### 1 - China-Biotech DA v2 (1:45)

#### The US leads and will continue to dominate biotech unless we do something truly stupid, like give China our cutting-edge, dual-use mRNA research

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It was supposed to be China’s moment of technological triumph—one that would show the world Beijing had not only conquered the coronavirus but also emerged as a biotechnology superpower. But when clinical data on China’s flagship CoronaVac vaccine finally flowed in, they showed it was barely more than 50 percent effective—just clearing the minimum standard set by the World Health Organization. In contrast, not one but two vaccines developed by U.S. firms have been found to be upward of 95 percent effective, a standard no other country’s vaccines have yet met in rigorous clinical trials. The United States’s overall track record in responding to the pandemic has been awful. Yet the success of its vaccine development efforts shows that when it comes to biotechnology, the industry of the future, the U.S. is way ahead of China and most of its other rivals. A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing. Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons. That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or products.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness. Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners. For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization. Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation. At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector. The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science. Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come. When it comes to biotechnology, the industry of the future, the U.S. remains well ahead of its rivals, including China. That’s something Americans can, and should, take pride in. But the U.S. must make proactive investments and undertake significant reforms now to ensure that things stay that way.

#### WTO weakening IPR would give China our cutting-edge, dual-use mRNA research

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David Lawder, Andrea Shalal, Carl O’Donnell, Reuters, U.S. wants COVID vaccine patent waiver to benefit world, not boost China biotech. May 8, 2021. <https://www.reuters.com/world/china/us-wants-covid-vaccine-patent-waiver-benefit-world-not-boost-china-biotech-2021-05-08/> -CAT

The Biden administration is examining ways to ensure that a waiver of COVID-19 vaccine patents to aid poor countries will not hand sensitive U.S. biopharmaceutical technology to China and Russia, responding to a chorus of concerns, U.S. and industry officials say. President Joe Biden on Wednesday backed the U.S. entering negotiations at the World Trade Organization for the waiver of intellectual property rights as a means to boost vaccine supplies by allowing poorer countries to make their own. So far, vaccines have gone overwhelmingly to richer nations, which scooped up contracts for them earlier this year. COVID-19 infection rates in wealthy countries have dropped as vaccination rates increased this year, but infections are still rising in 36 countries, with India’s daily cases skyrocketing to nearly 400,000 a day. Western pharmaceutical companies, many of which have received government support to develop vaccines, strongly oppose the transfer of intellectual property to make them. They say poorer countries will be slow to set up manufacturing capacity and compete for scarce supplies, hitting production. Albert Bourla, CEO of Pfizer Inc, said on Friday that the proposed waiver would disrupt progress made so far in boosting vaccine supplies. “It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine. Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk.” Many companies and now some U.S. officials fear the move would allow China to leapfrog years of research and erode the U.S. advantage in biopharmaceuticals. A senior Biden administration official said that while the priority is saving lives, the United States "would want to examine the effect of a waiver on China and Russia before it went into effect to ensure that it's fit for purpose." A question and answer document produced by the administration and shared with industry representatives also acknowledges concerns that intellectual property sharing could damage the United States's competitive advantage over China, an industry source familiar with the discussions told Reuters. The contents of the document read to a Reuters reporter by an industry representative said the Biden administration believes it can address those concerns through the WTO negotiations, but did not specify how. The source added that some agencies in the Biden administration have conflicting views of how to address the concerns in negotiations that are expected to take months. Spokespersons at the White House and U.S. Trade Representative's office had no immediate comment on the matter. Pfizer and Moderna spokespersons did not respond to requests for comment on technology transfer concerns, while a Novavax spokesperson referred Reuters to the company's statement opposing the waiver on Friday, which said proposals to "weaken intellectual property protections would not achieve equitable vaccine access." Enforcing limits on use of the technology could be very difficult, once handed over, some analysts say. Messenger RNA, used in COVID-19 vaccines by leaders Pfizer/BioNTech and Moderna, is a newly developed biotechnology that holds promise for treatments far beyond vaccines. China and Russia have their own vaccines that do not use this biotechnology. "It took Pfizer and Moderna years and years of research to develop these vaccines," said Gary Locke a former U.S. ambassador to China and U.S. Commerce Secretary. "China, Russia, India, South Africa and others want to gain access. Their intention is to get the underlying know-how so they can use it to develop further vaccines," Locke said. China's Fosun Pharma has struck a deal with BioNTech on COVID-19 vaccine product development, which would potentially give it access to some of the technology. China has high ambitions for its pharma industry and already is developing its own mRNA vaccine. Patents themselves are publicly accessible, noted James Pooley, intellectual property attorney and former deputy director general of the United Nations' World Intellectual Property Organization. But trade secrets developed by Pfizer/BioNTech, Moderna and others, "cook books" of manufacturing processes such as temperature and growing conditions, have not been made public. That may ultimately be a dual problem for negotiators. Before they protect the knowledge, U.S. officials would have to ensure access to it. Those companies would need to be persuaded to come to the bargaining table to give up such trade secrets. “What happens when it turns out that the U.S. can’t actually deliver the information that is critically important to implementing the inventions?” Pooley asked. “This will be seen as another failure by the U.S. and other rich countries to keep their promises.”

