# Voices R2 Neg vs Mitty AS

# 1NC

### 1

#### Interpretation: “intellectual property protections” is a generic bare plural. The aff may not defend WTO member nations reducing a subset of intellectual property protections for medicines.

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It applies to “medicines” – upward entailment test – “reduce intellectual property protections for medicines” doesn’t entail reducing protections for aids, because it doesn’t prove that we should derestrict other beneficial tech

#### **Violation – they only defend data exclusivity**

#### Vote neg:

#### 1] Limits – you can pick anything from COVID vaccines to HIV/AIDS to random biotech to insulin treatments and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible. Limits key to reciprocal engagement since they create a caselist for neg prep.

#### 2] TVA – read the aff as an advantage to a whole rez aff.

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

### 2

#### Interpretation – Affs must defend a reduction in intellectual property protections that protect the medicines.

#### Medicines are physical substances

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### Violation - Data exclusivity protects clinical trial data, NOT MEDICINE. The plan doesn’t affect the actual production of Medical Substances, just the structural factors that influence it.

Thrasher 5-25 Rachel Thrasher 5-25-2021 "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices" <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/> //sid

Data exclusivity is a form of intellectual property protection that appliesspecifically to data from pharmaceutical clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law. Data exclusivity operates independently of patent protection and can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection. Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### Limits – allowing Affs that relate to the factors and structures surrounding Medicines allows treatments, drug discovery techniques, computer programs, and production techniques that all have IP protections to be topical which eviscerate a stable locus of predictability.

### 3

#### Counterplan: Member nations of the World Trade Organization other than the United States ought to reduce IP protections for medicines by significantly reducing data exclusivity’

#### Solves the aff - the US doesn’t have a domestic generic market

Eban 19 KATHERINE EBAN 8.07.2019 <https://www.wired.com/story/8-ways-overseas-drug-manufacturers-dupe-fda/#:~:text=Ninety%20percent%20of%20the%20prescription,mostly%20in%20India%20and%20China>. SM

NINETY PERCENT OF the prescription drugs consumed in the United States are generics, and the majority of them are produced overseas, mostly in India and China. Let’s say you’re a manufacturer looking to get in on America’s $104 billion generic drug market. You want to make the lowest-cost drugs possible and sell them at the highest possible price. How best to proceed?

#### Their only ev ab the US is about its enforcement of FTA with smaller countries that increase exclusivity and hurts generic markets – the counterplan ends sufficiently reduces the effects of FTA because every other country reduces – no us exclusivity key warrant bc fiat solves norming

#### Infrastructure passes now due to Biden and Pelosi involvement – Biden PC and tight timetables makes the margin for error literally ZERO

Elliott 9-16 (Philip Elliott is a Washington Correspondent for TIME. Before joining TIME in early 2015, he spent almost a decade at The Associated Press, where he covered politics, campaign finance, education and the White House. He is a graduate of the E.W. Scripps School of Journalism at Ohio University, September 16, 2021, accessed on 9-17-2021, Time, "Democrats Face a Grueling Two Weeks as Infighting Erupts Over Infrastructure", https://time.com/6098810/house-democrats-reconciliation/)//babcii

