# 1

#### **Climate innovation is high and solving warming, but continued investment is key -- reducing IP collapses collaboration and investments.**

Brand 5-26, [Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/]

“If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis, can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth?” the discussions around waiving intellectual property (IP) rights set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are currently (and somewhat amorphously) limited to COVID-19 related drug and medical products, it is probably shortsighted to ignore the implications for other technologies critical to sustaining our environment and advancing a more healthful world. In fact, if we want to ensure continued investment in these technologies, we should be very concerned about the message conveyed by the international political tide: if you overcome a challenging scientific problem and your solution has the potential to save lives, be prepared to be subjected to intense political pressure and to potentially hand over your technology without compensation and regardless of the consequences. The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course we dispute this notion), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) Katherine Tai was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. International Pressure May Be Influencing Domestic IP Policy The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensation and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation raised over $1 billion in investment in the second quarter of 2019 alone. If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels. Next on the Chopping Block It is quite reasonable to be worried about the broad implications of a TRIPS IP waiver precedent. International campaigns to weaken IP rights seem to be taking hold in U.S. domestic policy. The TRIPS IP waiver discussions will not conclude in the near term and will not yield more shots in people’s arms. This is not even truly disputed, as our own administration acknowledges that the goal here is technology transfer abroad. Given the signaling that our Administration believes waiving IP rights is an appropriate measure to end global crises, it is proper to worry that facets of the biotech sector addressing climate change may be next on the chopping block.

#### Only a strong private sector can solve climate change

Gulker 19 [Max Gulker, 2-11-2019, "How a Strong Private Sector Will Address Climate Change," AIER, https://www.aier.org/article/how-a-strong-private-sector-will-address-climate-change/]

This is where a society with a free and well-developed private sector ought to shine. The engine of entrepreneurship combined with people responding to facts on the ground with which they alone are intimately aware will yield countless inventions, new construction, and other initiatives great and small. “The private sector” as a whole probably won’t get its due from pundits when the world is adapting to climate change since by its very nature its responses will be decentralized and often hidden in plain sight. We can speculate all we want on entrepreneurial solutions to problems that haven’t yet materialized–but the private sector can shine exactly where our speculation, and that of the public sector, inevitably falls short. Forbes contributor Willy Foote writes, “We need a comprehensive global effort to both mitigate and adapt to the impacts of climate change. But the latter is not a secondary challenge that can be put on hold until the world solves the former. It’s an immediate need.” The private sector is where much of this action will happen: “Social entrepreneurs, investors, and other private actors—unlike most governments—have inherent flexibility. They can experiment, identify the best solutions, and share that knowledge with others.” The environmental left is becoming less shy about wanting to greatly reduce the size and influence of the private sector. Climate change shows why we need a strong private sector–truly unleashing global knowledge and ingenuity to address changes around the world.

#### Climate change is existential and emerging technology is key

Espinosa 20 [Patricia Espinosa 04-xx-2020Frontier technologies to protect the environment and tackle climate change https://www.itu.int/en/action/environment-and-climate-change/Documents/frontier-technologies-to-protect-the-environment-and-tackle-climate-change.pdf]

Climate change is an existential crisis and represents the greatest challenge facing this generation. It is clear that business as usual is simply not good enough anymore. We need deep, transformational and systemic change throughout society if we are to truly build a low-emissions, highly-resilient and more sustainable future. Technological innovations have a critical role to play in this process, including enhancing and accelerating the implementation of Nationally-Determined Contributions, National Adaptation Plans and both long and medium-term climate change strategies. Specifically, technological innovation in adaptation and mitigation has received increased attention, thereby providing opportunities to accelerate climate action on all fronts. Frontier technologies present even greater potential in our fight against climate change. In the energy and renewables sector, innovations such as smart grids, through the Internet of Things (IoT), may substantially lower global emissions, helping to drive their necessary peak and decline. In the area of climate resilience, technologies such as satellite 2.0 and artificial intelligence offer enormous opportunities when it comes to identifying and addressing climate risks and their impacts, as well as promoting climate-resilient development. While the potential of these new technologies is extraordinary, as the United Nations family, it is our responsibility to not only promote the transfer and diffusion of new technologies, but also to ensure that their benefits are available to all people. For example, we must ensure that autonomous systems are free of biases and discrimination and we must also ensure they consider the interests of the most vulnerable. Technology, if harnessed correctly, offers enormous potential in our efforts to address climate change. It can not only offer unique opportunities—including economic—but it can have an immediate and significant impact and put countries on the path to low-carbon and climate-resilient development.

