## 1NC

#### I negate the resolution, resolved: The member states of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### First, I would like to offer a couple of definitions:

The World Trade Organization describes its purpose as

WTO, , "Overview: WTO," World Trade Organization, https://www.wto.org/english/thewto\_e/whatis\_e/wto\_dg\_stat\_e.htm

The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development. The WTO also provides a legal and institutional framework for the implementation and monitoring of these agreements, as well as for settling disputes arising from their interpretation and application. The current body of trade agreements comprising the WTO consists of 16 different multilateral agreements (to which all WTO members are parties) and two different plurilateral agreements (to which only some WTO members are parties).

Trevor Brewer, a business lawyer specializing in regulations and transactions, writes in May 2019 that

Trevor Brewer, 5-16-2019, "What Are The 4 Types of Intellectual Property Rights?," BrewerLong, https://brewerlong.com/information/business-law/four-types-of-intellectual-property/SJKS

There are four types of intellectual property rights and protections (although multiple types of intellectual property itself). Securing the correct protection for your property is important, which is why consulting with a lawyer is a must. The four categories of intellectual property protections include: TRADE SECRETS Trade secrets refer to specific, private information that is important to a business because it gives the business a competitive advantage in its marketplace. If a trade secret is acquired by another company, it could harm the original holder. Examples of trade secrets include recipes for certain foods and beverages (like Mrs. Fields’ cookies or Sprite), new inventions, software, processes, and even different marketing strategies. When a person or business holds a trade secret protection, others cannot copy or steal the idea. In order to establish information as a “trade secret,” and to incur the legal protections associated with trade secrets, businesses must actively behave in a manner that demonstrates their desire to protect the information. [Trade secrets are protected *without* official registration](https://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm); however, an owner of a trade secret whose rights are breached–i.e. someone steals their trade secret–may ask a court to ask against that individual and prevent them from using the trade secret. PATENTS As defined by the [U.S. Patent and Trademark Office](https://www.uspto.gov/help/patent-help#patents) (USPTO), a patent is a type of limited-duration protection that can be used to protect inventions (or discoveries) that are new, non-obvious, and useful, such as a new process, machine, article of manufacture, or composition of matter. When a property owner holds a patent, others are prevented, under law, from offering for sale, making, or using the product. COPYRIGHTS Copyrights and patents are not the same things, although they are often confused. A copyright is a type of intellectual property protection that protects original works of authorship, which might include literary works, music, art, and more. Today, copyrights also protect computer software and architecture. Copyright protections are automatic; once you create something, it is yours. However, if your rights under copyright protections are infringed and you wish to file a lawsuit, then registration of your copyright will be necessary. TRADEMARKS Finally, the fourth type of intellectual property protection is a trademark protection. Remember, patents are used to protect inventions and discoveries and copyrights are used to protect expressions of ideas and creations, like art and writing. Trademarks, then, refer to phrases, words, or symbols that distinguish the source of a product or services of one party from another. For example, the Nike symbol–which nearly all could easily recognize and identify–is a type of trademark. While patents and copyrights can expire, trademark rights come from the use of the trademark, and therefore can be held indefinitely. Like a copyright, registration of a trademark is not required, but registering can offer additional advantages.

### Framework

#### I value morality because the word ought in the resolution implies a moral obligation.

#### Thus, the value criterion must be maximizing well-being for everyone.

#### There are two main reasons for this:

#### Everyone does not like painful or emotionally harmful experiences, so naturally we should try to replace these things with good experiences.

#### Things like death and oppression are intuitively bad, and effect everyone, so we should try to prevent them.

#### In summary, if I can prove to you that reducing IP protections would have a bad impact on the world, then you should vote for the negative in today’s debate.

### 1NC – Biotech DA

#### 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. Expend iture 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 i n 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 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 i CarbonX 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 de sign, malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.

**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

#### China's winning the bilateral vaccine diplomacy race now---countries such as the US are focusing on domestic distribution, and others such as India are donating vaccines mostly through multilateral channels.

