## Pharma

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz 5-17-21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that countries with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

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The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

#### Climate change is causing catastrophic diseases to emerge from thawed permafrost. Some have been dormant for millennia—humans will have difficulty combatting them.

Goudarzi 16

Sara Goudarzi, 11-1-2016, "As Earth Warms, the Diseases That May Lie within Permafrost Become a Bigger Worry," Scientific American, <https://www.scientificamerican.com/article/as-earth-warms-the-diseases-that-may-lie-within-permafrost-become-a-bigger-worry/> (MLT)

This past summer anthrax killed a 12-year-old boy in a remote part of Siberia. At least 20 other people, also from the Yamal Peninsula, were diagnosed with the potentially deadly disease after approximately 100 suspected cases were hospitalized. Additionally, more than 2,300 reindeer in the area died from the infection. The likely cause? Thawing permafrost. According to Russian officials, thawed permafrost—a permanently frozen layer of soil—released previously immobile spores of Bacillus anthracis into nearby water and soil and then into the food supply. The outbreak was the region's first in 75 years. Researchers have predicted for years that one of the effects of global warming could be that whatever is frozen in permafrost—such as ancient bacteria—might be released as temperatures climb. This could include infectious agents humans might not be prepared for, or have immunity to, the scientists said. Now they are witnessing the theoretical turning into reality: infectious microorganisms emerging from a deep freeze. Although anthrax occurs naturally in all soil and outbreaks unrelated to permafrost can occur, extensive permafrost thaw could increase the number of people exposed to anthrax bacteria. In a 2011 paper published in Global Health Action, co-authors Boris A. Revich and Marina A. Podolnaya wrote of their predictions: “As a consequence of permafrost melting, the vectors of deadly infections of the 18th and 19th centuries may come back, especially near the cemeteries where the victims of these infections were buried.” And permafrost is indeed thawing—at higher latitudes and to greater depths than ever before. In various parts of Siberia the active layer above permafrost can thaw to a depth of 50 centimeters every summer. This summer, however, there was a heat wave in the region, and temperatures hovered around 35 degrees Celsius—25 degrees warmer than usual. The difference possibly expanded or deepened the thaw and mobilized microorganisms usually stuck in rigid earth. Although scientists have yet to calculate the final depth, they postulate that it is a number that has not been seen in almost a century. Permafrost thaw overall could become widespread with temperatures only slightly higher than those at present, according to a 2013 study in Science. Heat waves in higher latitudes are becoming more frequent as well. What thawing permafrost could unleash depends on the heartiness of the infectious agent involved. A lot of microorganisms cannot survive in extreme cold, but some can withstand it for many years. “B. anthracis are special because they are sporulating bacteria,” says Jean-Michel Claverie, head of the Mediterranean Institute of Microbiology and a professor at Aix-Marseille University in France. “Spores are extremely resistant and, like seeds, can survive for longer than a century.” Viruses could also survive for lengthy periods. In 2014 and 2015 Claverie and his colleague Chantal Abergel published their findings on two still infectious viruses from a chunk of 30,000-year-old Siberian permafrost. Although Pithovirus sibericum and Mollivirus sibericum can infect only amoebas, the discovery is an indication that viruses that infect humans—such as smallpox and the Spanish flu—could potentially be preserved in permafrost. Human viruses from even further back could also make a showing. For instance, the microorganisms living on and within the early humans who populated the Arctic could still be frozen in the soil. “There are hints that Neandertals and Denisovans could have settled in northern Siberia [and] were plagued by various viral diseases, some of which we know, like smallpox, and some others that might have disappeared,” Claverie says. “The fact that there might be an infection continuity between us and ancient hominins is fascinating—and might be worrying.”

### Safety

#### 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 cannot 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/unsafe vaccines

Brougher MPH 3/30/21

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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.

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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.