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#### Counterplan: High-income country governments, backed by the United States, should provide all necessary funding to purchase COVID-19 vaccines developed by drug companies at any reasonable cost and distribute them as requested world-wide.

Lindsay 6/11 - Brink Lindsay, Brookings, 6-11, 2021, Why intellectual property and pandemics don’t mix, https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/

Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort.¶ Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is¶ currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.¶ Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time.¶ The Nature of the Patent Bargain¶ When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs.¶ Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.¶ The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment.¶ For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology.¶ Unfortunately, the U.S. patent system at present is out of balance. Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: the number of patents granted annually has¶ skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, a law that is supposed to encourage innovation has turned into a¶ legal minefield for many would-be innovators. In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant “innovations” that allow them to¶ extend their monopolies and keep raising prices long beyond the statutorily contemplated 20 years.¶ Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that¶ conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.¶ Public Health Emergencies and Direct Government Support¶ For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response**. The basic patent bargain**, even when well struck, **is to pay for more innovation down the roa**d with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction. What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? **The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments** by the government **to buy large numbers of doses at set prices, and other, related payouts.** And when we pay drug makers, **we should not hesitate to pay generously**, even extravagantly**: we want to offer** drug companies **big profits so** that **they prioritize this work above everything else, and so that they are** ready and **eager to come to the rescue again the next time there’s a crisis.** It was direct support via Operation Warp Speed that made possible the astonishingly rapid development of COVID-19 vaccines and then facilitated a relatively rapid rollout of vaccine distribution (relative, that is, to most of the rest of the world). And it’s worth noting that a major reason for the faster rollout here and in the United Kingdom compared to the European Union was the latter’s misguided penny-pinching. The EU bargained hard with firms to keep vaccine prices low, and as a result their citizens ended up in the back of the queue as various supply line kinks were being ironed out. This is particularly ironic since the Pfizer-BioNTech vaccine was developed in Germany. As this fact underscores**, the chief advantage of direct support** isn’t to “get tough” with drug firms and keep a lid on their profits. Instead, it **is to accelerate the end of the public health emergency by making sure drug makers profit** handsomely **from doing the right thing.** Patent law and direct support should be seen not as either-or alternatives but as complements that apply different incentives to different circumstances and time horizons**. Patent law provides a decentralized system for encouraging innovation. The government doesn’t presume to tell the industry which new drugs are needed**; it simply incentivizes the development of whatever new drugs that pharmaceutical firms can come up with by offering them a temporary monopoly. It is important to note that patent law’s incentives offer no commercial guarantees. Yes, you can block other competitors for a number of years, but that still doesn’t ensure enough consumer demand for the new product to make it profitable. The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus. Under these circumstances, the decentralized approach isn’t good enough. There is no time to sit back and let drug makers take the initiative on their own timeline. Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. **If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return.** For the pharmaceutical industry, it is useful to conceive of **patent law** as the default regime for innovation promotion. It **improves pharmaceutical companies’ incentives to develop new drugs while leaving them free to decide which new drugs to pursu**e – and also leaving them to bear all commercial risk. In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease. In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. It should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading. That said, it is a serious mistake to try to cast the current crisis as a morality play in which drug makers wear the black hats and the choice at hand is between private profits and public health. We would have no chance of beating this virus without the formidable organizational capabilities of the pharmaceutical industry, and providing the appropriate incentives is essential to ensure that the industry plays its necessary and vital role. It is misguided to lament that private companies are profiting in the current crisis: those profits are a drop in the bucket compared to the staggering cost of this pandemic in lives and economic damage. What matters isn’t the existence or size of the profits, but how they are earned. We have good reason to want drug makers to profit from vaccinating the world: the comparative price is minuscule, and the incentive effects are a vital safeguard of public health in the event of future crises. What we want to avoid at all costs is putting drug makers in the position where drug companies can profit from standing in the way of rapid global vaccination. That is why intellectual property rights need to be taken out of the equation. Vaccinating the world in any kind of reasonable time frame will require large-scale technology transfer to drug firms in other countries and rapid expansion of their production capacity. And looking beyond the current pandemic to the longer term, we need ample, redundant global vaccine production capacity that is widely distributed around the planet. To achieve these goals as rapidly as possible will require the active cooperation of the U.S. pharmaceutical industry, which is why the direct support model now needs to be extended. What is needed now is an Operation Warp Speed for the world, in which we make it worth current vaccine producers’ while to share their know-how broadly and ramp up global capacity. Here again, we must recognize that the choice isn’t between people on the one hand and profits on the other. Rather, the key to good pandemic response policy is ensuring that incentives are structured so that drug company profit-seeking and global public health are well aligned. That means opting out of the default, decentralized patent bargain in favor of generous but well-focused direct government support.

