### 1

#### IP protections motivate innovators to take risks – that means long term development and prolif

Bacchus '20 (James Bacchus; James Bacchus is a 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. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland.; 12-16-2020; "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines"; https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#, Cato Institute, accessed 7-21-2021; JPark)

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

#### Innovation is k2 stopping bioterror

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." https://www.rand.org/pubs/perspectives/PEA407-1.html (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well recognized as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror is the largest medical threat—it outweighs natural pandemics

Bakerlee ‘21 Chris Bakerlee is a Ph.D. candidate studying evolutionary genetics at Harvard University and a fellow in the Council on Strategic Risks’s Fellowship for Ending Bioweapons Programs. "Mother Nature is not 'the ultimate bioterrorist' - STAT." STAT, 8 Jan. 2021, www.statnews.com/2021/01/08/mother-nature-is-not-the-ultimate-bioterrorist. [Quality Control]

Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a mistake to underestimate the threats from natural pathogens. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology to cause harm on a staggering scale, by either cruelty or carelessness. Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts. The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with no attention to maintaining or improving traits that enhance fitness in other environments. If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of an especially persistent horde of 5-year-olds, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time. By contrast, modern biologists are gaining the ability to see the whole field, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens poses serious concerns. It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist. It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about 23 are known or suspected to have maintained biological weapons programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ vulnerability to biological threats, has done little to mitigate this danger. Accidental releases pose an additional source of anthropogenic biorisk. Thanks to the U.S. government’s monitoring program, we know that dozens of agents and toxins with the potential to pose a severe threat to public health and agriculture are reported accidentally lost or released from U.S. labs every year. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength. Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing. Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.

### 2

#### Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) “As Washington Ties Pharma’s Hands, China Is Leaping Ahead” Barron’s Magazine: Commentary, China., 6/11/2021] RM

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](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) 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 innovation. 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](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) 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. It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in [contravention](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) with experimental concepts for biological and cognitive enhancement of soldiers and civilians. American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.

#### The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: “We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's “Wealth of Nations.” So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities.” Edited by Paul A. Gigot and Daniel Henninger, “Biden’s Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech.” The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We’ve already criticized President Biden’s bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon’s wage-and-price controls. In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America’s advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away. \*\*\* India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested. Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S. But suspending IP isn’t necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world. Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer’s 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year. AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn’t restraining vaccine production. Busting patents also won’t speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines. There’s also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that’s in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back? The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America’s crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals. Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches. Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own. China’s current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China’s theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation. \*\*\* Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck. Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism. Mr. Biden ought to listen to Angela Merkel. Pfizer’s partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: “The protection of intellectual property is a source of innovation and it must remain so in the future.” At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody’s intellectual property is safe in America.

#### China biotech heg causes a laundry list of impacts

Moore 19 Scott Moore - Director of the Penn Global China Program at the University of Pennsylvania, Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S. Department of State, Giorgio Ruffolo Post-Doctoral Research Fellow with the Belfer Center for Science and International Affairs at Harvard University, Truman, Fulbright, and Rhodes Scholar., Foreign Policy, "China's Genetic Experiments Are Pushing Ethical Limits", NOVEMBER 8, 2019, 2:53 PM, https://foreignpolicy.com/2019/11/08/cloning-crispr-he-jiankui-china-biotech-boom-could-transform-lives-destroy-them/ - BD

