## 1

## Framing:

#### The Standard is maximizing expected net well-being

#### 1. Weighability – only consequentialism can explain the ethical difference in breaking a promise to take someone to the hospital and breaking a promise to take someone to lunch – that outweighs –

#### A] Resolvability – there’s no way to weigh between competing offense under their fw which means their fw can’t guide action

#### B] Intuitions – they’re a necessary side constraint on all ethics – if a very well justified, logical theory concluded "rape good” you wouldn’t say “huh I guess rape is good” you would abandon it

#### 2. Uncertainty and social contract require governments use util - calc indicts are empirically disproven because governments use util

Gooden, 1995 **(**Robert, philsopher at the Research School of the Social Sciences, Utilitarianism as Public Philosophy. P. 62-63)

Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices—public and private alike—are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have on them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices. But that is all. That is enough to allow public policy-makers to use the utilitarian calculus—if they want to use it at all—to choose general rules of conduct. Knowing aggregates and averages, they can proceed to calculate the utility payoffs from adopting each alternative possible general rules.

#### Prefer actor specific obligations – different actors have different obligations.

# Compulsory License Threat CP

#### CP Text: Member nations of the WTO should inform patent holders that unless they reach voluntary licensing agreements with countries in need the WTO will pursue compulsory licensing.

### 1NC

#### The CP is mutually exclusive- licensing requires IP protections. The CP doesn’t reduce IP, it *solidifies* it

Raju, PhD, 17

(K D , Rajiv Gandhi School of Intellectual Property Law, Indian Institute of Technology Kharagpur, West Bengal-721 302, India Received 27 March 2016; accepted 11 November 2016 Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries Journal of Intellectual Property Rights Vol 22, January 2017, pp 23-31)

It has been observed that the pharmaceutical patents under the TRIPS Agreement have increased the drug prices exorbitantly, especially in developing countries. This made the patent regime itself most unpopular especially in developing countries. Right to health is the heart of the idea of CL provisions. Voluntary licenses and patent pools are promising and a new approach to delivering affordable medicines to developing and least developed countries under the TRIPS regimes of intellectual property protection. These concepts may be converted into practical realities in treating poor patients throughout the world rather than only protecting the intellectual property rights and the interest of multinational pharmaceutical companies. There must be a balancing act between the social welfare and the protection of innovation and intellectual property rights. The system of voluntary license in any form will make the medicines more affordable and faster delivery in developing country markets. The WTO members should promote voluntary agreement system at international level like MPP and through their domestic legal system with more incentives for VL. It is not an easy task for the developing countries on the background that CL is always issued when VL is denied.

#### The Counterplans threat of compulsory licensing causes companies to approve voluntary licenses. This is goldilocks- its solves the advantage while avoiding any DA

Raju, PhD, 17

(K D , Rajiv Gandhi School of Intellectual Property Law, Indian Institute of Technology Kharagpur, West Bengal-721 302, India Received 27 March 2016; accepted 11 November 2016 Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries Journal of Intellectual Property Rights Vol 22, January 2017, pp 23-31)

