# 1NC v. Ben Grapevine Trips

## 1

### DA

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

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

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

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

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

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

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

#### Warming causes Extinction

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

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

## 2

### CP

#### Text – States ought to

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

#### Fund private public partnerships with pharmaceutical companies over developing solutions to Neglected tropical diseases and AMR super bugs

#### Solves evergreening and drug prices while avoiding our innovation turns.

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

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

## 3

### Weed CP

#### Counterplan text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines except for cannabis, medical marijuana, and medicines containing chemicals from cannabis.

#### It competes – weed is a medicine and is used in medicine

WebMD 20 [WebMD Medical Reference, WebMD is an American corporation known primarily as an online publisher of news and information pertaining to human health and well-being. The site includes information pertaining to drugs. It is one of the top healthcare websites by unique visitors. It was founded in 1998 by internet entrepreneur Jeff Arnold., August 20, 2020, "Medical Marijuana FAQ,", WebMD LLC, https://www.webmd.com/a-to-z-guides/medical-marijuana-faq, 8-21-2021] //WHS MR

What is medical marijuana? Medical marijuana uses the marijuana plant or chemicals in it to treat diseases or conditions. It's basically the same product as recreational marijuana, but it's taken for medical purposes. The marijuana plant contains more than 100 different chemicals called cannabinoids. Each one has a different effect on the body. Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are the main chemicals used in medicine. THC also produces the "high" people feel when they smoke marijuana or eat foods containing it. What is medical marijuana used for? Researchers are studying whether medical marijuana can help treat a number of conditions including: Alzheimer's disease Appetite loss Cancer Crohn's disease Diseases effecting the immune system like HIV/AIDS or Multiple Sclerosis (MS) Eating disorders such as anorexia Epilepsy Glaucoma Mental health conditions like schizophrenia and posttraumatic stress disorder (PTSD) Multiple sclerosis Muscle spasms Nausea Pain Seizures Wasting syndrome (cachexia) But it’s not yet proven to help many of these conditions, with a few exceptions, Bonn-Miller says. "The greatest amount of evidence for the therapeutic effects of cannabis relate to its ability to reduce chronic pain, nausea and vomiting due to chemotherapy, and spasticity [tight or stiff muscles] from MS," Bonn-Miller says. How does it help? Cannabinoids -- the active chemicals in medical marijuana -- are similar to chemicals the body makes that are involved in appetite, memory, movement, and pain. Limited research suggests cannabinoids might: Reduce anxiety Reduce inflammation and relieve pain Control nausea and vomiting caused by cancer chemotherapy Kill cancer cells and slow tumor growth Relax tight muscles in people with MS Stimulate appetite and improve weight gain in people with cancer and AIDS Can medical marijuana help with seizure disorders? Medical marijuana received a lot of attention a few years ago when parents said that a special form of the drug helped control seizures in their children. The FDA recently approved Epidiolex, which is made from CBD, as a therapy for people with very severe or hard-to-treat seizures. In studies, some people had a dramatic drop in seizures after taking this drug. Has the FDA approved medical marijuana? The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. In addition, the FDA has approved two man-made cannabinoid medicines -- dronabinol (Marinol, Syndros) and nabilone (Cesamet) -- to treat nausea and vomiting from chemotherapy. The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. How do you take it? To take medical marijuana, you can: Smoke it Inhale it through a device called a vaporizer that turns it into a mist Eat it -- for example, in a brownie or lollipop Apply it to your skin in a lotion, spray, oil, or cream Place a few drops of a liquid under your tongue How you take it is up to you. Each method works differently in your body. "If you smoke or vaporize cannabis, you feel the effects very quickly," Bonn-Miller says. "If you eat it, it takes significantly longer. It can take 1 to 2 hours to experience the effects from edible products."