### Dollar Heg DA

#### IPR is key for U.S Dollar Centrality – it allows US firms near if not complete monopolies pushing dollars into international markets and stabilizing US financial influence

Schwartz ‘19

Schwartz, Herman Mark (2019). American hegemony: intellectual property rights, dollar centrality, and infrastructural power. Review of International Political Economy, (), 1–30. doi:10.1080/09692290.2019.1597754 // Phoenix

Mechanism one relates to Strange’s (1989) financial power: US current account deficits generate the dollar centrality that network analyses reveal through self-reinforcing dynamics prior to the network. US current account deficits result from deep seated domestic institutional arrangements in current account surplus economies that produce chronic domestic demand shortfalls. The more those export-led economies run surpluses with the United States, the more dollars they accumulate; the more dollars they accumulate, the more dollars flow through their banking systems back into dollar assets and liabilities; the more dollar assets and liabilities those banks hold on their balance sheets, the more those banks both rely on the Federal Reserve Bank (FED) as a lender of last resort or a supplier of outside money during (the inevitable) crises, and the more their staff develop habitus (Bourdieu, 1977) or the routinized behaviors at the heart of infrastructural power (Mann, 1986) that support continued use of the dollar in non-crisis times; the more those banks lend in dollars, the more counterparty debtor economies are drawn into use of the dollar; a parallel habitus emerges among export firms that reinforces use of the dollar in a Hirschman (1945)-like dynamic. If suppliers (or debtors) are borrowing those recycled dollars, they will demand payment in dollars to meet their liabilities. Contemporary late developers similarly need export markets to grow, and the United States constitutes both the biggest import market and biggest net importer in the global economy (netting intra-EU trade). This mechanism originates from institutional responses to the problem of late development and not, via lower transaction costs, the emergent network of dollar claims and liabilities itself. That said, surely dollar acceptability faces limits set by persistent US current account deficits? Prudent actors might well balk at accepting more assets denominated in a currency at risk of sustained depreciation (Bergsten & Williamson, 2004). Indeed, the 1960s Triffin dilemma pitted declining confidence about the dollar as a store of value given rising US inflation rates and a declining productivity gap between the United States and its main competitors against the need for global liquidity supplied by a US current account deficit. Today, as Eichengreen (2010) has argued, centrality for the dollar faces a similar collective action problem among holders of dollar-denominated assets – why do US current account deficits not motivate individual countries with relatively smaller dollar holdings to defect for fear of depreciation or capital losses? In today’s flexible exchange rate world, only above average US economic growth and/or profits for the firms constituting the bulk of equity market capitalization validates confidence in dollar assets. Because economic activity is organized through capitalist markets, the critical issue for differential growth (Nitzan, 1998) and asset validation is always: ‘who gets the profits and in what proportion’? Mechanism two is thus about profits, which corresponds to Strange’s (1989) productive power. US firms capture a disproportionate share of global profits, and within this firms with robust intellectual property rights (IPRs – patent, copyright brand and trademark) capture a disproportionate share of US and global profits. Here compliance with international trade treaties protecting IPRs is the focal point or center of gravity for this disproportionality. IPRs give some US firms monopoly or near monopoly power in the global (and local) commodity chains they construct. The extension of US IPR law through various trade treaties (Drahos & Braithwaite, 2003; Sell, 2003; Sell & Prakash, 2004) allows US IPR firms to capture a disproportionate share of global profits via that monopoly power. This shifts claims on value added towards those firms, concentrating profits into a small number of US firms. Though we explore this below in more depth, US firms account for a disproportionate 33.9% of cumulative profits generated by any firm appearing on the Forbes Global 2000 list from 2006 to 2018 and firms in sectors characterized by robust IPRs account for a disproportionate 26.6% of those profits. Profitability thus also rests on infrastructural power, via compliance with trade treaties and enmeshment in global value chains orchestrated by US firms. As with bank behavior, this compliance is not purely voluntary (Gruber, 2000), but rather reflects a gradient in which mutually beneficial cooperation shades into coercion as the proportion of local firms benefiting from those treaties declines. US firms are not the only ones that possess marketable intellectual property. Non-US firms that also benefit from robust global IPRs broaden the global political coalition for creating and expanding those IPRs. Yet US firms tend to control the commodity chains in which those foreign firms participate. These two mechanisms are connected: the first explains why non-US actors receive dollars (more precisely, dollar-denominated assets) and the second explains why they opt to hold those assets; put differently, the supply of and demand for dollars. The two mechanisms transform the exorbitant burden – current account deficits associated with use of the dollar as the international reserve currency – back into an exorbitant privilege. They represent a transfer of real resources back to the US economy in exchange for promises to pay back something in the future. Finally, though we will not explore this in depth, these two mechanisms are also linked to the military side of US power, where a similar logic of dominance over potential peer rivals has driven science policy and technological innovation. Put bluntly, a military-innovation complex (c.f. Eisenhower’s military-industrial complex (Hozic, 1999; Hurt, 2010; Mazzucato, 2015; Weiss, 2014)) is the research foundation for the high profit US IPR firms that in turn feed a substantial portion of cash back into the IMS. As with all such systems of power, these structural strengths contain endogenously generated weaknesses and face on-going challenges from the less powerful. Financialization and profit strategies built on IPRs endogenously produce income inequality among firms and people, which erodes compliance, potentially slows growth and destabilizes the global financial system. Domestically, the current account deficits necessary for a dollar-centric IMS (Germain & Schwartz, 2014) generated part of the anger motivating the populist voting bloc that elected Trump. In turn, the Trump Administration’s erratic trade policy, its assaults on parts of the military-innovation complex, and, most significantly, its efforts to eviscerate financial regulation simultaneously threaten the dollar’s role in the IMS and US firms’ ability to capture global profits.3 The Trump administration is one logical consequence of current account deficits that have hollowed out manufacturing employment and limited upward mobility to a narrow slice of the US population. The paper thus has four sections corresponding to the issues: Why does infrastructural power matter? Why the IMS? Why IPRs? The conclusion considers critical endogenous sources of decay.

