 2020	May 5, 2020 (+50 days) (in-house)	Jul 1, 2020 (+107 days) (external)	Nov 10, 2020 (+239 days) (external)	May 5, 2020 (+50 days) (in-house)
Moderna	Jan 23, 2020	May 1, 2020 (+99 days) (external)	N/A	May 28, 2020 (+126 days) (external)	Jun 25, 2020 (+154 days) (external)
AstraZeneca/Oxford	Mar 18, 2020	May 28, 2020 (+71 days) (external)	N/A	N/A	Jun 15, 2020 (+89 days) (external)
Johnson & Johnson	Mar 30, 2020	Apr 1, 2020 (+ 2 days) (in-house)	N/A	N/A	Apr 29, 2020 (+30 days) (external)
Notes: Day 0 is the earliest dated, publicly announced milestone toward development of a vaccine candidate. Days in parentheses are calendar days that elapsed from Day 0. In-house indicates the company's own facility; external indicates a contracted manufacturing or input partner. Where multiple contracts or partnerships exist for a given link, the earliest documented date is used, so as not to overstate the time required to form a link. N/A indicates the link is not applicable, or no dated entry was available. Source: Bown and Bollyky (2022), Appendix.					

C. The Cost of Building a Chain from Scratch

Incumbents had advantages in forming a GVC. A new entrant drawn in by a waiver would have had to replicate one from scratch, which could have delayed distribution further. Forming a

GVC requires time for learning, for forming partnerships, and for establishing collaboration and knowledge sharing arrangements, all without a guarantee of regulatory approval and all subject to production disruptions such as contamination.

Two cost mechanisms should be distinguished. The first is internal. The relevant window, the two years when the pandemic was at its severest, is a *short run* by construction: supply chains could not easily switch between modes, and capital and facilities could not be expanded quickly, so firms were moving along a short-run average cost curve with capital largely fixed, encountering diminishing returns to variable factors. They were not choosing among plant sizes along a long-run average cost curve. The second mechanism is external and operates at the industry level. The input constraint was severe: delivery times of sixty-six weeks were reported for single-use bioreactor bags.³¹ Additional entrants bidding for the same lipids, filtration units, single-use bioreactor bags, CDMO slots, and bioprocess engineers would have raised input prices, shifting every firm's cost curves upward, an external diseconomy operating through input markets.

Vaccines are biologics, and a follow-on version is not a generic. There is no abbreviated approval pathway for vaccines analogous to that for small-molecule generics, and no established biosimilar route for them either. An entrant cannot rely on the originator's trial data; it needs its own clinical program, and marketing approval in each jurisdiction. That is why a waiver could not have expanded supply quickly. A waiver addresses the legal right to manufacture but not the physical and human capital required to do so, and in the short run might have worsened shortages rather than relieved them.

D. Financing and Organizing Development and Distribution

1. National Measures

COVID-19 vaccine development and production were incentivized mainly through at-risk manufacturing and advance purchase commitments.

In the United States, the government coordinated clinical trials and funding through OWS, using both push and pull instruments. On the push side, the federal government funded R&D and clinical trial phases for several firms, including early grants to Moderna for late-stage clinical

³¹Cited by a European manufacturer at a supply chain meeting. See <https://www.fiercepharma.com/manufacturing/serum-institute-homes-400m-grant-to-make-az-shot-as-supply-shortages-mount>.

development and contracts to Johnson & Johnson, and it invested in expanding commercial-scale manufacturing before approval. On the pull side, the government established large procurement contracts guaranteeing a commercial market, agreeing to purchase doses conditional on approval or emergency use authorization by the Food and Drug Administration. Governments also subsidized input suppliers for enzymes, lipids, and packaging components.

Since it was difficult *ex ante* to know which vaccines would prove effective and be approved, the government diversified across multiple vaccine types and projects.³² The U.K. and the European Union did much the same, making advance purchases to provide demand ahead of time.

