## Offs

### 1

#### A. Interpretation: If the affirmative defends anything other than **The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines** then they must provide a counter-solvency advocate for their specific advocacy in the 1AC. *(To clarify, you must have an author that states we should not do your aff, insofar as the aff is not a whole res phil aff)*

#### B. Violation:

#### C. Standards:

#### 1. Fairness – This is a litmus test to determining whether your aff is fair –

#### a) Limits – there are infinite things you could defend outside the exact text of the resolution which pushes you to the limits of contestable arguments, even if your interp of the topic is better, the only way to verify if it’s substantively fair is proof of counter-arguments. Nobody knows your aff better than you, so if you can’t find an answer, I can’t be expected to. Our interp narrows out trivially true advocacies since counter-solvency advocates ensure equal division of ground for both sides.

#### b) Shiftiness-Having a counter-solvency advocate helps us conceptualize what their advocacy is and how it’s implemented. Intentionally ambiguous affirmatives we don’t know much about can’t spike out of DA’s and CP’s if they have an advocate that delineates these things.

#### 2. Research – Forces the aff to go to the other side of the library and contest their own view points, as well as encouraging in depth-research about their own position. Having one also encourages more in-depth answers since I can find responses. Key to education since we definitionally learn more about positions when we contest our own.

#### C/A paradigm issues from above

### 2

#### Interpretation: Precluding a future increase is not a reduction

Melinda **Harmon 12**, Judge, United States District Court for the Southern District of Texas, Houston Division, 3/6/12, Zieche v. Burlington Res., Inc., 2012 U.S. Dist. LEXIS 30134, p. lexis

Zieche contends that the Court erred when it concluded that "there was no reduction in Zieche's salary or bonus percentage" that would constitute "good reason" for his resignation. Doc. 70 at 8, 9. The Court relied on the fact that Zieche received "his full 2006 performance bonus" after he began working at ConocoPhillips and that the bonus percentage increased from 30% in 2005 to 40% in 2006 as proof that Zieche did not suffer a reduction in salary.

Zieche contends that an increase in his bonus is irrelevant to a determination of whether his salary was reduced because a "bonus is not part of the salary," but is instead [\*12] "something in addition to what is expected or strictly due." Doc. 72 at 4. Additionally, Zieche alleges that "the [C]ourt's analysis ignores the specific provisions of the retention agreement," which defines "good reason" to include "any reduction from your annual rate of base salary." Id.

Initially, although Zieche alleges that ConocoPhillips reduced his salary, he introduced no summary judgment **ev**idence to support this contention. In his Response to ConocoPhillip's Motion for Summary Judgment, Zeiche repeatedly asserts that, in his new position at ConocoPhillips, he would "**not be eligible for annual merit salary *increases***" as he had previously received at Burlington. Doc. 54 at 4 (emph. added). The summary judgment evidence before the Court included Zieche's deposition, in which he admitted that his salary "remained the same . . . up to the time [he] resigned from ConocoPhillips." Doc. 48-1 at 50 (emph. added). Nevertheless, Zieche argues that the Court unnaturally should read the word "reduce" in the retention agreement to mean "**not increase**," rather than interpreting the word according to its plain meaning. **The Court does not agree with this reasoning**, and Zieche has introduced [\*13] no evidence to convince the Court otherwise.

#### Violation: They just preclude future secondary patents

#### Vote neg:

#### 1] Limits and ground– their model allows affs to defend anything from secondary patents to eightieth patents to future pandemics — there's no universal DA since it’s impossible to know the future where there won’t be IP— that explodes neg prep and leads to random future patent of the week affs which makes cutting stable neg links impossible — limits key to reciprocal engagement since they create a caselist for neg prep (innovation, collaboration, econ, ptx: all core neg literature thrown away)

#### 2] TVA – defend the advantage to a whole reduction aff. We don’t prevent new FWs, mechanisms, or advantages. PICs don’t solve – our model allows you to specify countries and medicines but your model still allows for shifty word PICs.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – a] deter future abuse and b] set better norms for debate.

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices, c] kills topic ed by forcing me to collapse to a shell rather than getting back to substantive education, if the shell is friv you should be able to answer it

### 3

#### Biotech industry strong now – new innovation and R&D coming

Cancherini et al. 4/30 [Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company] “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide> //ajs

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Secondary patents are necessary for innovation of otherwise mediocre drugs—core to cancer and HIV treatments

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “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/> September 21, 2018)DR 21

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.**

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Big pharma relies on evergreening as a major source of profit—empirics prove.

Chandler 15

Dr. Kelley Chandler, J.D. (B.S., Villanova University, 2015; J.D., Cornell Law School, 2020; Executive Editor, Cornell Journal of Law and Public Policy, Vol. 29); “PATENTS AND THE PHARMACEUTICAL INDUSTRY: CURBING THE ABUSIVE PRACTICES EMPLOYED BY BLOCKBUSTER DRUG COMPANIES TO PROLONG MARKET EXCLUSIVITY”; CORNELL JOURNAL OF LAW AND PUBLIC POLICY [Vol. 29:467]; 2015; <https://ww3.lawschool.cornell.edu/research/JLPP/upload/Chandler-note-final.pdf>; EMJ