**Collapse of dollar centrality decks the US economy, prevents stimulus, and undermines security spending which emboldens China aggression.**

**Zoffer 12** - Josh Zoffer (Legal Intern at the IMF, Yale Law), "Future of Dollar Hegemony", Harvard International Review, July 7, 2012. [http://hir.harvard.edu/article/?a=2951] DM

Despite the dollar’s long history as the international reserve currency, the past few years have seen a growing number of calls for the end of dollar hegemony. Countries as diverse as France, Russia, and China have decried the dollar’s monopoly in foreign exchange markets, while in 2009 reports of a shift away from dollar-based oil trading surfaced in the Middle East. Reported plans to move away from the dollar reflected international frustration at a system fueling the United States’ “exorbitant privilege,” as the French have called it, one that rests its stability on the financial conditions of a country mired in debt and facing a financial meltdown. **The implications of a** true **end to dollar hegemony, a shift away from the dollar as** a reserve currency and **pricing** standard **for oil** transactions**, could be catastrophic** for the United States. In the worst case scenario, **a drastic drop in demand for dollar-denominated assets would cause the interest rates** on Treasury Securities **to skyrocket, sending ripples through the US economy as the value of the dollar plummets.** What is certain, however, is that **whatever decrease in demand for US debt occurs will constrain the federal government’s ability to spend and** the ability of the United States **to defend itself.** The United States has built its foreign policy around its vast military capability; **a sudden budgetary shock and drop in military spending would leave the United States vulnerable as it scrambles to regroup** in a new security environment. **The ability** of the United States **to respond to threats** across the globe **would be diminished, and enemies would be incentivized to take aggressive action to take advantage of this new weakness. In particular, a rapidly militarizing China might be emboldened by its** partial **decoupling from US economic fortunes to adopt a bolder stance** in the South China Sea, **threatening US allies and heightening tensions** with the United States. While war with China is all but off the table in the status quo, **an international system devoid of both US military might and Chinese dependence on US debt as a place to park excess liquidity might lead to the conflict feared on both sides of the Pacific.**

