# D31NC Nano R1

## Off

### 1NC --- T Reduce

#### 1] Interpretation - Reduce means permanent reduction – it’s distinct from “waive” or “suspend.”

**Reynolds 59** (Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959, lexis)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway.  [\*\*\*13] The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Waiver is temporary.

Green 5/6 [Andrew Green (Devex Contributing Reporter based in Berlin, his coverage focuses primarily on health and human rights and he has previously worked as Voice of America's South Sudan bureau chief and the Center for Public Integrity's web editor). “US backs waiver for intellectual property rights for COVID-19 vaccines”. Devex. 06 May 2021. Accessed 7/31/2021. <https://www.devex.com/news/us-backs-waiver-for-intellectual-property-rights-for-covid-19-vaccines-99847> //Xu]

In a stunning reversal, U.S. President Joe Biden’s administration came out in favor of waiving intellectual property protections for COVID-19 vaccines Wednesday. The move follows months of U.S. opposition that began under former President Donald Trump to a proposal from South Africa and India to temporarily set aside intellectual property rights around products that would protect, contain, and treat COVID-19. Its supporters have argued that the proposal, first tabled at the World Trade Organization in October and now backed by more than 100 countries, is necessary to expand vaccine production and overcome global shortages.

#### 2] Violation – the plan waives intellectual property protections “during public health emergencies”, which is a suspension – don’t let them get We Meets since their Plan defends a waiver.

#### 3] Vote neg for limits and neg ground – re-instatement under any infinite number of conditions doubles aff ground – every plan becomes either temporary or permanent – you cherry-pick the best criteria and I must prep every aff while they avoid core topic discussions like reduction-based DAs which decks generics like Pharma Innovation and Bio-Tech.

#### 4] TVA solves – permanently reduce COVID patents.

#### 5] Paradigm Issues –

#### a] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### b] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation.

#### c] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

### 1NC --- Climate Patents DA

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

#### 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.

### 1NC --- Info Sharing CP

#### The World Trade Organization ought to increase intellectual property protections for medicines deemed essential during public health emergencies. The United States ought to designate intellectual property protections on medicines deemed essential during public health emergencies as adversely affecting the international transfer of technology.

#### Member states can waive IP rights if they hamper the international flow of medical technology.

WTO ’21 (World Trade Organization; 2021; “Obligations and exceptions”; World Trade Organization; Accessed: 8-30-2021; exact date not provided, but copyright was updated in 2021)

Article 8 Principles […] 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, **may be needed** to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or **adversely affect** the **international transfer of technology**. SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES Article 40 1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have **adverse effects on trade** and **may impede** the **transfer and dissemination** of technology. 2. Nothing in this Agreement **shall prevent** Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member **may adopt**, consistently with the other provisions of this Agreement, **appropriate measures** to **prevent or control** such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member. […]

#### Designating IP protections as antithetical to the global health system revitalizes info-sharing.

Youde ’16 (Jeremy; writer for World Politics Review; 4-29-2016; “Technology **Transfer** Is a **Weak Link** in the Global Health System”; World Politics Review; <https://www.worldpoliticsreview.com/articles/18639/technology-transfer-is-a-weak-link-in-the-global-health-system>; Accessed: 8-30-2021)