# 2

#### The United States federal government should commit to purchasing sufficient doses of COVID-19 vaccines to meet global demand and establish public-private partnerships to expand global vaccine manufacturing capacity.

#### Buying and exporting vaccines solves while avoiding the innovation DA.

Gianna Gancia 21, (IT, ID) is a member of Parliament’s Development Committee, “Why waiving patents on vaccines is not a good idea,” Parliament Magazine, 5-14-2021, https://www.theparliamentmagazine.eu/news/article/why-waiving-patents-on-vaccines-is-not-a-good-idea

In fact, there would be no incentive for pharmaceutical companies to conduct research, not only into COVID-19 (let's not forget that much still needs to be done to achieve an effective and minimally invasive therapeutic treatment in case of infection and severe symptoms) but also for future pandemic crises that, in a globalised world, are unfortunately entirely predictable. But the negative effects would not stop with pandemic crises. What would happen if one day, hopefully very near, an extremely effective anti-cancer drug was discovered by a pharmaceutical company? Would patents be suspended yet again? It is obvious that investment in cancer drug research would be drastically reduced. I strongly believe that the US position is short-sighted in this case, and to align with it would mean thwarting efforts to build an autonomous, strategic, and resilient European pharmaceutical sector. Such a decision would strongly disincentivise private investors and would effectively undermine the European sector's ability to be a world leader in research. We must remember that the United States has contributed very marginally to the export of vaccine doses, unlike the European Union which has exported 200 million doses, as many as the US has administered to its own citizens. Suspending the patents is a very hypocritical decision. If the United States really wants to help eradicate the virus from the world, the only thing they have to do is heavily subsidise, with public money, the production of a large number of vaccines by their pharmaceutical companies. “Giving” the patent to these countries is a cynical way of appearing good and humanitarian, without contributing in any way to actually helping them.

# 3

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND. As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds. The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends. As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level. Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4 In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37). The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution. Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments. The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015). Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

#### 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.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/> C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger. While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities. COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life. The Need to Rethink Likelihood Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly. There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely. In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that: The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm. The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7 As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9 Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

# Case

## Framing

#### Extinction o/ws under any framework, even under moral uncertainty – infinite future generations

Pummer 15 — (Theron Pummer, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford, “Moral Agreement on Saving the World“, Practical Ethics University of Oxford, 5-18-2015, Available Online at http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/, accessed 7-2-2018, HKR-AM) \*\*we do not endorse ableist language=

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions.There are so many possible future people that reducing existential risk is arguably the most important thing in the world,even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period.Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### And, it’s a gateway issue – dying ends the morality question so you must prevent extinction to resolve the fw debate

#### Ep modesty – framework prioritizes not precludes impact so only its logical – weigh by the degree a team is winning FW \* offense under that fw

#### Low probability framing makes IR perspective accurate – its pedagogically valuable even if they win its unlikely

Timothy Junio 13, cybersecurity postdoctoral fellow at CISAC, PhD in political science from the University of Pennsylvania, and Thomas Mahnken, Naval War College, “Conceiving of Future War: The Promise of Scenario Analysis for International Relations”, September, International Studies Review Volume 15, Issue 3, pages 374–395