#### China already has a terrifying biosurveillance infrastructure that could supply the raw data for novel bioweapons

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The certainty that China will play an increasingly important role in the global biotechnology sector poses several issues for U.S. policymakers. The gravest of these pertain to national security. Though there is presently no sign that China’s capabilities exceed those of the United States, some researchers have noted that biotechnology is a focus of increasing attention GLOBAL CHINA CHINA’S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY TECHNOLOGY 5 by the People’s Liberation Army.42 U.S. policymakers and security analysts have also raised concerns that the dominant market position of Chinese firms in producing active pharmaceutical ingredients might allow Beijing to disrupt U.S. access to lifesaving drugs in the event of a conflict.43 On the other hand, the use of tools like CRISPR, which is increasingly inexpensive and easy to use, by terrorists and non-state actors to potentially create novel bioweapons poses severe security threats to both the United States and China. It would seem to be in the interest of all states, including China, to strengthen efforts, currently led mostly by the private sector, to prevent dangerous actors from gaining access to DNA templates and other relevant materials.44 Though these prospects are alarming, the theft and use of biomedical data presents more immediate policy concerns. American life sciences research institutions have been subject to what U.S. officials characterize as prolific intellectual property theft and non-traditional intelligence collection by Chinese actors.45 At home, Beijing has already incorporated biometric data on certain populations, such as the Uighur minority group, into its already-formidable social control and surveillance apparatus.46 Chinese actors also appear to have targeted foreign citizens for covert biomedical data collection.47 Last year, the U.S. government forced a Chinese firm to sell its majority stake in an American social network that aggregates health care data from users, primarily over worries this information could be used to persuade Americans with access to sensitive information to spy for China.48 Such added U.S. government scrutiny has contributed to a sharp decline in Chinese investment in the U.S. biotechnology sector. Though small overall, such investment had been growing rapidly, and in 2018 the biotechnology sector constituted the single largest source of Chinese investment in the U.S. overall, surpassing real estate.49 As this impact suggests, access to and control over biomedical data also has profound implications for the economic competitiveness of the U.S. biotechnology sector. Many frontier areas of biotechnology, including the use of artificial intelligence for biomedical applications, depend on access to large quantities of individual patient data. Chinese biotechnology firms are likely to have access to larger quantities of such data than their competitors elsewhere thanks to the size of China’s population and relatively weak rules governing data collection and sharing. An existing biomedical database of patients from China’s national health care system, for example, allegedly covers some 600 million patients.50 The Chinese government is moreover increasingly aggressive about preventing foreign firms and organizations from accessing such data. In 2016, biomedical data was proclaimed a “national strategic resource,”51 and the export of such data is strictly controlled. Rules specifically bar any foreign use of Chinese biomedical data that “may jeopardize national security, national interests, or public security,” and in 2018 these were used to shut down several high-profile scientific collaborations including one involving Peking University and the University of Oxford.52 It should be noted, however, that while data quantity is important, so is data quality, and a combination of poor and inconsistent record-keeping and limited population diversity may diminish the utility of biomedical data produced in China for key applications like therapeutics development.53 In any case, the availability of biomedical datasets will be a key determinant of the relative competitiveness of the U.S. and Chinese biotechnology industries going forward. A final, and more hopeful, policy implication of China’s growing role in biotechnology is its potential to help address shared global challenges like infectious disease prevention and biodiversity protection. In the near term, the COVID-19 crisis has highlighted the need for expanded international cooperation on epidemiological data collection and analysis, vaccine development, and other areas related to biotechnology. While China’s openness to such cooperation at the moment is unclear, there are likely to be future opportunities to engage China in COVID-19 tracing, vaccine development, and deployment initiatives in third countries, especially in the less-developed world. In the longer term, synthetic biology, especially the use of gene drives to rapidly spread genetic modifications throughout a population, offers great promise to eliminate insect-borne diseases like malaria, and could also help endangered species adapt to climate change effects. As the 21st century advances, advanced biotechnology will both demand new forms GLOBAL CHINA CHINA’S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY TECHNOLOGY 6 of global governance and present new arenas for both competition and cooperation between researchers, business leaders, and policymakers.

#### State-created bioweapons uniquely risk extinction in the hands of bioterrorists.

Millett & Snyder-Beattie ‘17. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed -CAT

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 biotechnology 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 mutually assured destruction 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 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32 What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, even with the most conservative models, we find that reduction of low-probability, high-consequence risks can be more cost-effective, as measured by quality-adjusted life year per dollar, especially when we account for the lives of future generations. This suggests that despite the low probability of such events, society still ought to invest more in preventing the most extreme possible biosecurity catastrophes.

