## 1

#### CP text: The member nations of the world trade organization should add more stringent requirements for filing secondary patents by requiring secondary patent filers to demonstrate increased efficacy as compared to the original. Solves all your offense by reducing purely strategic patents while permitting R and D for genuine improvements.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

Lowell provides some precedent for creating a higher utility standard. 07 This new standard would focus on a drug's overall improved efficacy, rather than a minor tweak in the formula that would mitigate or resolve a previously caused side effect. This standard would require holding the pharmaceutical industry to a higher standard than other industries, which could potentially conflict with the United States' TRIPS Agreement obligations with the WTO.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5z

### 2 – Biodiversity DA

#### The COVID epidemic has exposed massive flaws in biosecurity, lack of public health compliance, anti-vaxxers, and PPE shortages have shown unique vulnerabilities – the US is specifically exposed

Lyon 21 (Regan Lyon; 7/1/21; Military Medicine, Volume 186, Issue7-8, July-August 2021, Pages 193-196; *“The COVID-19 Response Has Uncovered and Increased Our Vulnerability to Biological Warfare”*; accessed 8/13/21; <https://academic.oup.com/milmed/article/186/7-8/193/6135020>; Department of Defense Analysis at the Naval Postgraduate School) HB \*We do not endorse the ableist language of the card\*

