# Greenhill R4 – 1AC v Immaculate Heart BC

### Framing

#### Ethics must begin a priori:

#### [A] Naturalistic fallacy – experience only tells us what is since we can only perceive what is, not what ought to be. But it’s impossible to derive an ought from descriptive premises, so there needs to be additional a priori premises to make a moral theory.

#### [B] Empirical uncertainty – evil demon could deceive us, dreaming, simulation, and inability to know others’ experience make empiricism an unreliable basis for universal ethics. Outweighs since it would be escapable since people could say they don’t experience the same.

#### [C] Constitutive Authority – practical reason is the only unescapable authority because to ask for why we should be reasoners concedes its authority since it uses reason – anything else is nonbinding and arbitrary.

#### [D] Action theory – only evaluating action through reason solves since reason is key to evaluate intent, otherwise we could infinitely divide actions. For example: If I was brewing tea, I could break up that one big action into multiple small actions. Only our intention, to brew tea unifies these actions if we were never able to unify action, we could never classify certain actions as moral or immoral since those actions would be infinitely divisible.

#### Next, the relevant feature of reason is universality – any non-universalizable norm justifies someone’s ability to impede on your ends i.e. if I want to eat ice cream, I must recognize that others may affect my pursuit of that end and demand the value of my end be recognized by others which also means universalizability acts as a side constraint on all other frameworks. It’s impossible to will a violation of freedom since deciding to do would will incompatible ends since it logically entails willing a violation of your own freedom

#### Thus, the standard is consistency with the categorical imperative. Prefer:

**[1] Consequences fail: [A] They only judge actions after they occur, which fails action guidance [B] Every action has infinite stemming consequences, because every consequence can cause another consequence. Probability doesn’t solve because 1) Probability is improvable, as it relies on inductive knowledge, but induction from past events can’t lead to deduction of future events and 2) Probability assumes causation, we can’t assume every act was actually the cause of tangible outcomes [C] Every action is infinitely divisible, only intents unify action because we intend the end point of an action – but consequences cannot determine what step of action is moral or not. [D] You can’t aggregate consequences, happiness and sadness are immutable – ten headaches don’t make a migraine**

**[2] Performativity**

#### [3] Ethical frameworks are topicality interpretations of the word ought so they must be theoretically justified. Prefer on resource disparities—focusing on evidence and statistics privileges debaters with the most preround prep excluding lone-wolfs who lack huge evidence files. A debater under my framework can easily be won without any prep since minimal evidence is required. That controls the internal link to other voters because a pre-req to debating is access to the activity.

### Advocacy

#### Plan text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines during pandemics.

#### Enforcement through limited IP waivers solve – patent term extensions are normal means and solves innovation and scale-up.

Young and Potts-Szeliga 21 [Roberta; Counsel in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Los Angeles; Jamaica Potts-Szeliga; Partner in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Washington, DC. She also provides advice on FDA regulatory issues and is part of the firm’s Health Care, Life Sciences, and Pharmaceuticals team; “A Third Option: Limited IP Waiver Could Solve Our Pandemic Vaccine Problems,” IP Watch Dog; 7/21/21; <https://www.ipwatchdog.com/2021/07/21/third-option-limited-ip-waiver-solve-pandemic-vaccine-problems/id=135732/>] Justin

Limited Waiver Approach

This article suggests a third option, between voluntary vaccine donation and the full IP waiver proposal, that may offer a way forward. The third proposed solution is incentivized limited IP waivers that could encourage (or require) private companies to engage in licensing agreements with nations to share some, but not all, of the knowledge and designs covering the COVID-19 vaccines to the developing world. The limited IP waivers could cover the minimum necessary portions of the technology to produce basic COVID-19 vaccines. The waivers could be limited in time to the duration of the pandemic, or another term agreed to by the WTO. The term could also be defined as ending when widespread vaccination and immunity goals are achieved. The incentive for pharmaceutical companies to support such limited IP waivers could be provided in the form of patent term extensions for the technology covered by the limited IP waivers.

Extensions of patent term are already known and widely used. In the U.S., patent term adjustments are automatically added on to the patent lifespan to account for any delays by the USPTO in the patent prosecution process. In some cases, these mechanisms may extend the patent term for years. Patent term extensions also are available for regulatory delays (35 U.S.C. § 156). In particular, patents covering, inter alia, drug products approved by the United States Food & Drug Administration may be eligible for up to five years of additional patent term to give back time required to complete the regulatory review process. Both patent term adjustments and patent term extensions arise from activities beyond the control of the pharmaceutical companies. A pandemic patent term extension fashioned after such known extensions could be made used to compensate for the current pressing global health needs.

This third proposal may be achievable at the WTO. Hurdles remain and it could be months or years before the WTO reaches an agreement on any waiver of IP protections, and years before countries build factories, gather materials, and gain the expertise to produce the vaccines. A steep hurdle is that mRNA is a new technology, with no machines or experts for hire. Nonetheless, the third solution offers hope to find a middle ground that may begin to be implemented before the end of the current pandemic and be in place for the future.

The patent term extension could be provided for countries with patent offices and could be adapted based on laws and conditions in each country. Pandemic-related patent term extensions could be given for a period of time that the compulsory license is in force. With current pandemic projections of six months to two years for sufficient distribution, providing a patent term extension is reasonable and in line with the time period of many patent term extensions. Given that most pharmaceutical patents are prosecuted in multiple countries, this provides an incentive to participate in a limited waiver program.

Let’s Not Repeat Past Mistakes

It’s been a century since the last pandemic devastated the globe and the only certainty is that this will not be the last pandemic. Solutions created today lay a foundation for mitigation of the next pandemic. It’s been said that those who refuse to learn from history are doomed to repeat it, a thought too painful to contemplate with a pandemic. The industrial nations of the world have technology that others are literally dying to obtain—a high price to pay. Incentivized limited IP waivers may offer a compromise to bridge the gap between maintaining IP rights (and thus relying on charity alone) and arbitrary compulsory licensing that could deter the technological investment to create life-saving solutions in the future.

### Offense

#### [1] IPP unjustifiably restricts agents from setting and pursuing ends in healthcare because patents prevent people from taking part in scientific advancements in medicine – that violates freedom in multiple ways

**Hale 18** (Zachary Hale, 4-4-2018, accessed on 8-22-2021, The Arkansas Journal of Social Change and Public Service, "Patently Unfair: The Tensions Between Human Rights and Intellectual Property Protection - The Arkansas Journal of Social Change and Public Service", <https://ualr.edu/socialchange/2018/04/04/patently-unfair/>) BHHS AK

Although the right to the protection of “moral and material interests resulting from any scientific, literary, or artistic production,”[32] is a human right as defined in the UDHR and the ICESCR, the current system of intellectual property protection conflicts with and even violates rights that are considered to be fundamental to human life. Although intellectual property instruments are certainly used to violate essential civil and political freedoms like the freedom of expression, and economic and social freedoms like the freedom to share in the scientific advancements of society, the most blatant violations of human rights caused by intellectual property protection occur in the fields of nutrition, healthcare, and culture.[33] Of these essential entitlements, the rights to food and health are made even more significant by their relationship to the most fundamental of all human rights: the right to life.

#### [2] IPP is inconsistent with free market principles

**Kinsella 11** (Stephan Kinsella, 5-25-2011, accessed on 8-23-2021, Foundation for Economic Education, "How Intellectual Property Hampers the Free Market | N. Stephan Kinsella", <https://fee.org/articles/how-intellectual-property-hampers-the-free-market/>) BHHS AK

But are they? There are good reasons to think that IP is not actually property—that it is actually antithetical to a private-property, free-market order. By intellectual property, I mean primarily patent and copyright. It’s important to understand the origins of these concepts. As law professor Eric E. Johnson notes, “The monopolies now understood as copyrights and patents were originally created by royal decree, bestowed as a form of favoritism and control. As the power of the monarchy dwindled, these chartered monopolies were reformed, and essentially by default, they wound up in the hands of authors and inventors.” Patents were exclusive monopolies to sell various goods and services for a limited time. The word patent, historian Patricia Seed explains, comes from the Latin patente, signifying open letters. Patents were “open letters” granted by the monarch authorizing someone to do something—to be, say, the only person to sell a certain good in a certain area, to homestead land in the New World on behalf of the crown, and so on. It’s interesting that many defenders of IP—such as patent lawyers and even some libertarians—get indignant if you call patents or copyright a monopoly. “It’s not a monopoly; it’s a property right,” they say. “If it’s a monopoly then your use of your car is a monopoly.” But patents are State grants of monopoly privilege. One of the first patent statutes was England’s Statute of Monopolies of 1624, a good example of truth in labeling. Granting patents was a way for the State to raise money without having to impose a tax. Dispensing them also helped secure the loyalty of favorites. The patentee in return received protection from competition. This was great for the State and the patentee but not for competition or the consumer. In today’s system we’ve democratized and institutionalized intellectual property. Now anyone can apply. You don’t have to go to the king or be his buddy. You can just go to the patent office. But the same thing happens. Some companies apply for patents just to keep the wolves at bay. After all, if you don’t have patents someone might sue you or reinvent and patent the same ideas you are using. If you have a patent arsenal, others are afraid to sue you. So companies spend millions of dollars to obtain patents for defensive purposes. Large companies rattle their sabers or sue each other, then make a deal, say, to cross-license their patents to each other. That’s fine for them because they have protection from each other’s competition. But what does it do to smaller companies? They don’t have big patent arsenals or a credible countersuit threat. So patents amount to a barrier to entry, the modern version of mercantilist protectionism. What about copyright? The roots literally lie in censorship. It was easy for State and church to control thought by controlling the scribes, but then the printing press came along, and the authorities worried that they couldn’t control official thought as easily. So Queen Mary created the Stationer’s Company in 1557, with the exclusive franchise over book publishing, to control the press and what information the people could access. When the charter of the Stationer’s Company expired, the publishers lobbied for an extension, but in the Statute of Anne (1710) Parliament gave copyright to authors instead. Authors liked this because it freed their works from State control. Nowadays they use copyright much as the State originally did: to censor and ban books. (More below.) IP, American Style The American system of IP began with the U.S. Constitution. Article 1, Section 8, Clause 8 authorizes (but doesn’t require) Congress “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Despite modern IP proponents’ claims to the contrary, the American founders did not view intellectual property as a natural right but only as a policy tool to encourage innovation. Yet they were nervous about monopoly privilege, which is why patents and copyrights were authorized only for a limited time. Even John Locke, whose thought influenced the Founding Fathers, did not view copyright and patent as natural rights. Nor did he maintain that property homesteading applied to ideas. It applied only to scarce physical resources. Granted, some state constitutions had little versions of copyright before the American Constitution. (See Tom W. Bell, Intellectual Privilege: Copyright, Common Law, and the Common Good, part 1, chapter 3, section B.1.) On occasion, the language of natural rights was used to defend it, but this was just cover for the monopolies they granted to special interests. Natural rights do not expire after 15 years. Natural rights are not extended to Americans only. Natural rights wouldn’t exclude many types of innovation and intellectual creativity and cover only a few arbitrary types. And what is the result of this system? In the case of patents we have a modern statute administered by a huge federal bureaucracy that grants monopolies on the production and trade of various things, which means holders may ask the federal courts to order the use of force to stop competitors. But the competitors have not done anything that justifies force. They merely have used information to guide their actions with respect to their own property. Is that compatible with private property and the free market?