#### The weed industry is growing, but needs investors to stay afloat – patents draw in investors and help companies expand

Roberts 20 [Chris Roberts, An award-winning investigative reporter and covered the legalization movement and the cannabis industry with a political economy lens for more than a decade. He launched northern California’s first cannabis-centric print vertical and founded San Francisco’s first dedicated drug-policy column. His work’s been featured in VICE, The Daily Beast, The Guardian, Deadspin, Observer, Curbed, Leafly News, High Times, SF Weekly, and many other places. He hold a master’s degree in politics from Columbia Journalism School, 5-28-2020, "Why Patent Cannabis? For Markets, Mostly.," Forbes, https://www.forbes.com/sites/chrisroberts/2020/05/28/why-patent-cannabis-for-markets-mostly/, 8-21-2021] //WHS MR

On May 20, Charlotte’s Web, the Colorado-based CBD giant and arguably one of the biggest names in legal cannabis, announced that the company was awarded its second federal patent on a cannabis plant. Unlike the company’s 2018 plant patent on a Farm Bill-compliant high-CBD hemp cultivar—which was the first hemp strain to receive federal intellectual property protection—US Patent No. 10,653,085 is a utility patent. This means, after satisfying a more rigorous process, including dropping off thousands of seeds at an official United States depository, Charlotte’s Web now claims as its intellectual property both the cultivar of hemp the company calls CW1AS1 as well as “methods” of plant production and cannabinoid extraction. Okay! But so what? Why patent a hemp strain—why patent two? What does it all mean? Does Charlotte’s Web now have legal claim to the entire CBD game?To the last question, no. And as for what this means, for normal people and cannabis consumers, very little. For patent attorneys or competitors of Charlotte’s Web in the CBD industry, it portends a little more, but just a little. At least for now, cannabis patents like this one aren’t really intended to defend intellectual property in court—which is where a patent has its most practical value. No, this patent is probably meant for the market. Patents like this exist mostly for companies to satisfy and woo investors, for whom a company’s ability to say “Look! I have a patent” might be the difference between signing a check, or not. And like all publicly traded cannabis companies, Charlotte’s Web has a lot of spooked and angry investors who need pleasing. Patents “generate interest in the company, and are something investors would look at,” said Jonathan Hyman, an attorney and partner at the Los Angeles office of Knobbe Martens. Whether Charlotte’s Web would enforce the patent, and how, “remains to be seen,” he added. Company officials were not available to discuss the matter. In a statement provided by Sylvia Tawse, the company’s director of communications, CEO Deanie Elsner said Charlotte’ Web “will continue to pursue patent protection for unique and novel hemp genetics developed by our horticulture division.” Whether that meant there are any pretenders the company plans to sue, she did not say. Though cannabis-related patent applications have been a thing since well before legalization and have tripled since 2015, as IP Watchdog noted, the mere phrase “cannabis patent” can still be triggering in cannabis circles. Patent talk can often lead to galaxy-brain thinking like the “Monsanto is supporting legalization in order to steal cannabis” or the “Philip Morris is buying up land in Humboldt County” conspiracy theories. In the case of Charlotte’s Web, the company’s already locked up what’s probably its most valuable asset: its name. Charlotte’s Web is named for Charlotte Figi, the sufferer of childhood epilepsy who enjoyed relief from her symptoms after taking an extract of high-CBD cannabis grown by the Stanley brothers (and who died earlier this month after contracting COVID-19). The world came to know Charlotte Figi and the Stanley brothers, seven photogenic Coloradans whose first names all begin with J, after they were prominently featured in a 2014 CNN special hosted by Sanjay Gupta. A very famous children’s book and a very famous and recognizable name, the company was sure lock down the name “Charlotte’s Web” with a trademark—one the company is currently defending in federal court, after a rival company dared market CBD products called Charlotte’s Web. That’s what patents are for in terms of the law. But markets are another matter—and it’s worth observing that the company went public after securing its first patent. Like almost all publicly traded companies in the cannabis sector, Charlotte’s Web is stuck in high-loss doldrums after hitting early peaks. For the past week, shares in Charlotte’s Web have been trading in the $7 to $9 range in the Toronto Stock Exchange. That’s a big gain from the $4.24 seen at the company’s mid-March nadir, but still far below last summer’s high-water mark of $28.21, set in August. Despite being sold in more than 11,000 stores, the company still lost $1.7 million in 2020—a hit smaller than other companies in the cannabis sector, but still in the red. Patenting hemp genetics and the processes to achieve them won’t be enough to rescue the rest of the company’s lost value. But if Charlotte’s Web wants to be a global CBD brand, with product in supermarkets and convenience stores all over the globe—and why wouldn’t it?—this means something. "Having this patent, that they can wave around and say, 'Hey, we've got coverage on it, and it's the best variety [of CBD rich hemp] that you're going to get,’ ” said Andrew Merickel, who holds a Phd in neuroscience and is also an attorney and partner at the San Francisco office of Knobbe Martens. “That’s pretty valuable.” How valuable? That’s all up to the logic of the market.