The philosophy of granting patent is to provide incentive to innovation and monopoly for a limited period of time.1 The patenting supporter argues that the patent system is indispensable as it encourages research and creativity, and enhances a country’s technological and economic development.2 However, patent rights should not be a license to exploit and misused by the benefit of the multinational companies that are detrimental to the interest of public health protection. The social good and public rights cannot be overridden by private rights under the intellectual property protection umbrella of the TRIPS agreement. The human right to health guarantees a system of health protection for all under many international law conventions.3 “Compulsory licensing (CL)” is a nonvoluntary licensing from the Government without the consent of the patentee in order to protect public interest which acts as a cushion to balance the interest between patentee’s rights and rights of public at large. Thus the “CL therefore serves to strike balance between two disparate objectives- rewarding patentees for their invention and making the patented products, particularly pharmaceutical products, available to large population in developing and under developed countries at a cheaper and affordable price”.4 The CL may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.5 However, the pharmaceutical industry all over the world has opposed to CL and they argue that it will kill innovation and discourage R&D.6 India issued its first compulsory licensing order in favour of a domestic pharma company NATCO against the pharmaceutical giant Bayer, which has generated a lot of attention all over the world and compulsory licensing, has been viewed as a remedy to curb abuse of exclusivity protected by IPRs. One of the conditions for granting CL is that, before filing of an application, the applicant must take efforts to get a voluntary license from the patent owner in mutual terms and such effort must have been failed. The first CL grant itself is met with stiff opposition from the multinational pharma companies and end up in a series of litigations and apex court later upheld the validity of the CL. These litigations take lot of time, cost and tension between the patent owner and the prospective licensees. On the other hand, voluntary licensing between the patent holder and another manufacturer in developing countries may reduce the cost as well as offer opportunities to the patent owner as well as the licensee. The kind of opportunity depends upon the terms of license and the capacity of the licensee to build a relationship in a longer term within the purview of the intellectual property regimes. This paper argues that a threat of issuing CL encourages the parties to negotiate a voluntary licensing and agreements which enable reduction of opportunity cost and availability of patented drugs in developing countries. But it is not my intention to argue that voluntary licensing can be replaced by CL in all circumstances. It analyses the CL provisions in the TRIPS agreement followed by CL provisions in the Indian patent law and first CL case in India in order to expose the arguments of multinational companies and will examine how India was successful in granting the CL. Third part of the paper will examine the voluntary licensing system and agreements which can demonstrate how it can provide an alternate mechanism for a harmonious relationship between the patent owner and the domestic industries and thus a viable and TRIPS legitimate mechanism to enhance access to medicines in developing countries.

**1NC -- Disease**

**Biotech strong now -- boosted by COVID and it's an inherently stable sector**

**Cancherini et al. 4-30** [Laura Cancherini, Engagement Manager @ McKinsey & Company. Joseph Lydon, Associate Partner @ McKinsey & Company. Jorge Santos da Silva, Senior Partner @ McKinsey & Company. Alexandra Zemp, Partner @ McKinsey & Company. "What’s ahead for biotech: Another wave or low tide?," McKinsey &amp; Company, 4-30-2021, accessed 8-25-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] HWIC

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6 Exhibit 3 We strive to provide individuals with disabilities equal access to our website. If you would like information about this content we will be happy to work with you. Please email us at: McKinsey\_Website\_Accessibility@mckinsey.com What about SPACs? The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story. Fundamentals continue strong When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances. In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development. Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries. Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising. For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic. More innovation on the horizon The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science. Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

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The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences 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 context.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 competition 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 pharmaceutical 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 sector. 2 It is therefore unsurprising that we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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 combination product that is being tested for therapeutic potential 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious 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 contributions 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 innovation conditions.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

## 1nc: Biotech DA

**The US is winning the biotech race, but strong domestic support and unilateral vaccine leadership are key**

**Moore 2-17** [Scott Moore, political scientist and administrator at the University of Pennsylvania and the author of a forthcoming book, “How China Shapes the Future,” on China’s role in public goods and emerging technologies.. "In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China," Lawfare, 2-17-2021, accessed 8-25-2021, https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china] HWIC

It was supposed to be China’s moment of technological triumph—one that would show the world Beijing had not only conquered the coronavirus but also emerged as a biotechnology superpower. But when clinical data on China’s flagship CoronaVac vaccine finally flowed in, they showed it was barely more than 50 percent effective—just clearing the minimum standard set by the World Health Organization. In contrast, not one but two vaccines developed by U.S. firms have been found to be upward of 95 percent effective, a standard no other country’s vaccines have yet met in rigorous clinical trials. The United States’s overall track record in responding to the pandemic has been awful. Yet the success of its vaccine development efforts shows that when it comes to biotechnology, the industry of the future, the U.S. is way ahead of China and most of its other rivals. A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing. Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons. That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or products.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness. Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners. For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization. Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation. At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector. The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science. Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come. When it comes to biotechnology, the industry of the future, the U.S. remains well ahead of its rivals, including China. That’s something Americans can, and should, take pride in. But the U.S. must make proactive investments and undertake significant reforms now to ensure that things stay that way.