### 2 - Business Confidence DA v2

#### Biotech innovation is high now and K2 solving warming but reducing IP protections decks investor confidence and multinational collaboration in biotech.

Brand 21, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid –recut CAT

The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensation and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels**.**

#### **Reducing IP protections chills future investment – even the perception of wavering commitment scares off companies.**

Grabowski et al. ’15 (Harry; Professor Emeritus of Economics at Duke, and a specialist in the intersection of the pharmaceutical industry and government regulation of business; February 2015; “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation”; Health Affairs; <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>; Accessed: 8-31-2021; AU)

Patents and other forms of **intellectual property** **protection** play **essential roles** in encouraging innovation in biopharmaceuticals. As part of the “21st Century Cures” initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand. We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting. We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances. Technological innovation is widely recognized as a key determinant of economic and public health progress. 1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is **long, costly, and risky**, and the costs of imitation are low. After a new drug has been approved and is being marketed, its **patents protect it** from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. **For firms** to have an **incentive** to **continue to invest** in innovative development efforts, they must have an **expectation** that they can **charge enough** during this period to **recoup** costs and make a profit. After a drug’s patent or patents expire, **generic rivals** can enter the market at **greatly reduced development cost** and prices, providing added consumer benefit but **eroding** the **innovator drug** company’s revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug’s marketing exclusivity while providing a regulatory framework for generic drug approval. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases. Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the “21st Century Cures” initiative, 3 following earlier recommendations by the President’s Council of Advisors on Science and Technology on responding to challenges in “propelling innovation in drug discovery, development, and evaluation.” 4 In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. We also review the R&D incentives that complement patents in certain circumstances. Finally, we consider the pros and cons of selected voluntary (“opt-in”) or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition. The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection **particularly important** to **innovation incentives** for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a **billion** dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the **few successful, on-market products** (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections** that allow marketing exclusivity, innovative firms would be **unlikely** to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, **they do not guarantee demand**, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an **essential role** in the economic “ecosystem” of **discovery and investment** that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### Carbon capture K2 solving warming

McKie 21

Robin McKie, Robin McKie is science and environment editor for the Observer, Carbon capture is vital to meeting climate goals, scientists tell green critics. The Guardian. Jan 16, 2021. <https://www.theguardian.com/environment/2021/jan/16/carbon-capture-vital-meeting-climate-goals-scientists-cut-emissions> -CAT

Engineers and geologists have strongly criticised green groups who last week claimed that carbon capture and storage schemes – for reducing fossil fuel emissions – are costly mistakes. The scientists insisted that such schemes are vital weapons in the battle against global heating and warn that failure to set up ways to trap carbon dioxide and store it underground would make it almost impossible to hold net emissions to below zero by 2050. “Carbon capture and storage is going to be the only effective way we have in the short term to prevent our steel industry, cement manufacture and many other processes from continuing to pour emissions into the atmosphere,” said Professor Stuart Haszeldine, of Edinburgh University. “If we are to have any hope of keeping global temperature [increases] down below 2 degrees C then we desperately need to develop ways to capture and store carbon dioxide.” Carbon capture and storage involves the extraction of emissions from power plants and factories, condensing them and then pumping the resulting carbon dioxide into underground stores. Britain is considered to be well placed to develop and operate such technology given its many depleted North Sea oil fields where this sequestrated carbon dioxide could be stored. Several CCS development programmes have been launched over the past 20 years but have been cancelled as governments have vacillated over funding. However, Boris Johnson – as part of his commitment to fight climate change – has pledged £1bn of public funds to help develop four major CCS schemes in Britain by 2030 as part of his plan for a “green industrial revolution”. The aim is to make the UK a “world leader” in the technology and create thousands of jobs. But campaigners at Global Witness and Friends of the Earth Scotland said last week that a reliance on CCS was not a reliable way to decarbonise the energy system, and published a paper last Monday from the Tyndall Manchester climate change research centre that they said proved that CCS has a “history of over-promising and under-delivering”. Both groups claimed CCS would not make “a meaningful contribution to 2030 climate targets” despite the investment, and instead urged the construction of more renewable energy plants to be given priority. But the claims were last week dismissed by engineers and geologists. “These claims are quite unfair,” said Michael Stephenson, director of science and technology at the British Geological Survey. “The science behind carbon capture and storage is extremely good. It offers us a genuine solution to some of the problems we face in trying to tackle global warming.” At present, most successes in reducing UK carbon emissions have come from the power industry where renewable energy sources have taken over electricity generation from coal, gas and oil plants. However, some industries – such as steel and cement industries – emit vast amounts of carbon dioxide on top of those produced by generating the power they consume. It will be much more difficult to bring down carbon emissions from these plants even though these industries are vital to the UK’s economic strength. This point was stressed by Haszeldine. “When CCS was first touted, it was seen as a way of cleaning up electricity generated by fossil fuels, in particular those burning coal. But now it is clear it can play a key role in cleaning up other industries. “We just need to push ahead with its development so that Britain can find ways of removing carbon dioxide from the atmosphere. The longer we delay then the worst things are going to be and claims that CCS will not work do not help.” Bob Ward, policy director at the Grantham Research Institute on Climate Change and the Environment, was also critical of the green groups’ claims. “The opposition to CCS technology from some campaigners seems driven by a hatred of fossil fuel companies that is preventing a level-headed understanding of how we can stop climate change,” he told the Observer. “Together with dithering policymakers, they share responsibility for stopping the UK from leading a global effort to develop this technology.”