The DPA gave COVID-related suppliers priority for production, so that critical inputs from outside the pharmaceutical sector could be diverted to plants producing vaccines. The same instrument that accelerated domestic output restricted the export of inputs that licensed manufacturers abroad depended on.

2. International Measures

Globally, COVAX, the COVID-19 Vaccines Global Access facility, began in April 2020 and launched in June, organized jointly by the WHO, Gavi the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI).³³ It coordinated funding, procurement, and distribution of COVID tests, vaccines, and treatments. The key delivery partner was the United Nations Children’s Fund (UNICEF), which had extensive procurement and logistics experience and began distributing vaccines in February 2021. By mid-August 2021 distribution had fallen short, owing to shortages and to vaccine nationalism, including India’s export restrictions, which held back doses the Serum Institute of India (SII) was licensed to manufacture for COVAX.

Supplementing the GVC were the Medicines Patent Pool (MPP) and open pledges, together with mechanisms such as forbearance, under which companies refrained from enforcement during the pandemic. Voluntary licensing was widespread, with over 140 licensing partnerships and bilateral transfers.³⁴

³² Michael King, “How Manufacturing won or lost the COVID-19 Vaccine Race,” *Vaccine* 42 (2024), 1004-1012. Only five out of 32 vaccines authorized by the WHO or a national agency had a significant impact on reducing mortality.

³³ World Health Organization, “COVAX,” <https://www.who.int/initiatives/act-accelerator/covax>.

³⁴ Pharmaceutical Research and Manufacturers of America, “Partnerships Are Driving Global COVID-19 Treatment Access,” <https://phrma.org/blog/partnerships-are-driving-global-covid-19-treatment-access>.

E. Where Bottlenecks Occurred

The most instructive cases are those in which IP was not the constraint. Novavax and AstraZeneca licensed voluntarily to SII and Biological E, yet production did not expand accordingly. SII took seven months to prepare for distribution and then faced shortages of lipids, bioreactor bags, and trained engineers. It received funding from organizations such as CEPI and committed doses to COVAX. Biological E had likewise contracted with Johnson & Johnson to do manufacturing.

Several explanations were offered for the shortfall, all contested at the time. SII's executives described difficulty obtaining U.S.-origin filtration units, single-use bags, and other consumables. Customs records, however, show that SII's imports of such U.S. inputs rose by 28.3 percent between April-September 2020 and October 2020-March 2021, and Biological E's by 221.9 percent, which rebuts claims of export restrictions, though exports might still have been insufficient relative to need.³⁵ Capital was also a constraint. SII sought and received roughly thirty billion rupees in Indian government support in April 2021 to raise monthly output from about seventy million to over one hundred million doses.³⁶ In any case, commitments had run ahead of installed capacity, and AstraZeneca served SII a legal notice for failing to meet delivery obligations.³⁷ In spring 2021, dealing with a severe domestic wave, the Government of India restricted vaccine exports to prioritize domestic demand. COVAX then informed participants about the delivery shortfalls due to the Indian situation.³⁸ Emergent BioSolutions, also in AstraZeneca's chain and a licensee of Johnson & Johnson, separately suffered contamination at its Maryland facility.³⁹

³⁵ Chad P. Bown and Chris Rogers (2021), "The US Did Not Ban Exports of Vaccine Supplies. But More Help Is Needed," *PIIE Trade and Investment Policy Watch*.

³⁶ Aftab Ahmed, "India to fund capacity boost at Serum Institute, Bharat Biotech as vaccines run short," Reuters (April 19, 2021). <https://www.reuters.com/world/india/india-fund-capacity-boost-serum-institute-vaccines-run-short-source-2021-04-19/>

³⁷ Rupali Mukherjee, "Covid-19: AstraZeneca sends legal notice to SII over delays in vaccine supply," *Times of India* (April 8, 2021). <https://timesofindia.indiatimes.com/india/astrazeneca-sends-legal-notice-to-sii-over-delays-in-vaccine-supply/articleshow/81960902.cms>

³⁸ UNICEF, "COVAX updates participants on delivery delays for vaccines from Serum Institute of India and AstraZeneca," (March 25, 2021). <https://www.unicef.org/press-releases/covax-updates-participants-delivery-delays-vaccines-serum-institute-india-sii-and>.

