#### 1] No link:

#### A] Developing nations like India and Vietnam already have robust capabilities for mRNA that scale up quickly – 1AC Kumar.

#### B] Vaccines still have to go through approval with the WHO which ensures quality.

#### C] The DA is the worst form of discrimination and ignores empirical precedent.

Merelli 21 [Annalisa; Reporter at Quartz. She hails from Bergamo (Italy) but has worked and lived in Paris and Delhi before settling in the US (for now). She was the founding editor of art, culture and lifestyle portal The India Tube and a writer and editor at Narratively, Global Voices, Timbuktu, Motherland, W+K Delhi, and Fabrica. She holds a master's degree in semiotics and a bachelor's degree in mass communication from the University of Bologna; “Big pharma wants you to think sharing vaccine patents overseas is very dangerous,” Quartz; 5/28/21; <https://qz.com/2013661/big-pharma-argues-poor-nations-cant-be-trusted-to-make-vaccines/>] Justin

The myth that making vaccines in poor countries might be dangerous is very dear to pharmaceutical companies. “Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” wrote Pfizer CEO Albert Bourla in a statement.

A narrative as old as AIDS

“The history behind this particular tactic of questioning the safety of manufacturers in other parts of the world has been played out on various occasions,” says Tahir Amin, the co-founder of I-MAK, a US-based organization working to increase global access to medicines

Perhaps the most egregious precedent is the dispute between big pharma and poor countries over the making of antiretroviral drugs for AIDS, which cost about $10,000 per person per year before the introduction of generics that brought the price down to $300 per person per year.

A famous episode of that battle culminated in court in 1998, when a coalition of multinational drugmakers and the South African Pharmaceutical Manufacturers Association sued the Nelson Mandela-led South African government for its attempts to encourage the local, patent-free production of more affordable AIDS medications, although eventually the charges were dropped. At the time, western pharmaceutical companies claimed drugs made in developing countries didn’t meet the necessary quality standards, though research repeatedly found that there was no reason to think so.

“Had it not been for generics manufacturers in the global south, we wouldn’t have gotten more people treated with antiretrovirals, and we’ve seen that generics are very much safe and the quality is not questioned,” says Amin.

#### 1] Aff solves the DA – it’s wraps:

#### B] It’s a question of access: we aren’t accessing our full innovation potential because smaller countries don’t have the resources to innovate. Allowing for patents incentivizes third-world innovations and improvements to vaccines.

#### C] Frame this through scale-up: even if innovation occurs access to innovation is limited because of lack of distribution – only the aff has a risk of distribution of innovation to solve pandemics.-erfani

#### 2] Evergreening DA: patents are being misused to extend monopolies with useless tweaks that shields producers from competition which prevents innovation and prevent competitors from innovating – 1AC Gurgula. No new 2n responses—allows for sandbagging and time crunches the 3 minute 2ar.

#### 3] Non-unique – innovation stalling because of failing clinical trials, drug prices, econ.

Langley 4/21 [(Kare, reporter for The Wall Street Journal in New York, where she primarily covers the U.S. stock market), “Biotech Stocks Fall Out of Favor After Disappointing Trial Results, Big Rally “, WSJ, 4/21/2021, https://www.wsj.com/amp/articles/biotech-stocks-fall-out-of-favor-after-disappointing-trial-results-big-rally-11619016330] TDI // Re-Cut Justin