**Merelli 21**, Annalisa. "Vaccines Are The Hottest New Way To Establish Global Influence." Quartz. April 02, 2021. Web. August 17, 2021. <https://qz.com/1991486/is-china-winning-the- vaccine-diplomacy-game/>.

China’s shot of soft power Vaccine diplomacy is a touchy subject. While countries—much like pharmaceutical companies—would undoubtedly like to reap the soft power benefits of helping other nations end the pandemic, admitting as much defies the purpose. This explains why, for instance, India isn’t talking about vaccine diplomacy, but “Vaccine Maitri” (vaccine friendship) to describe its program to donate 22 million doses of Covishield—the Indian version of the AstraZeneca vaccine—to developing countries. China went a step beyond, outright rejecting the “sinister” notion that it would exploit vaccine distribution to strengthen its global influence. “In advancing anti-epidemic cooperation, China has never pursued any geopolitical goals, has no economic calculations, and has never attached any political conditions,” reads a state-run press agency‘s report. China may not be openly participating in the vaccine diplomacy race, but it is winning it anyway. The country—which has so far manufactured about 170 million doses, the most in the world—has donated vaccines to 53 nations, and exported them to 27. Russia follows, with bilateral agreements to donate and export its Sputnik vaccine to 37 countries. India, too, stands as a major player in Covid-19 vaccine diplomacy, although with a difference: Of the 76 countries the India-made vaccine has reached, the vast majority are part of the Covax program, so they are receiving the vaccine through international cooperation. Only a handful of countries in the region (Nepal, Afghanistan) are getting shots directly donated by India. Wealthy western countries stand significantly behind, as they remain focused primarily on ensuring immunity to their own populations first. European countries are major money donors to Covax, but haven’t so far distinguished themselves in bilateral donations—quite the opposite. As EU countries struggle with procurement and vaccine rollouts at home, they’ve resorted to canceling exports. Italy, for example, blocked shipments of AstraZeneca doses to Australia. Perhaps the main indication of China’s leadership in vaccine diplomacy is others’ attempts to catch up. Last month, the US, Japan, India, and Australia agreed to fund the production and delivery of vaccines in Asia—where the Chinese vaccine is already being delivered to 10 countries—despite the fact that other parts of the world might be in greater need.

### Contention 2 is Innovation

#### Intellectual Property is the backbone of innovation, but the affirmatives removal of IP destroys it.

Pier DeRoo, from the University of Michigan Law School, writes in 2011

Pier DeRoo (J.D. Candidate 2011, University of Michigan Law School; A.B. 2006, Chemistry, Princeton University). “Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Go Pharmaceutical Drugs in Government Health Car ernment Health Care Programs.” Michigan Journal of International Law, vol. 32, issue 2. 2011. JDN. https://repository.law.umich.edu/mjil/vol32/iss2/3/

