# Safety DA

#### Covid-19 vaccines are safe and effective right now.

Moline, 21

(Heidi L. Moline, MD; Michael Whitaker, MPH; Li Deng, PhD; Julia C. Rhodes, PhD; Jennifer Milucky, MSPH; Huong Pham, MPH; Kadam Patel, MPH; Onika Anglin, MPH; Arthur Reingold, MD Shua J. Chai, MD; Nisha B. Alden, MPH; Breanna Kawasaki, “Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years” <https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e3.htm> , August 13)

Clinical trials of COVID-19 vaccines currently authorized for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) indicate that these vaccines have high efficacy against symptomatic disease, including moderate to severe illness (1–3). In addition to clinical trials, real-world assessments of COVID-19 vaccine effectiveness are critical in guiding vaccine policy and building vaccine confidence, particularly among populations at higher risk for more severe illness from COVID-19, including older adults. To determine the real-world effectiveness of the three currently authorized COVID-19 vaccines among persons aged ≥65 years during February 1–April 30, 2021, data on 7,280 patients from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) were analyzed with vaccination coverage data from state immunization information systems (IISs) for the COVID-NET catchment area (approximately 4.8 million persons). Among adults aged 65–74 years, effectiveness of full vaccination in preventing COVID-19–associated hospitalization was 96% (95% confidence interval [CI] = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Effectiveness of full vaccination in preventing COVID-19–associated hospitalization among adults aged ≥75 years was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products. COVID-19 vaccines currently authorized in the United States are highly effective in preventing COVID-19–associated hospitalizations in older adults. In light of real-world data demonstrating high effectiveness of COVID-19 vaccines among older adults, efforts to increase vaccination coverage in this age group are critical to reducing the risk for COVID-19–related hospitalization. COVID-NET includes data on laboratory-confirmed COVID-19–associated hospitalizations in 99 U.S. counties in 14 states, representing approximately 10% of the U.S. population.† COVID-NET cases were hospitalizations that occurred in residents of a designated COVID-NET catchment area who were admitted within 14 days of a positive SARS-CoV-2 test result. COVID-NET program personnel collected information on COVID-19 vaccination status (vaccine product received, number of doses, and administration dates) from state IISs for all sampled COVID-NET cases.§ Some sites expanded collection of information on vaccination status to all reported COVID-NET cases, not only sampled cases, which were included for analysis if all cases in a single month had vaccination status available. Data from 13 sites were included for analysis; one site (Iowa) does not have access to the state IIS and cannot collect vaccination data.¶ Population-level vaccination coverage was determined using deidentified person-level COVID-19 vaccination data reported to CDC by jurisdictions, pharmacies, and federal entities through the IISs,\*\* Vaccine Administration Management System,†† or direct data submission.§§ The study was restricted to adults aged ≥65 years and included the period February 1–April 30, 2021. The Janssen vaccine was authorized for use during the study period beginning March 15, 2021.¶¶ Patients were classified as 1) unvaccinated (no IIS record of vaccination), 2) partially vaccinated (1 dose of Moderna or Pfizer-BioNTech received ≥14 days before hospitalization or 2 doses, with the second dose received <14 days before hospitalization), or 3) fully vaccinated (receipt of both doses of Moderna or Pfizer-BioNTech with second dose received ≥14 days before hospitalization or receipt of a single dose of Janssen ≥14 days before hospitalization). Patients with only 1 dose of any COVID-19 vaccine received <14 days before hospitalization were excluded. Daily county-level coverage data for adults aged 65–74 and ≥75 years in the COVID-NET catchment area were estimated using population denominators from the U.S. Census Bureau; vaccination status was classified as described for hospitalized cases.\*\*\* For vaccine records missing county of residence, county of vaccine administration was used. To estimate vaccine effectiveness and corresponding 95% CIs, methods were adapted based on previously published literature (4). Poisson regression was used to compare case counts by vaccination status (outcome) and the proportion of the population vaccinated and unvaccinated (offset).††† Data were stratified by age group because of the potential for confounding by age, and adjusted for COVID-NET site, time (number of weeks since the start of the study period as a categorical covariate), and monthly site-specific sampling frequency.§§§ Vaccine effectiveness was calculated as one minus the exponent of the estimated coefficient of the exposure (vaccination status) variable. For estimating effectiveness of full vaccination, partially vaccinated persons were excluded; for estimating effectiveness of partial vaccination, fully vaccinated persons were excluded. Vaccine product–specific estimates excluded persons who had received other COVID-19 vaccines. To account for the interval between infection and hospitalization, sensitivity analyses were conducted using a reference date 1 week and 2 weeks before admission, rather than admission date, for classification of vaccination status for cases (i.e., adding 7 and 14 days, respectively between last vaccine dose and hospital admission date); the same adjustment was included for population vaccination coverage. Statistical analyses were conducted using SAS software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶¶ During February 1–April 30, 2021, among 7,280 eligible COVID-NET patients, 5,451 (75%) were unvaccinated, 867 (12%) were partially vaccinated, and 394 (5%) were fully vaccinated; 568 (8%) who received a single vaccine dose <14 days before hospitalization were excluded from the analysis (Table). Vaccination coverage in the population increased rapidly during this period among persons aged ≥65 years and varied by age and vaccine product (Figure 1). Among adults aged ≥65 years in the COVID-NET catchment area, full vaccination coverage from any of the three authorized vaccines ranged from 0.7% on February 1, 2021, to 72% on April 30, 2021. Effectiveness of full vaccination in preventing hospitalization among adults aged 65–74 years was estimated at 96% (95% CI = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Among adults aged ≥75 years, effectiveness of full vaccination was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products (Figure 2). Effectiveness of partial vaccination among adults aged 65–74 years was 84% (95% CI = 76%–89%) for Pfizer-BioNTech and 91% (95% CI = 87%–93%) for Moderna vaccine products. Among those aged ≥75 years, effectiveness of partial vaccination was 66% (95% CI = 48%–77%) for Pfizer-BioNTech and 82% (95% CI = 76%–86%) for Moderna vaccine products. Sensitivity analyses accounting for interval between infection and hospitalization did not yield notably different vaccine effectiveness estimates, with point estimates varying by <1% for Pfizer-BioNTech and Moderna vaccine models. Point estimates for Janssen COVID-19 vaccine models varied by <10%, with few cases eligible for inclusion and wide CIs.

