# Harvard Westlake CR v Marlborough JK

### Advantage CP

#### Counterplan text: States should increase Covax support, prioritise trade facilitation, commit to aid for trade, and invest in preparedness.

Gonzalez 21 [Violeta Gonzalez Behar is head of partnerships, communications, and resource mobilization at the Enhanced Integrated Framework, a sustainable trade multilateral partnership at the World Trade Organization. In this capacity, she leads a global team in helping EIF build strategic partnerships, communicate results, and secure financing for operations in 51 developing economies. “Opinion: 4 ways to promote vaccine equity through trade”. 8-1-2021. Devex. https://www.devex.com/news/opinion-4-ways-to-promote-vaccine-equity-through-trade-100457. Accessed 8-12-2021; MJen]

Vaccine inequity is one of the most striking — but solvable — challenges of the [COVID-19](https://www.devex.com/focus/covid-19) pandemic. It also provides a wake-up call for what can happen when so-called least-developed countries, or LDCs, are not able to participate fully in global trading systems. By supporting programs such as COVAX, advancing trade facilitation efforts, and directing more aid toward trade initiatives such as [Aid for Trade](https://www.wto.org/english/tratop_e/devel_e/a4t_e/aid4trade_e.htm), the global community can help right this imbalance. As of Monday, only [1.1 % of people in low-income countries](https://ourworldindata.org/covid-vaccinations) had received at least one COVID-19 vaccine dose. This is making it harder to battle a third wave of infections, as the highly transmissible [delta variant](https://news.un.org/en/story/2021/07/1095152) spreads across many nations. In the [World Health Organization](https://www.devex.com/organizations/world-health-organization-who-30562)’s Africa region — where a [high number](https://www.uneca.org/sites/default/files/com/2021/E2100045-English-CoM21-Progress-in-the-implementation-of-the-priority-areas-of-the-Programme-of-Action-for-the-Least-Developed-Countries-for-the-Decade-2011-2020_Istanbul-Programme-of-Action.pdf) of LDCs are located — COVID-19 fatalities [surged 44.2%](https://apps.who.int/iris/bitstream/handle/10665/342715/OEW28-0511072021.pdf) over one week in July. The coronavirus is [devastating](https://www.un.org/development/desa/dpad/2021/major-study-on-covid-19-impact-on-ldcs-released/) many LDCs’ already fragile economies and causing poverty and inequality to rise. Without equitable access to vaccines, [global economic recovery cannot be sustained](https://www.wto.org/english/news_e/news21_e/gc_05may21_e.htm) and progress toward the Sustainable Development Goals will be derailed. While trade alone cannot eradicate vaccine unequity or its negative consequences for the [economy](https://news.un.org/en/story/2021/05/1091732) and [vulnerable groups](https://observatoryihr.org/news/covid-19-vaccine-distribution-highlights-social-inequality/), it has a powerful contribution to make. Here are four actions that would make an impact:

1. Increase COVAX support

Vaccine equity can only be achieved if the global community eschews vaccine nationalism. High-resource countries should [ramp up donations](https://www.devex.com/news/wto-chief-to-g-20-donate-2-3b-more-covid-19-vaccine-doses-100306) through the vaccine-sharing initiative COVAX and commit to securing a swift, workable resolution to ongoing debates around [technology transfers and intellectual property waivers](https://www.devex.com/news/wto-council-offers-hope-for-trips-vaccine-proposal-100125). While countries in the G-7 group of nations have [pledged to increase their support](https://www.who.int/news/item/13-06-2021-g7-announces-pledges-of-870-million-covid-19-vaccine-doses-of-which-at-least-half-to-be-delivered-by-the-end-of-2021) for COVAX, the initiative has faced hurdles in the form of [supply bottlenecks](https://www.devex.com/news/india-crisis-puts-covax-150-million-doses-behind-schedule-99860), [export restrictions](https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19), and [logistical weaknesses](https://www.devex.com/news/the-cold-chain-storage-challenge-99869). Many currently available COVID-19 vaccines have short shelf lives and must be stored at low temperatures. LDCs can only benefit from donated doses if they have fast and efficient processing at their borders, modern transportation systems, and access to cold chain infrastructure.

