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## Covid CP

#### 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.

## 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:

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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.”

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

# Case

## AT COVID aff

#### 1. No inherency – governments and the WTO are already reducing IP protections for medicines related to COVID-19. WTO No Date

WTO, no date, "TRIPS, the intellectual property system and COVID-19," No Publication, <https://www.wto.org/english/tratop_e/trips_e/trips_and_covid19_e.htm> accessed 8/10/2021//JH

TRIPS, the intellectual property system and COVID-19 ¶The way in which an intellectual property (IP) system is designed at national or regional levels – and how effectively it is put to work - can be a significant factor in facilitating access to existing technologies and in supporting the creation, manufacturing and dissemination of new technologies, such as medicines, vaccines and medical devices, in response to the COVID-19 pandemic. This question – the relationship of IP to the pandemic response – has sparked a vigorous debate within and beyond the WTO, and is a high priority for technical assistance and policy support for WTO members. This page gives access to background information and current WTO documents (including members’ proposals) on this urgent question. ¶Introduction ¶From the beginning of the pandemic, the pressing need was clear for both the development of new vaccines and treatments, and access to these medicines for all – a global challenge unprecedented in both scope and urgency. ¶Governments and other stakeholders have therefore focused on how innovation mechanisms and tools for enhancing access to medical technologies can contribute to the pandemic response, well beyond a reliance on “business as usual”. This has led to a range of initiatives by international organizations, governments and private actors for the voluntary sharing, pooling or non-assertion of IP rights (IPRs), responding to the spirit of collaboration that dominates the global effort to tackle the pandemic. ¶A range of pro-health policy options and interventions are also available for WTO members under the TRIPS Agreement, as implemented in domestic law. ¶Transparency and the availability of up-to-date information on IP and COVID-19 respond to an immediate and critical need. They contribute to the empirical basis that is essential for policy-making in a rapidly evolving trade landscape in the mutual interest of all stakeholders, including governments and economic operators. ¶In furtherance of this objective, the following sections provide access to useful WTO and other resources that specifically address the interface between IPRs and COVID-19, as well as to the work of the TRIPS Council ¶Work of the [TRIPS Council](https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm) ¶Members have exchanged information and experiences relating to IP measures taken in the context of COVID-19 at the TRIPS Council, and have considered members’ proposals. The interface between IPRs and COVID-19 has been considered in TRIPS Council meetings since July 2020, supported by [communications](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=IP%2fC%2fW%2f*&Serial=&IssuingDateFrom=&IssuingDateTo=&CATTITLE=COVID-19&ConcernedCountryList=&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList=&OrganizationList=&ArticleList=&Contents=&CollectionList=&RestrictionTypeName=&PostingDateFrom=&PostingDateTo=&DerestrictionDateFrom=&DerestrictionDateTo=&ReferenceList=&Language=ENGLISH&SearchPage=FE_S_S001&ActiveTabIndex=0&HSClassificationList=&ServicesClassificationList=&EnvironmentClassificationList=&ICSClassificationList=&ICSClassificationDescList:EnvironmentClassificationDescList:ServicesClassificationDescList:HSClassificationDescList=&languageUIChanged=true) to the TRIPS Council. ¶WTO resources **¶**Members have exchanged information and experiences relating to IP measures taken in the context of COVID-19 at the TRIPS Council, and have considered members’ proposals. The interface between IPRs and COVID-19 has been considered in TRIPS Council meetings since July 2020, supported by communications to the TRIPS Council. **¶**[COVID-19 and world trade](https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm) **¶**[COVID-19: Measures regarding trade-related intellectual property rights](https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm) ¶A non-exhaustive list has been compiled by the WTO Secretariat from official sources and confirmed with WTO members concerned. It represents an informal situation report and an attempt to provide transparency with respect to measures regarding trade-related IPRs taken by WTO members in the context of the COVID-19 crisis. The list is regularly updated. **¶**[Information Note: The TRIPS Agreement and COVID-19](https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf)¶This note discusses the role and some of the key contributions that the global IP system, including its policy options and flexibilities as implemented in domestic law, can make to address COVID-19. It also provides an overview of measures taken by members. **¶**[Information Note: How WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services](https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pdf) ¶This note on access to COVID-19 critical medical goods and services includes information on using IPRs and policy tools to facilitate innovation in and access to COVID-19-related technologies. **¶**[Information Note: Developing and delivering COVID-19 vaccines around the world](https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf) ¶This note looks at issues with trade impact and discusses trade policy choices, including in the area of intellectual property rights, that may be considered along the vaccine value chain to support access to COVID-19 vaccines. **¶**[An integrated health, trade and IP approach to respond to the COVID-19 pandemic](https://www.wto.org/english/res_e/booksp_e/extract_who-wipo-wto_2020_e.pdf) **¶**A standalone section on COVID-19 in the 2020 study jointly published by the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and WTO, [Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition)](https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm), maps the multiple challenges posed by the pandemic in relation to the integrated health, trade and IP policy frameworks set out in the study. **¶**[Working Paper: Patent-related actions taken in WTO members in response to the COVID-19 pandemic](https://www.wto.org/english/res_e/reser_e/ersd202012_e.htm)**¶**This working paper provides an overview of the patent landscape of medical treatments and technologies related to COVID-19, and of the patent status of two investigational medical treatments: remdesivir and lopinavir/ritonavir. It presents various patent-related actions taken by legislators, policymakers, industry sectors and civil society organizations in members since the outbreak. Furthermore, it elaborates on patent-related policy options provided by the TRIPS Agreement, and members' national implementation and utilization of these options in their response to the COVID-19 pandemic.

