### Climate Patents DA

#### Climate Patents and Innovation high now and solving Warming but IPP waiver sets a dangerous precedent for appropriations - the mere threat is sufficient is enough to kill investment.

Brand 5-26, 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

The biotech industry is making remarkable advancestowards 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 proprietaryknow-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 internationalcollaborations. 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 investat the current and required levels**.**

#### Private sector innovation is key to solve climate change – short term politicking and priority shifts means government can’t solve alone.

Henry 17, Simon. “Climate Change Cannot Be Solved by Governments Alone. How Can the Private Sector Help?” World Economic Forum, 21 Nov. 2017, www.weforum.org/agenda/2017/11/governments-alone-cannot-halt-climate-change-what-can-private-sector-do/.  Programme Director, International Carbon Reduction & Offset Alliance (ICROA) //sid

Climate leadership is also an opportunity for many organizations, and this was the most popular reason for purchasing carbon credits in Ecosystem Marketplace’s [2016 survey of buyers](http://www.forest-trends.org/documents/files/doc_5677.pdf%5Bforest-trends.org%5D). Companies are looking to differentiate from their competitors, and build their brand, by taking a leadership role on climate. Offsetting plays an integral role in delivering this climate leadership status, alongside direct emissions reductions. The survey indicated that companies that included offsetting in their carbon management strategy typically spend about 10 times more on emissions reductions activities than the typical company that doesn’t offset.

Beyond these direct commercial reasons for companies to take voluntary action, there are many broader, societal motivations at play. Climate change is a global, multidecade challenge that needs solutions and input from all stakeholders. It transcends the short-term nature of politics, which will inevitably experience changes in priorities, personnel and knowledge. Because of this, climate change cannot be solved by governments alone. Instead, it needs significant and long-term investment from the private sector. Companies that take a longer-term outlook recognise this and want to contribute to the solution to help secure the viability of their businesses.

#### 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 c**hallenges 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.

### Single-payer CP

#### Counterplan – States ought to

#### individually domestically establish single-payer national health insurance.

#### Fund private public partnerships with pharmaceutical companies over developing solutions to Neglected tropical diseases

#### Solves access to medicine while avoiding the disads.

Narayanan 19 Srivats Narayanan 8-15-2019 "Medicare for All and Evergreening" <https://medium.com/@srivats.narayanan/medicare-for-all-and-evergreening-cb84c930e0ea> (UMKC School of Medicine)//Elmer

Drug companies rake in massive profits. The pharmaceutical industry has some of the largest profit margins among American industries. Unfortunately, pharmaceutical giants don’t always have patients’ best interests in mind — they make a big portion of their money by exploiting the patent process instead of making breakthrough drugs that would meaningfully improve patients’ lives. Pharmaceutical corporations aren’t as innovative as one might expect. Although the Food and Drug Administration (FDA) has been consistently approving new (and expensive) drugs every year, most of these drugs aren’t impacting healthcare much. Many studies have revealed that a whopping 85–90% of new drugs since the mid-1990s “provide few or no clinical advantages.” This is because pharmaceutical firms are spending their time and money on a technique known as “evergreening.” Evergreening is when drug companies produce redundant drugs that are nothing but minor modifications of old drugs. By making slight alterations to their medicines, biotech companies continue to hold patents for drugs with minimal spending on research and development (R&D). Pharmaceutical companies then use those patents to prevent competitors from selling generic versions of their drugs. Without any competition, these corporations get away with ridiculously high drug pricing and can thus make big profits on their drugs. The companies simultaneously justify their absurd drug prices by pointing to the inflated R&D costs of producing new drugs. This excuse has been used time and again by the profit-hungry pharmaceutical industry, and it’s coming at the expense of patients who struggle to afford their medicines. A well-known example of evergreening pertains to the anticonvulsant medication gabapentin, which was first sold by Pfizer under the brand name Neurontin. When the drug became available as a generic medication over a decade ago, Pfizer created a very similar medicine, pregabalin (Lyrica), that didn’t have any significant benefits over the original drug. As a result, Pfizer has kept a control over the market for anticonvulsant drugs with negligible innovation. The drug industry’s reliance on evergreening is undoubtedly stifling innovation. This is where Medicare for All, which would impose the government as the only health insurer, would be useful. In our current system, there are many insurers and they each have little market power and consequently little negotiating power to reduce treatment prices. Since the government would have consolidated control over healthcare financing under Medicare for All, its stronger bargaining power would force drug companies to charge lower prices for their products. In addition, prescription drugs would be paid for by the government and not by patients under Medicare for All. Medicare for All would prevent evergreening. National healthcare financing would align how much the government pays a drug company with how much patients benefit from the company’s drugs. If a new drug had more clinical benefits than an older version, the government would pay more for it. If a new drug produced the same results as an older version, the government wouldn’t pay more for the new drug. So, Medicare for All would encourage pharmaceutical companies to pursue truly innovative drugs because such drugs would be more profitable. The policy would incentivize companies to invest in R&D for more useful drugs, instead of just producing redundant and expensive medications. A national healthcare plan would prioritize “patient and community needs” and match up pharmaceutical companies’ interests with actually improving public health. Evergreening has become the name of the game for the pharmaceutical industry. A major solution to the evergreening problem is Medicare for All. A single-payer system like Medicare for All would sharply curtail evergreening, since drug companies wouldn’t be able to profit from it. Medicare for All would usher in a new era of medical innovation.