Shares of Sarepta Therapeutics Inc., Amicus Therapeutics Inc. and Frequency Therapeutics Inc. are among the recent losers for biotech investors, having lost more than half their value so far this year. “It’s felt like a kitchen sink in terms of the number of factors weighing on biotech sentiment in the near term,” said Andy Acker, who manages the Janus Henderson Global Life Sciences Fund. Among those are disappointing clinical trials, concern about the possibility of renewed focus on drug prices in Washington and the recent rotation into economically sensitive stocks. Biotech shares enjoyed a powerful rally last year. The Nasdaq biotech gauge soared 26% in 2020 on excitement about the potential for Covid-19 treatments and vaccines as well as a broader rally in shares of companies that can perform when the economy is struggling. The S&P 500, meanwhile, gained 16% last year, and the Nasdaq Composite surged 44%. Rapid gains or losses in share prices following clinical-trial results or regulatory decisions are a feature of biotech investing, but a smattering of negative news has damped enthusiasm in recent months. Shares of Sarepta Therapeutics plunged 51% on Jan. 8 after mixed results from a study of a drug targeting a form of muscular dystrophy. The shares are now down 58% for the year. Amicus Therapeutics shares dropped 33% on Feb. 12 after trial results for its treatment of a rare disorder called Pompe disease disappointed investors. And shares of Frequency Therapeutics plunged 78% on March 23 after the company found its lead drug aimed at treating sensorineural hearing loss didn’t lead to any hearing benefit when given in a four-dose schedule. Those stocks are down 57% and 72%, respectively, this year. Also weighing on sentiment: The Federal Trade Commission has indicated it is preparing to take a harder line on drug-company mergers, which are a source of potential value for investors in small biotech shops. The commission in March said it would reconsider its approach to scrutinizing deals that could harm competition. “Biotech can be driven by mergers,’ said Jeremie Capron, director of research at ROBO Global, a research and investment-advisory firm. “A change at the FTC, it reduces the probability of a favorable outcome in terms of an acquisition.” Analysts will also be keeping an eye on any efforts in Washington to reduce drug prices. Some investors are betting against companies in the industry. Biotech stocks accounted for five of the 10 most-shorted stocks on U.S. exchanges at the end of March, according to S&P Global Market Intelligence. Short interest in Esperion Therapeutics Inc.stood at 34% of shares outstanding as of March 31, followed by Clovis Oncology Inc. at 31% and Inovio Pharmaceuticals Inc. at 26%, an S&P analysis showed. As Covid-19 vaccines reach more people and the economy picks up, investors have favored shares of banks, energy producers and other companies that tend to do well in a strong economy. They have been less interested in stocks that hold out the prospect of innovation-driven growth in fields like technology and biotech. Expectations of a strong recovery have also been seen in the bond market, where falling prices lifted the yield on the benchmark 10-year U.S. Treasury note to 1.566% on Wednesday from 0.913% at the end of last year. As yields climb, borrowing costs for businesses also rise. That often lands hard on biotech companies, where hefty bills for research and development can arrive long before revenue.

#### 4] No link.

Gupta and Ramachandran 9/24 [Ravi and Reshma; 9/24/21; Penn LDI and Yale School of Medcine; “A Covid-19 Vaccine IP Waiver Won’t Kill Pharma Innovation,” Bloomberg, <https://news.bloomberglaw.com/ip-law/a-covid-19-vaccine-ip-waiver-wont-kill-pharma-innovation>] Justin