When James Clapper, the U.S. director of national intelligence at the time, appeared before Congress in early January 2016 for an annual briefing of threats to the United States, he didn’t lack for material. Just a few weeks earlier, North Korea had tested a nuclear device, and Russia had begun deploying cruise missiles that appeared to violate a crucial arms-control agreement. But to the surprise of many experts, Clapper devoted a good chunk of his time to describing a much more exotic threat: biomedical research. Specifically, Clapper warned, “Research 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.”Clapper’s statement didn’t explicitly mention China—but it didn’t need to. As his testimony went on to make clear, while in the 20th century the United States and Soviet Union held the keys to preventing planetary catastrophe, in the 21st the principal players are the United States and China. And while in a previous age keeping Pandora’s box closed meant preventing nuclear war, today it’s about preventing biotech dangers. In just the past few years, the development of inexpensive gene-editing techniques has democratized biomedical research, producing a biotech bonanza in places such as China and creating a whole new category of security threats in the process, from the use of genetic information to persecute dissidents and minority groups to the development of sophisticated bioweapons.When it comes to the United States, China, and technology, artificial intelligence tends to grab most of the attention. But policymakers need to come to grips with the even bigger threat of biotechnology—and soon. Fortunately, though, shared concerns about China’s role in biotechnology also provide a rare chance for meaningful and productive engagement in shaping the rules of a new world. China’s starring role in preventing the 21st century’s biotech perils stems from its skyrocketing investment in biomedical research. Historically, Western countries, and especially the United States, have been the epicenter of research in the life sciences. The United States alone accounted for some 45 percent of biotech and medical patents filed in the 14-year period ending in 2013. But now, thanks to heavy state-backed investment, China is catching up. Economic plans instituted in 2015 call for the biotechnology sector to account for more than 4 percent of China’s total GDP by 2020, and estimates suggest that as of 2018, central, provincial, and local governments had already invested over $100 billion in the life sciences. Chinese venture capital and private equity investment in the life sciences, meanwhile, totaled some $45 billion just from 2015 to 2017. China has also invested considerable effort in competing with countries like the United States for biotech talent. Of some 7,000 researchers recruited under the Thousand Talents Plan since 2008, more than 1,400 specialized in the life sciences. A leading American geneticist, Harris Lewin, has warned that the United States is “starting to fall behind … the Chinese, who have always been good collaborators, [are] now taking the lead.” For the United States and other Western countries, China’s growing role in biomedical research is raising plenty of concern. Several Chinese researchers have shown a willingness to ignore ethical and regulatory constraints on genetic research. In 2018, He Jiankui became a poster child for scientific irresponsibility when he announced he had edited the genes of two twins in utero without following basic safety protocols. He reportedly dismissed them as guidelines, not laws. Yet the reaction at home was not what He had hoped for. His research had been made possible by the relatively lax standards of Chinese universities, even as he had kept the true nature of it secret from many involved – while discussing it with a small group of Western bioethicists and scientists, who stressed their disapproval. It’s not uncommon in China to break the rules and be lauded for the results anyway, whatever the field. For He, though, the vast international attention that came after the story broke cost him his career and possibly his freedom. Chinese media rushed to stress official disapproval of the experiments. Even the overt purpose of the editing – to ensure that the babies, born to HIV+ mothers, enjoyed protection against the virus – turned out to be scientifically weak. As China’s biotech sector grows, so too do fears that Chinese researchers like He will be more willing to push the limits of both science and ethics than those in the United States. Earlier this year, Chinese researchers recorded another mind-bending milestone when they implanted human genes linked to intelligence into monkey embryos—and then said that the monkeys performed better on memory tests. The dominance of the party-state in China raises serious concerns around biotechnology, especially because it carries increasingly ethnonationalist tone. When in 2018 Chinese researchers created the world’s first primate clones, for example, they dubbed them Zhong Zhong and Hua Hua, from the term zhonghua meaning “The Chinese Nation”—an oddly jingoistic moniker for a pair of monkeys. Chinese government policies often blur the line between eugenics and education, lumped together as improving the “quality” (suzhi) of the population, which received another stamp of official endorsement following the recent Fourth Plenum. These programs are carried out through the country’s huge so-called family planning bureaucracy—originally established to enforce the one-child policy. Moreover, Beijing