2. Prioritize trade facilitation

Accelerating implementation of the [World Trade Organization](https://www.devex.com/organizations/world-trade-organization-wto-44694)’s 2017 [Trade Facilitation Agreement](https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm) is critical for helping LDCs overcome these challenges. A total of [154 WTO members](https://www.tfafacility.org/ratifications) now support the agreement, which pledges investment in the simplification and modernization of the movement, release, and customs clearance of goods globally. It also aims to help low-income countries overcome these same barriers through technical assistance and capacity building. The [Global Alliance for Trade Facilitation](https://www.devex.com/organizations/global-alliance-for-trade-facilitation-102992) has made good progress in identifying barriers to vaccine equity and introducing solutions. In [Mozambique](https://www.tradefacilitation.org/article/two-new-mozambique-projects-aim-to-ease-access-to-vaccines-medical-products/), for example, the alliance is working to digitalize pre-shipment authorization for vaccine imports — a process that can take as long as two weeks, during which vaccine doses must be kept in storage. This digitalization should help Mozambique decrease wait times, improve shipment traceability, and reduce storage and inventory management costs. Yet more work remains to help governments overcome [challenges associated with implementing](https://www.wto-ilibrary.org/trade-facilitation-and-customs-valuation/world-trade-report-2015_f2985d96-en) the Trade Facilitation Agreement, such as changing domestic legislation and involving the private sector. Lower-income countries and LDCs have flagged a need around human resources and training, legal assistance, and the acquisition of information and communication technologies.

3. Commit to Aid for Trade

For LDCs to participate fairly in global vaccine supply chains — as importers or exporters of inputs and finished products — they need financial and technical assistance to strengthen their [productive capacity](https://www.devex.com/news/cepi-ceo-concerted-effort-needed-to-build-lmic-vaccine-manufacturing-100013), streamline their cross-border standards and processes, and improve their logistics infrastructure and [technological know-how](https://www.wto.org/english/news_e/news21_e/dgno_21may21_e.htm). The Aid for Trade initiative exists to provide that support — but can only deliver if donor countries maintain or increase their official development assistance, or ODA. Preliminary figures from the [Organisation for Economic Co-operation and Development](https://www.devex.com/organizations/organisation-for-economic-co-operation-and-development-oecd-29872) show that [Development Assistance Committee](https://www.devex.com/organizations/development-assistance-committee-dac-100607) members [expanded their ODA by $10 billion](https://www.devex.com/news/what-to-make-of-the-2020-dac-stats-99641) between 2019 and 2020, mostly as part of their COVID-19 response. However, with several government donors having reprogrammed their aid budgets to focus on immediate health priorities, [fears are growing](https://www.weforum.org/agenda/2021/01/helping-small-businesses-build-resilience/) that their overall ODA may also be slashed — and, with this, their support for Aid for Trade. The generosity of some countries provides hope. Norway, for example, recently stepped up to help plug such gaps with [45 million Norwegian kroner](https://www.wto.org/english/news_e/news21_e/if_22jun21_e.htm) of additional funding for the WTO-backed [Enhanced Integrated Framework](https://www.devex.com/organizations/enhanced-integrated-framework-eif-78046), a global Aid for Trade program that aims to reduce poverty.

4. Invest in preparedness

In 2019, only [$374 million](http://www.healthdata.org/sites/default/files/files/policy_report/FGH/2020/FGH_2019_Interior_Final_Online_2020.09.18.pdf) — or less than 1% — of the world’s total development assistance for health was spent on pandemic preparedness. Within months, the consequences of that underinvestment became clear. Integrating lower-income countries and LDCs into global and regional [pharmaceutical value chains](https://unctad.org/news/unctad-report-says-least-developed-countries-position-improve-access-medicines-through-local-0) is vital for ensuring the world is better prepared next time. Directing increased aid to help these countries become [producers and exporters](https://www.bloomberg.com/news/articles/2021-07-26/africa-must-build-vaccine-production-capacity-wto-chief-says) of medical equipment and vaccines has never been more needed. LDCs would not only receive more of the [vaccines and therapeutics they need now](https://trade4devnews.enhancedif.org/en/op-ed/access-denied-ensuring-vaccines-worlds-poorest-countries) but could actively contribute to the global response when the next pandemic inevitably hits.

#### A waiver for Covid takes too long---only the CP solves. 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.

#### And it competes off the net benefit: the perm wouldn’t solve because it would still link to the Innovation DA.

## Innovation DA

#### 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.

#### 2. 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.

#### 3. 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.

#### 4. 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.

# CASE

### Impact D- covid over soon

#### Pandemic will be over in a year

Reuters, 9-23, 21, Moderna chief executive sees pandemic over in a year – newspaper, https://news.trust.org/item/20210923052810-q5d40