### Bioterror DA

#### Covid exposed new vulnerabilities and motivation for bioterror BUT technical challenges still outweigh.

Koblentz and Kiesel 7/14 [Gregory D. Koblentz (Deputy Director of the Biodefense Graduate Program and Assistant Professor of Government and Politics in the Department of Public and International Affairs at George Mason University) and Stevie Kiesel (Biodefense PhD Student, Schar School of Policy and Government, George Mason University). “The COVID-19 Pandemic: Catalyst or Complication for Bioterrorism?”. Studies in Conflict & Terrorism. Published online 14 Jul 2021. Accessed 7/22/21. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2021.1944023?journalCode=uter20> //Xu recut Adam]

Since COVID-19 was declared a pandemic in March 2020, there has been no major bioterrorist incident that challenges or validates the core beliefs of the optimists, pessimists, or pragmatists. Extremists with violent apocalyptic or accelerationist ideologies—chiefly jihadists and far-right extremists—have sought to capitalize on the pandemic, but they still rely on conventional weapons. Based on available open-source information, terrorist interest in weaponizing SARS-CoV-2 seems limited. While some individuals and groups who subscribe to violent apocalyptic or accelerationist ideologies have shown some interest in crudely spreading the virus, most terrorists have sought to exploit the conditions the pandemic created rather than the virus itself. An increase in the risk of bioterrorism cannot be completely discounted as the equipment, knowledge, and expertise to work with high-risk pathogens is increasingly available and there are a small number of groups with the ideologies and objectives consistent with the use of biological weapons. Still, important technical barriers to acquiring and using a biological weapon capable of causing mass casualties, even far below the effects of a pandemic pathogen, will remain even after the pandemic is contained. While COVID-19 graphically demonstrated the vulnerability of modern societies to infectious diseases, the lessons learned from this experience, if properly implemented, should significantly improve the capability of governments around the world to detect and respond to future pandemics as well as deliberate disease outbreaks. Counterterrorism and biodefense efforts should not be dictated by the latest “‘risk of the month’ policies crafted in the wake of visible or highly publicized events.”117 Instead, strategies for reducing the likelihood and consequences of bioterrorism in the wake of the COVID-19 pandemic should be based on a realistic appraisal of the risk and investments should be optimized to strengthen preparedness against the full spectrum of biological threats.

#### IP protections are the only limit on proliferating dual-use biotech – losing patents puts financial pressure on companies to outsource R&D, which skyrockets bioterror acquisition.

Finlay 10 [Brian Finlay (President and Chief Executive Officer of the Stimson Center, M.A. from the Norman Patterson School of International Affairs at Carleton University, a graduate diploma from the School of Advanced International Studies, the Johns Hopkins University and an honors B.A. from Western University in Canada). “The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”. The Fletcher Forum of World Affairs. Vol. 34, No. 2 (Summer 2010), pp. 51-64. <https://www.jstor.org/stable/45289504?seq=1#metadata_info_tab_contents> //Xu]