1. Evergreening The practice of evergreening is described as “obtaining multiple patents that cover different aspects of the same product,” which has the effect of extending the patent term of the drug in question.83 Evergreening may take the form of acquiring additional patents on the active ingredients, methods of manufacturing, formulations, or chemical intermediates of a drug, to name a few.84 When a company first files a patent application on the active ingredient, its patent will be set to expire 20 years from the filing date.85 However, if the company files an application for a secondary patent five years later based upon a secondary feature of the drug, such as an improved method of manufacturing, the approval of the secondary patent will prevent a generic company from using that method until the secondary patent expires.86 The practical effect of this strategy is that a generic company seeking to enter the market will not be able to use the method of manufacture until the end of the second patent term, five years after the original patent term has expired.87 Although a generic company is free to produce and sell the active ingredient once the patent on that ingredient expires, development of a generic drug is often difficult and costly without the ability to employ certain manufacturing methods.88 In this way, brand companies build a “patent portfolio” around single drugs as a creative way to avoid surrendering market exclusivity due to primary patent expiration.89 Studies show that evergreening has increased significantly since Hatch-Waxman passed.90 Features of a drug which are covered by a secondary patent are considered “peripheral”91 and include things such as tablet coating or products produced from drug ingestion, dosages, or delivery routes.92 For example, the patent application for the active ingredient of the drug Paxil, which is used to treat depression, was filed on December 17, 1974.93 Of the several peripheral patent applications that were filed, the most recent patent was filed in 1998.94 If a generic had not succeeded in Paragraph IV litigation in 2003, this would have given Paxil an additional sixteen years of patent term exclusivity beyond the initial 20 years.95 Even given the generic challenger’s success, Paxil’s developers still enjoyed years of exclusivity beyond the original patent term due to their peripheral patents.96 Similarly, peripheral patents on internal coatings for the heartburn drug, Prilosec, afforded the manufacturer extra market exclusivity.97 Through strategically staggering patent applications on active drug ingredients and incremental drug improvements, a brand company can very “effectively extend the aggregate period of patent protection that applies to that product”98 even where the patent is later invalidated.99 Another consequence of the Hatch-Waxman Act on evergreening practice was that brand companies were being granted multiple 30-month stays on generic approval by the FDA.100 Before the generic’s approval, brands could acquire secondary patents and list them in the Orange Book, triggering an obligation for the generic to certify a challenge to the new patent and notify the brand of their intent to continue to market.101 Because this notification provided the brand company with the right to initiate a lawsuit, companies could plan their patent applications strategically in order to be able to file multiple lawsuits so as to trigger a new 30-month stay months after the existing 30-month stay began to run, giving the brand extra exclusivity through precluding generic approval at the FDA.102 Congress addressed this issue in 2003 through an amendment to the Hatch-Waxman Act, known as the Medicare Modernization Act, which prohibits multiple 30-month stays.103 Despite this change, evergreening remains a significant issue in the pharmaceutical space because secondary patents “remain enforceable proprietary rights against generic firms”104 which “increase the infringement minefield that generics must navigate when bringing a product to market.”105 The costs to society are rising drug prices and reduced access to necessary treatments.106 2. Product Hopping A related strategy within the evergreening category is the practice of product hopping, which denotes the brand-company practice of making an incremental change to a blockbuster drug which will soon be facing patent expiry, “secur[ing] patents on that new formulation, and then discontinu[ing]” the first drug.107 This takes place before any generics are on the market, and is usually combined with an aggressive marketing scheme in order to promote the new drug to consumers and physicians.108 Once the new drug has permeated the market, people are less likely to switch again, even if a generic alternative becomes available.109 Further, as Arti Rai and Barak Richman noted in their May 2018 article, because the new drug is not “therapeutically equivalent” to the old formation, State-level drug substitution laws that allow pharmacists to substitute generic drugs prevent substitution of the generic version of Drug 1 for Drug 2 prescriptions. In short, patients . . . pay monopoly prices for a branded Drug 2 because there is no generic alternative, and the market for Drug 1 evaporates just as a generic becomes available.110 Prilosec is a potent example of product hopping because the manufacturer successfully introduced an ostensibly new and improved version of Prilosec, widely known as “Nexium,” and influenced the market to “hop” before the patent expired on Prilosec.111 Although Prilosec was not completely withdrawn from the market, the manufacturer switched it from the prescription market to the over-the-counter market, and pharmacists were not able to substitute generic Prilosec for prescription Nexium due to the fact that they were technically different.112 While it is true that patients sometimes have the option to purchase the cheaper drug or the over-the-counter version when it remains on the market, the fact that pharmaceuticals represent a “unique market with noticeable information asymmetry” makes this much less likely.113 Additionally, because doctors are not actually purchasing the drugs, cost considerations are often overlooked when they are writing prescriptions, and they may have other incentives that factor into their decisions.114 3. The New Business Model Given the stakes, it is no surprise that brand pharmaceutical companies are increasingly turning to evergreening strategies to gobble up more market exclusivity for their blockbuster drugs.115 In the year 2000 alone, Prilosec’s manufacturer, AstraZeneca, reported that the drug brought in $6.3 billion,116 which is a substantial percentage of their overall revenue of $15.8 billion during that year.117 Due to the sheer amount of revenue that brand-pharmaceutical companies stand to gain or lose, it is reasonable to conclude that there is a new business model that pervades the pharmaceutical market.118 This model consists largely of evergreening and product hopping practices “turning out scores of minor variations, some of which become market blockbusters”119 which then “generate steady profits throughout the ups and downs of blockbusters coming off patents.”120 Notwithstanding that one of the goals of Hatch-Waxman was to spur brand companies to truly innovate and pioneer NCEs, only a miniscule percentage of brand company expenditures go towards researching new molecules.121 However, it would seem that the Hatch-Waxman Act lead to a pharmaceutical market which now “depend[s] less on the breakthrough research that executives emphasize than on rational actors exploiting ever broader and longer patents and other government protections against normal free market competition.”122 Contrary to Congressional intent, evergreeing and product hopping issues have only been exacerbated in the post-Hatch-Waxman atmosphere.123 It seems more and more that “when patent law realities are combined with…rational business decisions, all considerations point towards a focus on incremental drugs.”124 Hence, the new business model.125

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

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

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

### 4

#### CP TEXT: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by increasing penalties for patent abuse and evergreening fraud in the pharmaceutical industry.

