# HC Round 2

**I value morality.**

**The value criterion is minimizing material violence. For clarity, I defend utilitarianism.**

**Prefer for three reasons:**

#### Pleasure and pain are intrinsic factors of moral reasoning

**Moen 16** [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281]

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that **pleasure is intrinsically valuable and pain is intrinsically disvaluable.** On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels,** and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. **If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.**3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that **if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.**

#### Actor specificity— States must use util

**Goodin 90**. Robert Goodin 90, [professor of philosophy at the Australian National University college of arts and social sciences], “The Utilitarian Response,” pgs 141-142

### My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about public officials and their situations that make it both more necessary and more desirable for them to adopt a more credible form of utilitarianism. Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices, but that is all. That is enough to allow public policy-makers to use the utilitarian calculus – assuming they want to use it at all – to choose general rules or conduct.

## Innovation

**Covid-19 has spurred pharmaceutical innovation in the status quo**

**Ramalingam & Prabhu 20** [Ben Ramalingam- Overseas Development Institute, United Kingdom. Jaideep Prabhu University of Cambridge, United Kingdom. “Innovation, development and COVID-19: Challenges, opportunities and ways forward.” OECD. 1 December 2020. Link: <https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/>] JV

Coronavirus (COVID-19) innovation: what is happening? A global perspective At the same time as causing a huge impact on health and livelihoods around the world, COVID-19 has a created fertile breeding ground for novel solutions and approaches (OECD Observatory of Public Sector Innovation, n.d.[2]). The most comprehensive survey of global research and development (R&D) funding commitments for COVID-19, undertaken by the US-based Policy Cures programme, shows that investment in health-related innovation has been unprecedented (Policy Cures, 2020[3]). The scale of innovation resources mobilised globally is remarkable: USD 9 billion in seven months. By comparison, the total global funding disbursed for Ebola R&D between 2014 and 2018 was USD1.9 billion. The nature of the innovation processes that have been deployed is also notable. In the six months since the outbreak began, the US Food and Drug Administration (FDA) has approved almost 100 COVID-19 tests, in contrast to the three months the FDA took to approve the first Ebola test during the 2014 West Africa outbreak. The first COVID-19 vaccine entered into human trials within a record-breaking 69 days of identifying the causative agent of the outbreak[1](https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/#endnotea0z2) – a remarkable achievement, considering that it took 25 months for the first vaccine to reach the human trial stage during the previous global coronavirus outbreak (SARS in 2002–04).

**Waiving patent on COVID-19 vaccine would hurt innovation needed to combat future pandemics**

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

One major concern is a loss of incentives for costly research and development. Pharmaceutical research has a low success rate and requires enormous sums of money. Without the profits generated from intellectual property rights, "there would be no new drugs," as companies would have no hope of recouping their investments, a JPMA spokesperson said. Ito said this raises "concerns about how to respond to future pandemics." Speedy vaccine development, he said, is driven in part by the chance to corner the market. If the patents are to be waived, Ito suggested other steps to spur innovation will be needed, such as establishing a fund to buy such knowledge. But setting prices and deciding how to deal with the technical secrets would be no easy task. Ito said a quicker solution might be for Group of Seven countries to "consider policies to expand production capacity and strengthen the [World Health Organization's] COVAX initiative to purchase and distribute vaccines to developing countries."

**Future pandemics are a non-linear, existential risk---encompasses AND outweighs other threats. Empirically proven by historic epidemics such as the Black Death and Spanish flu**

**Pamlin and Armstrong 15**, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, <https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf> //Re DE EK

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a **large region**; for instance **several continents**, or even **worldwide**. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the **greatest causes of mortality in history**. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a **power law with a small exponent**: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the **single largest pandemic**. **Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.**267 There are other grounds for suspecting that such a highimpact epidemic will have a ***greater probability*** *than* ***usually assumed****.* All the features of an extremely devastating disease **already exist in nature**: essentially **incurable** (Ebola268), nearly always **fatal** (rabies269), **extremely infectious** (common cold270), and **long incubation periods** (HIV271). If a pathogen were to emerge that somehow **combined these features** (and influenza has demonstrated **antigenic shift**, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that **modern transport** and **dense human population** allow infections to spread much more rapidly, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the **ripple effect** of the fatalities and the policy responses. These would include **political and agricultural disruption** as well as **economic dislocation** and damage to the world’s **trade network** (including the food trade). **Extinction risk** is only **possible** if the aftermath of the epidemic **fragments and diminishes human society** to the extent that recovery becomes impossible277 before humanity succumbs to **other risks** (such as **climate change** or **further pandemics**). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in.