#### Warming causes Extinction

Kareiva 18, Peter, and Valerie Carranza. "Existential risk due to ecosystem collapse: Nature strikes back." Futures 102 (2018): 39-50. (Ph.D. in ecology and applied mathematics from Cornell University, director of the Institute of the Environment and Sustainability at UCLA, Pritzker Distinguished Professor in Environment & Sustainability at UCLA)//Re-cut by Elmer

In summary, six of the nine proposed planetary boundaries (phosphorous, nitrogen, biodiversity, land use, atmospheric aerosol loading, and chemical pollution) are unlikely to be associated with existential risks. They all correspond to a degraded environment, but in our assessment do not represent existential risks. However, the three remaining boundaries (**climate change**, global **freshwater** cycle, **and** ocean **acidification**) do **pose existential risks**. This is **because of** intrinsic **positive feedback loops**, substantial lag times between system change and experiencing the consequences of that change, and the fact these different boundaries interact with one another in ways that yield surprises. In addition, climate, freshwater, and ocean acidification are all **directly connected to** the provision of **food and water**, and **shortages** of food and water can **create conflict** and social unrest. Climate change has a long history of disrupting civilizations and sometimes precipitating the collapse of cultures or mass emigrations (McMichael, 2017). For example, the 12th century drought in the North American Southwest is held responsible for the collapse of the Anasazi pueblo culture. More recently, the infamous potato famine of 1846–1849 and the large migration of Irish to the U.S. can be traced to a combination of factors, one of which was climate. Specifically, 1846 was an unusually warm and moist year in Ireland, providing the climatic conditions favorable to the fungus that caused the potato blight. As is so often the case, poor government had a role as well—as the British government forbade the import of grains from outside Britain (imports that could have helped to redress the ravaged potato yields). Climate change intersects with freshwater resources because it is expected to exacerbate drought and water scarcity, as well as flooding. Climate change can even impair water quality because it is associated with heavy rains that overwhelm sewage treatment facilities, or because it results in higher concentrations of pollutants in groundwater as a result of enhanced evaporation and reduced groundwater recharge. **Ample clean water** is not a luxury—it **is essential for human survival**. Consequently, cities, regions and nations that lack clean freshwater are vulnerable to social disruption and disease. Finally, ocean acidification is linked to climate change because it is driven by CO2 emissions just as global warming is. With close to 20% of the world’s protein coming from oceans (FAO, 2016), the potential for severe impacts due to acidification is obvious. Less obvious, but perhaps more insidious, is the interaction between climate change and the loss of oyster and coral reefs due to acidification. Acidification is known to interfere with oyster reef building and coral reefs. Climate change also increases storm frequency and severity. Coral reefs and oyster reefs provide protection from storm surge because they reduce wave energy (Spalding et al., 2014). If these reefs are lost due to acidification at the same time as storms become more severe and sea level rises, coastal communities will be exposed to unprecedented storm surge—and may be ravaged by recurrent storms. A key feature of the risk associated with climate change is that mean annual temperature and mean annual rainfall are not the variables of interest. Rather it is extreme episodic events that place nations and entire regions of the world at risk. These extreme events are by definition “rare” (once every hundred years), and changes in their likelihood are challenging to detect because of their rarity, but are exactly the manifestations of climate change that we must get better at anticipating (Diffenbaugh et al., 2017). Society will have a hard time responding to shorter intervals between rare extreme events because in the lifespan of an individual human, a person might experience as few as two or three extreme events. How likely is it that you would notice a change in the interval between events that are separated by decades, especially given that the interval is not regular but varies stochastically? A concrete example of this dilemma can be found in the past and expected future changes in storm-related flooding of New York City. The highly disruptive flooding of New York City associated with Hurricane Sandy represented a flood height that occurred once every 500 years in the 18th century, and that occurs now once every 25 years, but is expected to occur once every 5 years by 2050 (Garner et al., 2017). This change in frequency of extreme floods has profound implications for the measures New York City should take to protect its infrastructure and its population, yet because of the stochastic nature of such events, this shift in flood frequency is an elevated risk that will go unnoticed by most people. 4. The combination of positive feedback loops and societal inertia is fertile ground for global environmental catastrophes **Humans** are remarkably ingenious, and **have adapted** to crises **throughout** their **history**. Our doom has been repeatedly predicted, only to be averted by innovation (Ridley, 2011). **However**, the many stories of human ingenuity **successfully** **addressing** **existential risks** such as global famine or extreme air pollution **represent** environmental **challenges that are** largely **linear**, have immediate consequences, **and operate without positive feedbacks**. For example, the fact that food is in short supply does not increase the rate at which humans consume food—thereby increasing the shortage. Similarly, massive air pollution episodes such as the London fog of 1952 that killed 12,000 people did not make future air pollution events more likely. In fact it was just the opposite—the London fog sent such a clear message that Britain quickly enacted pollution control measures (Stradling, 2016). Food shortages, air pollution, water pollution, etc. send immediate signals to society of harm, which then trigger a negative feedback of society seeking to reduce the harm. In contrast, today’s great environmental crisis of climate change