#### But, waiving patent rights does not guarantee vaccine safety

Smith Spark, 21

(Laura,- Former Senior Broadcast Journalist for the BBC, and Newsweek editor of CNN,,“Right Countries Urged to Share Vaccine Knowledge as WTO Debates Waving Patents” <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>, May 05)

If the proposed waiver were to be approved, then **technological know-how** must be transferred to new production sites as well as the intellectual property rights, Rockwell said. Countries must also ensure that they have a strict but transparent regulatory infrastructure in place, he added. The proposed waiver has previously been obstructed by a ["small number" of wealthier nations](https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations), according to Doctors Without Borders. When it was blocked at the WTO in March, aid organization [Oxfam](https://reliefweb.int/report/world/oxfam-response-wto-trips-waiver-covid-19-vaccines-being-blocked-again-rich-countries) slammed the decision as a "massive missed opportunity" to speed up worldwide vaccine production, and accused rich countries of "siding with a handful of pharmaceutical corporations in protecting their monopolies against the needs of the majority of developing countries who are struggling to administer a single dose."**Gross Failure of Leadership** Rights group Amnesty International and the People's Vaccine Alliance urged G7 leaders Wednesday to listen to their people and ensure vaccine knowledge is shared. "G7 governments have clear human rights obligations to put the lives of millions of people across the world ahead of the interests of the pharmaceutical companies that they have funded," said Steve Cockburn, head of economic and social justice at Amnesty International, [in a news release](https://www.amnesty.org/en/latest/news/2021/05/an-average-of-7-in-10-across-g7-countries-think-their-governments-should-force-big-pharma-to-share-vaccine-know-how/). "It would be a gross failure of leadership to continue blocking the sharing of life-saving technologies, and would only serve to prolong the immense pain and suffering caused by this pandemic." Wednesday's WTO meeting comes a day after the chief of Pfizer said the company was expecting approximately $26 billion in revenue from its Covid-19 vaccine in 2021.More than 300 public health experts [signed a letter](https://www.publichealth.columbia.edu/sites/default/files/trips_sign_on_letter_4-30-21.pdf) Friday arguing that the United States should join an effort to force vaccine makers to waive intellectual property rights to coronavirus vaccines and treatments so more countries can start making them. The group, led by Columbia University professors Terry McGovern and Chelsea Clinton, said the so-called TRIPS waiver would allow local manufacture of vaccines, treatments and diagnostics. "Allowing countries to manufacture locally will speed access to vaccines and treatment, prevent unnecessary deaths, and facilitate a stronger, faster economic recovery," they wrote. "Until vaccines, testing, and treatments are accessible to everyone everywhere we risk recurring new variants, drug resistance, and greater loss of life and suffering at home and globally." That appeal came a fortnight after more than 170 former world leaders and Nobel laureates, including former UK Prime Minister Gordon Brown, former President of Liberia Ellen Johnson Sirleaf and former French President François Hollande sent an [open letter to the White House](https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704) urging President Joe Biden to support the temporary waiver on IP rights for Covid-19 vaccines at the WTO. **Legal Battles** But even as public pressure grows, some experts argue that handing over the IP rights for Covid-19 vaccines won't necessarily mean that more can be rapidly produced worldwide at large scale. US infectious diseases chief Anthony Fauci [told the UK's Financial Times](https://www.ft.com/content/2f41b122-5738-4707-a822-0d79276710c5) on Monday that he was not convinced that forcing companies to share their intellectual property was the most effective approach, warning that legal battles could slow the process."Going back and forth, consuming time and lawyers in a legal argument about waivers -- that is not the endgame. People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible," he said. Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the **transfer of know-how,**" he said. "I **don't think there's clear evidence** that a waiver of an intellectual property is going to be the best way for that technology transfer to occur."Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. It's **very different for vaccines**, where it's really a **biological process** as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "**It requires a lot of knowledge that's not part of the IP."** The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said.