## Case

#### Waiving patents on the COVID-19 vaccine would not guarantee generic production and could go on to hurt current production and distribution of the vaccine

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

There is a precedent for this. In the case of AIDS and HIV drugs, prices did drop thanks to relaxed intellectual property protections under the WTO Doha Declaration in 2001 and a related agreement in 2003. Countries suffering from health emergencies were allowed to make patented products without the consent of the patent owners. Countries lacking their own production capabilities were given the option of importing cheaper generics made in places such as India. But in the case of COVID-19 vaccines, information not included in the patents is needed to copy them. And pharmaceutical companies argue the waiver would not immediately mean better access. "Waiving intellectual property rights cannot assure the production of comparable vaccines," George Nakayama, president of the Japan Pharmaceutical Manufacturers Association (JPMA), said in a statement. Nakayama warned that production by more players "may accelerate the shortage of raw materials" and other necessary equipment such as vials -- with no guarantee that the alternative shots would match the originals' quality. Critics also say that materials shortages could make it harder for existing players to increase output, potentially even pushing prices up.

#### No ev IP hurts access, waivers don’t address root problem of capacity and turn—this hurts innovation

Mercurio 21 Bryan Mercurio [Chinese University of Hong Kong - Faculty of Law], 15 March 2021, “WTO Wavier from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review”, https://poseidon01.ssrn.com/delivery.php?ID= 732088024087092091113064080127110089026050064018017000018 0031221260080940690 05111120099022017 06202305700711703012701708109509505 1090012016041007114071124113127008068012087073001083113027126083074031005 001016117022001025118004082004113091069075097031&EXT=pdf&INDEX=TRUE accessed 7/20/2021 EH

. 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

#### Misconception – IP protections won’t help developing countries

Gary Locke, SEPT-8-2021, (Gary Locke, Former U.S. Secretary of Commerce) Weakening IP protections won’t help developing countries fight COVID-19, 9/8/21, Seattle Times https://www.seattletimes.com/opinion/weakening-ip-protections-wont-help-developing-countries-right-now/ //DebateDrills AP

The COVID-19 delta variant is ravaging the world and as of September, a majority of developing countries have vaccinated less than 15% of their populations.

The Biden administration needs to immediately convene an accelerated global vaccination campaign to stop the delta variant — and any new variation that may arise.

In some ways and in some parts of the world, the vaccine rollout has gone better than expected. At this time last year, many people thought it would be years until the world had effective shots. But not only have companies invented multiple inoculations, they’ve pulled out all the stops to maximize production.

The biggest vaccine developers have licensed their formulas and technology for free to generic manufacturers like the Serum Institute of India, which will make 1 billion COVID vaccine doses this year, and Aspen Pharmacare in South Africa, which will make 300 million doses of Johnson & Johnson’s vaccine. Pfizer-BioNTech teamed up with Novartis and Sanofi to expand production, and Johnson & Johnson did the same with Sanofi and Merck.

Despite this cooperation, production capacity is still limited. Every scientist and company that knows how to make the vaccines is already working to scale production. And every facility on earth that can safely and reliably produce shots is doing so. Before COVID, the world’s manufacturers produced about 5 billion vaccine doses annually for such diseases as polio, measles, chickenpox and the flu. Now, in addition to doing that, they need to produce 14 billion COVID shots.

Simply put, current production capacity is maxed out. World leaders must focus on expanding production.

President Biden pledged to donate 580 million doses to other countries. Indeed a few weeks ago, more than 188,000 of those doses were shipped to Rwanda. That’s a welcome step, but we can and must do more.

By the end of 2021, even counting “booster” shots, America will likely have hundreds of millions of surplus doses, while many countries still lack enough shots to vaccinate their populations. We should immediately start sending surplus vaccines to India and other developing countries.

In many countries, though, the barrier isn’t just a lack of vaccines, but a lack of capacity to administer them. The Democratic Republic of the Congo returned 1.3 million doses to COVAX, the global vaccination-sharing initiative, in part because it couldn’t get the doses into rural areas.

To solve such local distribution problems, the U.S. and other wealthy countries could donate ultra-cold-storage freezers to developing countries that otherwise can’t store mRNA vaccines, a new type of vaccine to protect against infectious diseases. We could deploy FEMA teams and even the military to airlift supplies into remote locations, as we have done in past times of natural disasters and famine.

We’re in a war against the coronavirus — we should spare no expense fighting it.