**A vaccine waiver gives China the edge in biotech and decks innovation in every sector**

**Duesterberg 6-3** [Thomas J., Duesterberg, senior fellow at the Hudson Institute. "Biden says he wants to out-compete China — so why attack US medical innovation?," TheHill, 6-3-2021, accessed 8-25-2021, https://thehill.com/opinion/healthcare/556043-biden-says-he-wants-to-out-compete-china-so-why-attack-us-medical] HWIC

Congress has been burning the midnight oil to pass legislation aimed at investing billions of dollars to out-compete China in critical sectors and champion American innovation. Yet at the very moment that value of the U.S. model of medical innovation is being most vindicated, that model has come under attack from our own government, as well as long-time critics in the developing world.

These critics are proposing to waive the intellectual property (IP) rights guaranteed by the World Trade Organization (WTO) for vaccines and treatments for COVID-19 — a move that would undermine the economic model of innovation that produced the historically unprecedented effectiveness, and speed to market, of vaccines developed by major U.S. and British firms.

The assault — spearheaded by South Africa and India — is not only unlikely to help get more vaccines to the developing world in a timely manner, but **has the potential to unravel decades of progress in building an internationally agreed regime for IP rights**, which incentivizes and rewards fundamental research and long-term capital investment. This could harm not only the medical products industry, but also spill over to other high-technology sectors that require long years of research and huge, risky capital investments before bearing fruit.

Proponents of the waiver argue that it would facilitate more rapid production and distribution of much-needed shots for hard hit regions in South Asia and Africa. However, it’s well-established that any increased production — even in India, which is home to the world’s largest manufacturer of vaccines — would require at least a year of preparation and investment to begin large-scale production of the newer vaccines.

What’s more, opponents to the waiver — led by European countries, home to the world’s second leading medicines industry — can delay the waiver approval for months at the WTO, if not bury the idea altogether. And with plans in place to ramp up production of approved vaccines in the U.S., Europe and India, there will be sufficient surplus production to start exporting to the global South later this summer.

Any forced transfer of the new vaccines technologies **almost certainly will benefit China**, with its growing manufacturing prowess and ambitions to spend whatever is required to offset the damage to its reputation resulting from its attempt to mask the severity of the SARS-CoV-2 virus in the early days of the pandemic.

A closer look at the South Africa-India waiver proposal, which is supported by some 100 other nations, gives insight into the longer-term and broader danger of the reversal of IP rights protections for advanced technologies. Their language tabled at the WTO in late May calls for waiving not only the fundamental patents behind COVID-19 vaccines but extending the waiver to products including “diagnostics, therapeutics, medical devices, personal protective equipment” and to the raw materials and “means of manufacture” of anything used to contain this virus. It is not a huge leap of logic to speculate that **such broad waivers, in the future, could be suggested for any severe threat to world health**, with the example of treatments for AIDS as a reminder.

The proposed waiver would extend for a period of “at least three years,” and could be lifted only by agreement in the General Council of the WTO, which requires unanimous consent of all 164 members and rarely has been achieved since its inception in 1995. It is hard to imagine that once the long-sought goal of removing IP rights protection for medical technologies — supported by developing countries and by progressive groups in developed countries alike — is achieved, it can be reversed easily.

Other high-technology industries characterized by the need for long-term investments in basic research and the development of new manufacturing technologies such as semiconductors, medical equipment or aerospace, or nascent industries such as quantum computing, robotics or 3D printing, would be wise to pay attention to the debate over waiving IP rights for COVID-19 vaccines.