INTRODUCTION Biological warfare has been an unlikely, but serious, concern for military operations and national security. The 2018 National Biodefense Strategy (NBS) articulated a collaborative plan to prevent, detect, and respond to biological threats to the USA.1 The NBS highlights recent, isolated outbreaks of Systemic Acute Respiratory Syndrome (SARS), Ebola, and Zika viruses as warnings to nation states and justification for enhanced biological threat responses. Although these events are not considered deliberate threats, clandestine bioweapon programs and terrorist groups seeking such programs are known to exist and capitalize on such natural outbreaks.1 The NBS’s emphasis on prevention and response drives the requirement to enhance biological weapon deterrence and defense strategies to avert the employment of biological weapons on U.S. civilians or military personnel.1 The public health crisis that ensued with SARS-associated coronavirus-2 (SARS-CoV-2) has highlighted our nation’s bioweapon vulnerabilities on the international stage and has the potential for disastrous effects on national security. Previous questions regarding how the USA would respond to a large biological outbreak (or biological weapon) have now been answered for potential adversaries across the world. The ambiguity of both our capabilities and weaknesses, which provided deterrence to adversarial employment of biological weapons before the pandemic, no longer exists. This article will provide an overview on biological weapons and the concepts of deterrence and defense in the context of bioterrorism. Then, it will analyze how the national personal protective equipment (PPE) shortage, public resistance to public health measures, the anti-vaccination movement, and USNS (United States Navy Ship) Comfort deployment to New York City have increased our vulnerability to bioterror attack by impacting our deterrence and defense measures. Finally, it will offer recommendations to restore our bioterrorism security after the detrimental effects from the events unfolding in the USA. BIOLOGICAL WEAPONS REGULATIONS, DETERRENCE, AND DEFENSE Even though biological warfare is considered a “weapon of mass destruction” and is prohibited by a treaty drafted by the 1972 United Nations Biological Weapons Convention (BWC), not all adversaries adhere to these standards. Terrorist groups and covert operations have utilized biological weapons for small operations because the actors, by nature, are either non-eligible to ratify the treaty or would not do so if they could. Although there have been no intentional large-scale attacks, especially by adversarial nation states, this is not guaranteed to be the case in the future.2 The BWC does not prohibit ratified nations from having pathogens or toxins for peaceful purposes, such as the development of vaccines. After the natural outbreak of smallpox and its subsequent eradication accomplished by the World Health Organization in 1980, less virulent poxviruses have continued to be used in a variety of laboratories for research and development of vaccines for a variety of diseases.3 The original, more deadly strain of smallpox has been retained at two facilities in Russia and Atlanta.4 Because smallpox’s virology makes it an ideal biological weapon, the samples in Atlanta and Russia offer defense through researching countermeasures should an attack occur and simultaneously provide a repository from which a biological weapon can be acquired. “Deterrence” and “defense” are two concepts which are typically described in terms of nuclear warfare, but they can also be applied to national security from a biological attack.5 Deterrence is the ability to prevent an adversary from taking some action during peacetime.5 For biological warfare deterrence, vaccines and preventative medicine measures prevent susceptibility to a microbe. For a largely vaccinated and/or health-conscious population, the costs of production, storage, and dissemination of a bioweapon greatly outweighs the rare chance of the target contracting the disease. New Zealand’s robust public health measures, citizen compliance, and continued efforts to sustain a caseload under 20 since April is a strong deterrent for biological attack.6 Defense mechanisms decrease the effectiveness of the attack, putting a high cost-to-benefit burden on the adversary.5 A defense measure for bioterrorism would be an adequate medical treatment response to casualties of the bioweapon, decreasing mortality and the overall effectiveness of the weapon. COVID-19 PANDEMIC ANALYSIS The novel SARS-CoV-2 has several characteristics of an ideal biological weapon, including high transmission rate, long incubation period, airborne transmission, and significant morbidity/mortality.7 In fact, early in the pandemic, suspicion was cast that the virus was being developed as a biological weapon by a laboratory in Wuhan, China.8 Although these allegations have been deemed conspiracy theories as a result of misinformation operations, the resulting pandemic and the panicked public share similarities to a bioterror attack. The events occurring within the USA during the coronavirus disease 2019 (COVID-19) pandemic create a global narrative on how we respond to a biological crisis. The 2018 NBS emphasized the continued threat of biological weapons to national security and identified the need to deter and defend against bioterrorism acts.1 This section will analyze events in the USA during the pandemic, how they bolstered or negated our current bioterrorism deterrence or defense strategies, and offer areas for improvement to restore our bioterror security. Personal Protective Equipment Shortage The 2018 NBS mandates having a robust mobilization of PPE for frontline healthcare workers and an adequate communication plan on preventative health measures for the general public in the event of an attack.1 The ability to provide sufficient quantities of PPE for medical personnel is a vital defense tactic as it increases the efficiency of the healthcare system to treat casualties in response to a biological outbreak. Having the ability to mobilize these resources to hospitals strengthens bioterror deterrence by demonstrating to a potential adversary that a bioterror attack would have a limited effect on a population given the healthcare preparedness. As conflicting information was published across multiple media platforms from January to March, panic spread that the virus was more dangerous than originally believed. Citizens flooded stores in town and online, buying “essential items” in preparation for a lockdown. Items such as masks, gloves, and sanitizers were out of stock everywhere, including healthcare supply chains. More importantly, citizens heard N95 masks could prevent contracting the virus, suddenly increasing N95 demand.9 Demand exceeded supply quickly, and healthcare workers began complaining of the nation-wide shortage of appropriate PPE required to care for infected patients.10 The inability to acquire necessary PPE supplies due to crippled supply chains and general public hoarding caused a ripple effect within the healthcare system. As a result, hospitals began to institute resource conservation measures, attempting to extend the life of supplies intended for one-time use. These PPE conservation measures, however, were interpreted by some healthcare workers as putting their lives in jeopardy and instigated lobbying and campaigning for government involvement. News reports flourished of disgruntled healthcare workers who were at risk of infection due to a lack of PPE. Such reports of general public hoarding, inadequate PPE logistical chains, and inappropriate PPE conservation measures by hospitals demonstrate the USA’s poor public health response. The NBS calls for an extensive mobilization of adequate PPE in response to a biological outbreak to decrease the pathogen spread, minimize its effects, and improve our resiliency.1 The capability to decrease the pathogen’s effects increases an attacker’s “sunk costs” should they choose to release a biological weapon. An impaired, or presumably impaired, capability adversely affects our defense strategy. In addition, the decrease in cost-to-risk ratio impairs our deterrence measures by showing worsened biological denial. The rapid healthcare PPE disappearance secondary to pandemic panic demonstrated a critical vulnerability in one of the most important defense strategies for a bioterror attack. To improve our defense capability, our healthcare workers must have an adequate supply of PPE, which can be mobilized expeditiously. Bioweapons have a high transmission rate and are easily disseminated, which make airborne and droplet transmission favorable. Public health experts should retrospectively analyze the types and amounts of PPE utilized in areas highly impacted by SARS-CoV-2. With these data, models can be created to make recommendations for phase-based mobilization of PPE and to determine the size of stockpile needed for immediate release. Government agencies need to establish agreements with PPE manufacturers to prioritize production in declared biological emergencies. Anti-Vaccination Movements Non-compliance with recommended public health and protective measures, including vaccines, also cripples our nation’s biodefense. Public health measures such as social distancing, aggressive sanitation, and mask mandates are examples of defense tactics for the COVID-19 pandemic. The individualistic U.S. culture fueled widespread non-compliance with these measures and has had significant effect on our ability to “flatten the curve” compared to other countries.11 The preference for “freedom…without interference from the state” is present in 58% of U.S. citizens, compared to 30-38% of European countries.11 The USA’s inability to uniformly employ these measures and decrease the virus spread compared to other countries signals to adversaries a weakness in our defense to decrease the effects of a biological outbreak. Furthermore, the speculation and conspiracy theories surrounding COVID-19 vaccines suggest an inevitable resistance to receiving the vaccine when available. Resistance to vaccinations is nothing new and caused challenges for vaccination against smallpox in the 19th-century U.K. epidemic.12 Then in 2019, the U.S. measles outbreak was amplified by anti-vaxxer campaigns.13 Since early in the COVID-19 pandemic, social media posts have warned that future coronavirus vaccines contain either tracking devices for the U.S. government or toxic chemicals.13,14 This unopposed and contagious anti-vax movement directly affects future biological deterrence because our adversaries know that the population will not be universally compliant with vaccination and will be susceptible to certain pathogens. Recent polls indicate that one-third of U.S. citizens,14 compared to 14% of U.K. citizens,12 would avoid receiving a SARS-CoV-2 vaccine, even if available and affordable. A poor vaccination rate increases a population’s disease susceptibility and decreases biological weapon deterrence by denial. The anti-vaccination movement has caught traction from massive information operations and propaganda on multiple media platforms. Since May 2020, anti-vaxxers have been propagating lies about the side effects of the coronavirus vaccine, but as of June, the Centers for Disease Control, which is responsible for vaccine education, had only a “plan” to counter such anti-vaccine campaigns.14 When the first vaccines were being administered to healthcare workers in the USA in December 2020, multiple social media efforts were started to promote the vaccine.15 Hashtags such as #vaxup, #IGotTheShot, #vaccineswork, and many more were used with social media posts of doctors, nurses, and other medical personnel receiving their vaccine.16 Some posts continued with threads of updates on any side effects encountered to quell public concerns. Information operations such as these may be more effective to counter the anti-vaccination propaganda than government-sponsored campaigns and require further research by public health officials.

#### Patents are the key to preventing bioweapon development – they prevent technology from being accessible to hostile state and non-state actors

Finlay 10 (Brian Finlay; Summer 2010; The Fletcher Forum of World Affairs, *“The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”*; accessed 8/13/21; Brian Finlay is a senior associate at the Stimson Center in Washington, DC, where he directs the Managing Across Boundaries Program. He has worked at the Brookings Institution, the Century Foundation, and Canadas Laboratory Center for Disease Control/Health Canada; pages 54-58; ask me for the pdf) HB