#### 2. No inherency - The Covid vaccine waiver will pass in the status quo—many countries are switching their positions now . Meyer 6/10

David Meyer [senior writer for fortune], 6/10 - ("COVID-19 vaccine-patent pressure grows in Europe as lawmakers back temporary waiver," Fortune, 6-10-2021, accessed 7-5-2021, https://fortune.com/2021/06/10/covid-vaccine-patent-waiver-european-parliament-commission-wto/)//ML

The [temporary suspension of COVID vaccine patents](https://www.keionline.org/wp-content/uploads/W669Rev1.pdf)—a move that's intended to help expand manufacturing and speed up the global vaccination drive, thus [shortening the pandemic](https://fortune.com/2021/05/07/the-vaccine-patent-debate-heats-up/)—was originally proposed by South Africa and India last year. Over recent months, it has gained new supporters like the World Health Organization (WHO), [the Pope](https://www.theguardian.com/world/2021/may/09/pope-adds-voice-to-call-for-pharma-giants-to-waive-vaccine-patents), and, crucially, [the Biden administration](https://fortune.com/2021/05/06/covid-vaccine-patent-waiver-protections-rights-waiver-biden-next/).¶ However, Europe—home to major players such as BioNTech and AstraZeneca—has resisted the waiver. Just last week, the European Commission submitted an [alternative plan](https://www.reuters.com/world/europe/eu-executive-submits-vaccine-access-proposal-wto-2021-06-04/) to the World Trade Organization (WTO), proposing other measures such as limits on export restrictions, and the compulsory licensing of the patents in some circumstances.¶ That doesn't go far enough, said members of the European Parliament on Thursday, as it passed [an amendment](https://www.europarl.europa.eu/doceo/document/RC-9-2021-0306-AM-008-016_EN.pdf) calling for a temporary waiver of the WTO's TRIPS Agreement, the global intellectual-property rulebook, in relation to COVID-19 vaccines, treatments, and equipment.¶ The amendment passed by 355 votes to 263, with 71 abstentions. The European Parliament cannot tell the Commission to change its influential tune on the issue, but the vote sent a strong political message nonetheless: Europe, with its many national votes at the WTO, is gradually shifting to the pro-waiver camp.¶ Within the Parliament—the only EU lawmaking institution whose members are directly elected by citizens—[the split](https://www.europarl.europa.eu/news/en/press-room/20210517IPR04116/meps-split-over-waiver-for-covid-19-vaccine-patents) over the issue has largely followed left-right lines, with leftists such as the Socialists and Democrats (S&D, Parliament's second-biggest voting bloc) backing the waiver and those on the right, such as the European People's Party (EPP, the biggest bloc), opposing it.¶ "With today’s vote, the European Parliament calls on the Commission to finally do the right thing and save lives by supporting the lifting of patents for COVID-19 vaccines and medical equipment," said Kathleen Van Brempt, the S&D's lead negotiator on the subject, in a statement after the vote. "The TRIPS waiver may not prove to be a miracle solution, but it is one of the essential building blocks of a strong global vaccination campaign. Exceptional situations call for exceptional measures.¶ "The alternative proposal submitted by the European Commission to the WTO falls short in the face of the epochal challenge we are facing," she added.¶ But it is not just the European Commission that is becoming more isolated on the issue. Germany, too, is increasingly lonely in its opposition to the waiver.¶ French President Emmanuel Macron, who has [previously sided](https://www.theguardian.com/world/2021/may/07/macron-voices-concerns-over-covid-vaccines-patent-waiver) with Germany, [traveled to South Africa](https://www.voanews.com/covid-19-pandemic/macron-south-africa-talks-covid-vaccine) a couple of weeks ago to discuss the waiver with President Cyril Ramaphosa. On Wednesday, just ahead of the G7 summit, he flipped and joined the patent-suspension camp. That means at least two G7 leaders (also including U.S. President Joe Biden) now favor the waiver.¶ Add to that the fact that the WTO agreed on Wednesday to [fully debate the waiver](https://www.moneycontrol.com/news/business/economy/wto-decides-to-hold-text-based-negotiations-on-indias-global-vaccine-waiver-proposal-7010561.html)—a step that the EU and some other countries had previously resisted—and it seems the tide may be turning.¶ There is still a way to go, though. World Bank President David Malpass [slammed the waiver idea](https://www.reuters.com/business/healthcare-pharmaceuticals/world-bank-chief-says-does-not-support-vaccine-intellectual-property-waiver-wto-2021-06-08/) on Wednesday, saying “it would run the risk of reducing the innovation and the R&D” in the pharmaceutical sector. (Malpass, a Trump appointee, is therefore now in opposition to the current White House.)¶