**Economic collapse leads to oppressive populism and great power war.**

**Liu 11/13/18 -** Qian Liu [Economist; the first Chinese analyst to join The Economist Intelligence Unit, the research arm of the group. Before becoming the managing director, she was the director of the global economics unit and director of Access China for the EIU. She also served as the chairwoman for internal review at EIU with the European Securities and Markets Authority. Ms Liu adopted econometric models to analyse economic data and produce macroeconomic forecasts.; guest lecturer at New York University, Tsinghua University, the Chinese Academy of Social Sciences and Fudan University.; PhD in economics from Uppsala University, Sweden, and spent a year as a visiting researcher at the University of California, Berkeley.], “The next economic crisis could cause a global conflict. Here's why,” *World Economic Forum* (Web). Nov. 13, 2018. Accessed Feb. 16, 2019. <<https://www.weforum.org/agenda/2018/11/the-next-economic-crisis-could-cause-a-global-conflict-heres-why/>> AT

As monetary tightening reveals the vulnerabilities in the real economy, the collapse of asset-price bubbles will trigger another economic crisis – one that could be even more severe than the last, because we have built up a tolerance to our strongest macroeconomic medications. A decade of regular adrenaline shots, in the form of **ultra-low interest rates and unconventional monetary policies, has severely depleted their power to stabilize and stimulate the economy.**¶ If history is any guide, the consequences of this mistake could extend far beyond the economy. According to Harvard’s Benjamin Friedman, **prolonged periods of economic distress have been characterized** also **by public antipathy toward minority groups or foreign countries** – attitudes that can help to **fuel unrest, terrorism, or** even **war.**¶ For example, during the Great Depression, US President Herbert Hoover signed the 1930 Smoot-Hawley Tariff Act, intended to protect American workers and farmers from foreign competition. In the subsequent five years, global trade shrank by two-thirds. Within a decade, World War II had begun.¶ To be sure, WWII, like World War I, was caused by a multitude of factors; there is no standard path to war. But there is reason to believe that high levels of inequality can play a significant role in stoking conflict.¶ According to research by the economist Thomas Piketty, a spike in income inequality is often followed by a great crisis. Income inequality then declines for a while, before rising again, until a new peak – and a new disaster. Though causality has yet to be proven, given the limited number of data points, this correlation should not be taken lightly, especially with wealth and income inequality at historically high levels.¶ This is all the more worrying in view of the numerous other factors stoking social unrest and diplomatic tension, including technological disruption, a record-breaking migration crisis, anxiety over globalization, political polarization, and rising nationalism. All are symptoms of failed policies that could turn out to be trigger points for a future crisis.¶ Voters have good reason to be frustrated, but the emotionally appealing **populists to whom they are increasingly giving their support** are offering ill-advised solutions that will only **make matters worse.** For example, despite the world’s unprecedented interconnectedness, multilateralism is increasingly being eschewed, as **countries** – most notably, Donald Trump’s US – **pursue unilateral, isolationist policies.** Meanwhile, proxy wars are raging in Syria and Yemen.¶ Against this background, we must take seriously the possibility that **the next economic crisis could lead to** a **large-scale military confrontation.** By the logic of the political scientist Samuel Huntington, considering such a scenario could help us avoid it, because it would force us to take action. In this case, the key will be for policymakers to pursue the structural reforms that they have long promised, while replacing finger-pointing and antagonism with a sensible and respectful global dialogue. The alternative may well be global conflagration.

