### 1

#### CP: Member nations of the World Trade Organization ought to declare COVID a national emergency on the basis of public health and issue compulsory licenses for medicines for COVID-19. Member nations should offer regulatory and legal assistance to nations filing a compulsory license.

#### Compulsory licensing solves access- empirics and past precedent

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\*\*\*Note: EST= Environmentally Sound Technologies\*\*\*

Even though there are limits to their effectiveness, compulsory licences are considered a valuable tool for governments to facilitate access to medicines through the prevention of patent abuses as well as the “encouragement of domestic capacities for manufacturing pharmaceuticals”. 289 According to the UNDP Human Development Report (2001), after the adoption of the TRIPS Agreement, compulsory licences were initially mainly used in Canada, Japan, the UK and the United States for products such as pharmaceuticals – particularly as a remedy to address anti-competitive practices and prevent higher prices – while no compulsory licence was issued then in developing countries largely due to pressure from Europe and the United States and the fear of long and expensive litigation against the pharmaceutical industry.290 As demonstrated in Section 5.4.1.2, in order to address developing countries’ concern, the 2001 Doha Declaration explicitly reaffirmed the right of countries to issue compulsory licences where necessary, in the interests of public health.

In order to enable countries with insufficient manufacturing capacity in the pharmaceutical sector to benefit from the compulsory licensing system, the WTO General Council adopted the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the so-called paragraph 6 system).291 This decision essentially expanded the TRIPS flexibilities, involving two waivers: (1) with respect to the exporting country, a “waiver” of obligations to use the authorised compulsory licence predominantly for the supply of the domestic market under Article 31(f); and (2) with regard to the importing country, a waiver of the adequate remuneration requirement under Article 31(h) when remuneration is paid in the exporting Member. “Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorised in the exporting Member”. 292

In 2005, WTO Members agreed to make the waivers permanent by amending the TRIPS Agreement.293 With the approval of two-thirds of the WTO Members, the amendment entered into force on 23 January 2017. As the very first legal amendment to a WTO multilateral agreement, it was said to have shown that “[M]embers are determined to ensure the WTO’s trading system contributes to humanitarian and development goals”. 294 Likewise, such amendment could be extended to address other global concerns such as climate change in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement.

In effect, the compulsory licensing system established within the WTO framework is not a panacea, but rather a legal guarantee of rights and ability to make effective use of compulsory licences. Since the adoption of the Doha Declaration, a number of developing countries (e.g., Thailand, Brazil, Ecuador, India and Indonesia) have issued compulsory licences to lower the price of patented medicines such as HIV/AIDS drugs.295 Additionally, in 2007, Rwanda became the first country without sufficient manufacturing capacities to use the WTO “paragraph 6 system” to import Apo-TriAvir from Apotex, a Canadian firm.296 Commentators note that since the Doha Declaration was adopted in 2001, the threat of compulsory licenceshas motivated multinational companies to “voluntarily make proactive efforts to realistically make their drugs accessible**”** either through dramatically lowering the price or by offering voluntary licences on favourable terms.297 Meanwhile, many countries have successfully used the threat of compulsory licences as leverage in drug price negotiations with pharmaceutical companies.298

#### It’s goldilocks - protects patents while allowing urgent access – the perm or the aff shatters IP protections which crushes innovation while the CP strikes an accepted balance

**Bacchus 2020** (James, Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization’s Appellate Body. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” *Cato* <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto> December 16, 2020)DR 21

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance **struck by the members of the WTO** between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

Does a Novel Virus Present Novel Issues?