A False Choice Between Access and IP Waivers and Innovation But the trade-off between ensuring global access to Covid-19 vaccines through IP waivers and innovation is a false choice for several reasons, especially amidst a devastating pandemic. First, in the case of Covid-19 vaccines, such monopoly rights are duplicative and unnecessary. Through Operation Warp Speed, the U.S. government underwrote Covid-19 vaccine development, spending an unprecedented $18 billion. This included advance purchasing agreements for the vaccines before they were shown to be effective, essentially eliminating companies’ risk of failure. Moreover, key technology that led to the currently available mRNA vaccines was developed by the U.S. government. For Moderna, continued development of booster vaccines has been in collaboration with and through the support of the National Institutes of Health. Second, companies have already profited handsomely from Covid-19 vaccines. Pfizer will earn $33 billion and Moderna $18 billion in sales in 2021 alone. Because this pandemic will likely not end anytime soon, companies will continue to make profits from Covid-19 vaccines, including from more expensive booster shots. The White House recently purchased an additional 200 million doses of the Pfizer/BioNTech vaccine at a higher price than last year, and prices were also set higher in recent EU orders. Such trends will likely continue. Third, manufacturers’ prioritization of higher-revenue markets in wealthier countries has meant that vaccines, particularly for infections with pandemic potential, have historically been neglected. An Ebola vaccine, for instance, languished since the early 2000s. Promising vaccine candidates for SARS-CoV-1, the coronavirus that led to the SARS outbreak in 2003, quickly lost funding once the outbreak ended. If this research had continued, we may have had earlier vaccine and treatment options for the related Covid-19. While long-term reform is needed to address this innovation void, democratizing Covid-19 vaccine manufacturing through an IP waiver would have minimal, if any, negative effect. Fourth, a Covid-19 IP waiver is unlikely to harm drug development for non-pandemic diseases. As currently constructed, the waiver is limited in time and scope to only Covid-19. But to the extent that an IP waiver would diminish Covid-19 vaccine profits, the non-partisan Congressional Budget Office recently found that limiting pharmaceutical profits would lead to a relatively small reduction in new drug launches. Moreover, these few drugs may not reflect truly transformative innovation that meets the needs of our patients to begin with. Companies frequently invest in new drugs that treat diseases with existing treatments (“me-too” drugs) and focus more on stock buybacks than on research and development. There is thus little reason to believe that reducing further profit margins from Covid-19 vaccines through an IP waiver would harm innovation for non-pandemic diseases. Fifth, Covid-19 has quickly validated novel vaccine platforms, particularly mRNA, which holds the tantalizing potential of treating other serious infections and cancers. This ability to repurpose largely publicly funded vaccine platforms for other diseases means that companies will continue to benefit beyond the current pandemic. Concerns that an IP waiver could affect future uses of mRNA are tempered by the reality that ownership rights such as patents will still exist. Unquestionably, the remarkable organizational capacity of pharmaceutical companies helped bring Covid-19 vaccines to fruition and they have been rewarded. But enacting an IP waiver to allow additional manufacturers to overcome the ongoing supply shortfall is essential in curbing the threat of new variants, ending this pandemic, and saving millions of lives around the world. There are admittedly real challenges even after an IP waiver, but these are addressable difficulties and many manufacturers stand ready to collaborate. Continued, long-term inequity that further fuels what is now a preventable disease ought to be an unacceptable outcome to this plague. During the UN General Assembly, our world leaders would do well to fight for equitable vaccine access to end this pandemic and to stand on the side of people over profits.

#### China is donating more vaccines to America

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.

#### 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; 7/16/21; <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.

### 1AC – Framing

#### *Ethics must begin a priori*

#### [A] Empirical Uncertainty – evil demon could deceive us 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.

#### [B] Constitutive Authority – The meta-ethic is bindingness. Practical reason is the only unescapable authority because to ask why I should be a reasoner concedes it’s authority since you’re actively reasoning.

#### [C] 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.

#### That justifies universality – a] a priori principles like reason apply to everyone since they are independent of human experience and b] 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.

#### Additionally:

#### [A] 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.

#### [B] Only universalizable reason can effectively explain the perspectives of agents – that’s the best method for combatting oppression.

Farr 02 Arnold Farr (prof of phil @ UKentucky, focusing on German idealism, philosophy of race, postmodernism, psychoanalysis, and liberation philosophy). “Can a Philosophy of Race Afford to Abandon the Kantian Categorical Imperative?” JOURNAL of SOCIAL PHILOSOPHY, Vol. 33 No. 1, Spring 2002, 17–32.