is increasingly extending its formidable social control apparatus into the realm of genetics. While there are considerable restrictions on private firms sharing biomedical data, largely because of an ugly history of popular discrimination against hepatitis carriers, the government has no such restrictions. A New York Times report earlier this year suggested, for example, that Chinese authorities had assembled a vast trove of genetic data on Chinese citizens without their consent, with the Uighur minority group having been specifically targeted.Beijing’s brand of bio-nationalism also directly threatens the United States. U.S. officials have been warning universities and research institutions that the biotech sector is a focal point for Chinese industrial espionage activities in the United States. And this past August, a senior Defense Department official warned Congress that China’s growing role in pharmaceutical manufacturing could allow it to disrupt deliveries of critical battlefield medicines, or potentially even alter them to harm U.S. forcesYet the biggest risks posed by biotech, for China, the United States, and other countries, pertain to nonstate actors. A critical feature of modern biotech, in contrast to technology like nuclear weapons, is that it’s cheap and easy to develop. A technique known as CRISPR, which the Chinese researcher He used in his illicit gene-editing work, makes it practical for just about anyone to manipulate the genomes of just about any organism they can lay their hands on. CRISPR makes it much simpler to skirt ethical restrictions and terrifyingly straightforward for terrorist groups to develop fearsome biological weapons. Researchers have already shown it’s possible to reconstruct the smallpox virus, which was eradicated in the real world in the 1970s, for as little as $200,000 using DNA fragments you can order online. If a terrorist or rogue state were to successfully do so, virtually no one alive would have any resistance to the virus—and most stockpiles of the vaccine were destroyed long ago. There is an organization, the International Gene Synthesis Consortium, that tries to screen suspicious orders for DNA fragments that might be used to build such bioweapons. And while most of the world’s major DNA synthesis firms belong to the consortium, membership is completely voluntary, and there’s also a thriving and entirely unregulated black market—much of it based in China.All of this means that biosecurity standards in places like China matter more than ever. After all, if a major bioweapon were to be unleashed, it’s unlikely that any major, globally integrated country could escape unharmed. Fortunately, there are growing signs China is open to better regulation of its biotech sector. In February, the Chinese government announced that “high risk” biomedical research would be overseen by the State Council, China’s equivalent of the cabinet—a sign of the concern with which Beijing views incidents like the He Jiankui CRISPR scandal. In a further sign of this concern, in August, the Chinese Communist Party announced the creation of a new committee to advise top leaders on research ethics. Government worry is matched by growing public concern within China. Opposition to genetically modified organisms is arguably stronger in China than in the West, and health concerns top the list of public issues. Rumors and panics largely center around health issues, especially after a series of vaccination scandals. That means that the government has to walk unusually carefully and offers plenty of scope to build ethical concerns into both law and practice. There are plenty of issues for U.S.-China cooperation on biotechnology and biosecurity to address. Given China’s role in the He Jiankui scandal, meanwhile, it would make sense to partner with the United States and other countries as part of a new World Health Organization effort to set international guidelines for the use of CRISPR. Another promising area of U.S.-China cooperation, especially in the research community, relates to so-called gene drives, the process of editing genomes and then spreading them through an entire population in just a few generations. Using gene drives to prevent select mosquito species from reproducing, for example, might finally banish the world of debilitating, widespread diseases such as malaria and Zika, while endangered species might be engineered to survive climate change.Microsoft founder Bill Gates once observed that “The world hasn’t had that many technologies that are both promising and dangerous. … We had nuclear weapons and nuclear energy.” But thanks in large part to the efforts of biomedical researchers in the United States and China, biotechnology is opening a similar Pandora’s box. And while the world has so far avoided nuclear war or conflict, it’s done so largely though efforts by governments, aided by the fact that nuclear technology is extremely difficult and expensive to master. The new wave of synthetic biology is exactly the opposite: It’s cheap to use and employ. For that very reason, while the U.S., Chinese, and other governments will be critical to dealing with the threat of new technologies, the discussions can’t be limited to nation-states. They’ll also have to gather together individual researchers, institutions, companies, and organizations like the International Gene Synthesis Consortium. When it comes to the risks posed by emerging technologies, Beijing, like Washington, will have to face the limits of its ability to solve the problem on its own.