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”[12](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref12)

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”[13](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref13)

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”[14](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref14)

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”[15](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref15) But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. **Subordinating IP rights temporarily** to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth **in the 21st century is increasingly** ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus **preventing** the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules **recognize that “intellectual property rights are private rights”** and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

### 2

#### 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.

#### 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.

#### Bioterror causes extinction---quick innovation key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, Bill Gates will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose charitable foundationis funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

### 3

#### The Aff’s portrayal of a world with reduced IP protections as an “information commons” where global health inequality is solved by deregulation perpetuates the neoliberal myth of increased competition ensuring a perfect market **Kapczynski 14** [(Amy, a Professor of Law at Yale Law School, Faculty Co-Director of the Global Health Justice Partnership, and Faculty Co-Director of the Collaboration for Research Integrity and Transparency. She is also Faculty Co-Director of the Law and Political Economy Project and cofounder of the Law and Political Economy blog. Her areas of research include information policy, intellectual property law, international law, and global health.) “INTELLECTUAL PROPERTY’S LEVIATHAN” Duke Law, Law & Contemporary problems, 2014. <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=4710&context=lcp>] BC

Over the last decade or so, a powerful set of critiques has emerged to contest the dominant account just sketched out as well as the contemporary state of IP law.12 These arguments have come from many directions, some even arising from scholars who previously were champions of the dominant account.13 The most prominent and potent line of theoretical critique in the legal literature has come in the guise of arguments for free culture and the “information commons” and has been most influentially articulated by Lawrence Lessig and Yochai Benkler.14 Both have stressed the problems with expansive exclusive rights regimes in information and have also sketched a set of actually existing alternatives to market-based exclusionary forms of information and cultural production. Lessig has written a series of influential books that have made him a “rock star of the information age,”15 particularly for young Internet and free-culture activists. He has argued powerfully, for example, that existing copyright law is in deep conflict with the radical new possibilities for creativity in the digital age. As he points out, when a mother posting a video of her toddler dancing to a Prince song on YouTube is threatened with a $150,000 fine for copyright infringement, something has gone seriously awry.16 Lessig also contends that copyright law today is too long, too expansive, and instantiates a “permission culture” that is antithetical to free expression in the age of the remix.17 As he puts it, “the Internet has unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches far beyond local boundaries,” creating the possibility of markets that “include a much wider and more diverse range of creators,” if not stifled by incumbents who use IP law to “protect themselves against this competition.”18 Benkler’s work has also been extraordinarily formative in the field, particularly for his insights into the multiplicity of modes of information production. As he has stressed, the conventional justification for IP does not account for the many successful and longstanding modes of market nonexclusionary information production.19 For example, attorneys write articles to attract clients, software developers sell services customizing free and opensource software for individual clients, and bands give music away for free to increase revenues from touring or merchandise.20 More pathbreaking still is Benkler’s account of the importance of “commons-based peer production,” a form of socially motivated and cooperative production exemplified by the volunteer network that maintains Wikipedia or the groups of coders who create open-source software products such as the Linux operating system.21 In the digital networked age, as Benkler describes, the tools of information production are very broadly distributed, “creating new opportunities for how we make and exchange information, knowledge, and culture.”22 These changes have increased the relative role in our information economy of nonproprietary production and facilitate “new forms of production [that] are based neither in the state nor in the market.”23 Because commons-based peer production is not hierarchically organized and is motivated by social dynamics and concerns, it also offers new possibilities for human development, human freedom, a more critical approach to culture, and more democratic forms of political participation.24 This line of critique has been profoundly generative and has helped launch an important new conceptualization of the commons as a paradigm. That paradigm, as a recent book puts it, “helps us ‘get outside’ of the dominant discourse of the market economy and helps us represent different, more wholesome ways