**One** of the most popular **criticism**s **of Kant’s moral philosophy is that it is too formalistic.**13 That is, the universal nature of the categorical imperative leaves it devoid of content. Such a principle is useless since moral decisions are made by concrete individuals in a concrete, historical, and social situation. This type of criticism lies behind Lewis Gordon’s rejection of any attempt to ground an antiracist position on Kantian principles. The rejection of universal principles for the sake of emphasizing the historical embeddedness of the human agent is widespread in recent philosophy and social theory. I will argue here on Kantian grounds that **although a distinction between the universal and the concrete is** a **valid** distinction, **the unity of the two is required for** an understanding of human **agency.** The attack on Kantian formalism began with Hegel’s criticism of the Kantian philosophy.14 The list of contemporary theorists who follow Hegel’s line of criticism is far too long to deal with in the scope of this paper. Although these theorists may approach the problem of Kantian formalism from a variety of angles, the spirit of their criticism is basically the same: The universality of the categorical imperative is an abstraction from one’s empirical conditions. **Kant is** often **accused of making the moral agent an abstract, empty**, noumenal **subject. Nothing could be further from the truth. The Kantian subject is** an embodied, empirical, concrete subject. However, this concrete subject has a dual nature. Kant claims in the Critique of Pure Reason as well as in the Grounding that human beings have an intelligible and empirical character.15 It is impossible to understand and do justice to Kant’s moral theory without taking seriously the relation between these two characters. The very concept of morality is impossible without the tension between the two. By “empirical character” Kant simply means that we have a sensual nature. We are physical creatures with physical drives or desires. **The** very **fact that I cannot simply satisfy my desires without considering the rightness** or wrongness **of my actions suggests that my empirical character must be held in check** by something, or else I behave like a Freudian id. My empiri- cal character must be held in check **by my intelligible character**, which is the legislative activity of practical reason. It is through our intelligible character that **we formulate principles that keep our** empirical **impulses in check.** The categorical imperative is the supreme principle of morality that is constructed by the moral agent in his/her moment of self-transcendence. What I have called self-transcendence may be best explained in the following passage by Onora O’Neill: In restricting our maxims to those that meet the test of the categorical imperative we refuse to base our lives on maxims that necessarily make our own case an exception. The reason why a universilizability criterion is morally signiﬁcant is that it makes our own case no special exception (G, IV, 404). In accepting the Categorical Imperative we accept the moral reality of other selves, and hence the possibility (not, note, the reality) of a moral community. **The Formula of Universal Law enjoins no more than that we act only on maxims that are open to others also.**16 O’Neill’s description of the universalizability criterion includes the notion of self-transcendence that I am working to explicate here to the extent that like self-transcendence, universalizable moral principles require that the individ- ual think beyond his or her own particular desires. The individual is not allowed to exclude others **as** rational **moral agents** who have the right to act as he acts in a given situation. For example, if I decide to use another person merely as a means for my own end I must recognize the other person’s right to do the same to me. I cannot consistently will that I use another as a means only and will that I not be used in the same manner by another. **Hence,** the **universalizability** criterion **is a principle of consistency and** a principle of **inclusion.** That is, in choosing my maxims **I** attempt to **include the perspective of other moral agents.**

#### [C] Practical identities – we find our lives worth living under practical identities such as student but that presupposes agency.

**Korsgaard 92** CHRISTINE M. Korsgaard 92 [I am a Professor of Philosophy at Harvard University, where I have taught since 1991. From July 1996 through June 2002, I was Chair of the Department of Philosophy. (The current chair is Sean Kelly.) From 2004-2012, I was Director of Graduate Studies in Philosophy. (The current DGS is Mark Richard.) Before coming here, I held positions at Yale, the University of California at Santa Barbara, and the University of Chicago, as well as visiting positions at Berkeley and UCLA. I served as President of the Eastern Division of the American Philosophical Association in 2008-2009, and held a Mellon Distinguished Achievement Award from 2006-2009. I work on moral philosophy and its history, practical reason, the nature of agency, personal identity, normativity, and the ethical relations between human beings and the other animals], “The Sources of Normativity”, THE TANNER LECTURES ON HUMAN VALUES Delivered at Clare Hall, Cambridge University 16-17 Nov 1992, BE