### Innovation DA

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### This sets a precedent that spills over to all future diseases – Hopkins 21:

Jared S. Hopkins {Jared S. Hopkins is a New York-based reporter for The Wall Street Journal covering the pharmaceutical industry, including companies such as Pfizer Inc. and Merck & Co. He previously was a health-care reporter at Bloomberg News and an investigative reporter at the Chicago Tribune. Jared started his career at The Times-News in Twin Falls, Idaho covering politics. In 2014, he was a finalist for the Livingston Award For Young Journalists for an investigation into charities founded by professional athletes. In 2011, he was a finalist for the Pulitzer Prize in Investigative Reporting for a series about neglect at a residential facility for disabled kids. Jared graduated from the Merrill College of Journalism at the University of Maryland-College Park with a bachelor's degree in journalism}, 21 - ("U.S. Support for Patent Waiver Unlikely to Cost Covid-19 Vaccine Makers in Short Term ," WSJ, 5-7-2021, https://www.wsj.com/articles/u-s-support-for-patent-waiver-unlikely-to-cost-covid-19-vaccine-makers-in-short-term-11620414260)//marlborough-wr/

The Biden administration’s unexpected support for [temporarily waiving Covid-19 vaccine patents](https://www.wsj.com/articles/u-s-backs-waiver-of-intellectual-property-protection-for-covid-19-vaccines-11620243518?mod=article_inline) won’t have an immediate financial impact on the companies making the shots, industry officials and analysts said. Yet the decision could mark a shift in Washington’s longstanding support of the industry’s valuable intellectual property, patent-law experts said. A waiver, if it does go into effect, may pose long-term risks to the vaccine makers, analysts said. [Moderna](https://www.wsj.com/market-data/quotes/MRNA) Inc., [MRNA -4.12%](https://www.wsj.com/market-data/quotes/MRNA?mod=chiclets) [Pfizer](https://www.wsj.com/market-data/quotes/PFE) Inc. [PFE -3.10%](https://www.wsj.com/market-data/quotes/PFE?mod=chiclets) and other vaccine makers weren’t counting on sales from the developing countries that would gain access to the vaccine technology, analysts said. If patents and other crucial product information behind the technology is made available, it would take at least several months before shots were produced, industry officials said. Yet long-term Covid-19 sales could take a hit if other companies and countries gained access to the technologies and figured out how to use it. Western drugmakers could also confront competition sooner for other medicines they are hoping to make using the technologies. A World Trade Organization waiver could also set a precedent for waiving patents for other medicines, a long-sought goal of some developing countries, patient groups and others to try to reduce the costs of prescription drugs. “It sets a tremendous precedent of waiving IP rights that’s likely going to come up in future pandemics or in other serious diseases,” said David Silverstein, a patent lawyer at Axinn, Veltrop & Harkrider LLP who advises drugmakers. “Other than that, this is largely symbolic.”

**1. IPR is key to stopping counterfeits.**

**Kilbride 2020** [Patrick, vice president of International Intellectual Property for the Global Intellectual Property Center at the U.S. Chamber of Commerce, IP Watchdog, "Calls for WTO to Suspend IP Rights for Vaccine Innovation Would Jeopardize Incredible Progress" December 9, https://www.ipwatchdog.com/2020/12/09/calls-wto-suspend-ip-rights-vaccine-innovation-jeopardize-incredible-progress/id=128085/

Finally: A safe, legitimate marketplace. Patents facilitate a market for innovative medicines, throughout the development stage, as well as in commercialization. Licensing arrangements facilitate the types of collaborations that have proven so successful in 2020; they also ensure that third-party manufacturers are making, using, and selling COVID-19 solutions safely and ethically. Without it, counterfeiters and other bad actors could put shoddy, unreliable, and downright dangerous dupes on the market, all the while marketing them as legitimate products. It’s literally a matter of life and death: Thousands, if not millions, of people die each year at the hands of counterfeit drugs.