of being.”25 Proponents of the commons concept draw upon contemporary articulations of successful commons-based resource management by Elinor Ostrom and her followers.26 They do mobilize retellings of the political and economic history of the commons in land in Europe before enclosure,27 and recent evidence from psychology and behavioral economics that suggests that humans have deep tendencies toward cooperation and reciprocation.28 They argue that A key revelation of the commons way of thinking is that we humans are not in fact isolated, atomistic individuals. We are not amoebas with no human agency except hedonistic “utility preferences” expressed in the marketplace. No: We are commoners—creative, distinctive individuals inscribed within larger wholes. We may have unattractive human traits fueled by individual fears and ego, but we are also creatures entirely capable of self-organization and cooperation; with a concern for fairness and social justice; and willing to make sacrifices for the larger good and future generations.29 This stands, of course, as a powerful rebuke to the neoliberal imaginary, which “constructs and interpellates individuals as . . . rational, calculating creatures whose moral autonomy is measured by their capacity for ‘self-care’— the ability to provide for their own needs and service their own ambitions.”30 III Given this radical—and, in my view, critically important—attempt to rethink the subject at the core of neoliberal accounts, it is all the more striking that proponents of the commons often appear to adopt a neoliberal image of the state. For example, the introduction to a recently edited volume that gathers writings on the commons from seventy-three authors in thirty countries (entitled, tellingly, The Wealth of the Commons: A World Beyond Market and State) has this to say: The presumption that the state can and will intervene to represent the interests of citizens is no longer credible. Unable to govern for the long term, captured by commercial interests and hobbled by stodgy bureaucratic structures in an age of nimble electronic networks, the state is arguably incapable of meeting the needs of citizens as a whole.31 The commons, they suggest, is a concept that seeks not only to liberate us from predatory and dysfunctional markets, but also from predatory and dysfunctional states. Something immediately seems incongruous here. If people are inherently cooperative reciprocators, why are states irredeemably corrupt? After all, as Harold Demsetz famously wrote in his 1967 attack on Arrow’s optimism about state production of information, “[g]overnment is a group of people.”32 Lessig, one of the progenitors of the language of the commons in the informational domain, often leads with a similar view of the state: [I]f the twentieth century taught us one lesson, it is the dominance of private over state ordering. Markets work better than Tammany Hall in deciding who should get what, when. Or as Nobel Prize-winning economist Ronald Coase put it, whatever problems there are with the market, the problems with government are more profound.33 Lessig reveals his own sense of the power of this conception of the state when he seeks to tar IP law with the same brush; we should rebel against current IP law, he suggests, because we should “limit the government’s role in choosing the future of creativity.”34 Benkler is more measured but admits as well to viewing the state as “a relatively suspect actor.”35 We should worry, he suggests, that direct governmental intervention “leads to centralization in the hands of government agencies and powerful political lobbies,”36 a view that echoes the neoliberal account described above. It should perhaps not surprise us that leading critics of neoliberal information policy embrace a neoliberal conception of the state. After all, neoliberalism is not merely an ideology, but also a set of policy prescriptions that may have helped to call forth the state that it has described. As David Harvey puts it, “[t]he neoliberal fear that special-interest groups would pervert and subvert the state is nowhere better realized than in Washington, where armies of corporate lobbyists . . . effectively dictate legislation to match their special interests.”37 There are, it must be said, few areas of law that better exemplify this problem than IP law. For example, Jessica Litman has documented the astonishing process through which the 1976 Copyright Act was drafted, in which Congress delegated most of the drafting to interest groups that were forced to negotiate with one another.38 Other scholars have offered similarly startling accounts of the genesis of the most important IP treaty today, the TradeRelated Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS came into force in 1996, revolutionizing international IP law by both imposing new standards and by rendering them enforceable through the WTO’s disputeresolution system, which authorizes trade retaliation to enforce its judgments. Most countries in the world are members of TRIPS, and the Agreement introduced, for developing countries in particular, substantial new obligations, such as the obligation to grant patents on medicines and food-related inventions. Several excellent histories of the treaty have been written, documenting its beginnings as a brash idea proposed by “twelve chief executive officers (representing pharmaceutical, entertainment, and software industries).”39 As Susan Sell has described, the TRIPS Agreement was a triumph of industry organizing. Through TRIPS, Industry revealed its power to identify and define a trade problem, devise a solution, and reduce it to a concrete proposal that could be sold to governments. These private sector actors succeeded in getting most of what they wanted from a global IP agreement, which now has the status of public international law.

