## 1NC Meadows R3

### 1NC – DA

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

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

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

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

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

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

#### Warming causes Extinction

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

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

### 1NC – 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.

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 – CP

#### The World Trade Organization ought to increase intellectual property protections for medicines. The United States ought to designate intellectual property protections on medicines 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.

## Case

### Insulin

#### Patents are not the issue w/ patents for Insulin – this evidence is phenomenal.

HAI 16 Health Action International April 2016 “FACT SHEET Insulin Patent Profile” <https://haiweb.org/wp-content/uploads/2015/05/HAI_ACCISS_factsheet_insulinpatent.pdf> (a non-profit organization based in The Netherlands. Established in 1981, HAI works to expand access to essential medicines through research, policy analysis and intervention projects)//Elmer

The Insulin Patent Profile, published in April 2016, contributes to a better understanding of whether patents could be a barrier to access to insulin. This fact sheet provides an overview of the key findings of this research. Publicly-accessible **databases** **from** the **US, European, Chinese and Indian patent offices**, and the US Food and Drug Administration (Orange Book) and Health Canada, **were reviewed to determine** the **patent status of** human and analogue **insulins**. The profile and related fact sheet is the result of the mapping work completed in phase one of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study and is one of several profiles on the global insulin market to be published. The Leona M. and Harry B. Helmsley Charitable Trust and Stichting ICF are funding the ACCISS Study. The analysis included in this fact sheet is that of the authors alone and does not necessarily reflect the views of the Helmsley Charitable Trust or Stichting ICF. All references and conclusions are intended for educational and informative purposes and do not constitute an endorsement or recommendation from the Helmsley Charitable Trust or Stichting ICF. Patents on Insulin Products Already on the Market • **There are no patents on any formulations of human insulins**. • Based on the filing date and a 20 year patent period, patents on analogue insulins already on the market in the US and Canada have expired or will soon expire in these countries and elsewhere (Figure 1). • Four companies, Eli Lilly, Sanofi, Novo Nordisk, and Pfizer, own these patents. • The patents were most commonly filed in North America, Europe, Australia, and China. Patents on Insulin in Development • Across the four companies, the patent expiration dates of insulins in development are generally later than those of insulin products already on the market. Any insulin patents that might eventually be granted will expire as late as the 2030’s (Figure 2). • The patents and patent applications were filed in more regions of the world compared to the filings of insulin products already on the market. [Figure 1 omitted] Other Insulin Manufacturers • Patent applications for insulin were found for only four other companies: Biocon and Wockhardt (India), and Tonghua Dongbao, and Zhuhai United Laboratories (China). Recent work by Luo and Kesselheim in The Lancet Diabetes & Endocrinology on this topic in the US highlighted 1: • 19 active patents on insulin in 2014 with 10 of these filed by Novo Nordisk, six by Sanofi, and three by Eli Lilly. • **More than half of patents were for insulin-containing devices** **rather than** the active **ingredient**. (See also reference 2). • **At the end of 2015**, **there will be no patent protection on 11 common insulin products sold in the US.** • Intellectual property cannot be seen as a barrier to entry for biosimilar manufacturers. This data confirms that **for insulin products already marketed**, **the expiration of key patents** on analogues **has already taken place** or will soon take place (albeit some patents filed by Sanofi have later expiration dates than their competitors). A different picture is seen for insulin in development where there is no obvious patent cliff. Patents, if granted, will extend into the future particularly for Novo Nordisk and Sanofi products. **Of concern** **should be the increase in patents on devices**, **which might tie individuals to certain types of insulin**. That said, **unlike other medicines where i**ntellectual **p**roperty **could be seen as a barrier to access this is not the case for human insulin**. Certain limitations in the search methodology should be noted, including the exclusion of products marketed outside of North America. Additionally, publicly disclosing patent information with Health Canada is optional and listing patents may be delayed as they first screen and review them.

