# 1NC Valley Octos

## Offs

### 1

#### 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

### 2

#### 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

#### 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.

### 3

#### CP Text: The member nations of the World Trade Organization should integrate centralized medical records and genetic information with machine learning technology and make data commercially available for biotechnology and pharmaceutical companies.

#### Combining centralized records with genetic info shifts research to a genotype first approach---both are key for synching gene variants with their medical effects. Excluding people from coverage ensures bottlenecks that undermine research.

Broad 14. (The Eli and Edythe L. Broad Institute of MIT and Harvard, often referred to as the Broad Institute, is a biomedical and genomic research center located in Cambridge, Massachusetts. Innovative “genotype first” approach uncovers protective factor for heart disease. June 31, 2014.https://www.broadinstitute.org/news/innovative-“genotype-first”-approach-uncovers-protective-factor-heart-disease)

**Extensive sequencing of DNA from thousands of individuals** in Finland has **unearthed scores of mutations that** destroy gene function **and are found at unusually high frequencies**. Among these are two mutations in a gene called LPA that may reduce a person’s risk of heart disease. **These findings are an exciting** proof-of-concept **for a new “**genotype first**” approach to identifying** rare genetic variants **associated with, or protecting from, disease followed by** extensive medical review **of carriers**. The new study by researchers from the Broad Institute, Massachusetts General Hospital (MGH), the University of Helsinki, and an international team of collaborators appears in a paper published online July 31 in PLOS Genetics. The **researchers** studied exomes — the portions of the genome that correspond to protein-coding genes — from 3,000 Finns and compared them to those of 3,000 non-Finnish Europeans. They identified 83 gene-deactivating variants that were at least twice as prevalent in Finns and went on to study these variants in over 35,000 Finns. Recent examples in heart disease, HIV, type 2 diabetes and Crohn’s disease have demonstrated that such mutations – known as “loss-of-function” mutations – in some cases protect from, rather than cause, disease and thereby **suggest** new paths **toward** therapeutics. **Geneticists have known that** Mendelian, **recessive genetic diseases** – such as Tay-Sachs or cystic fibrosis that **are caused by a single, mutated gene** – are **more common in** isolated populations **because of a phenomenon known as “**bottlenecking**.”** When a small population is isolated for tens to hundreds of generations, the population’s genetic diversity becomes restricted, and occasional rare genetic variations can by chance become much more common. While this has long been recognized as the source of the unique rare disease patterns seen in isolated populations, this paper demonstrates that the same principles can help researchers identify rare, loss-of-function variants in genome-wide association studies on these isolated populations. In the current study, researchers chose to study modern Finns – a population that descended from a well-documented bottleneck that occurred around 4,000 years ago. Comparing Finns with their non-Finnish European counterparts gave the researchers strong, empirical data. The LPA gene encodes Lipoprotein(a), a type of lipoprotein, first identified in 1963 and a known risk factor for heart disease. The variants described in this paper reduced levels of LPA gene expression causing lower levels of Lipoprotein(a) in the blood. The research team examined Finnish medical records and found that the loss-of-function variants were not associated with other health problems, making blocking LPA expression a potentially exciting therapeutic approach. **The availability of** centralized medical records **available in Finland enabled the researchers to** shift the paradigm **of** medical genetics **to a “genotype first” approach**. “**This new approach could significantly change how researchers analyze rare variants for complex diseases**. **It gives us a** window **into the** genetics of complex diseases **that we haven’t had before**,” said co-senior author Mark Daly, co-director of the Program in Medical and Population Genetics at the Broad Institute and chief of the Analytic and Translational Genetics Unit for the Center for Human Genetic Research at MGH. “By combining the information from detailed medical records with the information contained in the genomes of a bottlenecked population, we’re uncovering rare variants that contribute to complex diseases.” Heart disease is a leading killer globally. The World Health Organization reports that cardiovascular disease was responsible for 30 percent of all global deaths, or 17.3 million people in 2008. Therapeutics able to specifically address this risk by targeting LPA could have a global impact on medical outcomes. This work highlights the potential for using rare variant analysis in isolated populations to study complex diseases, an approach that had previously been largely limited to Mendelian traits. **The approach can now be applied to other complex diseases that have many contributing genetic factors.** “We’ve illustrated the validity of this approach by identifying rare, loss-of-function variants with promising therapeutic potential for the treatment of heart disease, but **this work also represents a** reproducible approachthat can be used to increase our understanding of other complex diseases as well,” said co-senior author Aarno Palotie (Broad Institute, Massachusetts General Hospital, Harvard Medical School, Institute for Molecular Medicine Finland FIMM, University of Helsinki).