#### Attempts to reform the WTO are neoliberal attempts to sustain the US regime of accumulation – the contradictions of neoliberalism are why credibility is low, not IP protection

Bachand 20 [(Remi, Professor of International Law, Département des sciences juridiques, member of the Centre d’études sur le droit international et la mondialisation (CÉDIM), Université du Québec à Montréal, Canada) “What’s Behind the WTO Crisis? A Marxist Analysis” The European Journal of International Law, 8/12/2020. https://academic.oup.com/ejil/article-abstract/31/3/857/5920920?redirectedFrom=fulltext] BC

To offer our own explanation, we must recall two aspects of our theoretical framework. The first is Robert Cox’s claim113 that the function of international organizations is to ensure the creation and reproduction of hegemony. To be more accurate, they serve, if we follow his argument, to defend and to expand the ‘mode of production’ (we elected to substitute this term for the concept of ‘regime of accumulation’ that appears to be more appropriate for our means) of the dominant social classes of the dominant state. Joining this idea with the école de la régulation and social structure of accumulation theory writing114 according to which a regime of accumulation needs some regulation institutions to help resolve its contradictions (and ensure profits and capital accumulation to dominant social classes), we can conclude that the Geneva organization’s function in the US hegemonic order is to make sure that neoliberalism works well enough to provide a satisfying rate of profit for US capitalists. Going in that direction, Kristen Hopewell shows that the WTO’s creation participated in a shift in global governance from ‘embedded liberalism’ to neoliberalism115 and was slated to be an important part of that governance. Using the conceptual framework developed earlier, we can infer that the WTO was thus given a regulation function that was to ensure the operationalization of counteracting factors to the fall of the rate of profit for US capitalists. Now, as we have seen, the US rate of profit has been extremely unstable in the last two decades and Chinese expansion (and that of other ‘emerging countries’) allows one to predict that the situation could easily worsen in the future. Consequently, it should come as no surprise that the crisis that has been striking neoliberalism for the last 20 years may also result in a crisis of the organizations that are supposed to manage its contradictions, especially the WTO. Concretely, this organization seems unable to fulfil its regulatory function anymore, which is to ensure US capitalists a good rate of profit and opportunities to operationalize enough counteracting factors to negate its fall. To go further, we now need to return to Stephen Gill’s claim that the function of an international organization is to limit political and economic possibilities. It is to exclude, in other words, options that are incompatible with the social order promoted by the hegemon from what is possible and achievable.116 Effectively, the WTO was created to play such a role. Indeed, promoting liberalization of goods and services, protecting (notably intellectual) property rights and attacking subsidies (in non-agriculture sectors), just to give a few examples, all serve to severely reduce state interventions into the economy and to circumscribe or at least to strongly impede the turn towards an alternative model to neoliberalism

#### Neoliberalism rips apart communal bonds to maintain the illusion that structural inequalities are individual problems – the impact is systemic victim-blaming, poverty, and violence.

Smith 12 [(Candace, author for Societpages, cites Bruno Amable, Associate Professor of Economics at Paris School of Economics) “Neoliberalism and Individualism: Ego Leads to Interpersonal Violence?” Sociology Lens is the associated site for Sociology Compass, Wiley-Blackwell’s review journal on all fields sociological] AT

There appears to be a link between neoliberalism, individualism, and violence. In reference to the association between neoliberalism and individualism, consider neoliberalism’s insistence that we do not need society since we are all solely responsible for our personal well-being (Peters 2001; Brown 2003). From a criminological standpoint, it is not hard to understand how this focus on the individual can lead to violence. According to Hirschi’s (1969) social control theory, for instance, broken or weak social bonds free a person to engage in deviancy. Since, according to this theory, individuals are naturally self-interested, they can use the opportunity of individualization to overcome the restraining powers of society. Bearing in mind neoliberalism’s tendency to value the individual over society, it could be argued that this ideology is hazardous as it acts to tear apart important social bonds and to thereby contribute to the occurrence of ego-driven crimes, including violent interpersonal crimes. Such a thought suggests that as neoliberalism becomes more prominent in a country, it can be expected that individualism and, as a result, interpersonal violence within that country will increase. When it comes to individualization, this idea is one of the fundamental aspects of neoliberalism. In fact, Bauman (2000:34) argues that in neoliberal states “individualization is a fate, not a choice.” As Amable (2011) explains, neoliberals have realized that in order for their ideology to be successful, a state’s populace must internalize the belief that individuals are only to be rewarded based on their personal effort. With such an ego-driven focus, Scharff (2011) explains that the process of individualization engenders a climate where structural inequalities are converted into individual problems.