#### **Evergreening collapses innovation, BUT the downsides are empirically debunked media hype – shifting enforcement for existing patent law solves abuse without harming pharma**

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

This week, the Senate Judiciary Committee was to mark up a bill limiting patent eligibility for combination drug patents—new forms, uses, and administrations of FDA approved medicines. While the impetus was to curb so-called “evergreening” of drug patents, the effect would have been to stifle life-saving therapeutic innovations. Though the “No Combination Drug Patents Act”—reportedly to be introduced by Senator Lindsey Graham (R-SC)—was wisely withdrawn at the last minute, it’s likely not the last time that such a misconceived legislative effort will be introduced.

An Exaggerated Response to a Disputed Theory

The bill would have established a presumption of obviousness for drug or biologic patent applications whose invention was a new: dosing regimen, method of delivery, method of treatment, or formulation. While there was a rebuttal provision where the claim covered a new treatment for a new indication or “increase[d] . . . efficacy,” the latter was almost certain to introduce years of uncertainty and litigation. Further, the bill would have covered a broader class than true combination drug patents, in which one active ingredient is combined with another or with a non-drug.

Like many recent legislative efforts, the amendment sought to address a perceived lack of affordability of prescription drugs. After praising the America Invents Act of 2011 and subsequent Supreme Court rulings for strengthening the US patent system, the bill claimed that rising drug prices have outpaced “spending on research and development with respect to those drugs.” In addition to applauding Supreme Court decisions that have injected unquestionable uncertainty into patentable subject matter standards, the amendment went on to blame high drug prices on continually overstated issues related to advanced drug patents.

According to critics, combination drug patents have granted drug makers unearned and extended protection over existing drugs or biological products. But, quite simply, when properly issued by the USPTO under existing patentability standards, these are new patents for new products or processes.

Combination patents have been maligned as anticompetitive, resulting in a “thicket” of patents that impedes innovation through transaction costs and other inefficiencies. Unfortunately, notwithstanding a lack of empirical evidence validating the harm of follow-on innovation patents, patent thicket rhetoric is now being echoed by the media, the academy, courts, and policy makers in a fraught attempt to fix drug pricing.

Reports (see here, here, here, and here) from leading antitrust experts and intellectual property scholars have detailed the value of incremental innovation and challenged the notion that patent thickets are a true threat to competition and innovation. These studies have exposed patent thicket claims—much like the “troll” narrative that for years infected patent law debates—as an empty strawman theory, the repetition of which has led to undue confidence in its accuracy. The reality is that what critics point to as problematic cases of combination patents are in fact infrequent outliers, strategically highlighted to discount evidence of the value of new and innovative drug uses and administrations.

#### CP solves the aff while fostering innovation – directly comparative to the aff

Holman 20 [Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection” p. 29-30 https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3593954]

Senator Thom Tillis, in his opening remarks prepared for one of the Senate’s hearings on drug pricing and intellectual property, expressed his concern that “[some members of Congress are] trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel[, and that] by just focusing on patent protections, and the number of patent protections available to a single product, [Congress] may be doing more harm than good to our nation’s innovation economy.”112 Instead, he would support legislation that will “promote innovation and competition, allow the United States to continue to be the leader in medical and pharmaceutical research, and will ultimately lower drug prices for consumers.”113 It is important to bear in mind that the reason there has been such an uproar over the price of drugs is that these drugs provide huge benefits for society, far exceeding most other patentable innovation, and were it not for the patent incentive, it is very unlikely these products would have been made available to patients in the first place. In his testimony prepared for the same Senate hearing, Professor Olson reminded the Judiciary Committee that “even studies casting doubt on patent law’s efficacy generally tend to find that in the area of pharmaceuticals, patent law has a large, positive effect on social welfare by providing incentive for significant levels of drug development that otherwise simply would not occur.”114 By ~~impairing~~ impeding the ability of pharmaceutical companies to obtain patents on their inventions, the legislation discussed in this Article could discourage the investment necessary to bring the next generation of pharmaceutical innovation to patients. If pharmaceutical companies are deemed to be misusing patents to the detriment of patients and third-party payers, then it is that misuse of patents that should be targeted by legislation, not the patents themselves. For example, if the allegations regarding product hopping are true, and doctors are prescribing and patients using far more expensive follow-on products that provide little if any benefit to the patient, then that is a problem with the market that should be addressed, rather than denying patent protection for truly worthwhile product improvements. If pharmaceutical companies are using anticompetitive means to coerce patients and doctors into switching drugs, then antitrust laws can provide the remedy, as discussed above.115 Likewise, if the sheer number of patents that could be infringed by a single generic or biosimilar product exceeds the litigation capacity of any company attempting to bring such a product to market, then courts have it within their means to require the patent owner to limit infringement litigation to some reasonable number of patents and patent claims, and Congress could pass legislation that would encourage courts to do so, if such a reform is deemed necessary. By targeting misuse of patents by pharmaceutical companies, rather than pharmaceutical patents per se, it should be possible to address any valid concerns with the way pharmaceutical companies are using the patent system, while maintaining adequate incentives for the next generation of innovation.

### 5

#### Counterplan text: The member nations of the World Trade Organization ought to require stricter patentability standards for follow on patents by the drug’s originator.