House Democrats yesterday finished penning a 2,600-page bill that **finally outlines the specifics** of their ambitious “soft” infrastructure plan that won’t attract a single Republican vote. But no one was really rushing to Schneider’s for bottles of bubbly. For a party ready to spend $3.5 trillion to fund its social policy agenda, there were plenty of glum faces on Capitol Hill. In fact, one key piece of the legislation—a deal that would finally let Medicare negotiate lower prices with drug companies—fell apart in the Energy and Commerce Committee when three Democrats voted against it. It found resurrection a short time later when Leadership aides literally plucked it from the Energy and Commerce team and delivered it to the Ways and Means Committee for its approval instead. Even there, though, one Democrat voted against it, saying the threat it posed to pharmaceutical companies’ profits would doom it in the Senate. “Every moment we spend debating provisions that will never become law is a moment wasted and will delay much-needed assistance to the American people,” Rep. Stephanie Murphy of Florida later argued. Put another way? Brace **for some nasty politics** over the next two weeks as House Speaker Nancy Pelosi tries to get this bill to a vote before the budget year ends on Sept. 30. And those 2,600 pages had better be recyclable. Democrats can **only afford three defectors** if they want to usher this bill into law, **and they’re perilously close to failure**. So far, five centrist Democrats in the House have said they prefer a scaled-back version of the Medicare component. But if Pelosi gives the five centrists that win, she risks losing the support of progressives who are already sour that things like a punitive wealth tax and the end to tax loopholes aren’t present in the current version of the bill. As it stands now, letting Medicare negotiate drug prices would save the government about $500 billion over the next decade. The scaled-back version doesn’t have an official cost, but a very similar version got its score in the Senate last year: roughly $100 billion in savings. Because Democrats are using a budgeting loophole to help them avoid a filibuster and pass this with bare majorities, that $400 billion gap matters a lot more than on most bills. Scaling back the Medicare savings means they would also have to scale back their overall spending on the bill—a big line in the sand for progressives who say they’ve already compromised too much. All of this, of course, comes as President Joe Biden and his top aides in the White House have been trying to get Senate **centrists onboard**. Just yesterday, he **met separately with Sens. Kyrsten Sinema and Joe Manchin**, fellow Democrats who have expressed worries about the $3.5 trillion price tag but have been vague about what exactly they want to cut back on. With the Senate evenly divided at 50-50, and Vice President Kamala Harris in position to break the ties to Democrats’ victories, any shenanigans from those two independent thinkers scrambles the whole package. Oh, and that other bipartisan infrastructure plan that carries $550 billion in new spending? It’s still sitting on the shelf in the House. Pelosi said she’d bring it to the floor only when the bigger—and entirely partisan—bill was ready. And there’s plenty of grumbling about that package, too. If this is all beginning to sound like a scratched record that keeps repeating, it’s because this has become something of a pattern here in Washington. Things look pretty grim for legislation in town these days, despite Democrats controlling the House, the Senate and the White House. Their margin for error **is literally zero**, and so hiccups from a half-dozen centrists can forewarn a doomed agenda. So far, Pelosi has been a master of holding the line on crucial votes and has managed to maneuver her team to victories, including on an earlier pandemic relief package that passed with only Democratic votes. Now she’s trying again, but the clock is ticking, and $3.5 trillion is an eye-popping sum of money that rivals the spending the United States unleashed to close out World War II.

#### Ev from this week proves its on the brink

Cochrane, et al 10/1 (Emily Cochrane, Luke Broadwater and Jonathan Weisman, [], 10-8-2021, “Biden puts the infrastructure bill on hold, saying Democrats need to unite on social spending.“, No Publication, accessed: 10-8-2021, https://www.nytimes.com/2021/10/01/us/politics/house-infrastructure-delay-vote.html) ajs

Mr. Cuellar noted that moderates had an agreement with Speaker Nancy Pelosi of California to vote on the bill this week, and said it was up to her how to handle that promise.

On Friday evening, Ms. Pelosi indefinitely postponed a vote on the infrastructure bill that she had promised to moderates who had publicly pushed for a stand-alone vote. She wrote in a letter to colleagues, “Clearly, the bipartisan infrastructure bill will pass once we have agreement on the reconciliation bill.”

“Our priority to create jobs in the health care, family and climate agendas is a shared value,” she wrote, adding that leading lawmakers were “still working for clarity and consensus.”

Representative Pramila Jayapal of Washington, the chairwoman of the Congressional Progressive Caucus, said Mr. Biden “was very clear” that the two bills were tied together.

He emphasized that he supported the bipartisan infrastructure bill, according to Ms. Jayapal, and said, “If I thought I could do it right now, I would, but we need to get this reconciliation bill.”

“It’s going to be tough,” Ms. Jayapal added. “Like we’re going to have to come down in our number, and we’re going to have to do that work and see what we can get to.”

The House will now leave Washington for two weeks of remote committee work, with the promise of 72 hours’ notice before being called back.