#### Cannabis is key to agricultural tech innovation – k2 long term sustainability and security

Yamazaki 17 Kevin Yamazaki (founder and CEO of [Sidebench](http://sidebench.com/), a leading digital product and venture studio that creates custom software and apps), 3-27-2017, "High Tech: How Marijuana Legalization Breeds Innovation," Observer, https://observer.com/2017/03/high-tech-how-marijuana-legalization-breeds-innovation/, SJBE

With the competition blazing and increased legalization on the horizon, we can expect to see the weed market become a hotbed for tech innovations. Forecasts indicate that revenue in the U.S. from medical marijuana alone will reach at least [$10.8 billion by 2018](http://fortune.com/2016/02/01/marijuana-sales-legal/). When states expand to allow recreational use, this number will surely increase. As investors become more comfortable deploying capital around cannabis, tech will revolutionize the marijuana ecosystem for producers, distributors, and consumers alike. The future of marijuana innovation Innovation has begun to outpace legalization as tech organizations make groundbreaking strides in researching and developing applications for marijuana. For example, [Kalytera](https://kalytera.co/) is exploring how cannabidiol — a non-psychoactive cannabinoid with a number of potential medical applications — can be used to target diseases such as obesity and osteoporosis. The findings of such research could transform how people cope with chronic illness and pain. Companies are also experimenting with improvements in [weed-growing processes](http://www.ibtimes.com/legal-marijuana-cultivation-driving-technology-revolution-industrial-agriculture-1925167). Cannabis is a finicky crop, so the ability to fine-tune growing processes could generate products far superior to today’s. Several organizations are devising smart, energy-efficient systems that automatically adjust growing environments according to changes in moisture, temperature, and sunlight. Meanwhile, data-capture technologies enable growers to identify optimal conditions for their plants, leading to larger and better-quality yields. The primary speed bump for the industry at this point is that marijuana is still classified as a Schedule I drug and is illegal at the federal level. Even if this factor doesn’t inhibit marijuana-centric technology innovation directly, it certainly has a strong indirect effect, as many potential financiers (and entrepreneurs) are scared away by either fear of prosecution or skepticism about the industry’s stability. That said, as more states allow for medical marijuana or legalize the drug entirely, the potential market size for marijuana-centric products expands as well. Perhaps more importantly, with some form of state legalization becoming the norm rather than the exception, there is a degree of safety in numbers. Assuming we see the trend of legalization for medical and recreational uses continue, production will inevitably become an even bigger business. Technology will play an increasing role in ensuring quality, consistency, and efficiency on the production side. We’re already seeing startups like [Cannafuse](http://cannafuse.com/) and [Teewinoit Life Sciences](https://tlscorp.com/) focusing on providing a tech-enabled scientific approach to the mass scientific production and distribution of cannabis. Advances in the irrigation systems, efficiency lamps, and data tracking processes used to grow marijuana may have far-reaching effects beyond the cannabis industry. Industrial farmers could adopt these techniques to increase their outputs and reduce energy expenses, while building managers can use them to lower energy loads from their properties. On the consumer side, the medical marijuana industry, in particular, will likely see an explosion of on-demand delivery services. Consumers are accustomed to using their smartphones to book cars, buy groceries, and mail packages. Why wouldn’t they receive their medical marijuana that way, too? Expect to see personalized services as well — think apps that recommend strains of marijuana on the basis of your preferences. Apps such as [MassRoots](https://massroots.com/) bring the social media aspect to what is, for many people, a social product by connecting weed enthusiasts to one another through news updates and other types of content. Even Microsoft is throwing its hat into the ring with [marijuana tracking software](http://www.businessinsider.com/microsoft-marijuana-tracking-software-2016-11) that ensures growers comply with their tax obligations and prevents legally grown pot from ending up on the black market. As the cannabis industry expands, the opportunities for growth are diverse and extensive. Tech-enabled companies will inevitably spur that growth, driving breakthroughs in medicine, crop development, and customer experiences. The momentum created by legalization will transform a once-taboo drug into a mainstream commodity, and the tech world stands to benefit enormously.