NEW CHALLENGES: THE BIOTECH REVOLUTION AND THE ROLE OF THE PRIVATE SECTOR Myriad private sector actors, ranging from single-employee enterprises to major multinational pharmaceutical giants dominate today's biopharmaceutical marketplace. Privately owned companies not only develop, produce, and operate the lion's share of biological industrial equipment, but carry out the greatest share of the scientific research and development for the relevant technologies, goods, and methods of application. University and other non-profit research is often commercially-funded, and many governments around the globe have built public-private partnerships, even in some of the most sensitive areas of biotechnology, to capitalize on cost reductions and innovation. According to a recent Ernest and Young study of the industry, today more than 80 percent of biotechnology firms-and, thus, the technologies they innovate-are in the hands of the private sector." In the United States, the industry's compound annual growth rate has historically hovered around 15 percent, yielding aggregate revenues of more than $70 billion in 2008.18 With fortunes to be made, unprecedented new applications to be discovered, and practically unlimited possibilities for growth, the biopharmaceutical industry has swelled dramatically over the past decade. It is estimated that the biotech sector supports about 3.2 million jobs across the U.S. economy-a little more than one job for every 100 Americans.' 9 In Europe, publicly traded biotech companies' revenues increased 17 percent in one year, from f9.6 billion in 2007 to £11.2 billion in 2008. And although the recent global financial crisis had a negative impact, the product pipelines of European industry are growing across all phases of clinical development.20 By virtually any measure, the United States and Europe remain unmatched global hubs for biotechnological investment and innovation. For national security analysts, this reality has long provided some measure of comfort. Although the system of security assurances mandated by technologically advanced (principally Western) governments is far from a panacea against biothreats, the absence of similarly robust legal barriers in many countries raises serious international security concerns. 2' For instance, although the United States, Canada, the United Kingdom, Germany, and Singapore have all introduced strict regulations on pathogenic agents that may be of interest to committed bioterrorists, most countries have not. Similarly, export controls and enforcement over many sensitive technologies are often extremely lax, particularly in countries of the Global South.22 And because terrorists and proliferant states may shop for pathogens and dual-use production technologies where controls are the weakest, this uneven patchwork of regulations leaves open a significant gap in global biosecurity standards.23 It was in this porous regulatory environment that President Obama released his National Strategy for Countering Biological Threats in November 2009. His plan cited both unparalleled innovations in the life sciences and imperfections in existing control regimes as the principle motivations for a new strategy that seeks to prevent biotechnology products from being used for harmful purposes.24 However, while the President's plan presented a more forward-leaning agenda to counter the rising risk of proliferation by explicitly leveraging public health in support of international security, at its root, the strategy extends the traditional state-centric approaches to a problem that is increasingly one of the private sector. A proper approach to the issue-and its solution set-must place industry at its epicenter. In short, the Obama strategy exemplifies the continued mismatch between governments' near singular focus on regulation of the industry on the one hand, and the elusive nature of privately-driven biotech innovation on the other. Beyond encouraging the industry to adopt more stringent security standards in the public interest, governments have generally proven bereft of innovative ideas that more directly link these measures to the private sector's enlightened self-interest. This mismatch is aggravated by the reality that the biotech and pharmaceutical community stands on the brink of yet another grand transformation that will render traditional control efforts, however effective they may have proven in the past, even more anachronistic. Over the course of the coming decade, the traditional drug development strategies employed so successfully by Western biopharmaceutical companies in the past will run headlong into two realities that will fundamentally alter biopharmaceuticals' business model: continued and rampant globalization of the life sciences and big pharma's patent expiration challenges. These forces will have profound implications on the future of drug development and the internationalization of intellectual property. Further, it threatens to open a new era of biological weapons proliferation by pushing bio-innovation into regions that are ill-prepared to manage the leakage of sensitive knowledge and equipment to those intent on developing biological weapons. Accelerating Globalization of the Life Sciences As globalization began to take firm root in the 1980s, virtually every industrial sector across the Western world sought to capitalize upon its underlying forces to promote efficiency and financial gain. Conceptions of tightly integrated firms whose product development was bound by national borders gave way to an internationalization of R&D, production, and supply chains. Expedited global trade, hastened by advances in everything from information to transportation technologies, allowed profit and efficiency to be maximized through outsourcing, off-shoring, supply-chaining, and other activities that drove intellectual and manufacturing capacity far beyond Western shores. The corresponding transfer of information, processes, and technology generated new local enterprises, including subsidiary operations that collaborated with or competed for global market share. This dynamic, in turn, created a virtuous cycle that accelerated the biotechnological competencies of these new markets. Soon, states that were seen to have lacked the indigenous expertise to perform complex R&D and manufacturing operations began to develop advanced, competitive industrial sectors.25 By the late 1990s, the spread of biotechnological knowledge and equipment allowed even more companies, universities, and research institutes around the world to benefit from advances in the life sciences. Today, developing countries nurture competitive industrial sectors that challenge traditional suppliers in Western Europe. According to the United Nations, many developing countries, including Argentina, Brazil, China, Cuba, Egypt, India, Mexico, and South Africa are already approaching the leading edge of biotechnological applications and have "significant" research capacity in the biosciences.26 In aggregate, this can only be seen as a significant boon to global development. As in the North, the developing South is putting these biotech capacities to work for peaceful purposes. Recent technological breakthroughs are indicative of this new geographic diversity of biological talent: the first vaccine against meningitis B was developed in Cuba; South Africa was the first country involved in HIV-C strain preventive treatment; India is the world's largest producer of the hepatitis B vaccine; and China was the first country to license gene therapy.27 Meanwhile, biotechnology is providing an infusion of high-skilled, stable, and lucrative jobs, and endowing struggling economies with critical growth and diversification. For the security conscious, however, the globalization of biotechnology has also expanded the locus of the bioproliferation challenge from technologically advanced countries of the North into far-flung places around the globe.28 Thus, even as humankind reaps the benefits of the biotech revolution, governments around the world are increasingly challenged by the confluence of rapidly advancing science and technology and by globalization itself. High technical hurdles to isolation and weaponization of dangerous pathogens once confined fears about the development and use of biological weapons to advanced industrial states. But now, the spread of dual-use biotechnologies means that a growing number of countries-and even terrorist groups-may gain access to the capacities necessary to develop a bioweapon.