#### Attacks on pharmaceutical profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Big pharma loves data exclusivity – it gives them generics and makes them lots of money

Ragavan 18 Srividhya Ragavan, The Drug Debate: Data Exclusivity is the New Way to Delay Generics, 50 Conn. L. Rev. Online 1 (2018). Available at: <https://scholarship.law.tamu.edu/facscholar/1184> mvp

Nevertheless, most governments award a drug company that undertakes clinical trials, typically the innovator drug company, with a period of “exclusivity” which can range anywhere from three to eight years.15 In the United States, for example, the FDA grants New Chemical Entities a total data exclusivity period of up to five years.16 That is, during the term when data exclusivity prevails, competing drug companies cannot get access to the clinical trial data. Importantly, such access to data is unavailable even when the patent application fails. Taking the example above, even if Company A’s compound is found to be unpatentable for whatever reasons, and hence falls in the public domain, the data from the clinical trial will remain protected, thus indirectly awarding Company A market exclusivity. In stock market parlance, this is a situation where even though the pharmaceutical company has taken a bad risk in the form of a patent application, data exclusivity provides adequate insurance for a few years of market exclusivity. Even though patent protection has failed, which means that a generic version can be manufactured legally, the clinical trial data remains protected, thus indirectly providing Company A market exclusivity on a product which does not enjoy patent protection. Therefore, generic drug applications of the drug will be delayed, not because there is a patent on the drug, but because the clinical trial information is protected by data exclusivity. In this scenario, generic drug companies are not allowed to access the information related to a chemical that is in the public domain. For consumers, Company A’s market exclusivity comes at a financial cost, as well as at the cost of access to the medication. Of course, generic drug companies are free to conduct their own clinical trials, considering that the drug is not a subject of patent protection. However, such duplication of clinical trials will result in subjecting a new set of patients to the same clinical trials and involves additional cost to conduct the trials and delays in manufacturing the generic drug while trials are being conducted. Thus, generic drug companies duplicating a clinical trial already conducted elsewhere will result in duplicative burdens in terms of time and cost. While the cost of the trial will be added to the cost of the drug and passed onto consumers by raising the cost of generic drugs unnecessarily, the delay from duplicating the clinical trial will result in delaying access to the consumers.

#### Sinema specifically jumps ship.

Hancock and Lucas 20 Jay Hancock and Elizabeth Lucas 5-29-2020 "A Senator From Arizona Emerges As A Pharma Favorite" <https://khn.org/news/a-senator-from-arizona-emerges-as-a-pharma-favorite/> (Senior Correspondent, joined KHN in 2012 from The Baltimore Sun, where he wrote a column on business and finance. Previously he covered the State Department and the economics beat for The Sun and health care for The Virginian-Pilot of Norfolk and the Daily Press of Newport News. He has a bachelor’s degree from Colgate University and a master’s in journalism from Northwestern University.)//Elmer

Sen. Kyrsten **Sinema formed** a **congressional caucus to raise** “**awareness of the benefits of personalized medicine**” in February. Soon after that, employees of **pharmaceutical companies** **donated** $35,000 to her campaign committee. Amgen gave $5,000. So did Genentech and Merck. Sanofi, Pfizer and Eli Lilly all gave $2,500. Each of those companies has invested heavily in personalized medicine, which promises individually tailored drugs that can cost a patient hundreds of thousands of dollars. **Sinema** is a first-term Democrat from Arizona but has nonetheless **emerged as a pharma favorite in Congress** as the industry steers through a new political and economic landscape formed by the coronavirus. She is a **leading recipient of pharma campaign cash** even though she’s not up for reelection until 2024 and lacks major committee or subcommittee leadership posts. For the 2019-20 election cycle through March, political action committees run by employees of drug companies and their trade groups gave her $98,500 in campaign funds, Kaiser Health News’ Pharma Cash to Congress database shows. That stands out in a Congress in which a third of the members got no pharma cash for the period and half of those who did got $10,000 or less. The contributions give companies a chance to cultivate Sinema as she restocks from a brutal 2018 election victory that cost nearly $25 million. Altogether, pharma PACs have so far given $9.2 million to congressional campaign chests in this cycle, compared with $9.4 million at this point in the 2017-18 period, a sustained surge as the industry has responded to complaints about soaring prices. Sinema’s pharma haul was twice that of Sen. Susan Collins of Maine, considered one of the most vulnerable Republicans in November, and approached that of fellow Democrat Steny Hoyer, the powerful House majority leader from Maryland. It all adds up to **a bet by drug companies that** the 43-year-old **Sinema**, first elected to the Senate in 2018, **will** gain influence in coming years and **serve as an industry ally** in a party that also includes many lawmakers harshly critical of high drug prices and the companies that set them.