This article introduces political scientists to scenarios—future counterfactuals—and demonstrates their value in tandem with other methodologies and across a wide range of research questions. The authors describe best practices regarding the scenario method and argue that scenarios contribute to theory building and development, identifying new hypotheses, analyzing data-poor research topics, articulating “world views,” setting new research agendas, avoiding cognitive biases, and teaching. The article also establishes the low rate at which scenarios are used in the international relations subfield and situates scenarios in the broader context of political science methods. The conclusion offers two detailed examples of the effective use of scenarios.¶ In his classic work on scenario analysis, The Art of the Long View, Peter Schwartz commented that “social scientists often have a hard time [building scenarios]; they have been trained to stay away from ‘what if?’ questions and concentrate on ‘what was?’” (Schwartz 1996:31). While Schwartz's comments were impressionistic based on his years of conducting and teaching scenario analysis, his claim withstands empirical scrutiny. Scenarios—counterfactual narratives about the future—are woefully underutilized among political scientists. The method is almost never taught on graduate student syllabi, and a survey of leading international relations (IR) journals indicates that scenarios were used in only 302 of 18,764 sampled articles. The low rate at which political scientists use scenarios—less than 2% of the time—is surprising; the method is popular in fields as disparate as business, demographics, ecology, pharmacology, public health, economics, and epidemiology (Venable, Li, Ginter, and Duncan 1993; Leufkens, Haaijer-Ruskamp, Bakker, and Dukes 1994; Baker, Hulse, Gregory, White, Van Sickle, Berger, Dole, and Schumaker 2004; Sanderson, Scherbov, O'Neill, and Lutz 2004). Scenarios also are a common tool employed by the policymakers whom political scientists study.¶ This article seeks to elevate the status of scenarios in political science by demonstrating their usefulness for theory building and pedagogy. Rather than constitute mere speculation regarding an unpredictable future, as critics might suggest, scenarios assist scholars with developing testable hypotheses, gathering data, and identifying a theory's upper and lower bounds. Additionally, scenarios are an effective way to teach students to apply theory to policy. In the pages below, a “best practices” guide is offered to advise scholars, practitioners, and students, and an argument is developed in favor of the use of scenarios. The article concludes with two examples of how political scientists have invoked the scenario method to improve the specifications of their theories, propose falsifiable hypotheses, and design new empirical research programs.¶ Scenarios in the Discipline¶ What do counterfactual narratives about the future look like? Scenarios may range in length from a few sentences to many pages. One of the most common uses of the scenario method, which will be referenced throughout this article, is to study the conditions under which high-consequence, low-probability events may occur. Perhaps the best example of this is nuclear warfare, a circumstance that has never resulted, but has captivated generations of political scientists. For an introductory illustration, let us consider a very simple scenario regarding how a first use of a nuclear weapon might occur:¶ During the year 2023, the US military is ordered to launch air and sea patrols of the Taiwan Strait to aid in a crisis. These highly visible patrols disrupt trade off China's coast, and result in skyrocketing insurance rates for shipping companies. Several days into the contingency, which involves over ten thousand US military personnel, an intelligence estimate concludes that a Chinese conventional strike against US air patrols and naval assets is imminent. The United States conducts a preemptive strike against anti-air and anti-sea systems on the Chinese mainland. The US strike is far more successful than Chinese military leaders thought possible; a new source of intelligence to the United States—unknown to Chinese leadership—allowed the US military to severely degrade Chinese targeting and situational awareness capabilities. Many of the weapons that China relied on to dissuade escalatory US military action are now reduced to single-digit-percentage readiness. Estimates for repairs and replenishments are stated in terms of weeks, and China's confidence in readily available, but “dumber,” weapons is low due to the dispersion and mobility of US forces. Word of the successful US strike spreads among the Chinese and Taiwanese publics. The Chinese Government concludes that for the sake of preserving its domestic strength, and to signal resolve to the US and Taiwanese Governments while minimizing further economic disruption, it should escalate dramatically with the use of an extremely small-yield nuclear device against a stationary US military asset in the Pacific region.¶ This short story reflects a future event that, while unlikely to occur and far too vague to be used for military planning, contains many dimensions of political science theory. These include the following: what leaders perceive as “limited,” “proportional,” or “escalatory” uses of force; the importance of private information about capabilities and commitment; audience costs in international politics; the relationship between military expediency and political objectives during war; and the role of compressed timelines for decision making, among others. The purpose of this article is to explain to scholars how such stories, and more rigorously developed narratives that specify variables of interest and draw on extant data, may improve the study of IR. An important starting point is to explain how future counterfactuals fit into the methodological canon of the discipline

