



## POLICY BRIEF

### **Third-Way Proposals from Big Pharma and the WTO are the Same-Old Way – Commercial Control of Supply, Price, and Distribution**

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Page | 1

#### **Summary**

A growing chorus of voices worldwide is demanding the lifting of intellectual property restrictions on Covid-19 vaccines and technologies and open technology transfer to enable global access. In response the pharmaceutical industry, the WTO and other actors like the Gates Foundation are promoting a 'third way' where industry retains total control of supply, price and distribution of Covid-19 vaccines and other health technologies. This is in fact nothing new and is a continuation of the same failed system. This paper gives a clear critique of this proposed solution, and the urgent need to take back control over vaccine production and distribution. It outlines the arguments instead for government-led, open technology transfer and equitable access.

#### **Introduction: A choice between industry-controlled, inequitable access to COVID-19 vaccines and open technology transfer and equitable access**

The world stands at yet another cross-road in the effort to increase supply, moderate price, and equitably distribute COVID-19 medical technologies across the globe. The current practice is one of industry control, resulting in limited manufacturing capacity, even when it is co-financed by governments. Industry control also results in needlessly high prices and preferential advance purchase agreements disproportionately directing initial supplies to rich countries.

An alternative approach proposed by health activists, low- and middle-income countries, WHO, Unitaid, UNAIDS, and others emphasizes open technology transfer of critical COVID-19 health technologies, most especially vaccines, but also including diagnostics, medicines, personal protective equipment (PPE), medical devices and e-health technologies. This open, public health approach, represented by the [WHO COVID-19 Technology Access Pool \(C-TAP\)](#), focused initially on encouraging voluntary transfer of patent rights, knowledge, and data to the pool. C-TAP would allow open-science innovation, broader supply, and equitable distribution from additional qualified manufacturers.



After no biopharmaceutical company joined C-TAP or its associated [Medicines Patent Pool](#), India and South Africa launched a [proposal](#) to the World Trade Organization (WTO) to waive intellectual property (IP) protections under the [Agreement of Trade Related Aspects of Intellectual Property Rights](#) (TRIPS) relating to health technologies that would prevent, contain, or treat COVID-19 until global herd immunity is achieved. COVID-19 relevant IP includes patent, trade secret, copyright, and industrial design rights.

Page | 2

Recently, in response to public outcry over vaccine nationalism and the support of over a hundred countries for the TRIPS waiver proposal, Big Pharma has launched a broad-spectrum campaign to continue its IP-based, hegemonic control over manufacturing supplies, price, and distribution. Pharma co-convened a [Vaccine Manufacturing and Supply Chain Summit](#) seeking additional government support to address upstream supply bottleneck and promised to explore additional contract manufacturing agreements. Unfortunately, the [Director General of the WTO](#) and [several governments](#) have indicated support for these so-called *third-way* proposals. In reality, the *third way* is really just the same old-way, repackaged and burnished with unrealistic promises about the billions of doses to be manufactured. The *third way* will not overcome artificially constricted production capacity, excessive pricing, and grossly inequitable distribution that plague the COVID-19 response. The *third way* is a side-show that might, at best, modestly increase vaccine supplies in the short term. But it will fail to deliver the regionally distributed biopharmaceutical manufacturing capacity needed in LMICs to respond not only to COVID-19, but to future pandemics and other pressing health needs in the Global South.

### ***Historic Forms of Industry Control over Supply of IP-Protected Biopharmaceuticals***

Historically, vertically integrated biopharmaceutical companies tightly controlled their intellectual property and maintained strict control over manufacturing, price, and distribution. If they needed more capacity, they built it or bought it, but only if it would be highly and sustainably profitable. However, as industry became more dependent on start-ups for medical innovations, which they would buyout or partner with, and as they became more dependent on [contract research organizations](#) to conduct their clinical trials, they also became more willing to outsource manufacturing to [contract manufacturing organizations](#). These agreements freed them from the expense and risk of capital investment and allowed them to take advantage of both highly specialized firms and firms with lower-cost structure. Agreements with contract manufacturers can require some degree of technology access, especially for complex biopharmaceutical products. Accordingly, although companies give limited access to technical knowledge and resources sufficient to enable their expanded supply goals, they maintain tight control over the terms and conditions of such technology access.

