# NC vs Tays KM

## 1

#### Biotech industry strong now., Cancherini et al. 21

[(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 [recut Lynbrook MD]

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, 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 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 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 [recut Lynbrook MD]

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 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 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 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 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### 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 [recut Lynbrook MD]

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.

## 2

#### US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages, Moore 20

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 [recut Lynbrook MD]

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 sciencesresearch 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 reducing IP protections doesn’t solve but it does give away national security info that allows China to lead ahead in biotech, Rogin 21

Josh Rogin 4-8. [(Washington Post Columnist covering National Security Issues.) 4-8-2021 “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 [recut Lynbrook MD]

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, Kuo 17

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 [recut Lynbrook MD]

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 technological 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.

## Case

#### COVID patent waivers don’t solve – technology transfer difficult, supplies limited due to US restrictions, and mRNA never produced at scale before

Tabarrok 21 Tabarrok, Alex. "Patents Are Not The Problem! - Marginal REVOLUTION." Marginal REVOLUTION. N.p., 2021. Web. 9 Aug. 2021. Alex Tabarrok is Bartley J. Madden Chair in Economics at the Mercatus Center and a professor of economics at George Mason University. Along with Tyler Cowen, he is the co-author of the popular economics blog Marginal Revolution and co-founder of Marginal Revolution University. He is the author of [numerous academic papers](https://mason.gmu.edu/~atabarro/TabarrokCV.pdf) in the fields of law and economics, criminology, regulatory policy, voting theory and other areas in political economy. He is co-author with Tyler of [Modern Principles of Economics](https://marginalrevolution.com/our-textbook), a widely used introductory textbook. He gave a [TED talk](https://www.ted.com/talks/alex_tabarrok_foresees_economic_growth) in 2009. His articles have appeared in the New York Times, the Washington Post, the Wall Street Journal, and many other publications.

For the last year and a half I have been shouting from the rooftops, “invest in capacity, build more factories, shore up the supply lines, spend billions to save trillions.” Fortunately, some [boffins in the Biden administration](https://twitter.com/AmbassadorTai/status/1390021205974003720?s=20) have found a better way, “the US supports the waiver of IP protections on COVID-19 vaccines to help end the pandemic.” Waive IP protections. So simple. Why didn’t I think of that??? Patents are not the problem. All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. Licenses are widely available. AstraZeneca have licensed their vaccine for production with [manufactures around the world](https://www.astrazeneca.com/what-science-can-do/topics/technologies/pushing-boundaries-to-deliver-covid-19-vaccine-accross-the-globe.html), including in India, Brazil, Mexico, Argentina, China and South Africa. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but technology transfer isn’t easy and there are [limited supplies of raw materials](https://endpts.com/as-fears-mount-over-jj-and-astrazeneca-novavax-enters-a-shaky-spotlight/): Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to transfer their technology there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country. [Plastic bags are a bigger bottleneck than patents](https://www.news18.com/news/opinion/single-use-plastic-bioreactor-bags-to-filters-why-india-needs-them-from-us-for-covid-vaccines-3681092.html). The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, [another potential mRNA vaccine](https://www.reuters.com/business/healthcare-pharmaceuticals/curevac-says-mass-vaccine-rollout-thrown-into-doubt-by-us-restrictions-2021-05-04/), is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As [Derek Lowe said](https://blogs.sciencemag.org/pipeline/archives/2021/04/22/a-look-at-novavax): Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a lot of potential choke points and rate-limiting steps in them, and there is no wand that will wave that complexity away. Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). Why do you think China hasn’t [yet produced](https://www.scmp.com/news/china/politics/article/3128998/revolutionary-mrna-vaccines-made-chinese-firms-will-be-ready) an mRNA vaccine? Hint: it isn’t fear about violating IP. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can. The US trade representative’s announcement is virtue signaling to the anti-market left and will do little to nothing to increase supply. What can we do to increase supply? Sorry, there is no quick and cheap solution. We must spend. Trump’s Operation Warp Speed spent on the order of $15 billion. If we want more, [we need to spend more and on similar scale](https://science.sciencemag.org/content/371/6534/1107). The Biden administration paid $269 million to Merck to retool its factories to make the J&J vaccine. That was a good start. We could also offer Pfizer and Moderna say $100 a dose to produce in excess of their current production and maybe with those resources there is more they could do. South Africa and India and every other country in the world should offer the same (India hasn’t even approved the Pfizer vaccine and they are complaining about IP!??) We should ease up on the DPA and invest more in the supply chain–let’s get CureVac and the Serum Institute what they need. We should work like hell to find a s[ubstitute for Chilean tree bark](https://www.theatlantic.com/science/archive/2020/10/single-tree-species-may-hold-key-coronavirus-vaccine/616792/). See [my piece in Science](https://science.sciencemag.org/content/371/6534/1107) co-authored with Michael Kremer et. al. for more ideas. (Note also that these ideas are better at dealing with current supply constraints and they also increase the incentive to produce future vaccines, unlike shortsighted patent abrogation.) Bottom line is that producing more takes real resources not waving magic patent wands. You may have gathered that I am angry. I am indeed angry that the people in power think they can solve real problems on the cheap and at someone else’s expense. This is not serious. I am also angry that they are sending the wrong message about business, profits and capitalism. So let me end on positive note. Like the Apollo program and Dunkirk, the creation of the mRNA vaccines by Pfizer and Moderna should be lauded with Nobel prizes and major movies. Churchill called the rescue at Dunkirk a “miracle of deliverance,” well the miracle of Moderna will rescue many more. Not only was a vaccine designed in under a year, an entirely new production process was set up to produce billions of doses to rescue the world. The creation of the mRNA vaccines was a triumph of science, logistics, and management and it was done at a speed that I had thought [possible only for past generations](https://patrickcollison.com/fast). I am grateful that greatness is still within our civilization’s grasp.