### AT their FW

#### Materiality controls their impacts – they cannot explain why suffering is bad outside of a lense where death and pain is bad, and extinction is the ultimate culmination of that

#### The top ev on their fw concedes extinction first – extinction is the ultimate common vulnerability since we all die together. And, not focusing on extinction ignores the ultimate suffering it threatens

#### The santos ev doesn’t say what extinction calculus justified the atrocities they talk about, so insufficient specificity. And, extinction just outweighs

#### Extinction is human suffering and its dehumanizing so it ow under their fw

## Case

#### No UQ, Moderna already released COVID Vaccine IP – means generics can produce now

**Moderna** On, **10-8-2020**, "Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic," Moderna, Inc., <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19> *(Harker AM)*

Moderna is a pioneer in the development of messenger RNA (mRNA) vaccines and therapeutics. From its inception in 2010, Moderna saw the potential of this new class of medicines to make a significant difference in patients’ lives. With the support of our investors we have invested billions of dollars into research and development to make mRNA medicines a reality. One of the exciting discoveries advanced by Moderna was the combination of mRNA and lipid nanoparticles (LNPs) to make vaccines, and the demonstration of this potential in human clinical trials for eleven different infectious disease vaccines since 2015. Those discoveries and the expertise we developed have uniquely positioned Moderna to respond to the COVID-19 pandemic quickly. Information on our work toward a COVID-19 vaccine can be found here. As a company committed to innovation, Moderna recognizes that intellectual property rights play an important role in encouraging investment in research. Our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines. A summary of our intellectual property can be found here. A selection of representative issued US patents relevant to our mRNA-1273 vaccine against COVID-19 is available here. Beyond Moderna’s vaccine, there are other COVID-19 vaccines in development that may use Moderna-patented technologies. We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period. Moderna is proud that its mRNA technology is poised to be used to help end the current pandemic.

#### Squo solves – manufacturing, not IP, is the bottleneck and removing IP raises prices

Michelle **Mcmurry**-Heath Aug. 18, 2021, 8-18-2021, "Waiving intellectual property rights would harm global vaccination," STAT, <https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/>

To do that, some countries have sought to suspend intellectual property (IP) protections on Covid-19 vaccines and therapies. India and South Africa sponsored a proposal to that effect at the World Trade Organization (WTO). The proposal has since been endorsed by other countries, including the United States. They argue that eliminating IP protections would allow any willing company to produce lifesaving Covid-19 vaccines, making them cheaper and more widely accessible in low-income nations. If true, that would be a compelling argument. But it isn’t. Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive. Here’s why. Before Covid-19 emerged, the world produced at most 5.5 billion doses of various vaccines every year. Now the world needs an additional 11 billion doses — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease. Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months. The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit. Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production. Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another four to six months to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available. That’s slower than our current production rate. According to a report from Duke University’s Global Health Innovation Center, companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity. Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid $23.50 per dose for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during just two days of shutdowns in the country. Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose. Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. COVAX, the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year. President Biden vowed to make America the world’s “arsenal of vaccines.” The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate 500 million more by the end of summer. Other countries are following the administration’s leadership and ramping up their donations. To be sure, the United States and other wealthy nations still need to give considerably more. But the fact remains that ramping up production in bona fide facilities and donating doses are the most straightforward steps to producing the vaccine doses needed to end the pandemic. The effort to strip intellectual property rights, by contrast, would put success against the global scourge of Covid-19 even further out of reach.