In addition to entering into contract manufacturing agreements, biopharmaceutical companies also enter into distribution- and/or manufacturing-and-distribution agreements.



Companies often enter into distribution-agreements to take advantage of the superior marketing and supply-chain systems of other companies. They might also enter into manufacturing-and-distribution agreements that grant the other company the right to sell in particular markets, generally ones that are either less attractive to the rightholder or where the distributor's superior marketing and supply systems reach more customers and produce greater profits.

The critical aspect of these contract-manufacturing, distribution, and hybrid agreements is that the rightholder company maintains stringent control over its IPRs and over the medical product itself. Typically, the medical product is sold under the originator's brand name, however, in some cases the contract manufacturer/distributor sells under a different brand name. Even so, the rightholder can specify the source of active pharmaceutical ingredients, quantity produced, where distribution rights are granted if any, and prices that can be charged. Because of their claims to underlying IP, the rightholder can also ordinarily claim the major portion of profits.

### ***COVID-19-Era Industry Control***

COVID-19 has seen many traditional forms of vaccine rightholder control over supply and distribution, but with new twists. The first new twist is that governments, most especially the U.S. but also countries in Europe and elsewhere, have invested significantly in vaccine development and production. The U.S., for example, invested over [\\$17 billion in vaccine platform technologies before 2020](#) and another [\\$21.774 billion](#) to COVID-19 vaccine developers, contract manufacturers, and pipeline suppliers for R&D, clinical trials, expanded manufacturing capacity, upstream components, and early and preferential advance purchase agreements. (An estimated [\\$100 billion](#) has been invested by governments worldwide in COVID-19 vaccine development.) The U.S. paid [\\$5.75 billion](#) for initial orders and 100% of Moderna's costs in developing, testing, and first producing its mRNA vaccine. Similarly, it is estimated that more than [97% of the development](#) of the Oxford/ AstraZeneca vaccine was financed by the UK government and charitable funders. More recently the U.S. government has invested [\\$268.8 million](#) to help Merck repurpose some of its spare capacity to produce the Johnson & Johnson vaccine. Although industry relied substantially on these public investments, some companies also invested in new capacity themselves either by buying existing production facilities and repurposing them or by making greenfield investments in new facilities. Moderna, for example, because it had no preexisting manufacturing capacity, has entered into [manufacturing agreements](#) with Lonza, Baxter BioPharma Solutions, Catalent, and Recipharm to supplement the manufacturing capacity of its own newly acquired [former-Polaroid plant in Massachusetts](#). Even in this case, however, Moderna has appeared to [rely to some extent on U.S. funding](#).



Some smaller companies, especially vaccine start-ups with little or no manufacturing capacity, have partnered with Big Pharma firms to take advantage of their manufacturing and distribution systems. Thus, [Oxford University partnered with AstraZeneca](#) and [BioNTech partnered with Pfizer](#). In addition, and to an unusual degree, COVID-19 manufacturers have also partnered with other Big Pharma companies to increase manufacturing supplies. Johnson & Johnson's agreement with Merck is a prime example, but there are many others where major companies, within the Pharma cartel, are "co-producing" on an unprecedented scale. For example, [Novartis is partnering with both Pfizer and CureVac](#) to produce mRNA vaccines.

Finally, biopharmaceutical companies are reportedly entering into quite standard contract-manufacturing and contract-manufacturing-and-distribution agreements, though exact terms are usually kept hidden. Thus, for example, [Oxford/AstraZeneca has entered into a major contract-and-distribution agreement with Serum Institute of India](#) (SII) whereby SII will produce the Oxford/AstraZeneca vaccine, but also have rights to distribute it in designated low- and lower-middle income countries. AstraZeneca sells the Oxford/AstraZeneca vaccine under the brand name Vaxzevria® where as its manufacturing partner SII sells under the brand name Covishield®. The SII contract, even though not fully transparent shows how AstraZeneca maintains rigorous control. Pursuant to the contract, AstraZeneca can direct SII to provide supplies outside SII's contract territory to AstraZeneca's customers when its faces shortfalls, as it did ordering millions of SII's doses to the UK and Canada. It also committed to use its [global supply chain](#) to make up shortfalls for the EU. Further, AstraZeneca gave SII permission to charge differential prices to different customers, which has paradoxically resulted in some Africa countries paying higher prices than does the EU for AstraZeneca's vaccine. SII has another tightly controlled supply contract with Novavax, which initially relied solely on active vaccine ingredient supplies from Novavax, but which has [since been amended](#) to allow Serum to manufacture.

