## 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.

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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.

#### Heg solves arms races, land grabs, rogue states, and great power war.

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6 From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep. This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance. Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate. American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap. Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled. THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors. First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment. Second, the international outlaws are no longer so weak. North Korea’s conventional forces have atrophied, but it has amassed a growing nuclear arsenal and is developing an intercontinental delivery capability that will soon allow it to threaten not just America’s regional allies but also the continental United States.12 Iran remains a nuclear threshold state, one that continues to develop ballistic missiles and A2/AD capabilities while employing sectarian and proxy forces across the Middle East. The Islamic State, for its part, is headed for defeat, but has displayed military capabilities unprecedented for any terrorist group, and shown that counterterrorism will continue to place significant operational demands on U.S. forces whether in this context or in others. Rogue actors have long preoccupied American planners, but the rogues are now more capable than at any time in decades. Third, the democratization of technology has allowed more actors to contest American superiority in dangerous ways. The spread of antisatellite and cyberwarfare capabilities; the proliferation of man-portable air defense systems and ballistic missiles; the increasing availability of key elements of the precision-strike complex— these phenomena have had a military leveling effect by giving weaker actors capabilities which were formerly unique to technologically advanced states. As such technologies “proliferate worldwide,” Air Force Chief of Staff General David Goldfein commented in 2016, “the technology and capability gaps between America and our adversaries are closing dangerously fast.”13 Indeed, as these capabilities spread, fourth-generation systems (such as F-15s and F-16s) may provide decreasing utility against even non-great-power competitors, and far more fifth-generation capabilities may be needed to perpetuate American overmatch. Finally, the number of challenges has multiplied. During the 1990s and early 2000s, Washington faced rogue states and jihadist extremism—but not intense great-power rivalry. America faced conflicts in the Middle East—but East Asia and Europe were comparatively secure. Now, the old threats still exist—but the more permissive conditions have vanished. The United States confronts rogue states, lethal jihadist organizations, and great-power competition; there are severe challenges in all three Eurasian theaters. “I don’t recall a time when we have been confronted with a more diverse array of threats, whether it’s the nation state threats posed by Russia and China and particularly their substantial nuclear capabilities, or non-nation states of the likes of ISIL, Al Qaida, etc.,” Director of National Intelligence James Clapper commented in 2016. Trends in the strategic landscape constituted a veritable “litany of doom.”14 The United States thus faces not just more significant, but also more numerous, challenges to its military dominance than it has for at least a quarter century.

## Innovation

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

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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.

# Case

#### Waiver greenlights counterfeit medicine – turns case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Vote neg on presumption – the aff can’t solve any of their impacts

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

## A2 Prices

#### 1] We will answer below on covid

#### 2] Innovation straight turns

#### 3] no terminal impact

#### 4] don’t solve for medical model

## A2 Bio Piracy

#### 1] You don’t solve, reducing Ip doesn’t give poorer countries money

#### 2] Herbs are not medicines, you cannot claim IP over them, the contention is flat up not T

#### 3] You cant solve for environmental destruction, root cause of destruction exists well beyond patents

#### 4] Big countries just wont aggree to pay, smaller countries don’t have the leverage to do so

## A2 Vaccines

#### 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