#### Turn – COVID waiver would lead to more vaccine skepticism, lower production, and energy taken away from other initiatives

Wilson 21 Wilson, Simon. Why Joe Biden’s Big Pharma patent grab is a terrible idea, Moneyweek.com. N.p., 2021. Web. 30 Aug. 2021. Simon Wilson is the head of Journalism Europe and Americas at BBC World Service.

What’s happened? Earlier this month the US surprised the global community – and stunned investors in drugs companies – by backing the temporary suspension of some globally agreed rules covering intellectual-property (IP) protections for Covid-19 vaccines. A waiver of World Trade Organisation (WTO) rules to help tackle the Covid-19-emergency was first proposed by India and South Africa last October, covering patents not just for vaccines, but also diagnostic tools and therapeutic treatments. Both countries have a large manufacturing sector making generic (off-patent) pharmaceuticals. The US is not signed up to a broader waiver of that kin, but its support for a narrower waiver on vaccine patents is a surprise. Why’s that? Because the US has a vast and powerful pharmaceutical sector and Washington has a long history of opposition to public-health measures that affect intellectual property rights. In 1996, it even threatened sanctions against Brazil for weakening patent laws to improve access to life-saving Aids drugs. Still, there’s no guarantee that a patent waiver – that is, a temporary suspension of certain rules set out in the WTO’s Trade-Related Aspects of Intellectual Property Rights (Trips) agreement – will actually happen. Until earlier this month, the idea had gained little traction, with the US, EU (notably Germany), UK and Japan all opposed. But US support makes it far more likely that some kind of waiver will be agreed. What’s the case for a waiver? The hope is that the waiver will encourage a wider and more geographically diverse production base, as well as encouraging international co-operation. And also that the prospect of a waiver will encourage pharmaceutical companies to enter into more voluntary arrangements and non-exclusive licensing to enable the transfer of technology in a controlled and transparent way. The lesson of the Aids pandemic is that patents “stymie accessible treatment, cost lives, and offer little bona fide enhancement of innovation”, says Laurie Garrett in Foreign Policy. What’s the case against? First, that waiving patents on Covid-19 vaccines would not actually speed up global production or get more shots into arms. Second, that doing so would have damaging long-term effects on future innovation. To take the first, it’s not IP issues that lie behind vaccine supply issues, it’s a range of factors including shortages of critical raw materials, a lack of production facilities and the technology and expertise to manufacture them. We know vaccine patents are not the bottleneck to making more vaccines because “there are no factories capable of producing Covid-19 vaccines sitting idle because they don’t have a patent”, says Matthew Lesh on CapX. Moderna announced last October that it would not be enforcing its own patents – yet there is no generic non-Moderna production. Why not? Because it’s too hard to copy given the obstacles. Pfizer’s vaccine, for example, requires 280 components from 86 suppliers in 19 countries, from glass vials to lipids to special plastics. And AstraZeneca, having established a global supply network with more than 20 partners across 15 countries, ran out of engineers qualified to transfer its technology. Moreover, waiving patents will increase competition for scarce ingredients, with the risk that less efficient and less expert manufacturers would hinder the ability of existing producers to ramp up capacity. And there’s an obvious issue with safety – and the knock-on effects on global confidence in Covid-vaccines as a whole. And the long-term consequences? Security of property rights underpins the whole pharmaceutical sector, which is driven by massive – and massively high-risk – upfront investment in research and development. Weakening or waiving those rights would inevitably discourage companies from investing in future innovation. That would make the world less safe and more vulnerable to the next pandemic threat – and could conceivably even disincentivise investment in pharmaceuticals more broadly. Biden’s “bewildering” support for this is “the single worst presidential economic decision since Nixon’s wage-and-price controls”, says The Wall Street Journal – destroying tens of billions of dollars in US intellectual property and surrendering America’s advantage in biotech, a key growth industry. Certainly, when the next pandemic hits, the world will want the pharmaceutical industry to once again “drop everything and work like hell to make vaccines”, says Tom Chivers on Unherd. “Maybe waiving IP rights will have no impact on their willingness to do that next time, but if there’s even a small chance that it will, it seems a bad bet.” Will it happen? Any agreement will need the backing of all 164 WTO members, and will take weeks or months to secure. Meanwhile, many poor countries have jabbed less than 1% of their populations, 44% of vaccine doses have gone to Europe and North America, and Covid-19 is raging in south Asia and Latin America – and all the while new variants are raising the risk-level globally. Investors are worried about a fall in pharma profits, says The Economist, but the danger – in terms of both health and economy – is far broader than that. If protracted negotiations at the WTO “suck energy away from other initiatives to transfer technology and increase vaccine supplies, that would really be something to fear”. Far more useful than waiving patents, says The Washington Post, would be a concerted effort by Western governments to share their vaccine surpluses, and by Western pharma firms to strike more licensing deals and “share manufacturing know-how, experienced personnel, quality control methods, oversight and raw materials”.