# 1NC v. Cierra Valley R6

## 1

### DA

#### Climate Patents and Innovation high now and solving Warming but COVID 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 compensationand 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**.**

#### Climate Patents are critical to solving Warming – only way to stimulate Renewable Energy Technology Investment.

Aberdeen 20 Arielle Aberdeen October 2020 "Patents to climate rescue: how intellectual property rights are fundamental to the development of renewable energy" <https://www.4ipcouncil.com/application/files/4516/0399/1622/Intellectual_Property_and_Renewable_Energy.pdf> (Caribbean Attorney-at-Law with extensive experience in legal research and writing.)//Elmer

**Climate change is** the **most pressing** global **challenge** and with the international commitment to reduce greenhouse gas emissions under the Paris Agreement,1 there **needs to be a global energy revolution** and transition.2 This is where **innovative technology can help** meet the challenge of reducing our dependency on finite natural capital resources. The development and deployment of innovative technology play a pivotal role in enabling us to replace fossil fuel use with more sustainable energy solutions. **Patents** have **facilitated** the **development of such innovative technologies** thus far **and** will **continue to be the catalyst for this transition**. Patents are among a group of intellectual property rights (‘IPRs’). 3 These are private and exclusive rights given for the protection of different types of intellectual creations. IPRs are the cornerstone of developed and knowledge-based economies, as they encourage innovation, drive the investment into new areas and allow for the successful commercialisation of intellectual creations. IPRs are the cornerstone of developed and knowledge-based economies. Empirical evidence has shown that a **strong IPRs** system **influences** both the **development and diffusion of technology**. Alternatively, **weak IPRs** protection has been shown to **reduce** **innovation**, **reduce investment** and prevent firms from entering certain markets.4 Once patent protection has been sought and granted, it gives a time-limited and exclusive rights to the creator of an invention. This allows the inventor or patentor the ability to restrict others from using, selling, or making the new invented product or process. Thereby allowing a timelimited monopoly on the exploitation of the invention in the geographical area where it is protected. During the patent application procedure, the patentor must make sufficient public disclosure of the invention. This will allow others to see, understand and improve upon it, thereby spurring continuous innovation. Therefore, the patent system through providing this economic incentive is a successful tool which has encouraged the development and the dissemination of technology. Patents like all IPRs are key instruments in the global innovation ecosystem.5 When developing innovative technology, patents play a role throughout the “technological life cycle”,6 as shown in Figure 1. This lifecycle involves the invention, research and development (‘R&D’), market development and commercial diffusion. Patents are most effective when sought at the R&D stage. Once a patent has been granted, it becomes an asset which can then be used to7: Gain Market Access: Patents can create market advantages; to develop and secure market position; to gain more freedom to operate within a sector and reduce risks of infringing on other patents; protect inventions from being copied, and removes delaying by innovative firms to release new or improved technology and encourage the expansion of their markets. Negotiation leverage: Patents can build a strong brand or company reputation which can enhance the company’s negotiation power and allow for the creation of equal partnerships. Funding: Patents can generate funding and revenue streams for companies. Having a strong patent portfolio especially in small businesses or start-ups can be used to leverage investor funding; while also be a source of revenue for companies through licensing fees, sales, tax incentives, collateral for loans and access to grants and subsidies. Strategic value: Patents can be used to build “synergistic partnerships”8 through which collaboration on R&D and other partnerships; be used to improve in-house R&D and build and/ or develop more products. As such, obtaining and managing patent as part of a patent and broader IPRs strategy are key tools for business success, especially within highly innovative and technology-driven industries.9 Renewable Energy: The Basics Renewable energy is derived from natural unlimited sources which produce little to no harmful greenhouse gases and other pollutants. 10 Innovative renewable energy technologies (‘RETs’) have created the ability to tap into these sources and convert them to energy which can then be stored, distributed, and consumed at a competitive cost. RETs have developed into a technology ecosystem which consists of alternative energy production, energy conservation and green transportation.11 For energy production, RETs have been developed to generate energy from six main sources. These are: Wind energy: Technology, via off-shore and/or on-shore wind turbines, harnesses the energy produced by the wind. Solar energy: Technology either through concentrated solar power (‘CSP’)and solar photovoltaic (‘PV’) harnesses the energy produced by the sun. Hydropower: Technology either through large-scale or small-scale hydropower plants, captures energy from flowing water. Bioenergy: Technology is used to convert organic material into energy either through burning to produce heat or power or through converting it to a liquid biofuel. Geothermal: Technology is used to capture the energy from the heat produced in the earth’s core. Ocean/Tidal energy: Technology is used to capture the energy produced from waves, tides, salinity gradient energy and ocean thermal energy conversion. Out of these six sources, the wind, solar and hydropower energy sectors are the biggest, the most developed and the most widely used. While geothermal and ocean energy sources are used in a more limited capacity. In particular, the RETs in ocean energy is still at its infancy and thus presents an opportunity for future innovation and commercialisation. Renewable energy is the fastest-growing energy source, with the electricity sector showing the fastest energy transition. 