## BioTech

#### **U.S dominance over biotech now BUT Misguided policy cedes control to China.**

Gupta 6/11 [“As Washington Ties Pharma's Hands, China Is Leaping Ahead.”, Gaurav Gupta, *Opinion | America Risks Ceding Its Biotech Dominance to China | Barron's*, Barrons, 11 June 2021, www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808., *Gaurav Gupta, a physician, is the founder of the biotechnology investment firm Ascendant BioCapital.]//Lex AKu*

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, 47% of all new medicines were invented by U.S. biopharma companies, with homegrown startups driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market. An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy. From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. China saw over $28 billion invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast. In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies. The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

#### The plan chills American biomed innovation and cedes control to China.

Paulsen 7/9 [ERIK PAULSEN: We can save the world with our vaccines — without surrendering our IP to China," Bakersfield Californian, https://www.bakersfield.com/opinion/erik-paulsen-we-can-save-the-world-with-our-vaccines-without-surrendering-our-ip-to/article\_b0b87692-df61-11eb-9a13-d7fa02eefaee.html]//Lex AKu

The Biden administration gave Beijing a gift when it endorsed a petition before the World Trade Organization to force the American developers of Covid-19 vaccines and therapeutics to relinquish their intellectual property rights to these medicines. The Chinese government seeks to take over in biotech, a sector where U.S. innovators lead. Biotech is included in its “Made in China 2025” plan, which lists 10 sectors that China aims to dominate. The government intends to force anyone doing business in China in those spheres to hand over know-how. Surrendering IP protections on biomedical technology has dire consequences. Foremost, it guts the foundation of biomedical innovation, which takes huge investments spanning many years to bear fruit. IP protections assure innovators that they can recover those investments and make a profit. Losing IP protection would have a chilling effect on investments in the sector. Equally injurious to America, the IP waiver would allow China to become a biotech powerhouse by piggybacking on American innovation. A waiver on IP for Covid-19 vaccines would accelerate the timeline for “Made in China 2025.” The mRNA technology, which undergirds the Pfizer-BioNTech and Moderna vaccines has uses beyond this pandemic. It has the potential to take on cancers and other diseases. With the waiver, China and others will be emboldened to use the once-proprietary mRNA know-how for broader research and applications. Is this in America’s interest? Mark Cohen, an expert on Chinese IP theft, recently told the Washington Post that the waiver would deliver “a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense.” Beyond the damage that an mRNA giveaway will inflict on US R&D investments, the waiver sends a signal that America could agree to force American innovators to part with trade secrets every time there’s a global crisis. That attitude will arrest biopharmaceutical innovation. Small biotech firms spearhead 70 percent of the R&D pipeline, relying heavily on private investors to fund that work. If investors know that innovators may have to give away their discoveries in a global crisis, they’ll deploy their money elsewhere. That’ll make it even harder to draw the R&D investments needed to address infectious diseases, including drug-resistant infections and viruses. America is benefitting greatly from the early access to COVID-19 treatments and vaccines, saving lives and speeding economic recovery. Preserving U.S. leadership in biomedical innovation includes preserving the incentives that helped make it the world’s leader. A final downside of the waiver is the ability for American firms to find a cure for the next pandemic. Among the greatest threats is bacteria resistant to our current arsenal of antibiotics that becomes a pandemic-inducing superbug. Already, the market for new antimicrobials is broken. Only a handful of biotechs have them in development, and many have gone bankrupt trying to commercialize one. “A lot of people have rightly said we need to start thinking about preparing for the next pandemic now,” noted Craig Garthwaite, a healthcare-business professor at Northwestern University. “Suspending IP for vaccine manufacturers would send exactly the wrong signal for the future.” For the sake of patients everywhere, American IP rights must stay protected. It’s the only way to keep China at bay and American innovators at work.

#### Biotech leadership key to future military primacy.

Moore 21 [(Scott Moore is a 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.) 8-8-2021, "In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China," Lawfare, https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china]//Lex AKu

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.

#### C/A their heg good card

## I Law

#### Intellectual property rights cannot be discriminated on the basis of field, or place of invention

WTO <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm>, Article 27.1, Section 5 on patents, World trade Organization, WTO, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [(5)](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fnt-5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

#### The WTO’s appellate body no longer exists to mediate disputes, without immediate buy in by states, and no mechanism to make disobedient states obey, the system collapses

Horton, 08/3, Lessons from Trump’s assault on the World Trade Organization, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization, Chatham House – International Affairs Think Tank, Communications Manager; Project Lead, Common Futures Conversations

The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly risk becoming irrelevant. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the entire system of global trade rules risk collapsing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur.