may cause some harm but there are generally long time delays between rising CO2 concentrations and damage to humans. The consequence of these delays are an absence of urgency; thus although 70% of Americans believe global warming is happening, only 40% think it will harm them (http://climatecommunication.yale.edu/visualizations-data/ycom-us-2016/). Secondly, unlike past environmental challenges, **the Earth’s climate system is rife with positive feedback loops**. In particular, as CO2 increases and the climate warms, that **very warming can cause more CO2 release** which further increases global warming, and then more CO2, and so on. Table 2 summarizes the best documented positive feedback loops for the Earth’s climate system. These feedbacks can be neatly categorized into carbon cycle, biogeochemical, biogeophysical, cloud, ice-albedo, and water vapor feedbacks. As important as it is to understand these feedbacks individually, it is even more essential to study the interactive nature of these feedbacks. Modeling studies show that when interactions among feedback loops are included, uncertainty increases dramatically and there is a heightened potential for perturbations to be magnified (e.g., Cox, Betts, Jones, Spall, & Totterdell, 2000; Hajima, Tachiiri, Ito, & Kawamiya, 2014; Knutti & Rugenstein, 2015; Rosenfeld, Sherwood, Wood, & Donner, 2014). This produces a wide range of future scenarios. Positive feedbacks in the carbon cycle involves the enhancement of future carbon contributions to the atmosphere due to some initial increase in atmospheric CO2. This happens because as CO2 accumulates, it reduces the efficiency in which oceans and terrestrial ecosystems sequester carbon, which in return feeds back to exacerbate climate change (Friedlingstein et al., 2001). Warming can also increase the rate at which organic matter decays and carbon is released into the atmosphere, thereby causing more warming (Melillo et al., 2017). Increases in food shortages and lack of water is also of major concern when biogeophysical feedback mechanisms perpetuate drought conditions. The underlying mechanism here is that losses in vegetation increases the surface albedo, which suppresses rainfall, and thus enhances future vegetation loss and more suppression of rainfall—thereby initiating or prolonging a drought (Chamey, Stone, & Quirk, 1975). To top it off, overgrazing depletes the soil, leading to augmented vegetation loss (Anderies, Janssen, & Walker, 2002). Climate change often also increases the risk of forest fires, as a result of higher temperatures and persistent drought conditions. The expectation is that **forest fires will become more frequent** and severe with climate warming and drought (Scholze, Knorr, Arnell, & Prentice, 2006), a trend for which we have already seen evidence (Allen et al., 2010). Tragically, the increased severity and risk of Southern California wildfires recently predicted by climate scientists (Jin et al., 2015), was realized in December 2017, with the largest fire in the history of California (the “Thomas fire” that burned 282,000 acres, https://www.vox.com/2017/12/27/16822180/thomas-fire-california-largest-wildfire). This **catastrophic fire** embodies the sorts of positive feedbacks and interacting factors that **could catch humanity off-guard and produce a** true **apocalyptic event.** Record-breaking rains produced an extraordinary flush of new vegetation, that then dried out as record heat waves and dry conditions took hold, coupled with stronger than normal winds, and ignition. Of course the record-fire released CO2 into the atmosphere, thereby contributing to future warming. Out of all types of feedbacks, water vapor and the ice-albedo feedbacks are the most clearly understood mechanisms. Losses in reflective snow and ice cover drive up surface temperatures, leading to even more melting of snow and ice cover—this is known as the ice-albedo feedback (Curry, Schramm, & Ebert, 1995). As snow and ice continue to melt at a more rapid pace, millions of people may be displaced by flooding risks as a consequence of sea level rise near coastal communities (Biermann & Boas, 2010; Myers, 2002; Nicholls et al., 2011). The water vapor feedback operates when warmer atmospheric conditions strengthen the saturation vapor pressure, which creates a warming effect given water vapor’s strong greenhouse gas properties (Manabe & Wetherald, 1967). Global warming tends to increase cloud formation because warmer temperatures lead to more evaporation of water into the atmosphere, and warmer temperature also allows the atmosphere to hold more water. The key question is whether this increase in clouds associated with global warming will result in a positive feedback loop (more warming) or a negative feedback loop (less warming). For decades, scientists have sought to answer this question and understand the net role clouds play in future climate projections (Schneider et al., 2017). Clouds are complex because they both have a cooling (reflecting incoming solar radiation) and warming (absorbing incoming solar radiation) effect (Lashof, DeAngelo, Saleska, & Harte, 1997). The type of cloud, altitude, and optical properties combine to determine how these countervailing effects balance out. Although still under debate, it appears that in most circumstances the cloud feedback is likely positive (Boucher et al., 2013). For example, models and observations show that increasing greenhouse gas concentrations reduces the low-level cloud fraction in the Northeast Pacific at decadal time scales. This then has a positive feedback effect and enhances climate warming since less solar radiation is reflected by the atmosphere (Clement, Burgman, & Norris, 2009). The key lesson from the long list of potentially positive feedbacks and their interactions is that **runaway climate change,** and runaway perturbations have to be taken as a serious possibility. Table 2 is just a snapshot of the type of feedbacks that have been identified (see Supplementary material for a more thorough explanation of positive feedback loops). However, this list is not exhaustive and the possibility of undiscovered positive feedbacks **portends** even greater **existential risks**. The many environmental crises humankind has previously averted (famine, ozone depletion, London fog, water pollution, etc.) were averted because of political will based on solid scientific understanding. We cannot count on complete scientific understanding when it comes to positive feedback loops and climate change.