Until recently, these investment risks were frequently mitigated by income generated from past drug development successes. In most markets, that income was guaranteed by strict patent protections that closed the window to outside competition for a set period of time. More recently, however, the uncertainty of R&D investments has been complicated not only by the global economic downturn, but more importantly by looming patent expirations that will open many of big pharma's patent-protected drugs to generic competition. Between 2007 and 2012, more than three dozen drugs will lose patent protection, removing an estimated $67 billion from big pharma's annual sales.33 With existing drug development pipelines unable to fill the gaps, biopharmaceutical companies are under intense pressure not only to cut costs - which would provide only temporary relief to the bottom line - but also to rapidly replenish their development pipelines. Some industry analysts have described this "perfect storm" as an "existential" moment for big pharma.34 Many pharmaceutical companies have approached this challenge by accelerating and widening the outsourcing and off-shoring of both R&D and manufacturing, and by aggressively buying promising assets from small biotech companies through acquisitions and strategic alliances. Interestingly, these partnerships are less frequently linked with American or even Western-owned and-operated companies than in the past. Many pharmaceutical giants like Indiana-based Eli Lilly are turning to alliances with firms in Asia and elsewhere around the world, outsourcing key technical operations. Instead of functioning as fully integrated firms, big pharma companies have found value in networked relationships with independent small to large firms, universities, and non-profit biotechnology laboratories around the globe.35 The net result has accelerated technology proliferation - for both beneficial and nefarious uses - far beyond the traditional hubs for biotech innovation. Pharma's increasingly desperate search to seed and ultimately acquire innovative new biotechnologies means that foreign (non- Western) markets are pulling ahead in biotech innovation. Indeed, the quantity of biotech companies outside the United States has grown remarkably in recent years: in Israel, the number grew from 30 in 1990 to about 160 in 2000; in Brazil, from 76 in 1993 to 354 in 2001; and remarkably, in South Korea, from one in 2000 to 23 in 2003. 36 More generally, the Asia-Pacific region has emerged as one of the world s fastest-growing biotechnology hubs, with the growth of publicly traded companies handily outpacing growth in the United States and Europe over recent years.37 As fruitful partnerships lead big pharma to increasingly generate resources, technologies, and knowledge, these capacities spin off new competitor firms in a self-executing multiplier effect. With the number of facilities and highly trained individuals increasing, the likelihood of a serious biological accident or nefarious incident will similarly rise, which will be particularly risky when dual-use technologies are introduced into insufficiently regulated markets. CONCLUSIONs In statements, U.S. officials continue to cite several countries believed to have or to be pursuing a biological weapons capability.38 But globalization exports the challenge of bioproliferation far beyond these geographic boundaries and transcends multiple societal layers well beyond government actors. As a result, it is increasingly clear that states no longer have a monopoly on dual-use biological R&D. Recent evidence suggests a growing threat of terrorist acquisition of biological weapons. As technological advancement in the life sciences is progressively pushed into countries of the Global South, some of which are also potential hotbeds for terrorist activity, the nexus of science and terrorism becomes especially acute.While far from perfect, the current system of stringent controls levied by Western governments over the biopharmaceutical sector has proven remarkably effective, especially given the diffusion of technologies and the ease of their redirection for hostile purposes. As the biotech revolution continues to widen, however, advanced industrialized governments are increasingly playing catch-up with changing technological realities. As these technologies proliferate, security analysts have become uneasy with the lack of controls in many states. The dearth of legal controls, the lack of rigor in their enforcement, and the growth in private-actor involvement in dual-use activities has sobering implications for global security.

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public again and again. It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

## Case

### Framing

#### Reducing existential risks is the top priority in any coherent moral theory

Pummer 15 (Theron, Philosophy @St. Andrews http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/)

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### On Structural violence First -

#### 1---Prefer util---even if its flawed, alternatives are worse because they justify the same ends but create decision paralysis, and requires saying some lives are more valuable than others, which turns all their impacts

#### 2---Tautological---devolves into consequentialism---either their maxims are created to minimize harm, which means they’re utilitarian consequentialist, or they’re inflexible in cases of moral atrocity worse than utilitarianism because they requires saving some people over others

### Contention 1

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Turns case – hesitancy is on the brink worldwide