#### A major country operating outside WTO consensus wrecks global trade norms

Bacchus 20 [James Bacchus, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, [https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines]/Kankee](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines%5d/Kankee)

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health. Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two‐​decades‐​old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19. Background In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic. In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2 Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021. Balancing IP Rights and Access to Medicines Not New to WTO This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease. Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8

#### WTO cred solves nuclear war – allows an off-track for nuclear weapons.

Hamann 09 [(Georgia Hamann is a J.D. Candidate, Vanderbilt University Law School, “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System,” 2009.] TDI

**Voluntary compliance with WTO rules** and procedures is of the utmost importance **to the international trading system**.'0 0 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO **as a cohesive force and arbiter of disputes that likely will become more frequent and injurious**. **01' The work of the WTO cannot be overstated in a nuclear-armed world,** as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance. 10 2 Demagogues in the Unites States may decry the rise of China as a geopolitical threat, 0 3 and extremists in Russia may play dangerous games of brinksmanship with other great powers, **but trade keeps politicians' fingers off "the button**. ' 10 4 **The WTO offers an astounding rate of compliance** for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO. 105 **In order to promote voluntary compliance, the WTO must maintain a high level of credibility**. 106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions. 10 7 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization's credibility. 108

## 1NC – Production CP

#### The United States federal government should:

**- substantially increase production and global distribution of the COVID-19 Vaccine,**

**- cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.**

**That comparatively solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.**

Hans **Sauer 6-17** [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

## Innovation

#### IP protection is critical to innovation – it incentivizes risk-taking by boosting investments

Ezell and Cory 19 [(Stephen, vice president, global innovation policy, at the Information Technology and Innovation Foundation, B.S. from the School of Foreign Service at Georgetown University, and Nigel, associate director covering trade policy at the Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies, MA in public policy from Georgetown University) “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, 4/25/2019] TDI

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.

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

#### Medical innovations key to future

Remes et al 20 (<https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-innovations-that-can-improve-global-health>, [McKinsey Global Institute](https://www.mckinsey.com/mgi/overview) Ten innovations that can improve global health July 15, 2020 | Article, [Jaana Remes](https://www.mckinsey.com/our-people/jaana-remes) is a partner of the McKinsey Global Institute, where [Jonathan Woetzel](https://www.mckinsey.com/our-people/jonathan-woetzel) is a director and [Sven Smit](https://www.mckinsey.com/our-people/sven-smit) is co-chair and a director. [Katherine Linzer](https://www.mckinsey.com/our-people/katherine-linzer) is a partner in McKinsey’s Chicago office. [Shubham Singhal](https://www.mckinsey.com/our-people/shubham-singhal) is a senior partner in the Detroit office. [Martin Dewhurst](https://www.mckinsey.com/our-people/martin-dewhurst) and [Penelope Dash](https://www.mckinsey.com/our-people/penny-dash) are senior partners in the London office, where [Kristin-Anne Rutter](https://www.mckinsey.com/our-people/kristin-anne-rutter) is a partner. [Matthias Evers](https://www.mckinsey.com/our-people/matthias-evers) is a senior partner in the Hamburg office. Matt Wilson is a senior partner in the New York office. Aditi Ramdorai is a consultant in the Berlin office.//lex AL)