#### Their ev concedes that infosharing is necessary to solve - green

**1ac Public Citizen 3/29 -** Public Citizen [“Public Citizen is a nonprofit consumer advocacy organization that champions the public interest in the halls of power. We defend democracy, resist corporate power and work to ensure that government works for the people – not for big corporations. Founded in 1971, we now have 500,000 members and supporters throughout the country. We don’t participate in partisan political activities or endorse any candidates for elected office. We take no government or corporate money, which enables us to remain fiercely independent and call out bad actors – no matter who they are or how much power and money they have.”], “Waiver of the WTO’s Intellectual Property Rules: Facts vs. Common Myths,” *Public Citizen Global Trade Watch Series*. March 29, 2021. Accessed Aug. 10, 2021. <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/> AT

In the press and on Capitol Hill, Big Pharma is pushing a Big Lie. The claim is that a lack of manufacturing capacity, not pharmaceutical corporation’s monopoly intellectual property (IP) protections, are thwarting greater production of COVID-19 vaccines. A related argument, with decidedly racist overtones, is that COVID-19 vaccines are too complicated for producers in developing countries to make successfully. The reality is that in every region of the world, there are multiple producers that could be greatly increasing global vaccine supplies if the technology and know-how were shared.¶ Just in Africa, “Biovac and Aspen in South Africa, Institute Pasteur in Senegal, and Vacsera in Egypt could rapidly retool factories to make mRNA vaccines,” notes a group of medicine-production experts in a recent Foreign Policy article. Indeed, a former Moderna director of chemistry revealed that with enough technology transfer and know- how-sharing, a modern factory should be able to get mRNA vaccine production online in, at most, three to four months. The Serum Institute in India already is slated to produce the AstraZeneca and Novavax vaccines, while Moderna declined to partner with a qualified Bangladeshi vaccine maker, claiming its engineers were too busy to focus beyond U.S. and EU production. In Latin America, existing facilities in Brazil, Argentina and Mexico under contract to monopoly holders are already pumping out vials, and in countries like Chile and Colombia, the pharmaceutical industry has expressed willingness to kickstart vaccine production.¶ Existing and planned contract manufacturing arrangements prove facilities in developing countries certainly can produce COVID-19 vaccines. But unless technology and know-how are shared more openly, the monopoly holders maintain absolute control over how much can be produced, what the price is and where it will be sold. So, 91% of the Johnson & Johnson vaccine that South African firm Aspen will manufacture must be shipped for sale outside South Africa, according to South Africa’s WTO Counselor. And the Serum Institute is barred from supplying upper- middle-income and high-income countries with the AstraZeneca vaccines it makes, meaning AstraZeneca can artificially segment the global market and ensure that it is the only supplier of the Oxford vaccine in the most profitable national markets, according to Doctors Without Borders.¶ Most critically, there simply is not enough supply to go around now or for every year in the future during which the whole world will need regular COVID vaccination to keep the virus under control. Thankfully, scores of countries are ready to invest in building new or repurposing existing production capacity. That is why more than 100 countries support a waiver of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). These countries seek certainty that if they adjust their domestic laws and practices to support that investment by providing access to the necessary technology, they will not get dragged into expansive WTO litigation or face retaliatory sanctions from countries claiming WTO violations. The waiver will also serve as a worldwide buffer against the political pressure and legal harassment to which Big Pharma subjects countries that seek to promote affordable access to medicines.¶ In many countries, the regulatory authorities that had to approve domestic use of various vaccines and other COVID-related medical products have significant information from the firms that they could share with skilled teams from local universities, government agencies and pharmaceutical manufacturers — if they were not obliged by WTO rules to guarantee monopoly control of it. And world-class pharmaceutical firms already are making generic versions of new cutting-edge HIV-AIDS medicines and pumping out vaccines based on the platform that, for instance, the Johnson & Johnson vaccine uses.

