## 1

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over reducing intellectual property protections for vaccines. Member nations will support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

## 1

#### America’s maintaining hegemony and countering China’s rise through “counter-punching” strategies, but sustained innovation and private sector investment are key – reject “US declining now” args – the US has historically punched over its weight whenever it’s challenged

**Harr 8/3** [Scott, Army Special Forces Officer and Ph.D. Candidate at the Helms School of Government, Liberty University. He holds an undergraduate degree in Arabic Language Studies from West Point and a Master’s degree in Middle Eastern Affairs from Liberty University. A trained Arabic and Farsi speaker with over four years of cumulative deployment time in the Middle East, his work has been featured in The Diplomat, RealClearDefense, The Strategy Bridge, Modern War Institute, Military Review, The National Interest, and Joint Force Quarterly among other national security-focused venues, “By Avoiding Arms Races, America Can Counter China’s Rise”, 08-03-2021, https://nationalinterest.org/feature/avoiding-arms-races-america-can-counter-china%E2%80%99s-rise-191094]//pranav

**Rather than falling into the power projection arms race “trap“ that China desires, U.S. competitive strategies addressing China** should **adopt a framework based on “counter-punching**.” As its name suggests, the counterpunch incorporates both defensive (“counter”) and offensive (“punch”) elements. Additionally, it is an adaptive maneuver that requires disciplined understanding and controlled strength that, effectively employed, offers better alternatives towards protecting and preserving U.S. power in the face of challenges from China. The defensive element of an American counterpunch towards China involves adopting military restraint and a revamped examination of deterrence. Classic deterrence strategy involves presenting the credible threat of force to adversaries to create undesirable risks for would-be aggressors. The key to deterrence, as Kenneth Waltz famously argued, is determining how much deterrence is “enough” to dissuade aggressors. That is, deterrence does not necessarily require the presentation of power projection assets capable of completely destroying an adversary, but only enough assets to make the risks of aggressive behavior not worth the projected losses involved. Seen in this light, a strategy that diligently examines how much deterrence is “enough” potentially eliminates the impulse to sustain the ever-increasing stakes in costly arms races while, critically, **offering a chance to reinvest excess “deterrence” resources into areas that will preserve and protect U.S. power**. The national resources freed up by foregoing an arms race with China represent the potent offensive element of the counterpunch. **These resources can be reinvested in other areas such as the private sector which, besides being the hallmark of American prosperity and thus the critical reason for protecting American power in the first place, has historically played a decisive role in the United States’ successful war efforts**. **Buoyed by a strong and vibrant private sector where the United States remains a desirable global hub for innovation and technology, the needed capabilities for war (or intense competition) can be adaptively produced and rapidly called forward to tip the competitive (or combative) scales towards victory when required.** Of course, the “punch” loses its effectiveness without clearly articulated triggers for employment. If China seeks to induce the United States into an uncontrolled arms race, then the current U.S. obsession with China—which seems to interpret every Chinese action in any sphere as a threat requiring a U.S. response—must be viewed as very encouraging in Beijing. An effective U.S. counterpunch requires clearly defined red lines that regulate and set behavior expectations between great powers and indicate when a Chinese competitive action warrants a U.S. response. Detractors of the counterpunch framework will immediately note the call for military restraint and interpret it as a reactive recipe for military weakness at precisely a time requiring proactive military strength. But military restraint does not imply weakness any more than eating fewer calories implies malnutrition. It simply means making smarter decisions that play to U.S. strengths and away from Chinese strategy. It also entails properly viewing the risks inherent in competition with China. The counterpunch skeptic incorrectly perceives greater risks in short-term military restraint (traded for economic investment and fortification) than in long-term arms races (traded for potential economic collapse). The counterpunch skeptic also fails to appreciate the United States’ historic strengths in adopting this approach. In fact, **America has demonstrated exceptional skill as an adaptive counter-puncher—reacting and adapting to adversity and setbacks to rise above them and create positive effects preserving U.S. power and ideas.** U.S. institutions have counter-punched their way to success in the political (from the failed Articles of Confederation to the Constitution), social (from abhorrent slavery to civil rights), and military (from disastrous Pearl Harbor to WWII victory) arenas to produce the stable and prosperous nation that exists today. As John Mearsheimer points out, **China has the population size and economic capacity (the “sinew of power”) to pose unique and unprecedented challenges to U.S. power**. Additionally, wasteful military exploits—often employed as a means of competing with rivals—have contributed to bringing down world powers again and again throughout history. China understands this apparent axiom and has woven its truth into its competitive strategy to displace the United States as the world’s preeminent power in the twenty-first century. U.S. competitive strategy against China must, therefore, resist the powerful (but seemingly prudent) urge to continually increase the stakes projecting power against China. Rather, the United States needs to adopt a disciplined counterpunch framework focused on protecting and preserving (not projecting) power. This **framework leverages the elements of a successful counterpunch: it demonstrates a superior understanding of adversary strategy (China’s desire to economically exhaust the United States with power projection), it leverages smart defensive elements (adopting only “enough” deterrence to influence China’s actions), and it fortifies conditions of economic strength to ensure offensive actions can be brought to bear when required in competition or conflict (re-investing resources into a globally-leading private sector).** Employing a counterpunch framework asks Americans to trust its institutions—which is a difficult task in the face of a rising China. But the ask is not for blind trust. As a country with less than one-sixth of the world’s population, **the United States as a superpower has been punching above its weight for decades and has historically counter-punched successfully to muster adaptive and superlative responses whenever challenged with adversity. America must follow these historical impulses to remain a superpower in the twenty-first century**.