Unfortunately, too much energy is being spent on an initiative that won’t provide immediate relief. The Biden administration announced support for a petition before the World Trade Organization that would suspend intellectual property protections on COVID vaccines.

A suspension is not necessary, given that WTO rules already allow governments to issue compulsory licenses — which require drugmakers to license products to local manufacturers — when doing so would help end a public health crisis. Countries haven’t used this provision to fight COVID because it wouldn’t solve the actual obstacles. Licenses have already been granted around the world.

Likewise, no expert seriously thinks suspending IP protections will boost vaccine supply, given that we’re already maxing out manufacturing capacity. Legal negotiations surrounding the scope of the required tech transfers would stretch into December. And it would take years for new companies to learn to make the vaccines and build specialized factories.

People in developing countries are dying at an alarming rate. They need America and other wealthy nations to do the hard work of expanding manufacturing capacity and distributing vaccines. Some members of Congress seem to think an IP waiver is good politics. But it won’t get shots into arms when people really need it — which is right now.

#### Even if IP was reduced for COVID vaccines, there would be no change in production

**Abbott 21**, Alden Abbott, Alden Abbott is a senior research fellow with the Mercatus Center at George Mason University and formerly served as the Federal Trade Commission’s General Counsel, May 7 2021, National Review, “Waiving IP Protection for COVID Vaccine Is Anti-innovation and Anti-Public Health”<https://www.nationalreview.com/2021/05/waiving-ip-protection-for-covid-vaccines-is-anti-innovation-and-anti-public-health/> Livingston RB

Waiving intellectual property protections (including patents) for COVID-19 vaccines, which, as U.S. trade representative Katherine Tai announced Wednesday, the Biden administration supports, will if implemented prove disastrous for American innovation — and detrimental to public health as well. Patents are property rights that allow inventors to exclude third parties from copying and using novel patented technologies for 20 years from the time a petition for a patent is filed. Patents are particularly important in the medical field, underpinning the “miracle drugs” and vaccines that save and better countless lives. In October 2020, India and South Africa petitioned the World Trade Organization (WTO) to bypass granting or enforcement of all forms of intellectual property (IP) rights (patents, trade secrets, industrial designs) on COVID-19-related drugs, vaccines, diagnostics, and other medical technologies for the duration of the COVID-19 pandemic. IP rights are protected under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement overseen by the World Trade Organization. U.S. support for the petition, announced by Tai, strengthens the prospect for its adoption in upcoming WTO negotiations. Patent rights were key to the unprecedentedly rapid development and rollout of COVID-19 vaccines in 2020. A number of highly successful COVID-19 vaccines (including the Moderna and Pfizer vaccines) came about due to earlier innovative mRNA research that was spurred by patents. Significantly, patents have not affected the mass production of important COVID-19 vaccines. As former U.S. Patent and Trademark Office chief [Andrei Iancu explains](https://www.statnews.com/2021/04/13/no-evidence-patents-slow-vaccine-access/), vaccine makers already have entered into a web of agreements with countries around the world, and “almost every factory on the planet that can make these vaccines is already doing so.” Indeed, patent experts recently indicated that patent-inspired “mRNA vaccines could open the door for the approval of other mRNA-based medicines, creating a wide range of new markets.” Indeed, as Iancu points out, “there’s robust collaboration and cooperation within the industry to ensure that vaccines are made quickly and safely. And patents actually facilitate such cooperation, because each entity can rest assured that its proprietary technology is protected in the long run.”

#### Waiving patents on the COVID-19 vaccine would not guarantee generic production and could go on to hurt current production and distribution of the vaccine

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

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#### Waiving covid patents will start a scramble for resources that will actually slow vaccine production

**Breuninger 21** [Kevin Breuninger: CUNY Graduate School of Journalism. “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues.” CNBC. 7 May 2021. Link: <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] JV