#### That affirms: Free market economies are the only ones that allow people to be free to pursue their own interests.

**Richman 12** [Sheldon Richman, 8-5-2012, "The Free Market Doesn't Need Government Regulation," Reason, <https://reason.com/2012/08/05/the-free-market-doesnt-need-government-r/>] // SJ AME

What regulates the conduct of these people? Market forces. (I keep specifying "in a freed market" because in a state-regulated economy, competitive market forces are diminished or suppressed.) Economically speaking, people cannot do whatever they want—and get away with it—in a freed market because other people are free to counteract them and it's in their interest to do so. That's part of what we mean by market forces. Just because the government doesn't stop a seller from charging $100 for an apple doesn't mean he or she can get that amount. Market forces regulate the seller as strictly as any bureaucrat could—even more so, because a bureaucrat can be bribed. Whom would you have to bribe to win an exemption from the law of supply and demand? (Well, you might bribe enough legislators to obtain protection from competition, but that would constitute an abrogation of the market.) It is no matter of indifference whether state operatives or market forces do the regulating. Bureaucrats, who necessarily have limited knowledge and perverse incentives, regulate by threat of physical force. In contrast, market forces operate peacefully through millions of cooperating participants, each with intimate knowledge of her own personal circumstances and looking out for her own well-being. Bureaucratic regulation is likely to be irrelevant or (more likely) inimical to what people in the market care about. Not so regulation by market forces.

#### [3] IPP is nonuniversalizable – universalizing the act of restricting the production of a certain medicine terminates in a contradiction because it entails that you restrict your own ability to produce the medicine

### Underview

#### [1] Permissibility and presumption affirm: [A] Negating an obligation requires proving a prohibition – they prohibit the aff action. [B] If agents had to reflect on every action they take and justify why it was a good one we would never be able to take an action because we would have to justify actions that are morally neutral.

**[2] Aff gets 1AR theory and RVIs – otherwise the neg can be infinitely abusive and there’s no way to check against this**

**1AR theory is drop the debater, competing interps, and the highest layer of the round – [A] the 1ARs too short to be able to rectify abuse and adequately cover substance, [B] they get to go for their shell and beat back mine in the long 2NR but the 2AR is too short to do both**

### Advantage 1: COVID

#### Only the plan can solve covid access – inequalities heighten the risk of mutations and uneven development – neg objections miss the boat.

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According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11 Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14 This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution. TRIPS: Barrier to Equitable Health Care Access The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16 Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19 A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21 The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding. Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines. One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally. India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing. Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic. India’s Role in Ensuring Vaccine Equity India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver. India’s Vaccine Maitri initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.29 The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries’ regulatory bodies approve the vaccine. If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed. Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country’s generic medicine industry and boost India’s economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines’ production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics. Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's Vaccine Maitri initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region. In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

#### Yes scale-up for covid.

Erfani et al 21 [Parsa; Lawrence Gostin; Vanessa Kerry; Parsa Erfani is a Fogarty Global Health Scholar at Harvard Medical School and the University of Global Health Equity. Lawrence Gostin is a professor at Georgetown University Law Center, director of the school’s O’Neill Institute for National and Global Health Law, and director of the World Health Organization Center on National and Global Health Law. Vanessa Kerry is a critical care physician at Massachusetts General Hospital, director of the Program for Global Public Policy at Harvard Medical School, and CEO of Seed Global Health, a nonprofit that trains health workers in countries with critical shortages; “Beyond a symbolic gesture: What’s needed to turn the IP waiver into Covid-19 vaccines,” STAT; 5/19/21; <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/>] Justin

Currently many idle suppliers can’t begin vaccine production until they upgrade and repurpose existing manufacturing capacity for new technology. Opponents often argue that this step is the true barrier to rapid scale-up. One high-profile detractor, BIO President and CEO Michelle McMurry-Heath, argues that “handing [needy countries] the blueprint to construct a kitchen that — in optimal conditions — can take a year to build will not help us stop the emergence of dangerous new Covid variants.”

This argument ignores two core truths: In many cases, manufacturing capacity needs only repurposing which can take mere months. And Covid-19, at the current global response and vaccination rates, will be a threat for years.

Both truths suggest that we pass the blueprint and build the kitchen.

Facilitating structures to transfer technology and capacity are already in place. The WHO launched the mRNA technology transfer hub model last month to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up vaccine manufacturing capacity. Scores of manufacturers in these countries have already expressed interest. This initiative, however, requires recipient manufacturers to acquire the IP necessary for mRNA technologies— which is currently missing.

#### Independently strategic patenting harms innovation incentives during pandemics – encourages reproduction of generics and decrease breakthroughs.

Gurgula 20 [Olga; Lecturer in Intellectual Property Law at Brunel Law School, Brunel University London. She is also a Visiting Fellow at the Oxford Martin Programme on Affordable Medicines, University of Oxford; “Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?” Springer Link; 10/28/20; <https://link.springer.com/article/10.1007/s40319-020-00985-0#Sec4>] Justin