#### Solves evergreening, but also leaves room for genuine innovation.

Christie et. al 21, A.F., Dent, C.H.R.I.S. and Studdert, D.M., 2021. Evidence of 'Evergreening' in secondary patenting of blockbuster drugs. *Melbourne University Law Review*, *44*(2), pp.537-564. //sid

It is reassuring that **the majority of follow-on innovation** associated with blockbuster drugs **is undertaken by entities other than the drug’s originator, and occurs both before and after expiry of the patent** over the drug’s API and the expiry of associated secondary patents held by the originator of the API. Th**is shows that patents** — both primary and secondary — **which are owned by the originators of blockbuster drugs do not give them a monopoly over further innovation in relation to the drug**. Thus, it appears that **policymakers do not need to be concerned that drug originators’ secondary patents stifle welfare-enhancing innovation by others**. The fact that **most of the follow-on innovation by others occurs after the granting of regulatory approval to market** the drug provides policymakers with a potentially valuable lever**.** It seems likely that any regulatory reforms which expedite the granting of drug approval will also expedite the commencement — and thus potentially increase the amount — of follow-on innovation that is undertaken by third parties. **Since such follow-on innovation is generally regarded as socially desirable, policymakers should seek to identify mechanisms that speed up the assessment of drug approval without compromising the effectiveness of that assessment**. Although the majority of blockbuster drug follow-on innovation is undertaken by third parties, a substantial amount (27%) is undertaken by the originator of the drug — resulting in an average of 13 secondary patents per drug. These secondary patents have greater private value than those held by others, and their typology is consistent with the theorised evergreening behaviour of drug originators. Considered together with our earlier study’s findings, these findings provide support for the view that secondary patenting by drug originators can have adverse welfare effects through extending the originator’s marketplace exclusivity over the drug. Policymakers must be alert to this possibility, and need to consider how to reduce its likelihood. We consider that those responsible for implementing, reviewing, validating and correcting patent examination practices — patent offices and, ultimately, courts — should ensure that the patentability requirements, especially those of inventive step (non-obviousness) and industrial application (utility), are applied rigorously to the types of follow-on innovation with the greatest potential to have an evergreening effect — namely, delivery mechanisms for, and formulations of, APIs.

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to– reasonability checks 2AR sandbagging by preventing really abusive 1NCs while still giving the 2N a chance.

#### No new 1ar theory paradigm issues- A] the 1NC has already occurred with current paradigm issues in mind so new 1ar paradigms moot any theoretical offense B] introducing them in the aff allows for them to be more rigorously tested which o/w’s on time frame since we can set higher quality norms. C] They get new 2ar paradigm issues that I cant contest which means they can just auto win every theory debate by setting paradigm issues that exclude all my offense

### 6

#### **Genocidal settlement is** a structure, not an event meaning ontological logic of elimination is an everyday manifestation that defines settler identity.

Rifkin 14, Mark. Settler common sense: Queerness and everyday colonialism in the American renaissance. U of Minnesota Press, 2014. (Associate Professor of English & WGS at UNC-Greensboro)//Elmer

If nineteenth-century American literary studies tends to focus on the ways Indians enter the narrative frame and the kinds of meanings and associa- tions they bear, recent **attempts to theorize settler colonialism** have sought to **shift attention from its effects** on Indigenous subjects **to** its **implications for nonnative political attachments**, forms of inhabitance, **and modes of being**, illuminating and tracking the pervasive operation of **settlement as a system**. In Settler Colonialism and the Transformation of Anthropology, Patrick Wolfe argues, “Settler colonies were (are) premised on the elimination of native societies. The split tensing reflects a determinate feature of settler colonization. The colonizers come to stay—invasion is **a structure not an event**” (2).6 He suggests that a “**logic** **of elimination” drives settler** governance and **sociality**, describing “the settler-colonial will” as “a historical force that ultimately derives from the primal drive to expansion that is generally glossed as capitalism” (167), and in “Settler Colonialism and the Elimination of the Native,” he observes that “elimination is an organizing principle of settler-colonial society rather than a one-off (and superceded) occurrence” (388). Rather than being superseded after an initial moment/ period of conquest, colonization persists since “the logic of elimination marks a return whereby the native repressed continues to structure settler- colonial society” (390). In Aileen Moreton-Robinson’s work, whiteness func- tions as the central way of understanding the domination and displacement of Indigenous peoples by nonnatives.7 In “Writing Off Indigenous Sover- eignty,” she argues, “As a regime of power, patriarchal white sovereignty operates ideologically, materially and discursively to reproduce and main- tain its investment in the nation as a white possession” (88), and in “Writ- ing Off Treaties,” she suggests, “**At an ontological level** the **structure of subjective possession** **occurs through** the **imposition of one’s will-to-be on the thing which is perceived to lack will,** thus it is open to being possessed,” such that “possession . . . forms part of **the ontological structure of white subjectivity**” (83–84). For Jodi Byrd, the deployment of Indianness as a mobile figure works as the principal mode of U.S. settler colonialism. She observes that “colonization and racialization . . . have often been conflated,” in ways that “tend to be sited along the axis of inclusion/exclusion” and that “misdirect and cloud attention from the underlying structures of settler colonialism” (xxiii, xvii). She argues that settlement works through the translation of indigeneity as Indianness, casting place-based political collec- tivities as (racialized) populations subject to U.S. jurisdiction and manage- ment: “the Indian is left nowhere and everywhere within the ontological premises through which U.S. empire orients, imagines, and critiques itself ”; “**ideas of** Indians and **Indianness** have **served as the ontological ground through which U.S. settler colonialism enacts itself** ” (xix).

#### That results in land exploitation and ecocide – specifically manifests in knowledge institutions making forefronting Settler Colonialism a prior question.