[Pfizer](https://www.cnbc.com/quotes/PFE) CEO Albert Bourla warned Friday that waiving patent protections for Covid vaccines — [a proposal President Joe Biden just endorsed](https://www.cnbc.com/2021/05/05/us-backs-covid-vaccine-intellectual-property-waivers-to-expand-access-to-shots-worldwide.html) — would set off a worldwide race for raw materials that threatens the safe and efficient manufacturing of Covid shots. The Biden administration said Wednesday it supports the limited waiver of intellectual property rules in service of expanding vaccine distribution to the lower-income nations currently being battered by [the pandemic](https://www.cnbc.com/coronavirus/). But Bourla, whose company produces one of three vaccines approved for emergency use in the U.S., said that he believes “categorically” that the waiver proposal will “create more problems.” “Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague [letter posted on LinkedIn](https://www.linkedin.com/pulse/today-i-sent-letter-have-candid-conversation-our-drivers-bourla/?trackingId=d3cDOlWvR4SUfMQpxVeLbw%3D%3D). “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.” Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients. “Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote. He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.” “It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote. “Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.The White House referred CNBC’s outreach on Bourla’s post to the Office of U.S. Trade Representative, which did not immediately respond to a request for comment. World Trade Organization leaders have recently urged member nations to come to an agreement on the potential vaccine patent waivers. But even with the U.S. backing, a deal is hardly guaranteed, since the WTO’s rulings are based on consensus, requiring approval from all 164 members. Germany, a WTO member and the largest economy in Europe, came out against the waiver proposal on Thursday. [BioNTech](https://www.cnbc.com/quotes/BNTX), which partnered with Pfizer in developing the vaccine, is based in Germany. Bourla on LinkedIn also expressed concern that the possible vaccine waivers “will disincentivize anyone else from taking a big risk.” “The recent rhetoric will not discourage us from continuing investing in science. But I am not sure if the same is true for the thousands of small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected,” the CEO wrote.

#### Waivers destroy innovation and can’t solve for low vaccine production

**Siripurapu 21** [Anshu Siripurapu: BA in political economy from the University of Southern California. “The debate over a patent waiver for COVID-19 vaccines: What to know.” Council on foreign relations. 26 May 2021. Link: <https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know>] JV

To opponents, the waiver is a red herring that will do little to improve global vaccine distribution while eliminating incentives for innovation. Pharmaceutical companies, health experts, and some governments argue that IP rules—and the profits they allow—promote the development of breakthrough technologies such as the COVID-19 vaccines. They also say that [low manufacturing capacity](https://finance.yahoo.com/news/us-talks-on-vaccine-patent-waivers-appears-symbolic-experts-214914469.html), not patents, is the biggest impediment to global vaccination efforts. Even if the patents were waived, critics argue, many countries would be unable to produce the vaccines without the technical expertise of the inventors or access to critical ingredients that are already in short supply. Meanwhile, some U.S. lawmakers and experts are leery of allowing China and other rival countries to [obtain essential IP](https://news.bloomberglaw.com/ip-law/china-will-steal-u-s-vaccine-ip-via-waiver-gop-senators-say). Instead of an IP waiver, the United States should [stop hoarding vaccines](https://www.wsj.com/articles/patent-busting-wont-help-vaccinate-the-world-faster-11620591133?reflink=desktopwebshare_twitter) and increase its exports, argue former U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb and former Acting FDA Chief Scientist and CFR Senior Fellow Luciana Borio. In addition, they say, vaccine-producing countries such as Australia, Belgium, France, Japan, and the United Kingdom should invest in a major manufacturing expansion. CFR’s Thomas J. Bollyky and Jennifer Nuzzo say a patent waiver [will not be enough](https://www.worldpoliticsreview.com/articles/29672/building-global-vaccination-capacity-requires-more-than-a-covid-vaccine-patent-waiver), and have urged countries to create a “geographically distributed vaccine manufacturing network” to produce vaccine prototypes for the COVID-19 crisis and future pandemics.

#### The plan can’t solve manufacturing expertise and reduces international distribution.

**Pooley 21** [James Pooley, 5-25-2021, "The Big Secret Behind the Proposed TRIPS Waiver," IPWatchdog, <https://www.ipwatchdog.com/2021/05/25/big-secret-behind-proposed-trips-waiver/id=133905/>] //DD PT

So, this is why a temporary waiver of TRIPS—which would suspend national obligations to enforce IP rights—can’t possibly help countries like India get more vaccines to its citizens. The know-how required to manufacture at scale is owned by the companies like Pfizer and Moderna that are producing doses in record volumes. To effect the demanded “technology transfer,” governments would have to secure the agreement of those companies not just to hand over their entire “cookbook” but also to send qualified scientists and technicians to spend time at the foreign facilities, basically consulting on how to implement the secret processes to produce a safe vaccine. And even if that transfer happened tomorrow, getting to the point of actually manufacturing in volume would take more than a year. Not only would the TRIPS waiver not produce the results the proponents want, it would likely reduce the current level of international distribution of vaccines, by interfering with access to the limited supplies of required ingredients. In fact, this supply chain disruption was recently cited by none other than the government of India in pushing back against popular demands for a compulsory license on Gilead’s Remdesivir and other COVID-19 treatments, noting that the “main constraint” was not intellectual property rights but preventing competition for scarce “raw materials and other essential inputs.”