In mid-April, a spokesperson for the Ugandan government admitted that the country’s only functioning cancer treatment machine had broken earlier that month. The radiotherapy machine, donated by China to Uganda in 1995 and housed at Mulago Hospital in Kampala, is now considered beyond repair. While the government did acquire a second radiotherapy machine in 2013, it has not been operational because of delays in allocating 30 billion shillings—just shy of $9 million—to construct a new building to house it. The funding delay has lifted, but the machine won’t be up and running for at least six months. The government has announced plans to airlift some cancer patients to Nairobi for treatment, but that plan will only accommodate 400 of the estimated 17,000 to 33,000 cancer patients who need treatment annually in Uganda. This breakdown of technology is a human tragedy for the cancer patients from Uganda as well as elsewhere in East Africa that the radiotherapy machine helped treat. Beyond the personal level, though, the episode illustrates a larger shortcoming in global health. Total annual development assistance for health is approximately $36 billion, but that funding is overwhelmingly concentrated on specific infectious diseases. Noncommunicable diseases like cancer receive relatively little international funding—only 1.3 percent in 2015, and the dollar amount has declined since 2013. Funds to strengthen health systems, geared toward building and supporting a resilient health care system, are similarly low, making up only 7.3 percent of development assistance in 2015. Noncommunicable diseases kill more people every year than infectious diseases and accidents do, but this balance is not reflected in global health spending. ... These shortcomings also speak to larger problems in global health around issues of **technology transfers** and long-term **commitments** to keep that technology working. It’s one thing to provide necessary medical technologies in the first place; it’s another to ensure that those technologies are accessible and operational going forward. Despite the **importance** of technology transfers, questions of **long-term support** for them have received relatively little attention from the global health regime. As noncommunicable diseases like cancer cause an even-higher proportion of deaths each year, it will become all the more **imperative** that the international community address this gap in **sharing** and funding **crucial health care** technology. This does not mean that there are no efforts to facilitate technology transfers around the world. The Fogarty International Center, a part of the U.S. National Institutes of Health, has had an [Office of Technology Transfer](http://www.fic.nih.gov/News/GlobalHealthMatters/march-april-2014/Pages/technology-transfer-nih-ott.aspx) since 1989 to make medical innovations developed in the United States more widely available. The World Health Organization (WHO) also has a [Technology Transfer Initiative](http://www.who.int/phi/programme_technology_transfer/en/) to improve access to health care technologies in developing countries. These efforts are laudable, but their interpretation of technology transfer is almost entirely rooted in access to pharmaceuticals and vaccines. To be sure, that is a very important issue—but it only deals with one narrow element of technology transfer. The problems of global health technology transfers illustrated in Uganda underscore a larger issue: the need for a so-called fourth industrial revolution, what has been described as “blurring the real world with the technological world.” This idea gained prominence earlier this year when it served as the theme for the World Economic Forum in Davos. For global health, this means embracing technology to find low-cost ways to promote health, spread education, and reach communities whose access to the health care infrastructure is weak. It expands on the notion of telemedicine and eHealth to make it more encompassing. According to health care entrepreneur Jonathan Jackson, the fourth industrial revolution could change global health by encouraging a shift in focus “from healthcare to health promotion.” Moving from high-cost treatment to low-cost prevention, he has argued, will have significant and far-reaching positive economic implications for developing countries around the world. Its inspiring sense of technological optimism notwithstanding, this sort of approach cannot be the sole focus of technology transfers in global health. Prevention is indeed important, but the fact of the matter remains that people will get sick—and those sick people will need treatment. Mobile applications and electronic access to health care providers can be useful, but they cannot replace a radiotherapy machine. Understanding the root causes of noncommunicable diseases goes far beyond individual choices and intersects with the larger political, economic and social context, so we cannot assume that cybertechnology alone can stop cancer. It is also important to remember that the results of greater technological innovation and integration won’t be free. Sub-Saharan African states, on average, spend $200 per person per year on health care. Even if technology allows costs to decline, they are still likely to be out of reach for many people in most of these countries—in the same way that the purchase and maintenance of medical technologies are prohibitively expensive in these same states today. Technology in and of itself is not useful unless it can be maintained over the long term. This, then, is a weak link in the larger global health system: How do we ensure access to life-prolonging medical technologies beyond pharmaceuticals and vaccines in a sustainable way? Consider two ideas. First, development assistance for health must orient more of its resources toward treating noncommunicable diseases and strengthening health systems. These are the areas in which these technologies are likely to be used, but are not currently supported by the international system. The changing nature of health and disease will only make them even more important in the years to come. Second, longer-term funding commitments would provide a greater opportunity to incorporate medical technologies into health care systems sustainably. Machines will break down, and technologies will fail. That is inevitable. But the global health regime, from the WHO and its regional organizations like the Regional Office for Africa to major donors like the **U**nited **S**tates government and the Bill and Melinda Gates Foundation, needs to figure out how to ensure that these problems do not put **lives in peril**. Technology alone will not improve global health unless it is properly supported and funded.

