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**US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages**

Scott **Moore** **2020** [(Director of the Penn Global China Program at the University of Pennsylvania. Previously, Moore was a 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.) “China’s Role In The Global Biotechnology Sector And Implications For U.S. Policy” https://www.brookings.edu/wp-content/uploads/2020/04/FP\_20200427\_china\_biotechnology\_moore.pdf]TDI

EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

**The aff’s waiving of IP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech**

Josh **Rogin 4-8**. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] TDI

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

**China will convert biotechnology gains to military advantages, undermining US primacy – specifically true in the context of vaccines**

Mercy A. **Kuo 2017** [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines**, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

**Maintenance of the ILO is key to reduce a host of existential threats – establishes great-power peace.**

**Brands 18**. [(Hal Brands is a Henry Kissinger Distinguished Professor at Johns Hopkins University’s School of Advanced International Studies, Scholar at the American Enterprise Institute. “America’s Global Order Is Worth Fighting For, Bloomberg Opinion, Politics & Policy,” August 14, 2018, Bloomberg. <https://www.bloomberg.com/opinion/articles/2018-08-14/america-s-global-order-is-worth-fighting-for>] TDI

The first argument is **easily disposed** of. Yes, the postwar world has been **thoroughly imperfect**, featuring nuclear arms races, genocides, widespread poverty and other scourges. But the world has **always been** imperfect, and by **any** meaningful **comparison**, the last **seven decades** have been a **veritable golden age**. The **liberal international** economic order has led to an **explosion** of **domestic** and **global prosperity**: According to World Bank data, both U.S. and global **per capita** income have increased **roughly three-fold** (in inflation-adjusted terms) since 1960, with U.S. gross domestic product increasing nearly six-fold. The U.S. **system** of alliances and forward military deployments has **contributed critically** to the **longest period** of **great-power peace** in modern history, and **the incidence of war** and conquest **more broadly** have dropped **dramatically**. The number of **democracies** in the world has **increased** from perhaps a dozen during World War II to well over 100 today; **respect for basic** human rights has also reached **impressive levels**. As a **bevy of scholarship** has shown, the policies that the U.S. has **pursued** and the **international order** it has built have contributed **enormously** and **directly** to these **outcomes**. If the **liberal international order** can’t be considered a **smashing success**, no **international order** could be. The second critique is also overstated. It is true that Washington, like all great powers throughout history, has been willing to bend the rules to get its way. It is hard to reconcile Cold War-era interventions in Guatemala, Chile and other countries with a professed solicitude for human rights and democracy; the Iraq War of 2003 is only one instance in which the U.S. brushed aside the concerns of international organizations such as the U.N. Security Council. Likewise, when the U.S. government determined that the Bretton Woods system of monetary relations no longer suited its interests in the 1970s, it terminated that scheme and insisted on creating a more favorable one. But again, the proper standard here is not sainthood but reality. And the U.S. has **generally** enlisted its power in the **service** of **universal values** such as **democracy** and **human rights**; it has, more often than not, promoted **a positive-sum** international system in which **like-minded** nations can be **secure** and **wealthy**. This goes back to the very beginning of the liberal order: Washington did not seek to hold its defeated adversaries in subjugation after World War II; it rebuilt Japan and western Germany into thriving, democratic allies that became fierce economic competitors to the U.S. The U.S. has taken this approach not simply because it wanted to do good in the world — powerful as this motivation is — but because of a hard-headed desire to do good for itself. In an interdependent global environment, American officials have long calculated, the U.S. cannot divorce its own well-being from that of the wider world. And in contrast to how other great powers — Imperial Japan, for instance, or the Soviet Union — ruled their spheres of influence, American behavior has been positively enlightened. It is this relatively benign behavior that has convinced so many countries to tolerate American leadership — and it is the emergence of a darker form of U.S. hegemony under the Trump administration that so profoundly worries them today. As for the third critique, the premise is right, but the **conclusion** can easily **go too far**. It is always **dangerous** to become **so enraptured** by past **achievements** that one **loses sight** of the **need for adaptation** in **the future**. This is particularly true today, because the strength of the liberal order is being tested from within and without, by issues ranging from unequal burden-sharing among American allies to the ambivalence of the American people themselves. There is **little evidence** to suggest, however, that either American power or **the liberal order** it supports have **eroded** so **dramatically** that **Washington**’s postwar project cannot be **sustained**. Quite the contrary — the U.S. is likely to remain the **world’s strongest power** for **decades to come**.

## 2

**Biotech industry strong now.**

**Cancherini et al. 4/30** [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide>] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

**IPR key to innovation.**

**Bacchus 20** [(James, 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) "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, 12-16-2020, https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines] TDI

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

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](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) 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.