12 In 2016, renewable energy accounted for 12% of final global energy consumption and in 2018, a milestone was reached with renewables being used to generate 26% of global electricity. The source of this energy has been driven by renewable hydropower, as shown in Figure 2, with wind and solar energy trailing behind in energy production. However, the International Energy Agency (‘IRENA’) forecasts that Solar PV will lead RETs to increase capacity in the upcoming years. 13 This rise in renewable energy is due to the increased investment into the sector and the development, diffusion and deployment of innovative RETs. For the period between 2010 and 2019, there were 2.6 trillion US dollars invested in renewable energy. 14 The majority of which being focused on solar energy. 15 This investment has surpassed the investment made into the traditional fossil fuel energy 16 and has been heavily driven by the private sector. 17 The International Energy Agency recent report showed that its members increased the public budgets for energy technology R&D, with the biggest increase in the low-carbon sectors.18 The geographic sources of this investment shown in Figure 3, reveals that the European Union, the United States and Japan are part of the largest investors. This reflects the historic involvement these countries have had in the renewable energy arena and the development of RETs. However, there is now the emergence of China, India and Brazil as large investors in this field. This trend in investment has also coincided with the increase in patenting technology in renewable energy compared to fossil fuels.19 Reports from the World Intellectual Property Office (WIPO), have shown that there has been a **steady increase in patent filing rates in RETs since the mid-1990s**.20 This increase has occurred in the four major renewable sectors, 21 where RETs patents applications were growing steadily from 2005 until reaching a peak in 2013.22 Post-2013, there has been a slight decline in patent filings, which can indicate a maturing of sectors and deployment of technologies.23 Each renewable energy sector is at a different stage of maturity and thus there is a variation of patent ownership. The wind sector is the most mature and consequently has the highest intellectual property ownership and patent grants compared to that of the biofuel sector. 24 IRENA also provides a comprehensive and interactive database for RETs patents. As seen in Figure 4 below, they have collected patent data from the major patent filing jurisdiction25 which shows the breakdown of the patents per type. This information reveals that there is a dominance of patent filings focused on solar technology. This data corresponds to the focus of the investment in renewable energy into solar energy. Upon closer look at the data, the geographic source of these patents shows that RETs patents have been concentrated in a few developed OECD countries and China. This also corresponds to the source of investment shown in Figure 3 and reflects the historical concentration of RETs innovation within these countries. 26 The latest WIPO report for 2019, which looks at the data for PCT patent applications, shows that 76 % of all PCT patent application came from the United States, Germany, Japan, the Republic of Korea and China.27 China is the newest entry into the top ten list and has made one of the largest jumps to become one of the biggest RETs patent filers at the PCT. This geographic data is also mirrored by IRENA’s statistics, as shown in Figure 5 below. This data also reflects China’s emerging renewable dominance. China is heavily **investing in solar energy** **technology** and has filed numerous patents in this area and the underlying technologies.28 The successful flow of investment in this sector can only **occur in** the **presence of a strong IPRs system** and protection. Government policies and initiatives to improve the **patent system** can be used to promote the development of RETs and drive private capital and investment into this area.29 This direct **effect on RETs** through policies was **shown in** the United States with the ‘**Green Tech Pilot Program’**.30 This was a special accelerated patent application procedure developed by the United States Patent and Trademark Office for inventions falling under the green technology category. This program ran from 2009-2011 and led to a boost in RETs patent applications, with the office issuing 1062 RETs patents from the programme. Other jurisdictions, such as the European Union and China have used policy and incentives to promote the development of RETs and the advancement of their renewable energy sector. In particular, the European Union and China began the renewable energy path at different starting points but are now both dominant players in this area.

#### 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.

## 2

### DA

#### Low prices independently cause AMR disease outbreaks.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### AMR is an existential threat – it’s non-linear and has an invisible tipping point.