#### Removing IP would cause ineffective and unsafe vaccines

Brougher, 21

Joanna T. Brougher, Esq., Mph &amp; Andrew Kingsbury, 3-30-2021, "Calls for Compulsory Licensing and IP Waivers of COVID-19 Vaccines Ignore Technical Complexities," IPWatchdog, <https://www.ipwatchdog.com/2021/03/30/calls-compulsory-licensing-ip-waivers-covid-19-vaccines-ignore-technical-complexities/id=131617/> // AW

While seeking compulsory licensing or IP waivers may seem an attractive solution to address technological disparities across human populations, these mechanisms ignore some of the more technical hurdles to increasing accessibility to vaccination. This post will first briefly explain what compulsory licensing and IP waivers are and then examine three possible causes for why compulsory licenses and IP waiver are not a feasible solution to the current COVID-19 pandemic. Compulsory Licensing One of the agreements that countries must ratify upon joining the World Trade Organization (WTO) is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was negotiated in 1994 to harmonize intellectual property laws across different countries and to establish minimum standards for protecting and enforcing intellectual property rights for all WTO member countries. There are several provisions under TRIPS that allow governments to provide for limitations to intellectual property rights. In [Article 31](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf), for instance, TRIPS allows governments to order domestic manufacturers to make a patented product without permission from the patent holder. This practice is known as compulsory licensing. Article 31 permits countries to engage in compulsory licensing if there is a “case of a national emergency or other circumstances of extreme urgency,” or in cases of “public non-commercial use.” Under these circumstances, the country is first required to negotiate with, or seek approval from, the patent holder of the drug, but if the negotiations fail, is ultimately just permitted to manufacture patented products, such as essential medicines, for its domestic market. For countries that cannot manufacture drugs themselves, and who would thus not be able to issue compulsory licenses under Article 31, Article 31bis was created to permit a developed country to export a generic drug under a compulsory license to a less developed country. IP Waivers Contrary to compulsory licensing, IP waivers simply ask that countries be exempt from the provisions of TRIPS that require countries to protect and enforce patent rights to COVID-19 treatments and vaccines. In October 2020, [India and South Africa petitioned the WTO](https://www.ipwatchdog.com/2021/01/02/india-south-africas-covid-vaccine-proposal-wto-patent-waiver-must-considered-compulsory-licensing/id=128652/) for a temporary waiver from specific provisions of the TRIPS Agreement that could essentially put entire realms of existing intellectual property law on hold at the international level until widespread vaccination has become globally implemented. Perhaps unsurprisingly, this proposal was met with strong resistance from developed nations while developing and less developed nations were more welcoming towards it. In March 2021, the proposal failed to pass resolution at the WTO. Covid-19 Vaccines are New What these proposals fail to take into account is the nature of the Pfizer and Moderna vaccines. The efficacy of both of these proposals turns on a country’s internal technological capabilities to recreate and administer the vaccine. The Pfizer and Moderna vaccines, however, are not typical vaccines. Whereas traditional vaccines functioned by introducing parts of a virus — or a weakened form of a virus — Pfizer’s and Moderna’s vaccines use messenger RNA to cause host cells to produce the protein themselves. These are the [first vaccines to utilize this type of technology](https://www.abc27.com/news/health/coronavirus/vaccination-frustration/digital-original-how-do-covid-19-vaccines-compare-to-other-vaccinations/). The novelty of these vaccines potentially degrades the utility of a compulsory license or IP waiver. For instance, remdesivir received a great deal of focus early in the pandemic. Bangladesh managed to recreate the drug without Gilead Science’s approval because it is exempt from Article 31 of TRIPS, and Bangladesh [was able to produce a sufficient supply for the country by the summer of 2020](https://patentlyo.com/patent/2021/01/shortages-compulsory-licensing.html) because information about the drug was available. Given the fact that Pfizer’s and Moderna’s vaccines represent a new form of vaccine, lacking technical information on how to make this new form of vaccine could lead the countries to create entirely ineffective vaccine replicas. These issues may be compounded by the fact that many vaccine manufactures [rely on trade secret protection more heavily](https://www.jdsupra.com/legalnews/trade-secret-protection-the-covid-19-37383/) following the [Ass’n for Molecular Pathology v. Myriad Genetics, Inc](https://www.leagle.com/decision/insco20130613e08). decision. These trade secrets can withhold critical scientific know-how that might be necessary for replicating a vaccine. Thus, the new technology behind these messenger RNA vaccines and the lack of accessibility to the related know-how might deter countries from attempting to manufacture them. Lack of Information Yet another more fundamental problem exists for replicating these vaccines. Not only do these vaccines represent a new form of vaccine, but information about these particular vaccines is simply unavailable. Even if the Pfizer and Moderna vaccines do not utilize any trade secrets, the discovery of these vaccines is fundamentally different than remdesivir’s timeline, which resulted in Bangladesh’s recreation of the drug. [A patent for remdesivir was filed as early as 2015](https://patents.google.com/patent/US20170071964A1/en), and thus the information had been publicly available for years. While the technology underlying mRNA vaccines has been in development for decades, there are likely specific technological hurdles associated with, for instance, the coronavirus, mass production and scale up, and delivery mechanisms that needed to be developed for this specific application of the legacy technology. This additional information will not be found in scientific journals or magazine articles, nor can it be found in any patent application, yet. Patents, moreover, can take up to 18 months from filing to be published. BioNTech made an [F-1 filing with the SEC](https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm) on July 21, 2020, in which it acknowledged its partnership with Pfizer to develop the vaccine. If this filling is at all indicative of when a patent could have been filed, then this would mean the patent may not be available to the public until late-2021–mid-2022. With Novelty Comes Difficulty The newness of these vaccines also creates problems due to the complexity in how these types of vaccines function and how to produce them. According to a [Wall Street Journal report](https://www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401), manufactures say that vaccine production is difficult both “because some steps are difficult to scale up quickly or because they simply haven’t been done before.” Even Pfizer is [having difficulty obtaining](https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787) the necessary materials for vaccine production. Here, the complexity of these vaccines demonstrates the potential futility of a compulsory license or IP waivers. Even if other countries could compel manufactures to license the underlying intellectual property and provided them with the information about how to do so, the complexity of manufacturing these types of vaccines could be a particularly high barrier to overcome. It’s Complicated Countries face roadblocks for producing a viable vaccine candidate based on Pfizer’s and Moderna’s vaccines. The new technology that utilizes messenger RNA vaccines, coupled with the lack of public information about these vaccines and the vaccines’ complicated nature, present significant hurdles to seeking compulsory licenses or IP waivers.

#### The plan leads to uncontrolled use of patented technologies, which turns vaccine access, and causes dangerous health consequences.

Crosby and Diamond, 21

(Daniel Crosby JD@Washington University of Law, Evan Diamond JD@Harvard Law School M.S. Biochemistry@UPenn, Isabel Fernandez de la Cuesta JD@Complutense University Madrid, Jamieson Greer JD@University of Virginia Law School, Jeffery Telep JD@University of Florida, Brian White JD@University of Virginia, “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for Covid-related Medical Projects” <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/>, March 05)

Waiver risks uncontrolled use of patented technologies, without improving vaccine access.Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

# Threat CP

#### Plan text: The member nations of the WTO ought to threaten to reduce IP protections for medicines pertaining to treatment of COVID-19.