As the COVID-19 pandemic is sweeping through the world, thousands of people urgently need access to affordable medicines. Based on past experience of treatments for other life-threatening diseases, there is a fear that access to any vaccines and treatment that may be developed in the future will be affected by patents, leading to unaffordably high prices. However, the problem of high drug prices is not new. It had been inflating healthcare budgets and posing a serious risk to the affordability and accessibility of medicines for society well before the pandemic.Footnote3 This problem is further exacerbated by the fact that, despite the alleged surge in investments into pharmaceutical R&D, current statistics indicate that the number of new breakthrough medicines is decreasing.Footnote4 On the other hand, the number of drugs that contain modifications of existing medicines is growing, demonstrating that pharmaceutical companies have been increasingly focusing their research on incremental drug development, rather than on breakthrough innovation.Footnote5 Various reasons for high drug prices and the growing focus on incremental innovation are put forward by pharmaceutical companies, including the complexity of drug discovery and development, as well as the expensive and lengthy regulatory procedures involved.Footnote6 While these reasons play an important role in this regard, some practices by pharmaceutical companies substantially contribute to this problem.Footnote7 In particular, pharmaceutical companies have been increasingly engaging in strategic patenting to delay or even block generic competition.Footnote8 These practices attracted the attention of the European Commission, which discussed them more than a decade ago in its 2009 Pharmaceutical Sector Inquiry Report.Footnote9 The Commission identified a series of patent strategies which it described as aiming “to extend the breadth and duration of [originators’] patent protection”Footnote10 and “to delay or block the market entry of generic medicine”.Footnote11 Such findings have fuelled debates as to whether these strategies may be deemed unlawful and violate EU competition rules, while also being justifiable business practices under patent law. Until today, no agreement has been reached either on the legality of these practices, or on an efficient legal tool to assess them. As a result, despite there being solid evidence that such strategies may block generic competition, allowing originators to maintain artificially high drug prices and preventing patients from accessing cheaper generics, they remain outside the ambit of the Commission’s activities. Instead, the Commission has been focusing on more straightforward patent-related practices, such as reverse payment agreements. This article argues that strategic patenting by pharmaceutical companies requires a long-overdue intervention by competition authorities. It aims to attract their attention to the harmful effects of strategic patenting. Specifically, it will contest the argument traditionally put forward by originator pharmaceutical companies that the intervention of competition law into patenting practices will reduce their incentives to innovate. The paper will argue to the contrary that, along with a more immediate negative effect in the form of high drug prices that is widely explored in the literature,Footnote12 strategic patenting also affects dynamic competition by stifling innovation. Importantly, it will be explained that the assessment of the effect of this practice should focus not only on innovation by originators, but should also take a wider market perspective by assessing its effect on follow-on innovation by generic companies. The latter argument is often overlooked. The paper will outline the current approach to strategic patenting that considers this practice lawful, and will provide arguments for the intervention of competition law. This, in turn, will open the possibility for competition authorities to investigate this practice in order to prevent its harmful effect on innovation and consumer welfare. Moreover, while patent law may provide certain mechanisms to deal with strategic patenting, such as raising the bar for patentability of pharmaceutical follow-on inventions,Footnote13 these tools may not be effective in all cases. Therefore, as will be explained further, competition law may be a more suitable tool to address the negative effects of strategic patenting.Footnote14 The article will be organised as follows. It will first discuss the complex structure of the pharmaceutical industry, focusing on its key players for the purpose of this article: originators and generic companies. It will further explore patenting practices employed by pharmaceutical companies and will define the notion of strategic patenting. The article will then argue that the latter strategy is against the rationale of patent and competition laws, as it stifles competition by impairing incentives to innovate of both originators and generic companies. Finally, it will discuss the current approach to strategic patenting that considers this practice lawful, and will argue that it should be subject to scrutiny under the rules of competition law, to address its negative effects. Pharmaceutical Innovation and Generic Competition in the Pharmaceutical Industry The pharmaceutical industry is unique in its complexity. It is characterised by heavy state regulation and, sometimes, by the competing interests of the pharmaceutical business and society. It also involves multiple actors, including originators,Footnote15 marketing authorisation bodies, generic companies,Footnote16 doctors, pharmacies and patients. Each of them plays their part in the lengthy and complicated process of transforming a chemical compound into an effective and affordable medicine, which is then prescribed, dispensed and consumed. In these complex relationships, the two key players have crucial roles. On the one hand, originators play an important role in developing new and improved medicines for the benefit of society. On the other hand, generic companies benefit society by supplying cheaper equivalents of the originators’ medicines, which leads to the reduction of drug prices and facilitates access to affordable medicines. When the interests of these two players are kept in balance, benefits are maximised for society, which receives innovative and improved medicines, as well as timely access to generic drugs. However, if the balance swings towards one of the players, then society loses out, as there will be insufficient access to either innovative or affordable medicines. Therefore, both pharmaceutical innovation and generic competition must be duly incentivised and protected. Moreover, these two elements of the pharmaceutical industry are constantly interacting and have a profound impact on each other. In particular, pharmaceutical innovation is the backbone of the pharmaceutical industry, in which originators play an important role. The process of drug development is long and complicated, requires significant investments, and bears considerable commercial risks.Footnote17 It is also highly regulated, including, among other things, the requirement for originators to obtain a special authorisation from a designated state authority to market a drug. Such marketing authorisations are granted to the originators only if they can prove that the drug is safe and effective, which typically requires lengthy and expensive clinical trials.Footnote18 In order to protect these significant efforts and investments, pharmaceutical companies rely heavily on the exclusivity granted by intellectual property rights, and in particular, patents.Footnote19 Patents provide a 20-year monopoly right, during which a pharmaceutical company enjoys market exclusivity and can charge a monopoly price for its products. Originators argue that strong patent protection is essential in order to recoup investments, as well as to incentivise them to engage in further innovation.Footnote20 Once such patent protection expires, however, other companies may develop generics of a branded drug, and start competing with the originator for the market. This is called generic competition. Generic drugs are bioequivalent versions of a branded drug that has lost its patent protection.Footnote21 It is estimated that the generic entry typically leads to, on average, an 80 per cent market share loss and a 20–30 per cent reduction of a drug price, with further price decreases with each additional generic entrant, leading, in some instances, to a fall in price of up to 90 per cent.Footnote22 A representative example of the effect of generic competition on the originators’ drug prices is the significant decrease in price and dramatic loss of profits by Eli Lilly. The expiration of a patent protecting its blockbusterFootnote23 antidepressant Prozac in 2001 resulted in a loss of almost 70 per cent of its market and $2.4 billion in annual U.S. sales.Footnote24 This effect of generic competition is beneficial for society, as it reduces the financial pressure on healthcare budgets and increases the accessibility of drugs. Patenting Practices by Pharmaceutical Companies As was mentioned above, generic competition is prevented during the life of a patent protecting an active compound of a drug (a so-called “basic” or “primary” patent).Footnote25 Such a basic patent covers an active ingredient itself and, therefore, provides the strongest protection for the product. Therefore, generic competition normally starts only after the basic patent expires, or if a generic company succeeds in invalidating it. While in the past pharmaceutical companies mainly protected their products with a single patent covering an active compound,Footnote26 they now increasingly seek additional patent protection on various aspects of a drugFootnote27 in order to protect their market position.Footnote28 Such additional patents are often called secondary patents.Footnote29 A pharmaceutical company may want to obtain secondary patents, which protect such aspects of a drug as, for example, its process of manufacture, formulation and/or specific form, etc. Therefore, even after the basic patent protecting an active compound expires, a drug may still be protected by other secondary patents. This may result in the extension of the scope and length of the protection of a product, especially if secondary patents have a later expiration date than a basic patent.Footnote30 This, in particular, may occur if, for example, the process of producing an active compound disclosed in the basic patent is sufficient only for reproducing this compound in a laboratory, but it is unsuitable for producing it on a large commercial scale.Footnote31 If the originator was able to secure a secondary patent that protects such a large scale manufacturing process, it would prevent generics from using this process for producing their generic versions of a drug; otherwise they would risk infringing this secondary patent.Footnote32 However, a unique feature of pharmaceuticals is that an active ingredient can be manufactured using different methods and processes, can exist in different forms or can be used in different formulations. Therefore, when a basic patent on an active ingredient expires, other companies can develop alternative methods of production, forms or formulations of this active compound and start competing with the originator company.Footnote33 While such patenting strategies by originators are lawful in principle, some of them may be problematic. In particular, in anticipation of the loss of patent protection, originators may engage in strategic patenting which artificially prevents generic competition and results in an extension of their market monopoly.Footnote34 Defining Strategic Patenting In its Sector Inquiry Report, the European Commission explained that the drug development process consists of three main stages: (i) the R&D stage, which ends with the launch of a drug on the market; (ii) the period between the launch and the patent expiry; and (iii) the period after the patent expiration, when generics can enter the market.Footnote35 During the second stage, i.e. after the launch of a drug, originators seek to maximise their income from the product in order to recoup their R&D investments and earn profits before the commencement of generic competition.Footnote36 It is also during this stage that pharmaceutical companies seek to prolong their market exclusivity. In recent years, pharmaceutical companies have been increasingly relying on the strategic use of the patent system to combat the pressure of generic competition. Such practices are often called “life cycle management” by originators and proponents of the practice. For example, as Burdon and Sloper explained, “[a] key element of any life cycle management strategy … is to extend patent protection beyond the basic patent term for as long as possible, by filing secondary patents which are effective to keep generics off the market”.Footnote37 However, critics have characterised the practice as “evergreening”,Footnote38 as it essentially evergreens the patent protection and the exclusivity of a product.Footnote39 For instance, Bansal et al. explain that evergreening “refers to different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly, particularly over highly lucrative ‘blockbuster’ drugs, by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the ‘parent’ patent”.Footnote40 During its investigation into the pharmaceutical industry, the European Commission found that the number of patents granted and pending applications significantly increases with the value of a drug, i.e. “blockbuster medicines can even be protected by up to nearly 100 INNFootnote41-specific EPO patented bundles and applications …, which in one particular case led to 1,300 patents and applications across all the EU Member States”.Footnote42 The Commission also found that the ratio of primary to secondary patents is 1:7, where the latter “mostly concern formulations, processes and non-formulation products…, such as salts, polymorphic forms, particles, solvates and hydrates”.Footnote43 As a result, the Commission concluded that the practice of “maximising patent coverage in such a way is the creation of a web of patents”, which affects the generics’ ability to “develop a generic version of the medicine in form of a salt, crystalline or amorphous form”, because it “would inevitably infringe a patent (for example, a patent for the relevant salt, crystalline or amorphous form of the medicine)”.Footnote44 Each of such patents would typically have a later expiration date, which effectively extends a period of market exclusivity beyond the expiration of a basic patent.Footnote45 In addition, most of these patents that protect such follow-on modifications are so-called “sleeping” patents, i.e. patents which a company has no intention of commercialising.Footnote46 Moreover, such modifications may provide little or no therapeutic benefits to the patient compared to the original drug.Footnote47 Nevertheless, such patents allow originators to secure the most efficient, broadest and longest possible protection for their successful products.Footnote48 The denser the web of secondary patents, the more difficult it is for generics to develop their generic equivalents, even if they know that only a few patents of a large portfolio would, in fact, be valid and infringed by their products.Footnote49 Despite such knowledge, it is impossible to be certain before introducing a generic whether this will be the case and, thus, whether the generic company will be subject to injunctions preventing the sale of their generic products.Footnote50 Such practice, therefore, provides an appreciable competitive advantage for originators by creating a significant legal and commercial uncertainty for generics in relation to the possibility of their market entry.Footnote51 This paper argues that such a strategic use of the patent system by pharmaceutical companies is against the shared goal of patent and competition laws of facilitating innovation for the benefit of society. As will be explained further, in addition to a more immediate negative effect in the form of high drug prices, strategic patenting may also impair innovation by reducing originators’ incentives to innovate, and affecting generics’ ability to develop alternative generic products. Strategic patenting, therefore, may enable originators to avoid competitive pressures by preventing generic competition without a need to engage in genuine innovation. Strategic Patenting Contradicts the Rationale of the Patent System and Competition Law In the competitive markets, the success of a company is based on its business performance.Footnote52 In order to compete on performance by “offering better quality and a wider choice of new and improved goods and services”Footnote53 firms must innovate. Realising the importance of protecting innovation, which is considered to be the main driver of economic growth,Footnote54 states have put in place various mechanisms to ensure a suitable environment for its advancement. These include granting the property rights to the results of innovation in the form of patents, as well as implementing competition law rules to stimulate dynamic competition.Footnote55 Specifically, one of the main justifications for the patent system is the encouragement of innovationFootnote56 that serves as an engine for economic growth and development.Footnote57 The patent system pursues this aim by offering the patent owners a period of exclusive rights as a reward for their innovative efforts and an incentive to engage in further innovation.Footnote58 Therefore, intellectual property rules, and patents in particular, are seen as an essential element of undistorted competition on the internal market.Footnote59 These exclusive rights are considered to be a necessary incentive to invest in R&D and innovation, particularly in such sectors as pharmaceuticals, where the R&D costs are high, but the costs of copying the R&D results are marginal.Footnote60 At the same time, the “innovation theory”, embodied in the EU competition law rules and policy, is designed to stimulate innovation by fostering competition on the markets.Footnote61 The competition law rules keep markets innovative by maintaining effective competition through preventing the foreclosure of markets and maintaining access to them.Footnote62 The rationale is that firms react to pressures of competition by continuously seeking to innovate.Footnote63 Therefore, patent and competition laws complement each other, as on the one hand, existing competition creates pressures on firms, forcing them to innovate, the so-called “stick”, while on the other hand, patent law provides a “carrot” in the form of the exclusive right, thus inducing innovators to innovate.Footnote64 These two bodies of laws are seen as “complementary efforts to promote an efficient marketplace and long-run, dynamic competition through innovation”.Footnote65 As the European Commission noted “both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof”.Footnote66 These two bodies of laws, therefore, have the same fundamental goal of enhancing innovation for the benefit of consumer welfare. Importantly, patent and competition laws are designed to stimulate not only innovation of “pioneer” innovators, but they are also aimed at facilitating follow-on innovation.Footnote67 Patent law contains provisions that require inventors to disclose information about their inventions, as well as providing exceptions such as experimental use and compulsory licensing, which allow third parties to access the inventions still under patent protection.Footnote68 Therefore, along with pioneer innovators, the rationale of incentives to innovate in patent law also applies to follow-on innovators, balancing the interests of these two types of inventors.Footnote69 Similarly, competition law aims at stimulating all types of innovation, including follow-on innovation. On the other hand, EU competition law proscribes practices that reduce incentives to innovate both for “pioneer” and follow-on innovators. This is enshrined in Art. 102(b) TFEU, which prohibits abuses that consist of, inter alia, limiting technological development. For example, in AstraZeneca the General Court considered that the company’s practice of misusing the patent system had the potential of reducing its incentives to innovate and was anticompetitive.Footnote70 In MagillFootnote71 and Microsoft,Footnote72 the courts found that the IP rights owners abused their dominant positions by blocking innovation of their potential competitors. More recently, several decisions by the European Commission also emphasised the importance of protecting innovation. In January 2018, the Commission fined QualcommFootnote73 €997 million for abusing its market dominance in LTEFootnote74 baseband chipsets.Footnote75 The Commission considered that the exclusivity payments that Qualcomm paid to Apple denied rivals the possibility to compete on the merits, and deprived European consumers of genuine choice and innovation.Footnote76 Furthermore, in July 2018, the Commission found in Google Android that Google abused its dominant position, and fined the company €4.34 billion for anticompetitive restrictions it had imposed on mobile device manufacturers and network operators to strengthen its dominant position in general internet search.Footnote77 The Commission considered that Google’s restrictive practices denied other companies the chance to compete on the merits and innovate.Footnote78 Finally, in 2017 the Commission issued its decision, in which it took the view that Amazon abused its dominant positions on the markets for the retail distribution of e-books by inserting the so-called “parity clauses” in the agreements with its e-book suppliers.Footnote79 It concluded that these clauses had the potential of reducing the incentives to innovate both by e-book suppliers and retailers.Footnote80 These decisions demonstrate that the European Commission recognises the fundamental importance of protecting innovation. They confirm that strategies that are capable of stifling innovation and reducing the incentives to innovate may constitute an abuse of dominance under Art. 102 TFEU. It is argued in this article that, along with the practices condemned by the Commission in the decisions discussed above, strategic patenting can also harm innovation by impairing incentives to innovate of both originators and generic companies, and therefore should raise competition law concerns. Strategic Patenting Impairs Originators’ Incentives to Innovate While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish. Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84 the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share. In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85 Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92 Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93 A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly. Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns. Strategic Patenting Impairs Follow-on Innovation of Generic Companies Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators: The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97 Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100 As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns.