³⁹ Lucien Bruggeman and Sasha Pezenik, "Emergent BioSolutions discarded ingredients for 400 million COVID-19 vaccines, probe finds," *ABCNews* (May 10, 2022). <https://abcnews.com/US/emergent-biosolutions-discarded-ingredients-400-million-covid-19/story?id=84604285>

South Africa is the sharper case. Aspen Pharmacare had been formulating and filling Johnson & Johnson's vaccine at Gqeberha since November 2020, and in March 2022 was licensed to sell it across Africa under its own brand. It never sold a single dose and closed the line for want of orders.⁴⁰ The country had already asked Pfizer and Johnson & Johnson to defer deliveries in late 2021, while holding 16.8 million unused doses.⁴¹ Here the constraint was neither rights nor inputs but demand and procurement.

What unites these cases is that the operative constraints were consumables, capital, demand, domestic politics, or commitments made ahead of capacity. None of these was access to patented technology. The world's largest vaccine manufacturer was constrained upstream and Africa's first licensed producer downstream.

By mid-2022 a global surplus of vaccines had emerged, though not in low-income countries.⁴² The surplus arose from a decline in demand, driven by acquired immunity and high coverage in upper-middle-income and high-income countries, rather than from an increase in manufacturing capacity alone. A surplus coexisting with persistent low-income shortfalls is consistent with distribution and supply chain bottlenecks rather than IP as the binding constraint.

VI. Assessing the Role of IP

A. Did Firms Need IP Protection?

If the government funded clinical trials, supported R&D, and provided advance purchase orders, did firms need IP protection? The government provided at-risk investment and procurement contracts, so firms must have recouped their R&D costs sufficiently. According to Brink Lindsey: "... the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver."⁴³ What is the case for giving firms IP rights, particularly patent rights?

⁴⁰ Kerry Cullinan, "Important Lessons From the African Vaccine Manufacturer That Could Not Sell a Single Dose," *Health Policy Watch* (November 5, 2023). <https://healthpolicy-watch.news/important-lessons-from-the-african-vaccine-producer-that-never-sold-a-single-dose/>

⁴¹ Promit Mukherjee, "South Africa delays COVID vaccine deliveries as inoculations slow," *Euronews* (November 25, 2021). <https://www.euronews.com/2021/11/25/us-health-coronavirus-safrica-vaccine>

⁴² Nguyen Quan, Nguyen Anh, and Andrew Taylor-Robinson, "The Global COVID-19 Vaccine Surplus," *Infectious Diseases of Poverty* (2023), 12:21.

⁴³ Brink Lindsey, "Why intellectual property and pandemics don't mix," *Brookings* (June 3, 2021). <https://www.brookings.edu/articles/why-intellectual-property-and-pandemics-dont-mix/>.

Of course, not all firms received direct R&D subsidies. Moderna, Johnson & Johnson, and Novavax did. Pfizer did not accept government R&D funding, though it did obtain APAs. Its partner, BioNTech, received a German government grant, but no U.S. government funding.⁴⁴

B. Why IP Still Mattered

First, public funding of discovery does not eliminate the need for appropriability at the development stage. This is the problem the Bayh-Dole Act was enacted to solve. Before 1980, inventions arising from federally funded research were largely retained by the government and were rarely licensed, because no private party would ordinarily fund the much larger downstream cost of development, trials, and manufacturing without exclusive title. Permitting contractors to retain title was a remedy. A subsidy that de-risks discovery still leaves a gap in second-stage investment. During COVID-19, firms still had to execute an unprecedented global manufacturing effort, and exclusivity helps induce them to reorganize their operations to do so. Companies had to risk billions in capital expenditure to pre-build manufacturing facilities and run Phase 3 trials before drugs were proven safe.