Andrea **Taylor, 2/6** [Andrea Taylor, (Andrea leads a portfolio of global innovation programs focused on evaluation, scaling, and adaptation of healthcare innovations to address critical access and quality challenges. Her work with the Duke Global Health Innovation Center and Innovations in Healthcare drive evidence-based recommendations for scaling transformative models of care, adapting models into new contexts, and facilitating system change. She is the research lead for the Launch and Scale project’s COVID-19 workstream, analyzing global data on vaccines, partnerships, and therapeutics to combat the pandemic. She led design and research for the USAID-funded Social Entrepreneurship Accelerator at Duke (SEAD) and the development of several publications for the recent evaluation of the Saving Lives at Birth program, with USAID and GCC.)]. "VACCINE HESITANCY WILL SOON BECOME THE PRIMARY OBSTACLE TO GLOBAL IMMUNITY – Global Health Innovation Center." 2-16-2021, Accessed 8-5-2021. https://dukeghic.org/2021/02/16/vaccine-hesitancy-will-soon-become-the-primary-obstacle-to-global-immunity/ // duongie

Vaccine hesitancy will soon become the primary obstacle to global immunity Global manufacturing capacity has been the primary rate limiter for Covid-19 vaccinations. Our vaccine manufacturing infrastructure was not designed to produce enough doses to cover 70% of the world’s population within a year (in addition to regular and routine vaccines) and, as expected, demand is outstripping supply. There has been good news on the manufacturing front, however, with several large pharma companies recently joining with rivals to ramp up production. At the same time, data on vaccine hesitancy suggest that it may soon overtake manufacturing capacity as the primary obstacle to global coverage and reaching herd immunity. If this is the case, we will soon find that producing enough vaccines does not translate to enough vaccinations. Covid-19 vaccine hesitancy is growing around the world. A survey of 15 countries found that willingness to get a Covid-19 vaccine dropped in nearly all of the countries between October and December 2020. France and Russia had the lowest rates of vaccine intent in the survey, below 50%

. Another survey of 32 countries found that fewer than half of the population in Lebanon, France, Croatia, and Serbia intend to get vaccinated. In Peru, vaccine hesitancy grew by 26 percentage points (from 22% to 48%) between August and December and the population is now evenly split between those willing and those not willing to receive the vaccine. Other data indicate some countries fall much lower: in the Philippines, fewer than a third are willing to have a Covid-19 vaccine. Even in China, a country with historically high rates of vaccine take-up, intent to get a Covid-19 vaccine dropped in late 2020 (though at 80% China was still at the top of the chart). Negative coverage of western-developed vaccines in Chinese state media appears to be fueling mistrust of even Chinese-developed Covid-19 vaccines and slowing vaccination rates. In both the US and UK, recent studies found that hesitancy rates are highest among younger adults, racial minorities, and people with lower education and income. A similar trend was noted this week in Israel, where vaccine take-up has slowed and is particularly low among minority communities and younger populations. There was improvement in vaccine intent among Black and LatinX populations in the US between December and January; however, these groups are still most likely to say that they will “wait and see” rather than get the vaccine as soon as possible. Experts suggest that supply may outstrip demand in the US as early as April. Public health leaders in countries around the world have pulled every lever they can to secure vaccine doses to protect their populations. Each dose is the result of unprecedented scientific and industry cooperation, complex negotiations, and a flat-out global effort. But the race to develop, manufacture, and distribute vaccines must result in vaccinations. We need to get ahead of vaccine hesitancy now, with strong outreach campaigns, before it becomes the rate limiter.

#### The Plan can’t solve COVID - Lack of key supplies

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags.

We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### The plan only hurts manufacturing moving bottlenecks to less efficient manufacturers

Alex **Knapp, 5/7** [Alex Knapp, (senior editor at Forbes covering healthcare, science, and cutting edge technology.)]. "Patent Waivers Won’t Impact Big Pharma’s Bottom Line—But Could Slow Covid Vaccine Rollouts." Forbes, 5-7-2021, Accessed 8-5-2021. https://www.forbes.com/sites/alexknapp/2021/05/07/patent-waivers-wont-impact-big-pharmas-bottom-line-but-could-slow-covid-vaccine-rollouts/?sh=78866f727862 // duongie