#### Pharma backlash turns case

Huetteman 19 [Emmarie Huetteman, former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School, 2-26-2019, "Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash," Kaiser Health News, https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/]

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public outrage over drug prices, the fact that drugmakers gave most to the lawmakers working to change the patent system belies how important securing the exclusive right to market a drug, and keep competitors at bay, is to their bottom line. “Pharma will fight to the death to preserve patent rights,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the pharmaceutical industry has spent about $233 million per year on lobbying, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the Affordable Prescriptions for Patients Act, which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to prosecute them: “product-hopping,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “patent-thicketing,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. PhRMA opposed the bill. The next day, it gave Cornyn $1,000. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The pharmaceutical industry lobbied tooth and nail against it,” she said. “And when the bill finally came out of committee, the strongest provisions — the patent-thicketing provisions — had been stripped.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

#### This time it’s actually try or die – the planet is screwed absent infrastructure

Rebecca Leber 21 (Rebecca Leber, [], 10-7-2021, “The US is closer than ever before to making major progress on the climate crisis“, Vox, accessed: 10-8-2021, https://www.vox.com/22685920/democrats-infrastructure-build-back-better-climate-change) ajs

The United States — the largest carbon polluter in history — is closer than it’s ever been to taking sweeping and lasting action on the climate crisis.

The bad news is that if Democrats can’t pull it off, they may never get another opportunity like this — and the planet certainly won’t.

Democratic leaders are trying to pass two major pieces of legislation — the $1 trillion bipartisan infrastructure bill and the up to $3.5 trillion Build Back Better Act — that they say can slash US pollution by up to [45 percent](https://www.eenews.net/articles/schumer-outlines-reconciliation-emissions-targets/) in the coming decade. In the outlined Build Back Better Act, Congress would flex its power to transform the electricity sector so that it runs on mostly clean energy, steer the transportation sector toward electric vehicles, and finally take action on methane pollution, one of the most harmful greenhouse gases.

But there have been many recent moments when the precarious dealmaking in Congress [seemed close to falling apart](https://www.vox.com/22704198/congress-infrastructure-budget-reconciliation). One of the biggest sticking points has been with West Virginia Sen. Joe Manchin, who has questioned the party’s approach to passing both bills simultaneously. “What’s the urgency that we have?” Manchin asked on [CNN’s State of the Union](https://www.cnbc.com/2021/09/12/sen-joe-manchin-says-theres-no-way-to-pass-budget-bill-by-september-27.html) in late September.

In part because of Manchin’s opposition, even progressive leaders have begun to manage expectations, signaling the ultimate bill will be less ambitious. Sen. Bernie Sanders of Vermont [suggested](https://news.yahoo.com/sanders-3-5-trillion-reconciliation-153700106.html) that the $3.5 trillion figure would see some “give and take.” The package is likely to [shrink to $2.3 trillion or less](https://www.nytimes.com/2021/10/05/business/biden-agenda-congress-democrats.html), the New York Times reported on Wednesday.

So what is the urgency?

Democrats only have one year before midterm elections could take away their narrow majorities in the House and Senate. That would leave them powerless to pass any legislation without help from Republicans.

At the same time, the planet faces a rapidly closing window to avert the worst catastrophes of global warming. Every fraction of a degree will translate into lives and livelihoods lost. The world can’t afford another decade of American inaction, and what Congress does next will help determine the future of the climate.

### 4

#### CP: The member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over whether to reduce IP protections for medicines by significantly reducing data exclusivity. Member nations should support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation boosts strong leadership, authority, and cohesion among member states – key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

#### Ought means should

Merriam Webster n.d. – Merriam Webster’s Learner’s Dictionary, “ought”, <http://www.learnersdictionary.com/definition/ought>  
ought /ˈɑːt/ verb  
Learner's definition of OUGHT [modal verb] 1 ◊ Ought is almost always followed by to and the infinitive form of a verb. The phrase ought to has the same meaning as should and is used in the same ways, but it is less common and somewhat more formal. The negative forms ought not and oughtn't are often used without a following to. — used to indicate what is expected They ought to be here by now. You ought to be able to read this book. There ought to be a gas station on the way. 2 — used to say or suggest what should be done You ought to get some rest. That leak ought to be fixed. You ought to do your homework.