#### Bioweapons destroy biodiversity – targeting, interspecies spread, and fungal adaptation

Abboud 18 (Nura Abboud; 9/22/18; EcoMENA; *“Catastrophic Impacts of Biological Warfare on Biodiversity”*; accessed 8/15/21; <https://www.ecomena.org/impacts-of-biological-warfare-on-biodiversity/>; Nura A. Abboud is an environmental activist and Founder of the Jordanian Society for Microbial Biodiversity (JMB), the only NGO in the Middle East concerning the microbial biodiversity. Nura specializes in molecular biology, biological sciences, microbial biodiversity, genetic fingerprinting and medical technologies. Her vision is to establish an eco-research center in the astonishing desert south of Jordan. She has received several scholarships and awards including honorary doctorate in Environmental leadership) HB

Biological weapons are considered the most dangerous of all known weapons of mass destruction. They are used to deliberately cause epidemics among humans; destroy the environmental components, including water, air, and soil; and target crops and livestock. Examples of diseases used in biological warfare include anthrax, smallpox, plague, cholera, and avian flu. In addition to the catastrophic effects of biological warfare on the biodiversity and the environment, their danger lies in their low cost and rapid spread, as well as their easy preparation, transport, and use. Unlike nuclear and chemical bombs, biological bombs are without odor or color and therefore cannot be detected. Additionally, bioweapons are dangerous because of their effects on untargeted organisms in a military attack, and the clinical symptoms they create may be difficult to distinguish from normal diseases. Bioweapon pathogens remain in nature for several years and are able to survive in harsh environmental conditions. Threat to Natural Resources Bioweapons spread germs that contaminate air, food, water, and the environment, causing epidemiological diseases for different living organisms. Air: A wide variety of germs can contaminate air and are used in biological warfare. Fungi are the most common, and they travel by air over long distances to infect healthy plants. Food: Food contamination is also one of the most powerful methods used to carry out biological warfare attacks. Disease is transmitted either directly to humans through contaminated food or drink or indirectly by hosts. Water: Water can spread a number of lethal infectious agents as well. For example, one gram of Clostridium tetani poison is able to kill eight million people within six hours. Threats to Biodiversity Diseases are one of the main drivers of extinction in endangered species; therefore, disease control is fundamental to preserve biodiversity. Despite the presence of vaccines and drugs for most bioweapons, they may not be available in adequate quantities to cope with an epidemiological disease outbreak. Biological attacks pose a threat to naturally rare wild plants and animals and to species whose natural habitats have been degraded by human activities. Furthermore, diseases that humans, domestic animals, and domestic plants have been able to develop immunity to can be fatal in wild animals and plants. Bioweapons are not only having direct effects on the genetic biodiversity of indigenous species but also are having direct and indirect catastrophic effects on vital plant and animal communities. Threats to Animal Biodiversity Conservation of livestock breeds is essential to maintaining genetic diversity, which in turn is vital to increasing the ability of living organisms to adapt to environmental changes. The danger of bioweapons regarding animal biodiversity is summarized in three main points: The direct impact of diseases on wild species Some deadly diseases in humans or domestic animals can infect wild animals. For instance, an epidemic destructive impact on endangered species is reflected in the effects of Canine distemper, a natural viral disease that infects wild dogs and wild animals belonging to the same group. Canine distemper was also developed in bioweapon laboratories. Over the past decade, the spread of this disease has resulted in habitat loss and in the extinction of a large number of wild species in North America. Additionally, it led to the elimination of about one-third of the lion population in Tanzania and had serious impacts on the endangered leopard population. Invasive species The history of rinderpest in Africa provides a model for predicting the potential effects of lethal diseases on wild species and livestock. In 1887, European colonial armies introduced the rinderpest virus to Africa through imported cattle, which led to a rinderpest outbreak among domestic cattle breeds and wild species, killing an estimated 90–95% of African cattle and buffaloes within three years. To control the epidemic, African herds and buffaloes have been destroyed in most parts of Africa. Despite efforts to combat rinderpest over the past century, the disease is still strong, and its outbreak in the region occurs frequently. Elimination of animal species, hosts, and vectors Threatened species may be destroyed in areas that have been subjected to biological attacks with the aim of eradicating the disease. For example, in the United States, programs to control brucellosis in livestock have resulted in killing large numbers of wild animals, including the Bison and the white tailed deer. Threats to Plant Biodiversity Microbes can be used in crop destruction. For instance, “Rice blast” is a disease affecting rice and therefore leads to crop destruction and genetic changes in the plant. Conclusion and Recommendations The discussion about controlling destructive bioweapons is growing, as they pose a vast danger to both humanity and the environment alike. Any failure to prevent biological attacks can lead to the deterioration of genetic diversity in animals and plants, the extinction of endangered species, and the destruction of human livelihoods and traditional cultures. Biotechnology has increased the economical value of genetic diversity of living organisms; hence, it has increased the risk of eliminating genetic diversity through the use of GMO bioweapons. Most of all, the environment will be the silent victim of this war.

#### Biodiversity loss causes extinction—turns and outweighs everything

Torres 16 (Phil Biologist, conservationist, science advocate & educator. 2 years based in Amazon rainforest, now exploring science around the world. “[Biodiversity Loss: An Existential Risk Comparable to Climate Change](http://futureoflife.org/2016/05/20/biodiversity-loss/)” http://futureoflife.org/2016/05/20/biodiversity-loss/)