#### International collaboration’s key to check future pandemics – otherwise, extinction.

Dulaney ’20 [Michael; digital journalist with the ABC June 2020; "'A question of when, not if': Another pandemic is coming – and sooner than we think", No Publication; https://www.abc.net.au/news/science/2020-06-07/a-matter-of-when-not-if-the-next-pandemic-is-around-the-corner/12313372, accessed 4-12-2021]

And as recently as September last year — just a few months before COVID-19 was detected in China — an independent watchdog set up by the WHO warned the world was "grossly" unprepared for the "very real threat" of a pandemic. But even more alarming is what the new coronavirus indicates about the future. Researchers say human impacts on the natural world are causing new infectious diseases to emerge more frequently than ever before, meaning the next pandemic — one perhaps even worse than COVID-19 — is only a matter of time. "We know that it's a probability, not a possibility," Dr Reid says. "The roulette wheel will start to spin again. "If you don't resolve the conditions that generated the problem, then we sit waiting for the next probability equation to come through. "And it will, and sadly it's possible that it's in our lifetime." The growing threat to human health Nearly all emerging pathogens like COVID-19 come from "zoonotic transfer" — essentially, when a virus present in animals jumps to infect humans. The US Centers for Disease Control and Prevention estimates three out of every four new infectious diseases, and nearly all pandemics, emerge this way. Researchers have counted around 200 infectious diseases that have broken out more than 12,000 times over the past three decades. On average, one new infectious disease jumps to humans every four months. Animal species like civet cats (SARS), camels (MERS), horses (Hendra), pigs (Nipah) and chimpanzees (HIV) have all been implicated in the spread of new viruses at different times.

### 1NC --- Infrastructure DA

#### Reconciliation passes now – the delay gives Biden time to work magic in the wings, but PC and focus are key

Herb et al. 10-1 (Jeremy Herb, CNN Politics Reporter, Kevin Liptak, Reporter, Phil Mattingly, Senior White House Correspondent, Lauren Fox, CNN Congressional Correspondent, Melanie Zanona, Capitol Hill Reporter, “'It doesn't matter when': How Biden gave feuding House Democrats an off-ramp”, CNN Politics, 10-1-21, <https://www.cnn.com/2021/10/01/politics/dems-biden-infrastructure-delay/index.html)//babcii>