#### Threat of waiver is distinct from action and avoids any disads therefore competitive

**Zarocostas quoting Appleton, 21**

~John, Geneva-based independent international correspondent and broadcaster; Arthur, adjunct professor at Johns Hopkins University, May 22, 2021, The Lancet, Vol 397, [https://doi.org/10.1016/S0140-6736(21)01151-X//lhs-ap~~](https://doi.org/10.1016/S0140-6736(21)01151-X/lhs-ap~~)

“Even if a waiver is approved, there may still be bottlenecks related to production capacity, distribution, and the production of raw materials and equipment used to manufacture package and transport vaccines”, said Appleton. “Of course, just the threat of a waiver may help drive down the cost of vaccines, therapeutics, and diagnostic tools, and result in increased access in the developing world. The threat may also lead to voluntary licensing agreements on terms favourable to developing countries.”

# Case

### Circumvention

#### The plan gets circumvented through prioritization of bilateral trade agreements.

Durand and Milberg, 18

[Cédric, Associate Prof. Political Economy @ U-Geneva, member @ Paris Nord Economics Center; and William, Dean @ The New School for Social Research: “Intellectual Monopoly in Global Value Chains,” published in 2018, https://hal.archives-ouvertes.fr/hal-01850438]//AD

The contention over IPRs exemplified by the dispute between the US and China, reflects the heightened sensitivity of the US and other high-income economies to IPRs in an era where their governments and businesses consider innovation as their main competitive advantage. The US today is the leader of the movement toward stricter international IP norms, in contrast to its position in earlier periods (Peng, Ahlstrom, Carraher, & Shi, 2017). It is the most active complainant at the WTO under the TRIPS agreement but, as illustrated by the recent actions of the Trump administration, TRIPS is not enough (Sell, 2010). The US seeks other ways to extend internationally the standard of IP protection found in U.S. law and in particular to apply existing IP protection to digital media (Akhtar & Ferguson, 2011, p. 25). In order to circumvent the flexibility in the WTO TRIPS Agreement, and the reluctance of developing countries at the WTO to raise WTO standards of IP protection (Helfer, 2004), developed economies have relied increasingly on bilateral and regional preferential trade agreements (PTAs) to accomplish the objective of securing intellectual property related economic advantages (Abbott, 2006; Shadlen, 2008). The international intellectual property policymaking arena has grown ever more complex with overlapping transnational norms. For example, the 33 pages of the chapter dedicated to IPRs in the US-CAFTA agreement details the treaties and conventions that the parties shall ratify, which defines precisely and extensively the scope of IPRs concerned (copyrights, performance, patents, communication, trademarks, plants, microorganisms, industrial design, geographical indication, name domains…). Additionally, it describes enforcement mechanisms to be implemented in national legislation and considers supplementary protection of intellectual property under the investment chapter (CAFTA, 2004). IP provisions included in Japanese and EU international trade agreements are more general but they also provide supplementary coverage and additional obligations (Liberti, 2010). Moreover, investment treaties and chapters dedicated to investment protection in trade agreements open additional routes for IP protection, which can exercise a powerful chilling effect on government actions via the exposure to the risk of costly investor-state arbitration disputes (Ho, 2015, 2016; Kasolowsky & Leikin, 2017). The DESTA database (Dür et al., 2014) allows us to track this qualitative evolution in bilateral and regional trade agreements. IP provisions of trade agreements were nonexistent before the North American Free Trade Agreement (NAFTA) was signed in 1992. They became a standard feature of trade agreements in the 2000s. Figure 6 shows the number of PTAs signed each year and of those, the ones which included IPRs. It also shows the percentage of PTAs with an IP provision. By 2016, every PTA signed included an IP provision.

#### Turn--Bilateral trade agreements are worse than TRIPs – at least TRIPs allows for collective bargaining by the global south.

Kingston, 4

[William, School of Business Studies @ Trinity College (Dublin, Ireland): “Removing Some Harm from the World Trade Organization,” Oxford Development Studies, Vol. 32, No. 2, June 2004. http://www.tara.tcd.ie/bitstream/handle/2262/8696/Removing%20some%20harm.pdf?sequence=1]//AD

Also, now that TRIPS exists, it is better for the poorer countries that it should be maintained in existence, and reformed. This is because as an instrument of international law, it has the potential to enable them to withstand the power of the USTR in bilateral negotiations. As Cancu´ n showed, when a significant group of these countries act together, they can resist being bullied.

