**NEG**

In today’s debate we look at both sides of the topic of whether or not the members of World Trade Organizations ought to reduce the intellectual property for medicines. For today’s round I will represent the NEG and the CONS of reducing intellectual property for medicines.

I start off the debate by stating my value:

In today’s debate I value **Societal Good**

Which is defined by Investopedia dot com as: something that benefits the largest number of people in the largest possible way, such as clean air, clean water, healthcare, and literacy. Also known as "common good,"

To achieve this value it is best that we use the value criterion of **Utilitarianism:**

Which is defined by Marium Webster as: a theory that the aim of action should be the largest possible balance of pleasure over pain or the greatest happiness of the greatest number

***The biotech industry is strong now.***

**Cancherini et al. April 2021**[(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“,  McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide>] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

***IPR key to innovation.***

**Bacchus 20** [(James, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland) "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, 12-16-2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>] TDI

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐ making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which **many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.**

Technically, IP rights are exceptions to free trade. A long‐ standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐ term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐ how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐ based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐ related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

***Biopharmaceutical innovation is key to prevent future pandemics and diseases.***

**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, <https://www.rand.org/pubs/perspectives/PEA407-1.html>] TDI

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.

***MRNA solves a litany of diseases, but continued innovation is key***

**Gupta 5/7 [(Swati,**vice president and head of emerging infectious diseases and scientific strategy at IAVI, a nonprofit scientific research organization that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19) and neglected diseases, PhD and MPH from Yale University**) “**The Application and Future Potential of mRNA Vaccines,” Yale School of Public Health, 5/7/2021] JL

The implications of mRNA technology are **staggering**. Several vaccine developers are studying this technology for deployment against **rabies, influenza, Zika, HIV and cancer**, as well as for veterinary purposes. Its potential utility is based upon its being a “platform technology” that can be developed and scaled rapidly. Given that only the genetic code for a protein of interest is needed, synthetically produced mRNA vaccines can be made rapidly, in days. Other vaccine approaches involve growing and/or producing proteins in cells, a process that can take months. Messenger RNA vaccines are generally regarded as safe, since they do not integrate into our cells’ DNA and naturally degrade in the body after injection. They also can be safely administered repeatedly, as we are seeing with the two-dose regimen for both the Pfizer-BioNTech and Moderna vaccines.

Despite the current success of mRNA vaccines for COVID-19, scientists continue to work on making the technology better. A number of laboratories are testing more thermostable formulations of mRNA vaccines, which currently must be kept at freezing or ultra-cold temperatures. Others are investigating second-generation vaccines that will only require a single shot, and “universal” coronavirus vaccines that could protect against future emerging coronaviruses. **Messenger RNA vaccines that target a broad range of different diseases, all in one shot, are also in development**; this approach has the potential to greatly simplify current vaccination schedules.

Taken together, these advantages and potential future developments position mRNA vaccines as an increasingly important technology in our arsenal of tools against infectious disease outbreaks, and are likely to be **critical to fighting future epidemics and pandemics**. Global partnerships like the Coalition for Epidemic Preparedness and Innovation (CEPI), tasked with facilitating the development of vaccines to stop future epidemics, have called for vaccines to be able to be tested in the clinic within months after a new pathogen is identified. With the latest discoveries in mRNA technology, we are well on our way to this goal; the ability of this platform technology to be transformative is no longer a hope, but more likely to be a reality in the very near future.

**Rebuttal**

**Now that I finished my case I will use my remaining time to attack my opponents case.**

**The problem is resources not IP**   
**Garde et al 21** Damian Garde [national biotech reporter for STAT], Helen Branswell [writer at STAT covering infectious diseases and global health], Matter Herper [senior writer at STAT covering medicine], May 6, 2021, “Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive " <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/> //kangu

Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, **vaccines** like the ones from Pfizer and Moderna — **using**[**messenger RNA technology**](https://www.statnews.com/2020/10/26/mrna-vaccines-face-their-first-test-in-the-fight-against-covid-19-how-do-they-work/)**— require skilled expertise that even existing manufacturers are having trouble sourcing**. **“In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said.**There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said **supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well**. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing.