While the acute and existential issues arising from a pandemic represent a perhaps unique set of circumstances, one can conceive of arguments to justify the social goal of sharing some newer technologies. For example, if innovations in “green hydrogen,” more powerful batteries, or more efficient photovoltaic cells are achieved and promise early returns to combat climate change, the advantages of sharing the technologies for the global common good could be adduced to justify waivers in the appropriate enabling technologies. Or, would a waiver be considered for the advanced semiconductors and computers required for artificial intelligence and needed to find cures for cancer and to perfect climate mitigation strategies?

U.S. support for the vaccine IP rights waiver is especially baffling because it **affects one of its most successful industries in terms of global technology leadership and market share**, responsible for so many advances of enormous benefit for global health. It is not a mystery why the rapid discovery and ramping up of production for new vaccines came from the unique U.S. innovation ecosystem, in contrast to the more highly regulated and centrally controlled health care sectors in much of the rest of the world.

Graham: Biden 'has signed the death warrant for thousands of Afghans...

The Hill's Morning Report - Presented by Facebook - Biden sticks to...

There are better ways to achieve the goal of eradicating COVID-19, and U.S. actions would be more effective if directed toward expanding production and assisting in the distribution of vaccines. This includes the use of foreign aid and help with purchasing agreements for countries in the global South, as well as facilitating licensing agreements. (For example, Johnson & Johnson is arranging a major project with Indian manufacturers, which has the support of the other Quad countries, Japan, Australia and the U.S.)

If Congress truly cares about protecting American innovation, it ought to assert its constitutional authority over international trade to block this danger to domestic high-technology industries.

**China is a revisionist power and rise triggers war with the U.S. – history, rhetoric, and values**

**Choi, PhD, 18**

(Ji Young, IR@Purdue, DirectorEastAsianStudies+AssocProfInternationalStudies@OhioWesleyan, Historical and Theoretical Perspectives on the Rise of China: Long Cycles, Power Transitions, and China’s Ascent, Asian Perspective, 42(1), 61–84)