#### The plan doesn’t do anything – most pharmaceutical companies are already mass manufacturing vaccines.

Wright 21 [Elizabeth Wright, 5-10-2021, "Biden Trips Badly on Intellectual Property in TRIPS," Citizens Against Government Waste, <https://www.cagw.org/thewastewatcher/biden-trips-badly-intellectual-property-trips>] //DD PT

The waiver is not only dangerous, it is also superfluous, because Johnson & Johnson, Moderna, and Pfizer are already producing tens of millions of doses of vaccines and gearing up to produce more, and all have plans to distribute them around the world without any need for the WTO to intervene or allow their IP to be stolen. Moderna [stated](https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-agreement-sanofi-fillfinish-manufacturing) on April 26 that it was working with Sanofi to produce 200 million doses by September 2021 and [announced](https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-gavi-500-million-doses-covid) on May 3 a supply agreement with Gavi (the Vaccine Alliance that supplies vaccines to the COVAX Facility) to make up to 500 million doses to help end the pandemic in the lowest income countries. Moderna is [also](https://www.expresspharma.in/covid19-updates/who-issues-emergency-use-listing-for-modernas-covid-19-vaccine/) working with the World Health Organization for the emergency use of their vaccine and UNICEF to help with distribution of vaccines. Pfizer is in the [process](https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-supply-us-100-million-additional-doses) of delivering 200 million doses in the U.S. by July 31, 2021 and [stated](https://news.yahoo.com/pfizer-supply-4-5-million-174132337.html) on May 2 it would be shipping 4.5 million doses of its COVID-19 vaccine to South Africa by June. While the company is still [waiting](https://www.msn.com/en-us/news/politics/pfizer-ceo-discussing-expedited-vaccine-approval-with-india/ar-BB1gk2qO) for India to register its COVID-19 vaccine (making it highly suspicious that the waiver is simply an attempt to steal the patents since it would be faster to finalize approval), Pfizer is already [sending](https://www.msn.com/en-us/news/politics/pfizer-ceo-discussing-expedited-vaccine-approval-with-india/ar-BB1gk2qO) other free medicines to assist their public hospitals in fighting COVID-19. Johnson & Johnson, in spite of some setbacks, resumed production on April 23 and had administered [6.8 million](https://www.baltimoresun.com/coronavirus/bs-hs-jj-returns-in-maryland-20210430-zabqvbxhwrb3dpswdtthehl3be-story.html) single-shot doses.

**Patent waiver doesn’t solve; patents don’t contain manufacturing instructions**

**Turner and Rourke 21**, Mark Eccleston-Turner and Michelle Rourke, American Society of International Law, “The TRIPS Waiver is Necessary, but it Alone is not Enough to Solve Equitable Access to COVID-19 Vaccines” May 21st 2021, Insights Volume 23 Issue 9<https://www.asil.org/insights/volume/25/issue/9> Livingston RB

Unlike chemical pharmaceuticals (most drugs**), vaccines are large-molecule biological products requiring a great deal of information and know-how to manufacture—information that is not disclosed through patents.** Thus, **waiving patent rights alone will not enable new manufacturers to come online**. The initial text of the proposed waiver by India and South Africa recognizes the crucial role that know-how plays in vaccine manufacturing capacity. However, unlike with patent rights, **there is no** clear, easy **fix contained within the proposed waiver, and pharmaceutical companies will likely strenuously resist such technology transfer. Without knowledge transfer, it will be** extremely **difficult** for LMICs **to start COVID-19 vaccine manufacturing, regardless of the removal** of patent barriers from the **TRIPS** waiver.The TRIPS Agreement recognizes the importance of technology transfer through its Objectives, and Article 66.2 of TRIPS states that "developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." The WHO has set up a mRNA technology transfer hub to provide a mechanism to facilitate the sharing of know-how related to manufacturing mRNA vaccines, but **none of the technology holders have** thus far **engaged** with the hub. This is reflective of wider efforts by **the WHO to** facilitate the **transfer** of **technology from established** vaccine **manufacturers to new manufacturers in developing countries**. In recent history this was most notably attempted through the WHO's Pandemic Influenza Preparedness Framework (PIP Framework), where the WHO has attempted to use multilateral access and benefit-sharing arrangements to negotiate the sharing of technology in the field of pandemic vaccine manufacturing. To this end, pandemic influenza vaccine manufacturers who wish to receive influenza virus samples from the WHO's network of specialized laboratories must sign a contract with the WHO called a Standard Material Transfer Agreement, committing to at least two of the following options:

#### A waiver can’t solve for supply shortages – the squo sufficiently solves vaccine production but a waiver will disrupt supply chains.