#### China will leapfrog the US through biotech primacy

Cumbers 20 [John Cumbers, “I am the founder and CEO of SynBioBeta, the leading community of innovators, investors, engineers, and thinkers who share a passion for using synthetic biology to build a better, more sustainable universe. I publish the weekly SynBioBeta Digest, host the SynBioBeta Podcast, and wrote “What’s Your Biostrategy?”, the first book to anticipate how synthetic biology is going to disrupt virtually every industry in the world. I also founded BetaSpace, a space settlement innovation network and community of visionaries, technologists, and investors accelerating the industries needed to sustain human life here and off-planet. I’ve been involved with multiple startups, I am an operating partner and investor at the hard tech investment fund Data Collective, and I'm a former bioengineer at NASA. I earned my PhD in Molecular Biology, Cell Biology, and Biochemistry from Brown University and am originally from the UK.”) “China’s Plan To Beat The U.S. In The Trillion-Dollar Global Bioeconomy” Forbes, 2/3/2020] RM

The report, entitled “Safeguarding the Bioeconomy,” looks at how research and innovation in the life sciences is driving rapid growth in agriculture, biomedical science, information science and computing, energy, and other sectors of the U.S. economy. This economic activity—collectively referred to as the bioeconomy—presents many opportunities to create jobs, improve the quality of life, and continue to drive the U.S. economy as a whole. The report says that while the U.S. has been a leader in advancements in the biological sciences, other countries are actively investing in and expanding their capabilities in this area—and the U.S.’s lead is beginning to slip. Four reasons everyone should care about the U.S. bioeconomy It might be easy for some to dismiss the report out of hand as a bunch of alarmist professors lobbying for more research money. But when you consider all the ways that biotechnology powers the economy and impacts our daily lives, it becomes clear that this is about something more: The economy: at $1 trillion in value, the U.S. bioeconomy represents hundreds of thousands of quality, high-paying jobs for Americans. Health & medicine: innovators in the bioeconomy are making next-generation therapies for cancer and diabetes, tackling emerging diseases like Coronavirus, and even increasing human longevity. Food & farming: biotechnology is not only making agriculture more sustainable, it’s also bringing to market new and improved crops that are more nutritious, more affordable, and more delicious. The environment: humanity’s health and well-being depend on our ability to stop and reverse climate change, and we can’t do it without biological solutions that treat carbon not as a waste product, but as the starting point for chemicals and materials that today use petroleum. Considering all this, it doesn’t seem like an overstatement when the report authors say that U.S. competitiveness in the bioeconomy is key to maintaining the economic health and security of the country. The very real risks to the U.S. bioeconomy There are many things that can go wrong, causing the U.S. to lose its current edge in the global bioeconomy. Some of these are economic risks, and others present serious national security risks. All of them are related to a failure of our government to act now. Here’s a sampling of the risks to U.S. leadership at the frontiers of tech and bio: Insufficient government R&D investment. Money for basic research and development builds the foundations of the bioeconomy. We learn, achieve new results, and create new applications. Investments that help develop enabling tools, technologies, and standards have the potential to maintain the U.S. bioeconomy competitive in a global bioeconomy. Ineffective or inefficient regulations. Regulatory uncertainty stifles creative new approaches that may have unknown paths, long delays, or that might be prohibited by later changes. Inadequate workforce. The U.S.’s K-12 education system may not prepare students to study STEM subjects at the university and postgraduate level, hindering the quality of workers. A skilled workforce gives U.S. companies the best talent to choose from, and it also encourages international firms to establish research and production facilities here. Ineffective or inefficient intellectual property protections. Uncertainty over what is patentable could discourage innovators who are considering whether and how to bring their innovations to market. Patent eligibility is also important to venture capitalists and private equity investors when considering whether to invest in biotechnology companies. Cybersecurity. As biological engineering depends more and more on massive datasets, the emerging bioeconomy now exists at the intersection of information science and biotechnological science. The bioeconomy’s growing reliance on software, networking, and computer hardware tools yields the same cyber vulnerabilities present in any other sector, including hacking, sabotage, breached privacy, or theft of intellectual property. Biosafety and biosecurity risks. The