#### Corona escalates security threats that cause extinction – cooperation thesis is wrong.

Recna 21 [Research Center for Nuclear Weapon Abolition; Nagasaki, Japan; “Pandemic Futures and Nuclear Weapon Risks: The Nagasaki 75th Anniversary pandemic-nuclear nexus scenarios final report,” Journal for Peace and Nuclear Disarmament; 5/28/21; <https://www.tandfonline.com/doi/full/10.1080/25751654.2021.1890867>] Justin

The Challenge: Multiple Existential Threats The relationship between pandemics and war is as long as human history. Past pandemics have set the scene for wars by weakening societies, undermining resilience, and exacerbating civil and inter-state conflict. Other disease outbreaks have erupted during wars, in part due to the appalling public health and battlefield conditions resulting from war, in turn sowing the seeds for new conflicts. In the post-Cold War era, pandemics have spread with unprecedented speed due to increased mobility created by globalization, especially between urbanized areas. Although there are positive signs that scientific advances and rapid innovation can help us manage pandemics, it is likely that deadly infectious viruses will be a challenge for years to come. The COVID-19 is the most demonic pandemic threat in modern history. It has erupted at a juncture of other existential global threats, most importantly, accelerating climate change and resurgent nuclear threat-making. The most important issue, therefore, is how the coronavirus (and future pandemics) will increase or decrease the risks associated with these twin threats, climate change effects, and the next use of nuclear weapons in war.5 Today, the nine nuclear weapons arsenals not only can annihilate hundreds of cities, but also cause nuclear winter and mass starvation of a billion or more people, if not the entire human species. Concurrently, climate change is enveloping the planet with more frequent and intense storms, accelerating sea level rise, and advancing rapid ecological change, expressed in unprecedented forest fires across the world. Already stretched to a breaking point in many countries, the current pandemic may overcome resilience to the point of near or actual collapse of social, economic, and political order. In this extraordinary moment, it is timely to reflect on the existence and possible uses of weapons of mass destruction under pandemic conditions – most importantly, nuclear weapons, but also chemical and biological weapons. Moments of extreme crisis and vulnerability can prompt aggressive and counterintuitive actions that in turn may destabilize already precariously balanced threat systems, underpinned by conventional and nuclear weapons, as well as the threat of weaponized chemical and biological technologies. Consequently, the risk of the use of weapons of mass destruction (WMD), especially nuclear weapons, increases at such times, possibly sharply. The COVID-19 pandemic is clearly driving massive, rapid, and unpredictable changes that will redefine every aspect of the human condition, including WMD – just as the world wars of the first half of the 20th century led to a revolution in international affairs and entirely new ways of organizing societies, economies, and international relations, in part based on nuclear weapons and their threatened use. In a world reshaped by pandemics, nuclear weapons – as well as correlated non-nuclear WMD, nuclear alliances, “deterrence” doctrines, operational and declaratory policies, nuclear extended deterrence, organizational practices, and the **existential risks** posed by retaining these capabilities – are all up for redefinition. A pandemic has potential to destabilize a nuclear-prone conflict by incapacitating the supreme nuclear commander or commanders who have to issue nuclear strike orders, creating uncertainty as to who is in charge, how to handle nuclear mistakes (such as errors, accidents, technological failures, and entanglement with conventional operations gone awry), and opening a brief opportunity for a first strike at a time when the COVID-infected state may not be able to retaliate efficiently – or at all – due to leadership confusion. In some nuclear-laden conflicts, a state might use a pandemic as a cover for political or military provocations in the belief that the adversary is distracted and partly disabled by the pandemic, increasing the risk of war in a nuclear-prone conflict. At the same time, a pandemic may lead nuclear armed states to increase the isolation and sanctions against a nuclear adversary, making it even harder to stop the spread of the disease, in turn creating a pandemic reservoir and transmission risk back to the nuclear armed state or its allies. In principle, the common threat of the pandemic might induce nuclear-armed states to reduce the tension in a nuclear-prone conflict and thereby the risk of nuclear war. It may cause nuclear adversaries or their umbrella states to seek to resolve conflicts in a cooperative and collaborative manner by creating habits of communication, engagement, and mutual learning that come into play in the nuclear-military sphere. For example, militaries may cooperate to control pandemic transmission, including by working together against criminal-terrorist non-state actors that are trafficking people or by joining forces to ensure that a new pathogen is not developed as a bioweapon. To date, however, the COVID-19 pandemic has increased the isolation of some nuclear-armed states and provided a textbook case of the failure of states to cooperate to overcome the pandemic. Borders have slammed shut, trade shut down, and budgets blown out, creating enormous pressure to focus on immediate domestic priorities. Foreign policies have become markedly more nationalistic. Dependence on nuclear weapons may increase as states seek to buttress a global re-spatialization6 of all dimensions of human interaction at all levels to manage pandemics. The effect of nuclear threats on leaders may make it less likely – or even impossible – to achieve the kind of concert at a global level needed to respond to and administer an effective vaccine, making it harder and even impossible to revert to pre-pandemic international relations. The result is that some states may proliferate their own nuclear weapons, further reinforcing the spiral of conflicts contained by nuclear threat, with cascading effects on the risk of nuclear war.

#### Studies show that vaccine distribution solve COVID. Reject any ev that don’t assume vaccine nationalism.

* Compares two models of HARs and LARs
* Allows for mutation simulations

**Princeton University 8/17** Princeton University. "Vaccine stockpiling by nations could lead to increase in COVID-19 cases, novel variant emergence, study finds." ScienceDaily. ScienceDaily, 17 August 2021. <www.sciencedaily.com/releases/2021/08/210817152552.htm>. //Nato

The allocation of COVID-19 vaccine between countries has thus far tended toward vaccine nationalism, wherein countries stockpile vaccines to prioritize access for their citizenry over equitable vaccine sharing. The extent of vaccine nationalism, however, may strongly impact global trajectories of COVID-19 case numbers and increase the potential emergence of novel variants, according to a Princeton University and McGill University study published Aug. 17 in the journal Science. "Certain countries such as Peru and South Africa that have had severe COVID-19 outbreaks have received few vaccines, while many doses have gone to countries experiencing comparatively milder pandemic impacts, either in terms of mortality or economic dislocation," said co-first author Caroline Wagner, an assistant professor of bioengineering at McGill University who previously served as a postdoctoral research associate in Princeton's High Meadows Environmental Institute (HMEI). "As expected, we have seen large decreases in case numbers in many regions with high vaccine access, yet infections are resurging in areas with low availability," said co-first author Chadi Saad-Roy, a Princeton graduate student in ecology and evolutionary biology and the Lewis-Sigler Institute for Integrative Genomics. "Our goal was to explore the effects of different vaccine-sharing schemes on the global persistence of COVID-19 infections -- as well as the possibility for the evolution of novel variants -- using mathematical models," Saad-Roy said. The researchers projected forward the incidence of COVID-19 cases under a range of vaccine dosing regimes, vaccination rates, and assumptions related to immune responses. They did so in two model regions: One with high access to vaccines -- a high-access region (HAR) -- and a low-access region (LAR). The models also allowed for the regions to be coupled either through case importation, or the evolution of a novel variant in one of the regions. "In this way, we could assess the dependence of our epidemiological projections on different immunological parameters, regional characteristics such as population size and local transmission rate, and our assumptions related to vaccine allocation," Wagner said. Overall, the study found that increased vaccine-sharing resulted in reduced case numbers in LARs. "

### Advantage 2: Diplomacy

#### American vaccine diplomacy is failing in Latin America – that allows for Chinese influence. Only the plan can return the world back to a US led order.

