## DA – China

#### The US still leads the world in pharmaceutical innovation, but China’s catching up – to keep the advantage, we need to maintain our strong IP framework

**Ezell 20** – Ezell, Stephen, 16 July 2020, “Ensuring U.S. Biopharmaceutical Competitiveness,” Information Technology & Innovation Foundation, <https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness> Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program. [Harker KB]

Many nations, including China, have targeted the biopharmaceuticals industry—an industry which the United States has long led—especially in drug innovation. One result has been that over the last decade U.S. biopharmaceutical manufacturing value-added output has fallen by almost one-third, as the U.S. trade deficit in drugs and inputs has increased. Fortunately, America still leads in innovation and drug development, in large part due to effective life-science policies, including significant federal investment in life-sciences basic research, robust intellectual property (IP) protections, effective technology transfer policies, investment incentives, and, importantly, drug pricing policies that enable companies to invest in high-risk drug development. But if the story of the past decline, and even loss, of other critical U.S. industries provides any guide, loss of U.S. production will ultimately lead to the loss of innovation capabilities as well. It is not enough for the United States to lead in drug development, it must also at least hold its own in drug production. This is especially true given the coming challenge from China, which intends to dominate the global drug industry, at all phases, from innovation to production to marketing. Now is not the time for free-market complacency, hoping that America’s entrepreneurial spirit and rule of law will somehow suffice (the United States didn’t gain its biopharma lead from a laissez faire approach, and it certainly won’t keep its lead with it alone). Nor is it the time for drug populism, a political movement that both sides of the aisle, but especially progressives, have unfortunately embraced. Drug populism and its accompanying policies of weaker IP protections and draconian drug price controls would likely result in cheaper drugs. But there should be no confusion that it will lead to a hollowing out of U.S. capabilities, not just in production but also in innovation (and, not to mention, fewer new lifesaving drugs). If the United States is serious about competitiveness overall, and competitiveness in the biopharma sector specifically, an industry that the United States still has strong capabilities in—unlike the telecom equipment or flat-panel display industries, to name just two—then it’s time for Washington to articulate and embrace a robust national biopharmaceutical competitiveness strategy.

#### Reducing IP rights guts US pharmaceutical innovation and leadership – profit incentive is key to undertaking the risks.

James M. Roberts, PhD Candidate, 21 [PhD Candidate in Public Policy @ VA Tech, MA International and Development Economics from Yale, MA Business Administration from the University of Pittsburgh, Research Fellow For Economic Freedom and Growth @ Heritage], "Biden’s OK of Global Theft of America’s Intellectual Property Is Wrong, Dangerous," Heritage Foundation, 6-25-2021, <https://www.heritage.org/public-health/commentary/bidens-ok-global-theft-americas-intellectual-property-wrong-dangerous> C.VC

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.

Signaling that the United States will not fight to defend their intellectual property rights actively undermines innovation and manufacturing in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the future development of vaccines needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, compulsory licensing legalizes the theft of intellectual property. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding. It is and has been a bulwark of American prosperity, but the strength of that protection has been weakening in the past few decades. Compulsory licensing contributes to the erosion of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

#### Chinese biotech leadership risks planetary catastrophe – lack of ethical and legal regulations increases the possibility of bioweapon attacks and other security threats.

Scott Moore, PhD, 19 [PhD Politics from Oxford, Director of China Programs and Strategic Initiatives @ Penn], “China’s Biotech Boom Could Transform Lives—or Destroy Them,” Foreign Policy, 11-8-2019, <https://foreignpolicy.com/2019/11/08/cloning-crispr-he-jiankui-china-biotech-boom-could-transform-lives-destroy-them/> C.VC

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. forces.

Yet 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.

#### Weaponized biology is an existential threat.

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

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## Case

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#### Reductions in IP do not improve accessibility, and some protections are necessary for balancing public and private interests.

Krattiger ‘13 (Anatole Krattiger,; Adjunct Professor, School of Integrative Plant Science Plant Breeding and Genetics Section ; September 2013; "Promoting access to medical innovation"; https://www.wipo.int/wipo\_magazine/en/2013/05/article\_0002.html, WIP Magazine, accessed 7-29-2021; JPark)

The rationale of the intellectual property (IP) system in general, and the patent system in particular, is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in patent applications is accessible to society. In this way, it seeks to balance competing private and public interests. Anyone applying for a patent is required to disclose the details of their technology so that the public is aware of, and can eventually use, the knowledge contained in patent documents. Patent information available through public databases, such as WIPO′s PATENTSCOPE, offers useful insights about innovation trends and freedom-to-operate, and can help shape patenting and licensing strategies. Data indicate overall long-term growth in patenting of medical technologies (a sign of renewed investment in this area) and that an increasingly diverse range of public and private users (see Figures 2 and 3), including from emerging economies, are using the international patent system. While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated. Just as the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access. As noted in the WHO′s Framework for Access to Medicines, access to medicines is rarely dependent on a single factor; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems, among others.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

Like most forms of innovation, the development of medicines and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are major advancements, but often they are incremental steps forward. In the pharmaceutical field, incremental or follow-on innovation frequently results in new therapeutic uses for existing drugs, which address serious challenges related to adverse effects, delivery systems, and dosing schedules. While they might not sound like medical breakthroughs on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve public health and save lives.