Second, mRNA was the platform IP of several private firms. Removing or limiting IP rights because of a signed government purchase order would mean appropriating decades of privately funded platform technology. The threat of losing foundational IP could have deterred companies from entering partnerships with governments.

Third, secure IP assures firms that underlying investments will not be expropriated, which gives them an incentive to share trade secrets through authorized channels. During the pandemic, secure rights enabled inventors to enter voluntary partnerships with arm's-length manufacturers.⁴⁵ In negotiating such partnerships, companies must disclose information about their research. But “sharing information to demonstrate its value paradoxically destroys its value.”⁴⁶ While a patent right can, upon expiry of a waiver, resume excluding others from commercial exploitation, a trade secret, once disclosed, cannot be recalled like a library book. The consequence, as Ivus, Park, and

⁴⁴ “BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162,” BioNTech (September 15, 2020). <https://www.biontech.com/int/en/home/mediaroom/news/press-releases/2020/09/biontech-receive-eu375m-funding-german-federal-ministry.html>.

⁴⁵Mark Schultz, “Trade Secrecy, Knowledge Sharing, and Cooperation: the Case of Developing and Manufacturing COVID-19 Treatments,” in Walter Park (eds.), (2024), op cit.

⁴⁶ Id.

Saggi show,⁴⁷ is that under weakened IP firms shift toward in-house production, which in a pandemic concentrates capacity in the originator's own locations rather than distributing it across qualified facilities.

Fourth, dynamic incentives must be preserved. While an international emergency requires immediate actions, those actions should not jeopardize the ability to deal with future emergencies. Investments in vaccines for pathogen outbreaks are like a lottery: the probability of a pandemic is low and the payoff to the investment is concentrated in the event of a pandemic. A waiver invoked when demand for vaccines is greatest reduces expected payoffs in states of the world when the returns accrue. This is a time-inconsistency problem. Society promises a large reward to induce investments in preparedness. After the fact, society can require that medicines be priced at marginal cost, denying firms their economic profits *ex post*. In anticipation, there may be underinvestment in preparedness. The remedy against renegeing is a commitment device, such as *ex-ante* contracting, which negotiates terms and commits to rewards in advance.

C. Advance Purchase Agreement Fallacy

APAs are pull mechanisms: they pay on successful delivery, and if the product fails, they pay nothing. The argument that APAs render IP unnecessary conflates guaranteed buyers with market exclusivity. An APA de-risks demand by providing a procurement contract contingent on regulatory approval, but it does not confer a legal monopoly. Without IP, entrants could reverse-engineer the product and sell it to other governments.

APAs also demand large volumes that originators may not be able to satisfy alone. Originators must partner with contract manufacturers, and those with secure IP are more willing to share sensitive trade secrets and tacit know-how, since otherwise a partner could defect and become a direct competitor.

Finally, APAs are national or regional. They do not protect against follow-on manufacturers elsewhere and so confer no market control there. Global IP helps manage a complex value chain and prevents unauthorized grey market sales and exports from one jurisdiction into another that would undermine supply chains elsewhere. Whether APAs should have been global is a question Section VI.D takes up.

⁴⁷ Ivus, Park, and Saggi, *supra* note 13.

D. Where the Shortfalls Lay

The analysis suggests that ex-post waivers are a blunt, reactive instrument for supply chain bottlenecks in complex biopharmaceutical manufacturing. Stripping patent rights retroactively does not solve the actual barrier, the transfer of tacit manufacturing know-how. A waiver can withdraw legal protection over undisclosed information, but it cannot compel disclosure. As an illustration, consider Moderna's pledge not to enforce its COVID-19 patents against manufacturers supplying low- and middle-income countries. This amounted to a de facto patent waiver, though it did not extend to manufacturing know-how, which Moderna declined to share. Yet the WHO mRNA hub at Afrigen in South Africa replicated the vaccine from published sources, but very slowly. It was still scaling up its candidate nearly two years after the project's launch in June 2021.⁴⁸ Nor would disclosure by itself have been sufficient. Transferring tacit knowledge often requires site visits by personnel from the originator and sustained technical assistance, forms of cooperation more reliably secured through voluntary partnership.