#### The 1AC’s reduction of IPP for vaccines is America “handing over its crown jewels” to competing nations by disincentivizing record setting innovation that causes spillover to other fields and destroys American hegemony.

**Iancu 8/11** [Andrei, American-Romanian engineer and intellectual property attorney, who served as the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office from 2017 to 2021, “Biden is trying to undermine America's world-leading IP protections”, https://m.washingtontimes.com/news/2021/aug/11/biden-is-trying-to-undermine-americas-world-leadin/]//pranav

In May of this year, the Biden administration announced its support for a proposal at the World Trade Organization that would allow other countries to seize American intellectual property on COVID-19 technologies, including vaccines. On cue, those countries promptly modified their ask. **Whereas the original proposal called for the waiver to last a limited number of years, the new proposal makes the waiver effectively permanent.** And why not? **If America is willing to hand over its crown jewels, it might as well demand to keep them forever.** As a former Director of the U.S. Patent and Trademark Office, I know that America’s world-leading IP protections laid the foundation for our economic success and technological prowess. And as an immigrant from a communist nation, **I know all too well how disrespect for private property rights undermines innovation and saps economic vitality.** Since the Founding Fathers, Americans have understood that private property extends well beyond land, buildings, factories, and machines. **The real source of America’s power and promise are ideas. Walls, locks, or guards can protect physical property, but the implementation of ideas — new songs, artificial intelligence, or medicines — requires special protections and trust in the rule of law**. That’s why the Founders included intellectual property rights in the Constitution — in the form of an “exclusive right” for authors and inventors — to “promote the progress of science and useful arts.” Indeed, this is the only time the word “right” appears in the Constitution (amendments aside). The Founders knew that only the rule of law, and our respect for it, can protect and enable the development of these ideas. Yet, President Biden undermined that respect by signaling his support for the appropriation of America’s intangible assets. In doing so, he jeopardized America’s uniquely successful intellectual property system. The history of our nation — indeed, much of the history of the world — **since 1789 has been the revolution in knowledge led by American ingenuity in agriculture, industry, medicine, and information technology. Progress like this does not just happen**. Indeed, it didn’t, for the millennia of the entire human history until our nation’s founding a couple of hundred years ago! **It’s not a coincidence that the last two centuries of uninterrupted, IP-driven innovation — up to and including the miraculous creation in a record time of the Covid vaccines themselves — began when one nation finally committed itself to protect intangible assets as much as physical property.** The reason is simple: knowledge is cumulative. **Every new discovery becomes the basis for new research. The revolutionary mRNA technology behind Pfizer and Moderna’s vaccines is, in fact, an evolutionary iteration of previous — patented — breakthroughs over the last two decades.** Sen. Bernie Sanders, among others, turns up his nose at all this science, history, and progress. Like President Biden, he supports waiving vaccine patents because, he says, “We need a people’s vaccine, not a profit vaccine.” **Ignore for a moment that many companies have agreed to sell their vaccines at non-profit prices for the duration of the pandemic, or that the vaccines are completely free for all patients at pharmacies nationwide, or that the federal government pays $19.50 per Pfizer dose, about $15 per Moderna dose, and $10 for the Johnson & Johnson shot — less than the cost of a pizza for medicines that are saving millions of lives and restoring our economy.** Instead, **focus on the fact that intellectual property protections enabled the creation of “people’s vaccines” in the first place.** **The choice isn’t between cheap vaccines and even cheaper vaccines — it’s between shots that are protected by strong IP laws or no shots at all.** The same goes for every industry. **If President Biden doesn’t protect the IP behind new vaccines, investors and inventors will ask, what other technologies are next?** Will similar takings be imposed on climate change technologies, for example? Food processing? Essential semiconductor technologies? **Companies will scale back investments in medical devices, microchips, energy, and everything in between if they think the U.S. Government might waive IP protection after the fact so that others may copy their inventions with impunity.** Of immediate concern is the need for more treatments for Covid-19, especially as the pandemic keeps raging with new variants. **Knowing that their IP may be appropriated as soon as it is developed, private industry — especially start-ups and smaller businesses that depend heavily on outside capital — may not invest the resources necessary to develop these new technologies that are desperately needed right now.** Here’s the reality: **remove patents and other forms of intellectual property, and private-sector investment in innovation dries up**. The government will then try to step in to fill the gap, inefficiently as always. **Like the taking of factories to nationalize industry, this taking of intellectual property is effectively the nationalization of our innovation economy**. The result will be the same as in every other socialist regime that nationalized its industries: the kind of poverty, corruption, and misery that my family escaped from decades ago. **American innovation** has cured diseases, enabled human flight, led to the development of computers, and **made our nation the envy of the world. Waiving intellectual property rights could forfeit it all.**