(CNN)President Joe Biden didn't [travel to Capitol Hill on Friday](https://www.cnn.com/2021/10/01/politics/house-vote-infrastructure-democrats/index.html) to close the deal, or to rally the troops through a final legislative gantlet. There was nothing cinematic -- or dramatic -- about the trip down Pennsylvania Avenue for the 36-year Senate veteran, who has more than once informed aides of [his unparalleled ability](http://www.cnn.com/2021/09/27/politics/biden-agenda-congress-deal-maker/index.html) to read, speak to and corral lawmakers. Instead, in remarks that lasted less than 30 minutes, Biden served a singular purpose: a presidential pressure relief valve. In a week deemed an "inflection point" by top aides, where the President was rarely seen in public as his entire domestic agenda hung in the balance, it marked a seemingly low bar to clear for success. There would be no miraculous deal to unlock the formula to move forward on the two key components Democrats are attempting to pass. The promised vote on the [$1.2 trillion infrastructure bill](https://www.cnn.com/politics/live-news/congress-infrastructure-bill-vote-10-01-21/index.html) would not materialize. But after days of intraparty warfare and feverish late-night negotiations, a reset was desperately needed -- and the best Biden could offer. In delivering an unscripted and at times unwieldy message that the infrastructure vote wasn't likely to happen -- and the top-line cost of the economic and climate package was going to have to come down -- the President made the bet that he can keep both sides of the intraparty feud on board in the critical days and weeks to follow. **White House and Democratic leaders will now launch an all-out effort to win** over the two Senate Democratic holdouts, Sens. [Joe Manchin of West Virginia](https://www.cnn.com/2021/09/30/politics/joe-manchin-budget-bill-1-5-trillion-schumer/index.html) and [Kyrsten Sinema of Arizona](https://www.cnn.com/2021/09/30/politics/kyrsten-sinema-arizona-reaction/index.html), as they shape what the multitrillion-dollar economic and social package looks like -- and how high its price tag will be. Congressional Democrats and White House officials say progress was made this week getting all sides closer to an agreement on the massive economic, climate and health care spending package that Democratic leaders intend to pair with the bipartisan $1.2 trillion infrastructure bill that's passed the Senate already. But in the House, moderate and progressive Democrats were engaged in a **slow-motion game of chicken** over the infrastructure vote, with moderates demanding a vote on the infrastructure bill this week that had been pledged by House Speaker Nancy Pelosi -- and [progressives standing firm that they would vote it down](https://www.cnn.com/2021/09/30/politics/house-infrastructure-negotiations-vote/index.html) without an agreement on the framework for the larger economic package. On Friday, Biden sought the off-ramp. It marked his most direct effort to date to cajole the House Democratic caucus at a moment when its members have grown increasingly frustrated about the amount of attention the President and his team have paid to their side of the Capitol. Though well received with several ovations, the appearance didn't serve to salve those wounds entirely -- with some saying afterward that his pep talk had actually exacerbated them. But it did deliver a critical message and a consequential moment, multiple members said: Compromise now -- or end up with nothing. It's likely too soon to say whether the debate this week is just a preamble to Democrats' enacting their historic agenda or if it's a feud that leads to legislative defeat, hobbling the President's party ahead of a tough midterm election cycle with little to show for controlling both chambers of Congress and the White House. 'Who knows what label I get' After the roughly half hour meeting with the President, Democrats described a leader who was in his element and not working to change minds as much as remind members of their shared and unified goals as a caucus. Throughout the infrastructure push, Biden has made clear to Democrats that party unity -- or, in some participants' interpretation, loyalty -- is of utmost importance with only the slimmest of majorities in the House and Senate. He tried to break down the stalemate and the tensions that have hung over the party for weeks, reminding them that he's not on one side or the other. At one point, he made a reference to his own political ideology, saying, "Who knows what label I get." To which Pelosi replied: "President," prompting loud laughter from the room. Biden also talked about how he had redone his office to have paintings hung of Lincoln and FDR -- "A deeply divided country and the biggest economic transformation," said Rep. David Cicilline of Rhode Island, "which is kind of the moment we're in." White House officials think the President accomplished what he went to do on Capitol Hill: Remind Democrats of what is at stake while relieving some of the pressure that had built up over the last several days and reiterating his commitment to passing both pieces of legislation. With that done, officials believe, negotiators have a better environment to be able to push toward a deal. "We're going to get this done," Biden told reporters as he left the meeting. "It doesn't matter when. It doesn't, whether it's in six minutes, six days or six weeks -- we're going to get it done." 'As long as we're still alive' Even before Friday, Biden had alluded in recent days to negotiations slipping beyond the week's end. With the stakes simply too high -- on both the political and policy fronts -- there are no plans to walk away. "It may not be by the end of the week," the President had responded when asked Monday how he would define success at the end of this week. "I hope it's by the end of the week." "But as long as we're still alive ...," Biden said before shifting course in his thought.