#### Extinction – food insecurity causes conflict and goes nuclear

FDI 12 FDI Team, 25 May 2012, “Food and Water Insecurity: International Conflict Triggers & Potential Conflict Points,” Future Directions International, <https://www.futuredirections.org.au/publication/international-conflict-triggers-and-potential-conflict-points-resulting-from-food-and-water-insecurity/>, SJBE

There is little dispute that conflict can lead to food and water crises. This paper will consider parts of the world, however, where food and water insecurity can be the cause of conflict and, at worst, result in war. While dealing predominately with food and water issues, the paper also recognises the nexus that exists between food and water and energy security. There is a growing appreciation that the conflicts in the next century will most likely be fought over a lack of resources. Yet, in a sense, this is not new. Researchers point to the French and Russian revolutions as conflicts induced by a lack of food. More recently, Germany’s World War Two efforts are said to have been inspired, at least in part, by its perceived need to gain access to more food. Yet the general sense among those that attended FDI’s recent workshops, was that the scale of the problem in the future could be significantly greater as a result of population pressures, changing weather, urbanisation, migration, loss of arable land and other farm inputs, and increased affluence in the developing world. In his book, Small Farmers Secure Food, Lindsay Falvey, a participant in FDI’s March 2012 workshop on the issue of food and conflict, clearly expresses the problem and why countries across the globe are starting to take note. . He writes (p.36), “…if people are hungry, especially in cities, the state is not stable – riots, violence, breakdown of law and order and migration result.” “Hunger feeds anarchy.” This view is also shared by Julian Cribb, who in his book, The Coming Famine, writes that if “large regions of the world run short of food, land or water in the decades that lie ahead, then wholesale, bloody wars are liable to follow.” He continues: “An increasingly credible scenario for World War 3 is not so much a confrontation of super powers and their allies, as a festering, self-perpetuating chain of resource conflicts.” He also says: “The wars of the 21st Century are less likely to be global conflicts with sharply defined sides and huge armies, than a scrappy mass of failed states, rebellions, civil strife, insurgencies, terrorism and genocides, sparked by bloody competition over dwindling resources.” As another workshop participant put it, people do not go to war to kill; they go to war over resources, either to protect or to gain the resources for themselves. Another observed that hunger results in passivity not conflict. Conflict is over resources, not because people are going hungry. A study by the International Peace Research Institute indicates that where food security is an issue, it is more likely to result in some form of conflict. Darfur, Rwanda, Eritrea and the Balkans experienced such wars. Governments, especially in developed countries, are increasingly aware of this phenomenon. The UK Ministry of Defence, the CIA, the US Center for Strategic and International Studies and the Oslo Peace Research Institute, all identify famine as a potential trigger for conflicts and possibly even nuclear war.

## Case

### 1NC – AT: Underview

#### Reject 1AR theory- A] 7-6 time skew means it’s endlessly aff biased B] I don’t have a 3nr which allows for endless extrapolation C] 1AR theory is skewed to the aff because they have a 2ar judge psychology warrant.

#### Reasonability on 1AR shells –it checks 2AR sandbagging by preventing really abusive 1NCs while still giving the 2N a chance.