#### Only U.S. hegemony prevents global instability---alternatives can't maintain peace

**Haass, 17** - President of the Council on Foreign Relations (Richard, "Who Will Fill America’s Shoes?," *Project Syndicate*, 6-24-2017, https://www.project-syndicate.org/commentary/global-leadership-successor-to-america-by-richard-n--haass-2017-06)

Still, a shift away from a US-dominated world of structured relationships and standing institutions and toward something else is under way. What this alternative will be, however, remains largely unknowable. What we do know is that **there is no alternative great power willing and able to step in and assume what had been the US role**.

China is a frequently mentioned candidate, but its leadership is focused mostly on consolidating domestic order and maintaining artificially high economic-growth rates to stave off popular unrest. China’s interest in regional and global institutions seems designed mostly to bolster its economy and geopolitical influence, rather than to help set rules and create broadly beneficial arrangements.

Likewise, Russia is a country with a narrowly-based economy led by a government focused on retaining power at home and re-establishing Russian influence in the Middle East and Europe. India is preoccupied with the challenge of economic development and is tied down by its problematic relationship with Pakistan. Japan is held back by its declining population, domestic political and economic constraints, and its neighbors’ suspicions.

Europe, for its part, is distracted by questions surrounding the relationship between member states and the European Union. As a result, the whole of the continent is less than the sum of its parts – **none** of which **is large enough to succeed America on the world stage**.

But the absence of a single successor to the US does not mean that what awaits is chaos. At least in principle, the world’s most powerful countries could come together to fill America’s shoes. In practice, though, **this will not happen**, as these countries lack the capabilities, experience, and, above all, a consensus on what needs doing and who needs to do it.

#### Goes nuclear---extinction

Thomas H. **Henricksen 17**, emeritus senior fellow at the Hoover Institution, 3/23/17, “Post-American World Order,” <http://www.hoover.org/research/post-american-world-order>

The tensions stoked by the assertive regimes in the Kremlin or Tiananmen Square could **spark a political or military incident** that might set off a chain reaction leading to a **large-scale war**. Historically, powerful rivalries nearly always lead to at least skirmishes, if not a full-blown war. The anomalous Cold War era **spared** the United States and Soviet Russia a direct conflict, largely from concerns that one would trigger a **nuclear exchange destroying** both states and much of **the world**. Such a repetition **might** reoccur in the unfolding three-cornered geopolitical world. It seems safe to acknowledge that an ascendant China and a resurgent Russia will persist in their geo-strategic ambitions.