The repercussions of biodiversity loss are potentially as severe as those anticipated from climate change, or even a nuclear conflict. For example, according to a 2015 [study](http://www.ncbi.nlm.nih.gov/pubmed/26601195) published in Science Advances, the best available evidence reveals “an exceptionally rapid loss of biodiversity over the last few centuries, indicating that a sixth mass extinction is already under way.” This conclusion holds, even on the most optimistic assumptions about the background rate of species losses and the current rate of vertebrate extinctions. The group classified as “vertebrates” includes mammals, birds, reptiles, fish, and all other creatures with a backbone. The article argues that, using its conservative figures, the average loss of vertebrate species was 100 times higher in the past century relative to the background rate of extinction. (Other scientists have suggested that the current extinction rate could be as much as 10,000 times higher than normal.) As the authors write, “The evidence is incontrovertible that recent extinction rates are unprecedented in human history and highly unusual in Earth’s history.” Perhaps the term “Big Six” should enter the popular lexicon—to add the current extinction to the previous “Big Five,” the last of which wiped out the dinosaurs 66 million years ago. But the concept of biodiversity encompasses more than just the total number of species on the planet. It also refers to the size of different populations of species. With respect to this phenomenon, multiple studies have confirmed that wild populations around the world are dwindling and disappearing at an alarming rate. For example, the 2010 [Global Biodiversity Outlook](https://www.cbd.int/gbo3) report found that the population of wild vertebrates living in the tropics dropped by 59 percent between 1970 and 2006. The report also found that the population of farmland birds in Europe has dropped by 50 percent since 1980; bird populations in the grasslands of North America declined by almost 40 percent between 1968 and 2003; and the population of birds in North American arid lands has fallen by almost 30 percent since the 1960s. Similarly, 42 percent of all amphibian species (a type of vertebrate that is sometimes called an “ecological indicator”) are undergoing population declines, and 23 percent of all plant species “are estimated to be threatened with extinction.” [Other studies](http://commondreams.org/views/2016/02/10/biodiversity-loss-and-doomsday-clock-invisible-disaster-almost-no-one-talking-about) have found that some 20 percent of all reptile species, 48 percent of the world’s primates, and 50 percent of freshwater turtles are threatened. Underwater, about 10 percent of all coral reefs are now dead, and another 60 percent are in danger of dying. Consistent with these data, the 2014 [Living Planet Report](http://bit.ly/1ssxx5m) shows that the global population of wild vertebrates dropped by 52 percent in only four decades—from 1970 to 2010. While biologists often avoid projecting historical trends into the future because of the complexity of ecological systems, it’s tempting to extrapolate this figure to, say, the year 2050, which is four decades from 2010. As it happens, a 2006[study](http://science.sciencemag.org/content/314/5800/787) published in Science does precisely this: It projects past trends of marine biodiversity loss into the 21st century, concluding that, unless significant changes are made to patterns of human activity, there will be virtually no more wild-caught seafood by 2048. 48% of the world’s primates are threatened with extinction. Catastrophic consequences for civilization. The consequences of this rapid pruning of the evolutionary tree of life extend beyond the obvious. There could be surprising effects of biodiversity loss that scientists are unable to fully anticipate in advance. For example, prior research has shown that localized ecosystems can undergo abrupt and irreversible shifts when they reach a tipping point. According to a 2012 [paper](http://www.nature.com/nature/journal/v486/n7401/full/nature11018.html) published in Nature, there are reasons for thinking that we may be approaching a tipping point of this sort in the global ecosystem, beyond which the consequences could be catastrophic for civilization. As the authors write, a planetary-scale transition could precipitate “substantial losses of ecosystem services required to sustain the human population.” An ecosystem service is any ecological process that benefits humanity, such as food production and crop pollination. If the global ecosystem were to cross a tipping point and substantial ecosystem services were lost, the results could be *“*widespread social unrest, economic instability, and loss of human life.” According to Missouri Botanical Garden ecologist Adam Smith, one of the paper’s co-authors, this could occur in a matter of decades—far more quickly than most of the expected consequences of climate change,yet equally destructive. Biodiversity loss is a “threat multiplier” that, by pushing societies to the brink of collapse, will exacerbate existing conflicts and introduce entirely new struggles between state and non-state actors. Indeed, it could even fuel the rise of terrorism. (After all, climate change has been [linked](http://thebulletin.org/climate-change-and-syrian-uprising) to the emergence of ISIS in Syria, and multiple high-ranking US officials, such as former US Defense Secretary [Chuck Hagel](http://www.defense.gov/News-Article-View/Article/603441)and CIA director [John Brennan](http://www.cnsnews.com/news/article/cnsnewscom-staff/cia-director-cites-impact-climate-change-deeper-cause-global), have affirmed that climate change and terrorism are connected.) The reality is that we are entering the sixth mass extinction in the 3.8-billion-year history of life on Earth, and the impact of this event could be felt by civilization “in as little as three human lifetimes,” as the aforementioned 2012 Nature paper notes. Furthermore, the widespread decline of biological populations could plausibly initiate a dramatic transformation of the global ecosystem on an even faster timescale: perhaps a single human lifetime. The unavoidable conclusion is that biodiversity loss constitutes an existential threat in its own right. As such, it ought to be considered alongside climate change and nuclear weapons as one of the most significant contemporary risks to human prosperity and survival.

## Case

### TL

#### [1] No solvency, no evidence that the aff spurns innovation.

#### [2] If second companies can repurpose that means a. they don’t solve innovation since companies will just direct r and d towards repurposing research instead of developing new drugs. B. plan gets circumvented. Companies can just acquire smaller companies to get their patents.

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

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

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

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

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

#### Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

### 1NC – Exclusitivites Defecit

#### THE AFF ONLY IMPACTS PATENTS AND NOT NON-PATENT EXCLUSIVITIES-THEY ARE DISTINCT WHICH MEANS THE AFF DOESN’T SOLVE

FDA 20 (FDA, 2/5/2020, Frequently Asked Questions on Patents and Exclusivity, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What\_is\_the\_difference\_between\_patents\_a)

[1. What is the difference between patents and exclusivity?](https://www.fda.gov/drugs/development-approval-process-drugs/null)  
Patents and exclusivity work in a similar fashion but are distinct from one another and governed by different statutes. Patents are a property right granted by the United States Patent and Trademark Office anytime during the development of a drug and can encompass a wide range of claims.  Exclusivity refers to certain delays and prohibitions on approval of competitor drugs available under the statute that attach upon approval of a drug or of certain supplements.  A new drug application (NDA) or abbreviated new drug application (ANDA) holder is eligible for exclusivity if statutory requirements are met.  See 21 C.F.R. 314.108, 316.31, 316.34 and sections 505A, 505E, and 505(j)(5)(B)(iv) of the FD&C Act.  Periods of exclusivity and patent terms may or may not run concurrently. Exclusivity was designed to promote a balance between new drug innovation and greater public access to drugs that result from generic drug competition.