#### The aff forces countries to protect IP beyond TRIPs standards – turns case.

Bhala, 7

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\*FTA=Free Trade Agreement

Many of America’s newer FTAs, especially accords negotiated after the Uruguay Round, call upon partner countries to go beyond IP protection and enforcement measures set out in the TRIPs Agreement. In part, that reflects America’s bitter experience with lax IP enforcement in major markets like China. US trade negotiators relied, to the detriment of the American IP sector, on promises made by China of future implementation and enforcement during talks for Chinas accession to the WTO, which culminated in a November 1999 US–China bilateral agreement, and accession effective 11 December 2001.30 The subsequent history, from the US vantage point, was one of failure to adhere to the promises. One lesson learned by US trade negotiators was to insist on results – actual implementation and enforcement – before accession. They drilled the point in WTO accession talks with the Kingdom of Saudi Arabia, which culminated with a bilateral accord in the fall of 2005, and accession on 11 December 2005.31 A second lesson from the adverse experience with China was to use FTAs as a vehicle to go beyond the TRIPs Agreement, i.e., to demand TRIPs Plus commitments from a would-be FTA partner. Consider the following examples: In the U.S.–Jordan FTA, Jordan agreed to ratify and implement within two years two IP agreements that are not part of its TRIPs obligations: the World Intellectual Property Organization (WIPO) Copyright Treaty, and the WIPO Performances and Phonograms Treaty. The aim of these agreements, which are known as ‘‘Internet Treaties,’’ is to protect copyrighted works in a digital network environment. Thus, for example, they provide a creator with the exclusive right to make its creative works available online. The same TRIPs Plus provisions, incorporating the most up-to-date international copyright protection standards, exist in the U.S.–Morocco FTA. In the U.S.–Chile FTA and U.S.–Singapore FTA, Chile and Singapore agreed to TRIPs Plus commitments not only for patents, trademarks, and copyrights, but also for trade secrets. The two countries also accepted the obligation of ensuring its legal system contains meaningful penalties for piracy and counterfeiting. In negotiations for a U.S.–Australia FTA, the US had two key objectives concerning IP. First, it sought better IP protection, especially with respect to grey (parallel) market products. The US achieved this objective through provisions in the FTA that not only complement, but also enhance, existing international standards for both protection and enforcement of IP rights. These TRIPs Plus provisions include strong penalties for counterfeiting and piracy. Second, the US opposed the Australian pharmaceutical benefits scheme of pricing. On this point, agreement proved difficult and the end result – though TRIPs Plus – was nebulous. The two countries affirmed their shared objectives of (1) maintaining high quality healthcare and (2) improving public health standards. They agreed on three principles in pursuit of these objectives: (1) the importance of innovative pharmaceuticals, (2) the significance of research and development in the pharmaceutical industry, with appropriate governmental support including IP protection, and (3) the need for timely and affordable access to innovative pharmaceuticals through procedures that value objectively pharmaceuticals based on their therapeutic relevance. The sticking point was the procedures by which a federal health care program lists and prices new pharmaceuticals for reimbursement. Both sides agreed the procedures should demand transparency and accountability. But, how could the US be certain Australia would not discriminate against drugs from US pharmaceutical companies when listing and pricing medicines in its Pharmaceutical Benefits Scheme? From Australias perspective, how could its consumers be assured they would have access to effective US drugs at non-astronomical prices? The FTA establishes a Medicines Working Group to continue the conversation between the two countries on pharmaceutical issues, and creates in Australia an independent review process for listing decisions. The conversation indeed continues on this and other controversies. For example, when approving the FTA, the Australian Parliament added an ‘‘Anti-Evergreening’’ amendment to Australian law.32 This change blocks a pharmaceutical company from evergreening a patent or using the judicial process to preclude introduction of a generic medicine. The US opposes the amendment. In June 2006, NGOs – 416 of them, including the AFL-CIO, Citizens Trade Campaign, Communications Workers of America, Friends of the Earth, National Farmers Union, Sierra Club, and United Steel Workers – signed a letter urging Congress to reject the U.S.