Carman and Carl 6/15 [Ezequiel and Joseph; Argentine lawyer and global health and trade policy consultant. Previously, he served as a legal advisor to the Ministry of Justice of Buenos Aires, an assistant professor of international public law at the Universidad Católica Argentina, and a research assistant at the O’Neill Institute for National and Global Health Law; Graduate of Liberty University, where he studied international relations and strategic international studies. He has worked for the U.S. Department of State and the Heritage Foundation; “A U.S. vaccine diplomacy strategy for Latin America and the Caribbean,” Global Americans; 6/15/21; <https://theglobalamericans.org/2021/06/a-u-s-vaccine-diplomacy-strategy-for-latin-america-and-the-caribbean/>] Justin

Once again, history seems to be repeating itself. The United States, along with the world’s other rich and mostly Western countries, continue to be accused of hoarding medical supplies, having purchased one billion surplus vaccine doses (more than is required to vaccinate their citizens). In their absence, China—and, to a lesser extent, Russia—have rushed to take advantage of the vaccine gap in the Global South, particularly in Latin America and the Caribbean. A lack of leadership from Washington in sharing vaccines and their intellectual property (IP) earlier in the pandemic has allowed its geopolitical competitors to take advantage of Latin America’s desperate need to acquire scarce vaccines. Although the region represents only eight percent of the global population, it has experienced nearly one-third of all COVID-19 deaths. Historical precedent demonstrates this is not the first time that Washington’s international moral standing has been damaged during a global health crisis, due to the lack of political will to share lifesaving drugs and other vital resources. However, this time around, unlike in such past episodes, there will be concrete geopolitical consequences to Washington’s inaction.

In recent years, the U.S. has lost significant political and economic influence among its southern neighbors; without swift remedial action, its geopolitical rivals may cement such losses through their campaigns of vaccine diplomacy. To rebuild its influence in the region, Washington will need to muster the political will to increase Latin America and the Caribbean’s access to vaccines and develop a sound strategy for its own vaccine diplomacy. Already, some countries in the region have been sufficiently strong-armed by other global powers, the implications of which could be damaging for U.S. interests. As the world transitions into the next stage of the pandemic, those nations that continue to be most ravaged by COVID-19 will likely continue to remember which countries provided them with aid and succor in their time of need.

History repeats itself

In 1981, the first cases of acquired immunodeficiency syndrome (AIDS) were reported; the following decade was defined by a devastating global AIDS epidemic (which would eventually be recognized as a pandemic). Analogous to how Latin America and the Caribbean have borne disproportionately the burden of COVID-19, Africa was hit hardest by the AIDS epidemic. Many parallels can be drawn between the international handlings of both the COVID-19 and AIDS pandemics.

By the late 1980s, once antiretroviral therapies (ARV) were approved by the U.S. Food and Drug Administration (FDA), AIDS deaths in the U.S. began to decline immediately. Nevertheless, high levels of AIDS-related deaths in Africa continued for another decade. Africa’s enduring fight against AIDS was largely due to the cost of ARVs, which, at the time, were priced at USD $10,000 per person annually—completely out of reach for most developing countries.

Pharmaceutical companies argued that the drug’s high selling price was necessary to procure a return on its investment in the research and development (R&D) of the ARV, and that pricing the drugs at a marginal cost would maximize consumer surplus while also halting future development in the industry.

When pricing a drug, a pharmaceutical company needs to factor-in several costs: 1) the cost of R&D for drugs that never enter the market; 2) clinical trials necessary to comply with regulatory requirements; 3) and the marketing cost of promoting the new drug. While the original price of the patented ARV was USD $10,000 per patient per year, the price of the generic version, manufactured by the Indian pharmaceutical company Cipla, was only USD $1.00 per day.

During the AIDS pandemic, since many developing countries were members of the World Trade Organization (WTO), they were forbidden from importing generic pharmaceutical products because in order to maintain compliance with regulations imposed by the Trade Related Aspects of Intellectual Property (TRIPS) agreement. Western pharmaceutical companies—the owners of the IP rights for the medications—blocked access to generic ARV drugs out of fear that the importation of these generic alternatives would ultimately threaten their net profitization. Despite the protests of the pharmaceutical industry, India and South Africa continued to compete with and defy the U.S. and the WTO (a body in which powerful industrialized economies—those of the U.S., Europe, and Japan—wield disproportionate influence).

Drug companies eventually sued to keep lifesaving therapies out of the hands of dying AIDS-sufferers in Africa, a state of affairs that engendered a forceful reaction from international activists. After years of political pressure, Washington was forced to yield, eventually pushing for the relaxation of stringent IP protections for ARVs, making generic versions of the drugs more accessible and affordable. Despite its eventual concession, the perception that the U.S. had fought bitterly to prioritize pharmaceutical company profits over human lives in the Global South only helped bolster negative narratives surrounding the Western superpower.

However, unlike the unipolarity that characterized the 1990s and early 2000s, the U.S. is no longer the only global superpower, and the humanitarian decisions it makes now—during a new global health crisis—have the potential to be hugely consequential for the country’s influence and image. Similar to its trajectory at the height of the AIDS crisis, Washington only recently voiced its desire to back the WTO patent waiver proposal, having come under tremendous international pressure. Granted, the U.S. backed a patent waiver for COVID-19 vaccines much faster than it did for ARVs in the 1980s. However, having been presented with a rare opportunity to make amends for past moral missteps—by eliminating vaccine IP protections to ensure that affordable, generic versions of COVID-19 vaccines could be manufactured en masse around the world—the U.S. once again hesitated, limiting opportunities for developing nations to recover from the pandemic and again amplifying criticisms of the United States.

Backed by over 100 developing countries, India and South Africa are once again leading the current fight to eliminate IP protections. India and South Africa filed a waiver with the WTO requesting a temporary suspension of patent obligations under TRIPS (Sections 1, 4, 5, and 7 of Part II) so that developing countries can access vaccines in a timely manner. The intent of this effort is to boost domestic manufacturing capacity by facilitating the widespread production of generic versions of COVID-19 vaccines, evening the odds with respect to global vaccine procurement and accessibility. The waiver would also allow developing countries to procure vaccines more expeditiously, either by producing them themselves or by streamlining the cumbersome institutional and legal requirements of importing pharmaceutical products from other countries that possess the necessary manufacturing capacity.

After months of pushback from activists and political leaders, the U.S. finally expressed its support for patent waivers, with several key Western powers (notably France and the European Union (EU)) following suit. However, Germany—a major political player in the patent waiver debate due to its powerful pharmaceutical sector—continues to oppose the move. Other European countries remain similarly split on the patent waiver proposal, reflecting the fact that any patent waiver proposal will still requires extensive negotiation (in order for it to be accepted, there must be unanimous consent among WTO members).

Political leaders and activists continue to call on the West to support the waiving of IP protections, noting that current projections anticipate that wealthy countries will be able to immunize their entire populations by the end of 2021, while developing countries will only see the same results in the next three to four years. Unlike the AIDS pandemic, COVID-19 has generated not only massive medical concerns, but also a global economic crisis: vaccination campaigns in richer countries have already allowed them to begin to rebuild their economies, while mass unemployment and lockdowns continue to strangle the economies of many developing nations. Increasing the supply and accessibility of vaccines in the developing world will undoubtedly facilitate a faster, and more equal, economic recovery. Continuing to allow the virus to spread unencumbered throughout the Global South, however, will only increase the likelihood of further viral mutations, possibly jeopardizing the efficacy of existing vaccines and further perpetuating already grave economic and medical concerns.

Washington’s initial unwillingness to cross the pharmaceutical industry has undeniably damaged the moral standing of the United States. Moreover, this decision also created a humanitarian void eagerly filled by Beijing and Moscow, as they actively seek to position themselves as the benefactors of the most COVID-19-stricken region of the world: Latin America and the Caribbean. To date, Russian and Chinese vaccine diplomacy have already led to economic, diplomatic, and political losses being felt by Washington; this trend, if allowed to continue, will only further limit U.S. regional influence with its neighbors to the south.

A lack of strategy and political will

In the absence of an effective vaccine diplomacy strategy from Washington, and with the perpetuation of its current nationalistic vaccine policy, some of the pharmaceutical companies that the U.S. so readily protects have pushed countries throughout Latin America and the Caribbean into the waiting arms of Beijing and Moscow. While some Latin American countries have received a few vaccines from Western companies, most nations in the region continue to struggle to obtain doses. Pfizer, a U.S. pharmaceutical company, was accused of bullying Latin American countries during vaccine procurement negotiations, using its own leverage to attempt to force desperate nations to offer sovereign assets—such as their embassies—as collateral. Pfizer’s efforts resulted in a lost deal with Argentina, which has continued to grow increasingly closer to China.

While the U.S. possesses a surplus of COVID-19 vaccines, it has failed to develop an effective, far-reaching donation strategy. Only recently did the Biden administration announce its plans to ship 80 million vaccines—a small portion of its surplus supply—abroad. Of the initial 25 million doses destined to be distributed internationally, 19 million will be donated to the largely mismanaged UN-backed COVAX program, with only six million of these COVAX doses designated for Latin America and the Caribbean. In comparison, China alone has donated or sold over 165 million vaccines to Latin America, with countries like Chile and Uruguay having vaccinated 80 and 63 percent of their populations, respectively, with Chinese vaccines.