I have explored in light of historical and theoretical perspectives whether China is a candidate to become a global hegemonic power. The next question I will address is whether the ascent of China will lead to a hegemonic war or not. As mentioned previously, **historical and theoretical lessons** reveal that a rising great power tends to challenge a system leader when the former’s economic and other major capabilities come too close to those of the latter and the former is dissatisfied with the latter’s leadership and the international rules it created. This means that **the rise of China could produce intense hegemonic competition** and even a **global hegemonic war**. The **preventive motivation** by an old declining power can cause a major war with a newly emerging power when it is combined with other variables (Levy 1987). While a preventive war by a system leader is historically rare, a newly emerging yet even relatively weak rising power at times challenges a much more powerful system leader, as in the case of Japan’s attack on Pearl Harbor in 1941 (Schweller 1999). A **historical lesson** is that “incomplete catch-ups are **inherently conflict-prone**” (Thompson 2006, 19). This implies that **even though it falls short of surpassing the system leader**, the rise of a new great power can produce **significant instability** in the interstate system when it develops into a revisionist power. Moreover, the United States and China are deeply involved in major security issues in East Asia (including the North Korean nuclear crisis, the Taiwan issue, and the South China Sea disputes), and we cannot rule out the possibility that one of these **regional conflicts will develop into a much bigger global war** in which the two superpowers are entangled. According to Allison (2017), who studied **sixteen historical cases** in which a rising power confronted an existing power, a war between the United States and China is not unavoidable, but escaping it will require enormous efforts by both sides. Some Chinese scholars (Jia 2009; Wang and Zhu 2015), who emphasize the transformation of China’s domestic politics and the pragmatism of Beijing’s diplomacy, have a more or less optimistic view of the future of US-China relations. Yet my reading of the situation is that since 2009 there has been an increasing gap between this optimistic view and what has really happened. It is premature to conclude that China is a revisionist state, but in what follows I will suggest some important signs that show China has revisionist aims at least in the Asia Pacific and could develop into a **revisionist power** in the future. Beijing has concentrated on economic modernization since the start of pro-market reforms in the late 1970s and made efforts to keep a low profile in international security issues for several decades. It followed Deng Xiaoping’s doctrine: “hide one’s capabilities, bide one’s time, and seek the right opportunity.” Since 2003, China’s motto has been “Peaceful Rise” or “Peaceful Development,” and Chinese leadership has emphasized that the rise of China would not threaten any other countries. Recently, however, Beijing has adopted increasingly assertive or even aggressive foreign policies in international security affairs. In particular, China has been adamant about territorial issues in the East and South China Seas and is increasingly considered as a **severe threat** by other nations in the Asia Pacific region. Since 2009, for example, Beijing has increased naval activities on a large scale in the area of the Diaoyu/Senkaku Islands in the East China Sea. In 2010, Beijing announced that just like Tibet and Taiwan, the South China Sea is considered a core national interest. We can identify drastic rhetorical changes as well. In 2010, China’s foreign minister publicly stated, “China is a big country . . . and other countries are small countries and that is just a fact” (Economist 2012). In October 2013, Chinese leader Xi Jinping also used the words “struggle and achieve results,” emphasizing the importance of China’s territorial integrity (Waldron 2014, 166-167). Furthermore, China has constructed man-made islands in the South China Sea to seek “de facto control over the resource rich waters and islets” claimed as well by its neighboring countries (Los Angeles Times 2015). As of now, China’s strategy is to delay a direct military conflict with the United States as long as possible and use its economic and political prowess to pressure smaller neighbors to give up their territorial claims (Doran 2012). These **new developments** and rhetorical signals reflect significant changes in China’s foreign policies and signify that **China’s peaceful rise seems to be over**. A rising great power’s consistent and determined policies to increase military buildups can be read as one of the **significant signs** of the rising power’s dissatisfaction with the existing order and its **willingness to do battle** if it is really necessary. In the words of Rapkin and Thompson (2003, 318), “arms buildups and arms races . . . reflect substantial dissatisfaction on the part of the challenger and an attempt to accelerate the pace of military catchup and the development of a relative power advantage.” Werner and Kugler (1996) also posit that if an emerging challenger’s military expenditures are increasing faster than those of a system leader, parity can be **very dangerous** to the international political order. China’s GDP is currently around 60 percent of that of the United States, so parity has not been reached yet. China’s military budget, however, has grown enormously for the past two decades (double-digit growth nearly every year), which is creating concerns among neighboring nations and a system leader, the United States. In addition to its air force, China’s strengthening navy or sea power has been one of the main goals in its military modernization program. Beijing has invested large financial resources in constructing new naval vessels, submarines, and aircraft carriers {Economist 2012). Furthermore, in its new defense white paper in 2015, Beijing made clear a vision to expand the global role for its military, particularly its naval force, to protect its overseas economic and strategic interests (Tiezzi 2015). Sea power has special importance for an emerging great power. As Mahan (1987 [1890]) explained cogently in one of his classic books on naval strategy, Great Britain was able to emerge as a new hegemonic power because of the superiority of its naval capacity and technology and its effective control of main international sealanes. Naval power has a special significance for China, a newly emerging power, as well as for both economic and strategic reasons. First, its economy’s rapid growth requires external expansion to ensure raw materials and the foreign markets to sell its products. Therefore, naval power becomes crucial in protecting its overseas business interests and activities. Second, securing major sea-lanes becomes increasingly important as they will be crucial lifelines for the supply of energy, raw materials, and other essential goods should China become involved in a hegemonic war or any other major military conflict (Friedberg 2011). In light of this, it is understandable why China is so stubborn over territorial issues in the South China and East China Seas. In fact, history tells us that many rising powers invested in sea power to expand their global influence, and indeed all the global hegemons including Great Britain and the United States were predominant naval powers. Another important aspect is that Beijing is beginning to voice its dissatisfaction with the existing international