#### Only data integration solves pharma collapse---the plan saves the industry

**Shaywit**[**z**](https://www.forbes.com/sites/davidshaywitz/)**13** (David, Medicine reporter for Forbes, “What's Holding Back Cures? Our Collective Ignorance (And No, Not A Pharma Conspiracy)” <https://www.forbes.com/sites/davidshaywitz/2013/05/10/whats-holding-back-cures-our-collective-ignorance-and-no-not-a-pharma-conspiracy/#eda1100236fd>)

The unfortunate truth is that drug companies really want to cure disease, but rarely know how. [Medical science simply isn’t up to the challenge](http://www.forbes.com/sites/davidshaywitz/2011/12/02/biopharmas-dirty-secret-revealed-science-is-fragile-forecasting-is-unreliable-now-deal-with-it-2/). Most diseases aren’t well enough understood to enable the rational development of truly transformative treatments. When high-profile pharma studies fail – such as the slew of recent Phase 3 Alzheimer’s Disease trials – it’s fashionable to characterize them as yet another industry failure. There’s some truth to this: the proximal cause may well be a poor decision to continue the development of a questionable drug. But the root cause is likely insufficient understanding of disease pathophysiology. We should also be careful about dismissing the value of incremental advances– a reflex I know I still have, although I’ve [recognized](http://www.nytimes.com/2002/07/16/health/improved-drug-regimens-help-patients-take-their-medicine.html) the value of seemingly small tweaks from the time I was a resident. Even today, when I critique (as derivative) formulation plays like liquid Ritalin, I’m glad to be [reminded](https://twitter.com/kevintoshio/status/312306291261448192) of the kids who stand to benefit from just such a medication. What’s Next? As the healthcare system looks more critically at value – demanding more evidence of effectiveness from providers and products alike – drug companies will be faced with two options. The best choice, of course, would be to figure out how to come up with truly revolutionary treatments. Perhaps unexpected insights will emerge from big data and the [integration](http://www.forbes.com/sites/davidshaywitz/2012/12/30/turning-information-into-impact-digital-healths-long-road-ahead/) of phenotypic and genotypic information, in the [framework of system biology](http://www.nature.com/nrd/journal/v8/n4/abs/nrd2826.html); maybe a new therapeutic modality will arrive on the scene. It’s possible intensified [collaboration](http://www.forbes.com/sites/davidshaywitz/2012/03/29/youre-welcome-the-vital-role-companies-play-in-pressure-testing-academic-medical-research/) between academic and industry researchers will eventually yield something useful, or that [open-data approaches](http://www.sagebase.org/philosophy/) (as championed by organizations like [Sage Bionetworks](http://www.sagebase.org/)[disclosure: I served as a founding advisor]) will achieve critical mass, and deliver impactful insights. But unless something substantial changes, progress is likely to remain slow and stochastic, and truly game-changing novel therapeutics will continue to be the exceptions rather than the rule. Given the ongoing challenges of creating transformative medications, there’s likely to be intensified focus on capturing, in a more granular fashion, the benefits of incrementally improved drugs; such assessments will not be a “nice to have” but a “must have,” table stakes for consideration by payors, and (to the extent these measures are used to demonstrate efficacy) regulators as well. I also suspect pharmas will increasingly look to offer “solutions” (e.g. associated app or access to an online community) not just pills, to deliver value, though it’s unclear whether such approaches will either prove effective or represent an attractive value proportion for the relevant stakeholders.