#### 8. A TRIPS waiver for Covid takes too long---only vaccine donations solve. Fabricius 6/25

Peter Fabricius [institute for security services consultant], 6/20 - ("South Africa: Is Ramaphosa Tripping Over a TRIPS Waiver?," allAfrica, 6/25/2021, accessed 6-30-2021, https://allafrica.com/stories/202106260001.html)//ML

His fervour is prompting some suspicion that the waiver campaign is an ideological issue for South Africa and others on the left - who have always been suspicious of big pharma - rather than an objective solution to a crisis. That's because a TRIPS waiver cannot possibly rescue Africa from the immediate grips of the pandemic.¶ Even the mRNA project in South Africa would take at least around 12 months before manufacture can begin, WHO Chief Scientist Soumya Swaminathan said. And this would be with voluntary licensing and full technological cooperation and training from the patents' owners. Manufacturing vaccines from scratch and without that cooperation through a TRIPS waiver would take much longer.¶ The only immediate remedy is a vigorous campaign to pressure rich countries to donate vaccines¶ Yogesh Pai, Assistant Professor at the National Law University in Delhi, said the TRIPS waiver proposal was 'simplistic' in assuming that allowing the formulae of companies making vaccines to be copied would automatically enable other manufacturers to produce COVID-19 vaccines quickly.¶ Pai said most complex technologies, such as vaccines, comprised not only the knowledge, which is patented to prevent copying. It also involved undisclosed information and know-how about quality control measures for production and clinical data required for regulatory clearances.¶ An intellectual property waiver wouldn't give another company access to this deeper level of know-how. Only a cooperative agreement in which the technology owner helped the new manufacturer produce the vaccines could do this, Pai suggested.¶ Prashant Yadav, an expert on medical supply chains at Harvard Medical School, told ISS Today that it would probably take two to three years to produce a vaccine via a TRIPS waiver. First, the waiver would need to be secured, and then the necessary processes worked out without the help of the original developer.¶ Can Africa wait that long? At the launch of the mRNA project this week, Michael Ryan, Head of the WHO's Health Emergencies Programme, stressed that manufacturing COVID-19 vaccines in Africa, while commendable, wouldn't address the immediate crisis. The only solution was for rich countries to stop hoarding vaccines immediately. 'It will be a catastrophic moral failure at global level if we do not do that,' Ryan warned.¶ Yadav says the urgent strategy should be reallocating doses purchased by countries that don't need them and expanding vaccine production through voluntary licensing and tech transfer from the originator companies.¶ Of course, Ramaphosa could be right in suspecting that rich countries aren't altruistic enough to donate their 'surplus' vaccines, and so Africa and the rest of the global south must become more self-reliant.

#### 5. No solvency – There is no IP barrier in most countries. The fact that they are not manufacturing vaccine shows that they *can’t* without compulsory licensing.

**Mercurio 21**

Mercurio 2/12 - Bryan Mercurio; Chinese University of Hong Kong - Faculty of Law, ; 2-12-2021; "Wto Waiver From Intellectual Property Protection For Covid-19 Vaccines And Treatments: A Critical Review (February 12, 2021)”; Virginia Journal Of International Law Online (Forthcoming 2021), Available At Ssrn: Https://Ssrn.Com/Abstract=3789820 Or Http://Dx.Doi.Org/10.2139/Ssrn.3789820"; https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820, accessed 7-21-2021; JPark

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability. While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### 6. No solvency – the problem is supply. IP has already been voluntarily licensed.

Tabarrok 21 **-** Alex Tabarrok (Bartley J. Madden Chair in Economics at the Mercatus Center and am a professor of economics at George Mason University). “Patents are Not the Problem!” Marginal Revolution. 6 May 2021. JDN. https://marginalrevolution.com/marginalrevolution/2021/05/ip-is-not-the-constraint.html

For the last year and a half I have been shouting from the rooftops, “invest in capacity, build more factories, shore up the supply lines, spend billions to save trillions.” Fortunately, some boffins in the Biden administration have found a better way, “the US supports the waiver of IP protections on COVID-19 vaccines to help end the pandemic.”¶ Waive IP protections. So simple. Why didn’t I think of that???¶ Patents are not the problem. All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. Licenses are widely available. AstraZeneca have licensed their vaccine for production with manufactures around the world, including in India, Brazil, Mexico, Argentina, China and South Africa. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but technology transfer isn’t easy and there are limited supplies of raw materials:¶ Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to transfer their technology there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country.¶ Plastic bags are a bigger bottleneck than patents. The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, another potential mRNA vaccine, is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As Derek Lowe said:¶ Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a lot of potential choke points and rate-limiting steps in them, and there is no wand that will wave that complexity away.¶ Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). Why do you think China hasn’t yet produced an mRNA vaccine? Hint: it isn’t fear about violating IP. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can.¶ The US trade representative’s announcement is virtue signaling to the anti-market left and will do little to nothing to increase supply.