–Oman FTA (which Congress ultimately passed that summer.) They argued the accord not only lacked meaningful labor and environmental protections, but also would hurt poor and sick Omanis. The FTA IP provisions benefited large pharmaceutical companies by protecting their ‘‘unprecedented monopoly rights’’ of large pharmaceutical companies, forbidding for extended periods competition from generic products, and limiting access to affordable medicines.33 In the U.S.–Colombia FTA, signed in February 2006, but not implemented as of November 2006, Colombia agreed to join the WTO Information Technology Agreement (ITA).34 The ITA, an outgrowth of the Uruguay Round, lists a large number of computer and computer-related products subject to duty-free, quota-free treatment. However, it is a plurilateral accord, hence joining is required neither by TRIPs nor any other WTO accord. In January 2006, the US and Thailand were engaged in FTA negotiations, which commenced in June 2004. US insistence on TRIPs Plus IP commitments contributed to large-scale protests in Chiang Mai, Thailand, against an FTA, and brought talks to a halt.35 Four specific TRIPs Plus controversies arose:36 (1) The US insisted on 25-year span for patent protection, beyond the TRIPs Agreement norm of 20 years. (2) The US called for compensatory patent extensions by the Thai government to pharmaceutical companies, if the government ‘‘unreasonably’’ delayed either the grant of a drug patent, or approval of a drug for market use. The TRIPs Agreement does not contain this mandate. (3) The US sought a data exclusivity provision not found in the TRIPS Agreement. This provision would preclude manufacturers of generic drugs (which, of course, tended to be Thai companies) from using clinical trial data, or other scientific information, from any other company (e.g., an American pharmaceutical giant), to prove its generic product was safe and effective after the product had entered the market. Thailands Government Pharmaceutical Organization (GPO) objected. The GPO provides ‘‘first line’’ anti-retroviral medicines (i.e., older ones, some of which the patent had lapsed) to 80,000 AIDS patients (as of 2006), and sought to expand this program to 150,000 patients (by 2008). The GPO planned to offer generic ‘‘second line’’ drugs (i.e., newer, more sophisticated medicines still subject to a patent). Data exclusivity would inhibit its ability to do so. Further, data exclusivity would apply even to an unpatented drug, where no patent had been sought because the market for the drug was thought to be too small. (4) The US required tight language that would limit the terms and conditions under which the GPO could effect a compulsory license of a new drug. The US offered a side letter assurance that the language would be consistent with the November 2001 Doha Ministerial Conference Declaration on TRIPs and Public Health. Again, the GPO replied the language would adversely affect its ability to provide drugs to Thai AIDS patients. Thousands of Thai health care workers, AIDS victims, and activists – fearful of high-priced medicines should their government ‘‘cave’’ to the demands, demonstrated noisily, but peacefully (in front of the Sheraton Chiang Mai!) for about two days. Farmers, who were upset at US demands concerning agricultural trade (e.g., that Thailand reduce rice tariff barriers), joined them. The US team left the Sheraton as inconspicuously as possible, through a side door behind the concierge desk, into an unmarked van, and down a side street. The USTR blamed the ensuing stall in negotiations on Thai political unrest.37 Not surprisingly, some international trade law scholars offer persuasive arguments for the proposition that ‘‘TRIPs Plus’’ is ‘‘TRIPs Minus’’ for poor countries. For example, Dr Mohammed El-Said of the University of Central Lancashire cogently argues TRIPs Plus commitments in deals like the U.S.–Jordan and U.S.–Bahrain FTA end up doing greater harm than good to the US partners, hence rendering those countries worse off than under WTO disciplines.38 This line of argumentation would appear to be consistent with the competitive imperialism paradigm. In that paradigm, major trading powers race against one another to get the best possible deal for themselves. They neither intend to, nor hope to see, the IP provisions in their FTA and CU deals multilateralized. Obviously, if their provisions become WTO law, then their benefits no longer are specially tailored. All WTO Members, consisting of a not inconsiderable number of free riders (from the American or European perspective, at least), would enjoy whatever benefits they can realize for whatever IP industry they have.