#### Aff cant increase infosharing so no solvency. Reducing ip means brand name pharma cant sue generics for copying them, but it doesn’t mean that brand name pharma has to just give away their secret sauce

#### Removing IP is inferior to the squo – the aff removes incentives to cooperate and share know how

Rachel Silverman, 3-15-20**21**, "Perspective," Washington Post, https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/ Rachel Silverman is a policy fellow at the Center for Global Development There are better options than broadly waiving IP rules — notably, encouraging (and pressuring) vaccine manufacturers to cooperate and share knowledge with partners across the globe. Voluntary licensing is one route: It’s a common arrangement in which developers enter into binding contractual agreements with generic producers. Generic manufacturers get permission, know-how and assistance from the patent-holder to produce the vaccine for sales in specified markets; in exchange, the patent-holder can ensure quality of the generic product and may receive royalties on its sales, usually representing less than 10 percent of sales value. These royalties may be lower than the profit margin on direct sales; for example, Pfizer expects a 25 to 30 percent profit on its vaccine sales, or roughly $5 for every $19.50 dose. (The U.S. government has agreed to buy 300 million doses at that price.) But voluntary licensing deals offer a new revenue stream that would otherwise be captured by competitors — not to mention good publicity. Already, voluntary licensing deals from AstraZeneca and Novavax are facilitating large-scale production in India, Japan and South Korea; many of the resulting vaccines are destined for lower-income countries through Covax. The best route to vaccine equity involves creating the conditions to facilitate more of these voluntary deals. How can governments and activists help push things in the right direction? By lifting the export curbs on materials such as filters and bioreactor bags intended to protect domestic supply, countries can help lubricate supply chains, creating a better environment for cross-national collaboration. Governments and development-finance institutions can invest to build up the capabilities of potential vaccine manufacturing plants, making it easier for originators to say yes. Domestically, the Biden administration did something like this when it invested $269 million under the Defense Production Act to prepare Merck’s manufacturing facilities to produce the Johnson & Johnson vaccine — a crucial plank of the joint production deal announced this month. Similar efforts are underway abroad. On March 12, for example, the “Quad” — the United States, India, Japan and Australia — announced a joint pledge to produce and disseminate 1 billion vaccine doses; as part of this effort, the Biden administration announced that it would help finance an Indian generic manufacturer to make coronavirus vaccines, including the Johnson & Johnson product. The contractual language of licensing deals can explicitly protect IP from broader dissemination, helping originators feel more comfortable sharing commercially valuable information. In praise of vaccine selfies Sticks as well as carrots can facilitate partnerships. Under existing World Trade Organization rules, countries already have the right to issue “compulsory licenses” in certain cases pertaining to public health, allowing them to produce or import generic health products without permission from the patent-holder. Advocates correctly point out that countries face potential retaliation from industry and wealthy governments when they try to use these tools — a strong disincentive. (In 2006-2007, Thailand’s use of compulsory licenses to access more affordable AIDS drugs led the United States to revoke preferential trade status for some Thai exports.) This should change. The Biden administration and other global leaders should make clear that they will support legitimate compulsory licensees of coronavirus vaccines in cases where a valid voluntary license request has been rejected or ignored. But compulsory licensing is vastly inferior to voluntary deals in the case of vaccines, because with the former the generic producer would still need to figure out how to make the vaccines without the originator’s assistance — again, an extraordinarily difficult task. It is useful mainly as a threat held in reserve, paired with the “carrots” of subsidies to local plants and so on. Firms may choose to play ball on voluntary licensing deals rather than face a mess of legal challenges and bad publicity. This month, for example, Canadian biotech firm Biolyse Pharma publicly requested a voluntary license to manufacture the Johnson & Johnson vaccine for global distribution. If Johnson & Johnson is unwilling, Biolyse made clear in its announcement, the company will appeal to the Canadian government for a compulsory license. The ball is now in Johnson & Johnson’s court — but this seems like the type of offer it should choose to accept, both for the global good and its self-interest. Scaling up vaccine production is an imperative for equitable global access and an end to the pandemic. But it is smart incentives for sharing knowledge, not the wholesale elimination of intellectual-property rights, that will get us to the finish line.