#### 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

### 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

#### Carbon border tax coming now and key to solving warming.

Kellard 1/28 Neil Kellard [Dean, Professor in Finance, Essex Business School, University of Essex] “Why the EU’s proposed carbon border levy is an important test for global action on climate change” January 28, 2021 <https://theconversation.com/why-the-eus-proposed-carbon-border-levy-is-an-important-test-for-global-action-on-climate-change-154041> SM

In the more than two decades since the Kyoto Protocol was adopted, national policies on climate change have had dangerously and disappointingly little effect on global emissions.

Within the current economic system, perhaps the most ambitious attempt to reduce emissions has been the EU’s emissions trading system (or ETS). In operation since 2005, the ETS covers more than 11,000 heavy-energy-using power stations, factories and airlines, representing around 40% of the EU’s greenhouse gas emissions. The scheme operates via a cap-and-trade principle where an EU-wide cap on emissions means that firms must buy allowances, essentially paying for their polluting activities.

Yet although the ETS has had some success in reducing emissions, finance professor Panayiotis Andreou and I recently showed that the scheme is under-penalising those who pollute the most – primarily because the price of allowances has typically been too low.

The current price of an allowance to emit greenhouse gases is around €33 per tonne, a price already much higher than the average over the life of the ETS. However, to meet EU climate change targets, this price will need to be more like €40 by 2030 and close to €250 in 2050. Given the substantial costs this will impose on EU firms, either to pay for allowances or to invest in low carbon technologies, companies based outside the EU will have a hefty competitive advantage unless they face similar regulatory controls in their own countries.

This is why the European Commission, the EU’s executive branch, plans to present its carbon border levy in June 2021 as part of its Green Deal planning. Frans Timmermans, the first vice-president of the European Commission, recently stressed that:

It’s a matter of survival of our industry. So, if others will not move in the same direction, we will have to protect the European Union against distortion of competition and against the risk of carbon leakage.

Although its details are still undecided, the carbon border levy is expected to charge imports into the EU at an amount related to the emissions trading system price. As commission official Benjamin Angel notes, this could mean setting a carbon amount per product and multiplying it by the ETS price. For example, given production of each tonne of steel typically generates around 1.9 tonnes of CO₂ emissions, if we assume an ETS price of €30 then a firm would pay €57 extra to import it.

Having such a levy in place would send a strong signal to EU firms that potentially expensive investments in environmentally beneficial technologies would not result in undercutting, either by non-EU rivals that enjoy looser regulations, or by firms relocating to outside the EU – the so called “carbon leakage” that Frans Timmermans mentions.

Combining the EU ETS with a border levy is a sensible and workable strategy, providing a long-term context for firms that encourages the reduction of emissions by pricing in the pollution they produce. The benefits of a border levy may also spill over to outside the EU in at least one of two ways. First, and most obviously, non-EU firms that wish to export into Europe will be encouraged to reduce emissions to limit their charge. Secondly, other governments and regulatory authorities will be watching closely to see if the approach is workable and this could see the spread of cap-and-trade agreements more globally.

#### The plan revitalizes WTO credibility and generates momentum

Meyer 6/18 [(David Meyer is the Editor of CEO Daily and a senior writer on Fortune’s European team. Author of the digital rights primer, Control Shift: How Technology Affects You and Your Rights. “The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn,” Fortune, June 18, 2021. <https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/>] TDI

According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—**the WTO's future rests on what happens next.** "The credibility of the WTO will depend on its ability to find a meaningful outcome on this issue that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "Final nail in the coffin" The Geneva-based WTO isn't an organization with power, as such—it's a framework within which countries make big decisions about trade, generally by consensus. It's supposed to be the forum where disputes get settled, because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's founding agreement allows for rules to be waived in exceptional circumstances, and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) Consensus is the key here. Although the failure to reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an unprecedented and seismic event. In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union, and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. **It's a dispute between countries, but the result will be on the WTO as a whole**, say waiver advocates. "If, in the face of one of humanity's greatest challenges in a century, the WTO functionally becomes an obstacle as in contrast to part of the solution, **I think it could be the final nail in the coffin"** **for the organization**, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. "If the TRIPS waiver is successful, and people see the WTO as being part of the solution—saving lives and livelihoods—**it could create goodwill and momentum to address what are still daunting structural problems."** Those problems are legion.