#### YOUR OWN AUTHOR SAYS EXCLUSIVITIES ARE KEY PART OF EVERGREENING

**Feldman 2** (Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)

Anecdotal evidence has identified strategic behaviors various companies have deployed to great effect. One such practice is ‘evergreening’, which can be defined as artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period.[30](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn30) Scholarly work, including our own, has documented these behaviors as examples have emerged in individual cases and in press reports.[31](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn31) What has been missing from the literature, however, is a comprehensive empirical view.[32](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn32) Just how pervasive are such behaviors? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry? Only by answering this question can we contemplate the extent to which reforms are needed, as well as the extent to which strategic behavior to block generic competition may be contributing to rising drug prices. This study answers the questions. Providing a robust empirical analysis was no easy task. Transparency is not in the industry's interests, and companies have been known to go to great lengths to camouflage strategic behavior.[33](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn33) After all, a pharmaceutical company would be loath to let regulators and legislators know what it is up to, let alone competitors who might mimic the clever strategies. To accomplish our study, we turned to government sources, analysing more than a decade of data published by the US Food and Drug Administration (FDA). This involved extracting and analysing detailed information on as many as 11 different aspects of roughly 1800 drugs. The task would have been sufficiently challenging if the information were readily available. It was not. The project required teasing information painstakingly out of each monthly and annual publication, many of which are no longer available from the government in any form. Moreover, the complexities of pharmaceutical regulation and approval require intricate analysis of the information disclosed by the government, when that information is disclosed at all. In all, our work required assembling and analysing over 160,000 individual cells of data, all entered by hand. The results, however, were striking, and they show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. The data demonstrate that throughout the industry, companies create serial barriers to hold off the type of competitive entry that is fundamental to our innovative system. Key results from our 2005 to 2015 study include the following: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% had their protection extended at least once, with almost 50% having the protection cliff extended more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added on to them. Once a company starts down this road, there is a tendency to keep returning to the well. Eighty per cent of those who added protections added more than one. Among those adding more than one barrier, some were serial offenders, with almost half adding 4 or more protections and some adding more than 20. The problem is growing across time. The number of drugs that had a patent added on to them almost doubled during the time period. The addition of certain other types of barriers increased at an even greater rate, with some tripling.[34](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn34) These results may easily understate the landscape. In designing the methodology, we repeatedly adopted a conservative approach, following the path that would point away from suggesting a competitive barrier. In addition, the pharmaceutical industry has developed techniques for erecting competitive barriers that do not involve obtaining additional patents and exclusivities, techniques that would not be captured by our analysis.[35](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn35) Finally, we could only quantify those behaviors of which we are aware. Much behavior in the pharmaceutical industry remains obscured, and we cannot measure what we cannot see.[36](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn36)

#### YOUR SOLVENCY ADVOCATE SAYS EXCLUSVITIES NEED TO BE COVERED BY ONE AND DONE

**Feldman 3** (Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/)

One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented.

### 1NC – Disease Turn

#### INNOVATION OCCURS BY BUILDING ON EXISTING MEDICAL ADVANCES, ALSO IMPROVES EFFICACY FOR TROPICAL DISEASES

**Eger 10** (Eger, T. (,Professor of Law and Economics at the University of Hamburg) P. Ebermann, and P. Ramanujam. "Incremental innovation and patent protection for pharmaceutical products in India." Economic Analysis of India (2010): 129.)

The pharmaceutical industry provides an excellent setting to test determinants of incremental and radical innovation. Radical innovation refers to the identification of new chemical entities and their development into potentially useful pharmaceutical drugs. Incremental innovation, on the other hand, works with already known chemical compounds that are merely altered or employed in a different use (Cool)20. Drug enhancements such as new dosage forms may appear at first sight to be unimportant or even trivial but they are important avenues of learning for firms. Incremental progress gives rise to families or classes of related drugs. Although several agents within a class may have the same general action, they often differ significantly in specific actions, side effects, and suitability for individual patients (Levy,21 Banbury and Mitchell22). Consequently, incremental innovation takes many forms, including improved safety and effectiveness, fewer side effects, new formulations allowing greater ease of use and improved compliance, new indications, and new versions of the medicine developed for specific groups of patients (such as children).23 It can also take the form of greater product stability during storage and transport which can be especially important in tropical climates like some regions of India.24 Thus in the pharmaceutical sector incremental innovation connotes the continuous improvement of medicines, which also requires large-scale research and development, including clinical trials, along with approval from regulators before the new product can be offered to patients. It therefore becomes important to afford protection to such innovations. 7.3.2 The Importance of Incremental Innovation For many years radical innovation had been the primary goal of research for firms in many areas of science and technology. However, breakthrough innovations are important but rare in medical research. Most medical advances—like in all other technological fields—happen by ‘incremental innovation’ that is, innovation that builds on previous inventions. In the last 20 years, a number of noticeable changes have taken place in the type of research undertaken in all industries, and pharmaceutical industries in particular. These changes were motivated by the realization that due to long-run time horizons, high failure rates, and a low probability of returns the possibility of discovering new drugs was decreasing (Min et al.;25 Bhaskaran26). As a result, the focus of research shifted and concentrated on the discovery of new uses of known substances (Cool;27 Levy;28 Banbury and Mitchell29). Th e problem that confronted researchers working in the area of incremental innovation was that traditional patent law refused to recognize the discovery of new advantages of an old product as being novel. Lionel Bently and Brad Sherman conceptualize this problem in the following example. Assume someone discovered and patented aspirin as a drug useful in curing headaches. Later someone else found out that the consumption of aspirin also thinned the blood and was thus useful in preventing blood clots. Th e second use would be not patentable due to the fact that aspirin is already patented as a drug for curing headaches (Bently and Sherman30). Th e reason for this is that traditional patent law in many countries treated a claim to a ‘product for a particular use’ as a claim to the product per se; consequently the product would lack novelty even if it had previously been employed in a different use.