#### The alt is to reject the aff in favor of a critique that cultivates educated hope - evaluate the aff and alt on the level of ideological commitments – these policies won’t happen which takes out consequentialism good offense – BUT until we unlearn the assumption that getting government out of the way will let markets flourish and solve all our problems, we'll never be able to engage in robust, communitarian policymaking that truly centers human need and our obligations to others. Wilson 17:

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New Stories for New Worlds As we will see in our mapping of the neoliberal conjuncture, competition's totalizing yet tenuous power over our everyday lives is rooted in what Keating calls “status quo stories”—those stories that get told in popular culture, and that we often tell ourselves, which cement our relationship to our present conjuncture and our investment in the world as we currently know it. She explains: Generally spoken with great certainty, these and similar comments (commands, really) reflect unthinking affirmation of the existing reality and a stubborn, equally unthinking resistance to change. Because we believe that our status-quo stories represent accurate factual statements about ourselves, other people, and the world, we view them as permanent, unchanging facts. This belief in the status-quo's permanence becomes self-fulfilling: We do not try to make change because change is impossible to make. “It's always been that way,” we tell ourselves, “so why waste our energy trying to change things?” “People are just like that-it's human nature, so plan accordingly and alter your expectations! There's no point in trying to change human nature!" Status-quo stories trap us in our current circumstances and conditions; they limit our imaginations because they prevent us from envisioning alternate possibilities.10 Status-quo stories double down on reality, making it seem like those socially constructed forces impinging on us are natural rather than historical, political, and subject to change. “Status-quo stories have a numbing effect,” Keating writes. “When we organize our lives around such stories or in other ways use them as ethical roadmaps or guides, they prevent us from extending our imaginations and exploring additional possibilities."11 One of my students aptly described neoliberal culture as a “status-quo storytelling machine.” To keep us living in competition, neoliberalism generates a host of status-quo stories about the naturalness and inevitability of self-enclosed individualism. Indeed, we might say that self-enclosed individualism operates as the foundational status quo story of neoliberal culture, where competition has become synonymous with all of life. Self-enclosed individualism keeps us not only divided from one another, but also actively pitted against each other. We are stuck in an oppositional consciousness that refuses to acknowledge our social interconnections, even though, as our shared anxieties suggest, we've never had more in common than right now! No matter where we are or what we're doing, neoliberal culture encourages us to see each other through a competitive lens that makes the transformation of our social world, and ourselves, impossible. We become incapable of acknowledging how our fortunes and fates are entwined with those of others who are living very different realities. We become callous and hardened to the suffering of others. We see suffering and death everywhere, and while this might register as bad or wrong or upsetting, we nonetheless stay stuck within the horizons of our own self-enclosed bubbles. The devastating powers of status-quo stories are clear in so many of the conversations we have on college campuses about power, privilege, and difference. In fact, I started teaching courses on neoliberal culture to help my students understand the broader histories and contexts that were impinging on these conversations and making them so fraught, and ultimately so unproductive. Time and time again, in open community forums and classroom discussions of systemic inequalities, I watched students voice painful personal experiences only to get nowhere. Indeed, when asked to consider various forms of privilege, many of my white, male students get defensive. The idea that they haven't earned their place through their own decisions and hard work, but rather benefited from inherited wealth and opportunity, means that they are not good people from the perspective of neoliberalism. Talking about issues of privilege threatens to diminish their sense of self and individual value, so they recoil from conversations that ask them to see their place within broader legacies of settler colonialism, patriarchy, and capitalism. Accordingly, they hold on tight to status-quo stories of self-enclosed individualism to protect themselves, doubling down on their privilege to secure their status in a competitive world. However, it is important to see that status-quo stories of self- enclosed individualism also inform my students from historically oppressed and marginalized groups. These students suffer daily: they live in an environment that professes to celebrate “diversity,” while, in the context of their own lives, they are reminded again and again just how much they don't belong or matter. Not surprisingly, they