What Is To Be Done?

The first marching order is to dodge any kind of perpetual war of the sort that George Orwell outlined in “1984,” which engulfed the three super states of Eastasia, Eurasia, and Oceania, and made possible the totalitarian Big Brother regime. A long-running Cold War-type confrontation would almost certainly take another form than the one that ran from 1945 until the downfall of the Soviet Union.

What prescriptions can be offered in the face of the escalating competition among the three global powers? First, by **staying militarily and economically strong**, the United States will have the resources to deter its peers’ hawkish behavior that might otherwise trigger a **major conflict**. Judging by the history of the Cold War, the coming strategic chess match with Russia and China will prove tense and demanding—since **all the countries boast nuclear arms** and long-range ballistic missiles. Next, the United States should widen and sustain willing coalitions of partners, something at which America excels, and at which China and Russia fail conspicuously.

There can be **little room for error** in fraught **crises among nuclear-weaponized** and **hostile powers**. Short- and long-term standoffs are likely, as they were during the Cold War. Thus, the playbook, in part, involves a **waiting game** in which each power looks to its rivals to suffer grievous internal problems which could entail a collapse, as happened to the Soviet Union.

## 2

#### Interpretation: The affirmative debater must defend reducing intellectual property protections for substances that treat diseases. To clarify, they may not defend substances that prevent diseases.

#### Violation: They defend COVID vaccines

#### Medicines treat diseases

Webster (Merriam Webster is America's leading and most-trusted provider of language information, accessed on 6-30-21, Merriam Webster, "Definition of MEDICINE,” https://www.merriam-webster.com/dictionary/medicine)// ww pbj

Definition of medicine 1a: a substance or preparation used in treating disease cough medicine

#### Treatment is different than prevention

Pflanzer 20 (Lydia Ramsey Pflanzer is a healthcare editor for Business Insider. She joined Business Insider in 2015 after graduating from Northwestern University, 4-29-2020, accessed 6/30/21, "Scientists are racing to discover ways to treat and prevent coronavirus. Here's the difference between a treatment and a vaccine.," Business Insider, <https://www.businessinsider.com/whats-the-difference-between-a-vaccine-and-a-treatment-2020-4)//ww> pbj

Vaccines are used to prepare the body's immune system to fight off infections. They work by giving the body a small taste of what the virus is like so that way it can produce antibodies that fight off an intruding virus, ideally keeping people from falling ill. Some vaccines protect better than others, and they're typically administered across broad populations. There are vaccines for some infectious diseases, like the flu, smallpox, measles, and chickenpox. But others, like HIV and hepatitis C, don't have vaccines that protect against them. Vaccines that protect against two other deadly outbreaks, MERS and SARS, have yet to be approved after the outbreaks subsided. There are more than 70 potential coronavirus vaccines in the works, with a number in early human trials. Drugmakers are looking into ways to produce the billions of doses that might be needed to suppress the pandemic. Read more: There are more than 70 potential coronavirus vaccines in the works. Here are the top efforts to watch, including the 16 vaccines set to be tested in people this year. FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) Associated Press Treatments, on the other hand, are meant to do just that: treat COVID-19, helping patients sickened by the virus survive and recover more quickly. Treatments for disease are there to lessen symptoms and ultimately improve the outcomes of a particular disease. Sometimes, medications can be used preventatively. For instance, patients with high cholesterol might be prescribed a medication called a statin to prevent heart attacks. Some potential coronavirus treatments are being studied to see if they can prevent people from contracting the virus in the first place. For COVID-19, researchers are testing everything from antimalarial medications to antivirals, to even common heartburn medications in hospitalized patients with the hopes that more patients will survive severe forms of the illness and potentially recover faster. Some are looking at ways to use patients' own bodies to fight the virus with antibody treatments.