economic order and take actions that could potentially **change this order**. The Chinese economy has overall benefited from the post-World War II international liberal order, but the Bretton Woods institutions like the IMF and the World Bank have been dominated by the United States and its allies and China does not have much power or voice in these institutions. Both institutions are based in Washington, DC, and the United States has enjoyed the largest voting shares with its veto power. Along with other emerging economies, China has called for significant reforms, especially in the governing system of the IMF, but reform plans to give more power to China and other emerging economies have been delayed by the opposition of the US Congress (Choi 2013). In response to this, Beijing recently took the initiative to create new international financial institutions including the AIIB. At this moment, it is premature to say that these new institutions would be able to replace the Bretton Woods institutions. Nonetheless, this new development can be read as a **starting point for significant changes** in global economic and financial governance that has been dominated by the United States since the end of World War II (Subacchi 2015). China’s **historical legacies** reinforce the view that China has a willingness to become a global hegemon. From the Ming dynasty in the late fourteenth century to the start of the first Opium War in 1839, China enjoyed its undisputed hegemonic position in East Asia. “Sino-centrism” that is related to this historical reality has long governed the mentality of Chinese people. According to this hierarchical world view, China, as the most advanced civilization, is at the center of East Asia and the world, and all China’s neighbors are vassal states (Kang 2010). This mentality was openly revealed by the Chinese foreign minister’s recent public statement that I quoted previously: “China is a big country . . . and other countries are small countries and that is just a fact” (Economist 2012). This view is related to Chinese people’s ancient superiority complex that developed from the long history and rich cultural heritage of Chinese civilization (Jacques 2012). In a sense, China has always been a superpower regardless of its economic standing at least in most Chinese people’s mind-set. The strong national or civilizational pride of Chinese people, however, was severely damaged by “the Century of Humiliation,” a period between the first Opium War (1839) and the end of the Chinese Civil War (1949). During this period, China was encroached on by the West and invaded by Japan, experienced prolonged civil conflicts, and finally became a semicolony of Great Britain while its northern territory was occupied by Japan. China’s economic modernization is viewed as a national project to lay an economic foundation to overcome this bitter experience of subjugation and shame and **recover its traditional position and old glory** (Choi 2015). Viewed from this perspective, economic modernization or the accumulation of wealth is not an ultimate objective of China. Rather, **its final goal is to return to its traditional status** by expanding its global political and military as well as economic influence. What it ultimately desires is recognition (Anerkennung), respect (Respekt), and status (Stellung). These are important concepts for constructivists who see ideational motives as the main driving forces behind interstate conflicts (Lebow 2008). This reveals that constructivist elements can be combined with long cycle and power transition theories in explaining the rise and fall of great powers, although further systematic studies on it are needed. Considering all this, China has always been a territorial power rather than a trading state. China does not seem to be satisfied only with the global expansion of international trade and the conquest of foreign markets. It also wants to broaden its (particularly maritime) territories and spheres of influence to recover its traditional political status as the Middle Kingdom. As emphasized previously, the type or nature and goals or ideologies of a rising power matter. Nazi Germany and Imperial Japan (territorial powers) experienced rapid economic expansion and sought to expand their territories and influence in the first half of the twentieth century. For example, during this period Japan’s goal was to create the Japanese empire in East Asia under the motto of the East Asian Co-prosperity Sphere. On the other hand, democratized Germany and Japan (trading powers) that enjoyed a second economic expansion did not pursue the expansion of their territories and spheres of influence in the post-World War II era. Twentieth century history suggests that political regimes predicated upon nondemocratic or nonliberal values and cultures (for instance, Nazism in Germany and militarism in Japan before the mid-twentieth century, and communism in the Soviet Union during the Cold War) can pose **significant challenges** to democratic and liberal regimes. The empirical studies of Lemke and Reed (1996) show that the democratic peace thesis can be used as a subset of power transition theory. According to their studies, states organized similarly to the dominant powers politically and economically (liberal democracy) are generally satisfied with the existing international rules and order and they tend to be status quo states. Another historical lesson is that **economic interdependence alone cannot prevent a war for hegemony**. Germany was one of the main trade partners of Great Britain before World War I (Friedberg 2011), and Japan was the number three importer of American products before its attack on Pearl Harbor (Keylor 2011), A relatively peaceful relationship or transition is possible when economic interdependence is supported by a solid democratic alliance between a rising great power and an existing or declining one. Some scholars such as Ikenberry (2008) emphasize nuclear deterrence and the high costs of a nuclear war. Power transition theorists agree that the high costs of a nuclear war can constrain a war among great powers but do not view them as “a perfect deterrent” to war (Kugler and Zagare 1990; Tammen et al. 2000). The idea of nuclear deterrence is based upon the assumption of the rationality of actors (states): as long as the costs of a (nuclear) war are higher than its benefits, an actor (state) will not initiate the war. However, even some rationalists admit that certain actors (such as exceedingly ambitious risk-taking states) do not behave rationally and engage in unexpected military actions or pursue military overexpansion beyond its capacity (Glaser 2010). The state’s behaviors are driven by its values, perceptions, and political ambitions as well as its rational calculations of costs and benefits. Especially, national pride, historical memories, and territorial disputes can make states behave emotionally. The possibility of a war between a democratic nation and a nondemocratic regime increases because they do not share the same values and beliefs and, therefore, the level of mistrust between them tends to be very high. China and the United States have enhanced their cooperation to address various global issues like global warming, international terrorism, energy issues, and global economic stability. But these **issues are not strong enough to bring them together** to overcome their mistrust that stems from their **different values**, beliefs, and perceptions (Friedberg 2011). What is more important is whether they can set mutually agreeable international rules on traditional security issues including territorial disputes.