The Solution: Those who think that the human mind is internally luminous and transparent to itself think that the term “self-consciousness” is appropriate because what we get in human consciousness is a direct encounter with the self. Those who think that the human mind has a reflective structure use the term too, but for a different reason. The reflective structure of the mind is a source of “self-consciousness” because it forces us to have a conception of ourselves. As Kant argues, this is a fact about what it is like to be reflectively conscious and it does not prove the existence of a metaphysical self. From a third person point of view, outside of the deliberative standpoint, it may look as if what happens when someone makes a choice is that the strongest of his conflicting desires wins. But that isn’t the way it is for you when you deliberate. When you deliberate, it is as if there were something over and above all of your desires, something that is you, and that chooses which desire to act on. This means that the principle or law by which you determine your actions is one that you regard as being expressive of yourself. To identify with such a principle or law is to be, in St. Paul’s famous phrase, a law to yourself.6 An agent might think of herself as a Citizen in the Kingdom of Ends. Or she might think of herself as a member of a family or an ethnic group or a nation. She might think of herself as the steward of her own interests, and then she will be an egoist. Or she might think of herself as the slave of her passions, and then she will be a wanton. And how she thinks of herself will determine whether it is the law of the Kingdom of Ends, or the law of some smaller group, or the law of the egoist, or the law of the wanton that is the law that she is to herself. The conception of one’s identity in question here is not a theoretical one, a view about what as a matter of inescapable scientific fact you are. It is better understood as a description under which you value yourself, a description under which you find your life to be worth living and your actions to be worth undertaking. So I will call this a conception of your practical identity. Practical identity is a complex matter and for the average person there will be a jumble of such conceptions. You are a human being, a woman or a man, an adherent of a certain religion, a member of an ethnic group, someone’s friend, and so on. And all of these identities give rise to reasons and obligations. Your reasons express your identity, your nature; your obligations spring from what that identity forbids.

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

#### [1] Presumption and Permissibility affirm: a] Statements are true before false since if I told you my name, you’d believe me. b] If anything is permissible, then so is the aff since there is nothing prohibiting us.

#### [2] Consequences Fail: a] Every action has infinite stemming consequences, because every consequence can cause another consequence so we can’t predict. b] Induction is circular because it relies on the assumption that nature will hold uniform and we could only reach that conclusion through inductive reasoning based on observation of past events. c] Every action is infinitely divisible, only intents unify because we commit the end point of an action – but consequences cannot determine what step of action is moral d] Yes act/omission distinction – there are infinite events occurring over which you have no control, so you can never be moral

### Advocacy

Thus, the plan – Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines. CP **and PICs affirm because they do not disprove my general thesis.**

#### 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] Property rights minimize the opportunity of innovation which limits individual freedom through creating monopolies. They also limit the use of tangible objects such as medicines for good purposes.

Cernea and Uszkai 12 Cernea, Mihail-Valentin, and Radu Uszkai. *The Clash between Global Justice and Pharmaceutical Patents: A Critical Analysis*. 2012, the-clash-between-global-justice-and-drug-patents-a-critical-analysis.pdf. SJEP

To make this point clearer, we regard property as an ethical institution which emerged in the context of reiterated conflict between agents for tangible goods. A useful analogy would be, for example, the particular way in which David Hume discusses the emergence of justice in the context of scarcity in which agents pursue their own interests4 . As a result, the purpose of property rights would be that of avoiding or minimizing the possibility of conflict and that of increasing the costs of free-riding or trespassing. Let’s take the following example which will illustrate better our point. Assume that X is a philosophy student and has a copy of Immanuel Kant’s Groundwork of the Metaphysics of Morals. Y is a college of him but he does not have the book. They both have to write an essay on Kant’s categorical imperative. Because Y does not have the book, let’s assume that he decides, whether by the use of coercion or fraud to take his book. As a result, the theft leaves X without his property because tangible goods are rivalrous in consumption. Both student can’t, at the same time but in a different place read about Kant’s categorical imperative from the same copy. Now a different example: suppose X invents a new way of harvesting corn and Y harvests his corn accordingly. This situation is quite different in comparison to the case we presented earlier, because Y does not leaves X without either his new harvesting mechanisms which he created but neither without the idea behind the mechanism. It would be hard to say that Y stole something from X because the consumption of intangible goods such as ideas does not have the same rivalrous property as a copy of a book written by Kant. Actually, the existence of the patent system fosters the scarcity of ideas. In this context patents represent unjustified state-granted monopolies. Moreover, intellectual property rights have another profound immoral consequence: it limits the use of tangible objects which we acquired fully in line with market rules.