Not Patent Protected so they cant solve

Belluz 19 Julia Belluz 11-7-2019 "The absurdly high cost of insulin, explained" <https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive> (Julia Belluz is Vox's senior health correspondent, focused on medicine, science, and public health. She's covered topics as varied as the anti-vaccine movement, America's staggering maternal mortality problem, how dark chocolate became a health food, and what makes America's sickest county so unhealthy. She has also debunked numerous medical misinformation peddlers such as Dr. Oz, Gwyneth Paltrow, and Alex Jones.)//Elmer

**One real solution** to the problem, however, **would be to bring a generic version of insulin** to the market. There are currently no true generic options available (though there are several rebranded and biosimilar insulins). This is in part because companies have made those incremental improvements to insulin products, which has allowed them to keep their formulations under patent, and because older insulin formulations have fallen out of fashion. But **not all insulins are patent-protected**. For example, **none of Eli Lilly’s insulins are**, according to the drugmaker. **In those cases**, Luo said, **potential manufacturers may be deterred by secondary patents on non-active ingredients in insulins or on associated devices (such as insulin delivery pens).**

#### Petitions to the FDA swamp and deter generics.

Feldman 17 Robin Feldman 6-16-2017 "Pharma companies fight behind-the-scenes wars over generic drugs" <https://www.statnews.com/2017/06/16/generic-drugs-biosimilars-pharma/> (Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation.)//Elmer

One tactic that my colleague Evan Frondorf and I describe in our book, “Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market,” involves petitions to the Food and Drug Administration asking that the agency not give the green light to generic versions of a drug. Our research on 12 years of FDA data shows that in some years nearly 1 out of every 5 petitions filed on any topic — including food, tobacco, dietary supplements, and devices — was related to delaying generic entry. The FDA denies 80 percent of these petitions, but the process takes time, even for silly petitions, such as one asking the FDA to declare that a generic must provide information that the regulations already require. The time it takes to respond to these petitions delays the entry of the generic.

### Indigenous Access

#### Biopiracy thesis is wrong and misunderstands IP law.

Chen 6, Jim. "There's no such thing as biopiracy... and it's a good thing too." McGeorge L. Rev. 37 (2006): 1. (Associate Dean for Faculty and James L. Krusemark Professor of Law, University of Minnesota Law School)//Elmer