Paperson 17 la paperson or K. Wayne Yang, June 2017, “A Third University is Possible” (an associate professor of ethnic studies at the University of California, San Diego)//Elmer

Land is the prime concern of settler colonialism, contexts in which the colonizer comes to a “new” place not only to seize and exploit but to stay, making that “new” place his permanent home. Settler colonialism thus complicates the center–periphery model that was classically used to describe colonialism, wherein an imperial center, the “metropole,” dominates distant colonies, the “periphery.” Typically, one thinks of European colonization of Africa, India, the Caribbean, the Pacific Islands, in terms of external colonialism, also called exploitation colonialism, where land and human beings are recast as natural resources for primitive accumulation: coltan, petroleum, diamonds, water, salt, seeds, genetic material, chattel. Theories named as “settler colonial studies” had a resurgence beginning around 2006.[2] However, the analysis of settler colonialism is actually not new, only often ignored within Western critiques of empire.[3] The critical literatures of the colonized have long positioned the violence of settlement as a prime feature in colonial life as well as in global arrangements of power. We can see this in Franz Fanon’s foundational critiques of colonialism. Whereas Fanon’s work is often generalized for its diagnoses of anti/colonial violence and the racialized psychoses of colonization upon colonized and colonizer, Fanon is also talking about settlement as the particular feature of French colonization in Algeria. For Fanon, the violence of French colonization in Algeria arises from settlement as **a spatial immediacy of empire**: the geospatial collapse of metropole and colony into the same time and place. On the “selfsame land” are spatialized white immunity and racialized violation, non-Native desires for freedom, Black life, and Indigenous relations.[4] Settler colonialism is too often thought of as “what happened” to Indigenous people. This kind of thinking confines the experiences of Indigenous people, their critiques of settler colonialism, their decolonial imaginations, to an unwarranted historicizing parochialism, as if settler colonialism were a past event that “happened to” Native peoples and not generalizable to non-Natives. Actually, settler colonialism is something that “happened for” settlers. Indeed, it is happening for them/us right now. Wa Thiong’o’s question of how instead of why directs us to think of land tenancy laws, debt, and the privatization of land as settler colonial technologies that enable the “eventful” history of plunder and disappearance. Property law is a settler colonial technology. The weapons that enforce it, the knowledge institutions that legitimize it, the financial institutions that operationalize it, are also technologies. Like all technologies, they evolve and spread. Recasting land as property means severing Indigenous peoples from land. This separation, what Hortense Spillers describes as “the loss of Indigenous name/land” for Africans-turned-chattel, recasts Black Indigenous people as black bodies for biopolitical disposal: who will be moved where, who will be murdered how, who will be machinery for what, and who will be made property for whom.[5] In the alienation of land from life, alienable rights are produced: the right to own (property), the right to law (protection through legitimated violence), the right to govern (supremacist sovereignty), the right to have rights (humanity). In a word, what is produced is whiteness. Moreover, it is not just human beings who are refigured in the schism. Land and nonhumans become alienable properties, a move that first alienates land from its own sovereign life. Thus we can speak of the various technologies required to create and maintain these separations, these alienations: Black from Indigenous, human from nonhuman, land from life.[6] “How?” is a question you ask if you are concerned with the mechanisms, not just the motives, of colonization. Instead of settler colonialism as an ideology, or as a history, you might consider settler colonialism as a set of technologies —a frame that could help you to forecast colonial next operations and to plot decolonial directions. This chapter proceeds with the following insights. (1) The settler–native– slave triad does not describe identities. The triad—an analytic mainstay of settler colonial studies—digs a pitfall of identity that not only chills collaborations but also implies that the racial will be the solution. (2) Technologies are trafficked. Technologies generate patterns of social relations to land. Technologies mutate, and so do these relationships. Colonial technologies travel. In tracing technologies’ past and future trajectories, we can connect how settler colonial and antiblack technologies circulate in transnational arenas. (3) Land—not just people—is the biopolitical target.[7] The examples are many: fracking, biopiracy, damming of rivers and flooding of valleys, the carcasses of pigs that die from the feed additive ractopamine and are allowable for harvest by the U.S. Food and Drug Administration. The subjugation of land and nonhuman life to deathlike states in order to support “human” life is a “biopolitics” well beyond the Foucauldian conception of biopolitical as governmentality or the neoliberal disciplining of modern, bourgeois, “human” subject. (4) (Y)our task is to theorize in the break, that is, to refuse the master narrative that technology is loyal to the master, that (y)our theory has a Eurocentric origin. Black studies, Indigenous studies, and Othered studies have already made their breaks with Foucault (over biopolitics), with Deleuze and Guatarri (over assemblages and machines), and with Marx (over life and primitive accumulation). (5) Even when they are dangerous, understanding technologies provides us some pathways for decolonizing work. We can identify projects of collaboration on decolonial technologies. Colonizing mechanisms are evolving into new forms, and they might be subverted toward decolonizing operations. The Settler–Native–Slave Triad Does Not Describe Identities One of the main interventions of settler colonial studies has been to insist that the patterning of social relations is shaped by colonialism’s thirst for land and thus is shaped to fit modes of empire. Because colonialism is a perverted affair, our relationships are also warped into complicitous arrangements of violation, trespass, and collusion with its mechanisms. For Fanon, the psychosis of colonialism arises from the patterning of violence into the binary relationship between the immune humanity of the white settler and the impugned humanity of the native. For Fanon, the supremacist “right” to create settler space that is immune from violence, and the “right” to abuse the body of the Native to maintain white immunity, this is the spatial and fleshy immediacy of settler colonialism. Furthermore, the “humanity” of the settler is constructed upon his agency over the land and nature. As Maldonado- Torres explains, “I think, therefore I am” is actually an articulation of “I conquer, therefore I am,” a sense of identity posited upon the harnessing of nature and its “natural” people.[8] This creates a host of post+colonial problems that have come to define modernity. Because the humanity of the settler is predicated on his ability to “write the world,” to make history upon and over the natural world, the colonized is instructed to make her claim to humanity by similarly acting on the world or, more precisely, acting in his. Indeed, for Fanon, **it is the perverse ontology of settler becomings**—becoming landowner or becoming property, becoming killable or becoming a killer—and the mutual implication of tortured and torturer that mark the psychosis of colonialism. This problem of modernity and colonial psychosis is echoed in Jack Forbes’s writings: Columbus was a wétiko. He was mentally ill or insane, the carrier of a terribly contagious psychological disease, the wétiko psychosis. . . . The wétiko psychosis, and the problems it creates, have inspired many resistance movements and efforts at reform or revolution. Unfortunately, most of these efforts have failed because they have never diagnosed the wétiko.[9] Under Western modernity, becoming “free” means becoming a colonizer, and because of this, “the central contradiction of modernity is freedom.”[10] Critiques of settler colonialism, therefore, do not offer just another “type” of colonialism to add to the literature but a mode of analysis that has repercussions for any diagnosis of coloniality and for understanding the modern conditions of freedom. By modern conditions of freedom, I mean that Western freedom is a product of colonial modernity, and I mean that such freedom comes with conditions, with strings attached, most manifest as terms of unfreedom for nonhumans. As Cindi Mayweather says, “your freedom’s in a bind.”[11]