**3. 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.

**Turns case – increased vaccine hesitancy means you’ll never solve.**

**Baschuk 2021** [Bryce, reporter for Bloomberg News, "Covid-19 pandemic: WTO holiday from vaccine talks draws calls for action" July 26, https://www.business-standard.com/article/current-affairs/covid-19-pandemic-wto-holiday-from-vaccine-talks-draws-calls-for-action-121072601721\_1.html

Specifically, opponents to the waiver say it would create a chaotic patchwork of laws, unravel existing industry partnerships, lead to a supply crunch for scarce vaccine inputs and inject even more uncertainty into already complex arrangements.¶ There’s also the possibility that an IP waiver could result in the production of counterfeit and substandard medicines, which could increase vaccine hesitancy that’s already pervasive in even the world’s wealthiest nations.

#### 4. Turn: Reductions in IPR could result in unsafe or ineffective medicines. 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.

#### 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.

#### 7. No solvency - too many jurisdictional barriers, but the squo solves through cooperation and competition. Mercurio 6/24

Bryan Mercurio [Simon F.S. Li Professor of Law, The Chinese University of Hong Kong, Shatin, Hong Kong], 6-24-2021, "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," IIC - International Review of Intellectual Property and Competition Law, [https://link.springer.com/article/10.1007/s40319-021-01083-5 accessed 8/12/2021](https://link.springer.com/article/10.1007/s40319-021-01083-5%20accessed%208/12/2021) //JH

The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.[Footnote1](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn1) ¶The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.[Footnote2](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn2) The proposal attracted support from the majority of developing country Members,[Footnote3](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn3) but was opposed by a handful of Members including the United States (US).[Footnote4](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn4) Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.[Footnote5](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn5) ¶On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.[Footnote6](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn6) To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.[Footnote7](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn7) The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.[Footnote8](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn8) For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.[Footnote9](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn9) ¶Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[Footnote10](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn10) Issues of negotiation will include the scope of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[Footnote11](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[Footnote12](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[Footnote13](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[Footnote14](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[Footnote15](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations. ¶With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).[Footnote16](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn16) There is also a chance that the negotiations will continue past the calendar year 2021. ¶The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India’s and South Africa’s true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world. ¶It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.[Footnote17](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn17) ¶The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.[Footnote18](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn18) Second, it sends a strong signal that the US does not oppose others from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time. ¶Alan Beattie, writing in the Financial Times, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[Footnote19](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[Footnote20](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up. ¶When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”[Footnote21](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn21) I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”[Footnote22](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn22) I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.[Footnote23](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn23) IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.[Footnote24](https://link.springer.com/article/10.1007/s40319-021-01083-5#Fn24) Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. ¶Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