This Article begins, as do so many other works of legal scholarship, with a story.' Imagine a wonder plant teeming with extraordinary chemical properties. Like most living organisms in a diverse but fragile biosphere, it is native to one of the many poor countries of the global south. The local population and professional botanists agree that the wonder plant deserves the title of "village pharmacy."2 The developing country where this wonder plant is native supplies both the genetic material and the ethnobiological knowledge that an American life sciences company uses to develop pesticides, antiseptics, and even contraceptives. One product in particular, a pesticide and insect repellant, is markedly more stable and effective than traditional formulations known to and used by farmers in the source country. The American company proceeds to patent the new pesticide. The company not only fails to compensate the source country; it also asserts patent rights in this pesticide and other products developed from that wonder plant and traditional knowledge of its uses. In other words, the company stands in position to collect a patent-driven premium from the very villagers who informed it of the wonder plant's properties and who helped harvest the company's first samples of the plant. Writers of fiction are repeatedly told to draw the elements of their craft from real life. So too with this slightly more fact-driven version of storytelling. W.R. Grace's encounter with India's neem tree (Azadirachta indica) neatly fits this narrative.3 Approaching this story in notoriety is that of Eli Lilly & Company's derivation of vinblastine and vincristine, two cancer-fighting alkaloids, from the rosy periwinkle (Catharanthus roseus, formerly classified as Vinca rosea)." Vinblastine is used in treating Hodgkin's disease,5 while vincristine has become the drug of choice for treating childhood leukemia.6 Though neem and the periwinkle deserve more airspace, I shall offer a third story as the paradigmatic tale of alleged northern greed and southern victimhood in the global debate over biodiversity, biotechnology, and the proper relationship between the environmental protection, technological innovation, and social justice. The United States has literally gotten fat. In this Malthusian world,7 references to food security as an apology for American agricultural policies that constrict production and raise producer prices are nothing short of obscene.' "Only a nation that is obscenely rich by the West's historical standards and the larger world's contemporary standards can indulge in food aid either as a means of suppressing domestic supplies or as a tool for shaping foreign relations, much less both."9 The real public health crisis in America and other wealthy nations is not starvation, but obesity.'1 The prescription for this societal pathology is actually quite simple." Americans should eat less and exercise more. Having experienced a shocking increase of 26 years in life expectancy over the course of a mere 75 years of comprehensive food and drug regulation, however, American society as a whole evidently expects to continue the twentieth century's unprecedented and probably unrepeatable actuarial leap forward through pharmaceutical wizardry. 12 In other words, we would sooner take diet pills than limit portions or work out. What we want is a slick pharmaceutical solution: "One pill makes you small."' 3 As is **true of roughly four-fifths of all known drugs,** **an effective pharmaceutical remedy** for obesity **is** likely to be **derived from a natural source.**14 One plausible pharmacological candidate, the cactus Hoodia gordoniis, is prized for its appetite-suppressing, thirst-quenching, and awareness-heightening qualities. What the San people of South Africa have known for thousands of years about the plant they call "Xhoba" languished for three decades in the laboratories of the Council for Scientific and Industrial Research (CSIR). 6 Pfizer Corporation eventually acquired the rights to a hoodia-derived compound called P57 (so named because it was the 57th chemical tested) and at one time planned to market a diet drug that would compete against currently available concoctions that rely on the troubled combination of ephedra and caffeine. 7 A safe, effective substitute, if successfully tested and marketed, would earn massive profits. "Purchasers of diet products are often 'pathetically eager' to obtain a more slender figure."' 8 In July 2003, however, Pfizer withdrew from the project and discontinued clinical development of P57.' 9 The failure to exploit hoodia commercially mooted the immediate question of whether P57's developers owed the San people any compensation. As the stories of neem and the rosy periwinkle illustrate, however, demands for global justice hound almost every effort to extract agricultural or pharmaceutical value from the biological bounty of the developing world. So frequent, so familiar, and so uniform are **tales of biological exploitation** that they now **follow a predictable script**: <Large northern corporation> <seeks I is developing> a highly sophisticated <plant variety / pharmaceutical product> and sends researchers to <exotic place>. After interviewing local <farmers / foragers>, the company's researchers identify a <species / variety / breed> of <life form> that seems responsible for <desirable trait>. The researchers collect a few speciments and collate their interviews. The samples and the local lore inspire a successful program of <crossbreeding / genetic engineering / pharmaceutical development>, which saves the company thousands of hours and enables it to eclipse its competition. The company never shares its profits, however, with the local community from which it derived genetic resources and traditional knowledge. 