#### Lack of WTO legitimacy is key – the threat of disputes deters action.

Ashurst 7/16 Ashurst [A progressive global law firm] Proposed EU Regulation on CBAM, July 16 2021, <https://www.ashurst.com/en/news-and-insights/legal-updates/proposed-eu-regulation-of-cbam-published/> SM

Next steps for the Commission's proposal

Following publication of the detailed proposal for the CBAM, it will need to go through the ordinary legislative procedure, which involves being reviewed and modified by the European Parliament and the Council. This process will provide Member States with the opportunity to introduce significant changes.

Future developments

While only a proposal, the draft CBAM regulation also contains a reporting and review mechanism. Here, the draft CBAM regulation obliges the Commission to report before the end of the transitional period on the application of the CBAM, with a view to extending the scope of CBAM to indirect emissions and goods other than those listed in Annex I.

How might the proposal be challenged?

The CBAM is controversial outside the EU. Commentators have already started to map out potential challenges to it. In principle, these challenges follow two distinct routes:

that the CBAM breaches international obligations; and/or

that the CBAM breaches EU domestic law.

The main international route would be a WTO challenge by another WTO member government. As the WTO dispute settlement process is a government-to-government process, business would need to either lobby a government to bring a WTO Dispute Settlement Understanding (DSU) case, or, in certain jurisdictions, use formal processes (e.g. section 301 of the U.S. Trade Act of 1974) to stimulate a government to bring a case that it would not otherwise bring.

The obvious candidates are countries such as Brazil, India, Australia, China and Russia, all of which will be affected by the CBAM.

The WTO DSU process is currently functioning poorly since the US has refused to appoint new Appellate Body (AB) members, so the AB cannot function. This may have influenced the EU's decision to publish the draft regulation at this time, and until new AB members are appointed the prospect of the CBAM being held, definitively, to be incompatible with WTO obligations appears slim.

#### Even if the plan is done domestically by WTO member states that changes nothing, obviously its domestically done but its still every country of a major body taking the same course of action which boosts credibility of the organization they’re acting under.

#### Otherwise, countries dispute through the WTO

Brooks 7/21 “Trade experts positive on EU’s CBAM, despite risk of rich nation-poor nation rift”, July 21 2021 Cristina Brooks [Senior Journalist, Climate & Sustainability, IHS Markit] <https://ihsmarkit.com/research-analysis/--trade-experts-positive-on-eus-cbam-despite-risk-of-rich-nati.html> SM

In addition to EU due process, the CBAM will face international challenges. World Trade Organization (WTO) rules were not drafted to accommodate climate change policies, so countries slapped with new charges on exports may challenge the CBAM via a WTO dispute settlement case.

Stephen Woolcock, a lecturer in international political economy at the London School of Economics, told Net-Zero Business Daily there are several ways of challenging the CBAM. "If the EU were to introduce the measure, other countries would challenge this, and you then go through a dispute settlement mechanism. The WTO appellate body, if you like 'the international trade court,' would then rule on whether this is complying with the WTO rules," he said.

However, he said it seems likely countries will discuss it in other forums since the US under the Trump administration blocked appointees to the WTO's appellate body. "So, we don't have a functioning appellate body in the WTO at the moment," said Woolcock.

#### WTO-compliant carbon border measures are practically impossible – even the “domestic taxes” route fails. Prefer our ev – it doesn’t matter if WTO compliance is theoretically possible if it’s not pragmatically possible.