Silverman 16 Rachel Silverman 4-19-2016 “Confronting Antimicrobial Resistance: Can We Get to Collective Action?” <https://www.cgdev.org/blog/confronting-antimicrobial-resistance-can-we-get-collective-action> (MPhil with Distinction in Public Health @ the University of Cambridge, Senior Policy Analyst and Assistant Director of Global Health Policy @ the Center for Global Development, focusing on global health financing and incentive structures)//Elmer

Antimicrobial resistance is already causing huge harm – and the worst is yet to come. To open the panel, Dr. Chan issued a serious warning about the size and scope of the AMR threat: “everyone will be affected if we do not address this problem.” AMR is already responsible for an estimated 700,000 global deaths each year, 50,000 of which take place in the US and Europe. Extensively drug-resistant (XDR) tuberculosis—cases where the most effective first- and second-line drugs are rendered useless—infected an estimated 47,000 people worldwide in 2014, only one ‘last-line’ antimicrobial is available to reliably treat gonorrhea, and few new antimicrobial drugs are in the development pipeline. According to the latest review, AMR could cause 10 million deaths each year by 2050, with knock-on effects draining many trillions from the global economy. Summers suggested that AMR and potential pandemics, alongside climate change and nuclear proliferation, represent the top three existential threats to life on earth as we know it. And as Dr. Chan explained, the worst-case scenario implies the end of modern medicine as we know it. Even worse, Summers suggested that AMR seems like a “quintessential non-linear phenomenon, and therefore more dangerous.” Year by year the effects are small and mostly invisible. Butat some point in the future they could suddenly become catastrophic, like a “levee that doesn’t hold and unleashes a flood.” Dr. Chan concurred that “the tipping point is not predictable because…microbes are invisible. We don’t even know when they’re going to make the switch” to become resistant to existing drugs.

## 3

### CP

#### Text – Member states of the World Trade Organization ought to individually domestically establish single-payer national health insurance.

#### Single Payer solves High Drug Prices.

Rotolo 19 Shannon Rotolo 11-18-2019 "Letters: ‘Medicare for All’ would drive down drug costs" <https://www.chicagotribune.com/opinion/letters/ct-letters-vp-111819-20191118-3q6k5toz6fgmvafspzylpbs2ca-story.html> (pharmacist and member of the Illinois Single-Payer Coalition, Chicago)//Elmer

In 2017, a study found that more than 15% of people living in the United States went without a needed medication because of its cost. This is significantly higher than the nonadherence in a majority of European countries. While there are multiple bills at the state and federal level aimed at reducing drug prices for single classes of drugs, such as insulin, or targeting high-cost drugs as a category, **none of these bills has the potential to make the same impact as a switch to a single-payer system**, commonly known as “Medicare for All.” Creation of a single-payer system has the **ability to drive down drug prices by consolidating negotiating power**. This is something we’ve been told pharmacy benefit managers (PBMs), middlemen in our current system, could achieve. But despite their presence, drug costs have continued to skyrocket. A single-payer system, on the other hand, is **projected to reduce** brand name **drug prices by about 50%.** These changes in average wholesale price (AWP) or any other price measures used by the industry or in retail pharmacies aren’t necessarily tied to the copay you see at the pharmacy counter, though. Medicare for All would address that piece as well, **with no copays or deductibles** in one proposed version, and a maximum of $200 per year on prescriptions in the other. Another unique advantage of Medicare for All is that it would **restore patient choice in pharmacy**. **Private insurance** and PBMs **ensure** greater **profits** for themselves **by restricting choice**, **driving prescriptions to the chains they own.** When they do permit patients to use alternative pharmacies, the reimbursement to those small businesses can be so low that prescriptions are often filled at a loss. The end **result is** the **pharmacy deserts** we see on the South and West sides of Chicago, and closing of independent pharmacies in the Chicago area in general. Medication only helps if you can take it, and you can only take it if you can afford it. Everyone deserves to get the medication they need from a pharmacy they trust. I encourage everyone who takes medication or loves someone who takes medication to learn more about Medicare for All and to support the candidates who will fight for it.

## Case

### 1NC – AT: Contention

#### Alt Causes to lack of generics thump Aff solvency to zero – pay-for-delay, citizen petitions, authorized generics, and testing sample access – this is terminal since they’d just shift tactics to non-patent strategies.

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. 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.

#### Hurts Innovation

**Value Ingenuity 20** [Value Ingenuity, (The Value Ingenuity project is telling the story of innovation, its roots, its impact, its social and moral imperatives, and the public policy prescriptions that will assure a continued upward trajectory for the generations to follow. Our objective is to advance globally a shared purpose of mutual investment in sustainable innovation.)]. "WTO IP Waiver Would Undermine Covid Innovation." 10-2-2020, Accessed 8-5-2021. https://www.valueingenuity.com/2021/05/18/wto-ip-waiver-would-undermine-covid-innovation/ // duongie