20 **This is the paradigmatic biopiracy narrative.** That unmistakably accusatory word has set the rhetorical baseline in many debates within the international law of environmental protection and intellectual property for years to come. Many critics condemn the northern "[c]orporations [that] are surveying remote areas of the world for medicinal plants, indigenous relatives of common food crops, exotic sweeteners, sources of naturally occurring pesticides, and even the genetic material of once-isolated indigenous peoples."'" The epithets "biological colonialism, '22 "genetic imperialism, '23 and even plain "plunder"24 dominate many instances of the biopiracy narrative. I come not to praise the biopiracy narrative, but to bury it. Most **allegations of biopiracy** are so thoroughly **riddled with inconsistencies** and outright lies that the entire genre, pending further clarification, must be consigned to the realm of "rural" legend. **Grace has no patent on neem-derived products in India**,25 **and it is "not clear that the Grace patent**," **granted under American law,**26 "**will have any [negative] economic or social effect in India**., 27 The European Patent Office's decision to revoke the Grace patent further weakens its impact on India." **The fear that** the Grace **patent would deprive** **Indian villagers of the right to continue traditional uses of neem** (including the use of the tree's branches as toothbrushes) **is purely scurrilous**. **Neem in its natural form is unpatentable**.29 As for the rosy periwinkle, Madagascar has an even weaker claim of unjust treatment. 0 The rosy periwinkle is native to Madagascar but grows throughout the tropics. In 1952, Robert Laing Noble, a member of the medical faculty at the University of Western Ontario, received 25 rosy periwinkle leaves from his brother, Clark Noble, who in turn reported that the leaves were used in Jamaica for diabetes treatment when insulin was unavailable. The leaves had little effect on blood sugar but strongly inhibited white blood cells. By 1958, Robert Noble's research team at Western Ontario successfully isolated and purified the potent alkaloid extract now known as vinblastine. Working independently, Eli Lilly & Co. found that a crude extract of the whole periwinkle plant prolonged the lives of mice with leukemia. Eli Lilly eventually synthesized vincristine. Insofar as Jamaica has a much stronger claim as the source of traditional knowledge that facilitated the development of vinblastine and vincristine, even advocates of benefit-sharing find it difficult, if not altogether impossible, to fashion a convincing case that Eli Lilly should compensate Madagascar.3 1 Despite its implausibility, the **biopiracy narrative** now **dominates legal scholarship** on the commercialization of products whose development can be traced to a developing country. Advocates for the global south have been clamoring for proprietary protection against northern, industrial uses of ethnobiological knowledge, and that demand shows no sign of abating.32 Against this tide, piecemeal rebuttal of the biopiracy narrative seems futile. In any event, "[i]t would be a very easy and cheap display of commonplace learning" to pierce the "glowing and emphatic language" of the biopiracy narrative,33 as conveyed in individual stories about neem, rosy periwinkle, or hoodia. The time has come, in short, to dismantle the myth of biopiracy root and branch. This Article takes a modest first step toward deconstructing the biopiracy narrative. It will assess claims of biopiracy according to the layered model of information platforms. Every information platform consists of three distinct layers-physical, logical, and content-and biological information is no exception. Layer by layer, I will strip the biopiracy narrative of its plausibility. The conventional biological distinction between phenotypes and genotypes separates the physical from the logical layer of information in individual biological specimens and in species at large. Ethnobiological knowledge is best characterized as the inventive transformation of genetic information into commercially valuable applications. An appropriately utilitarian view of property and its relationship to each layer of biological information thus dissolves any allegation of biopiracy. Having drained the biopiracy narrative of its rhetorical power, this Article will conclude by briefly considering what the proponents of this narrative have been seeking and how the global community might give the global south what it needs (if not necessarily what it wants). Most of all, advocates for the global south seek some way of compensating traditional communities for their contribution to the global storehouse of biological knowledge. Although that goal remains out of reach, more modest-and in many ways more beneficial intermediate objectives are quite feasible. **Simple** and salutary **reforms of existing patent law can prevent outsiders from securing i**ntellectual **p**roperty **in knowledge already developed by traditional communities**. To the extent that bioprospecting will remain part of the global community's portfolio of tools for protecting the biosphere, countries rich and poor should develop a framework for regulating this practice and cooperate in encouraging the professionalization of parataxonomy.