#### REPURPOSED DRUGS ARE KEY, THEY ARE MORE AFFORDABLE CAN BE ACCESSED MORE QUICKLY, AND WE SOLVE RARE DISEASES BETTER

**Seymore 06** (Seymore, Sean (New York Alumni Chancellor’s Professor of Law and Professor of Chemistry, Vanderbilt University. J.D., University of Notre Dame, 2006; Ph.D., Chemistry, University of Notre Dame). "Patenting new uses for old inventions." Vand. L. Rev. 73 (2020): 479.)

Indeed, the quest to find new uses for old drugs like aspirin deserves special attention. Over two-thirds of the value of worldwide patents accrues to chemical and pharmaceutical firms, and more than half accrues to a small number of large pharmaceutical firms.13 The cost of new drug development has led these firms to pursue drug repurposing—the quest to find new uses for old drugs.14 Since older drugs have already been tested in humans, much is known about their pharmacology and toxicity.15 The U.S. Food and Drug Administration (“FDA”) approves drugs that have been shown to be safe and effective for the manufacturer’s intended use;16 however, it also permits doctors to prescribe approved drugs for “off-label” indications.17 This allows repurposed drugs to bypass much clinical testing and reach the market more cheaply, more quickly, and with less risk than new drug candidates.18 Revenues generated from repurposed drugs can be substantial—eclipsing those from the drug’s original indication19 and those from new drugs developed from scratch.20 Repurposed drugs can also provide remarkable health outcomes for neglected diseases or for patients who otherwise have limited treatment options.2

### 1NC – AT: Innovation

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The affs wholesale attack on secondary patents ruins innovation---prefer contingencies that solve evergreening.

Holman 18 [Christopher; 9/21/18; Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology; “*Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection*,” Intellectual property watch, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>] Justin

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” – 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.

#### Strong IP protection are the only incentive for drug innovation.

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

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment**

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

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).

#### EXTENDED PATENTS ARE KEY TO FUND RESEARCH, NO MONEY TO PAY FOR NEW INNOVATIONS POST PLAN

**Bloom 12** (Josh Bloom (director of chemical and pharmaceutical sciences at the American Council on Science and Health, a health-care education and advocacy group based in New York). Should Patents on Pharmaceuticals Be Extended to Encourage Innovation? 1/23/2012, https://www.wsj.com/articles/SB10001424052970204542404577156993191655000#)

The American pharmaceutical industry is seriously ill. And extended patent protection is just the medicine the drug companies need. Pharmaceutical companies have long been demonized by many politicians and others as heartless behemoths that place profit ahead of people's well-being. But that perception couldn't be more wrong. The profits these companies make on blockbuster medications support the research that produces such breakthroughs. And the scientists working in the labs are fervently committed to finding useful new medicines. Unfortunately, there are far fewer of those scientists at work than there were 10 years ago, and their companies are in trouble. What's the problem? A confluence of events in recent years has made drug discovery more difficult, expensive and time consuming. Most important, it has become less profitable, largely because longer development times mean companies have less time left under patents to exclusively market their discoveries. Now, the industry faces a financial crisis because of the recent or imminent expiration of the patents on many of its most profitable drugs. Without extended patent protection for new discoveries, the industry won't be able to fund the current level of research. And the consequences are profound: decreased innovation, fewer new drugs and more job losses. Ugly Numbers Next time you hear about a drug making billions of dollars for its maker, consider this: Currently, bringing one new drug to market takes roughly 14 years, at a cost of about $1.3 billion. For every drug that makes it to market, more than 50 other research programs fail. After all that, only two of every 10 newly approved drugs will be profitable. Those profits must fund not only all the research programs that failed, but also all the drugs that are launched but lose money. When the industry was producing a steady stream of blockbuster drugs, as it did beginning in the 1990s (for example, all the AIDS drugs), the math worked in its favor. But in recent years the numbers have turned against the drug industry, for several reasons. For one, the Food and Drug Administration has become more risk-averse in the wake of the 2004 Vioxx debacle. Drug makers are now required to conduct more studies with many more subjects. That adds to costs and stretches out development times. And every year spent in clinical trials equals one year of lost patent coverage. In 1968, when development time was much shorter than today, most drugs had an effective patent life of about 17 years. Now companies usually have only about 11 years of market exclusivity for their drugs. And this number is expected to continue dropping as development times grow even longer—approaching a point where the costs and risks of development outweigh the rewards and research will stop. Many of the diseases addressed in the 1990s were simply easier to tackle. Since then, despite increased research spending, fewer breakthrough drugs have been discovered. Difficult conditions such as cancer, Alzheimer's, Parkinson's and obesity remain problematic. Amid all these challenges, the drug industry is losing its financial cushion as patents from the 1990s expire. Since 2006, brand drugs have lost an estimated $60 billion in sales because of patent expirations; by 2015, this figure is projected to rise to $160 billion. This is the so-called patent cliff. It shouldn't be surprising, then, that the industry is showing signs of stress. The share prices of the major drug makers have fallen sharply in the past decade, and weakened companies have succumbed to mergers and acquisitions, causing the elimination of 300,000 jobs during this time. Stretch Some, Cut Others Extension of patent life for the most innovative drugs would, at the very least, postpone the rush toward the patent cliff, providing drug companies with extra time to discover the next cycle of new, innovative therapies. With U.S.-based drug companies scaling back their research, there will be fewer discoveries to fill the gap and keep new treatments coming to market. Academic researchers are very good at studying the basic biology of a disease, but this is just the very beginning of the discovery process. The lion's share of the work—progressing from basic biology to an actual drug—requires the expertise and resources that academic and government labs simply don't have. Of course, longer patents would mean that important drugs would remain relatively expensive for a longer time. But the expense of new drugs is preferable to not having them at all. The fact that drug companies thrived in the past without patent protection is irrelevant. Companies didn't face the regulatory and competitive environment of today. For example, generic competition was minimal until the 1980s. Remember that manufacturers of generic drugs contribute nothing to innovation. Yet they take up to 90% of sales away from the comparable brand-name drugs whose makers risked the time and money to bring breakthrough treatments to market. There are some drugs that deserve less patent protection. These are the so-called line extensions—where companies simply tweak existing drugs enough to earn a new patent. Virtually identical to the original compound, these provide little real innovation. When companies are under economic stress, line extensions may become an attractive way to keep revenue flowing, drawing resources away from innovative, more important work. To discourage that and to keep drug companies focused instead on innovative treatments, patents for line extensions should be shortened, perhaps by three years or so, while patents for high-risk, first-in-class drugs and those that address unmet medical needs should be extended significantly—five more years could be a starting point for discussion. (Most drugs now get 20 years of protection from the time a patent application is filed, which is effectively about 11 years after accounting for development time.) One alternative that has been suggested is that in order to gain FDA approval, new drugs should have to demonstrate superiority to existing ones. This would be unrealistic because that standard could hardly ever be met in clinical trials—in nearly all cases you can't tell the real differences between two drugs until they are in the marketplace and being taken by millions of people. A well-planned extension of patent protection, especially for innovative drugs, is both reasonable and necessary to keep what is left of the American pharmaceutical industry healthy enough to continue its crucial work. In the absence of a remedial measure like patent-life extension, the industry will continue its decline, resulting in incalculable losses to the U.S. economy and poorer medical care for its citizens. This would be a national disgrace.