demand “safe spaces” and protection for themselves and their peers, and they often draw hard lines between allies and enemies. Here too though, we see neoliberal stories at work. What matters for my students, and rightly so, is the way that “microaggressions”—those daily, mundane experiences of discrimination that accumulate over time-diminish their own capacities for flourishing as self-enclosed individuals. My point here is not to suggest that privileged students and marginalized students are the same because they are both invested in a version of self-enclosed individualism. Rather, my point is they share a situation; despite their different and unequal social positions, they have similar feelings-of defensiveness and a fear of failure—and status-quo stories in common. These commonalities do not imply evenness or equality, but rather interconnection, that is, a shared conjuncture. It is the recognition of this conjunctural interconnection that can thread our lives together and open up possibilities for more egalitarian futures. However, living in competition and the oppositional consciousness it demands obscure these commonalities and the interconnections that could bring students into new relations with one another. As a result, we stay caught up in the world as we know it. We stay stuck in competition, even though we all are yearning for different worlds. We desperately need new stories, stories that offer us different pathways to each other. As Keating puts it, we need stories that help us move from “me” to “we” consciousness.12 However, this book is not going to write these new stories for you. Rather, the goal of this book is to provide you with the resources for writing these new stories in and through your own lives. The Work of Critique Ultimately, writing new stories will require a new sense of yourself and your world, as well as what is possible, and realizing this new sense will require, first and foremost, cultivating a deeply critical orientation toward the world as we currently know and experience it. This critical orientation dislodges the sense of inevitability of neoliberalism, self-enclosed individualism, and living in competition; it knows that things don't have to be this way and, thus, senses the possibilities for resistance and transformation that are everywhere. It is so crucial to understand that this critical orientation is not simply about saying that aspects of neoliberal culture are “bad” or "wrong.” Rather, the work of critique is about seeing the flows of power and ways of thinking that make the neoliberal conjuncture possible and hold it together. Critique is therefore a mode of knowing—a form of everyday intellectual work—that is aimed at exposing the myriad workings of power and its status-quo stories. As Michel Foucault explains, “A critique is not a matter of saying that things are not right as they are. It is a matter of pointing out on what kinds of assumptions, what kinds of familiar, unchallenged, unconsidered modes of thought the practices that we accept rest.”13 To clarify Foucault's idea, let's think back to the student discussions of power and privilege discussed above. The work of critique is not simply about pointing out privilege, although this is, of course, vital work. The work of critique goes beyond pointing out what's wrong and seeks to unravel the socially constructed conjuncture in which these problems emerge and get negotiated. For only then can we step outside of the competitive, oppositional consciousness of neoliberal culture and begin to imagine a radically different future built on equality and shared security. This work of dislodging the inevitability of our conjuncture and its status-quo stories is hard but vital intellectual work that requires not only critique of our social world, but also transformation of ourselves. Indeed, truly critical work is always profoundly disruptive of our own identities and knowledges. This work can be immensely painful, as it strips away the certainty and comfort provided by status-quo stories. This work can also be, and should be, immensely joyful and life-giving, as it enables us to free ourselves from the status-quo stories and devastating limitations they put on our lives, imaginations, and social relationships. This mix of pain and joy at the heart of critical work comes from the way that critique asks us to “lose confidence” in our world. As feminist theorist Sara Ahmed writes, Losing confidence: it can be a feeling of something gradually going away from you, being eroded. You sense the erosion. You might stumble, hesitate, falter; things might gradually unravel so you end up holding onto the barest of threads. It might be an experience in the present that throws things up, throws you off balance.... When you lose confidence it can feel like you are losing yourself: like you have gone into hiding from yourself.4 Losing confidence in your world is thus a form of existential crisis —you are disoriented; your world is shattered. At the same time, losing confidence in status-quo stories means gaining confidence for resistance and transformation. We become bolder, less anxious, more optimistic, capable of social interconnection, political intervention, and acting on and from a place of commonality. This is real freedom. Critique is ultimately about unlearning our world