#### 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.

#### No solvency – The Last Mile Problem.

**In the squo, pharmaceutical companies have no incentive to ensure drugs are distributed and used properly. HIF incentivizes them to ensure rational use and positive health outcomes.**

**Hollis & Pogge ’08 -** Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008

As highlighted throughout this book, one main barrier to access to available drugs is price. When manufacturers’ prices are lower, then the prices consumers are charged through both public and private distribution systems will also be lower. Affordable manufacturers’ prices are therefore crucial to improved access. But manufacturers’ prices are not the sole determinant of the cost to the consumer. Import duties, port clearage charges, inspection fees, pharmacy board fees, central and regional government taxes, storage and transportation costs, and wholesale and retail markups add substantially to the manufacturers’ price.1 These supplementary costs are not always passed on to the consumer in their entirety, since the state or the nonprofi t sector may provide subsidies to consumers. But in this case the financial burdens placed on the state or the nonprofi t sector are increased by high prices. Even where supplementary costs are only partially passed on to consumers, they can significantly aff ect the aff ordability of essential medicines. Price, while crucial, is not the only determinant of access. In many low-income countries, weak health infrastructure signifi cantly limits the extent to which essential drugs are accessible. For example, Ministries of Health are often reluctant to distribute drugs to hospitals and health clinics if they believe these facilities lack the trained and motivated medical staff or the physical assets needed to ensure that the drugs are properly stored, prescribed and dispensed.2 Alternatively, a **Ministry of Health**’sadministrative systems **may be** such that it is **not able to manage** the **efficient distribution of** the **drugs** that are available to it**, resulting in shortages, particularly in less accessible parts of the country. Weaknesses in transportation** systems **and drug management** practices can also **result in spoilage**, thereby compromising the quality of available drugs.3 On the demand side, weak infrastructure oft en imposes significant costs and time burdens on poor people in need of health treatment. For example, **patients may have long distances to travel, and in many countries,** “informal payments” or **bribes are required** to obtain access to subsidized medicines (Lewis, 2007). The second main element of the last mile problem is the failure to use correctly the drugs to which patients do have access. The **WHO estimates that worldwide 50 percent of all medicines are** prescribed, **dispensed**, or sold **incorrectly, and that about half of all patients do not take medicines as directed** (WHO 2004b, 75). **This** incorrect use **exacts a huge toll in** increased **morbidity and mortality,** in addition to the toll exacted by lack of access. Estimates suggest that between 60 and 90 percent of household health expenditure in developing countries is on medicines (DFID 2006, 1). **Poor prescribing and dispensing practices, and weak adherence** by patients **to treatment requirements, means that** much of this **spending brings little in the way of health benefits**. It can actually be harmful, increasing the likelihood that certain diseases will develop resistance to the drugs that are used to treat them.5 These problems occur not only in developing, but also developed countries. Common types of incorrect medicine use include (WHO 2004b, 76): • use of too many types of medicines per patient (polypharmacy); • prescription of antimicrobials in inadequate dosage or for inadequate periods or the prescription of antibiotics for non-bacterial infections (the WHO estimates that around two-thirds of all antibiotics worldwide are sold without prescription); • use of injections where oral formulations would be better, increasing the transmission of hepatitis, HIV/AIDS and other blood-borne diseases; • failure to prescribe in accordance with clinical guidelines (survey data show that between 1990 and 2004 only around 40 percent of primary care level patients in Africa, Asia, and Latin America were treated in accordance with clinical guidelines for a number of common conditions, with no improvement over this period; WHO 2006c, 2); and • inappropriate self-medication, oft en of prescription-only drugs. A key cause of incorrect use is the lack of suitably qualifi ed medical personnel available to developing country health systems. Recent fi gures show that the number of health workers per 1,000 people was only 2.3 in Africa and 4.3 in South & East Asia, compared to 18.9 and 24.8 in Europe and the Americas respectively.6 Moreover, many developing-country health workers are poorly trained and paid and are not given adequate administrative support. This in turn contributes to low morale and a high incidence of absenteeism. This problem is especially acute in rural and remote areas. **Health facilities** that **are understaffed** or staffed **by