***The AFF increases price of scarce materials and results in costly, ineffective facilities***

**Mcmurry-Heath 8/18** (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination“, STAT, accessed: 8-19-2021, <https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/>)  ajs

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.

Here’s why. Before Covid-19 emerged, the world produced at most [5.5 billion doses](https://www.barrons.com/articles/a-plan-to-break-the-vaccine-manufacturing-bottleneck-51621952245) of various vaccines every year. Now the world needs an additional [11 billion doses](https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-g7-summit---12-june-2021) — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another [four to six months](https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/) to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available.

That’s slower than our current production rate. According to a report from Duke University’s [Global Health Innovation Center](https://launchandscalefaster.org/covid-19/vaccinemanufacturing), companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid [$23.50 per dose](https://www.timesofisrael.com/israel-said-to-be-paying-average-of-47-per-person-for-pfizer-moderna-vaccines/) for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during [just two days of shutdowns](https://www.bmj.com/content/372/bmj.n281) in the country.

Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose.

Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. [COVAX](https://www.who.int/initiatives/act-accelerator/covax), the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world’s [“arsenal of vaccines.”](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/) The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate [500 million more](https://www.npr.org/sections/goatsandsoda/2021/08/03/1023822839/biden-is-sending-110-million-vaccines-to-nations-in-need-thats-just-a-first-step) by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

***IPR hasn’t harmed access – manufacturing capacity alt cause***

**Mercurio 2/12** (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820>)  ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

***Waivers fail – license agreements are key to access and scaling up vaccines***

**Crosby et al 21** [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

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.

***Squo solves – voluntary licensing and other initiatives***

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3. Voluntary licensing and other initiatives are supporting access to COVID-19 vaccines Contrary to assertions the sponsors made at the TRIPS Council, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-19 medication. For instance, Gilead’s antiviral drug named Remdesivir was approved for emergency use for COVID-19 treatment by the US Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.35 As demand surged following the approvals for use in COVID-19, Gilead issued nonexclusive voluntary licences to generic producers based in India, Egypt and Pakistan in order to meet the growing demand for the product. Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir, as well as set their own prices for the generic drugs they produce. The arrangement allows the distribution of the drug in 127 countries, covering nearly all low-income and lower-middle-income countries.36 Another example of industry cooperation is the COVID-19 vaccine co-developed by AstraZeneca and University of Oxford. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicence agreements with several generic drugs producers to increase the supply of future vaccine, including with the Serum Institute of India (one of the world’s largest vaccine producers),37 Fiocruz in Brazil,38 BioKangtai in China39 and R-Pharm in Russia,40 enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization’s (WHO) COVID-19 Technology Access Pool (CTAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.41 This Pool, similar to Medicines Patent Pool (MPP) – established to pool and distribute generic licences for HIV/AIDS-related treatments – aims to accelerate the scale-up of production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.42 To date, 39 WHO member states and 4 intergovernmental bodies have indicated their support43 and a coalition of 18 generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together to accelerate access to millions of doses of new interventions for COVID-19 for lowand middle-income countries.

Another effort, the Access to Covid-19 Tools (ACT) Accelerator, has raised $5.8 billion from nearly forty countries and over 40 private and non-governmental sources for the deployment tests, treatments and vaccines. 44 COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As of January 2021, COVAX has agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible to access effective and approved vaccines in the first half of 2021.45 At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies.46

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary licence agreements and several newly established global initiatives, it is not only unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic but also unwise as the waiver would stifle cooperative efforts and potentially lead to less availability of needed treatments and vaccines.

 Spec Theory:

Reduce by how much? They are the affirmative and have the only 100% canned speech

This limits fairness by doing so.

Vote Neg on the grounds of fairness