#### Expansion of medical access is a form of settler colonial biomedical onslaught – humanitarian promotions of health proliferate genocidal assimilation.

Klausen 13, Jimmy Casas. "Reservations on hospitality: contact and vulnerability in Kant and indigenous action." Hospitality and World Politics. Palgrave Macmillan, London, 2013. 197-221. (Associate Professor in the Instituto de Relações Internacionais at the Pontifícia Universidade Católica do Rio de Janeiro)//Elmer

On the other hand and by contrast, the **governmental reach of public health initiatives** that would effect the improvement of isolated indigenous populations’ health **accords** with Kantian philanthropy – **with all the risks of violated freedom and smothered life** that entails. Public **health advocates** would **repair** the **disadvantaged morbidity profile of** isolated **indigenous groups through** a policy of initiating contact supported by the provision of modern **biomedical** health **care** services to ameliorate the epidemiological effects of contact. State-initiated contact without attendant health care has proved disastrous. Into the 1970s, FUNAI attempted to make friendly contact with isolated Indians. By relying on hired expert indigenous trackers, government contact expeditions located isolated groups and – demonstrating their interest in seeking commerce – enticed the latter with gifts of machetes and blankets. One FUNAI expedition to contact the Matis in 1978 resulted in high morbidity from pneumonia and other infectious diseases and killed one of every two Matis. 60 To correct such devastating policies, anthropologists Magdalena Hurtado, Kim Hill, Hillard Kaplan and Jane Lancaster have elaborated the following argument: Many anthropologists and indigenous-rights activists believe that uncontacted Indians should be left alone. These people are well-meaning, but they are wrong because they base their position on three incorrect assumptions. First, they assume that the Indians have chosen to remain isolated . . . . Those who oppose contact also assume that the Indians will inevitably be decimated by virgin-soil epidemics . . . . Finally, opponents of contact assume that isolated native groups will survive if not contacted. 61 However, even correcting for the fatal infelicities of past policy-driven, state-initiated contacts such as FUNAI’s, the preponderantly disadvantaged morbidity profile of such virgin-soil populations cannot be reduced by greater hospitality in the form of redoubled and more expert interventionary contacts. **Although public health efforts** like those advocated by Hurtado et al. **might reduce mortality**, highly **disease-vulnerable persons will still sicken** and will do so **through means that would pretend to foster life by actively disregarding how the people subject to these external machinations might** determine their own needs and **value their own health**. Isolated **indigenes’** biological **lives** would be **simultaneously fostered and risked**, while their free **personhood would count as nothing** morally–culturally. In short, there are serious political costs to be weighed in such an intervention. Because of – and not in spite of – their philanthropy, public health interventions of the type that Hurtado et al. advocate extend the reach of governmentality much more intrusively than land rights policies. Besides deciding on behalf of peoples in regard to the interpretation of their acts of self-quarantine, the advocated **public health policies surgically insert apparatuses of biomedicine directly into the contacted peoples’ living being**. Such policies thereby **displace** **indigenous norms of health and native cultural strategies** of living on with the norms and overall strategy embedded in the culture of scientific and clinical biomedicine. Though the pretence is that such acts demonstrate the hospitality of the wider national or global society, such health policy interventions cannot simply make a presentation for possible society; rather, qua philanthropy they initiate contact, which, because of the high degree of vulnerability of those contacted, must needs lead to the proliferation of contacts. It is not a hospitable policy of fostering life that Hurtado et al. support, not merely possible commerce but an obsessive philanthropy of biomedical life support and literally **unavoidable onslaught of commerce**, possibly forevermore. Most startlingly, such public health interventions presume as universal a standard of life that could certainly vary while retaining meaning and value. The anthropologist Tess Lea describes this universalising interventionary compulsion in withering words: When you are a helping bureau-professional, the **compulsion to** do something to **fix** the problems of **target populations** – those deemed as suffering from unequal and preventable conditions – exceeds all other impulses . . . . ‘They’ need our greater commitment. The idea that life might be lived differently with value and meaning or that ‘need’ might be conceived differently from the way in which we **calculate** it **through** our **interventionary lens**, becomes impossible to imagine. 62 Hurtado et al. assume that health professionals and policy makers must hospitably confer biomedically acquired immunity on heretofore isolated and now contacted virgin soil populations. Fostering indigenous lives by **imposing** an **alien conception of immunity**, they would inhospitably **destroy alternate strategies of living on**. Seeing through their interventionary lens, Hurtado et al. themselves become arbiters of successful and unsuccessful forms of life: they presume that self-quarantine cannot itself serve as an effective cultural strategy to immunise living bodies. Thus, ironically perhaps, these anthropologists choose biology above culture by seeing each from a standpoint authorised by the culture of biomedicine. From their interventionary lens and against Canguilhem’s admonition above, self-quarantine appears to be a failed strategy for living on because the immunity it would confer is imperfect or incomplete. Likewise, condoning self-isolation is imperfect or incomplete hospitality as against their more perfect interventionary hospitality in the name of life. Authorising themselves to make these judgements, they enact an altogether different collapse of morality into nature than the Kantian collapse I reconstruct above. Whereas Kant’s collapse of minimalism into abstentionism and moral duty into nature’s constraints opens hospitality and therefore strategies for living on, this other collapse binds moralising conceptions of ‘health’ to the biomedically conceived body. Yet if, according to Canguilhem, for humans especially, ‘health is precisely a certain latitude, a certain play in the norms of life and behavior’, 63 then it seems that the ‘**health’ that supposedly hospitable**, though strictly philanthropic, ‘life’-fostering interventionary contact **would impose** on the exuberance of self-quarantining **indigenous peoples** is **a sickness unto** that other perpetual peace Kant mentions: **death**.