#### Attacks on Pharmaceutical Profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Sinema specifically jumps Ship.

Hancock and Lucas 20 Jay Hancock and Elizabeth Lucas 5-29-2020 "A Senator From Arizona Emerges As A Pharma Favorite" <https://khn.org/news/a-senator-from-arizona-emerges-as-a-pharma-favorite/> (Senior Correspondent, joined KHN in 2012 from The Baltimore Sun, where he wrote a column on business and finance. Previously he covered the State Department and the economics beat for The Sun and health care for The Virginian-Pilot of Norfolk and the Daily Press of Newport News. He has a bachelor’s degree from Colgate University and a master’s in journalism from Northwestern University.)//Elmer

Sen. Kyrsten **Sinema formed** a **congressional caucus to raise** “**awareness of the benefits of personalized medicine**” in February. Soon after that, employees of **pharmaceutical companies** **donated** $35,000 to her campaign committee. Amgen gave $5,000. So did Genentech and Merck. Sanofi, Pfizer and Eli Lilly all gave $2,500. Each of those companies has invested heavily in personalized medicine, which promises individually tailored drugs that can cost a patient hundreds of thousands of dollars. **Sinema** is a first-term Democrat from Arizona but has nonetheless **emerged as a pharma favorite in Congress** as the industry steers through a new political and economic landscape formed by the coronavirus. She is a **leading recipient of pharma campaign cash** even though she’s not up for reelection until 2024 and lacks major committee or subcommittee leadership posts. For the 2019-20 election cycle through March, political action committees run by employees of drug companies and their trade groups gave her $98,500 in campaign funds, Kaiser Health News’ Pharma Cash to Congress database shows. That stands out in a Congress in which a third of the members got no pharma cash for the period and half of those who did got $10,000 or less. The contributions give companies a chance to cultivate Sinema as she restocks from a brutal 2018 election victory that cost nearly $25 million. Altogether, pharma PACs have so far given $9.2 million to congressional campaign chests in this cycle, compared with $9.4 million at this point in the 2017-18 period, a sustained surge as the industry has responded to complaints about soaring prices. Sinema’s pharma haul was twice that of Sen. Susan Collins of Maine, considered one of the most vulnerable Republicans in November, and approached that of fellow Democrat Steny Hoyer, the powerful House majority leader from Maryland. It all adds up to **a bet by drug companies that** the 43-year-old **Sinema**, first elected to the Senate in 2018, **will** gain influence in coming years and **serve as an industry ally** in a party that also includes many lawmakers harshly critical of high drug prices and the companies that set them.

#### Pharma backlash independently turns Case and causes circumvention.

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

### 1NC --- Pharma Innovation DA

#### Strong current IP guarantees causes massive Pharma innovation.

* Answers Evergreening/Me-Too Drugs

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

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

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

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

#### **R&D’s key to innovation – otherwise, future pandemics.**

Marjanovic et al. ’20 (Sonja; Ph.D. at the University of Cambridge; May 2020; “How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis”; RAND; <https://www.rand.org/pubs/perspectives/PEA407-1.html>; Accessed: 8-31-2021; AU)

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to **develop** medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also **infectious diseases** that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism context**.1 The general threat to public health that is posed by **antimicrobial resistance** is also well-recognised as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable partner** in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently **contributing in a variety of ways**. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The **primary purpose** of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider **how** pharmaceutical **innovation** for **responding to emerging** infectious diseases can best be enabled beyond the current crisis. Many **public health threats (including** those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) **are urgently in need** of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are **important policy questions** as to whether – and how – industry could engage with such public health threats to an even greater extent under **improved innovation conditions.**

#### We’ll concede the future pandemics existential argument

### 1NC --- Hobbes NC

#### TJFs first –

#### a] Frameworks are essentially T debates about the word ought which proves the better model of debate is what matters. b] Turns substance – it doesn’t matter how true a philosophy is if it can’t be engaged or is impossible to learn from

#### c] Exclusionary rule – we cant engage which means all their substantive arguments should be presumed false

#### The standard is consistency with absolute sovereignty.

#### 1] Predictability – every individual engages within the social contract when going to school or using public infrastructure which means it’s the one political engagement everyone is aware of.