so that we might reconstruct it anew. Losing confidence in neoliberal culture means being able to say no to it in the conduct of our daily lives. In these capacities for resistance, we gain confidence that another world might actually be better, worth opening ourselves up to, worth fighting for. We begin to cultivate what Henry Giroux calls educated hope. Educated hope is not “a romanticized and empty” version of hope; rather, it is a form of hope enabled by critique that “taps into our deepest experiences and longing for a life of dignity with others, a life in which it becomes possible to imagine a future that does not mimic the present.” With educated hope, our sense of who we are and of what might be possible shifts in profound ways. This is when those new worlds we are longing for open up. What’s to Come Each of the chapters that follow offer a variety of intellectual tools for mapping the neoliberal conjuncture. Taken together, they are designed to produce a holistic and thick understanding of neoliberalism and its myriad powers to shape our identities, sensibilities, social worlds, and political horizons. Having a thick understanding of neoliberalism means that you feel in your bones that there is nothing natural or inevitable about neoliberalism and its status-quo stories. It means that you understand that neoliberalism is the outcome of a range of contingent historical processes that have consequences across social, political, economic, and cultural fields. In other words, by the end of our journey, you'll know how our neoliberal conjuncture has been, and continues to be, constructed. You'll also, therefore, be able to sense the other worlds on the horizon that are just waiting to be constructed, so long as, together, we can develop the resources, capacities, and stories of interconnection for bringing them into being. More specifically, the book is divided into two sections. The first section, titled “Critical Foundations,” focuses on cultivating a broad, critical orientation toward neoliberal culture. The first chapter charts the rise of neoliberal hegemony through four historical phases. The goal is to illustrate exactly how competition came to be the driving cultural force in our everyday lives. As we will see, there is nothing natural or inevitable about neoliberalism. It was a political and class-based project to remake capitalism and liberal democracy that was conceived, organized for, and eventually won. In the second chapter, we delve into the world of neoliberal theory and its critical consequences. Here we'll explore exactly what neoliberal thinkers believe about the state, markets, and human actors, and what distinguishes neoliberalism from earlier schools of liberal thought. We'll also interrogate what I call the four Ds—disposability, dispossession, disimagination, and de- democratization—which, taken together, enable us to clearly see and articulate what is so devastating about the rise of neoliberalism. The third chapter examines the cultural powers specific to neoliberalism. Neoliberalism advances through culture, specifically through the promotion of an enterprise culture that works to impose competition as a norm across all arenas of social life. In order to see and specify how neoliberalism works through culture, we take contemporary education as a case study and unpack the entangled cultural powers of neoliberal governmentality, affect, and ideology. The second section is titled “Neoliberal Culture.” In these chapters, we explore the worlds of neoliberal labor, affect, and politics respectively, tracing what happens when our everyday lives as workers, individuals, and citizens become organized around living in competition. The fourth chapter examines how neoliberalism turns everyday life into a “hustle,” where all the contexts of daily life become animated by the demands of neoliberal labor. At stake here are the ways in which we are all hustling to get by, yet we stay radically divided from one another along lines of gender, race, and class thanks to the norm of self- enterprise. The next chapter hones in on what it feels like to inhabit enterprise culture by exploring neoliberal affect and the care of the self. As we already know, living in competition breeds widespread anxiety, not to mention depression and illness, making self-care an ongoing, pressing problem of everyday life. While neoliberal culture offers us plenty of tools for self-care that ultimately keep us stuck in our self-enclosed individualism, this chapter also considers how self-care might be a site for resistance and political intervention. The final chapter focuses on neoliberal politics, tracing what happens to citizenship and social action in our contemporary conjuncture. As we'll see, neoliberalism privatizes our political horizons by remaking democracy into a market competition for visibility and equality. Throughout this mapping of the neoliberal conjuncture, we will engage in a mode of critical work that will, hopefully, enable you to unlearn neoliberalism and thus begin to write new stories about our conjuncture—including both our commonalities and differences—and the alternative worlds we are yearning for. Indeed, our critical work will only matter to the extent that it opens up our individual and collective horizons to a future beyond living in competition.