By 2040, new technologies could reduce the total burden of disease by 6 to 10 percent. Today’s interventions are the innovations of the past. Without them, healthy lifespans would not be as long as they are. Innovation continues to be critical to tackle diseases without known cures and to help increase uptake and adherence to interventions that work. As part of the report [Prioritizing health: A prescription for prosperity](https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/prioritizing-health-a-prescription-for-prosperity), the McKinsey Global Institute identified ten promising innovations, now in progress, that could have a material impact on health by 2040. Focusing on technologies that address the greatest unmet needs, we determined the impact of these innovations by interviewing experts and evaluating the current biological understanding of each disease, as well as the effort and excitement surrounding the new techniques as measured by funding. Identifying and sizing the potential scope of innovations now in the pipeline is inherently difficult, but we estimate that these technologies could reduce the burden of disease by a further 6 to 10 percent, assuming aspirational yet realistic adoption rates by 2040—on top of the 40 percent from known interventions. Some of these innovations could not only fully cure a number of diseases but also significantly extend healthy lifespans by tackling the underlying biology of aging and therefore postponing the onset of several age-related conditions. These possibilities make a sharp contrast with the innovations of the past 30 years, many of which reduced the symptoms or delayed the progression of diseases but rarely prevented or cured them. In addition, the innovations we have identified here are more digitally enabled than those of the past; for example, [artificial intelligence](https://www.mckinsey.com/featured-insights/artificial-intelligence/applying-artificial-intelligence-for-social-good) (AI) systems make advances in omics and molecular technologies, such as gene editing, faster and more accurate. How can we improve health globally over the next two decades? Omics and molecular technologies These technologies—key components of the [Bio Revolution](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives)—are therapeutics or diagnostics that harness the various types of molecules within cells (such as DNA, RNA, and proteins). Some omics and molecular technologies (for instance, genome editing) engineer these intracellular components or analyze them (such as proteomics and transcriptomics). Example: CRISPR and curbing malaria The current treatment includes antimalarial prophylactics and nonpharmaceutical measures (such as indoor residual spraying and insecticide-treated bed netting) and antimalarial medications. Genetically modifying malaria-carrying mosquitos by using gene-editing technologies, such as [CRISPR](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/programming-life-an-interview-with-jennifer-doudna), may significantly reduce disease levels by propagating the modified genes across the mosquito population. Next-generation pharmaceuticals Newer iterations of traditional chemical compounds (small molecules) and classes of molecules could be used as medicinal drugs, possibly with multiple and concurrent target structures. Example: Senolytics and the regulation of cellular aging Cellular aging (senescence) is considered an unavoidable physiological process that is not a viable field for drug development. But senolytics (a class of small molecules) may decrease or eliminate aging cells that can cause cellular inflammation, dysfunction, and tissue damage. This has implications for delaying age-related diseases. Cellular therapy and regenerative medicine Cellular therapy is a biological product, derived from living cells, used for therapeutic purposes to replace or repair damaged cells or tissues. Regenerative medicine has the power to restore diseased or injured tissues and organs, potentially decreasing reliance on transplantation. Example: CAR T-cell therapy and the treatment of solid tumors Today, treatment is based primarily on unspecific radiotherapy and chemotherapeutic agents, plus surgical interventions. In many cases, these approaches are ineffective. [CAR T-cell therapy](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/driving-the-next-wave-of-innovation-in-car-t-cell-therapies) reprograms a patient’s T-cells (immune-system cells) to target tumor cells. When infused into the patient, the T-cells bind to an antigen on tumor cells, attacking and destroying them. Innovative vaccines Vaccines stimulate the immune system to respond to and destroy a bacterium or virus. Historically, they have eradicated or controlled the spread of infectious diseases around the world. In the future, vaccines may target noncommunicable diseases, such as cancer. Example: The AT04A vaccine and the lowering of cholesterol At present, patients take statins (lipid-lowering medicines) to control or lower high cholesterol levels in the blood. Patients with cardiovascular disease must take these daily, but adherence is often poor. AT04A is a vaccine made up of molecules that bind to blood cholesterol and degrade it. The vaccine would be required only once a year, potentially improving outcomes. Advanced surgical procedures These include treating injuries or disorders of the body with minimally invasive incisions or small instruments (including robotic surgery), as well as any technique that improves surgery-related processes outside the operating room. Example: Suspended animation for severe-trauma patients After patients suffer acute trauma (such as an accident) it may take time to get them to hospitals for surgery. That significantly decreases their chances of survival. Suspended animation for severe-trauma patients would involve, for example, injecting a cold saline solution into them on first contact to cool the body to 10–15ºC and stop its normal functions. This would give the surgeon time to operate before resuscitating the patient. Connected and cognitive devices Portable, wearable, ingestible, or implantable devices can monitor health and fitness information, engage patients and their communities of caregivers, and deliver self-regulated therapies autonomously. Example: E-tattoos for heart diagnostics Today’s technology relies on a Holter monitor (a battery-operated device) to monitor the heart continuously. The monitor’s batteries last for no more than 48 hours, and the procedure can cause immense discomfort for patients. Ultrathin e-tattoos can monitor hearts for longer periods and make patients more comfortable while providing a wider range of data to enhance clinical decision making. Electroceuticals Small therapeutic agents can target the neural circuits of organs. Such therapies map neural circuitry with neural impulses (administered by an implantable device) delivered to these specific targets. Example: Implantable microchips to mitigate chronic pain Today, managing chronic pain involves nonindividualized treatment with multiple drugs (including opioids) and relatively ineffective late-stage surgery. But one technique now under development—stimulating the spinal cord—can improve the patient’s quality of life by increasing mobility, enhancing sleep, and reducing the need for pain medication. Robotics and prosthetics A wide variety of programmable, self-controlled devices consisting of electronic, electrical, or mechanical units and of artificial substitutes or replacements for body parts are now under development. Example: Next-generation exoskeletons and mobility support Today’s mechanical mobility aids do not fully restore movement in the elderly, so they do not prevent a loss of independence and the risk of accidental injuries. Next-generation exoskeletons, powered by small motors that mimic human muscles, could allow older patients to recover their autonomy while reducing the likelihood of accidents and falls. Digital therapeutics These preventive and therapeutic evidence-based interventions, for a broad spectrum of physical, mental, and behavioral conditions, are controlled by software. Example: An AI-powered app to change behavior Apart from brief consultations, doctors now have few tools to help patients with chronic conditions adopt healthy lifestyles. In the future, digital therapeutics, powered by AI, patient data, and behavioral science, can use gamification and other forms of engagement to help patients adopt and sustain healthy behaviors. Tech-enabled care delivery These ways to deliver care incorporate new and larger data sets, use new analytics capabilities to generate insights, and help providers apply them to patients to improve the outcome, experience, and efficiency of care. Example: Multichannel care delivery Inefficient data management and poor communication among patients, payers, and providers hinder the continuity of care and therefore make treatment significantly less efficient. Innovative multichannel care delivery using online platforms may facilitate data sharing and make treatment more efficient. This is particularly relevant for chronic diseases, such as diabetes, because the glucose levels and other vital signs of patients are continuously shared with clinicians. Innovation—in the form of new medicines, procedures, medical devices, technologies, and delivery models—will clearly be critical to go on improving the health of the world’s population. Realizing these innovations, however, will require continual R&D investments by pharmaceutical companies, medical and other technology companies, and academia.