#### Vote negative to endorse a cartography of refusal, the rob is to reject settler colonialist ideologies. No perf cons, its good to experiment with ideological opposition and the cps don’t need to expand medicinal access.

Day 15 Iyko, Associate Professor of English. Chair, Critical Social Thought. “Being or Nothingness: Indigeneity, Antiblackness, and Settler Colonial Critique.” Source: Critical Ethnic Studies, Vol. 1, No. 2 (Fall 2015), pp. 102-121 //Elmer

And so the potential relations that Wilderson sets up through a critique of sovereignty are at best irrelevant or at worse false in Sexton’s absolute claim that slavery stands alone as the “threshold of the political world.”45 I suggest that this wavering relation/nonrelation of antiblackness and Indigeneity exhibited in Wilderson’s and Sexton’s work reveal the problem in any totalizing approach to the heterogeneous constitution of racial difference in settler colonies. Beyond this inconsistency, the liberal multiculturalist agenda that Wilderson and Sexton project into Indigenous sovereignty willfully evacuates any Indigenous refusal of a colonial politics of recognition. Among other broad strokes, Sexton states, “as a rule, Native Studies reproduces the dominant liberal political narrative of emancipation and enfranchisement.”46 This provides a basis for Wilderson’s assertion that Indigenous sovereignty engages in a liberal politics of state legitimation through recognition because “treaties are forms of articulation” that buttress “the interlocutory life of America as a coherent (albeit genocidal) idea.”47 But such a depoliticized liberal project is frankly incompatible with Indigenous activism and scholarship that emerges from Native studies in North America. The main argument in Glen Sean Coulthard’s book Red Skin, White Masks is to categorically reject “the liberal recognition-based approach to Indigenous selfdetermination.”48 **This is not** a politics of **legitimizing** Indigenous nations **through state recognition** **but** rather **one of refusal**, a refusal to be **recognized and** thus **interpellated by the settler colonial nation-state**. Drawing on Fanon, Coulthard describes the “necessity on the part of the oppressed to ‘turn away’ from their other-oriented master-dependency, and to instead struggle for freedom on their own terms and in accordance with their own values.”49 It is also difficult to reconcile the depoliticized narrative of “resurgence and recovery” that Wilderson and Sexton attribute to Indigenous sovereignty in the face of **Idle No More**, the anticapitalist Indigenous sovereignty movement in Canada whose national railway and **highway** **blockades** have seriously **destabilized** the **expropriation of natural resources** for the global market. These are examples that Coulthard describes as “**direct action**” rather tjhan negotiation—in other words, antagonism, not conflict resolution: The [blockades] are a crucial act of negation insofar as they seek to impede or block the flow of resources currently being transported to international markets from oil and gas fields, refineries, lumber mills, mining operations, and hydroelectric facilities located on the dispossessed lands of Indigenous nations. These modes of direct action . . . seek to have **a negative impact on** the economic **infrastructure** that is **core to** the **colonial accumulation of capital in settler-political economies** like Canada’s.50 **These tactics are** part of what Audra Simpson calls a “**cartography of refusal” that “negates the authority of the other’s gaze**.”51 It is **impossible to frame** the **blockade movement**, which has become the greatest threat to Canada’s resource agenda,52 **as a struggle for “enfranchisement**.” **Idle No More is** not in “conflict” with the Canadian nation-state; it is in **a struggle against the very premise of settler colonial capitalism** that requires the elimination of Indigenous peoples. As Coulthard states unambiguously, “For Indigenous nations to live, capitalism must die.”

## Case

### Advantage

#### They don't solve their aff -- all they do is ensure companies only get one protection per invention -- either orphan drug rights, a patent, or data exclusivity -- but theres no brightline for whats a new or old invention, so they cant stop evergreening. Companies will just slightly modify their invention and get a separate new patent and the aff has no litmus test for when an invention is significantlly new/different enough from past inventions.

#### These cards all equally apply to drug prices, there also just isn’t a terminal impact they’ve read which means extinction should ow under util, only irreversible impact.

#### Minor tweaks of drugs are key to ensure adequate treatment- otherwise patients skip doses or medicines fail in hot climates – forces people to go underground to get effective new drugs which decks aff solvency

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “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/> September 21, 2018)DR 21

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 **oral**ly 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).