Additionally, follow-on innovations are—and should remain—subject to the same patentability standards as any other technologies. Patents reward advancements that are novel, useful, and nonobvious, and our patent system has long recognized that patent claims are to be presumed patentable and nonobvious. The Graham amendment would have turned this established standard on its head, creating a separate and ill-defined hurdle for certain advancements in medicine.

The benefits of incremental innovation to public health and patients cannot be overstated. New formulations of malaria drugs, dosing regimens and delivery systems for AIDS patients, more efficient administrations of insulin for the treatment of diabetes, and developments in the treatment of cognitive heart disease have all been possible because of incremental innovation.

Imposing unjustified restrictions on the patentability of advancements like these would be disastrous for drug development, as the incentives that come with patent protection would be all but eliminated. Without the assurance that their innovative labor would be supported by intellectual property protection, pioneering drug developers would shift resources away from improving drug formulations and uses. The development of more effective treatments of some of the most devastating diseases would stall, as innovators would be unable to commercialize their products, recoup losses, or fund future research and development.

As critics continue to target myopically the patent system for a broader issue of drug prices in the American health care system, it’s likely not the last time that language like this will be proposed. In order to avoid the implementation of such ill-conceived standards into our patent laws, understanding what’s at stake is critical. The future of medical innovation depends on it.

#### It tips the entire industry into insolvency

Globerman & Lybecker 14 [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Incremental innovation is a financial necessity for high-tech industries such as biotechnology and pharmaceuticals. Given the paucity and unpredictability of radical innovation, incremental advances sustain the industry financially, for no mature industry can do so from income derived from breakthrough innovation alone. As described by Wertheimer, Levy, and O’Connor, “[t]he pharmaceutical industry must generate revenue based predominantly on incremental innovations, which characterize the majority of products and contribute the majority of revenue” (Wertheimer, Levy, and O’Connor, 2001: 108–109). Evidence of the prevalence of breakthrough relative to incremental innovations is shown in figure 2.2 below. Over the entire period, products based on incremental innovations outnumber breakthrough products. In addition, it is essential to recognize the importance of risk management. Any technology portfolio will comprise projects of differing risk levels. In the case of the pharmaceutical industry, incremental innovation projects are an essential—and significant—component of this portfolio. The incremental innovation projects will be characterized by lower risk and a greater probability of reaching the market (Wertheimer, Levy, and O’Connor, 2001: 110).

#### Patents are key to adequate regulation and testing of drugs -- AFF leads to rampant counterfeiting and unsafe medication, which threatens public health, kills most vulnerable patients, and causes narcotic/human trafficking to surge. Especially true now due to public desperation over COVID, rise in e-commerce, and expansion of substandard medicine manufacturers targeting critical life-saving drugs

IPKey 21 (IP Key – Run by EUIPO and the European Commission to provide news coverage and scientific knowledge concerning intellectual property rights, “Intellectual Property and Keeping Medicines Safe”, https://ipkey.eu/en/south-east-asia/news/intellectual-property-and-keeping-medicines-safe, 2 February 2021, EmmieeM)

If you are what you eat, and bad diets lead to bad health, imagine what unsafe medicines can do.

We ask today, why the provenance of vaccines has attracted so much attention when the origin of medicines we take, in some cases, every day and without even thinking, is not questioned at all? How do we know we can trust medicines readily available on the market from seemingly legitimate sources? Where does intellectual property (IP) come into all of this and why is a proper IP application and registration process important?

The global race to develop vaccines to fight the spread of COVID-19 has understandably captured the attention of the public worldwide. People of all generations and with little or no expertise in clinical trials have followed the process keenly, wishing and willing together that science can provide the answer to stopping the pandemic so what was called ‘normal’ life can return. This public interest has also rightly scrutinised the testing that is designed to make sure that these vaccines are safe and this same focus is thankfully putting medicines under the spotlight more broadly.

When we talk about medicines, they are universally understood to mean a drug or other preparation for the treatment or prevention of a disease or illness. In essence, they serve to keep us feeling healthy, or make us feel better. But what about when they achieve the exact opposite, when they are in fact harmful, or even fatal? The cause is usually because of fake and counterfeit medicines. This is because something they both have in common is the lack of rigorous inspections by public authorities that seek to guarantee the safety of medicines for widespread use.

What’s more, the proliferation of both kinds of these illegal medicines is worsened by a critical fact. Previously, they used to mainly be related to ‘lifestyle’ medicines, but now, even innovative or critical life-saving medicines, such as medicines that tackle cardiovascular diseases, are being increasingly created and are entering the market without official IP application and registration processes.

But if they are both illegal and both cause harm, what’s the difference between fake and counterfeit medicines? Fake medicines pass themselves off as real, authorised medicines but they may actually contain ingredients that are of low quality or in the wrong dosage. Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by authorisation procedures, they can be a major health threat. Counterfeit medicines, in contrast, are those medicines that do not comply with intellectual and industrial property rights, such as registered trade marks or patent rights. But it is important to stress, this is not just an IP issue. In the vast majority of cases (90%) they can also be harmful to a patient’s health, according to a study recently released by the European Union Intellectual Property Office (EUIPO