# CASE

### War

#### 1. Scenario is thumped by the US selling arms to Taiwan and patrolling the South China Sea.

#### 2. Taiwan doesn't go nuclear - their entire card is about the Taiwan Straight crisis of 1958. Deterrence is more stable now, both the US and China have second strike capability, Taiwan is not worth it for the US or China.

#### 3. Their Zhong and Schuetze card says that the US and Japan have already donated vaccines, that also thumps the scenario.

#### 4. a year and a half of the pandemic thumps the COVID war scenario

#### 5. NU – Taiwan has had a domestic vaccine since August.

Ting-Ting & Liu 10/26 - Han Ting-ting and Kay Liu, “CORONAVIRUS/WHO selects Taiwan's Medigen COVID-19 vaccine for international trial,” *CNA English News – Focus Taiwan*. 10/26/21. < <https://focustaiwan.tw/sci-tech/202110260025>> AT

Taipei, Oct. 26 (CNA) A COVID-19 vaccine developed by Taiwan's Medigen Vaccine Biologics Corp. has been chosen to take part in an international clinical trial platform co-launched by the World Health Organization (WHO), according to a statement released by the organization Tuesday.¶ The Medigen COVID-19 vaccine, a protein subunit vaccine, the rollout of which started in Taiwan on Aug. 23, was chosen along with a DNA vaccine encoding the spike protein developed by American company Inovio Pharmaceuticals, for the Solidarity Trial Vaccines platform, the WHO said.

### Trade

#### Their card has no warrant for how the WTO will collapse, just ominous assertions from random officials

#### If countries trade trillions a year and economies would collapse without it, uniqueness overwhelms the link on commitment to the WTO - structural factors outweigh disagreement over one vaccine

#### nonunique---countries have been mad at the WTO for decades despite anti-free-trade controversies---deindustrialization, the anti WTO protest in 1999, never caused collapse

#### TURN: countries all unanimously rejecting WTO’s TRIPS obligations collapses the WTO

#### DIDN’T READ - WTO isn't key to future trade AND its current mechanisms are resilient

Drezner 13

Daniel W. Drezner is professor of international politics at Tufts University's Fletcher School and a contributing editor to Foreign Policy, Foreign Policy, December 3, 2013, "The End of Multilateral Trade?", http://www.foreignpolicy.com/posts/2013/12/03/the\_end\_of\_multilateral\_trade

This kind of story is both overly optimistic and overly pessimistic about the state of the WTO. It's overly optimistic in assuming that, even if something is negotiated in Bali (and the odds aren't great of that happening), it's unlikely that the WTO will ever be the focal point for comprehensive trade talks ever again. Even getting agreement on the "easy" parts of Doha has been super-hard. There's very little upside to making the WTO the focal point of new talks, especially given that most of the regional and bilateral trade talks have been of the "open regionalism" variety.

On the other hand, the "slippery slope" argument of the WTO losing relevance is also way overplayed. Such a statement omits two very important facts. First, even if there's no further WTO-guided liberalization, the rounds negotiated to date constitute far more liberalization than what can be achieved in the future. In other words, the WTO rules still govern a lot of trade, and further liberalization won't erode the WTO's bailiwick that much.

Second, the WTO's Dispute Settlement Understanding remains the ne plus ultra of enforcement arrangements in global governance. Contrary to the WSJ story, there is zero evidence that WTO enforcement has weakened as Doha bogged down or as protectionism increased after 2008. That part of the trade system is still working pretty well.

For decades, trade commentary has implicitly embraced the "bicycle theory" - the belief that unless multilateral trade liberalization moves ahead, the entire global trade regime will collapse because of a lack of forward momentum. The last decade -- and particularly the post-2008 period -- suggests that there are limits to that rule of thumb. It is possible for the WTO to matter less on jump-starting multilateral trade negotiations while still mattering a great deal in enforcing the rules of the game.

### Solvency

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.

**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.

#### 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.

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

Kumar, PhD, 7-12-21

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

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).1 The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines. Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.2 It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal. On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.3 At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.4 The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.5 At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad. TRIPS and its Exceptions TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).6 In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).7 Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.8 Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver. The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.9 In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033. COVID-19 and TRIPS Waiver Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines. Vaccine Inequity According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11 Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021. Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14 This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution. TRIPS: Barrier to Equitable Health Care Access The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16 Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19 A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21 Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding. Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines. Source: Katharina Buchholz, “COVID-19 Vaccines Lift Pharma Company Profits”, Statista, 17 May 2021. One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity.

However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally. India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing. Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

#### 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.

#### 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.

#### 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.