tools of today’s bioeconomy are enabling new capabilities that can generate concerns regarding traditional biothreats. These can include the accidental or intentional creation or release of dangerous or lethal pathogens. Such biothreats can harm humans, animals, plants, agriculture, the environment, and materials. Risks from climate change. Food and feed crops, biofuels crops, and crops used with bio-based fermentation products are susceptible to temperature and water stresses, as well as insects and pathogens that migrate with changing weather patterns. China: the biotech elephant in the room I’ve written previously written how the Chinese government is already making substantial investments in its bioeconomy. Here are three scary statistics, courtesy of Greg B. Scott of the ChinaBio Group: China is out-investing the U.S. China’s private investors poured $14.4 billion into its bioeconomy in 2019. That compares to the United States’ more meager investment of $10.4 billion. China is building a bigger bioeconomy workforce. China graduates about 8-10 million students each year. In the U.S., that number is closer to 400,000. Many Chinese students graduating from U.S. institutions stay here, but they are increasingly returning home to start highly innovative companies. China is investing in itself. Historically, China has invested heavily in foreign companies, tech, and debt. Now we’re seeing an uptick in China-to-China investments—the country no longer needs to look abroad to find plenty of good biotech opportunities. Chinese investments have led to centers of excellence in the regional technology hub of Shenzhen, including the Institute of Synthetic Biology at the Shenzhen Institute of Advanced Sciences (SIAT) and BGI Genomics. Shenzhen will compete for technological and economic leadership with U.S. regional biotech powerhouses such as San Francisco/Silicon Valley and Boston/Cambridge in the years to come. Many of China’s long-standing challenges—environment, food, water, waste management, and rapid innovation to retain its global manufacturing competitiveness—are areas where synthetic biology is seen as a key technology for the future. In other words, synthetic biology is not just an academic pursuit for China. Rather, its leaders are thinking proactively about how biological engineering can be used to address the country’s strategic national interests—while U.S. leadership stands idly by. What do we do? So what can U.S. policymakers do to protect the U.S. bioeconomy and ensure continued technological and economic leadership in biology for the next twenty years? Straight from the top. China has made clear its ambition to become a global tech superpower, with President Xi Jinping calling science and technology one of the main battlefronts of the economy. The U.S. administration needs to step up its game, too. President Trump recently declared January 2020 to be National Biotechnology Month, citing “boundless possibilities for economic growth, national security, healthcare, manufacturing, and agriculture.” That’s the right sentiment—now we need real action. New legislation. Late last year, the U.S. House of Representatives passed the Engineering Biology Research and Development Act of 2019, which would direct the Office of Science and Technology Policy (OSTP) to implement a national research strategy for engineering biology. The explicit goal: maintain U.S. science, technology, and economic leadership in synthetic biology. The bill now resides in the Senate and awaits committee action. Legislative leadership is now needed to give this bill the appropriations necessary to give it real teeth, and then put it squarely on the President’s desk. Investing for returns. The Human Genome Project is said to have returned $141 for every dollar invested by taxpayers. While “Big Science” yields tremendous benefits for everyone, it doesn’t happen without federal funding. In 2019, politically courageous Republicans and Democrats came together to produce a 2020 final spending bill that is kind to science, in essence ignoring President Trump’s proposed cuts and instead giving increases to each of the NIH, NSF, NASA, and DOE’s Office of Science. But the U.S. isn’t even in the top ten for R&D spending as a percentage of GDP, while China continues to close in on the U.S., meaning that the U.S. is no longer the uncontested global leader in science. Leading the global bioeconomy: Have some courage There are many things the U.S. could do to protect the American bioeconomy. But above all else, policymakers need to come together and demonstrate the kind of courage and vision needed to be a world leader. Science and technology know no partisan lines. Everybody wants healthy lives, clean water, and good jobs. Federal initiative and assistance are needed to bring these benefits to everyone living in the U.S.. Today, the American synthetic biology industry may be unprepared for the global competition it will face, lacking initiative and leadership at the highest levels of government. But this could change quickly. If a country like the U.S. makes engineering biology a national priority, anything is possible in the new bioeconomy.