Rightholders have sometimes entered into contract manufacturing agreements that allow other companies to manufacture the vaccine's active ingredient, their most proprietary resource, but more frequently they negotiate agreements to [formulate, fill, and finish](#). The [formulation stage](#) is a little more complex for injectable vaccines as it involves mixing the active vaccine antigen with preservatives, stabilizers, surfactants, residuals, diluents, and sometimes adjuvants. [The fill and finish stage](#) is often simpler, but still requires proper filtration systems and stringent sterility as vials are filled, labeled, and packaged. As an example, [Aspen Pharmacare of South Africa has a formulate, fill, and finish agreement with Johnson & Johnson](#) for its viral vector vaccine. Some of these agreements, of which there have been dozens, have involved access to confidential technology, but with strict controls on the use thereon. Generally speaking, there is more [complex technology](#) access required for active ingredient (antigen) manufacturing and formulation, but much less for fill and finish. Fill and finish capacity and its supply components, e.g., special glass vials, is described as a



discrete bottleneck at this time because so much COVID-19 vaccine has to be produced to meet global need.

This is the system we have now, one of tight industry control over manufacturing supply, price, and distribution. This is the system which has produced grossly insufficient quantities – less than one billion doses after months of production. This is the system that has produced inflated prices with only [Oxford/AstraZeneca](#) and [Johnson & Johnson](#) promising short-term no-profit or cost-plus pricing (with [Pfizer](#) promising a limited quantity to COVAX for an undisclosed no-profit price). In contrast, companies like [Moderna](#) are charging as much as \$37/dose. [Pfizer's](#) announced price was \$19.50/dose but it has more recently discussed raising prices eventually to as much as \$150-175. And this is the system that has resulted in [rich countries reserving between 50-70% of initial supplies of vaccines](#) for only 14% of the world's population. [WHO reports](#) that these same rich countries have vaccinated hundreds of millions with reserved doses, while some LMICs have not even begun to vaccinate even their most vulnerable health care workers.

Page | 5

The [COVAX Facility](#), established within the Vaccine Pillar of the [Access to COVID-19 Tools Accelerator](#) (ACT-A) with the stated intention of increasing equitable access to vaccines to LMICs, is woefully under-resourced and unambitious with an initial goal of supplying only 3% and then up to 20% of need in low-income and lower-middle-income countries. COVAX is also highly dependent of vaccine supplies from SII, which is now confronting export controls in India that curtail [SII's ability to supply COVAX eligible countries](#). Of course, [export controls in the U.S.](#) and [Europe](#) are also threatening vaccine component supply chains and export of finished vaccines.

### ***Proposals to Overcome IP Barriers, Broaden Supply, and Ensure Equitable Access***

As briefly described above, almost as soon as the pandemic hit, activists, researchers, and certain pharmaceutical experts recognized that no vaccine manufacturers individually or collectively would expand production capacity sufficiently to vaccinate the world quickly and that rich countries would race to the front of the line to garner preferential access to initial supplies. Accordingly, [Costa Rica](#) and a broad civil society coalition advocated for the establishment of C-TAP, which was created by the World Health Organization with the support of 40 countries. [C-TAP](#) was established to aggregate knowledge both for the purpose of expedited and higher quality innovation and for licensing and technology transfer to qualified producers who could quickly begin to overcome supply shortages and ensure equitable access to life-saving PPE, diagnostics, therapeutics, and vaccines. Regrettably, industry has been stridently dismissive of this voluntary access/tech transfer initiative; [Albert Bourla, the CEO of Pfizer](#), called it “nonsense” and “dangerous.” As a result, C-TAP has [not received a single offer](#) of technology transfer from any biopharmaceutical company in its first year of existence.