#### 2] Political Education – politicians have to understand the social contract in order to know what powers they have and what they have to provide citizens and debating about Hobbes helps us learn about that.

#### 3] Topic Ed – the Hobbesian approach is ideal for dealing with IP in the context of public health disaster.

Ashcroft 05 [Richard E. Ashcroft (MA, PhD Reader in Biomedical Ethics in the Department of Primary Health Care and General Practice at Imperial College London). “Access to essential medicines: a Hobbesian social contract approach”. Dev World Bioeth. 2005 May;5(2):121-41. Accessed 7/31/2021. <https://pubmed.ncbi.nlm.nih.gov/15842722/> //Xu]

The problems I have described in these concluding remarks are serious and difficult. I do not think they are decisive. None of these problems demonstrate either the falsity or incoherence of a Hobbesian approach. Rather, they show that a Hobbesian approach needs further detailed development. I think that the merits of the Hobbesian approach are plain, so far as it takes serious notice of the features of the state of war, the instrumental nature of states and their legal and civil institutions, and the overarching objective of states to preserve their citizens from misery and disaster. More obviously ‘moral’ theories (such as utilitarian theory, or natural rights theories such as Lockean theory or modern human rights theories) are less illuminating, in that they fail to construct compelling perfect obligations lying with specific agents. The Hobbesian account I have constructed here has many loose ends, but I hope I have shown in this paper how a powerful argument for a perfect duty lying on the state to protect its citizens from public health disaster can be constructed, and the foundations of legitimate sovereign enforcement of powers of compulsory license over intellectual property. Public health takes priority over private economic interest. The only question is whether private economic interest is the only, or indeed an, effective means for promoting the public health in conditions of disaster.

#### 4] Resource Disparities – philosophical frameworks ensure big squads don’t have a comparative advantage since debates become about quality of arguments rather than quantity and require a higher level of analytic thinking that small schools have.

#### Negate –

#### 1] Sequencing – a sovereign can’t be obligated to do anything because they are the ones who choose what ethics and truth – the rez tries to coerce the sovereign to do something which challenges its authority.

#### 2] IP rights are implicit in the creation of the sovereign in expressing creativity.

Ghosh 04 [Shubha Ghosh (B.A., Amherst College; Ph.D., University of Michigan; J.D., Stanford Law School; Professor of Law, University at Buffalo, SUNY, Law School; Visiting Professor, SMU Dedman School of Law). “PATENTS AND THE REGULATORY STATE: RETHINKING THE PATENT BARGAIN METAPHOR AFTER ELDRED”. BERKELEY TECHNOLOGY LAW JOURNAL. 2004. Accessed 9/3/21. <https://lawcat.berkeley.edu/record/1119327/files/fulltext.pdf> //Xu]

As illustration of the limits of social contract theory,46 particularly the malleability of the notions of consent and promise, consider a social contract theory of intellectual property based on the thoughts of Thomas Hobbes rather than that of John Locke. No scholar has expressly developed a Hobbesian theory of patent or of copyright, but as a challenge to social contract theory, it may be useful to imagine what such a theory would look like.47 For Hobbes, humans created the leviathan-the sovereign state-to protect themselves from each other in the state of nature. 48 Without the leviathan, the state of nature was not an idyllic paradise but a condition of savagery and brutality. In the state of nature, to the extent that any creative activity occurred, the objects of creation would be cannibalized, thoughtlessly copied, adapted, distributed, and performed or used, sold, offered to sell, and made by others. Thus, intellectual property law under the leviathan would protect individuals from this state of nature by making them absolute, immutable, bountiful, and unlimited. Humans would consent to these terms if they were enforced equally for all creations, and each author and inventor would promise to all others to abide by this form of the intellectual property social contract.