Meyer and Tucker 21 “A Pragmatic Approach to Carbon Border Measures” Timothy Meyer [Professor of Law; Director, International Legal Studies Program at Vanderbilt, J.D. and Ph.D. in jurisprudence and social policy from Berkeley], and Todd N. Tucker [Director of Governance Studies at the Roosevelt Institute, PhD and MPhil from the University of Cambridge] World Trade Review (July 2021), 1–12 <https://www.cambridge.org/core/journals/world-trade-review/article/pragmatic-approach-to-carbon-border-measures/B0D224B3A59E9433D10E74DE6D40A0FD> SM

3. CBMs and the WTO

This variation in domestic authority and the resulting diversity of approaches to decarbonization has two consequences. First, it makes it likely that at least some countries interested in pursuing aggressive domestic decarbonization measures will have difficulty doing so in a way that can easily be married to a CBM that complies with the WTO’s primary rules. Second, it makes it virtually impossible to have a common CBM across countries that complies with those primary rules. The divergence in domestic approaches means that the domestic carbon price – whether explicit or implicit, i.e., calculated from the cost of complying with environmental regulations – will almost surely vary across countries. As a result, barring speedy and successful negotiations, the WTO-consistency of any CBM is likely to hinge on flexibilities, that have not been interpreted in a manner sufficiently deferential to national regulators.

3.1 The GATT’s Primary Rules

The GATT, the WTO’s chief agreement governing trade in goods, contains three main sets of primary obligations: 1) limits on tariffs; 2) a prohibition on import or export restrictions other than tariffs; and 3) a prohibition on discrimination against imports, a category that contains many permutations.40 The most blunt forms of a CBM will violate one of the first two sets of rules. A ban on imports from countries with weak climate laws would run afoul of the prohibition on import restrictions. A simple tariff on carbon-intensive products would violate a country’s tariff bindings.41

What is left are domestic taxes, either assessed on imported products behind the border or ‘charge[s on imports] equivalent to an internal tax’, 42 and regulations. At first glance, this looks quite promising. In recent years, prominent trade lawyers have argued that a non-discriminatory carbon tax, one applicable to both imports and domestic products, would be consistent with WTO rules.43 Just as a domestic sales tax or VAT can be assessed on imports consistent with WTO rules, a country with a domestic carbon tax could apply a charge to imports either ‘equivalent’ to the domestic tax (if the import charge was viewed as a tariff) or not ‘in excess of’ the domestic tax (if viewed as an internal tax). Similarly, product standards, such as energy efficiency standards, could be applied in a nondiscriminatory fashion to both imports and domestic products. Both President Biden’s Build Back Better initiative and the EU’s Green Deal are likely to feature new regulations of this kind.

In theory, then, nondiscriminatory taxes and regulations offer a path to WTO-consistent border measures. In reality, this path is more likely a mirage for many countries. As we have explained above, neither a US-wide nor an EU-wide carbon tax is politically feasible. Moreover, as Hillman notes, for any number of reasons governments might prefer taxes (or regulations) on production or the use of inputs, such as taxes on the generation of energy or the use of fossil fuels, to taxes on products.44 Under WTO rules, only taxes on products (so-called indirect taxes) can be adjusted at the border via nondiscriminatory measures. Deciding whether taxes on production processes or inputs are really taxes on products raises a host of novel questions under WTO law.45

Even if a CBM qualifies for analysis under nondiscrimination rules, its fate is uncertain at best. The WTO’s nondiscrimination rules require that an internal tax on imports be similar to or not in excess of the tax on ‘like’ domestic products, while regulations must offer imports treatment ‘no less favorable’ than that afforded ‘like’ domestic products.46 In various cases over the years, WTO members and panels have urged that either the standard for ‘likeness’ or the standard of treatment take into account regulatory purpose of a measure when that purpose is unrelated to national origin.47 Unfortunately, though, the Appellate Body (AB) declined to adopt such an ‘aim and effect’ test or anything similar. Instead, the current test for ‘like’ products focuses on the commercial relationship between products.48 Otherwise identical products – such as cement, steel, or chemicals – that differ only in the amount of carbon emitted during the production process would probably be found ‘like’ under this test.