## T - Reduce

#### Interpretation: Reduce means unconditional and permanent – the aff is a suspension.

Reynolds 59 – Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959, lexis)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway.  [\*\*\*13]  The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Violation: During pandemics

#### Vote neg:

#### 1] Limits and ground– their model allows affs to defend anything from pandemics to Biden’s presidency— there's no universal DA since it’s impossible to know the timeframe when there won’t be IP— that explodes neg prep and leads to random timeframe of the week affs which makes cutting stable neg links impossible — limits key to reciprocal engagement since they create a caselist for neg prep (innovation, collaboration, econ, ptx: all core neg literature thrown away)

#### 2] Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### 3] TVA – defend the advantage to a whole rez timeframe. We don’t prevent new FWs, mechanisms, or advantages. PICs don’t solve – our model allows you to specify countries and medicines.

#### Fairness- consittutive of comp activites, args presume

#### Edu- funded ny schools

#### DTD- dta illogical, time skew

#### No RVI’s- illogical, baiting

# Case

#### 1] Passing the aff doesn’t restore US cred, every country would pass out vaccines, CP comparatively solves better bc its driven by US

#### 2] Their carman and carl ev indicates that china is already a heg, no inherency

#### 3] Don’t solve evergreening

#### IP developed COVID vaccines rapidly and produced collaboration – turns case

Stevens and Schultz 21 [Philip Stevens and Mark Schultz, “WHY INTELLECTUAL PROPERTY RIGHTS MATTER FOR COVID-19”. Geneva Network, January, 2021. https://geneva-network.com/wp-content/uploads/2021/01/Why-IP-matters-for-Covid-19.pdf]