#### [vs disease/pandemics]

#### Impact calc – sequencing. Warming causes the diseases the 1AC is afraid of – we must address first

Lustgarten 20 Abrahm Lustgarten 5-7-2020 "How Climate Change Is Contributing to Skyrocketing Rates of Infectious Disease" <https://www.propublica.org/article/climate-infectious-diseases> (Abrahm Lustgarten is an environmental reporter, with a focus at the intersection of business, climate and energy. He is currently covering changes at the U.S. Environmental Protection Agency, and working on a project about pollution at U.S. Defense sites.)//Elmer

The scientists who study how diseases emerge in a changing environment knew this moment was coming. Climate change is making outbreaks of disease more common and more dangerous. Over the past few decades, the number of emerging infectious diseases that spread to people — especially coronaviruses and other respiratory illnesses believed to have come from bats and birds — has skyrocketed. A new emerging disease surfaces five times a year. One study estimates that more than 3,200 strains of coronaviruses already exist among bats, awaiting an opportunity to jump to people. The diseases may have always been there, buried deep in wild and remote places out of reach of people. But until now, the planet’s natural defense systems were better at fighting them off. Today, climate warming is demolishing those defense systems, driving a catastrophic loss in biodiversity that, when coupled with reckless deforestation and aggressive conversion of wildland for economic development, pushes farms and people closer to the wild and opens the gates for the spread of disease.

### 3 - Extend IP/Donations (offsets) CP

#### CP: The WHO should extend TRIPS patent protection to 20 years and one month to fund and oversee compulsory drug donations to developing nations

Andreassen 14

TOM ANDREASSEN PATENT FUNDED ACCESS TO MEDICINES Tom Andreassen is Ph.D-candidate at the Programme for Applied Ethics at the Norwegian University of Science and Technology, Trondheim. The paper was for a large part written during a one-year period as Visiting Assistant in Research at Yale University’s Global Justice Program, New Haven Developing World Bioethics ISSN 1471-8731 (print); 1471-8847 (online) doi:10.1111/dewb.12058 Volume 15 Number 3 2015 pp 152–161 <https://onlinelibrary.wiley.com/doi/abs/10.1111/dewb.12058> -CAT