### Compulsory licensing

#### Countries can already unilaterally override patent privileges to protect public health.

Okediji, 14

(Ruth, Professor @ Harvard Law School, “The Role of WIPO in Access to Medicines” in Balancing Wealth and Health, Chapter 13, 312-313)

The right of countries to adopt measures to protect public health is one of the grounds explicitly mentioned as part of the principles of the TRIPS Agreement,20 and the Doha Declaration subsequently established elements of this right, including the residual power of countries to unilaterally determine the conditions in which public health needs can override patent privileges.21 Access to medicines is an integral part of the human right to health in many countries (Lee and Hunt 2012). WIPO, however, has been far less embracing of human rights approaches to IP as a basis for access to medicines despite robust scholarly examination and affirmation of a positive effect of the IP-human rights link on access to medicines (Land, this volume; Land and Pakenham-Walsh 2012; Helfer and Austin 2011). To the extent patent grants circumscribe the terms of access, human rights norms provide countervailing arguments of equal or, arguably, greater moral force. These normative strategies of resistance to maximalist patent rights have had a measurable impact on access to medicines campaigns across Brazil, Latin America, South Africa, and East Africa. At a minimum, human rights arguments, because they so easily galvanize global public concern, can exert significant bottom-up pressure that eventually affects the scope and direction of the exercise of IP rights.22 Even when formally marginalized within politically agile organizations such as WIPO or the WTO, human rights arguments constitute a centripetal force compelling normative reconsideration of global patent norms. This overlapping regime complex, which frames the access to medicine challenge, requires shared competence across international organizations in addressing public health and access to medicines.