A TRIPS waiver for vaccines would do nothing to help — and could in fact hurt — the effort to produce billions of vaccine doses and get them in arms. Supply of these high-tech products is ramping up quickly, with about 10 billion doses projected to be produced by the end of 2021 — we shouldn’t distract attention away from that all-important goal. IP is not a barrier to vaccine access. It already enabled the creation of three vaccines, in record-breaking time, that have received FDA authorization. IP is also safely facilitating international partnerships (275+ to date) to share technology and information more easily with trusted partners across borders. An IP waiver could lead to untested and unregulated copycats. Some nations are looking to manufacture sophisticated vaccines without permission, exacerbating the shortage of the critical materials (raw materials, tubing, vials etc.) and increasing vaccine hesitancy due to the development of unsafe products and medicines. The proposal jeopardizes U.S. manufacturing & jobs. Allowing other countries to take and commercialize American-made technologies conflicts with President Biden’s goal to build up American infrastructure and create manufacturing jobs. In the U.S. alone, biopharmaceutical companies support 4 million jobs across all 50 states, with many more across innovation ecosystems in labs, finance, and SMEs. Waiving IP undermines America’s leadership in the life sciences. We should not be forfeiting IP to countries looking to undermine America’s global leadership in biomedical technology and innovation. IP protections enabled decades of R&D by biopharmaceutical research companies, allowing them to move quickly and effectively against COVID-19. Business welcomes the Biden Administration’s support for the global vaccine program, COVAX. This type of program can have a significant positive, practical impact on global rollout of vaccines and therapies without disrupting the incredible IP-enabled progress that has been made to date to defeat the pandemic. Its effects will be even more effective as trade barriers are removed and all countries allow vaccines to be exported internationally. GOOD TO KNOW: Today 57% of all new medicines globally come from the United States with its world-class IP ecosystem, and private companies in the life sciences community make up more than 80% of the investment in the research and development of those new drugs. The U.S. biopharmaceutical industry directly and indirectly supports over 4 million American jobs. SCIENTISTS, ACADEMICS, ADVOCATES AND POLITICAL LEADERS SKEPTICAL OF WAIVING IP RIGHTS “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WASHINGTON POST EDITORIAL BOARD, May 4, 2021 “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WALL STREET JOURNAL EDITORIAL BOARD, May 6, 2021 “The U.S. decision to support a temporary waiver of intellectual-property protections for Covid-19 vaccines won’t end debate on the issue, much less end the pandemic. Reaching a formal agreement could take months and even then may not accelerate vaccine production; opposition from countries such as Germany could yet doom any compromise.” BLOOMBERG EDITORIAL BOARD, May 12, 2021 “The collaboration that’s happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation […] I don’t think that waiving IP rights will suddenly enable other countries to ramp up the manufacturing of complex vaccines.” SEN. CHRIS COONS (D-DE), CSIS: April 22, 2021 “There are only so many vaccine manufacturers in the world […] people are very careful about the safety of vaccines […] The thing that is holding us back is not IP. There is no idle factory with regulatory approval that makes magically safe vaccines […] we have all the rights from the vaccine companies and the work is going at full speed” BILL GATES, Sky News: April 25, 2021 “There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” ADAR POONAWALLA, CEO SERUM INSTITUTE OF INDIA, February 14, 2021 “These [vaccines] are complex to make so just waiving IP and patents isn’t going to help […] you can only get trade secrets and knowhow with the cooperation of the originator companies, and they don’t have the bandwidth to do this in every part of the world … the only immediate solution is for rich countries to donate or sell their surplus vaccine to COVAX or other countries.” JAYASHREE WATAL, GEORGETOWN LAW PROFESSOR & FORMER WTO IP COUNSELOR, April 22, 2021 “It is also unclear whether a waiver of IP rights will make a difference […] Furthermore, as others have pointed out, IP rights are only a piece of what is needed to produce vaccines. There is currently a global shortage of raw materials and proper manufacturing facilities.” SAPAN KUMAR, LAW FOUNDATION PROFESSOR OF LAW AT THE UNIVERSITY OF HOUSTON LAW CENTER, May 9, 2021 “This is technology that’s every bit as critical as munitions and encryption codes […] It’s a platform technology that can be used to make all manner of treatments going forward, including vaccines.” DAVID KAPPOS, FORMER U.S. PATENT AND TRADEMARK OFFICE FOR PRESIDENT OBAMA, April 22, 2021 “The notion that we would then turn around and go to the World Trade Organization and basically endorse a policy of DARPA-funded technology transfer to China is just inconceivable. You’re basically aiding and abetting China’s ‘Made in China 2025’ plans for technological dominance.” CLETE WILLEMS, FORMER SPECIAL ASSISTANT TO THE PRESIDENT FOR INTERNATIONAL TRADE, INVESTMENT, AND DEVELOPMENT, April 22, 2021.