The administration of U.S. President Joe Biden previously donated a total of 4.2 million AstraZeneca vaccines to Canada and Mexico, the first vaccines that the U.S. had sent abroad. Still, this relatively modest donation was preceded by repeated calls from prominent Latin American leaders for President Biden to donate vaccines to U.S. allies in Latin America. Mexican President Andrés Manuel López Obrador (AMLO) was notably rebuffed in his request for shipments of U.S. vaccines, being told by the Biden administration that it was prioritizing the vaccination of the American public (despite the fact that Washington had already bought enough vaccines to inoculate the entire U.S. population several times over). Colombia President Iván Duque of Colombia, a country that is a key regional ally, has also called for the Biden administration to aid countries in the Western Hemisphere that are struggling to procure vaccines.

By contrast, some Latin American officials have described easier negotiations, cheaper prices, and overall better terms in their successful agreements with Russia and China. Last year, for example, Beijing offered a USD $1 billion loan to Latin American nations to help finance their purchasing of Chinese-made vaccines—an offer that was well-received by recipient countries. Due to a lack of vaccine support and assurance from Washington, countries are growing closer to Beijing and Moscow, succumbing to rival geopolitical powers that do not align with the diplomatic and economic interests of the United States.

Brazil remains one of the countries hardest hit by the COVID-19 pandemic. Despite President Jair Bolsanaro’s anti-science tendencies and hawkish stance towards Beijing, however, his government has still proven susceptible to the influence of China. Earlier this year, a New York Times report brought attention to the Bolsonaro government’s arrangement to allow Huawei, the Chinese telecommunications giant, to participate in upcoming biddings for contracts to construct Brazil’s 5G network. (Under the Trump Administration, Brazil had been one of the 50 countries to agree to the Clean Network Initiative—an agreement that committed signatories to forbidding Huawei from being involved in their 5G networks, due to national security concerns.) The announcement came after Brazil’s telecommunications minister, Fábio Faria, traveled to Beijing to meet with Huawei executives. Recounting his trip, Faria was quoted as saying that he had taken “advantage of the trip to ask for vaccines.” This development aligns with recent warnings from the U.S. Southern Command Chief Admiral Craig Faller, who claimed, during a U.S. Senate Armed Services Committee hearing, that China was using its vaccine leverage to push for Huawei’s integration into Latin America’s 5G networks.

In the absence of Washington, several countries have increased their engagement with China and Russia (or have at least been pressured to). Paraguay and Guyana, for instance, have been pushed by China to switch their official diplomatic recognition from Taiwan (Republic of China, or ROC) to China (People’s Republic of China, or PRC) and to increase bilateral trade relations. Colombia, historically one of Washington’s closest allies in Latin America, uncharacteristically applauded Beijing’s efforts to promote human rights at the United Nations Human Rights Council, only one week after it received half a million doses of a Chinese-made vaccine. In Mexico, Beijing and Moscow also scored points; after securing a second shipment of Chinese vaccines, Mexico announced it would expand its “strategic partnership” with China. With respect to Russia, when (AMLO) tested positive for COVID-19 in January, he received a call from Russian President Vladimir Putin, wishing his Mexican counterpart a quick recovery. Shortly thereafter, AMLO announced that Mexico would receive a shipment of 24 million Russian vaccines and that he had invited Putin to visit Mexico, which would mark the Russian leader’s first visit to the country in nearly a decade. These developments are especially relevant when considering the fact that, before President Biden announced the sharing of the U.S. supply of AstraZeneca vaccines with Mexico, he had initially rejected AMLO’s call for assistance.

In Bolivia, Putin has curried favor with President Luis Arce. President Arce’s political leanings are reminiscent of those of his predecessor, Evo Morales, who had an especially close relationship with Moscow; it would be reasonable to expect, therefore, that Arce may be similarly keen to deepen Moscow’s relationship with La Paz. After donating a large supply of vaccines to Bolivia, Putin sought out Arce to discuss the possible revival of several key Russian projects in the country: among them, the reactivation of a suspended nuclear power plant project, Russian development of Bolivia’s natural gas reserves, and investments in the country’s extensive lithium deposits (lithium being a mineral key to the global transition to clean energy, as it is a vital component in the production of high capacity batteries in both civilian and military hardware). In 2019, Russian businesses were beaten by other firms in the rush to invest in Bolivia’s nascent lithium industry; however, Arce has recently announced plans for new lithium projects that have received interest from both Russian and American companies.

Throughout Latin America and the Caribbean, Russia has continued to sign vaccine deals in an effort to increase its influence. Russia’s vaccine diplomacy has primarily been a soft power push, unlike China’s more brazen “wolf warrior” diplomacy. Nevertheless, it represents a re-establishment of a foothold in the region that Russia (and its predecessor, the USSR) has not boasted since the Cold War.

While some countries, like Mexico and Bolivia, appear genuinely interested in deepening their ties with U.S. geopolitical rivals, it is widely recognized that most other nations of Latin America and the Caribbean are being squeezed politically by vaccines. If Latin America is not offered a practical alternative, it will likely continue to conduct business with Moscow and Beijing, thus incurring more debts of gratitude to global powerhouses eager to expand their economic and political influence through vaccine diplomacy.

A forward-thinking strategy

To this point, the U.S. has been significantly outpaced by China and Russia when it comes to building and strengthening relations with its Latin American and Caribbean neighbors. The dynamic surrounding COVID-19 vaccine distribution is evocative of another era of recent history when the U.S. abandoned the suffering of the developing world for the sake of profit-maximizing pharmaceutical companies. With Latin America and the Caribbean being the region hardest hit in the world by the COVID-19 pandemic—much as Africa was at the height of the AIDS pandemic—the U.S. is only undermining its moral standing and regional influence by failing to more readily extend a helping hand.

As the war against COVID-19 reaches a détente in the U.S., the Biden administration should make this issue a top priority. First, the U.S. needs to aggressively push its Western partners to back the IP patent waiver at the WTO in order to push forward a patent proposal that will help increase vaccine production capacity worldwide. Doing so will demonstrate to the world that Washington has the political will to defy the wishes of the powerful pharmaceutical industry and and re-establish its leadership role among the Western powers.

Second, in order to counter its geopolitical rivals and restore its moral standing, the Biden administration will need to be more “present” in regional vaccine distribution, demonstrated through a vigorous campaign of public diplomacy. Unlike their American counterparts, Chinese and Russian diplomatic officials are always present whenever a new shipment of their vaccines enter a given country. These arrivals have frequently been met with fanfare and attention from the Latin American press—coverage that, in turn, helps to shape public opinion regarding Sino-Russian influence and elevate the political stature of the two revisionist powers among the Latin American electorate. Adopting this strategy would help convey the message that vaccines are coming from the American people, rather than from faceless multinational corporations, and help rebuild moral standing for the U.S. among Latin American and Caribbean citizenries. Public-private partnerships with these companies would allow the U.S. to obtain more accountability with respect to international vaccine distribution; previous agreements have proven successful in achieving similar public perceptions of transparency and accountability.

#### It's not over – Latin America is still skeptical of Chinese aid but lack of US presence means it’s the only choice – try or die to capitalize on this weakness.

Kneip 8/10 [Lucie; Student at the University of Notre Dame studying Political Science and Global Affairs. Her research interests include U.S. foreign policy and democratization, civil and criminal warfare, and the intersection of religion and politics; “China’s Vaccine Diplomacy in Latin America,” The Diplomat; 8/10/21; <https://thediplomat.com/2021/08/chinas-vaccine-diplomacy-in-latin-america/>] Justin

Chinese vaccine diplomacy in Latin America has skyrocketed in recent months. In preparation for the Copa America tournament, Sinovac donated 50,000 vaccines to the South American football governing body CONMEBOL. Beijing is investing in vaccine diplomacy to enhance its regional soft power. It’s time for the United States to pay more attention to a region that it often takes for granted.

Latin America and the Caribbean have registered over a million deaths from COVID-19, and new variants continue to drive economic shutdowns in Colombia and Trinidad and Tobago. While the United States’ $4 billion commitment to the World Health Organization’s COVAX initiative outstrips every other international donor, logistical obstacles and Western pharmaceutical companies’ need to prioritize U.S. government contracts have slowed down vaccine distribution.

Meanwhile, China has raced to fill the vaccine gap, and they’ve been successful. According to the Council of Americas, the majority of all vaccines administered in Latin America are sourced from Beijing. True, Uruguay, Costa Rica, and the Dominican Republic have questioned the efficacy of Chinese Sinovac inoculations, and a Chilean study found that Sinovac was only 54 percent effective in preventing contagion, while Pfizer and Moderna record much higher efficacy. Yet the speed and scale of Beijing’s vaccine campaign has forced governments to accept the less-effective Chinese vaccine; there are few alternatives on offer.

President Xi Jinping is already using vaccine diplomacy to advance other Chinese interests. China has pressured Honduras and Paraguay to sever diplomatic ties with Taiwan in order to receive Chinese vaccines, and successfully pushed Brazil to reverse its ban on telecom giant Huawei’s 5G network project.

Vaccine diplomacy is only the newest instance of increased Chinese trade and investment in Latin America. Meanwhile, Washington continues to entangle itself in exploits in distant regions rather than prioritizing ties in its own neighborhood. Latin American policymakers are growing increasingly disillusioned with Washington’s inattention to regional development and progress. Honduran chief cabinet coordinator Carlos Alberto Madero sums up the increasing frustration: “The Honduran people… see that China is helping its allies and we start to ask ourselves why ours are not helping us.” The pandemic is still raging in the region, and Washington has an opportunity to rebound by increasing the pace of vaccine donations.

#### Chinese influence ends the liberal order.

Cossu 7/16 [Elena; Early-stage researcher for the MSCA Innovative Training Network FATIGUE, PhD candidate in economics at Corvinus University of Budapest and recently finished her year as a visiting researcher at University College London and at the European Bank for Reconstruction and Development. Elena comes from a place culturally in between Germany and Italy. She has also had experience working in Greece, France, Latin America, Thailand, and Hungary. Elena is passionate about political and economic inequalities between states, and about understanding what prevents the political and economic convergence of different peripheries of the world; “In Latin America, Chinese vaccine diplomacy is directly challenging US’s declining authority,” Scroll.in; 7/16/20; <https://scroll.in/article/1000114/in-latin-america-chinese-vaccine-diplomacy-is-directly-challenging-uss-declining-authority>] Justin

It is impossible to enter a room these days without talking about Covid-19 vaccines. If, however, you happened to be talking to Latin Americans, you would notice an unusual pattern: considerable gratitude towards China for its vaccine rollout.