Some asserted that intellectual property would inevitably hold up urgent research. They theorised that the “winner-takes-all” nature of intellectual property rights, especially patents, would prevent scientists from rapidly disclosing research results, and discourage the sharing of unpatentable insights that may potentially lead to patentable treatments with further work. Members of Congress warned that IP would “put public health at risk”, while NGO Médecins Sans Frontières (MSF) called for “no patents or profiteering” on yet to be developed health technologies. A coalition of over 500 NGOs claimed that IP rights were a “hindrance” to efforts to tackle the pandemic, calling for all COVID-19-related IP to be rescinded. As events demonstrated, critics of IP were wrong by a wide margin. In January 2020 very little was known about COVID-19. By January 2021, three safe and highly efficacious vaccines had been authorised for use by stringent regulatory authorities, with several others poised to follow. As of 21st December 2o20, there were 1052 COVID-19-19 vaccines, therapeutics and diagnostic tools under development or approved globally, of which 219 are vaccines. This major achievement is a testament to how well the IP system has worked during the pandemic. Calls to override intellectual property rights in the early stages of the pandemic were seductive and were backed by respected global humanitarian NGOs and prominent political figures. But it is to the credit of the majority of governments that they held their nerve and ignored such calls, despite the growing urgency of the situation over 2020. V BUILDING ON EXISTING IP IP is the bedrock upon which today’s COVID-19 vaccines have been built. The technologies they are based on did not come out of thin air at the beginning of the pandemic, but had been under development for decades, with substantial research in academic labs followed by years of risky investment by commercial start-ups. Consider the messenger RNA (mRNA) technology that is the basis for two of the first vaccines approved in Western countries. Scientists discovered in 1961 that mRNA could be used to “reprogram” cells to battle disease. It took decades of lab research and private sector-funded development by startups BioNTech and Moderna to overcome major difficulties and turn the technology into an effective vaccine that can be safely given to patients. Both companies and their investors have spent billions of dollars on mRNA research prior to the pandemic. While academic research is fundamental, the end result would not have been possible without the private sector, which depends on intellectual property rights. Shortly before the pandemic started, we spoke to Dr. Derrick Rossi, the academic founder of Moderna. When asked whether the treatments could be brought from the academic lab to patients without the help of the private sector, Dr. Rossi’s reply was categorical: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.” Dr. Rossi explains that bringing a drug to market takes many professionals, sharing their labour and diverse expertise. “This industry of professionals is out there... The more people that are involved in the chain, post-academic discovery, the more you have pros involved — all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment. Developing a practical application for a great academic insight takes vast sums, and investors need some prospect of a return on that investment. As Dr. Rossi explains, “you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple.” V IP HELPS NOT HINDERS R&D COLLABORATION The other claim frequently heard at the beginning of the pandemic was that IP poses a barrier to collaboration and knowledge sharing, so in a time of emergency any related IP should be open licensed or pooled. In reality, the IP system encouraged the rapid establishment of dozens of partnerships around COVID-19-19, with even commercial rivals prepared to cooperate and share capital and proprietary intellectual resources such as compound libraries. Examples of consortia between the private sector and research centres include the COVID-19-19 Therapeutics Accelerator to evaluate new and repurposed drugs and biologics, the EU-backed Swift COronavirus therapeutics REsponse, Corona Accelerated R&D in Europe (CARE) as well as dozens of bilateral agreements between companies. Indeed, the Pfizer vaccine is the result of its collaboration with BioNtech, where partners shared and combined knowhow and proprietary knowledge to create the first vaccine authorized in the U.S. Far from being a barrier to such collaborations, IP is fundamental. Because patent rights require public disclosure, they enable drug developers to identify partners with the right intellectual assets such as knowhow, platforms, compounds and technical expertise. Without patents most of this valuable proprietary knowledge would be kept hidden as trade secrets, making it impossible for researchers to know what is out there. Second, the existence of laws protecting intellectual property helps rights-holders make the decision to collaborate in the first place. By allaying concerns about confidentiality, IP enables companies to open up their compound libraries, and to share platform technology and know-how without worrying they are going to sacrifice their wider business objectives or lose control of their valuable assets. For instance, rights holders might contribute IP that is useful for entirely different diseases to COVID-19 collaborations. IP rights and licensing ensure those rights can only be used for the agreed reason, preventing competitors freeriding to gain an unfair advantage in other areas. As the former Director General of WIPO noted in June 2020, the main challenge at the time was “not access to vaccines, treatments or cures for COVID-19-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation”. During this initial phase of the pandemic, the majority of governments followed this advice, especially by not threatening to remove IP of products yet to be invented. No government from a country with a significant life-science R&D industry, for instance, backed the WHO’s “Solidarity Call to Action” in which companies were asked to unilaterally cede IP and data related to COVID-19 to its new technology and IP pool, C-TAP. The WHO embarked on this initiative with no evidence that IP would stand in the way of R&D and access efforts, distracting efforts away from more practical initiatives that stood greater chance of success. V WHAT ABOUT THE PRICE OF PATENTED VACCINES AND THERAPEUTICS? Nevertheless, the emergence of several competing vaccines has shifted the debate. There are increasingly loud calls to suspend IP rights in order to promote affordable prices for low and middle-income countries, and to mandate forced transfer of know-how and technology in order to scale up global manufacturing . These calls have culminated in proposals at the WTO to implement a temporary suspension of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including obligations regarding patent rights and the protection of undisclosed information on all COVID-19-related technologies Such extreme proposals are based on muddled thinking. Specifically, the political campaigns that underpin them mischaracterise IP rights as “monopolies” that allow companies to charge unaffordable prices. One eminent scholar of patents, Prof. Edmund Kitch described the application of the term “monopoly” to patents as one of the “elementary and persistent errors in the economic analysis of Intellectual Property”. In reality, IP rights drive the emergence of competing products in the same category, putting a lid on the ability of manufacturers to charge premium prices. Owning IP rarely gives control over a market and IP markets are often intensely competitive. In medicines, for instance, there are usually many substitutes and alternatives. For example, a patient needing a cholesterol drug has a host of statins from which to choose, both patented and generic. Similarly, patients with osteoporosis and their doctors can choose from Fosamax®, Actonel®, or Boniva®. Recent years have seen the emergence of competing shingle vaccines, increased competition in the lung cancer therapeutic space, and a slew of promising clinical trials and new drug launches in the under-served area of lung disease. Each of the owners of patents in these products has a temporary exclusive right to their product; none of them has a monopoly over the market for this type of treatment. The most spectacular demonstration of this point is the recent emergence of multiple competing hepatitis C cures, which have opened up a wide range of treatment options and placed downward pressure on prices. As Geoffrey Dusheiko and Charles Gore wrote in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.” Every step of the development of this new market in hepatitis C cures was accompanied by calls to override their IP by civil society and certain intergovernmental organizations. Had those calls been heeded, it is doubtful such a competitive market would exist today. A similar story is unfolding in the COVID-19 vaccine space. Pharmaceutical market analysts predict competition will hold COVID-19 vaccine prices down even in the unlikely scenario of rights holders declining to license their IP to other manufacturers. “In two years’ time, there could be 20 vaccines on the market,” Emily Field, head of European pharmaceutical research at Barclays told the BBC. “It’s going to be difficult to charge a premium price.” V THE REAL CHALLENGES IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards. There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to The Lancet: “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic” John-Arne Røttingen, chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains. The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says. Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a range of issues need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population. The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official estimate of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic. V IP IS PART OF THE SOLUTION Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done. This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s BioKangtai (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of 2 billion doses by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middleincome countries. IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment. Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The Lancet Global Health concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear intercompany competition and economies of scale. But again, these licenses model were criticised by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken. As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. Prices of COVID-19 vaccines vary between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost, with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance. Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given the new strains of the virus which constantly emerge. Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil. Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global role out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside. Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