#### EVEN IF INDIVIDUAL PATENTS DON’T FOSTER INNOVATION, THE COLLECTION OF THOSE PATENTS DRIVE INNOVATION

**Thomas 09** (John R. Thomas (Visiting Scholar, Congressional Research Studies), November 13, 2009, Patent “Evergreening”: Issues in Innovation and Competition, <https://ipmall.law.unh.edu/sites/default/files/hosted_resources/crs/R40917_091113.pdf>)

Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas.... 67 Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.

### 1NC – AT: Feldman and Wang

#### Your author pulls warrants from a misleading and incomplete database – dates aren’t updated, protections are misidentified, and years are wrong.

**C-Ip 3/4** (C-Ip2, 3-4-2021, "UC Hastings’ Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called “Evergreening”," Center for Intellectual Property x Innovation Policy, <https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/#_ftn1>)The problems we have identified with the statistics provided by the Evergreening Database are numerous and multifaceted, and it would be beyond the scope of a single blog post to try to address them all. Instead, we have decided to focus on a single drug, ranolazine, which is used to treat angina and marketed by Gilead under the tradename Ranexa. There is nothing particularly unique about ranolazine—the problems with its statistics are representative of what we have generally observed to be pervasive throughout the Database. The ranolazine entry caught our attention because it purports to show that the drug was a subject of a relatively large number of “protections” (24 of them) and 13 years of “additional protection time,” even though the total time between the approval of the drug and expiration of all associated patents and exclusivities was only a little more than 13 years—about five years less than the average term of a U.S. patent. We will start with an initial explanation of the methodology underlying the Evergreening Database. As mentioned above, the statistics are derived from out-of-date versions of the FDA’s Orange Book, which is published on the FDA’s website and provides information on patents and “exclusivities” associated with FDA-approved drugs. The exclusivities can be any of a variety of non-patent regulatory exclusivities that Congress created to reward innovators that have achieved certain outcomes that Congress sought to incentivize. Examples include the “NCE exclusivity”—five years of data exclusivity awarded for the initial approval of a new active ingredient, i.e., a “new chemical entity”—and the seven years of orphan drug exclusivity awarded to an innovator that develops a drug for a rare disease or condition. The Orange Book provides a listing of these exclusivities, as well as a list of patents relating to the approved drug (i.e., patents claiming the drug’s active ingredient, formulations of the drug, and methods of using the drug). It also provides expiration dates for the patent and exclusivities. The FDA periodically revises the Orange Book, and when it does, it removes from the lists any patents and exclusivities that have expired. The creators of the Evergreening Database compiled this historical data in a Comma Separated Values file (“the CSV file”). The Database uses the patents and exclusivities derived from the CSV file to generate various statistics for each drug, including a total number of “protections” and “extensions,” as well as the “earliest protection date,” “latest protection date,” and the number of “months of additional protection” (which is the time between the earliest protection date and the latest protection date). Presumably, these statistics are intended to shed some light on the purported evergreening practices of pharmaceutical companies. Now let us turn to ranolazine. The Evergreening Database entry for ranolazine provides the New Drug Application (“NDA”) number for the drug (21526), the branded product name (Ranexa), the name of the innovator company associated with the branded drug (Gilead), and the date of FDA approval (January 27, 2006). The ranolazine entry also provides various statistics derived from the raw data, including the number of “protections” (26) and the amount of “additional protection time” (156 months, i.e., 13 years). This seems to provide an example of evergreening. The statistics appear to show that Gilead gamed the system to “artificially extend the protection horizon of its patents” by 13 years. However, a closer examination of the raw data tells a quite different story. First, what are the 26 purported “protections” that Gilead has apparently secured with respect to Ranexa? Eleven of them are patents that were once listed in the Orange Book for the drug. All the listed patents have expired, so none appear in the current Orange Book. While the Database lists the patents, it does not include expiration dates, which are necessary to understand the “protection time” statistics. Worse, the Database provides no information with respect to the other 15 “protections,” i.e., non-patent exclusivities. With some effort, the missing information can be found in the CSV file. The following step-by-step instructions will hopefully make it easier for others interested in following this path. Beginning on the homepage for the Evergreening Database, click on the “About the Data” hyperlink, which will take you to another page which states: To download the original dataset, that was used to develop the results for the article May Your Drug Price Be Evergreen, along with information about researching the FDA’s Orange Book, please see:

#### 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).