It is gratitude, moreover, that is very hard to find in Europe or the United States. The reason is simple: the number of vaccines provided by China to countries in need is truly impressive.

During a global vaccine shortage, China has been able to provide 252 million doses to the world. This includes the majority of total doses made available to Latin American countries.

Six national or regional entities can produce and distribute a consistent number of vaccines: Europe, the United States, China, South Korea and India. China has distributed the highest number, and almost half (42%) of these have gone outside its own country.

As of May, no other country can match this figure. Most countries are focused primarily on achieving their own herd immunity first.

Even more striking is the fact that the United States is exporting a mere 1% of its vaccines, almost solely to Canada and Mexico. In May, the US pledged to increase its exported doses by 100 million by the end of the year. Yet even if it had achieved this goal, it would not be even half of the Chinese figure. Chinese vaccine diplomacy in Latin America is challenging US authority in the region, at a time when US influence is in visible decline.

Declining ‘Washington Consensus’

The rationale behind American policy towards Latin America has long been that unstable neighbours (especially Communist ones) destabilise the region. In extreme cases, this has resulted in US involvement in various regime changes in Latin America. But the more frequently used mechanism of influence, especially since the end of the Cold War, has been economic diplomacy.

The main tool for this has been the infamous Washington Consensus. The logic of this was very simple: a state-led economic model is a bad thing. An “economist approved” liberal model should therefore solve all Latin America’s problems. It did not work out like that.

Despite good intentions, the International Monetary Fund and World Bank programmes did not alleviate Latin America’s problems. On the contrary, the Washington Consensus is often cited as having fuelled a resurgence of populism in Latin America. It is also held responsible for the succession of left-wing governments in the 1990s known as the Pink Tide.

Five of the nations subject to the Washington Consensus (Argentina, Brazil, Chile, Mexico and Venezuela) even displayed authoritarian tendencies. In the mid-2010s the region experienced a so-called Blue Tide: the rise of liberal governments to counterbalance the previous left-wing ones. This phenomenon was also considered a long-term consequence of the chronic failure of US economic diplomacy on the continent.

Today, Latin America still struggles with political instability and high levels of inequality. The United States’ top-down approach has failed. What is more, cooperation has dramatically declined because of the Trump administration’s approach and the US’s own internal problems.

Rising Chinese power

In this context, China has seen the Covid crisis as an opportunity to reinforce its ambitions as a rising power trying to exert more influence in the international order.

A scheduled $8 trillion for project infrastructure in sixty-eight countries through the New Silk Road programme vividly captures its approach. Brazil, Venezuela, Ecuador and Bolivia already have partnership projects with China and Mexico is considering joining one.

The US and Chinese tools for economic diplomacy are very similar in practice, yet fundamentally different in philosophy.

The US strategy is based on individualism: We as a nation will be the most economically successful by working hard to realise our individuality... We will export the idea that this is the best possible system through soft power and economic cooperation.

In contrast, Chinese economic diplomacy is an extension of a collective dream where individuals work hard to realise the success of the collectivity: everybody in their community and the world.

In the context of Latin America, this competition between two philosophical approaches is especially risky for the United States. Too many factors favour the Chinese way of thinking: the inward-looking diplomatic approach of the United States during the Trump administration; the perennial flirtation of some Latin American countries with various forms of socialism; and the failure of the US’s own economic and other (capitalist) strategies there.

Old international order

In this power vacuum, the rise of China during a crisis situation might push the world toward a new international bipolar order. Latin America’s enthusiasm for Chinese vaccines might constitute the first grouping of countries genuinely lost to US influence.

Latin America is not just showing an interest in vaccine rollout. It is also showing how the old dichotomy of capitalism versus socialism is becoming increasingly redundant in some parts of the world.

Analogous to the fading of the US-Russia dichotomy, rising Chinese influence in Latin America shows countries becoming more open-minded towards different economic and social narratives. They are less concerned with “good” and “bad” and more concerned with the concrete opportunities different choices offer.

#### Collapse of the liberal order causes extinction.

Yulis 17 [Max; Major in PoliSci, Penn Political Review; “In Defense of Liberal Internationalism,” Penn Political Review; 4/8/17; <http://pennpoliticalreview.org/2017/04/in-defense-of-liberal-internationalism/>] // Re-Cut Justin

Over the past decade, international headlines have been bombarded with stories about the unraveling of the post-Cold War world order, the creation of revolutionary smart devices and military technologies, the rise of militant jihadist organizations, and nuclear proliferation. Indeed, times are paradoxically promising and alarming. In relation to treating the world’s ills, fortunately, there is a capable hegemon– one that has the ability to revive the world order and traditionally hallmarked human rights, peace, and democracy. The United States, with all of its shortcomings, had crafted an international agenda that significantly impacted the post-WWII landscape. Countries invested their ambitions into security communities, international institutions, and international law in an effort to mitigate the chances of a nuclear catastrophe or another World War. The horrors and atrocities of the two Great Wars had traumatized the global community, which spurred calls for peace and the creation of a universalist agenda. Today, the world’s fickle and declining hegemon still has the ability, but not the will, to uphold the world order that it had so carefully and eagerly helped construct. Now, the stakes are too high, and there must be a mighty and willing global leader to lead the effort of diffusing democratic ideals and reinforcing stability through both military and diplomatic means. To do this, the United States must abandon its insurgent wave of isolationism and protectionism, and come to grips with the newly transnational nature of problems ranging from climate change to international terrorism.

First, the increase in intra-state conflict should warrant concern as many countries, namely in Africa and the Middle East, are seeing the total collapse of civil society and government. These power vacuums are being filled with increasingly ideological and dangerous tribal and non-state actors, such as Boko Haram, ISIS, and Al-Shabaab. Other bloody civil wars in Rwanda, Sudan, and the Congo have contributed to the deaths of millions in the past two decades. As the West has seen, however, military intervention has not been all that successful in building and empowering democratic institutions in the Far East. A civil crusade, along with the strengthening of international institutions, may in fact be the answer to undoing tribal, religious, and sectarian divisions, thereby mitigating the prospects of civil conflict. During the Wilsonian era, missionaries did their part to internationalize the concept of higher education, which has contributed to the growth of universities in formerly underdeveloped countries such as China and South Korea.[1] In addition, the teachings of missionaries emphasized the universality of humanity and the oneness of man, which was antithetical to the justifications for imperialism and the rampant sectarianism that plagued much of the Middle East and Africa.[2] Seeing that an increase in the magnitude of human casualty is becoming more of a reality due to advancements in military technology and the increasing outbreaks of civil war, international cooperation and the diffusion of norms that highlight the importance of stable governance, democracy, and human rights is the only recourse to address the rise in sectarian divides and civil conflicts. So long as the trend of the West’s desire to look inward continues, it is likely that nation states mired in conflict will devolve into ethnic or tribal enclaves bent on relying on war to maintain their legitimacy and power. Aside from growing sectarianism and the increasing prevalence of failed states, an even more daunting threat come from weapons that transcend the costs of conventional warfare.

The problem of nuclear proliferation has been around for decades, and on the eve of President Trump’s inauguration, it appeared that Obama’s lofty goal of advocating for nonproliferation would no longer be a priority of American foreign policy.[3] In addition, now that the American president is threatening to undo much of the United States’ extensive network of alliances, formerly non-nuclear states may be forced to rearm themselves. Disarmament is central to liberal internationalism, as was apparent by the Washington Naval Treaty advocated by Wilson, and by the modern CTBT treaty. The reverse is, however, being seen in the modern era, with cries coming from Japan and South Korea to remobilize and begin their own nuclear weapon programs.[4] A world with more nuclear actors is a formula for chaos, especially if nuclear weapons become mass-produced. Non-state actors will increasingly eye these nuclear sites as was the case near a Belgian nuclear power plant just over a year ago.[5] If any government commits a serious misstep, access to nuclear weapons on the behalf of terrorist and insurgent groups will become a reality, especially if a civil war occurs. States with nuclear weapons require domestic stability and strong security, which is why states such as Israel, North Korea, and Pakistan could be in serious trouble in the event of a domestic uprising or military coup. The disarmament of all states is essential for human survival, and if it is not achieved, then a world full of nuclear weapons and an international system guided by realpolitik could give rise to nuclear warfare. In today’s world, nuclear weapons leave all states virtually defenseless. But, for nuclear deproliferation to become a cornerstone of the global agenda, a pacifying and democratic power must rise to the limelight to advocate the virtues of peace, stability, and human rights.

#### Scientific consensus flows aff – nuke war leads to extinction and is the most probable impact scenario

Tegmark 17 Max Tegmark, 5-26-2017, "Why 3,000 Scientists Think Nuclear Arsenals Make Us Less Safe," Scientific American Blog Network, https://blogs.scientificamerican.com/observations/why-3-000-scientists-think-nuclear-arsenals-make-us-less-safe/, SJBE Max Erik Tegmark is a Swedish-American physicist and cosmologist. He is a professor at the Massachusetts Institute of Technology and the scientific director of the Foundational Questions Institute.