#### Vaccines specifically are different from medicines

Immunize BC 20 (Immunize British Colombia is a collaborative project of the BC Ministry of Health, the BC Centre for Disease Control (an agency of the BC Provincial Health Services Authority), the regional health authorities (First Nations Health Authority, Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health), the BC Pharmacy Association and the Public Health Association of BC. Our mission is to improve the health of British Columbians by continuing to reduce the number of vaccine-preventable diseases, along with the illness, disability and death that they cause, What are vaccines?, Date last reviewed: Thursday, Mar 19, 2020, accessed on 6-30-21, <https://immunizebc.ca/what-are-vaccines)//ww> pbj

Vaccines are products that protect people against many diseases that can be very dangerous and even deadly. Different than most medicines that treat or cure diseases, vaccines prevent you from getting sick with the disease in the first place.

#### Standards:

#### [1] Limits – they explode the topic to include tons of substances that prevent disease rather than treat them like soap, medical supplies, or food and make it so there is *no* unified neg generics. The aff still gets the core of the topic lit: they get medicine, innovation, and global inequality. Explosion of aff ground makes neg prep burden impossible, either killing neg ground or forcing the neg to read generics that barely link, always letting aff win. Force the 1AR to read a definition card with a clear list of what’s included and excluded – otherwise, vote neg since they can’t put a clear limit on the topic.

#### [2] Precision – not defending the text of the resolution justifies the affirmative doing away with random words in the resolution which a] means they’re not within the topic which is a voter for jurisdiction since you can only vote affirmative on the resolution and this debate never should have happened, b] they’re unpredictable and impossible to engage in so we always lose

#### Drop the Debater –

#### [1] sets a precedent that debaters wont be abusive

#### Voters:

#### [1] Fairness – constitutive to the judge to decide the better debater, only fairness is in your jurisdiction because it skews decision making

#### [2] Education – the only portable education from debate that we care about

#### Competing Interps:

#### [1] reasonability on t is incoherent: you’re either topical or you’re not – it’s impossible to be 77% topical, links to all limits offense

#### [3] judge intervention – judge has to intervene on what’s reasonable, creates a race to the bottom where debaters exploit judge tolerance for questionable argumentation.

#### No RVIs

#### [1] illogical for you to get offense just for being fair – it’s the 1ac’s burden

## Case

### COVID

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### 2] Public Citizen 3/29 says that these institutions are creating medicines for upper class, high income countries, meaning that “manufacturing capabilities” are not available in these low-income countries you try to solve for, your own evidence disproves.

#### 3] 1AC solvency is contingent on winning that a vaccine waiver would solve COVID, but they never prove the infrastructure exists in low-income countries – prefer the NC evidence – it’s a key internal link to aff solvency that they just didn’t bother reading.

#### TL -- their only COVID impact scenario is about future pandemics, there’s no reason in the 1AC why COVID waivers solve that--only new innovation can

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

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

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

#### The aff doesn’t solve – access to medicine is not a one-way street and there are multiple other factors that they just can’t resolve

Motari 21, Marion Motari, [Jean-Baptiste Nikiema](javascript:;), [Ossy M. J. Kasilo](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Ossy_M__J_-Kasilo), [Stanislav Kniazkov](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Stanislav-Kniazkov), [Andre Loua](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Andre-Loua), [Aissatou Sougou](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Aissatou-Sougou), [Prosper Tumusiime](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Prosper-Tumusiime) are Adjunct Faculty, Daystar University School of Law, Nairobi, Kenya, “The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement”, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y>, accessed apark 6/27/21

Although this paper focuses on the role of intellectual property rights on access to medicines, it is recognized that limited access to medicines in countries of the World Health Organization (WHO) African Region[Footnote3](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#Fn3) is a multidimensional problem. It is affected by other factors such as lack of public financing for health care and over-reliance on out of pocket expenditure[[7](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR7)], fragile logistics, storage challenges and high transport and distribution costs [[2](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR2)] and inadequate or inappropriate medicines regulatory frameworks [[8](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR8)]. These factors are further exacerbated by insufficient scientific, technological and local manufacturing capabilities in the Region [[9](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR9)].

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

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

Smith 05/05

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

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

#### Util hijacks stuff