After witnessing the excesses of vaccine/diagnostics/therapeutics/PPE nationalism, their own shortages of supply, and the refusal of companies to broadly license their COVID-19 medical technologies to all qualified producers, countries in the Global South sought freedom from IP barriers. They demanded that COVID-19 health technology supplies be manufactured and distributed globally. Thus, on October 2, 2020, India and South Africa introduced a proposal to the WTO TRIPS Council for a waiver of intellectual property rights (patents, copyrights, industrial designs, and confidential information) relating to COVID-19 health technologies for the duration of the pandemic. If adopted, this waiver proposal, provided for in the founding documents of the WTO, would relieve countries from the threat of state-state dispute settlement by setting aside recognition and enforcement of IPRs on COVID-19 health products. Countries would thereafter be free to adopt the waiver domestically by emergency declaration, executive action, legislation, or direct treaty incorporation.

Adopting the waiver would greatly change countries' bargaining power with industry and, if need be, allow countries to authorize "generic" production of key COVID-19 health technologies to fulfill unmet need. It would give legal certainty for private and public investments in local and regional biopharmaceutical manufacturing capacity in the Global South. Moreover, if widely implemented and supported with investments, the waiver could allow the kinds of North-South and South-South cooperation that could result in the establishment of sustainable longer-term biopharmaceutical capacity operating at efficient economies-of-scale that would be able to address future pandemic threats and other unmet medical needs.

Support for the waiver has grown by leaps and bounds with 60 countries now co-sponsoring and another 60 or so countries indicating support. In addition, at least [10 US Senators](#) and another 100 Members of Congress have supported the proposal as have over [400 Members of the European Parliament and national parliamentarians](#). Likewise, the [Pope](#), [175 former heads of state and Nobel Prize winners](#), and [hundreds of civil society organizations](#) in the U.S. alone have supported the waiver proposal.

The end goal of these initiatives is to move the tools needed to end the pandemic to the global commons instead of private enclosures. More specifically, the goal is to increase and distribute sustainable global manufacturing capacity and enable full and open technology transfer of mRNA and other vaccine platforms, antivirals, and biologic medicines including monoclonal antibodies. Related capacity could also be built for other medical supplies including PPE and diagnostics. This expanded capacity would in turn lead to greater self-sufficiency and more equitable access than the current rightholder-dominated approach. In instances where increased competition did not lower prices, additional price control measures could be adopted.



### ***A Renewed Industry Offensive and “Third Way” Proposals***

Although industry initially responded to the waiver proposal with shrugs and quips that it was “nonsense”, the rallying of support and the openness of the new Biden administration to consider the merits of the proposal has led to an industry counteroffensive. Strident op-eds and letters of alarm from [PhRMA](#), [BIO](#), [U.S. Chamber of Commerce](#) and [others](#) simultaneously argue that waiving IP won't help expand supply but that protecting IP is essential to the COVID-19 response and the survival of the industry. In addition to stridently defending IP, industry asserts two other easily refuted arguments.

Page | 7

First, Big Pharma claims that it has amassed all existing manufacturing capacity and that it has global supply needs totally under control. It estimates it can manufacture 8, 10, 12, or even 14 billion doses of vaccines in 2021. However, vaccine manufacturers were able to produce only 4% (31 million doses) of what they predicted they could produce by the end of the 2020. In the first 2+ months of 2021 (through March 5, 2021), all manufacturers, including Russian and Chinese ones, had produced only 413 million vaccine doses. Even by early April, fewer than 1 billion doses have been manufactured. Therefore it is not logical to expect that industry will be able to increase production 8-14 fold in the next nine months of 2021. Similarly, although it argues that it has scoured the global landscape and exhausted all potential sources of supply, vaccine manufacturers have rejected offers to produce additional vaccines from quality assured manufacturers in [Canada](#), [Bangladesh](#), and [Denmark](#). Likewise, they have seemingly ignored unused capacity [elsewhere](#).