Instead of suspending rights after a crisis, the more efficient framework is ex-ante contract design. When governments act as venture capitalists by funding at-risk R&D, they can negotiate explicit conditions for global access up front, including tiered pricing for low-income countries and targets for voluntary licensing, committing firms to equitable supply chain behavior as a condition of public support.

The systemic failure was not the IP system. It was a failure of international coordination and of advance contract design. Many countries defaulted to vaccine nationalism and wealthy nations stockpiled doses, imposing a substantial negative externality on the rest of the world.

Low vaccine coverage left large, unprotected host populations in which new variants could emerge. Variants then travelled back to high-income countries along the same trade and tourism linkages, producing further waves of illness and excess mortality. Equitable vaccination is therefore a matter not only of equity but of effectiveness.

⁴⁸ World Health Organization, "mRNA Technology Transfer Programme moves to the next phase of its development," (April 20, 2023). <https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development>

VII. Future Preparedness

A. Pandemic Agreement

The WHO Pandemic Agreement is an improvement over a waiver-type mechanism because it addresses the core problems: equitable allocation and distribution, knowledge and material sharing, production capacity, and supply chain resilience.⁴⁹ It reaffirms TRIPS flexibilities without creating new IP obligations and does not call for special waivers or suspensions. Its Pathogen Access and Benefit Sharing system provides that, in exchange for pathogen and sequence sharing, participating manufacturers make available 20 percent of real-time production during a pandemic, half as donations and half at affordable prices; other provisions address capacity building, stockpiling, and financing. Against that framework, five priorities follow from the analysis above.

1. Geographically diversified manufacturing capacity. Production is heavily concentrated. There are few manufacturers or exporters in Sub-Saharan Africa, Latin America, or Southeast Asia, aside from cases such as Brazil's Fiocruz or the Africa Centres for Disease Control mRNA technology transfer hub established in South Africa in 2021. Building capacity requires sustained pre-pandemic investment in quality systems, workforce and bioprocess engineering training, and cold chain infrastructure. Diversification does not, however, imply resilience: plants in low- and lower-middle-income countries will not improve access if they remain dependent on imported inputs. Nor does capacity guarantee a market: Aspen's plant closed for want of orders, not for want of capacity. Sustained value chain capacity, connected to international networks, is the objective.
2. Upstream input capacity. Preparedness must extend to suppliers of filtration units, bioreactor bags, and lipids, including at-risk public investment in inputs. The difficulty is that the inputs required to implement an invention are not fully known until the invention occurs. This affects how much to stockpile, given that future vaccines may run on a different platform and that stockpiled inputs can be stranded by a change of technology.
3. Ex-ante contract design. Advance market commitments should carry explicit technology transfer conditions: a non-exclusive license to at least one manufacturer in a lower-middle-

⁴⁹WHO Pandemic Agreement, adopted by the Seventy-Eighth World Health Assembly, Res. WHA78.1 (May 2025). Article 13 calls for establishing a *Global Supply Chain and Logistics Network*.

income country, or to a designated exporter serving low-income countries. Bayh-Dole is the model here, which grants exclusivity to induce commercialization while holding a public-interest lever in the form of march-in rights.

4. Pre-negotiated patent pools. Arrangements such as the MPP should be negotiated before a pandemic rather than during one, when originators hold the stronger bargaining position. Manufacturing structure, advance purchase terms, liability rules, and technology transfer agreements are all better settled in non-crisis periods.
5. A globally coordinated Operation Warp Speed. At-risk investment before authorization worked, and it worked nationally. The focus was on speed and scale. Future agreements should include access as a condition and should attend to delivery and vaccination infrastructure (at the healthcare provider and patient level) and not only to the availability of doses.