#### IPR hasn’t harmed access – manufacturing capacity alt cause

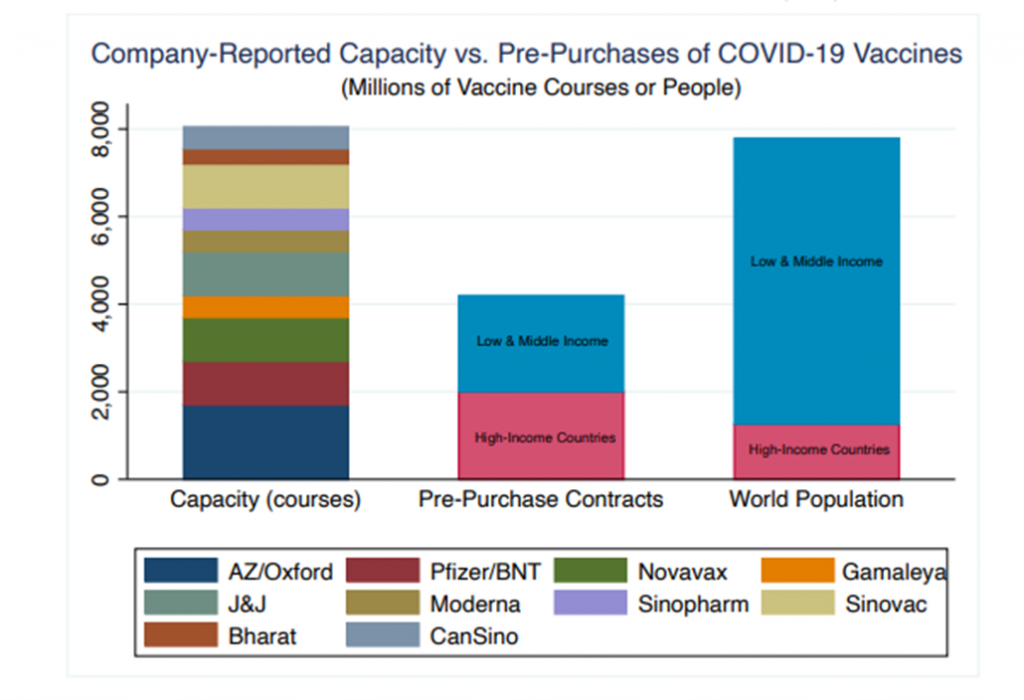
Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines 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. While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### The 1AC misdiagnoses the problem – the problem isn’t production of vaccines it’s the demand for them