* Specific solvency mechanism and advocate in the five-point text

Incentive for Governments of Developing Countries A strategy that is not focused in the above proposals is to provide governments in developing countries, where the obligation to fulfill the human right to essential medicines indeed rests, with incentives to make stronger efforts to meet them. Incentives often seem to be associated with trade, not with the building of capacity to deliver necessary medical treatment to people. Respecting and promoting human rights in the Universal Declaration and the Covenants is an obligation of course for all the signatory parties, but as there is a lack of sanctions to enforce compliance, incentives to promote this are an option to consider. Irrespective of the extent to which the TRIPS induced IP protection makes essential drugs unattainable to the poorest, solutions could be sought that utilize the patent system in creating such incentives to promote access, even in the short term. The opportunity to be explored is how an extension of the patent period in certain cases, beyond the time sufficient to recover the inventor company’s expenses and to make for a decent profit, could create funding for free supplies of essential drugs to developing countries according to need and capacity. If such a step, which should be both technically and politically feasible, were to be taken, the developing countries themselves would have an incentive to look for solutions as to how the medicines and treatments could be distributed and delivered. For reasons thoroughly discussed by others,41 the flexibility provisions in TRIPS have not resulted in any significant improvement of access to drugs among poor populations. Parallel imports, one of the provisions, show no sign of taking on the proportions needed to accommodate the severely poor.42 One other flexibility provision in TRIPS, that of compulsory licensing has proven not to be effective despite the fact that it was reiterated by the WTO ministers at the Doha meeting.43 The voluntary donations made by the pharmaceutical industry are selective instead of comprehensive, thus these cannot secure the human right to basic health for the poor.44 If the donations could be systematized, however, they might come closer to filling that function. Systematic donation of medicines, financed through time-extended patents, could be included in TRIPS, since the Agreement is so closely associated with the current situation of lack of access due to high prices. 37 For some of these critical points, and others, see K. Liddell. The Health Impact Fund: a critique, in T. Pogge, M. Rimmer & K. Rubenstein eds. 2010. Incentives for Global Public Health. Cambridge: Cambridge University Press. Also J. Sonderholm. 2010. Intellectual Property Rights and the TRIPS Agreement. The World Bank Development Research Group: Policy Research Working Paper 5228, and Pogge et. al’s reply to Sonderholm in M. Peterson, A. Hollis & T. Pogge. A Critique in Need of Critique. Public Health Ethics 2009; 1–8. 38 R.V. Van Puymbroeck. op. cit. note 36, p. 526. 39 C.M. Correa. 2000. Intellectual Property Rights, the WTO and Developing Countries. London: Zed Books. P.51. 40 UNHCHR. 2001. The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. UN Commission on Human Rights. E/CN.4/Sub.2/2001/13. Art.62. The reference given is to Art. 15 of the International Covenant on Economic, Social and Cultural Rights. Art. 15 concerns the enjoyment, and also the protection, of scientific, cultural and artistic productions. 41 For example B.M. Hoekman and P.C. Mavroidis. WTO Dispute Settlement, Transparency and Surveillance. The World Economy 2000; 23(4): 527–542; Kohler, Lexchim, Kuek and Orbinski Canada’s Access to Medicines Regime: Promise or Failure of Humanitarian Effort? Healthcare Policy 2010; 5(3); and D. Matthews. WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: a Solution To the Access To Essential Medicines Problem? Journal of International Economic Law 2004; 7(1): 73–107. 42 C.M. Correa. 2002. Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Geneva: WHO: 17–18. 43 As explained in J.C. Kohler et al. 2010, see note 42. 44 See R.E. Ashcroft. Access to Essential Medicines: a Hobbesian Social Contract Approach. Dev World Bioeth 2005; 5(2): 126 on why ‘dependence on charitable benevolence was a poor tool of public policy’. 159 Tom Andreassen © 2014 John Wiley & Sons Ltd As noted above, the recuperation of the investments in a new medicine is largely realized in high cost markets. It is estimated that between 80 and 90 per cent of the sales of patented medicine occur in the OECD countries.45 This is where the recovery of costs in research and development takes place, and not in the developing countries. Jean O. Lanjouw and William Jack have pointed out that the developed countries already offered patents on pharmaceuticals before TRIPS, and that ‘the main result of the harmonization of standards required by TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries.’46 Lanjouw and Jack comments on the effect of extending the patent period: ‘Lengthening patent protection for a couple of weeks in rich countries, for example, could provide returns equivalent to the introduction of 20-year patents in the developing world.’47 This concerns then the compensation for lost sales in developing countries. Another matter is the cost of producing the needed drugs for free supply. Here it is significant that the patent holder will already have its own, or they have out-licensed, ongoing production. The cost of R&D, marketing and testing for approval, as well as setting up production, will be covered by the ordinary patent period and should therefore be kept outside the calculation of cost for the added production. Details need to be worked out regarding the calculation of the cost and the length of the extended patent period, and the companies will most likely need to accept an authorized auditing instrument verifying the data necessary for the calculations. The average effective sales protection is, as shown above, ten years. It is safe to assume that the extension needed for added production is a small fraction of that. Indeed it has been said by Harvey Bale, then the director general of the International Federation of Pharmaceutical Manufacturers Associations, that ‘Companies are able, through sales they make in developed countries, to offset the cost of donating drugs to poor countries.’48 Here we see a strong reason to keep the patent institute in place instead of weakening it. If surplus values generated by extended patent protection could be used to make the donations programs comprehensive, then the patent system, instead of cutting people off from access to essential medicines, actually would be the arrangement that made them accessible to people that could not even afford generic medicines. Lanjouw and Jack in fact concludes that certain medicines should be made available to the very poorest countries free of charge.49 An extended patent period would imply that the introduction of generic drugs and the price competition