On Wednesday, the Biden Administration stated that it would support a proposal to temporarily waive protection of intellectual property (IP) rights for Covid vaccines during the pandemic, in a bid to boost production and accelerate vaccine distribution throughout the world. Industry trade groups immediately criticized the move, and investors reacted simultaneously—share prices plummeted, though they’ve been slowly recovering Thursday and Friday. Wall Street analysts at Morgan Stanley, Jefferies and Brookline Capital Markets, however, said in reports this week that waiving vaccine IP was unlikely to impact the financials of major vaccine makers, noting that current bottlenecks in vaccine production are related to supply chain, technical knowledge and difficulty in scaling up production. However, they caution that for the same reason, waivers could slow down current production by disrupting the market for raw materials. “Manufacturing supplies, raw materials, vials, stoppers and other key materials are in limited supply for 2021, and certainly for the 2021 calendar year,” wrote analysts from Jeffries, meaning that waivers can’t solve immediate vaccination needs in India and South Africa, where Covid-19 cases are surging. That report also notes that the mRNA vaccines from Pfizer and Moderna have yet to be authorized for use in India, as regulators desired local clinical trial data, which is another hurdle to overcome. Morgan Stanley commented that U.S. support alone doesn’t necessarily mean that a World Trade Organization agreement on the waiver would happen, especially since Germany has expressed opposition. The firm additionally notes that “manufacturing vaccines is a much more complicated process than making chemical drugs, and a patent waiver by itself would not enable other entities to manufacture their own copies of complex vaccines.” Jefferies analysts also remarked that another barrier to increased vaccine production is “ensuring the quality of the product, which is also not trivial.” Contractors for vaccine ma

kers Pfizer, AstraZeneca and Johnson & Johnson have all run into quality-control issues that have led to millions of vaccine doses being discarded. On a company earnings call yesterday, Moderna CEO Stéphane Bancel said he doubted that waiving IP rights would impact his company much, because it would take months or even years for other companies to scale up manufacturing. Meanwhile, the biotech company has recently committed to expanding its own manufacturing capacity and expects to be able to make up to 3 billion doses of vaccine in 2022. Morgan Stanley analysts noted that in October 2020, Moderna “stated it would not enforce its patents during the pandemic, but to our knowledge, no one else has started manufacturing a vaccine that would violate Moderna’s patents.” The team at Brookline Capital markets noted that if a company did begin manufacturing vaccines based on Moderna’s patents, the upside would be an additional licensing revenue stream for the company. On Friday, vaccine manufacturer Novavax, which has reached an agreement with the private-public global health partnership Gavi to provide 1.1 billion vaccine doses to low income countries, stated its opposition to the WTO waiving patents, arguing that it “could further constrain resources by diverting them to entities incapable of manufacturing safe and effective vaccines in the near term.” Jeffries analysts note that a waiver wouldn’t put Novavax at immediate risk, as a key component of the company’s vaccine “is in limited supply and a majority of the raw material has already been locked up” by the company. That said, Morgan Stanley struck a similar point to Novavax about the risk involved in waiving patents. The analysts point out waivers could be counterproductive and actually slow down vaccine manufacturing. “An IP waiver now may exacerbate supply issues,” they write, “if some countries start to try to secure raw materials ahead of being able to produce a vaccine and cause shortages and disruptions in the supply chain.”

### Contention 2

#### Alt Causes to lack of generics means they can’t solve lack of medical acess

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

The ways companies stop generics One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called “pay for delay” agreements, a brand drug company simply pays a generic company not to launch a version of a drug. The Federal Trade Commission estimates these pacts cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year. “Citizen petitions” offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they’re corporations. The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days. “Authorized generics” are another tactic to limit competition. These aren’t really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug.

[marked]

Why? By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product. But the company with the expiring patent is not barred from launching an “authorized generic.” By selling a drug they’re already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months. Another way pharmaceutical firms are thwarting generics is by restricting access to samples for testing. Generic drug makers need to be able to purchase a sample of a brand-name product to conduct bioequivalence testing. That’s because they have to prove they can make a bioequivalent product following the current good manufacturing practices (CGMP) standard. These manufacturers don’t need to conduct clinical trials like the original drug company did. But the original drug developer often declines to sell drug samples to generics manufacturers by citing “FDA requirements,” by which they mean the agency’s Risk Evaluation and Mitigation Strategies program. The idea behind this program is a good one: give access to patients who will benefit from these personalized medicines, and bar access for patients who won’t benefit and could be seriously harmed. However, brand drug makers are citing these requirements for the sole purpose of keeping generics from coming to market.