The Agreement's main limitation is that it is aspirational, and its central institutions do not yet exist. The supply chain and logistics network is deferred to a future conference of the parties, the financing provisions are not specific as to terms or process, and the benefit-sharing annex remains under negotiation. Commitments are largely voluntary, and the phrase "as mutually agreed" recurs throughout. That is a practical approach given the limits of international treaty law, and voluntary participation incentivizes joining. But it leaves the treaty's impact uncertain until the next pandemic.

B. Lessons

Two-thirds of the world was fully vaccinated by mid-2024, yet significant shortcomings remained. Vaccine development and production met the criteria of speed and scale but not of access. The problem was distribution rather than supply together with the lack of manufacturing capacity that left the Global South reliant on imports and donations. What made access difficult was not the multiplicity of IP rights covering COVID vaccines but organizing and coordinating an international supply chain. Not all production chains operate smoothly. Allowances must be made for failures in clinical trials and regulatory approval, contamination of supplies, and production disturbances. Building a GVC and forming reliable partnerships take time.

A patent waiver, or even the comprehensive waiver, would not have removed the global supply chain constraints on access. Take know-how for example. A comprehensive waiver

removes only legal barriers. If an entrant already possesses the originator's know-how (through employee departures or leaks), WTO members are not obliged to protect it under TRIPS Article 39. But the waiver itself does not compel originators to hand over anything, such as cell culture protocols or manufacturing recipes. In contrast, under voluntary licensing, the originator would share the know-how and provide the necessary training and technical assistance.

Could voluntary licensing have been more inclusive and widespread? That depends on the coordination costs of a spider GVC. The lead firm in a biologic value chain may have limited managerial bandwidth to enter into a large number of parallel licensing agreements without increased costs of monitoring and quality control. Thus, while Afrigen, which independently replicated an mRNA vaccine from published sources, might have entered production sooner had it received a voluntary license from an originator, it would have confronted the supply constraints that beset other producers. SII, for example, received voluntary licenses yet faced input and capital constraints.

At the extensive margin, a waiver potentially brings in additional suppliers – but only holding incumbent behavior constant. Originators may form fewer new partnerships or share less know-how with existing arm's length parties, given that the know-how would lose secrecy protection and that more competitors could be created post-COVID. The originators may also pull back on R&D and platform investments.

In hindsight, a global vaccine chain could have been better organized and coordinated under improved contract structures. This is the spirit of the Pandemic agreement, namely revising ex-ante contract design and developing geographically diversified manufacturing capacity. Governments funding at-risk R&D should include technology transfer conditions, such as sharing know-how, along with strengthened protection for what is shared. These are all best addressed before a pandemic rather than during one.

VIII. Concluding Thoughts

The chapter has examined global value chains in which production is sequential, each firm receiving an input and contributing output to the next stage. Such chains may exhibit sequential complements or sequential substitutes, and the effect of IP protection on how they are organized depends on which case applies. Stronger IP may enable more outsourcing and arm's-length

contracting, and with them partnership building and voluntary licensing. Knowledge transfers and spillovers through these channels can promote economic development and capacity building. Pharmaceutical chains, however, are less a single line than a set of parallel relationships that a lead firm must coordinate, and it was coordination rather than legal access that proved challenging during the pandemic. Among the lessons of COVID-19 is the need for improved technology transfer, knowledge sharing, and manufacturing capacity in the Global South.

The speed and scale of vaccine development and production were extraordinary by historical standards, but access fell short, particularly for lower-income economies. Lacking manufacturing capacity, all but a handful of countries relied chiefly on imports. R&D, production, and distribution need to become more diversified globally. In any future emergency, firms and governments will be operating under short-run constraints. Platforms for developing the next biopharmaceuticals must therefore be in place beforehand, along with financial mechanisms and the necessary materials and inputs, whether through local or global stockpiles or shared facilities.

Future research could examine how waiver threats influence firm behavior. Two opposing effects are possible: the threat of a waiver could induce voluntary licensing to pre-empt a relaxation of rights, while expectations of weakened protection could push technology transfer inside firm boundaries, reducing arm's-length licensing. Which effect dominated during COVID-19 remains an open question.