#### There’s a reason the aff’s authors are blogs not lawyers – Evergreen doesn’t prolong patents -- secondary patents *only* cover the improvement, but the original patent dies regardless.

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “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/> September 21, 2018)DR 21

“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.

#### That solves pricing and monopoly- the improvement might be patented but generics of the original compound become incredibly cheap.

**Holman 2016** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis. “IN DEFENSE OF SECONDARY PHARMACEUTICAL PATENTS: A RESPONSE TO THE UN’S GUIDELINES FOR PHARMACEUTICAL PATENT EXAMINATION” *Indiana Law Review* 50, 2016)DR 21

Rather than the blanket presumption against patents on new formulations endorsed by the Guidelines, which would tend to deny patent protection for both minor improvements and highly significant improvements, the needs of patients would be better served if the market and the judgment of patients and healthcare providers were allowed to determine the value of a new formulation on an existing drug. If the improvement is of such significance that it justifies a substantial cost premium, then society has benefited from the development of this improved mode of drug delivery, and payment of the premium is justified, in the same way that it is by development of a therapeutically useful new active ingredient. If the improvement is nominal, then payers should refuse to pay the premium, which they can do by simply purchasing the original formulation from generic companies at a discounted price. If there are market inefficiencies that somehow induce payers to pay the premium even though the improvement is minimal, then those market inefficiencies should be addressed, rather than attempting to address it by changing the standard for patentability in a discriminatory manner that targets specific categories of inventions.

#### It's illegal to extend a patent on the same drug—only new compounds can be patented

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

When critics of the pharmaceutical industry initially began talking about "evergreening," the discussion often seemed to imply that pharmaceutical companies were literally re-patenting the same product. However, those more familiar with patent law have responded by pointing out that, as a general matter, pharmaceutical companies are not simply re-patenting a product, and that various doctrines of patent law work in conjunction to prevent a company from obtaining new patents on a product that is **already on the market**. For example, at a May 7 Congressional Hearing entitled Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition, Professor David Olson of the Boston College Law School explained to lawmakers that:

It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong .... New patents can be filed on different formulations of a previous drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.

If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, **the new patent** is either **invalid** or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing. 9

#### Vague standards for new patents are unenforceable and explode costs – the link alone turns case because the plan is unenforceable

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

While the amendment provided for a rebuttal to the presumption of obviousness, the language was ambiguous and likely to render the patent system even more unreliable than it already is. The proposed statute said that an applicant may rebut the presumption of obviousness if the covered claimed invention “results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.” It is unclear what would qualify as “statistically significant,” and proving this vague standard would be nearly impossible.

In order to show a “statistically significant increase in efficacy,” long and costly head-to-head clinical trials would be necessary. To be clear, this is not a standard required by the FDA for new drug approval, let alone patentability.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

Like most forms of innovation, the development of medicines and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are major advancements, but often they are incremental steps forward. In the pharmaceutical field, incremental or follow-on innovation frequently results in new therapeutic uses for existing drugs, which address serious challenges related to adverse effects, delivery systems, and dosing schedules. While they might not sound like medical breakthroughs on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve public health and save lives.

#### All critiques of evergreening are wrong—it’s essential to encourage competition in the market, and improvements come in increments.

Thomas 09

John R. Thomas (Georgetown Law Center faculty, Visiting Scholar at the Congressional Research Service, inaugural Thomas Alva Edison Visiting Scholar at the U.S. Patent and Trademark Office);

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term “evergreening” to be inappropriate, and even derogatory in nature.62 They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn. First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,63 nonobvious,64 and fully disclosed in an application submitted to the USPTO.65 These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an “original” (such as a medication that has never been previously approved by the FDA) or an “improvement” (such as a new formulation of a known medication). 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… 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.68 Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements.69 The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.70

#### The purpose of evergreening is to make money—medical advances are direct effects of the money big pharma makes.

Collier 13

Roger Collier (consultant specializing in health care policy issues, CEO of national healthcare consulting firm, Principal-in-Charge off KPMG’s national health and welfare consulting practice); “Drug patents: the evergreening problem”; CMAJ Vol. 185, Issue 9; June 11, 2013; <https://www.cmaj.ca/content/185/9/E385/tab-e-letters>; EMJ

“Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company’s economic advantage,” says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. “The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.” Evergreening has been a hot topic of late because of the recent ruling by India’s Supreme Court to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (imatinib mesylate), or Glivec, as it’s known in some countries. Novartis claims the drug is more easily absorbed into the blood and, considering it is used to fight leukemia, that is enough of an improvement to warrant patent protection. But India’s trade and industry minister, Anand Sharma, has defended the decision, and was quoted by Agence France-Presse as saying it was “absolutely justified under the law” and that India’s patent law “does not accept evergreening.”

#### Squo solves—current patents check innovation and prevent evergreening.

Parker and Mooney 07

Scott Parker (senior associate in the Intellectual Property Group at Simmons & Simmons\*) and Kevin Mooney (partner in the Intellectual Property Group at Simmons & Simmons); Journal of Commercial Biotechnology, London Vol. 13, Iss. 4; August 7, 2007: 235. DOI:10.1057/palgrave.jcb.3050066; <https://www.proquest.com/docview/232906488/BEB34E662F134C80PQ/3>; EMJ

\*Simmons & Simmons is recognised worldwide as a pre-eminent law firm for the life sciences. It is Simmons &Simmons policy not to act for generic manufacturers in relation to patent expiry matters.

In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent 'evergreening'. It allows the use of 'old' technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of 'minor variations' is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace.

#### Evergreening is an incoherent concept

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 + Highlighted by Joey

“**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.