#### Developing nations support biopiracy – it’s economic and environmental benefits are key to reduce poverty and stop further environmental degradation.

Chen 6, Jim. "There's no such thing as biopiracy... and it's a good thing too." McGeorge L. Rev. 37 (2006): 1. (Associate Dean for Faculty and James L. Krusemark Professor of Law, University of Minnesota Law School)//sid

Stripped of its normative premises layer by layer, the biopiracy narrative loses all appeal. The Convention on Biological Diversity's endorsement of national sovereignty assigns national governments all responsibility for initial access to genetic resources. Access to physical biological specimens is the one aspect of bioprospecting that lies entirely within the control of individual nation- states. Few, if any, national governments have elected to throttle this economic chokepoint for fear of destroying all prospective profits from the commercial development of biological diversity. Within the logical sublayer, the TRIPS accord allows the principal jurisdictions of the North Atlantic alliance-the United States, Canada, and the European Union-to adopt radically diverse solutions to the problem of patenting genetic information. Developing countries such as India, which are the usual complaining parties in instances of alleged biopiracy, enjoy ample discretion under TRIPS to refuse patents on a wide range of biotechnological inventions. Finally, although traditional knowledge is susceptible to protection through a modified form of trade secret law, no convincing economic case for such protection can be made. Within the biopiracy debate, no country strikes a consistent posture toward intellectual property as a legal tool. The southern countries that urge recognition of intellectual property in indigenous knowledge are often proponents of weakening proprietary protection on pharmaceuticals, agricultural chemicals, and educational materials in the name of increased access. 56 A study by the World Intellectual Property Organization (WIPO) found that respondents in 28 less developed countries, despite their misgivings about intellectual property as a legal concept and about aspects of specific intellectual property laws, often "expressed interest in exploring further the actual and potential role" of intellectual property in protecting traditional knowledge. 51 7 Subsequent WIPO publications have committed the organization to the project of developing models for protecting genetic resources, traditional knowledge, and folklore at the international level. " 8 North and south, the local attitude toward intellectual property depends on what is being protected and what degree of protection delivers the greatest benefit to local interests. Global cries for justice demand more ethical starch than this. "[If you go chasing rabbits /.. you know you're going to fall."'5 9 There's no such thing as biopiracy, and it's a good thing too. The real point of the biopiracy narrative is that the global south wants its largest possible share of the world's wealth. As matters stand, it is quite simple: The north is rich, and the south is not. Developing countries will not soon cease clamoring for some compensatory mechanism, whether or not grounded in the law of intellectual property, that would reward their historical contributions to biological knowledge and applications within the global commons. Motivated by "post-colonial theories of obligation to peoples in areas long exploited by the northern hemisphere," much of the international community seeks some way to alleviate "the extreme distress of those living in bio-rich areas of the world." '60Thanks to the "deep antagonism" generated by even the mere perception of illicit international law "that inventors compensate traditional knowledge holders for sharing that knowledge.' 62 The rhetorical consequences of this attack can be quite grim for the developing world. Most obviously, bioprospecting could come to a complete halt. Given the relatively modest profits realized from the first decades of bioprospecting, a comprehensively "instrumental or economic rationale" for protecting the biosphere as a storehouse of commercial value "appears beyond reach.', 163 Paul Heald cogently recognizes, even if the most ardent proponents of the biopiracy narrative do not, that the repeated hurling of "biopiracy!" as a misleading epithets will hardly convince profit-driven multinational corporations to engage the developing world. Moreover, an emphasis on the traditional knowledge of developing countries invites the immediate application of the developed world's standards of environmental protection and performance to vastly poorer countries. Much of the developing world already regards the environmental imperatives of the developed world as imperialism in green drag.'64 The southern campaign to enhance the proprietary status of its germplasm and its ethnobiological knowledge will engage not only the law of property, but also the entire legal apparatus of the industrialized world. Many traditional practices may affirmatively harm the environment, or at least conflict with global values expressed through international environmental law. Asian folk medicine drives global demand for rhinoceros horns and black bear claws. 165 On opposite sides of the Pacific, Japanese appetites66 and Makah rituals clash with the International Convention on Whaling. 68 Consumers in Florida who prize the eggs of endangered sea turtles as aphrodisiacs pay $36 per dozen. 169 The uncomfortable truth is that the developing world enjoys no moral superiority vis-it-vis wealthier countries on matters of environmental ethics. "Small-scale communities are seldom as humane and ecologically sound" as their advocates "portray them to be."'"" "Small firms ... are responsible for a massively disproportionate share of water and air pollution."' 7 ' Agriculture is especially suspect. "One would be hard pressed to identify another industry with as poor an environmental record and as light a regulatory burden."'72 Smaller, family-owned farms routinely underperform their larger, corporate counterparts in core tasks such as soil conservation and erosion control. 173 The propensity to destroy the environment flourishes in any cultural setting. Any environmental advantage along the developmental divide favors countries whose legal systems have adopted the most comprehensive and coherent rules for managing their citizens' contact with the living world in an age of growing scarcity and declining diversity. In industrialized societies, the law has comfortably assimilated the achievements of life scientists and shaped their attitudes. Nations such as the United States routinely confer patents, plant variety certificates, and other intellectual property rights for biological innovations. With equal vigor, however, western nations also subject those scientists to rigorous regulatory schemes in order to preserve the environment and to prevent ethical abuses. 