The standard of treatment applicable to regulations covering products determined to be ‘like’ has a similar commercial flavor. The AB has said that a measure that disrupts the ‘equality of competitive opportunities’ among like products accords less favorable treatment, even if the distinction among products has nothing to do with national origin and has a legitimate regulatory basis.49 Because the entire purpose of a CBM is to disadvantage otherwise identical products based on how much carbon is emitted during production, some scholars have argued that a CBM will almost certainly run afoul of GATT nondiscrimination rules.50

These core issues present a challenge even to an ideally designed CBM. Government measures are, however, rarely designed on the basis of ideals alone. Instead, they typically include exceptions, variances, or differential treatment designed to ensure sufficient political support for the measure. While a comprehensive examination of all the ways a CBM might violate WTO rules is beyond the scope of this article, suffice it to say that a whole host of more technical, but not less weighty, issues present ripe targets for potential challengers: whether to adjust the price of imports, or also exports; whether to apply the CBM to all countries, or whether to exempt developing countries; whether to apply the CBM to only direct emissions for a given product, or also the indirect emissions that went into making it; and whether to calculate embedded emissions on a shipment-by-shipment level (or more distantly from the widget itself, such as on the basis of country averages).

The EU’s latest proposal illustrates some of these problems. First, the European CBM would provide importers a credit for any carbon price paid in their home market. It would not, however, give them credit for the cost of complying with decarbonization regulations in their home market.51 Two firms that pay equivalent carbon costs – one via an explicit carbon pricing mechanism and the second an implicit price via regulation – are thus treated differently. This is discriminatory, while failing to reward what the European Commission states as the goal of its CBM: global decarbonization.52 Both the GATT’s primary nondiscrimination rules, as well as the nondiscrimination rule applicable to the GATT’s general exceptions via the chapeau of article XX, would likely require the EU to take account of the implicit price of carbon in all countries if it does so for one. Doing so would create a significant administrative burden, with no guarantee that any ostensibly neutral formula to evaluate the implicit price of carbon across countries will ultimately hold up under review.53 Second, EU producers will benefit from the ability to trade emissions permits in private markets, and pay spot prices daily for doing so, while importers will be forced to buy permits from government at averages of past prices.54 Finally, the details on how verification of emissions will work, and how those procedures compare to the procedures that apply to domestic manufacturers, creates another possible basis for a discrimination complaint.

All of these difficulties apply to any single nation’s CBM. A common CBM presents an additional wrinkle. To be consistent with the WTO’s primary rules, countries imposing a common CBM would likely have to impose similar carbon costs on domestic producers. For example, the EU’s proposal requires importers to purchase permits for the amount of carbon emitted during the production of a product, with the price of the permits tied to the price of such a permit under the ETS. Under WTO rules, the United States could not impose a carbon tariff in the same amount as the EU’s price of a permit unless the cost of carbon in the United States were at least as high as the cost of carbon in the EU. Charging a higher tariff than the United States charges on its own domestic products would amount to discrimination. And while this difficulty could in principle be solved by setting the CBM equal to the lowest price charged in any member country, such an approach has several disadvantages. For example, determining those prices in countries, like the United States, that do not have an explicit carbon pricing system is possible but difficult. Worse, a lowest common denominator approach would reduce the environmental effectiveness of the system as a whole. As a result, a common carbon tariff is likely to leave at least some members exposed to claims that the common CBM is more stringent than their domestic decarbonization measures.

#### C/A Spector from the 1AC for climate change impact

## Case

#### 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.

#### Framing issue: One and done means companies can only get one patent on a pharmaceutical product but each pharmaceutical product builds off one another which means companies can still make small modifications and claim it’s a new invention and thus deserving of a new patent. Unless the aff’s argument is that every pharmaceutical company literally only gets one patent as a company for the rest of eternity (in which case they link to innovation) then that proves they’re just as arbitrary.

#### Every impact scenario rests on winning an IL to innovation, their India scenario about Generic exports is specifically about why if India innovates they can export more so they need to win innovation. They also don’t have uniquqness for Indian soft power low now and the card doesn’t say extinction so don’t give it to them. That menas winning any of our case turns are also straight turns to every 1ac scenario bc they make public health worse.

#### 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.