## Case

1. **No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez 5/10** [Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.

### Too Slow

#### Reducing IP rights aren’t quick enough to help the pandemic – legal battles slow the process – experts agree

Smith 05/05

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

But even as public pressure grows, some experts argue that handing over the IP rights for Covid-19 vaccines won't necessarily mean that more can be rapidly produced worldwide at large scale. US infectious diseases chief Anthony Fauci [told the UK's Financial Times](https://www.ft.com/content/2f41b122-5738-4707-a822-0d79276710c5) on Monday that he was not convinced that forcing companies to share their intellectual property was the most effective approach, warning that legal battles could slow the process. "Going back and forth, consuming time and lawyers in a legal argument about waivers -- that is not the endgame. People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible," he said.

## Squo Solves

#### Squo solves--cost and bureaucracy are barriers to patent protection and other countries violate IP laws without punishment now.

Chao and Mody 15 (Tiffany Chao [Editor in Chief of Journal of Medical Insight, adjunct professor at Stanford Med School] and Gita Mody [MPH Harvard, assistant professor at UNC Chapel Hill Med School], The impact of intellectual property regulation on global medical technology innovation, BMJ Innovations, 3/5/2015, https://innovations.bmj.com/content/1/2/49) hwof

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.[i](https://innovations.bmj.com/content/1/2/49#fn-4) High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.[4](https://innovations.bmj.com/content/1/2/49#ref-4) This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.[5](https://innovations.bmj.com/content/1/2/49#ref-5) As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.

\*\* Mercurio is COVID specific but warrants apply generally too

#### The TRIPS agreement and cheap vaccines in the squo solve the aff--independently, lack of manufacturing power and licensing transparency deck solvency.

Mercurio 21 (Bryan Mercurio [Simon F.S. Li Professor of Law at The Chinese University of Hong Kong], WTO WAIVER FROM INTELLECTUAL PROPERTY PROTECTION FOR COVID19 VACCINES AND TREATMENTS: A CRITICAL REVIEW, Virginia Journal of International Law, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820>, 2/12/2021) hwof

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26 Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level. Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31 While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs. Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices. 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.