#### [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.

## Underview

#### 1] 1AR theory is legit otherwise the neg can be infinitely abusive and there would be no way to check back against that.

#### Comes first because it indicts the neg’s positions and skews my time allocation on other flows like T.

#### Competing interps – rzn is artbitrary and invites judge intervention and race to the top

#### 1AR theory is drop the debater – a 4 minute 1AR doesn’t have time to win both theory and substance – you must be punished.

#### No RVI on 1AR theory-It would be impossible to check back against neg abuse because the 2NR could just spend 6 minutes railing on the theory debate and the aff couldn’t win

#### **[3] Weigh the case vs the K: a] Fairness – opposing frameworks moot our offense – there are infinite parts they could problematize which forces a 1ar restart b] Clash – Our scholarship is tied to the goodness of our framework and plan c]** Role playing is key to better tackle problems of oppression and create tangible solutions.

Nixon 2KMakani Themba-Nixon, Executive Director of The Praxis Project. “Changing the Rules: What Public Policy Means for Organizing.” Colorlines 3.2, 2000. Organic Intellectual

Getting It in Writing Much of the work of framing what we stand for takes place in the shaping of demands. By getting into the policy arena in a proactive manner, we can take our demands to the next level. Our demands can become law, with real consequences if the agreement is broken. After all the organizing, press work, and effort, a group should leave a decision maker with more than a handshake and his or her word. Of course, this work requires a certain amount of interaction with "the suits," as well as struggles with the bureaucracy, the technical language, and the all-too-common resistance by decision makers. Still, if it's worth demanding, it's worth having in writing-whether as law, regulation, or internal policy. From ballot initiatives on rent control to laws requiring worker protections, organizers are leveraging their power into written policies that are making a real difference in their communities. Of course, policy work is just one tool in our organizing arsenal, but it is a tool we simply can't afford to ignore. Making policy work an integral part of organizing will require a certain amount of retrofitting. We will need to develop the capacity to translate our information, data, stories that are designed to affect the public conversation [and]. Perhaps most important, we will need to move beyond fighting problems and on to framing solutions that bring us closer to our vision of how things should be. And then we must be committed to making it so.

### Advantage

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

Kumar 21 [Rajeesh; Associate Fellow at the Institute, currently working on a project titled “Emerging Powers and the Future of Global Governance: India and International Institutions.” He has PhD in International Organization from Jawaharlal Nehru University, New Delhi. Prior to joining MP-IDSA in 2016, he taught at JamiaMilliaIslamia, New Delhi (2010-11& 2015-16) and University of Calicut, Kerala (2007-08). His areas of research interest are International Organizations, India and Multilateralism, Global Governance, and International Humanitarian Law. He is the co-editor of two books;Eurozone Crisis and the Future of Europe: Political Economy of Further Integration and Governance (London: Palgrave Macmillan, 2014); and Islam, Islamist Movements and Democracy in the Middle East: Challenges, Opportunities and Responses (Delhi: Global Vision Publishing, 2013); “WTO TRIPS Waiver and COVID-19 Vaccine Equity,” IDSA Issue Briefs; <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>] Justin

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.

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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.

#### 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.

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

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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