#### Should means must and is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling in praesenti.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16) [CONTINUES – TO FOOTNOTE] [13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) In praesenti means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is presently or immediately effective, as opposed to something that will or would become effective in the future *[in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

#### 1AR theory is skewed towards the aff – a) the 2NR must cover substance and over-cover theory, since they get the collapse and persuasive spin advantage of the 3min 2AR, b) their responses to my counter interp will be new, which means 1AR theory necessitates intervention. Implications – a) reject 1AR theory since it can’t be a legitimate check for abuse, b) drop the arg to minimize the chance the round is decided unfairly, c) use reasonability with a bar of defense or the aff always wins since the 2AR can line by line the whole 2NR without winning real abuse

### Advantage

#### Solvency – framing issue – they’ve read a lot of reasons exclusivity hurts innovation but they haven’t read uq ev that innovation would skyrocket post plan or exclusivity controls sqo failure – here are thumpers!

#### Patent thickets massively thump

Feldman 1 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. **But that’s not happening**. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates **staggered across time**. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

#### Seriously the aff is a drop in the bucket compared to evergreening

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “

Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain** to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

#### Impacts

#### Actors turn inward NOT outward – covid proves

Ide 21, Tobias. "COVID-19 and armed conflict." World development 140 (2021): 105355. (School of Geography, The University of Melbourne, 221 Bouverie St, Carlton, VIC 3053, Australia Institute of International Relations, Brunswick University of Technology)//Elmer

However, **COVID**-19 might also **shape** **opportunity costs in a way** **to reduce armed conflict risks**, at least temporarily. If a **state’s capability is strained** and there is an **urgent need to deal with a health emergency**, **military offensives are** certainly **unlikely** (Price-Smith, 2009). Furthermore, existing as well as potential **rebel groups** and militias **face similar challenges** in the face of the pandemic. They need to raise money and food to supply to their fighters during an economic recession, convince their members to take part in operations rather than staying at home (to reduce infection risks and support their family or community), and deal with the logistical constraints of lockdowns and border closures. **Starting** or intensifying **attacks** **during** the **COVID**-19 crisis is **likely to decrease** the local (and international) **legitimacy** of armed groups, especially if health infrastructure is affected. The ceasefire declarations by armed conflict parties in several countries can also be interpreted as a sign that COVID-related capability and legitimacy concerns are warranted.

#### Infectious diseases don’t cause extinction – millett ab hypotheticd and bitoerror

Owen Cotton-Barratt 17, et al, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Data Exclusivity is key to Pharma Innovation Investment – turns the advantage

Gangil, J, et al 10. “Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?” Systematic Reviews in Pharmacy, vol. 1, no. 2, 22 Dec. 2010, p. 190., doi:10.4103/0975-8453.75088. //sid

The purpose of data exclusivity is to ensure that the initial registrants of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers challenge that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant’s approval and sell the same or similar drug at a lower price.[7] Experts argue that data exclusivity offers benefits to domestic innovators in developing countries and, in particular, that it provides incentives for research to identify new uses for the existing unpatented product. Data exclusivity is likely to have the largest effect in countries where for historical or other reasons there are many products with no current patent protection that may gain rights to exclusivity. Today in many developing countries, there are numerous medicines that are not patented. This is often the case in developing countries where TRIPS-based laws have only recently been introduced. In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. In contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[8] In certain cases it is observed that “data exclusivity” helps innovator companies to recover investments made on discovering and developing a new drug; for example, according to a published article, Aventis’s innovative drug Leflunomide for rheumatoid arthritis took 17 years from discovery to commercialization.[9] Data Exclusivity Plays a Key Role for Biologics New Economics Research supports 13–16 years of data exclusivity for biologics

. A new working paper by Duke University economist Dr. Henry Grabowski, “Data Exclusivity for New Biological Entities,” identifies 12.9–16.2 years or about 13–16 years of data exclusivity as necessary to sustain investment in the research and development (R and D) of new biologics in any approach to creating an abbreviated pathway for follow-on biologics (FOBs). The Duke University working paper states that without sufficient data exclusivity, there would be little incentive to develop and market new biologics with uncertain or few remaining years of patent protection. Under this scenario, innovators would be less likely to pursue the development of a molecule if there were uncertainty regarding the possibility of recouping their investments and achieving a positive return.[10]

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