#### 3.No solvency---their own card says that the aff does not do tech transfers or eliminate export restrictions. Marlborough reads yellow

Kumar, PhD, 7-12-21

(Rajeesh, Associate Fellow Manohar Parrikar Institute for Defence Studies and Analysis, https://www.idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721)

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).1 The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines. Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.2 It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal. On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.3 At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.4 The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.5 At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad. TRIPS and its Exceptions TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).6 In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).7 Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.8 Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver. The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.9 In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033. COVID-19 and TRIPS Waiver Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines. Vaccine Inequity 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 Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021. 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 Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. 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. Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. 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. Source: Katharina Buchholz, “COVID-19 Vaccines Lift Pharma Company Profits”, Statista, 17 May 2021. 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.

#### 4. No impact to Macpherson – the card is from April 2020 and says its impacts

#### a) would take place within a few weeks and

#### b) rely on global lockdown and not the spread of the virus which is their internal link

5. Kitfield is about Trump’s relationship with Xi and Putin – no relevance – we link harder into great power war because collapse of dollar heg leads to the **election** of populists like Trump

#### 6. Their own card says that the Aff can’t fiat increased manufacturing. Marlborough reads yellow

Human Rights Watch 6-3-21, 50 year old 100 country wide news site https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver#

Intellectual property is currently a barrier to swiftly scaling up and diversifying the production of Covid-19 health products, including vaccines. The European Commission claims that intellectual property (IP) is not a barrier to scaling up the manufacturing of vaccines or other health products needed for the Covid-19 response, suggesting that sharing IP would not immediately speed up manufacturing. Right now, there are manufacturers with capacity to produce additional Covid-19 vaccines and other health products at factories in Bangladesh, Canada, Denmark, India, and Israel, but they are unable to contribute because they do not yet have the right licenses. So, IP is a barrier to them. The TRIPS waiver proposal sponsors and experts at the leading science journal Nature, Médecins Sans Frontières (MSF) Access Campaign, the Third World Network, and others have presented many other concrete examples of how enforcement of IP rules blocked, delayed, or limited production of chemical reagents for Covid-19 tests, ventilator valves, Covid-19 treatments, and elements of Covid-19 vaccines. IP constraints have not only led to vaccine shortages but have also led to shortages of key raw materials like bioreactor bags and filters. Rather than manufacturers being held back by an inherent lack of manufacturing and technological capability, studies have shown that transnational claims to IP impede new manufacturers from entering and competing in the market. The same dynamics are playing out today with Covid-19. Even though a waiver will not automatically expand production overnight, it paves the way for speedy technology transfers and manufacturing. The waiver by itself will not automatically result in widespread and diversified manufacturing, but it will ease complex global rules governing IP and exports and give governments freedom to collaborate on technology transfers and exports without fearing trade-based retaliation. It will help reduce the dependence on any one country or region for medical products and mitigate the risks of export restrictions. With new variants emerging and some evidence that repeat vaccine boosters may be needed, the waiver will enable governments around the world to be prepared for a long-term response to Covid-19. Experts have mapped out plans for how the manufacturing of mRNA and other vaccines, could be dramatically expanded in a relatively short period of time. Waiving certain IP rules in the TRIPS agreement over the next three years could help create diverse regional manufacturing hubs and protect the EU and the rest of the world from future pandemics, supply chain disruptions, and resulting economic disaster. Concerns that widening the universe of producers may lower or compromise quality standards are unfounded because stringent regulatory authorities and the World Health Organization (WHO) would continue to play their existing role as arbiters of quality and safety for vaccines, which have a very stringent process for approval.