ZURICH, Sept 23 (Reuters) **- Moderna** Inc **Chief** Executive **Stéphane Bancel thinks the coronavirus pandemic could be over in a year as increased vaccine production ensures global supplie**s, he told the Swiss newspaper Neue Zuercher Zeitung. "If you look at the industry-wide expansion of production capacities over the past six months, **enough doses should be available by the middle of next year so that everyone on this earth can be vaccinated. Boosters should also be possible to the extent required,"** he told the newspaper in an interview. Vaccinations would soon be available even for infants, he said. **"Those who do not get vaccinated will immunize themselves naturally, because the Delta variant is so contagious. In this way we will end up in a situation similar to that of the flu. You can either get vaccinated and have a good winter. Or you don't do it and risk getting sick and possibly even ending up in hospital**." Asked if that meant a return to normal in the second half of next year, he said: "As of today, in a year, I assume." Bancel said he expected governments to approve booster shots for people already vaccinated because patients at risk who were vaccinated last autumn "undoubtedly" needed a refresher. Its booster shot had half the dose of the original dose, which meant more of them would be available. "The volume of vaccine is the biggest limiting factor. With half the dose, we would have 3 billion doses available worldwide for the coming year instead of just 2 billion," he said. The composition of the booster shot remains the same as the original for this year because Moderna had not had enough time to change it. "We are currently testing Delta-optimized variants in clinical trials. They will form the basis for the booster vaccination for 2022. We are also trying out Delta plus Beta, the next mutation that scientists believe is likely." Moderna can use existing production lines for the new variants as for the original COVID-19 vaccine. The price of vaccination will stay the same, he said. (Reporting by Michael Shields Editing by Robert Birsel)

1. Their climate excalation impacts were supposed to come within the year, after the first post-COVID grain harvest – it was written in april 2020 – this should’ve already happened
2. The Kitfield Card
   1. This person evidently has reason to believe both that the LIO is good and that China is always looking to destroy it with nuclear weapons – remember what happened last time we listened to these people and this ideology
   2. The card is pessimistic securitization– the facts say COVID is bringing countries closer together, but the rhetoric says they’re primed for war
   3. Xi was being more provocative in response to Trump blaming him for COVID, not COVID himself – Biden isn’t Trump
   4. The EU are the people that don’t support the vaccine waiver, but France is mad at us for deploying nuclear submarines against China – these alliances and grievances between countries don’t neatly match up across issues, so solving COVID won’t increase international cooperation
3. **We rehighlighted their OWN CARD whose tagline is “no alt cause” – that’s a lie – the US is mad at the WTO to the point of forcing its leadership to run aground AND barely participates anyway – the WTO is dying and useless, especially in the context of China and the US, and the EU doesn’t like it either so it’s already illegitimate and we’re still standing**

**Meyer 6-18-21**

(David, Senior Writer, https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/)