#### Hege 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

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#### TRIPS is essential to modern health diplomacy, improving access

Aginam 10 Obijiofor Aginam, Obijiofor Aginam is currently Deputy Director and Head of Governance for Global Health in the United Nations University-International Institute for Global Health, 2010 “HEALTH OR TRADE? A CRITIQUE OF CONTEMPORARY APPROACHES TO GLOBAL HEALTH DIPLOMACY,” <https://poseidon01.ssrn.com/delivery.php?ID=149097083081123105113085099123123091104014059082060018071001088023116023118119002064117119051059021051011085110010121013091016020070011051015018011008065019104127084042076098081007102099120087031085093119071127122005124010118009001092104124120121094&EXT=pdf&INDEX=TRUE>

The third limb of global health diplomacy critique reflects the complex linkages between “health and trade”18 where the modest achievements in global health diplomacy in the past decade are substantially driven not by events in the health sector but by the normative developments in the trade and economic relations of states enforced by the WTO. Although this sounds like “economic globalization triumphalism”, it is nonetheless hard to dispute the fact that it was the patent requirements for pharmaceuticals and other inventions in the WTO TRIPS Agreement that substantially catalyzed the health diplomacy on access to anti-retroviral drugs for HIV/AIDS for millions of poor HIV-positive who live mostly in developing countries. Food safety and security concerns and the hard diplomacy animated by biotechnology advances in food production, although global health issues in their own right, are catalyzed by the developments in the WTO on the SSPS Agreement, and not the subtle “diplomacy” around the WHO/FAO jointly administered Codex Alimentarius Commission standards. The migration of qualified health professionals from most of Africa to the West is now being driven in complex ways by one of the modes of service supply in the GATS Agreement.

#### Health diplomacy’s creates global cooperation solving multiple existential threats

James 17, Wilmot James, Honorary Professor in the Division of Human Genetics at the University of Cape Town's Medical School and Non-residential Senior Fellow at Bard College’s Hannah Arendt Centre, Ph.D. from University of Wisconsin at Madison, 2017 “In an Age of Zika and a Threat of Biochemical Terror, Health Security Must Be Everybody’s Concern”, Daily Maverick, 4-2, https://www.dailymaverick.co.za/article/2017-04-02-op-ed-in-an-age-of-zika-and-a-threat-of-biochemical-terror-health-security-must-be-everybodys-concern/#.WOY8xTvDHHw

With Zika there too was political failure to act quickly, give honest advice and confront the abortion conundrum head-on, the result being that 3,000 and likely more children with microcephaly will test the emotional resilience and financial resources of their families to breaking point. We should never cease to invest in the public health and medical science of disease, but it seems to me that our fundamental problem is not the quality of the health sciences but the grim mediocrity of our politics. Party-political bickering for short-term gain paralyses and drains the national effort in South Africa as much as it does in the United States, undermining our ability to see with compelling clarity the solutions the issues of the day deserve. Health security is humanity’s shared concern. Promoting health and preventing death define us at our most altruistic and advanced. The Hippocratic Ideal, the concept of the physician as the guardian of human health, encapsulates a fundamental human quality common to all the world’s great religions. Medicine is one of the earliest and greatest human achievements because it is a co-operative enterprise involving highly skilled individuals; and it is as a result of cooperation– and our unusual ability for complex language – that cumulative civilisation is possible. In the age of globalisation, it is health security, a recent Lancet editorial stated, that “is now the most important foreign policy issue of our time”. The rapid emergence and re-emergence of pathogenic infectious disease, of which Zika is the most recent, the slow but steady cumulative acts of nature associated with climate change, high-risk forced migration caused by desperation and war, the creeping reality of biochemical [use]terror and the threat of nuclear war, propel human survival and well-being to the frontline of what today must be everybody’s concern. The field of health diplomacy provides an unprecedented opportunity to build human solidarity. It is an area of human endeavour that cuts through inherited antagonisms. Governments that offer health improvements as part of aid to nations with whom they wish to develop stronger diplomatic links succeed in cultivating deeper cultural relationships precisely because of their direct benefit to citizens. To advance health diplomacy requires health leaders with an inclusive global vision...