#### Existing *compulsory licensing* exemptions are sufficient to solve

Bacchus, 20

(James, adjunct scholar at the Cato Institute, a professor of global affairs at the University of Central Florida, An Unnecessary Proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines <https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf>, 12-16)

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines. In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least-developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”14 India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case-by-case and product-by-product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”15 But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market. Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

#### Weakening IP is insufficient- multiple other barriers to equity

Bonadillo and Chandler, 21

(Enrico, Reader in Intellectual Property Law, City, University of London, Dhanay M. Cadillo, Postdoctoral research fellow, University of Turku, https://theconversation.com/intellectual-property-and-covid-19-medicines-why-a-wto-waiver-may-not-be-enough-155920)

One argument against the waiver is that the TRIPS Agreement already contains flexibilities. These include the freedom to use parallel imports and compulsory licences that help countries get access to medicines. Yet such flexibilities are not always easy to use. Take compulsory licences. Since 2003 a mechanism has been made available which in principle allows countries with no manufacturing capacity in the pharmaceutical field to use and benefit from compulsory licences. But the system is riddled with levels of complexity that render it useless and not fit for purpose. It’s only been used once in 17 years – in 2007, when Canada issued a compulsory licence to meet Rwanda’s need for AIDS drugs. Other arguments against the waiver are that it would not alleviate the burden of access to effective and affordable medicines and vaccines because of poor healthcare provision and infrastructure in some countries. And that it could potentially hamper R&D and innovation in the pharmaceutical sector. There are other barriers that the waiver wouldn’t address. One is that some developing countries have entered into bilateral agreements, especially with the US, the EU and other industrialised nations. These have limited the ability of generics producers to manufacture and distribute cheap medicines. One example is that this has limited the freedom to rely on parallel imports. These usually guarantee the importation of cheaper medicines purchased in countries where the drugs are sold at a lower price. Also, certain free trade agreements have introduced provisions which prevent national drug regulatory authorities from registering and allowing the sale of generics if the medicine is still patented. This is the so-called “patent linkage”. Among the countries that have signed these agreements are those who are part of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership. They include Brunei, Chile, Malaysia, Mexico, Peru and Vietnam. Other trade and partnership agreements have also obliged certain developing countries to provide an absolute protection of clinical test data submitted to regulatory agencies to demonstrate the quality, safety and efficacy of new medicines. This strong exclusivity stops the manufacturers of generics from using such data while applying for their own marketing authorisation. This inevitably slows down the availability of cheaper drugs. Countries like Morocco, Jordan, El Salvador, Guatemala, Honduras and Nicaragua do protect such data as a consequence of trade agreements concluded with the US. French President Emmanuel Macron and British Prime Minister Boris Johnson have recently pushed for plans to share vaccines instead.

### Vaccines won’t be made.

**No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez, 21**

[Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.

#### Tech transfer is key and not included under IP

Smith, 21

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the transfer of know-how," he said. "I don't think there's clear evidence that a waiver of an intellectual property is going to be the best way for that technology transfer to occur." Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "It requires a lot of knowledge that's not part of the IP." The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said. Michael Head, senior research fellow in global health at the University of Southampton, in England, told CNN that increasing regional manufacturing capacity, particularly in the global south, was key -- and should be a focus between pandemics. "Sharing intellectual property during the pandemic is something that should happen but that doesn't resolve the issues," he said. "Manufacturing vaccines is hard. It's hard to rapidly set up a new site with all the equipment, infrastructure, all the vaccine ingredients, with suitable staff to produce a large number of high quality vaccine products." Philanthropist Bill Gates, a major supporter of [global Covid-19 vaccine equity](https://www.cnn.com/2021/02/05/world/covax-explainer-intl/index.html) through the Bill & Melinda Gates Foundation, also [told Sky News](https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840) last month that he did not believe overriding IP rules was the answer. "There's only so many vaccine factories in the world and people are very serious about the safety of vaccines," he said. "The thing that's holding things back in this case is not intellectual property. There's not, like, some idle vaccine factory with regulatory approval that makes magically safe vaccines. You've got to do the trials on these things and every manufacturing process has to be looked at in a very careful way."