Second, after entering into multiple technology access agreements with contract manufacturers and building their own capacity in a few short months, Big Pharma argues that additional technology transfer to other unutilized producers would be too difficult and time consuming. To bolster this argument, Big Pharma characterizes LMIC manufacturers as technologically backward and substandard even though [72 out of 154 WHO prequalified vaccines](#) are produced by manufacturers from developing countries, including India, China, Brazil, Cuba, Thailand, Senegal, and Indonesia. This “[quality slander](#)” occurs at the same time that vaccine rightholders have entered into multiple industry-controlled contract manufacturing agreements with companies in India and other developing countries.

As part of its offensive, industry helped to organize the previously mentioned Manufacturing and Supply Chain Summit where, in its [background paper](#), it touted illusory claims of manufacturing capacity from leading candidate vaccine producers but bemoaned upstream supply bottlenecks. Simultaneously, the Director General of the WTO proposed to pursue a “Third Way” proposal in the WTO that would help voluntary match-making “on mutually agreeable terms” between vaccine manufacturers and potential manufacturing partners. In response, on March 9, 2021, [Australia](#), [Canada](#), [Chile](#), [Columbia](#), [New Zealand](#), [Norway](#), and [Turkey](#) tried to deflect attention from the waiver proposal and requested to the WTO General



Council that the Director General “promptly convene and hold discussion with both vaccine developers and vaccine manufacturers, as well as developers and manufacturers of other COVID-19-related medical products” to make use of unused or underutilized production capacity through mutually beneficial licensing and technology transfer agreements. At the same time, industry leaders and [lobbyists have swarmed Washington](#) and Brussels to argue their case with political leaders, simultaneously opposing the waiver but asking for additional government support. This request for resources has already resulted in at least one agreement by the [Quad Alliance](#) (U.S., India, Japan, and Australia) to invest resources in an Indian manufacturer, Biological E Ltd., to make additional doses of Johnson & Johnson’s vaccine to meet a portion of demand in Indo-Pacific region.

The most recent instantiation of the industry’s Third Way approach is a proposal to create a [COVID Vaccine Capacity Connector](#) in the ACT-A Vaccine Pillar that would “(1) [connect] manufacturers to alleviate bottle necks, particularly in the fill-finish step; (2) promote bilateral technology transfers under license; and (3) facilitate multilateral technology transfer to multiple manufacturers through a technology hub approach.” The first two approaches are clearly the same-old, industry-controlled way. The third approach, [originating within WHO](#), is potentially more promising and would seek to duplicate prior successful efforts to use a tech transfer hub that helped diffusion and expansion of [influenza vaccine manufacturing capacity](#).

### **Conclusion**

There is no doubt that the fundamental barrier to achieving global vaccination coverage is inadequate supply and skewed distribution. That problem persists because governments have left control over vaccine technologies, supply, price, and distribution solely to pharmaceutical companies. With evidence to date, there is no reason to trust industry’s self-serving assertions about their proprietary vaccine manufacturing capacity given the manufacturing mishmashes and production shortfalls we have already witnessed. To make things even worse, Europe and now India are restricting vaccine exports and the U.S. has not allowed export of any domestically produced vaccines except for 4 million doses of the Oxford/AstraZeneca vaccine to neighboring Mexico and Canada.

Instead of relying on industry’s promises, the world can rely instead on common sense – an informed common sense that industry will continue to undersupply, overprice, and underserve need in poorer regions of the world. The resulting shortfalls in immunization will directly cause additional deaths, economic losses, and social disruption. Shortfalls also create a breeding ground for new variants, with the risk that already scarce vaccine capacity will be split disproportionately again between prioritizing the resurgent needs of rich countries for booster and new-variant shots while ignoring the needs of the other 80+% of the global population. This dismal prospect will thereafter extend in the future, where inadequate



capacity will undermine efforts to respond to future pandemics by ignoring needs in developing countries.

Countries must reject third-way/same-way, industry-controlled solutions. The world must unify to meet the urgency of the pandemic. If IP rightholders stand in the way of increased supply, affordable prices, and equitable access, their rights must be overridden so that life-saving health technologies can enter the public sphere where they belong. Industry must be driven to the bargaining table, even if they are also granted incentives for open technology transfer and even as governments and others invest in new and repurposed manufacturing capacity.