174 It remains unclear whether traditional knowledge will ever qualify for proprietary protection in the world's wealthiest countries. Those practices having taken center stage in an international legal dialogue dominated by accusations of biopiracy, it hardly stretches the imagination to contemplate ways in which wealthier countries may test the developing world's commitment to the complete integration of their traditions into the positive law of the global community. What the global south and its advocates really seek in the struggle over biopiracy is a simple measure of justice. Massive wealth transfers are what they seek later; modest obstacles to patents on biotechnology may appease these advocates while the global community progresses, albeit at a snail's pace, toward some sort of profit-sharing scheme for spreading the rewards of the biotechnological revolution. Resolving disputes over alleged biopiracy does not require significant revision of existing intellectual property laws, let alone the novel and economically senseless solution of proprietary status for traditional knowledge of biological properties and applications. It may be enough simply to ensure that alleged acts of biopiracy do not form the basis for patents under existing intellectual property laws. Cleansing the current patent system of the taint of biopiracy requires little more than a few modifications that would effectively deny intellectual property rights to outsiders who export and exploit knowledge originally developed within a traditional community. American patent law in particular could withstand a modest degree of legislative revision. As the Patent Act of 1935 now reads, "[a] patent may not be obtained ...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.' 75 Prior art, if found, has a devastating effect on a patent. Prior art that defeats section 102's novelty requirement can also be used to crush a patent for failure to overcome 76 section 103's hurdle of nonobviousness. 1 The trouble lies in the definition of prior art. The Patent Act's definition of prior art embraces patenting or publication in any country, but includes public use or sale solely "in this country.' 77 To be exact: A person shall be entitled to a patent unless ... the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or ...the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.' In other words, "while almost all domestic prior knowledge, use, or invention is considered against a later United States patent, almost all similar foreign activity 179 is not.', The United States' policy of limiting prior art to domestic knowledge is out of step with patent law in other developed countries. The European Union considers evidence of foreign public use in assessing the validity of its patents.'80 Indeed, on the basis of foreign public use-specifically, widespread applications of the neem tree in India-the European Patent Office revoked W.R. Grace's patent on "Neemix," a pesticide and insect repellant derived from azadirachtin, a chemical naturally occurring in neem.'' Redefining "prior art" to include traditional knowledge found in other countries would limit the complicity of American patent law in instances of alleged biopiracy. 2 Even under the existing definition of prior art, the Patent and Trademark Office revoked a patent on turmeric after prior art on medicinal uses of the spice was demonstrated through an ancient Sanskrit text and a scientific paper published in 1953 by the Indian Medical Association.'"3 Eliminating American patent law's existing geographical limitation on prior art would, however, still allow "inventions based on traditional knowledge and genetic resources" to be "patentable as long as they are novel and nonobvious in view of [that] prior art. '" At the international level, TRIPS does not require that patent applications state the origin of genetic materials or biological knowledge used to invent a product. Although TRIPS directs members to "require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art,"'85 the treaty imposes no further disclosure obligations or other mandatory conditions on patent applicants. More comprehensive protection for traditional knowledge lies entirely beyond the scope of TRIPS, and even the most ardent advocates lament that a legal framework for protecting traditional knowledge is "highly unlikely" to "be inserted into TRIPS anytime soon."' What, in the meanwhile, might gainfully warrant the attention of countries both rich and poor? No matter how unprofitable, and no matter how modest in its impact on biodiversity conservation, commercial bioprospecting will persist for years to come. International policymakers should develop a joint framework for its regulation. International coordination on commercial exploitation of biodiversity can improve the very process of collecting rare specimens. Even though the collapse of global fisheries has shaken public confidence in official efforts to achieve "sustainability,"'87 bitter experience teaches that the lack of coordination would be worse. The slash-and-collect approach of Victorian orchid harvesters would probably prevail." Rationalized harvesting would limit instances of "the wonderfully unusual accomplishment of discovering and eradicating in the same instant a new species."'8 9 The international community might also facilitate the professionalization of parataxonomy,'19 especially in the developing world. Millions of species await collection and classification by properly trained field biologists. Transnational cooperation can help translate ethnobiological knowledge into terms understood by the global scientific community. Its economic impact is simple and immediate. "Scientific research," to put it bluntly, "generates jobs."' 9' The science of systematics is so labor-intensive that the task of classifying 10 million species would require 25,000 professional lifetimes.'92 Whether framed as cooperative bioprospecting or north-to-south technology transfer for the enrichment of parataxonomy, commercially oriented initiatives satisfy the Convention on Biological Diversity's exhortation that the international community should adopt "economically and socially sound measures ... as incentives" to conserve biodiversity and to contribute to its sustainable development.' 9' This much binds proponents and enemies of the biopiracy narrative. Bioprospecting represents merely one of many tools needed to stem the ongoing degradation of the global environment. Of this mutually dependent world's numerous environmental problems, "persistent poverty may turn out to be the most aggravating and destructive."' 94 We must remember "above all else" that "human degradation and deprivation.. . constitute the greatest threat not only to national, regional, and world security, but to essential life-supporting ecological systems. In environmental protection, as in any other challenge in international law, "[t]he threat of economic punishment does not deter nations with nothing to lose.' 96 Under the Biodiversity Convention, "economic and social development and eradication of poverty are the first and overriding priorities of' developing countries.'9'