inadequately trained** or motivated **workers** are very poorly placed to meet the requirements of rational drug use (Das, Hammer, and Leonard 2008). The WHO estimates that 57 countries suffer critical shortfalls of doctors, nurses, and midwives that prevent these countries from meeting even the most basic standards of health care (WHO 2006d, 5, 11–12). This human-resource crisis is complicated by the fact that in many low-income countries **staff salaries take up an inordinately large share of the** health **budget, leaving insufficient funds for** non-staff requirements such as **vaccines,** essential **drugs, diagnostic tools and infrastructure maintenance**. Public sector health payrolls are oft en poorly administered, and phenomena such as so-called ghost workers (people who are on payrolls but do not provide the relevant services) result in significant inefficiencies. Resource-constrained countries are confronted with the need to reduce the share of the wage bill in their health budgets while increasing the number and quality of health professionals, particularly in poorer areas. In many cases, greater efficiency in the use of existing resources, while necessary, will not be sufficient to remedy these problems entirely. There is no escaping the need for significantly larger amounts of resources to be made available to developing country health sectors.7 While public sector and not-for-profit private providers are key parts of the health sector in most low-income countries, the for-profit private sector— particularly in the form of private drug outlets—is often the first point of call for large parts of the populations of these countries when they fall sick. In Cambodia, for example, it is estimated that more than 70 percent of the population first approach private drug sellers when they fall sick, and that 75 percent of legal antimalarials are sold through the private sector. In Senegal, four private wholesalers linked to pharmacies and chemists represent nearly 65 percent of all sales of antimalarials (Institute of Medicine 2004, 40–41).8 Worldwide, **an increasing share of health care is being delivered through the private sector** (WHO 2006c, 4). Especially in low-income countries, governments often regulate private-sector drug outlets poorly. Even where suitable regulations and licensing procedures exist, **the supervisory and enforcement support needed to ensure compliance is often lacking.** Coupled with poor training of staff in private drug outlets, these regulatory, supervisory and enforcement shortcomings result in poor diagnosis and dispensing practices, and subsequently in the sale of unnecessary or contra-indicated drugs or incomplete courses of medication. This wastes resources, compromises successful treatment, and can lead to adverse patient reactions and the development of drug-resistant disease forms. **The incentives that private sellers have to maximize sales regardless of clinical requirements add to the likelihood of incorrect use.** These incentives are present not only in the private sector, but apply where the prescribing and dispensing functions are combined, as is sometimes the case in some public health facilities in low-income countries. Th is point notwithstanding, survey data available to the WHO show that, in developing and transition countries, the use of medicines is signifi - cantly worse in the private than in the public sector (WHO 2006c, 4).9 Even where **drugs** are correctly prescribed, they **are often sold in inappropriate packaging, with inadequate instructions** for patient use,or both. Th is creates serious problems when patients are illiterate or ill-informed about the implications of not taking medication as directed. Th is is particularly problematic with respect to medicines whose partial completion is oft en suffi cient to relieve symptoms. The result is a serious problem with patient adherence to the requirements of their drug treatment. Drug prices are also a factor in lack of patient adherence to treatment regimens. Poor patients may purchase insufficient amounts of the medicine, in an attempt to economize. A 2006 WHO report suggests that, unless effective action is taken, the problem of incorrect drug use is likely to get worse. This is so for two reasons. First, an increasing share of health care worldwide is being provided through the private sector. In developing countries and countries in transition to a market economy, provision through the private sector is likely to result in a higher incidence of incorrect drug use than provision through the public sector, which is important given the prominence of private drug sellers as a first point of call. Second, **many large-scale initiatives to treat diseases** of major public health importance, such as malaria, HIV/ AIDS, and tuberculosis, concentrate primarily on access and **give insufficient attention to the problem** of irrational use (WHO 2006c, 4). Irrational use also occurs in developed countries. As Avorn (2004) notes, there is a paucity of reliable clinical trials comparing the risks and benefits of different medicines, and at the same time, pharmaceutical companies’ marketing muscle sometimes leads to poor prescribing choices by clinicians.