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

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

**Bioterror causes extinction.**

**Millett & Snyder-Beattie ‘17** [(Piers Millett: Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford. Andrew Snyder-Beattie: M.S., Director of Research, Future of Humanity Institute, University of Oxford.) " Existential Risk and Cost-Effective Biosecurity," Health Security, 15(4), 08-01-2017, https://www.liebertpub.com/doi/full/10.1089/hs.2017.0028] TDI

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

**Biopharma key to solve future pandemics – turns case.**

**Macdonald 5/4** [(Gareth John, Freelance Journalism, 5-4-2021, “Biopharma’s Resilience to Future Pandemics Relies on Manufacturing Innovation“, GEN - Genetic Engineering and Biotechnology News, accessed: 8-8-2021, https://www.genengnews.com/topics/bioprocessing/biopharmas-resilience-to-future-pandemics-relies-on-manufacturing-innovation/] TDI

Manufacturing innovation and collaboration with technology developers will be vital to maintaining the supply of medicines in future public health emergencies, according to the organizations behind a new study. The research—called the Global Biopharma Resilience Index—was carried out by Cytiva and consulting firm Longitude. The aim was to rank biopharma capabilities and resilience in 20 countries, scoring each on five factors critical to meeting demand during a public health crisis.

The study also revealed some major shortcoming chains, says Cytiva chief innovation officer, Dirk Voelkel, PhD.

“We identified challenges in supply chain, talent, research and development, manufacturing, and government policy and regulation that require attention and focus to solve,” he explains. To develop greater manufacturing “agility” biopharmaceutical companies will need to invest in innovative technologies, notes Voelkel, citing product quality as an example.

“Automation is a key to improving the quality of drug products, increasing the speed to market as well as lowering manufacturing cost,” he continues.

## Case

**Restricting IP protections undermines innovation and profit margins – turns case by precluding vaccine distribution to developing countries.**

**Cueni 12/10** [(Thomas, Director General of IFPMA, chair of the AMR Industry Alliance, Industry Co-Chair APEC Biopharmaceutical Working Group on Ethics, MA in politics from the London School of Economics) “The Risk in Suspending Vaccine Patent Rules,” New York Times, 12/10/2020] TDI

It is unclear how suspending patent protections would ensure fair distribution. But what is clear is that if successful, the effort would **jeopardize future medical innovation**, making us more vulnerable to other diseases.

Intellectual property rights, including patents, grant inventors a period of exclusivity to make and market their creations. By affording these rights to those who create intangible assets, such as musical compositions, software or drug formulas — people will invent more useful new things.

Development of a new medicine is **risky** and **costly**. Consider that scientists have spent decades — and billions of dollars — working on Alzheimer’s treatments, but still have little to show for it. The companies and investors who fund research shoulder so much risk because they have a shot at a reward. Once a patent expires, generic companies are free to produce the same product. Intellectual property rights underpin the system that gives us all new medicines, from psychiatric drugs to cancer treatments.

In trying to defend these rights, the drug industry has made mistakes in the past that have lost people’s trust. More than 22 years ago, for example, a group of drug companies sued the South African government for trying to import cheaper anti-AIDS drugs amid an epidemic. With price standing between patients and survival, the suit, which the companies eventually dropped, was a terrible misjudgment. The current situation is not parallel.

**Several major drug companies**, including AstraZeneca, GlaxoSmithKline and Johnson & Johnson, have pledged to **offer their vaccines on a not-for-profit basis** during the pandemic. Others are considering differential pricing for different countries. As of last month, four major pharmaceutical companies had already agreed to eventually produce at least three billion vaccine doses for low- and middle-income nations, according to one analysis.

In South Africa and India, pharmaceutical companies are already working with local partners to make their vaccines available. Johnson & Johnson has entered into a technology transfer partnership for its candidate vaccine with South Africa’s Aspen Pharmacare, and AstraZeneca has reached a licensing agreement with the Serum Institute of India to develop up to 1 billion doses of its vaccine for low and middle-income countries.

**Companies can afford to license patents for free, or sell drugs at cost, precisely because they know that their intellectual property will be protected**. That’s not a flaw in the system; it’s how the system ensures that pharmaceutical research will continue to be funded.

**IP protections are key to pharmaceutical investment in developing countries.**

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

Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that **IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment**.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, **foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries**.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that **weak IP rights reduce pharmaceutical investment**.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, **at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights**; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41

Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that **weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries**.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that **developing countries can entice technology transfer from the North by providing IPR protection for incoming products** (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45

**Lack of IP protection makes medical innovation prohibitively risky and expensive**

**Grabowski et al 15** [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] TDI

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market**.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

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

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

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

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

**Reducing IP protections stifles innovation by undermining incentives**

**Bacchus 12/16** [(James, 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) “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” Cato Institute, 12/16/2020] TDI

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

**US leniency in vaccine IPR jeopardizes competitiveness across sectors – green tech, AI, semiconductors, aerospace, biotech, and robotics**