Delegates from most United Nations member states are gathering in New York next month to negotiate a nuclear weapons ban, and 30 Nobel Laureates, a former U.S. Secretary of Defense and over 3,000 other scientists from 84 countries have signed an [open letter](https://futureoflife.org/nuclear-open-letter/) in support. Why? We scientists like to geek out about probabilities, megatons and impact calculations, so we see the nuclear situation differently than many politicians and pundits. From the public debate, one might think that the cold war threat is over and that the most likely way to be killed by a nuke is by being attacked by Iran, North Korea or terrorists, but that’s not what nerdy number crunching reveals. Those media-dominating scenarios could potentially kill millions of people—except that Iran has no nukes and North Korea lacks missiles capable of reliably delivering their dozen or so Hiroshima-scale bombs. But scientific research has shown that a nuclear war between the superpowers might kill hundreds or potentially even thousands of times more people, and since it’s not a hundred times less likely to occur, the laws of statistics tell us that it’s the nuke scenario most likely to kill you. Why is superpower nuclear war so risky? First of all, massive firepower: there are more than [14,000 nuclear weapons](https://fas.org/issues/nuclear-weapons/status-world-nuclear-forces/) today, some of which are hundreds of times more powerful than North Korea’s and those dropped on Japan. Over 90 percent of these belong to Russia and the US, who keep thousands on hair-trigger alert, ready launch on minutes notice. A [1979 report by the US Government](https://www.princeton.edu/~ota/disk3/1979/7906/7906.PDF) estimated that all-out war would kill 28-88 percent of Americans and 22-50 percent of Soviets (150-450 million people with today’s populations). But this was before the risk of nuclear winter was discovered in the 1980’s.Researchers realized that regardless of whose cities burned, massive amounts of smoke could spread around the globe, blocking sunlight and transforming summers into winters, much like when asteroids or supervolcanoes caused mass extinctions in the past. A peer-reviewed analysis published by Robock et al (2007) showed cooling by about 20°C (36°F) in much of the core farming regions of the US, Europe, Russia and China (by 35°C in parts of Russia) for the first two summers, and about half that even a full decade later. Years of near-freezing summer temperatures would eliminate most of our food production. It is hard to predict exactly what would happen if thousands of Earth’s largest cities were reduced to rubble and global infrastructure collapsed, but whatever small fraction of all humans didn’t succumb to starvation, hypothermia or epidemics would probably need to cope with roving, armed gangs desperate for food. There are large uncertainties in Nuclear Winter predictions. For example, how much smoke is produced and how high up it rises would determine its severity and longevity. Given this uncertainty, there is no guarantee that most people would survive. It has therefore been argued that the traditional nuclear doctrine of Mutual Assured Destruction (MAD) be replaced by Self-Assured Destruction (SAD): even if one of the two superpowers were able to launch its full nuclear arsenal against the other without any retaliation whatsoever, nuclear winter might still assure the attacking country’s self-destruction. Recent research has suggested that even a limited nuclear exchange between India and Pakistan could cause enough cooling and agricultural disruption to endanger up to [2 billion people](https://hinwcampaignkit.org/section-4/section-4/), mostly outside the warring countries. The fact that nuclear powers are taking the liberty to endanger everyone else without asking their permission has led to growing consternation in the world’s non-nuclear nations. This has been exacerbated by a seemingly endless [series of near-misses](https://futureoflife.org/background/nuclear-close-calls-a-timeline/) in which nuclear war has come close to starting by accident, and leaders of many non-nuclear nations feel less than thrilled by the idea of being destroyed by something as banal as a malfunctioning early warning-system in a nation that they are not threatening. Such concerns prompted 185 non-nuclear nations to sign the 1970 Non-Proliferation-Treaty (NPT), promising to remain nuke-free in return for the nuclear nations phasing out theirs in accordance with NPT Article VI, whereby each party "undertakes to pursue negotiations in good faith on effective measures relating to cessation of the nuclear arms race at an early date and to nuclear disarmament, and on a Treaty on general and complete disarmament under strict and effective international control”. Nearly 50 years later, many of these "have-nots” have concluded that they were tricked, and that the "haves” have no intention of ever keeping their end of the bargain. Rather than disarming, the U.S. and Russia have recently announced massive investments in novel nuclear weapons. Russia has recently touted a cobalt-encased doomsday bomb reminiscent of the dark comedy "Dr. Strangelove,” and the U.S. plans to spend a trillion dollars replacing most of its nuclear weapons with new ones that are more effective for a first strike. Adding insult to injury, India, Pakistan and Israel have been allowed to join the nuclear club without major repercussions. "The probability of a nuclear calamity is higher today, I believe, that it was during the cold war," said former U.S. Secretary of Defense William J. Perry, who signed the open letter. This disillusionment from the “have-nots” prompted 123 of them to launch an initiative in the United Nations General Assembly, where the nuclear nations lack veto power. In late 2016, they voted to launch the aforementioned UN negotiations that may produce a nuclear weapons ban treaty this summer. But a ban obviously wouldn’t persuade the nuclear ``haves” to eliminate their nukes the next morning, so what’s the point of it? The way I see it, most governments are frustrated that a small group of countries with a minority of the world's population insist on retaining the right to ruin life on Earth for everyone else with nuclear weapons. Such “might makes right” policy has precedent. In South Africa, for example, the minority in control of the unethical Apartheid system didn't give it up spontaneously, but because they were pressured into doing so by the majority. Similarly, the minority in control of unethical nuclear weapons won't give them up spontaneously on their own initiative, but only if they're pressured into doing so by the majority of the world's nations and citizens. The key point of the ban is to provide such pressure by stigmatizing nuclear weapons. Nuclear ban supporters draw inspiration from the 1997 Ottawa treaty banning landmines. Although the superpowers still refuse to sign it, it created enough stigma that many people now associate mines not with national security, but with images of children who have had limbs blown off while playing in peace-time. This stigma caused leading arms manufactures to half production in response to investor pressure and dwindling demand. In 2014, the Pentagon announced that it was halting landmine use outside of the Korean peninsula. Today, the global landmine market has nearly collapsed, with merely a single manufacturer (South Korean Hanwa) remaining. The "have-not” negotiators hope that a nuclear ban treaty will similarly stigmatize nuclear weapons, persuading us all that we’re less safe with more nukes—even if they are our own. If this happens, it will increase the likelihood that the ``haves” trim their nuclear arsenals down to the minimum size needed for effective deterrence, reverting from SAD back to MAD and making us all safer. Here is the text of the letter. A list of some of the notable signatories follows. AN OPEN LETTER FROM SCIENTISTS IN SUPPORT OF THE UN NUCLEAR WEAPONS NEGOTIATIONS Nuclear arms are the only weapons of mass destruction not yet prohibited by an international convention, even though they are the most destructive and indiscriminate weapons ever created. We scientists bear a special responsibility for nuclear weapons, since it was scientists who invented them and discovered that their effects are even more horrific than first thought. Individual explosions can obliterate cities, radioactive fallout can contaminate regions, and a high-altitude electromagnetic pulse may cause mayhem by frying electrical grids and electronics across a continent. The most horrible hazard is a nuclear-induced winter, in which the fires and smoke from as few as a thousand detonations might darken the atmosphere enough to trigger a global mini ice age with year-round winter-like conditions. This could cause a complete collapse of the global food system and apocalyptic unrest, potentially killing most people on Earth – even if the nuclear war involved only a small fraction of the roughly 14,000 nuclear weapons that today’s nine nuclear powers control. As Ronald Reagan said: “A nuclear war cannot be won and must never be fought.” Unfortunately, such a war is more likely than one may hope, because it can start by mistake, miscalculation or terrorist provocation. There is a steady stream of accidents and false alarms that could trigger all-out war, and relying on never-ending luck is not a sustainable strategy. Many nuclear powers have larger nuclear arsenals than needed for deterrence, yet prioritize making them more lethal over reducing them and the risk that they get used. But there is also cause for optimism. On March 27 2017, an unprecedented process begins at the United Nations: most of the world’s nations convene to negotiate a ban on nuclear arms, to stigmatize them like biological and chemical weapons, with the ultimate goal of a world free of these weapons of mass destruction. We support this, and urge our national governments to do the same, because nuclear weapons threaten not merely those who have them, but all people on Earth.

#### Yes transition wars---both sides miscalculate.

Min-hyung Kim 20. Department of Political Science and International Relations, Kyung Hee University, Seoul, South Korea. “A real driver of US–China trade conflict: The Sino–US competition for global hegemony and its implications for the future” Emerald Insight. 02-04-2019. <https://www.emerald.com/insight/content/doi/10.1108/ITPD-02-2019-003/full/html> // Re-Cut Justin

Underlying these arguments for an inevitable war between the two superpowers is PTT. PTT originally formulated by Organski (1958) posits that **war is likely** when the power of the dominant state in the international system (i.e. hegemon) is **declining** and that a dissatisfied rising challenger **substantially reduces the power gap between the hegemon and itself**. Unlike balance of power theory, PTT argues that the war is most likely when there is near power parity between a dominant state and a rising and dissatisfied challenger (Organski and Kugler, 1980, pp. 19-20)[5]. A rising power here is generally dissatisfied with the existing international order and **initiates war against a declining hegemon in order to impose orders that are more favorable to itself** (Organski 1958, pp. 364-367). Layne (2018, p. 110) put these power transition dynamics quite succinctly as follows: “Over time, however, the relative power of states changes, and eventually the international order no longer reflects the actual distribution of power between or among the leading Great Powers. When that happens, the legitimacy of the prevailing order is called into question, and it will be challenged by the rising power(s).” And when the balance of power between a dominant state and a rising challenger changes sufficiently, a new order replaces an old one typically **by a hegemonic war** (2018, p. 104). Paying close attention to the **growing Sino–US competition** over hegemony in the twenty-first century, therefore, Shirk (2007, p. 4), China specialist, argues that “History teaches us that rising powers are likely to provoke war.” On the other hand, scholars like Gilpin (1981) contend that the power transition war between great powers is likely to occur when a hegemonic state whose power is declining due to imperial overstretch[6] views “**preventive war as the most attractive means of eliminating the threat** posed by challengers” (Ned Lebow and Valentino, 2009, p. 391), although they do acknowledge that there might be some “ways to prolong the period of its power preponderance vis-à-vis the rising challenger, so that the rapidly rising power will not dare to challenge the hegemonic leadership” (Kim and Gates, 2015, p. 221). In this case, the initiator of war is a declining hegemon, rather than a rising challenger. The declining hegemon who fears a rising challenger’s overtaking its power in the near future **sees war as a better option** than other options of maintaining its hegemony such as reducing its commitments abroad and appeasing a rising challenger.