Reed 21 (TRISTAN REED|JUNE 17, 2021, In the COVID-19 vaccine market, the problem has always been demand, n, ot supply, WorldBank Blogs, <https://blogs.worldbank.org/developmenttalk/covid-19-vaccine-market-problem-has-always-been-demand-not-supply)//ww> pbj

Some economies have now vaccinated more than half of their populations against COVID-19 and are reopening, while low- and middle-income economies still have limited access in the face of devastating outbreaks. Supply bottlenecks have been blamed. Though vaccine manufacturers report substantial capacity, essential vaccine manufacturing supplies like giant plastic bags and glass vials are hard to come by, understandably, as countries ordered more vaccines at one time than ever before. However, these supply-side challenges are overemphasized. The reason why low- and middle-income countries are not further along in their vaccination campaigns comes down to insufficient demand. As Ruchir Agarwal of the IMF and I show in a recent research paper, even though governments have substantial experience implementing vaccination campaigns and most individuals are not hesitant to take vaccines, governments did not commit to buy Covid-19 vaccines from manufacturers early enough (Figure 1). Figure 1: As of April 2021, despite available capacity for 10 vaccines showing effectiveness in Phase 3 trials, there were not enough advance purchases to cover the world’s population



#### States wouldn’t implement TRIPS – endless filibustering in the squo by Europe, the UK, Russia, etc. should be enough proof, but they also have no incentive to listen since countries are split on the issue, and its not unanimous

#### Circumvention and they don’t solve – even if they say “durable fiat”, they have not defined the scope of the plan in the 1AC so you don’t know what the plan would materially look like

Mercurio 6/24 [Simon F.S. Li Professor of Law, The Chinese University of Hong Kong, Shatin, Hong Kong. June 24, 2021. “The IP Waiver for COVID-19: Bad Policy, Bad Precedent” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/> Accessed 8/25 //gord0]

The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn1) The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn2) The proposal attracted support from the majority of developing country Members,[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn3) but was opposed by a handful of Members including the United States (US).[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn4) Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn5) On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn6) To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn7) The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn8) For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn9) Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn10) Issues of negotiation will include the scope of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations. With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn16) There is also a chance that the negotiations will continue past the calendar year 2021. The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India’s and South Africa’s true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world. It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn17) The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.[18](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn18) Second, it sends a strong signal that the US does not oppose others from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time. Alan Beattie, writing in the Financial Times, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up. When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”[21](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn21) I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”[22](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn22) I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn23) IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn24) Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

#### Low prices independently cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### Generic antibiotics don't treat infections and create superbugs.

**Eban, 19** **(Katherine Eban, investigative journalist, 5-17-2019, accessed on 9-4-2021, *Time*, "How Some Generic Drugs Could Do More Harm Than Good", https://time.com/5590602/generic-drugs-quality-risk/) //D.Ying**

Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it’s made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says that almost all the drugs his patients take are substandard, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.” Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said. Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.” Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who’d had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” For any given drug, he says, “There’s only one standard, and that standard was set by the originator,” meaning the brand-name company that developed the product. It’s not just those in developing markets who should be alarmed. Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.” USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an “independent pillar” in the global menace of drug resistance. The low cost of generic drugs makes them essential to global public health. But if those bargain drugs are of low quality, they do more harm than good. For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won’t be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, “The fact is, pathogens know no borders.”