#### Tying indigenous culture to environmentalism is part of the Western project to constrain indigenous identities.

Bosworth 10 (Kai A Bosworth - B.A.: Environmental Studies, Macalester College, Saint Paul, MN, 1/1/2010. “Straws in the Wind: Race, Nature and Technoscience in Postcolonial South Dakotan Wind Power Development,” <http://digitalcommons.macalester.edu/cgi/viewcontent.cgi?article=1007&context=envi_honors)//> rc sid

Some contemporary environmentalist discourses have built images of “authentic” ¶ indigenous experience, people, or knowledge to legitimate and authorize exclusionary ¶ and privileging practices (Braun 2002, Moore et. al. 2003). Romanticized images of ¶ Native American spiritual, physical, beneficial, and/or harmonious relationships to nature ¶ have become centralized around a discourse that anthropologist Shepard Krech has called ¶ the “Ecological Indian” (1999).¶ 5¶ These discourses are complex, and are articulated in ¶ different ways through social movements (Nadasdy 2005, Li 2000), popular television ¶ shows and movies (Sturgeon 2009), discourses of science and social science (Agrawal ¶ 1995, Latour 1993), and through economic development, tourism, and environmental ¶ politics (Braun 2002). For Braun, many contemporary conservation discourses have ¶ assumed, ¶ that safeguarding indigenous cultures would help protect nature, because ¶ indigenous peoples are thought to have an interest and/or expertise in sustaining ¶ existing ecological relations; or, alternately, that the preservation of nature is ¶ necessary to preserve indigenous cultures, because they are seen to have a ¶ necessary relation to nature…Indigenous identities are defined and contained ¶ within the environmental imaginaries of European environmentalists and the ¶ postcolonial nation-state” (2002, 81).

#### The most efficacious mainstream drugs come from Indigenous Knowledge – empirics are on our side.

King 91 Stephen King September 1991 "The Source of Our Cures: A new pharmaceutical company wants to provide reciprocal benefits and recognize the value of indigenous" <https://www.culturalsurvival.org/publications/cultural-survival-quarterly/source-our-cures-new-pharmaceutical-company-wants-provide> //Elmer