Zarocostas 21, Zarocostas, J., 2021. What next for a COVID-19 intellectual property waiver?. *The Lancet*, *397*(10288), pp.1871-1872., <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01151-X/fulltext?utm_campaign=WR&utm_content=167900285&utm_medium=social&utm_source=twitter&hss_channel=tw-27013292>, Debatedrills AS

Intellectual property industry consultants and health diplomats say the waiver will not solve the immediate problem of the huge shortfall in vaccine production aggravated by vaccine nationalism, hoarding of supplies, and poor sharing or donation of COVID-19 vaccines.

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

Thomas Cueni, director-general of the International Federation of Pharmaceutical Manufacturers and Associations, told *The Lancet*that “The waiver would also put into question the framework that gives companies the trust to sign contracts with other manufacturers they voluntarily collaborate with. The **waiver** is at best a distraction, at worst it will disrupt the supply chain and divert scarce resources.”

No coercion was needed, Cueni noted, to encourage the setting up of more than 280 partnerships and collaborations among vaccine manufacturers worldwide. “As a result COVID-19 vaccine production capacity has been scaled up in a matter of months from zero to 1·7 billion in April, and it is anticipated that 11·6 billion COVID-19 vaccine doses will be produced by the end of 2021.”

For technologies, such as medicines, 't Hoen has noted, an intellectual property waiver would be sufficient to allow generic production. However, for vaccines, in addition to the intellectual property “you need additional technology transfer or access to materials such as cell lines. Some of those may be in the public domain. But if not the original company or research institute would have to provide this”.

#### Lack of a clear consensus on the COVID waiver decks any risk of solvency – scope, timeframe and negotiation stalemates all prove.

Mercurio 21, Mercurio, B. The IP Waiver for COVID-19: Bad Policy, Bad Precedent. *IIC* (2021). <https://doi.org/10.1007/s40319-021-01083-5>, //Debatedrills AS

Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the **WTO** are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[Footnote 10](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn10) Issues of negotiation will include **the scope** of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[Footnote 11](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[Footnote 12](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[Footnote 13](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[Footnote 14](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[Footnote 15](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations.

The waiver is inefficient -**Moderna proves**

**Silverman 21**, Rachel Silverman, Policy Fellow at the Center For Global Development, Center for Global Development “Would Exempting COVID-19 Vaccines from Intellectual Property Rights Improve Global Access and Equity?”<https://www.cgdev.org/debate/would-exempting-covid-19-vaccines-intellectual-property-rights-improve-global-access> Livingston RB

With thanks to our contributors and commentators, I think this debate has generated greater clarity and nuance—if not necessarily consensus—about whether IP poses a meaningful barrier to COVID-19 vaccine access. We largely agree that knowledge-sharing and tech transfer are the crux of the IP issue—not patents and legal strictures per se**. Moderna**, for example, **has waived IP enforcement for COVID-19 vaccines but has not widely shared its know-how; without the latter, the former action has not generated any generic production.** We are left, in that case, with two broad areas of disagreement and/or uncertainty. First, is an IP waiver important as a first step and/or symbolic gesture, even if it will have limited impact without broader knowledge sharing? Some have argued “yes”—that it provides legal clarity to protect generic manufacturers against retribution and signals a shared commitment to human life and health over company profits and wealthy-country interests. From my perspective, I continue to feel largely agnostic on this point. I recognize the symbolic value and I’m not opposed to **the waiver** per se¸ but given its relatively low impact I continue to think it **is an inefficient use of limited** global advocacy/political **capital for vaccine access**.

#### IP hurts access, waivers don’t address root problem of capacity and turn—this hurts innovation

Mercurio 21 Bryan Mercurio [Chinese University of Hong Kong - Faculty of Law], 15 March 2021, “WTO Wavier from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review”, https://poseidon01.ssrn.com/delivery.php?ID= 732088024087092091113064080127110089026050064018017000018 0031221260080940690 05111120099022017 06202305700711703012701708109509505 1090012016041007114071124113127008068012087073001083113027126083074031005 001016117022001025118004082004113091069075097031&EXT=pdf&INDEX=TRUE accessed 7/20/2021 EH

. 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