B. The Pharmaceutical Development Outlook

Government health care programs, however, when combined with compulsory licensing and important pharmaceutical markets, represent a corresponding threat to the current R&D infrastructure of drug development, which is funded both by purchasers of pharmaceutical products and by taxpayers via public research entities. With **only one of every 5,000**-10,000 **tested compounds** reaching the market and taking an average of **11**.8 **years to get there**, drug R&D investment requires a high risk premium. Although the exact amount is disputed, current estimates to develop an innovative, new molecular entity drug range from $802-$868 million, and costs continue to rise. o0 Pharmaceutical development is also far from a purely private enterprise, with the NIH annually spending over $31 billion in taxpayer dollars in basic medical research, which supports downstream drug development by the pharmaceutical industry.'o4 R&D therefore usually targets drugs that have an expected return high enough to generate substantial profit and fund subsequent R&D. Because R&D investment decisions are guided by the expected economic return for a particular line of research, **palatability of risk is proportional to the magnitude of the expected returns.**'" Assuming that research into risky, unexplored areas of health is desirable, low expected returns, whether due to a small market for a particular drug or weakened patent exclusivity rights as a result of **compulsory licensing**, may chill such R&D. After a pharmaceutical drug runs the gamut of patenting, clinical trials, and regulatory approval procedures, the patent specification and a wealth of safety and efficacy data are available to the public, resulting in **serious appropriability concerns.**' In the absence of strong patent protection and regulatory data exclusivity, generic producers are able to rapidly reverse-engineer drugs, obtain regulatory approval by relying on the patent holder's safety and efficacy data, and sell the generic version on a competitive market against the innovative firm that incurred the stratospheric R&D and original regulatory approval costs.0o Without such protection, the innovative pharmaceutical developer could expect little return on investment, and private R&D would dissipate. Indeed, pharmaceutical appropriability in India resulted in a commodified Indian pharmaceutical market devoid of R&D. In the Indian Patents Act of 1970, India abolished pharmaceutical compound patentability in favor of short seven-year pharmaceutical production-process patents, creating incentives to devise increasingly efficient production processes while permitting any manufacturer to produce the pharmaceutical compound itself.'" Drug **firms flooded the market** as the number of licensed manufacturers grew from 2,237 enterprises in 1969-70 to an estimated 16,000 by 1992-93, illustrating that barriers to entry into the pharmaceutical market were not onerous. Profitability predictably plunged over that period, reducing R&D expenditures from 15.5% of sales prior to the 1970 Patents Act to a **mere 1.4%** in 1992-93 because of comparative declines in expected returns on R&D investment due to the absence of exclusivity for drug compounds.'" 1.4% does not fund much R&D: India has become the world's leading generic pharmaceutical producer, but contributes little to the development of new pharmaceutical medicines."2 The most powerful developing countries followed India in prohibiting patent protection for pharmaceuticals. Between 1971 and 1996, Brazil prohibited patents for both pharmaceutical products and processes."' Mexico and Argentina had similarly lowered pharmaceutical patent protection prior to TRIPS." 4 As a result, today only a handful of developed countries have a sufficiently sophisticated pharmaceutical industry and research base to conduct complex R&D. Compulsory licensing, if widely used as an escape-hatch from patent protection, presents a potential threat to continued research by relegating innovative producers to a level playing field with generic producers.' Once a compulsory license is granted, licensees simply have to send a royalty check to the patent holder.7 These royalty payments are uniformly puny. For example, Indonesia offered a mere **0.5%** royalty on the generic sale price for its HIV/AIDS compulsory licenses,"' Zambia offered 2.5%,"' and Mozambique offered 2%.120 Meanwhile, Thailand has offered 0.5% to 2.0%.121 The pharmaceutical market has already encountered the likely bleak effects of widespread compulsory licensing and its low royalty rates. The post-1970 Indian pharmaceutical industry demonstrated that extremely low margins do not incentivize R&D.122 In a similar vein, the Egyptian pharmaceutical industry is currently discovering that its cost-plus pricesetting system, using the costs of ingredients as the benchmark, establishes a profit ceiling that acts as a de facto limit on R&D expenditures.123 Limiting economic returns on pharmaceutical R&D through abusive compulsory licensing, especially if in one or more of the few countries with innovative pharmaceutical industries,'2 **therefore poses a threat to continued R&D** into unexplored areas of medicine.

#### Pharmaceutical innovation is key to stop bioterrorism and antimicrobial resistance

Carolina Feijao, a Ph.D in biochemistry from the University of Cambridge, writes in 2020

Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism con-text.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 compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives.

This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic.

In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6

The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10

Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror and biotechnology are the largest medical threat—only generating innovative drugs can prevent millions from death

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

Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a mistake to underestimate the threats from natural pathogens. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology to cause harm on a staggering scale, by either cruelty or carelessness.

Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts.

The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with no attention to maintaining or improving traits that enhance fitness in other environments.

If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of an especially persistent horde of 5-year-olds, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time.

By contrast, modern biologists are gaining the ability to see the whole field, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens poses serious concerns.

It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist.

It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about 23 are known or suspected to have maintained biological weapons programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ vulnerability to biological threats, has done little to mitigate this danger.

Accidental releases pose an additional source of anthropogenic biorisk. Thanks to the U.S. government’s monitoring program, we know that dozens of agents and toxins with the potential to pose a severe threat to public health and agriculture are reported accidentally lost or released from U.S. labs every year. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength.

Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing.

Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.

**Cross apply bioterror impact card**