**FOR 500 YEARS**, SINCE THE People of South America encountered Europeans on their soil, **the global pharmacopoeia** has been **enriched by a number of important plant-derived medicines discovered and utilized by indigenous people**. The skeletal **muscle relaxant d-tubocurarine** is derived from an Amazonian arrow poison better known as curare, Chonodendron tomentosum. The **antimalarial drug quinine**, obtained from the bark of the several species on Cinchona trees, was first called "Indian fever bark" by the Europeans until the name "Jesuit fever bark" became more popular. Quinidine, also produced from the bark of Cinchona species, is now used as an antiarrhythmic for people with cardiac problems. An important amoebocide and emetic drug **emetine**, obtained from the roots of Cephalis ipecacuana, was utilized by indigenous people in Brazil **to treat dysentery**. One of the world's most important local anesthetics, cocaine is derived from the leaves of Erthroxylum coca and is still used today as medicine by thousands of people in the Andean region of South America. **Pilocarpine**, a drug **used to treat glaucoma**, is derived from the plant Pilocarpups jaborandi and was utilized by indigenous people in Brazil as medicine. These are only a few examples of the mainstream drugs that have been developed based on the - acknowledged - traditional wisdom of indigenous people. Roughly **74 percent of the 121** **plant-derived compounds** currently **used in the global pharmacopoeia** h**ave been discovered through research based on** ethnobotanical information on the **use** of plants **by indigenous people**. It is well known that tropical forest ecosystems contain a tremendous diversity of plant species. Estimates cite a minimum of 250,000 flowering plant species worldwide, at least 90,000 of which are found in the neotropics. Fewer than one percent of these plants have been investigated even superficially for potential pharmacological activity. A surprisingly large proportion of this plant biodiversity is classified, utilized, and actively managed by indigenous and local people of tropical regions. Tropical forest people have a profound knowledge about the utility, of plants found in their environment - an observation confirmed by ethnobotanical and ethnopharmacological research in the past decade (see references). At the same time interdisciplinary research by anthropologists, ecologists, geographers, and tropical agrnomists has shown that indigenous people and rural inhabitants of the neotropics have been - and continue to - actively managing plant genetic resources in their environment (Balee and Posey 1989; Irvine 1987; Denevan and Padoch 1988; Posey 1985); plants used as medicine are often moved and maintained as cultivated or wild/cultivated medical resources.

### Inaccessibility

#### Authorized Generics decimate competition.

Sipkoff 4 Martin Sipkoff 8-4-2004 "Big Pharma uses effective strategies to battle generic competitors" <https://www.drugtopics.com/view/big-pharma-uses-effective-strategies-battle-generic-competitors> (Healthcare Writer)//Elmer

But, according to Cutting Edge, brand-name pharmaceutical companies have begun flanking generics in an inventive way: They enter into manufacturing and distribution agreements with a generic company before a patent is about to expire, attempting to preempt market share. "A typical agreement specifies that the generic company will serve as a distributor of the nonbranded, generic form of the drug, which will continue to be produced in the branded drug company's manufacturing facilities," said Hess. "It's an increasingly popular strategy, often stemming from out-of-court patent lawsuit settlements." A successful flanking strategy can be beneficial to a generic manufacturer because it saves on capital outlay by not having to build or modify manufacturing facilities. "The brand-name pharmaceutical company benefits because the partnership enables it to continue to operate its manufacturing lines and turn a profit, thereby recouping more of its R&D investment in the drug and more of its capital investment in the manufacturing plant," said Hess. Here's an example of effective flanking: Generic drugmaker Apotex launched a version of GlaxoSmithKline's blockbuster drug Paxil in September 2003, threatening to significantly dent GSK's $3.2 billion-a-year bestseller. In response to Apotex's entry into the market, GSK struck a licensing agreement with another generic drugmaker, Par Pharmaceutical, in April 2003. The agreement specifies that GSK will supply Par with generic Paxil, in immediate-release form. The tablets are made by a GSK subsidiary, and Parwhich pays a royalty to GSK on salesdistributes them in the United States. "The royalty payments help GSK capture a small segment of the generic Paxil market, which offsets the losses of its branded Paxil sales following the drug's patent expiration," said Hess. Flanking is very controversial because it virtually derails competition. In fact, some generic manufacturers say it's illegal. It's very similar to what the Generic Pharmaceutical Association and others regard as the illegitimate strategy of "authorized generics." "It's an easy concept to describe," said Robert Reznick, a partner with the national law firm Hughes Hubbard & Reed. He chairs the firm's Pharmaceutical and Healthcare Practice Group and has written about the legality of authorized generics. "An authorized generic is like any other generic in that it is deemed equivalent to a brand-name drug," he said. "But rather than being made by an independent generic drug manufacturer pursuant to an Abbreviated New Drug Application, it is either made by or under a license from the New Drug Application holder itself. It may be marketed by an affiliate of the brand-name manufacturer or by a third party." In a white paper titled "Are Authorized Generics Lawful?" Reznick and his colleagues recently concluded that agreements between brand and generic manufacturers to create authorized generics may be legal under antitrust law, but the issue has yet to be fully settled.

#### Generic companies are just incompetent – means even without patents, they wouldn’t be able to produce.

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

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.