**Duesterberg 21** Thomas J. (Thomas J. Duesterberg is a senior fellow at the Hudson Institute. An expert on trade, manufacturing, economics and foreign policy, he leads project work on trade with Europe and China.), 6-3-2021, "Biden says he wants to out-compete China — so why attack US medical innovation?," TheHill, <https://thehill.com/opinion/healthcare/556043-biden-says-he-wants-to-out-compete-china-so-why-attack-us-medical> ] TDI

Congress has been burning the midnight oil to pass legislation aimed at investing billions of dollars to out-compete China in critical sectors and champion American innovation. Yet at the very moment that value of the U.S. model of medical innovation is being most vindicated, that model has come under attack from our own government, as well as long-time critics in the developing world. These critics are proposing to waive the intellectual property (IP) rights guaranteed by the World Trade Organization (WTO) for vaccines and treatments for COVID-19 — a move that would undermine the economic model of innovation that produced the historically unprecedented effectiveness, and speed to market, of vaccines developed by major U.S. and British firms. The assault — spearheaded by South Africa and India — is not only unlikely to help get more vaccines to the developing world in a timely manner, but has the potential to unravel decades of progress in building an internationally agreed regime for IP rights, which incentivizes and rewards fundamental research and long-term capital investment. This could harm not only the medical products industry, but also spill over to other high-technology sectors that require long years of research and huge, risky capital investments before bearing fruit. Proponents of the waiver argue that it would facilitate more rapid production and distribution of much-needed shots for hard hit regions in South Asia and Africa. However, it’s well-established that any increased production — even in India, which is home to the world’s largest manufacturer of vaccines — would require at least a year of preparation and investment to begin large-scale production of the newer vaccines. What’s more, opponents to the waiver — led by European countries, home to the world’s second leading medicines industry — can delay the waiver approval for months at the WTO, if not bury the idea altogether. And with plans in place to ramp up production of approved vaccines in the U.S., Europe and India, there will be sufficient surplus production to start exporting to the global South later this summer. Any forced transfer of the new vaccines technologies almost certainly will benefit China, with its growing manufacturing prowess and ambitions to spend whatever is required to offset the damage to its reputation resulting from its attempt to mask the severity of the SARS-CoV-2 virus in the early days of the pandemic. A closer look at the South Africa-India waiver proposal, which is supported by some 100 other nations, gives insight into the longer-term and broader danger of the reversal of IP rights protections for advanced technologies. Their language tabled at the WTO in late May calls for waiving not only the fundamental patents behind COVID-19 vaccines but extending the waiver to products including “diagnostics, therapeutics, medical devices, personal protective equipment” and to the raw materials and “means of manufacture” of anything used to contain this virus. It is not a huge leap of logic to speculate that such broad waivers, in the future, could be suggested for any severe threat to world health, with the example of treatments for AIDS as a reminder. The proposed waiver would extend for a period of “at least three years,” and could be lifted only by agreement in the General Council of the WTO, which requires unanimous consent of all 164 members and rarely has been achieved since its inception in 1995. It is hard to imagine that once the long-sought goal of removing IP rights protection for medical technologies — supported by developing countries and by progressive groups in developed countries alike — is achieved, it can be reversed easily. Other high-technology industries characterized by the need for long-term investments in basic research and the development of new manufacturing technologies such as semiconductors, medical equipment or aerospace, or nascent industries such as quantum computing, robotics or 3D printing, would be wise to pay attention to the debate over waiving IP rights for COVID-19 vaccines. While the acute and existential issues arising from a pandemic represent a perhaps unique set of circumstances, one can conceive of arguments to justify the social goal of sharing some newer technologies. For example, if innovations in “green hydrogen,” more powerful batteries, or more efficient photovoltaic cells are achieved and promise early returns to combat climate change, the advantages of sharing the technologies for the global common good could be adduced to justify waivers in the appropriate enabling technologies. Or, would a waiver be considered for the advanced semiconductors and computers required for artificial intelligence and needed to find cures for cancer and to perfect climate mitigation strategies? U.S. support for the vaccine IP rights waiver is especially baffling because it affects one of its most successful industries in terms of global technology leadership and market share, responsible for so many advances of enormous benefit for global health. It is not a mystery why the rapid discovery and ramping up of production for new vaccines came from the unique U.S. innovation ecosystem, in contrast to the more highly regulated and centrally controlled health care sectors in much of the rest of the world. There are better ways to achieve the goal of eradicating COVID-19, and U.S. actions would be more effective if directed toward expanding production and assisting in the distribution of vaccines. This includes the use of foreign aid and help with purchasing agreements for countries in the global South, as well as facilitating licensing agreements. (For example, Johnson & Johnson is arranging a major project with Indian manufacturers, which has the support of the other Quad countries, Japan, Australia and the U.S.) If Congress truly cares about protecting American innovation, it ought to assert its constitutional authority over international trade to block this danger to domestic high-technology industries.