that follows from it would be slightly postponed. The cost for this, in that the price reduction is delayed in wealthier countries, would come as a result of expanded market protection through TRIPS and not from any new demands from patients in developing countries. They are cut off from generic medicines by the Agreement, a trait that needs to be addressed more actively by the Agreement itself. The criteria for triggering donations of drugs would, taken together, look similar to the rational justification for a compulsory license. They would be i. public noncommercial use or ii. The widespread outbreak of a disease in a WTO country. iii. The country itself has no production capacity or purchasing capacity to meet the need. iv. The country can show plans for distributing the medicines and treatment of patients. v. The first four criteria are confirmed by an independent body like the WTO itself, or more suitably the WHO. Regarding the fourth point, an auditing instrument might be necessary at this end also, assuring the accuracy of the receiving capacity. In TRIPS the compulsory licensing provision, which has not proven to be effective, should then be replaced by a requirement that patent protection is available in the WTO countries only under the condition that when the criteria are confirmed by WHO to prevail in any (WTO) country, the patentee is obliged to make the necessary drug donations.50 To compensate for the cost, an extension of the patent period is offered. The receiving country could not ask for more drugs than it can distribute and make effective use of. Focus would therefore shift to local conditions in the event that essential medicines do not reach where they are critically needed. Conditions that would need attention could be the host country’s distributive capacity, its allocation of 45 K. Outterson. op. cit, note 34. 46 J.O. Lanjouw & W. Jack. Trading Up: How Much Should Poor Countries Pay to Support Pharmaceutical Innovation? Center for Global Development November, 2004; 4(3): 5. Available at: http:// www.cgdev.org/publication/trading-how-much-should-poor-countriespay-support-pharmaceutical-innovation. [Accessed March 20, 2014]. 47 Ibid: 6. 48 Cited in K. Novak. The WTO’s balancing act. J Clin Invest November, 2003; 112(9): 1271. 49 J.O. Lanjouw & Jack, W. op. cit, note 46, p.6. 50 I have not discussed the issue of moral responsibilities of corporations here. Instead I am concerned with the duty policymakers have to respect human rights when making agreements and other policy decisions taking account of the problem of perfect duties. Dan W Brock describes it, somewhat dramatically, this way: ‘[I]t is widely held that our moral obligations to benefit others in the absence of any special relations are sharply limited’ (D.W. Brock. Some Questions About the Moral Responsibilities of Drug Companies in Developing Countries. Dev World Bioeth 2001; 1(1): 34. See also R.E. Ashcroft. op. cit. note 44. He frames it in terms of legitimacy of power. If it is true that the drug companies do not have special relations to the poor patients, the same could not be said of their political representatives, signing international agreements, as pointed out by Cullet in P. Cullet. Patents and Medicines: The Relationship Between TRIPS and the Human right to Health. Int Aff 2003; 79(1) (January): 140. Patent Funded Access Medicines 160 © 2014 John Wiley & Sons Ltd resources to meet an emergency and so forth.51 This access of free medicines would serve as an incentive for governments to provide infrastructure like electricity and clean water as argued by Novak, citing Ellen ‘t Hoen from Doctors Without Borders: ‘We have seen that in countries like Cameroon, Mozambique and Kenya that as the cost of drugs comes down, governments start to talk about infrastructure, and patient access to the drugs goes up.’52 The donated medicine would still be patented and adaptive measures should be built into the agreement to secure that such medicine will not flow into the wealthier markets. This would imply a revision of the parallel import article.53 In the event that the country where the emergency occurs is not capable or for other reasons is unready to receive donated medicine and distribute it, NGOs operating within its borders can act on behalf of national or regional athorities. The NGOs could hand in documentation on the quantity of medicine they are able to deliver to patients and function as the partner of the donation authority (WHO for example) in cases where national health authorities fail their obligation. The revised TRIPS would serve the interest of not only one party, i.e. society, but also the pharmaceutical industry, which would see a key reason for its poor reputation disappear. The main advantage for this industry would be the abolition of the threat of compulsory licenses and thereby the security and predictability of uninfringeable patents. The concern for intellectual property rights to essential medicines and the concern for the human right to access such medicine would be better balanced through a revision of TRIPS implying systematized and patent funded drug donations. The biggest gain that would result from the revision, however, might be the shift of focus mentioned above. The attention which has up until now been given to the pharmaceutical industry and the patent law in the WTO would give way to renewed attention to all those other factors that are making medicines inaccessible to the poor, thus providing incentives to their governments, their neighbors and the international institutions to build competence, health institutions and distribution capacity.

#### That straight turns the AFF

Rogin 21

(Josh Rogin, Washington Post Columnist on National Security, 4/8/21. “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)//HW-CC> -recut CAT

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.

### 4 - 1AR Theory Hedge

#### 1] No 1ar theory: [a] I only have one speech to respond which outweighs on infinite abuse because they can read any number of shells [b] aff frames the round means they pick neg ground and if the 1ar is hard, they should just write a better aff [c] 1ar restart, 4-6-3 time skew, infinite abuse. [d] No 3NR to address 2AR contextualization makes judge intervention inevitable as it comes down to whether the 2N coverage was “good enough”

#### 2] Use reasonability on 1ar theory – [a] Competing interps moots 7 mins of NC offense which outweighs minimal neg abuse. [b] Offense-defense disincentivizes substantive education by shifting the round from substance to a norm so their model prioritizes diminishing marginal skews over substance. That o/ws – the end goal of theory is better substantive debates.

#### 3] neg theory highest layer of the round a) framing of the round b) if the aff was abusive the neg is justified in responding

#### 4] Accept neg paradigm issues – otherwise they can put infinite spin on 1nc contextualization which means we never have good theory debates if we are disagreeing on the rules of the game. Leads to infinite theory debates, which kills the point of theory.