The World Trade Organization **knows all about crises**. Former U.S. President Donald Trump threw a wrench into its core function of resolving trade disputes—a blocker that President Joe Biden has not yet removed—and there is widespread dissatisfaction over the **fairness of the global trade rulebook**. The 164-country organization, under the fresh leadership of Nigeria's Ngozi Okonjo-Iweala, has a lot to fix. However, **one crisis is more pressing than the others**: **the battle over COVID-19 vaccines**, and whether the protection of their patents and other intellectual property should be temporarily lifted to boost production and end the pandemic sooner rather than later. According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—the WTO's future rests on what happens next. "The credibility of the WTO will depend on its ability to find a meaningful outcome on this issue that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "Final nail in the coffin" The Geneva-based WTO isn't an organization with power, as such—it's a framework within which countries make big decisions about trade, generally by consensus. It's supposed to be the forum where disputes get settled, because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's founding agreement allows for rules to be waived in exceptional circumstances, and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) Consensus is the key here. Although the failure to reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an **unprecedented and seismic event**. In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union, and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. It's a dispute between countries, but the result will be on the WTO as a whole, say waiver advocates. "If, in the face of one of humanity's greatest challenges in a century, the WTO functionally becomes an obstacle as in contrast to part of the solution, I think it could be the final nail in the coffin" for the organization, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. "If the TRIPS waiver is successful, and people see the WTO as being **part of the solution**—saving lives and livelihoods—it could **create** **goodwill and momentum to address what are still daunting structural problems**." Those problems are legion. Reform needs Top of the list is the WTO's Appellate Body, which hears appeals in members' trade disputes. It's a pivotal part of the international trade system, but Trump—incensed at decisions taken against the U.S. —blocked appointments to its seven-strong panel as judges retired. The body became completely paralyzed at the end of 2019, when two judges' terms ended and the panel no longer had the three-judge quorum it needs to rule on appeals. Anyone who hoped the advent of the Biden administration would change matters was disappointed earlier this year when the U.S. rejected a European proposal to fill the vacancies. "The United States continues to have systemic concerns with the appellate body," it said. "As members know, the United States has raised and explained its systemic concerns for more than 16 years and across multiple U.S. administrations." At her confirmation hearing in February, current U.S. Trade Representative Katherine Tai reiterated those concerns—she said the appellate body had "overstepped its authority and erred in interpreting WTO agreements in a number of cases, to the detriment of the United States and other WTO members," and accused it of dragging its heels in settling disputes. "Reforms are needed to ensure that the underlying causes of such problems do not resurface," Tai said. "While the U.S. [has] been engaging [with the WTO] it hasn't indicated it would move quickly on allowing appointments to the Appellate Body," says Bryan Mercurio, an economic-law professor at the Chinese University of Hong Kong, who opposes the vaccine waiver. "This is not a good sign. In terms of WTO governance, it's a much more important step than supporting negotiations on an [intellectual property] waiver." It's not just the U.S. that wants to see reform at the WTO. In a major policy document published in February, the EU said negotiations had failed to modernize the organization's rules, the dispute-resolution system was broken, the monitoring of countries' trade policies was ineffective, and—crucially—"the trade relationship between the U.S. and China, two of the three largest WTO members, is currently largely managed outside WTO disciplines." China is one of the key problems here. It became a WTO member in 2001 but, although this entailed significant liberalization of the Chinese economy, it did not become a full market economy. As the European Commission put it in February: "The level at which China has opened its markets does not correspond to its weight in the global economy, and the state continues to exert a decisive influence on China's economic environment with consequent competitive distortions that cannot be sufficiently addressed by current WTO rules." "China is operating from what it sees as a position of strength, so it will not be bullied into agreeing to changes which it sees as not in its interests," says Mercurio. China is at loggerheads with the U.S., the EU and others over numerous trade-related issues. Its rivals don't like its policy of demanding that Chinese citizens' data is stored on Chinese soil, nor do they approve of how foreign investors often have to partner with Chinese firms to access the country's market, in a way that leads to the transfer of technological knowhow. They also oppose China's industrial subsidies. Mercurio thinks China may agree to reforms on some of these issues, particularly regarding subsidies, but "only if it is offered something in return." All these problems won't go away if the WTO manages to come up with a TRIPS waiver for COVID-19 vaccines and medical supplies, Wallach concedes. "But," she adds, "**the will and the good faith** to tackle these challenges is **increased enormously** if the WTO has the **experience of being part of the solution, not just an obstacle."** Wallach points to a statement released earlier this month by Asia Pacific Economic Cooperation (APEC) trade ministers, which called for urgent discussions on the waiver. "The WTO must **demonstrate that global trade rules can help address the human catastrophe** of the COVID-19 pandemic and facilitate the recovery," the statement read in its section about WTO reform. Okonjo-Iweala's role The WTO's new director general, whose route to the top was unblocked in early 2021 with the demise of the Trump administration, is certainly keen to fix the problems that contributed to the early departure of her predecessor, Brazil's Robert Azevedo. "We must act now to get all our ambassadors to the table to negotiate a text" on the issue of an IP waiver for COVID vaccines, Ngozi Okonjo-Iweala, director general of the World Trade Organization, has said. Dursun Aydemir—Anadolu/Bloomberg/Getty Images Earlier this week, when the U.S. and EU agreed a five-year ceasefire in a long-running dispute over Boeing and Airbus aircraft subsidies, Okonjo-Iweala tweeted: "With political will, we can solve even the most intractable problems." However, Mercurio is skeptical about her stewardship having much of an effect on the WTO's reform process. "Upon taking [over she] stated it was time for delegations to speak to each other and not simply past each other, but at the recent General Counsel meeting delegations simply read prepared statements in what some have described as the worst meeting ever," he says. "On the other hand, Ngozi is very much someone who will actively seek solutions to problems, and in this way different to her predecessor. If the role of mediator is welcomed, she could have an impact not in starting discussions but in getting deals over the finish line." A spokesperson for the WTO Secretariat declined to offer comment on Mlumbi-Peter and Wallach's suggestions that the organization's credibility rests on the vaccine patent waiver issue, but pointed to a May speech in which Okonjo-Iweala said the WTO could help tackle vaccine supply chain monitoring and transparency, helping manufacturers scale up production, and creating a more geographically diversified manufacturing base. In her speech, the WTO chief also said members "must address issues related to technology transfer, knowhow and intellectual property," including the waiver proposal. "We must act now to get all our ambassadors to the table to negotiate a text," she said.

#### Turns solvency because too many people will be afraid of the vaccine to achieve herd immunity.

Crosby et al. 21Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jeffrey Telep, Brian White; Crosby specializes in international trade, investment and matters related to public international law. Diamond is a partner on our Intellectual Property, Patent, Trademark and Copyright Litigation team.; 3-5-2021; "Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products"; https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/, JD Supra, accessed 7-21-2021; JPark

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.” At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

ongoing quality assurance support.