## Advantage

### 1NC – AT: Solvency

#### All these case turns apply, if they say “covid specific” then at that point either covid medicines aren’t deemed essential in which case proves the aff is arbitrary bc theres no BL or covid medicines are essential so they apply.

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### Top-Level:

#### 1] A vaccine waiver greenlights counterfeit medicine – independently turns Case by increasing vaccine hesitancy.

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**.

#### 2] 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.

#### 3] 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.

#### Turns the Aff – Delta Variant proves current vaccines aren’t enough – we need new innovations.

Guarino 8-18 Ben Guarino 8-18-2021 “Vaccines show declining effectiveness against infection overall but strong protection against hospitalization amid delta variant” <https://archive.is/pvuzL#selection-747.0-750.0> (Education: University of Pennsylvania, BSE in bioengineering; New York University, MA in journalism)//Elmer

**Results** from a trio of studies, published in the CDC’s weekly report, **motivated** the **Biden** administration **to** **consider** **booster shots**. **Three studies published** Wednesday by the Centers for Disease Control and Prevention **show** that **protection against the** **coronavirus from vaccines** **declined** in the midsummer months **when** the more contagious **delta variant rose** to dominance in the United States. At the same time, protection against hospitalization was strong for weeks after vaccination, indicating the shots will generate immune fighters that stave off the worst effects of the virus and its current variations. Data from these studies persuaded the Biden administration to develop a plan for additional doses to bolster the immune systems of people vaccinated months earlier. The trio of reports, published Wednesday in the Morbidity and Mortality Weekly Report, the CDC’s scientific digest, also **reinforce** the **idea** that **vaccines** **alone will be unable to lift the nation out of the pandemic**. Masks and other precautions should be part of “a layered approach centered on vaccination,” wrote researchers from the New York State Department of Health and the University at Albany School of Public Health in their study of vaccine effectiveness across New York state. All three reports measure vaccine effectiveness, which compares the rates of infection or hospitalization among vaccinated people with the rates among people who had not been vaccinated. Until now, evaluations of vaccine effectiveness amid delta largely relied on observations from outside the United States. A recent New England Journal of Medicine study concluded the Pfizer vaccine was 88 percent effective against infections that caused symptoms in England. Others, such as **a study in Israel**, **found** **larger declines in protection against infection**. One U.S. report that has not yet gone through peer review, collecting data from Mayo Clinic Health System facilities in five states, **found** a **drop in** the **Pfizer**-BioNTech **vaccine’s** **effectiveness** **against delta infections to 42 percent**. The other mRNA vaccine, made by Moderna, was 76 percent effective. The new study from New York is the first to assess vaccine protection against coronavirus infection across the entirety of a U.S. state amid delta. The study authors found a modest drop in effectiveness: It descended from 92 percent in May to 80 percent in late July. Twenty percent of new infections and 15 percent of hospitalizations from covid-19, the disease caused by the coronavirus, were among vaccinated people. The second of the three studies published Wednesday by the CDC found effectiveness against infection declined for nursing home residents after delta emerged. It dropped from 75 percent in March through May to 53 percent in June and July. Vaccination for visitors and staff is crucial, the study authors wrote, and “additional doses of COVID-19 vaccine might be considered for nursing home and long-term care facility residents.” The third report, an analysis of patients at 21 hospitals in 18 states, found sustained protection against hospitalization. Effectiveness was steady at 86 percent, even in the midsummer months when delta outcompeted other variants of concern. For adults who do not have compromised immune systems, that effectiveness stood at 90 percent.

#### 4] Skill Disparities and Trade Secrets – Moderna proves IP isn’t the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control//**

within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

#### Every solvency card rests on the assumption that medicines and vaccines are already developed, expanding scope of production assumes strong R and D to develop vaccines so our innovation turns comes first.