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention

### 1NC – AT: AMR

#### 1] Low prices independently cause AMR.

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

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

#### 2] Alt causes outweigh innovation – antibiotics just aren’t profitable.

**Paton and Kresge 20** [James Paton and Naomi Kresge, James is a reporter at Bloomberg Business covering health, pharma, and Covid-19. Naomi is a reporter for Bloomberg Business covering pharmaceuticals. 8-8-2020, accessed on 8-28-2021, archive.is, "Superbugs Win Another Round as Big Pharma Leaves Antibiotics " <https://www.bloomberg.com/news/articles/2018-07-13/superbugs-win-another-round-as-big-pharma-leaves-antibiotics>] Adam

The fight against life-threatening infections suffered another blow when one of the world’s biggest drugmakers waved the white flag. [Novartis AG](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/NOVN:SW) is the latest drug giant to end antibacterial and antiviral research, joining the likes of [AstraZeneca Plc](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/AZLN:LN), [Sanofi](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/SAN:FP), [Allergan Plc](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/AGN:US) and [Medicines Co.](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/MDCO:US) [GlaxoSmithKline Plc](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/GSK:LN) has put some antibiotics assets under review. The pullback revives concern about a world in which routine infections again become lethal as bugs develop resistance to existing drugs. Sales of new antibiotics are too low for big pharma to recoup its investments, and public measures to encourage more activity aren’t moving the needle. “The market is broken,” said David Shlaes, a former pharmaceutical executive and consultant. “We’re at a point now where resistance is moving a lot faster than our ability to provide new antibiotics. This is just another in a long string of really bad news.” The latest retreat comes after a brief period when industry leaders appeared willing to take a [risk](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/news/articles/2016-06-30/superbugs-and-subsidies-draw-big-pharma-back-to-antibiotics) on the field. [Merck & Co.](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/quote/MRK:US) spent $8.4 billion on antibiotics leader [Cubist](https://archive.is/o/hm5Rm/https:/www.bloomberg.com/news/articles/2014-12-10/cubist-deal-a-rare-bright-spot-in-dismal-field-of-antibiotics) in 2014. Novartis, Glaxo and other companies pledged at the World Economic Forum in 2016 to fight the threat of drug-resistant bacteria. The U.S. government offered longer patent protection and subsidies, potentially worth hundreds of millions of dollars, to companies willing to invest. Not Selling But the new antibiotics just haven’t sold. Only five of the 16 brand-name antimicrobials approved from 2000 through last year were able to generate sales of more than $100 million annually, according to a study from Duke University’s Margolis Center for Health Policy. That’s a pittance compared with the billions of dollars for new cancer treatments. The problem for drugmakers is that new antibiotics are usually held in reserve and are not used unless they’re needed because patients develop resistance to an older medicine. Even the most expensive antibiotics, at around $1,000 a day, are cheap compared with a cancer medicine that will be given for months instead of a few days or weeks. Meanwhile, developing new antibiotics is becoming more expensive, said Gabrielle Breugelmans, director of research for the Access to Medicine Foundation. The roughly 275 research projects going on around the world might yield two or three medicines, she said.

### 1NC – AT: Bioterror

#### 1] no uq on the scenario

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

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

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

### 1NC – AT: Advantage

#### Feldman [\*\*and Wang\*\*] is a joke.

Risch 17 [Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs.

My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0.

Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue.

Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use.

Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

#### Secondary and Follow-on patents are key.

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

Why Protect Follow-On Innovation? The **attack on secondary** pharmaceutical **patents is based** in part **on** the **flawed premise** that **follow-on innovation is of marginal value** at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, **follow-on innovation** **can play** a **critical role in transforming** **an interesting drug candidate into a safe and effective treatment option** for patients. A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT **began** its life **as a** failed attempt at a **cancer drug**, and it was **only years later** that its potential **application in the fight against AIDS** was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

#### Evergreening is an incoherent concept AND anti-trust solves it

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

“Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.